DEVELOPMENT OF A REMOTELY SUPERVISED DIGITALLY FACILITATED MULTIBEHAVIOURAL PREHABILITATION INTERVENTION FOR PATIENTS APPROACHING MAJOR SURGERY

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Abstract

Improving outcomes following major surgery is a pressing public health challenge. Postoperative complications drive surgical mortality and a range of poorer outcomes for the individual patient (e.g., quality of life) and wider healthcare system (e.g., length of stay and cost). Preoperative improvement of physical and mental health enhancing readiness for major surgery is known as prehabilitation. Patients may experience fewer postoperative complications and overcome them more easily. Multiple prehabilitation models now exist. Delivery has been predominantly face to face, yet demand is growing for robustly developed, remotely supervised alternatives. The need is now acute following the Covid-19 pandemic. Little is known regarding patient preferences for remotely supervised prehabilitation. Equally, few systematically designed interventions currently exist. This thesis addresses these gaps. A discrete choice experiment undertaken in 164 patients preparing for major surgery across 10 NHS centres explored patient preferences for delivery of support. This work highlighted both appetite for remotely supervised models and strong views regarding their delivery. In particular, demand for a digitally facilitated option. This informed the application of a systematic co-design process utilising the Behaviour Change Wheel to develop a novel, multibehavioural, digitally facilitated prehabilitation programme prototype (iPREPWELL). This work aligned to the Medical Research Council framework for complex intervention development and encompassed structured questionnaires, semi-structured interviews and workshops involving patients preparing for major surgery and perioperative healthcare professionals. These data were combined with the existing evidence base and the input of a multidisciplinary design team. iPREPWELL is the first comprehensively theory and evidence informed intervention of its kind. The programme is poised and approved for feasibility testing in patients approaching major surgery at two NHS centres. If successful, it may offer services a route to improved uptake of prehabilitation support, with potential for flexible and cost-effective implementation across a range of surgical pathways.

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List of accompanying publications and presentations

Publications

- Durrand J, Singh SJ, Danjoux G. Prehabilitation. Clinical Medicine. 2019, 19(6): 458-464; DOI: 10.7861/clinmed.2019-0257
- Durrand J, Moore J, Danjoux G. Prehabilitation and preparation for surgery: has the digital revolution arrived? Anaesthesia. 2021; doi:10.1111/anae.15622
- Durrand J, Livingston R, Tew G, Gills C, Yates D, Gray J, Greaves C, Moore J, O'Doherty AF, Doherty P, Danjoux G, Avery L. Systematic development, and feasibility testing of a multibehavioural digital prehabilitation programme for patients approaching major surgery (iPREPWELL): A study protocol. PLOSone. 2022; manuscript in press.

Presentations

- September 2022. 4th world congress in prehabilitation (online): 'Exploring patient preferences for remotely supervised prehabilitation using a discrete choice experiment'
- September 2021. FUSE prehabilitation for major surgery event: 'Exploring patient preferences for remotely supervised prehabilitation using a discrete choice experiment'
- February 2020. Association of Anaesthetists Core Topics Aberdeen 2020: 'Prehabilitation'
- November 2019. UK preoperative association annual conference: 'Facilitated Self-managed Prehabilitation'
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Author declaration

I declare that the work contained in this thesis has not been submitted for any other award and that it is all my own work. I also confirm that this work fully acknowledges opinions, ideas, and contributions from the work of others.

Any ethical clearance for the research presented in this commentary has been approved. Approval has been sought and granted through the Researcher's submission to two NHS research ethics committees

1. Chapter 2: South Central (Hampshire B) NHS Research Ethics Committee on 18/02/2019.
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1.Chapter 1: Critical review of literature

This chapter presents a review of current literature placing this work in the wider context perioperative care in the United Kingdom. The epidemiology of major surgery is discussed, followed by the physiological impact upon the patient and the link to their surgical outcomes. The impact of a complicated recovery in the short and longer term is discussed from an individual and healthcare system perspective. The subsequent emergence of perioperative medicine as a specialty and the central role of preoperative risk assessment is then considered followed by the subsequent emergence of prehabilitation and its current evidence base as a route to improved perioperative outcomes. The experiences of active prehabilitation services are reviewed from which the need has emerged for novel, robustly developed, remotely supervised models of care to meet patient demand.

1.1. Epidemiology of elective surgery in the UK

Elective surgery is planned and undertaken with the intent to enhance or save life. The spectrum of available surgical care continues to expand. Hospital episode statistics from 2009-2014 estimated that the United Kingdom (UK) National Health Services undertook an average of 7.5 million surgical patient episodes annually(1). Operations can be considered in terms of their magnitude and complexity. Categorisation is challenging. Two operations of the same name may vary significantly in the technical challenge of the underlying pathology. Equally, an otherwise ‘simple’ surgery can become complex due to individual patient factors. The magnitude, complexity and overall risk of an individual operation is therefore a product of the technical requirements, considered in the context of the individual patient. Consequently, universally accepted definitions are yet to be established(2). Despite this, categorising procedures in this manner is useful for the planning of perioperative care. The UK National Institute for Health and Care Excellence (NICE) employs a ‘minor’, ‘intermediate’ and ‘major-complex’ framework to guide preoperative assessment and optimisation of surgical patients(3) and this minor-

intermediate-major framework can assists in the rationalisation and allocation of perioperative resources more broadly.

In general, ‘Minor’ operations deal with more common and non-life-threatening pathologies, are shorter in duration, typically limited to the body surface and may not require general or regional anaesthesia. These are routinely scheduled as ‘day-cases’ within care pathways avoiding overnight hospital admission. In contrast, ‘Major’ operations are necessary for more time-critical and life-threatening conditions including solid organ cancers and major vascular disease. Major surgery is typically longer in duration, usually involves the opening of a major body compartment (e.g., the abdomen, pelvis, or thorax) and necessitates general and/or regional anaesthesia. Consequently, major procedures require a longer hospital admission which may include postoperative time in a critical care environment. ‘Intermediate’ procedures fall between these extremes. Table 1.1. provides examples of procedures in each category.

Table 1.1 Example categorisation of surgical procedures (from NICE NG45) (3)

Category	**Example procedures**
Minor	• excising skin lesion • draining breast abscess
Intermediate	• primary repair of inguinal hernia • excising varicose veins in the leg • tonsillectomy or adenotonsillectomy • knee arthroscopy
Major-Complex	• total abdominal hysterectomy • endoscopic resection of prostate • lumbar discectomy • thyroidectomy • total joint replacement • lung operations • colonic resection • abdominal aortic aneurysm repair • radical neck dissection

Annual NHS surgical care costs are estimated at approximately £9.8 billion(1). Major-complex procedures account for a disproportionate £6 billion of this cost, reflecting the greater intensity and duration of perioperative care required per procedure. This is illustrated in Table 1.2.

Table 1.2. Breakdown of annual NHS surgical procedures by magnitude, case numbers, length of stay and costs. Adapted from(1).

Category (British United Provident Association-BUPA grading)	**Estimated Annual case numbers (n)**	**Estimated Median length of hospital stay (days)**	**Estimated Annual NHS cost (£ billions)**
Minor	11 414 356	1.0	1.3
Intermediate	14 045 849	1.0	2.5
Major	8 909 387	2.0	3.0
Major plus	2 041 560	3.0	2.0
Major-Complex	1 190 126	7.0	1.0
Total	**37 601 278**		**9.8**

Of more importance to the person contemplating or approaching major surgery, is that associated risk of postoperative morbidity (5-40%), mortality (2-3%) and longer-term adverse outcome(4) that must be weighed against the potential benefit of the procedure. This, in part, reflects the substantial physiological burden associated with a major elective procedure, resulting from the stress response to major surgery(5).

1.2. The surgical stress response

Surgery provokes both a local and systemic neuroendocrine, metabolic and inflammatory response proportional to the magnitude of the procedure(6). Whilst the intent may be to remove life threatening pathology, restore tissue and organ function and improve quality of life, in the immediate and short term, the physiological response is analogous to trauma(7). The response is driven by a range of contributing factors relating directly and indirectly to the operation. The magnitude may be increased further if a given procedure proves to be technically challenging, prolonged or unanticipated complications are encountered in theatre. Recognition that the size and severity of the response is linked to postoperative complications has driven the development of Enhanced-Recovery After Surgery (ERAS) protocols(8, 9). These perioperative quality improvement initiatives seek to mitigate this response and its impact upon the patient as a route to improved outcomes through bundled, procedure specific intervention before, during and after surgery.

1.2.1. Drivers of the surgical stress response

1.2.1.1. Direct tissue and cellular injury

Direct cellular injury occurs at the operation site. This may follow surgical access and the associated manipulation, dissection, and excision of tissues. Greater tissue disruption, typically during major surgery, generates higher systemic levels of inflammatory mediators(10, 11). A cornerstone of enhanced recovery is usage of ‘Minimally invasive’ techniques employing smaller incisions, laparoscopic and robotic assisted approaches. These continue to develop(12, 13) with the express aim of mitigating direct tissue injury, yet ‘open’ approaches remain necessary as the primary approach for many major procedures or a ‘fallback’ plan in the event of unanticipated technical difficulty. Cellular injury at the operation site begins a localised immune inflammatory response that can progress to systemic inflammation(10, 11).

1.2.1.2. Haemorrhage, fluid shifts and tissue perfusion

Haemorrhage and associated haemodynamic changes undermine global tissue and organ perfusion, compromising global oxygen delivery. This is compounded by microvascular perfusion changes at a tissue level. Minimally-invasive surgical approaches substantially reduce blood loss but anticipated and unanticipated haemorrhage remain a key challenge in several major operations notably major vascular, urological and cardiothoracic surgery(14).

In addition to blood loss, major surgery can provoke substantial fluid shifts away from the normal distribution across intra- and extra-cellular compartments leading to hypovolaemia and tissue oedema and further microcirculatory changes may exacerbate poor tissue and organ perfusion leading to organ dysfunction(15). Of particular interest is the role of the endothelial glycocalyx, the carbohydrate rich component of the endothelial surface layer (ESL) that fixes up to 1000mls of plasma in healthy adults in dynamic equilibrium with the circulating plasma volume. This layer is the source of oncotic pressure within starling mechanics that maintain balance between plasma and interstitial fluid. Damage results from both the inflammatory response to surgery, ischaemia-reperfusion injury and fluid overloading, contributing to capillary leak and tissue oedema(16).

This complex relationship is reflected by the lack of consensus around the ‘optimal’ approach to perioperative fluid management. Both ‘restrictive’ and ‘liberal’ strategies have been advocated and trialled with the potential risks of failing to support the circulating volume adequately and exacerbating tissue and organ oedema respectively(17, 18).

Tissue and organ perfusion are also influenced by the adverse haemodynamic effects of surgical positioning e.g. a prolonged period of ‘head-up’ or ‘head-down’(19) positioning and the insufflation of carbon dioxide into the abdomen under tension (pneumoperitoneum) to facilitate laparoscopic abdominal surgery(20).

A further downstream consequence of haemorrhage and haemodilution in the context of liberal fluid therapy, is the need for allogenic blood transfusion intra and

postoperatively, this is a profoundly immunogenic process in addition to that provoked by the operation itself(21). The perioperative 'patient blood management' (PBM) approach seeks to minimise this need for transfusion, yet elective surgery continues to account for approximately one third of UK NHS blood product use(22).

1.2.1.3. Bypass of innate immune barriers

Strict adherence to sterility and asepsis is a key tenet of surgical and perioperative care. Despite modern precautions, surgery inevitably requires breach of natural barriers to infection at the surgical site such as the skin or mucosa introducing a risk of infection to any surgical site(10, 11). Innate immune barriers are also breached at distal sites as part of ancillary procedures. General anaesthesia often requires bypass of the upper airways and insertion of an endotracheal tube alongside catheterisation of peripheral and central blood vessels. Regional anaesthetic techniques require insertion of needles and catheters to the spine or peripheral nerves. Patients often also undergo urethral catheterisation and may require nasogastric tube insertion for surgical or nutritional requirements. Each of these presents an additional point of vulnerability to infection and a focal point for localised inflammation to begin. An enhanced recovery approach aims to avoid use of these peripheral devices where possible or remove them as soon as possible(8, 23).

A key site of potential immune bypass is the gastrointestinal tract. In physiology, a delicate balance is maintained between a diverse gut microbiome essential for health and the immune mechanisms that prevent inappropriate translocation of organisms and bacterial endotoxins beyond the gut lumen(24). Injury and dysfunction of the gut barrier function can result from direct handling intraoperatively, the postoperative inflammatory response and postoperative gastrointestinal complications such as ileus(25). The normal microbiome may also become disturbed by perioperative antimicrobial therapy. Mitigation of these effects is a focus of perioperative immunonutrition strategies(26).

1.2.2. Characteristics of the surgical stress response

The above factors result in a widespread release of pro-inflammatory cytokines including tumour necrosis factors and a range of interleukin molecules. These factors, frequently referred to as a ‘cytokine storm’ drive development of a global systemic inflammatory response syndrome (SIRS). These mediators drive a release of acute phase reactants such as C-reactive protein (CRP) from the liver. The magnitude of release of these mediators is believed to reflect the magnitude of this inflammatory response and correlates with the development of postoperative complications with links made between minimally invasive surgical techniques and a reduced mediator release(10, 11). The inflammatory response promotes creation of toxic reactive oxygen species (ROS) at the cellular level causing further tissue injury. The hypothalamic-pituitary-adrenal (HPA) axis is simultaneously activated with a release of systemic stress hormones including cortisol, catecholamines, glucagon and growth hormone(27). This promotes an insulin resistant and catabolic state that persists for several days post-surgery. Salt and water retention is compounded by increased vascular permeability characteristic of the SIRS response, creating ideal conditions for tissue oedema and impaired organ function.

This initial inflammatory period in the immediate postoperative days is followed by a compensatory and proportionate period of immunosuppression, the compensatory anti-inflammatory response syndrome (CARS)(11). There is a compelling potential link between this biphasic pattern, illustrated in figure 11.1, and the observation that some perioperative ‘inflammatory’ complications resulting from heightened tissue metabolic demands e.g., myocardial injury after surgery (MINS) and stroke (28, 29), manifest earlier in the postoperative period than other ‘immunosuppressive’ complications such as wound sepsis(30) that reflect this shifting immune state(31).

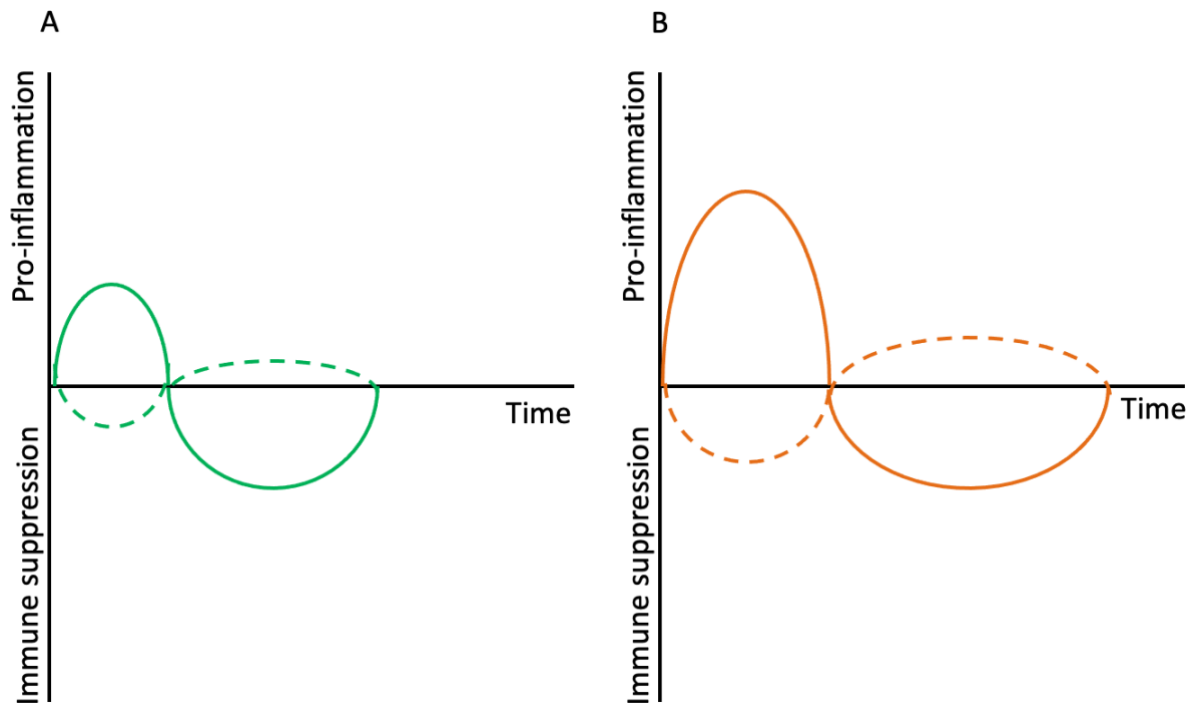

Figure 1.1 The biphasic stress response to surgery.

A demonstrates the typical response (solid green) with an initial pro-inflammatory phase followed by a phase of relative immune suppression. Both phases are constrained by simultaneous, compensatory anti- and pro-inflammatory processes (dotted green). **B** illustrates the higher-risk patient with more exaggerated and prolonged phases (solid orange) resulting from a looser compensatory envelope (dotted orange). Adapted from (11).

It is now accepted that at any given postoperative timepoint there are both pro- and anti-inflammatory processes at work and the biphasic pattern observed reflects the prevailing direction. The magnitude and extremes of these two phases and their contribution to surgical complications may be restrained within an envelope created by these parallel compensatory processes(10, 11).

A characteristic of 'higher-risk' surgical patients is that this restrictive envelope may be wider, allowing more pronounced and prolonged inflammatory and immunosuppressive phases(11). These patients are also characterised by higher rates of chronic health conditions such as diabetes mellitus(32), ischaemic heart disease(33) and chronic kidney disease(34) that are independently associated with

elevated surgical risk and united by by chronic inflammatory processes. These patients may present for surgery in a state of chronic inflammation and be poorly placed to manage the acute inflammatory burden of the operation.

1.2.3. Effects of the surgical stress response

1.2.3.1. Elevated tissue and organ oxygen demand

The changes outlined above force the major organ systems into a phase of heightened demand and activity, characterised by an increase in the global demand of those tissues and organs for oxygen to fuel their increased requirement(35). This observation was established by Shoemaker et al (1993). who documented, through use of invasive haemodynamic monitoring techniques, the tendency for global measures of oxygen consumption ($\dot{V}O_2$) to trend upward dramatically in the postoperative period. A key observation was the capacity for 'survivors' of major surgical intervention to elevate global tissue oxygen delivery (DO_2) to meet the demand, reflected by a capacity for their cardiovascular system, respiratory system and their organ tissues to deliver a coordinated increase oxygen delivery, extraction and utilisation to meet metabolic demand(36, 37), broadly referred to as 'cardiorespiratory reserve'. Subsequent failure to meet tissue oxygen demands may contribute to the development of significant postoperative complications. Notably, subsequent efforts to 'artificially' elevate global oxygen delivery to supranormal levels utilising invasive haemodynamic monitoring and cardiovascular pharmacotherapy were unsuccessful and potentially harmful (38, 39). This observation was an early suggestion that training patients to achieve this state 'physiologically' as exhibited by survivors, may be beneficial.

1.2.3.2. Disordered glucose homeostasis

Postoperative hyperglycaemia (blood glucose > 12 mmol/L) can occur in non-diabetic patients. Postoperative insulin resistance, measured by a blunted response to exogenous insulin, develops on day 1 and may persist for up to 3 weeks(40). These effects are most pronounced following intrabdominal surgery, and in skeletal muscle, the largest capacity tissue for glucose storage.

Metabolically active tissues within the cardiovascular, renal, and neurological systems alongside the healing wound are vulnerable to this uncontrolled hyperglycaemia. Hyperglycaemia leads to oxidative stress, endothelial injury, micro-thrombosis, and immune dysfunction. This manifests as increased rates of acute kidney injury, acute coronary events, postoperative cognitive deficits and wound infection(41, 42). This impact of a pre-existing insulin resistant state in the form of type II diabetes mellitus is unclear (43). Paradoxically, those with normal preoperative glycaemic control may be at greater risk than those with diabetes mellitus(42). In addition, It is increasingly recognised that several surgical pathologies, notably malignancies, may promote a state of preoperative impaired glucose regulation in those without established type II diabetes(44).

Enhanced recovery protocols therefore seek to control perioperative blood glucose, similar to the management of perioperative fluid balance, with adverse outcomes occurring when controls are either too liberal or restrictive(45).

1.2.3.3. Protein catabolism

Major abdominal surgery is associated with a nitrogen loss of 40-80g or 2kg of skeletal muscle.(46) This has implications for function in the preoperatively well-nourished patient and is a potentially life-threatening development in malnourished or frail individuals(47). Protein and skeletal muscle loss are associated with delayed postoperative mobility, potentially creating a vicious cycle of prolonged bed rest and

further muscle disuse atrophy, alongside the added perioperative risks of venous thromboembolism and respiratory tract infection in the non-mobilising patient(48).

This situation is compounded by the disturbances to normal enteral nutrition that can accompany the perioperative period including preoperative starvation and a delay to return of normal postoperative gut function, particularly in major abdominal surgery where the bowel is operated or handled resulting in Ileus. This is exacerbated by bowel-wall oedema resulting from circulatory changes and fluid shifts described above and the use of opioid analgesics.

A key tenet of enhanced recovery is the minimisation of this disruption and a rapid return to oral enteral feeding. Immediate perioperative nutritional supplementation may be necessary to prevent catabolic tissue loss, but must avoid exacerbating impaired glucose metabolism(46, 49).

1.2.3.4. Cognitive effects

The impact of surgery on cognitive function and postoperative neurocognitive decline is a developing area of research(50). Two conditions are recognised. Postoperative delirium (POD) is an acute complication characterised by disordered thinking, inattention, and a fluctuating conscious level detected on bedside cognitive assessment. Postoperative cognitive decline (POCD), typically identified on neuropsychological testing, is a chronic postoperative complication resulting in deficits across multiple cognitive domains including motor control, attention and recognition, concentration, memory, and executive function. Particular patient groups are at increased risk including older patients, those with pre-existing conditions impairing cognitive function such as vascular dementia (51). Perioperative protocols seek to remove and minimise the suspected triggers for these conditions e.g. long acting neuromodulatory agents and minimise the systemic inflammatory changes thought to drive these neurological changes(52). The emerging importance of ‘perioperative brain health’ is reflected in the publication of international consensus guidance for perioperative care teams(53).

1.2.4. Summary

The collective impact of these pathophysiological changes in the wake of an operation substantially stresses normal cellular, tissue and organ function placing demand upon the patient to ‘weather the storm’. This pattern is analogous to major trauma. Despite the intent for longer-term benefit, technical sophistication, and care with which the operation is undertaken, in the shorter-term from a physiological perspective, the patient is sustaining a controlled injury.

1.3. Why postoperative complications matter

Advances in the technical conduct of surgery and anaesthesia have thankfully made intraoperative death during major elective surgery an increasingly rare event. However, the most recent observational study of surgery in the United Kingdom reported an estimated mortality of 2-3%(54, 55). Despite advances in intraoperative safety, most of these deaths now occur in the postoperative period. Surgical morbidity, or complications of surgery are the key driver of postoperative and therefore perioperative deaths. Estimated incidences of postoperative complications vary, with 5-40% of the 1.6 million people undergoing major procedures annually affected(56, 57).

The spectrum of potential complications that may develop in the wake of the operation is wide(58). Complications may be directly related to and involve the site of the operation itself e.g., infective breakdown of an external wound or leak from an anastomosis, or indirectly reflecting distant organ dysfunction in response to the global stress response such as delirium, myocardial injury, acute kidney injury, pneumonia, or thromboembolic phenomena. Multiple tools have been developed to categorise and quantify the severity of complications such as the Postoperative Morbidity Survey (POMS)(59) and Comprehensive Complication Index (CCI)(60). Crucially, complications at the severe end of this spectrum carry their own additional physiological burden e.g., sepsis, compounding the insult and of the operation itself. Complications, if not promptly identified and treated can develop into more serious sequelae e.g., postoperative atelectasis and an increased oxygen requirement progressing to hospital acquired pneumonia and then sepsis. This compounds the physiological insult of the operation itself leading to a vicious spiral toward common paths of life-threatening organ failure and postoperative death. Failure to identify and interrupt this process has been termed ‘failure to rescue’(61).

This accounts for the observation that patients developing a major postoperative complication are significantly more likely to die following surgery(62). Whilst death is frequently considered the worst conceivable outcome for the patient and

perioperative team, most patients who develop a complication survive, yet go on to suffer other significant consequences in both the immediate and longer-term.

Whilst a universally agreed definition is yet to be established, the recovery process from major surgery confers a period of increased dependency, reduced functional status, and temporarily poorer health as the adverse effects of the operation and accompanying stress response resolve over days to weeks. This may involve reduced mobility due to pain, a period or abnormal feeding and gut function or fatigue. The recovery process, as the patient heals from the surgical insult and function is restored, sees a progressive return to baseline and logically supranormal levels of health, with a life-threatening pathology removed or function of an organ restored(63).

Complications delay and undermine this process, protracting the recovery period from weeks to months. In some cases, this prevents the patient from regaining their baseline preoperative level of health and function(57). This means more vulnerable, higher-risk patients cross a tipping point, losing their longer-term postoperative independence. This concept is illustrated in figure 1.2.

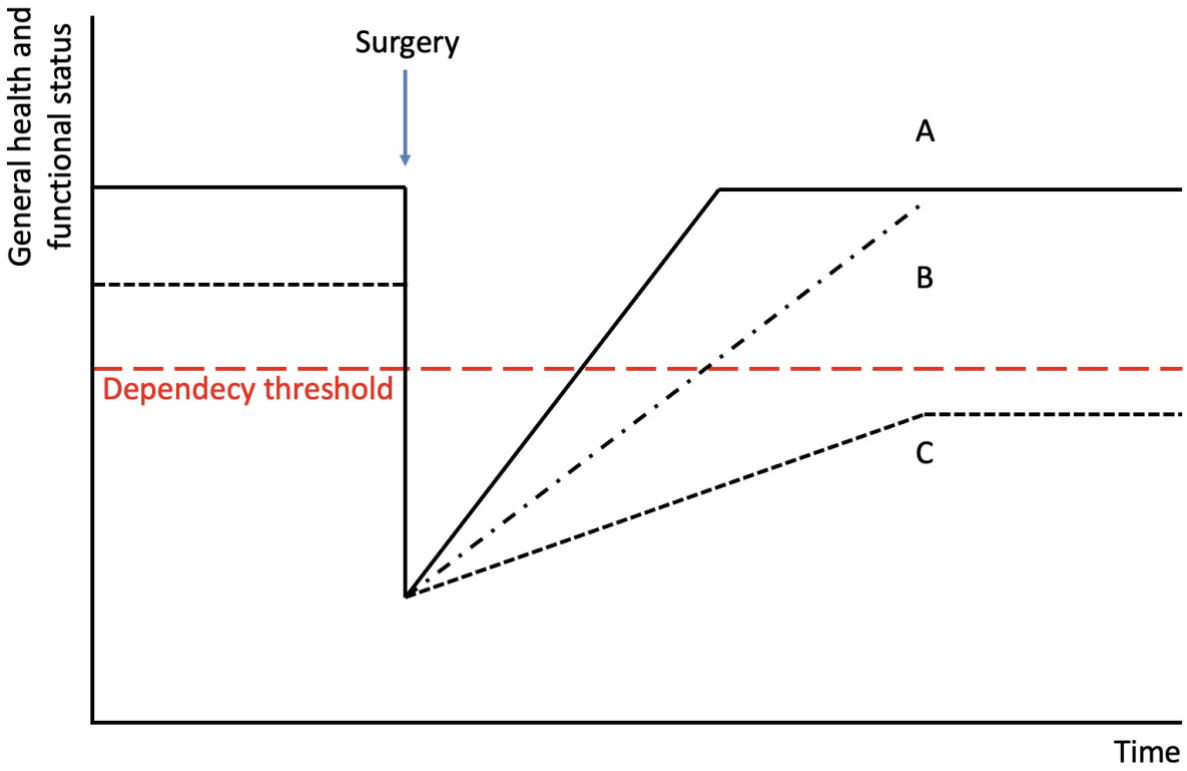

Figure 1.2. Routine and complicated recovery from surgery.

A demonstrates routine recovery, where the anticipated postoperative reduction in health and function is swiftly recovered to normal preoperative levels with restoration of function or removal of a life-threatening pathology. **B** highlights the impact of a complication, slowing the process resulting in a prolonged recovery of health and function. **C** demonstrates the potential effect of severe or multiple complications in a more vulnerable, higher-risk patient with poorer preoperative function and health status. The patient is unable to regain their preoperative level of independence and remains below a dependency threshold.

1.3.1. Shorter-term postoperative impacts of complications

In addition to an increased in-hospital mortality risk, patients developing a complication experience a prolonged hospital stay due to increased time to return to their preoperative level of function and need for additional treatment and potentially further procedures, which may themselves carry additional risks. The UK

Perioperative Quality Improvement Programme (PQIP) indicates that a single major complication may prolong average length of stay from 8 to 21 days following major surgery (64). This may incorporate a longer stay in a critical care environment, or an unplanned admission for organ support presenting additional risks. Patients may be slower to reach the key recovery milestones of drinking, eating and mobilising (DREAMing)(65). This lead to difficulty engaging with key postoperative interventions underpinning the enhanced recovery philosophy such as physiotherapy, dietetic support and occupational therapy(9, 23) raising the possibility of a protracted period of bedrest. The ill-effects of this are well known in general inpatient populations but hold particular significance for the older frailer patient(48). In those patients who leave hospital, the extent of the losses of lean muscle mass may make the difference between a postoperative life in or out of their own home.

1.3.2. Longer-term postoperative impacts of complications

The deleterious effects of a complicated recovery period, well beyond hospital discharge, suggests the effect of the stress response may persist beyond the short-term. Building on the work of Khuri et al.(66) and Straatman et al.(67), a cohort study by Moonesinghe et al(68). showed an increased risk of postoperative mortality (relative hazard 3.51) for the 1st postoperative year in patients sustaining a complication persisting to postoperative day 15. This risk of death did not return to baseline until 3 years after surgery(68). This work is part of a wider drive to extend perioperative observational research and outcome measures beyond the traditional metric of 30-day mortality. As we continue to follow-up patients beyond the 1st postoperative month, worrying findings continue to emerge for those whose recovery was complicated. There is a higher risk of readmission (odds ratio 3-10) (69) for further management of complications and their sequelae and, as outlined in figure 2, functional impairment may persist for months into the post-discharge period and never recover to baseline necessitating longer-term supportive care (57). These burdens collectively have a substantial impact upon quality of life. This has been shown to be significantly lower in patients experiencing a complex recovery for 3-5

years following surgery(57, 70, 71). Perhaps most concerning for perioperative teams is emergence of the ‘surgical regret’ phenomenon (72) in patients who given the opportunity again, would not have chosen to have undergone surgery. Recent estimates from the UK Centre for Perioperative Care (CPOC) suggest this may affect 1 in 7 patients (72).

1.3.3. Health system, health economic and socioeconomic impacts

The stakes for the individual undergoing major surgery and the impact of a major postoperative complication are potentially high. There are also wider consequences for healthcare systems and society. The collective impact of a prolonged hospital and critical care stay alongside additional treatments and procedures significantly elevate the cost of major surgical care before potential readmissions are considered. This inflates the total £6 billion expended annually by the UK NHS on major surgical care as outlined in table 2(1). Prolonged occupancy of level 1 and critical care beds by patients progressing more slowly though a complicated recovery also limits surgical throughput. UK surgical waiting lists are currently at unprecedented levels (>7 million (73)) following the Covid-19 pandemic. Maximising the efficiency of flow through surgical pathways is key to national ‘elective recovery’ efforts(74). In hospital costs also do not account for the longer-term social care costs associated with discharge into a supported care environment. In addition, whilst the average age of patients undergoing major surgery is 65 years old(75), younger patients encountering a complicated and incomplete recovery from surgery that threatens their longer-term functional status may prevent a return to work. This is a particular concern in the context of major orthopaedic surgery. Systematic reviews estimate return to work rates following total arthroplasty of the hip, knee and shoulder may range from 40-98%, with increasing proportions of younger adults presenting for joint replacement(76, 77).

1.4. Understanding the risk of major surgery

Other major health events such as severe infection, trauma or a vascular event also carry substantial risk to the individual and the potential for a complicated recovery. Major surgery holds a relatively unique position in that the decision to embark on the process is often fully in the hands of the patient and their healthcare team.

1.4.1. Perioperative medicine and the ‘high-risk’ surgical patient

Two patients contemplating technically identical procedures may be faced with markedly different risks. Older, frailer patients and those with more extensive and severe comorbidity are typically at greater risk, particularly in the context of more extensive, invasive, and physiologically demanding planned surgery. From this, the concept of the ‘high-risk’ surgical patient has emerged(78), individuals who, as outlined in figure 2, face the greatest likelihood of developing complications(79), account for the majority (80%) of postoperative deaths (80) and are most likely to encounter the ensuing poorer perioperative outcomes discussed above.

In a 2011 report ‘knowing the risk’ (81) the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) highlighted that contemporary models of care did not serve the needs of this population adequately (82). Despite the success of enhanced recovery initiatives, preoperative pathways were noted to remain fragmented and inefficient with key interventions to prepare the patient for surgery, including formal risk assessment left too late to yield maximal benefit (83). This has catalysed the emergence of ‘perioperative medicine’ as a medical subspecialty. The perioperative period has since been defined by Grocott and Mythen(80, 84) as the time from when surgery is first contemplated through surgery to the extended postoperative period. This pathway toward new models of care and fundamental shift in mindset for clinical teams caring for surgical patient was marked by a formal launch by the UK Royal College of Anaesthetists in 2015(80). The perioperative

medicine approach seeks to optimise every timepoint in this continuous pathway, with the overarching aim of facilitating a smooth and complete recovery from surgery and favourable postoperative outcomes through first the avoidance of complications and a rapid appropriate response should they develop.

1.4.2. Preoperative risk assessment

Individualised preoperative risk assessment is a cornerstone of the perioperative medicine approach and expanding component of modern perioperative care pathways(85). Understanding and communicating the associated risks of planned surgery also underpins another key component: 'Shared decision making' (SDM) between the patient and their perioperative team around whether a given operation is the best course of action for that individual compared to other operative and non-operative treatment options or no treatment at all(86). Here, the perioperative risk must be balanced against those of the underlying problem and alternative options. Multiple factors contribute to risk estimation, now usually undertaken within dedicated preoperative assessment or perioperative medicine clinics synthesising the findings of the patient's clinical history and examination with targeted investigations (bedside, laboratory, and imaging) and increasingly objective assessments of functional capacity such as cardiopulmonary exercise testing. Figure 1.3. outlines some of the factors that might be considered when evaluating risk.

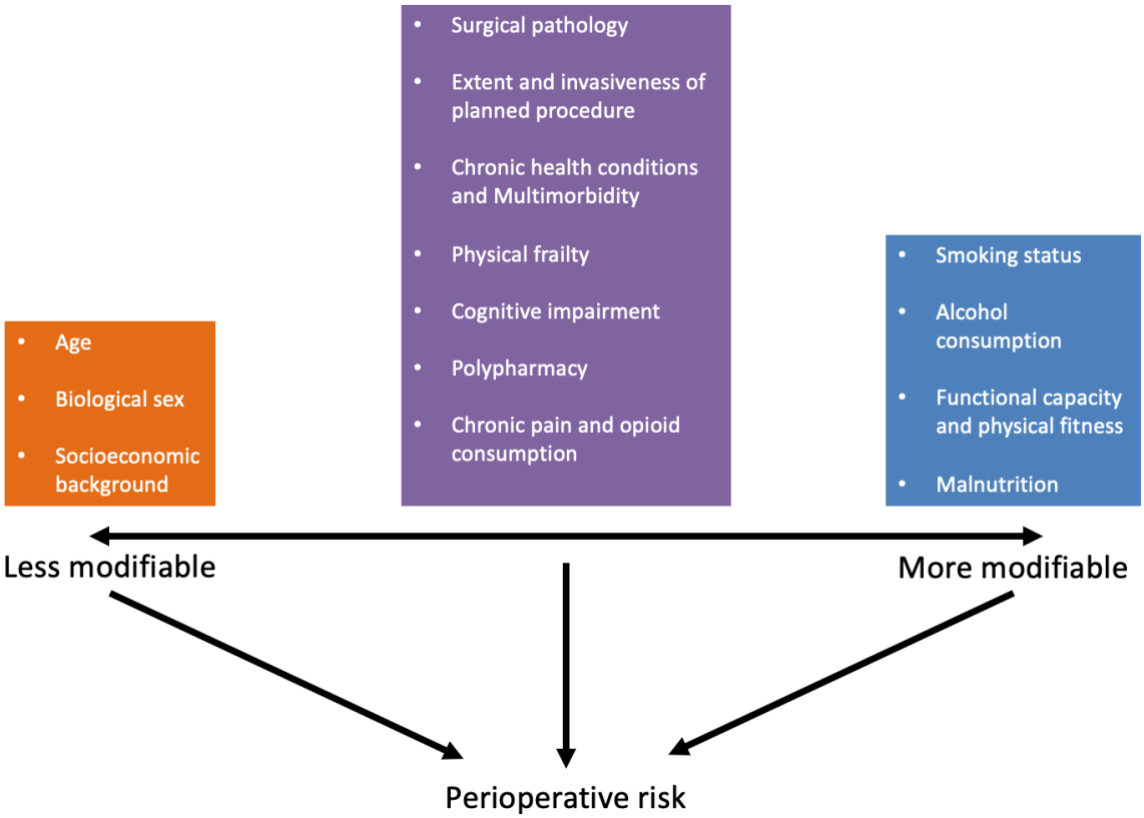

Figure 1.3. Factors contributing to perioperative risk and relative degree of preoperative modifiability.

Multiple elements are considered when estimating the risk associated with a given procedure in an individual patient. Some factors such as age are wholly unmodifiable. Others can be addressed and optimised preoperatively including comorbidities such as iron-deficiency anaemia or health risk behaviours such as smoking status.

If proceeding to surgery is deemed the optimal course of action the next logical step is to identify and address modifiable factors driving increased risk. The intent is to stack the odds of a smooth and uncomplicated recovery in the patient's favour.

1.5. From preoptimisation to prehabilitation

Efforts to mitigate perioperative risk before surgery are traditionally termed ‘preoptimisation’ and have focussed largely on the comorbidities assessed and identified during preassessment. Frustratingly for perioperative teams, prior to the emergence of the perioperative medicine movement, a relatively limited range of evidence-based interventions were available to significantly modify identified risk factors. Those available, such as interventions to improve glycaemic control in type 2 diabetes mellitus, rate control atrial fibrillation or optimise secondary prevention in ischaemic heart disease were limited by identification in preassessment clinics too close to surgical admission to allow the time needed to intervene, or for the patient to reap maximal benefits(83).

A key impact of the move toward ‘perioperative pathways’ is the attempt to shift these efforts earlier in the pathway to the point of referral for surgical opinion and listing for surgery. This creates sufficient preoperative time to assess and intervene effectively(83). This has increased the scope and ambition of what can be done to address specific comorbidities and enhance readiness for surgery. This is exemplified by the widespread emergence of preoperative anaemia pathways providing rapid access to intravenous iron infusions to address preoperative iron deficiency anaemia(87), dedicated comprehensive geriatric assessment (88) (CGA pathways) exemplified by the nationally recognised POPS (Proactive Care of the Older Person undergoing Surgery) service (89) and the publication of guidelines by the Centre for Perioperative Care incorporating the preoperative assessment and optimisation of key risk factors: Diabetes mellitus(90), anaemia(91) and frailty(92). Earlier and proactive preoperative identification and optimisation is now embedded as a core concept within policy by NHS England to recover elective activity and address the backlog of over 7 million people waiting for surgical treatment in the wake of the Covid-19 pandemic(74, 93).

This shift in emphasis from patient assessment toward optimisation has been accompanied by a widening of the scope of modifiable perioperative risk factors amenable to preoperative identification and intervention. A range of previously under-recognised and under addressed health risk behaviours are prevalent in surgical populations and potent drivers of increased perioperative risk. These have gained increasing prominence alongside established comorbidities and chronic health conditions as optimisation targets. These include Physical inactivity and resultant poor physical fitness, tobacco smoking, hazardous consumption of alcohol, malnutrition, and poor psychological health. Preoperative efforts to identify and address these risk factors have been collectively termed ‘prehabilitation’ (94-97).

1.5.1. The prehabilitation concept

Prehabilitation can been defined as structured preoperative support to enhance physical and mental health in readiness for surgery(94-97). The intent is to better prepare the patient to face the physical and mental burden of the operation. In practical terms, a prehabilitation approach seeks to reduce the incidence and severity of postoperative complications and leave the patient better placed to recover quickly and overcome a complication should one occur. This is illustrated in figure 1.4 that builds upon the patterns of surgical recovery illustrated in figure 1.2

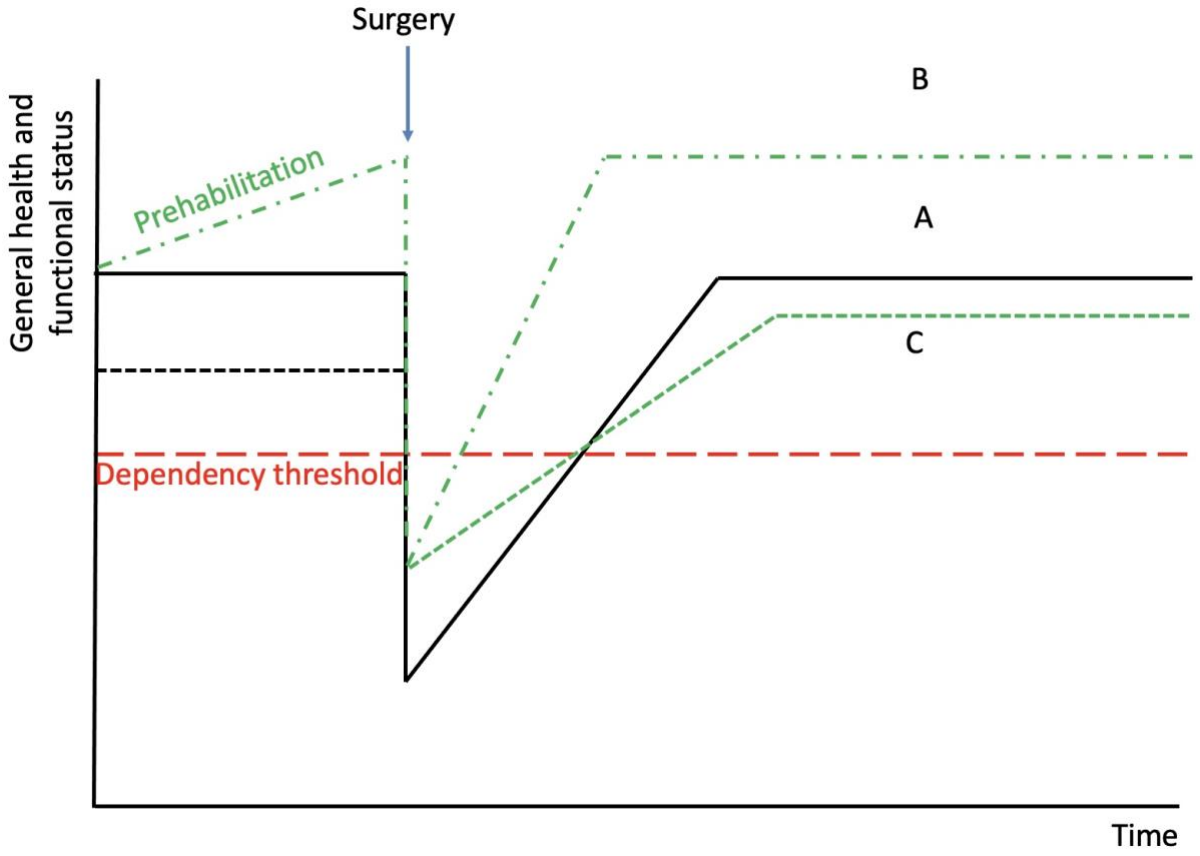

Figure 1.4. The prehabilitation concept.

A: Illustrates a routine recovery as described in figure 2. **B:** illustrates the prehabilitated patient experiencing an uncomplicated recovery. They may experience a less significant drop in functional status and recover more quickly to their baseline. **C:** Illustrates the prehabilitated patient who develops experiences a complication, in this scenario, preoperative intervention may allow the patient to overcome this more easily and return to a level of function that preserves their independence and quality of life.

The last decade has seen an explosion in publications relating to prehabilitation, reflecting its increasing prominence in perioperative pathways. PubMed listings indicate 1,200 citations in the year 2000 increasing to 5,290 by 2022. Specific 'preoptimisation' interventions for chronic health conditions are often considered separately from prehabilitation programmes focussed upon health risk behaviours. Both efforts ultimately aim to better prepare the patient for surgery and distinction between the two may be artificial. Health risk behaviours are persisting causative

drivers of key perioperative comorbidities such as type II diabetes and hypertension. Failure to address them perpetuates poor control. Supporting patients to tackle them is a key lever for optimisation alongside modification of pharmacological and other therapy(98-100).

Whilst the required components of a prehabilitation programme are flexible, three 'pillars' are frequently described(101): Physical activity and exercise training(102), nutritional support(46) and psychological support(103). Other elements frequently incorporated within a wider prehabilitation umbrella include smoking cessation(104) and alcohol reduction(105). Improvement of sleep health is a newly emerging area of focus. Preoperative patient education is also frequently included in the wider definition and could be considered as a component of support to enhance psychological readiness with all prehabilitation support is reliant on an educational component to enhance engagement. Figure 1.5. summarises the components that may be included within a prehabilitation programme.

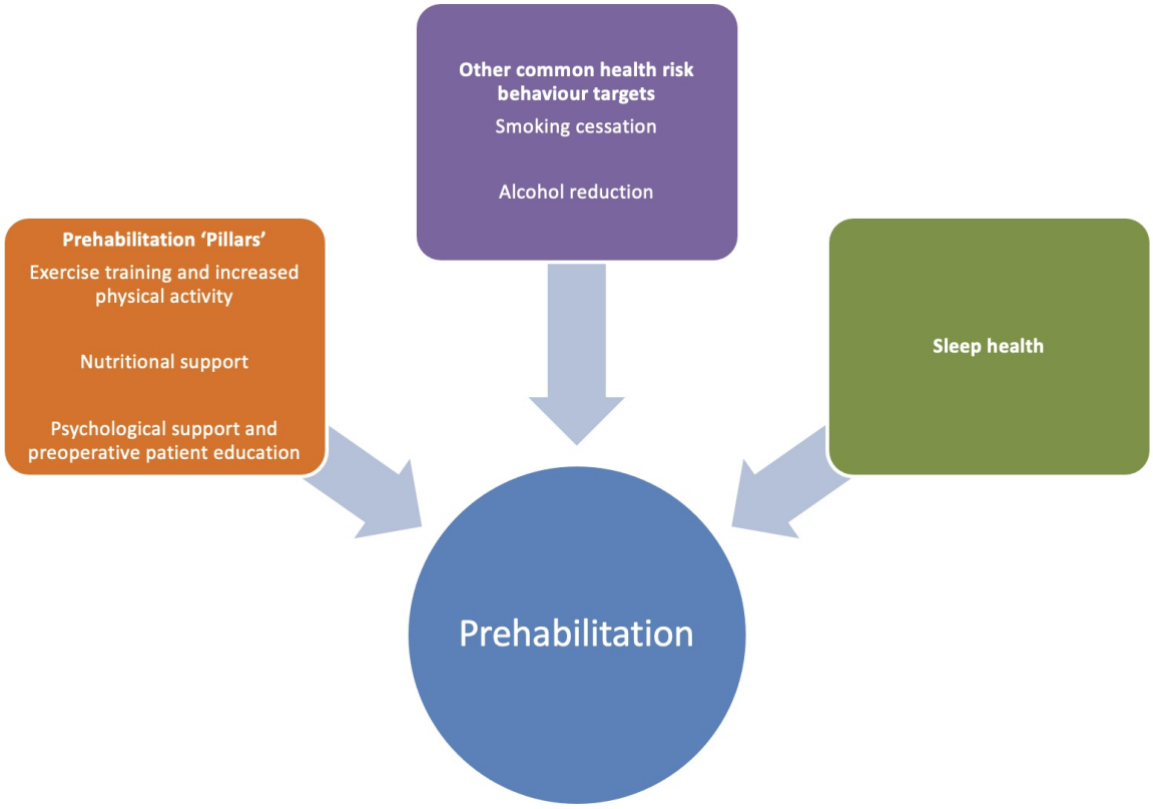

Figure 1.5. Potential components of a multimodal prehabilitation programme

1.5.2. Lifestyle medicine in a teachable moment

The health risk behaviours considered in a prehabilitation approach are widely accepted drivers of poor individual and population health and key aetiological factors in the development of major chronic health conditions and non-communicable diseases(106). These are overwhelmingly the leading causes of death in adults in more developed countries(107) and concerningly on the rise in the less developed world(108). These frequently inter-related conditions include Type 2 diabetes mellitus, obesity and the metabolic syndrome, ischaemic heart disease, hypertension and stroke, chronic obstructive pulmonary disease, and malignancy. Their collective burden on individual patients and health systems are immense. NHS England recently reported that Type 2 diabetes care alone accounts for £10 billion of healthcare spending, or 10% of the health service budget. Of note, these behaviours are also key contributors to the pathologies that predominantly require major surgical intervention such as solid organ cancers and cardiovascular disease.

There are therefore clear benefits to individual patients and the health system in addressing health risk behaviours. This can drive better patient and population health through both prevention and treatment of chronic disease(107). 'Lifestyle' intervention is a key initial component of national and international guidelines to manage these chronic conditions. Examples of both behaviour and condition specific interventions are widespread, leading to the emergence of the field of 'health behaviour change science' and the structured design and development of interventions most likely to help patients succeed in tackling these issues(109, 110).

There is also wider acceptance that our current health system is not currently well placed to deliver this preventative model of healthcare, delivering greater success in acute rather than chronic health healthcare(111, 112). The preventative and treatment opportunities offered by intervention to address health risk behaviours in favour of treating their downstream ill effects has led to the emergence of the specialty of 'lifestyle medicine' and initiatives to achieve parity between under-utilised

evidence-based health risk behaviour interventions the more widely utilised pharmacological and other therapies(98-100).

Helping individuals to achieve health behaviour change is not easy. Attempts outside of the perioperative context have had varied success(113, 114). Crucially, the individual and environmental factors most associated with those behaviours are also key barriers to engagement with and success of interventions to address them(115). Health risk behaviour rates and rates of downstream chronic health conditions are far higher in individuals and areas facing socioeconomic deprivation, higher rates of social isolation, poorer health literacy and lower rates of educational attainment(116-119). Comparable variation in mortality rates observed during the Covid-19 pandemic shone a spotlight upon health inequalities across the UK and internationally(120, 121). Supporting patients to tackle these issues before surgery must also acknowledge these realities.

One advantage prior to surgery may be the preoperative 'teachable moment' where individuals are psychologically better prepared to engage with and adhere to support despite their individual barriers. Work by McDonald et al.(122) highlighted the higher rates of motivation expressed by patients for this shorter-term perioperative benefit over the potential longer-term health benefits. Crucially, this study also underlined an accompanying lack of confidence among patients on how best to proceed. To capitalise on additional preoperative motivation, structured support on how to proceed with change must be offered.

Whilst the more extensive learning of longer established health behaviour change interventions and services from other areas of clinical practice are hugely valuable, the unique challenges of the preoperative period must also be acknowledged: These include compressed timeframes (potentially 6-8 weeks or less), the impact of neoadjuvant treatments and the psychological burden of a frightening diagnosis, and the upcoming operation as a potentially life-changing health event. 'Generic' interventions for health behaviour change in other clinical contexts with more open-ended timeframes may provide support that is insufficiently tailored to the preoperative period.

1.5.3. Multimodal prehabilitation

The tendency for health risk behaviours to cluster(106) is reflected in surgical populations. Prior work has indicated over 40% of patients presenting for major surgery exhibit two or more behaviours amenable to prehabilitation intervention(122). A consequence of limited preoperative time is the frequent need to undertake simultaneous intervention across those behaviours, rather than a sequential approach. This time efficient approach raises the possibility of overburdening patients and diluting impact, however prior work indicates that simultaneous and sequential approaches are equally efficacious(123, 124). There is clear face validity for synergy through combination of interventions such as a nutritional programme or smoking cessation supporting adaptations to exercise training and improvements in cardiorespiratory function. There may also be a behavioural advantage, with success and progress in one area building self-efficacy to engage with other available support(125). At present in the absence of clearer evidence around the advantages and disadvantages or optimal behaviour combinations, most active programmes are offering simultaneous multibehavioural support(126-129).

1.6. The current evidence for prehabilitation

The evidence base for preoperative intervention across the health behaviour targets of prehabilitation programmes continues to evolve.

1.6.1. Physical activity and exercise training

Physical inactivity or the non-achievement of physical activity guidelines for healthy adults predisposes to sedentary behaviour, or any waking time spent with an energy expenditure of ≤1.5 metabolic equivalents (METS). This is a major public health concern and key driver of major non-communicable disease and resulting chronic ill health(130, 131). Over 40% of UK adults are estimated to not currently meet current Chief Medical Officer (CMO) activity guidance for healthy adults(132, 133). This may increase to over to 60% in over 70s, compounded by the acknowledged progressive decline in physical that accompanies ageing(134, 135). Given the average age of patients presenting for major surgery in UK is 65(75) It is unsurprising that rates of inactivity and resultant poor fitness (a lack of capacity in a defined area such as cardiorespiratory or muscular function) are also estimated at around 50%(102) and frequently present alongside linked chronic health conditions including ischaemic heart disease, type II diabetes mellitus and obesity.

The comparative health benefits of regular physical activity, or the avoidance of time spent sedentary, are equally stark. Rates of those major non-communicable diseases are significantly lower in active adults(136). Whilst its preventative powers are recognised, perhaps under-appreciated is the value of activity as an effective treatment for those conditions such as hypertension, ischaemic heart disease and type 2 diabetes, enhancing the effectiveness of other pharmacological therapies(137). This has led to the concept of ‘exercise as medicine’(134). The previously inactive surgical patient may therefore stand to gain significantly in both the short and longer term from increased preoperative activity levels, through intervention seeking to reduce time spent sedentary.

Whilst for the most inactive and deconditioned patients, increasing activity alone may yield improvement in capacity, for other patients preparing for surgery seeking maximal changes in fitness in potentially compressed preoperative timeframes a change in mindset from ‘increasing activity’ to ‘exercise training’ may be needed to use the available time most effectively(102, 138). Exercise training can be distinguished from physical activity by a deliberate focus on achieving measurable improvement in an objectively measured element of physical fitness.

In the perioperative setting, work has focussed on two broad forms of exercise training: Aerobic and resistance. A third area, inspiratory muscle training is a subtype of resistance training that may offer particular benefit to surgical patients.

1.6.1.1. Aerobic training

There are clear parallels between the physiological demands of the surgical stress response, notably the total body demand for increased oxygen delivery, and those of strenuous exercise. In a landmark 1993 paper(139), Older et al. established the association between preoperatively assessed aerobic capacity and perioperative outcomes. Utilising cardiopulmonary exercise testing, Older and colleagues demonstrated that objectively measured aerobic fitness quantified by measured physiological parameters such as the anaerobic threshold (VO_2 AT) were greater in survivors of major surgery. This finding has since been replicated in multiple settings and surgical populations (140, 141) leading to the delineation of risk thresholds for several major surgical procedures. Poorer performance in CPET has been associated with greater short and intermediate term postoperative mortality and morbidity, prolonged lengths of stay, and poorer postoperative functional status(140, 141). This has supported the establishment of cardiopulmonary exercise testing (CPET) as the ‘gold standard’ of functional assessment within wider preoperative risk assessment, and CPET continues to be utilised at a growing number of surgical units across the UK(142).

Preoperative training for improved aerobic exercise capacity is a logical progression. Feasibility of training and enhancement of objectively measured aerobic fitness has

now been demonstrated in a range of surgical specialties including major colorectal(143), upper gastrointestinal(144), urological(145) and vascular(146) populations. A variety of training protocols across different surgical populations have been studied ranging from 'activity focussed' interventions to more structured exercise training programmes. The majority of studies have utilised 'moderate intensity' training(102) however high intensity interval training (HIIT) protocols have emerged as a time efficient route to measurable improvement in aerobic capacity within surgical timeframes, However, questions remain around the suitability and acceptability of this approach for the full range of patients who stand to benefit from improved preoperative aerobic fitness(147). Feasibility of preoperative training has also been demonstrated within both face to face and remotely supervised models. A key question remains around the individual response to a given protocol. Whilst patients are able to make clear improvements, this adaptive response to the training stimulus is not universal(148, 149). Making sense of the mechanistic drivers of this phenomenon is currently difficult given the range of protocols that have been studied in small numbers and heterogenous patient populations.

If aerobic capacity is successfully enhanced the question of impact on outcome follows. Here, there is also significant variation in reported findings reflecting the heterogeneity within the evidence base and the variation in individual patient response to a given protocol. Multiple systematic reviews (56, 146, 150-152) have identified single studies reporting marked reductions in postoperative morbidity, shortened lengths of stay, improved postoperative functional status, and enhanced postoperative quality of life but these are of insufficient size to confidently conclude benefit. In addition, studies widely report good patient acceptability and cost effectiveness has also been demonstrated(153, 154). There is a current lack of adequately powered multicentre randomised controlled trials. At time of writing, three studies are approaching publication likely to substantially alter this position: PREPARE ABC(155), WesFit(126) and the international prehabilitation study(156).

1.6.1.2. Resistance training

A distinct physiological effect of both a sedentary lifestyle and the ageing process and a clinical hallmark of the frailty syndrome is a loss of lean muscle mass & strength, or sarcopenia(157, 158). Whilst this is interlinked with and may develop in parallel to poor aerobic fitness, sarcopenia is an emerging independent risk factor for poorer perioperative outcomes(159, 160). Evidence for the importance of muscle development and maintenance to the health of adults and particularly older adults continues to emerge(161). This has prompted a change in CMO guidance to specifically incorporate additional deliberate resistance training over and above baseline physical activity guidance. Concerningly, the proportion of adults meeting this additional specific guidance is even lower than for aerobic activity targets(162, 163).

Adequate lean muscle tissue is believed to confer several advantages to the patient undergoing major surgery: It is a recognised objective marker of adequate nutrition and represents a reserve with which to meet the demands of the catabolic state encountered in part of the surgical stress response(46). In addition, global muscular strength and stamina is likely to assist patients in both engaging with postoperative physiotherapy and regaining the functional movement patterns necessary to return from a state of initial bedrest to independence and compensate for the impact of the operation impairing function of specific body areas, the concept of ‘prehab for rehab’.

Whilst there is significant scope for crossover in adaptation from both approaches, resistance training to maximally preserve and enhance lean muscular mass, strength and stamina requires a different approach to enhancing aerobic capacity. The evidence base for preoperative resistance training is less developed than for aerobic protocols, both in terms of mechanistic studies to illustrate adaptation to training and outcome studies of sufficient size to confirm perioperative benefit. Recent reviews have demonstrated improvements in postoperative muscle strength and joint function following total knee arthroplasty(164) and reduced rates of urinary incontinence through pelvic floor training prior to radical prostatectomy(165). Studies of more generalised resistance training are limited. A systematic review identified

only two purely resistance training protocols prior to major cancer surgery with inconclusive evidence of benefit(166). The strong face validity for preoperative resistance training and potential for synergy has led many protocols to incorporate resistance alongside aerobic training. A systematic review of 'total-body' prehabilitation by Santa-Mina et al(167) incorporating multimodal exercise demonstrated a reduction in hospital length of stay in mixed major surgical populations, however the relative contributions of the two training elements cannot be easily separated. Like aerobic training, whilst there is clear scope for benefit, optimal preoperative resistance protocols that confer benefit are yet to be fully established.

1.6.1.3. Inspiratory muscle training

Postoperative Pulmonary Complications (PPCs) including postoperative atelectasis, pneumonia, unexpected mechanical ventilation, and the adult respiratory distress syndrome (ARDS) are key contributors to the overall postoperative morbidity burden(168). A large multicentre UK prospective study estimated incidence at 7.1% in patients undergoing major surgery(169). Specific measures to reduce PPCs are a potentially valuable key element of perioperative care pathways, notably for 'major abdominal surgery' where the duration of anaesthesia, wound position, and associated pain alongside potential need for postoperative mechanical ventilation are believed to confer a greater risk.

Inspiratory muscle training (IMT) is a targeted form of resistance training. It is distinct from other forms of breathing training and incentive spirometry by the application of a mechanical load to the muscles of breathing to build strength and stamina using an inspiratory muscle training device. This is intended to enhance preoperative mechanical lung function supporting postoperative lung recruitment, atelectasis prevention, effective coughing and avoidance of respiratory failure(170-172).

Large multicentre randomised controlled trials and Recent systematic reviews have highlighted evidence for reduction in PPC rates and lengths of stay in both major

cardiac and non-cardiac surgery(170, 171, 173) and. The Perioperative Medicine Clinical Trials Network (POMCTN) multicentre INSPIRE trial is ongoing and will be the largest trial of preoperative IMT to date. (174).

1.6.1.4. Summary

Multiple individual studies have now illustrated potential benefit for uni- and multi-modal preoperative exercise training. Subsequent meta-analysis by Moran et al (175) indicated a reduction in postoperative complications, yet evidence was of insufficient quality to comment upon mortality or other key outcomes such as length of stay. Several larger randomised controlled are studies underway to consolidate these initial findings. Studied exercise interventions vary enormously with significant scope for further mechanistic work to identify the 'optimal' training protocols to enhance aerobic fitness, lean muscle mass, strength, and stamina. Clarity of intervention reporting to facilitate accurate clinical implementation is key, alongside adherence to the concept of 'exercise prescription' with clear parameters for the appropriate dosing of training in terms of volume and intensity and clear rules for progression supported by robust monitoring and 'before and after' objective assessment. This concept is highlighted in a national guideline for preoperative exercise which sought to synthesise the best currently available evidence for aerobic, resistance and IMT in several surgical populations(176).

1.6.2. Nutritional support

Good nutrition is a bedrock of the overall physiological reserve necessary to meet the systemic demands of the surgical stress response, notably the period of whole-body protein catabolism, insulin resistance and hyperglycaemia that follows surgery(49). Beginning this process from a state of malnutrition makes this substantially more difficult. Malnutrition can be broadly defined as an 'unbalanced nutritional state leading to changes in body composition and impaired physical function and subdivided into under and over-nutrition. 50% of patients admitted to hospital are either malnourished or at risk(46).

Under-nutrition reflects a state or chronic macronutrient or micronutrient deficiency leading to a progressive loss of body weight, notably lean muscle mass and a state of sarcopenia. Lean muscle is a key reservoir of amino acids necessary to support postoperative wound healing and immune function(46, 49) Patients presenting with a BMI of <18.5 kg/m^2 face markedly increased rates of morbidity, mortality alongside an elevated length of stay and associated increased healthcare costs(177, 178). The cause is frequently reduced oral intake, this may be pre-existing in the surgical patient or result directly from the surgical pathology (e.g., an oesophageal malignancy) or indirectly as a consequence of treatment e.g. nausea or diarrhoea following chemoradiotherapy(46, 49). These barriers are often compounded following surgery requiring supplemental nutrition both enterally and intravenously depending on the procedure.

Conversely, obesity reflects a state of chronic caloric excess resulting in excess adipose tissue. Paradoxically, sarcopenia may simultaneously exist alongside micronutrient deficiency leading to functional impairment. Obesity and the associated metabolic syndrome confer their own increase in anaesthetic and surgical risk with rates continuing to increase in surgical populations(179, 180). This reflects a concerning population trend, with diets amongst children and adults in developed countries(181) increasingly unbalanced toward an excessive sugar and refined carbohydrate load(182) resulting from consumption of ultra-processed food sources(183) at the expense of adequate lean protein, appropriate fat intake and micronutrients and fibre from fruit and vegetables. As outlined above, this is frequently no longer counterbalanced by sufficient physical activity. The resulting metabolic derangement and systemic inflammation caused is increasingly acknowledged as a key risk factor for multiple chronic health conditions including: Type II diabetes, ischaemic heart disease and the solid organ malignancies that may require surgical intervention(184).

Systematic reviews of preoperative intervention to address malnutrition have demonstrated 30-50% reductions in infectious and non-infectious complications reflected in a 2-day reduction in length of stay(185, 186). Preoperative screening is key, and whilst no single tool has yet emerged, an ideal tool might consider features of malnutrition from a physical, functional, and metabolic standpoint(46, 187). Once

identified, the central element of preoperative support to positively alter body composition is protein supplementation to support anabolism of lean muscle and offset the increased preoperative turnover that may develop in cases of malignancy, chronic illness, and advanced age. Requirements prior to surgery may reach 1.2-2.0g/kg/day on a background of intakes frequently <1g/kg/day in older adults. Intake should be spread across the 24hr period and ideally 20-35g consumed following exercise(46). Indeed a synergistic relationship exists between protein intake and exercise training, resistance training stimulates anabolism in muscle and adequate nutrition is essential to reap the adaptive benefits of any exercise training intervention(188). A further area of interest is immunonutrition, or supplementation of agents seeking to positively modify the immunological response to surgery with systematic reviews suggesting improved complication rates when utilised preoperatively(185). However, routes of administration and potential need for several days of hospital attendance or admission prior to surgery have limited practical utility within perioperative pathways(46, 189)

1.6.3. Psychological support

The third recognised pillar of prehabilitation is perhaps the most complex. Three key risk factors have emerged conveying increased perioperative risk: Chronic depression, chronic anxiety, and low self-efficacy(103). These factors may co-exist, and depression and anxiety represent recognised psychiatric conditions within the ICD-10 with an accompanying evidence base for diagnosis and management. Low self-efficacy, an individuals' belief in their capacity to act toward specific goals, is a psychological state widely associated with poorer health outcomes, highlighted by the adoption of the patient activation measure by the National Health Service(190). Low-self efficacy may hamper efforts to engage in preoperative support for other health behaviours(191).

Despite this clear association and acceptance that psychological health and wellbeing matters to patients and is necessary for better perioperative outcomes, there is a paucity of evidence for specific preoperative intervention. This was highlighted by recent traditional(192) and network(193) meta-analyses.

Treatment of depression and anxiety are distinct conditions with established treatments such as cognitive behavioural therapy, requiring a differing approach to the building of self-efficacy. These issues in turn are distinct from other efforts that are accepted as psychological preparation for surgery including educational interventions such as highly successful surgery schools(194) and dedicated pain management programmes(195) that aim to improve outcomes for patients presenting in chronic pain and hold increasing importance in the face of the growing opioid epidemic. It could also be argued that interventions to support the consent process and support shared decision making also fall under this umbrella.

In addition to chronic psychological issues requiring support, it is accepted that the preoperative period is an acutely stressful and anxiety provoking period even for patients without pre-existing mental health problems and demand exists for support for these issues, interest continues to grow in preoperative stress management techniques including mindfulness training(196, 197), however the evidence base here is also thin. Finally, an interesting concept is the 'knock-on' benefit to self-efficacy from successful engagement in non-psychological support. This in turn may contribute to the observation that success in modifying one health behaviour may support subsequent or simultaneous engagement in tackling others(125).

1.6.4. Smoking cessation

The deleterious effects of tobacco smoking on multiple organ systems and threat to longer-term health through increased rates of cardiovascular and respiratory comorbidity are well-documented(198). Rates of smoking in the western world continue to fall in the wake of persisting public health campaigns and a public ban in the UK(199). The landscape has been altered by the emergence of e-cigarettes and 'vaping' as a route to cessation and the phenomenon of previous non-smokers beginning to use these devices. The longer-term impact of these emerging devices on general health is unclear with little published evidence in the perioperative context(200). Notably, smoking is now a clear marker of associated socioeconomic deprivation with concern that efforts to achieve even lower rates may be stalling(201, 202). This raises the possibility that the remaining population of smokers may have

more difficulty engaging with support toward quitting. In particular, lower rates of educational attainment and psychiatric morbidity are emerging as key risk factors for difficulty in quitting using normal measures(203).

Rates in patients presenting for major surgery are estimated at 10-15% although this varies considerably across the UK in keeping with variation in population smoking rates(204). The impact on surgical outcomes is significant. The pathophysiological effects upon the cardiovascular and respiratory systems through direct cellular injury and resulting organ dysfunction render them less able to respond to the demands of major surgery(104). Rates of PPCs are twice that of non-smokers reflecting prior lung injury and poorer function particularly dysfunction of local immune mechanisms and mucociliary clearance(205). Impact on the cardiovascular system, notably injury to the arterial walls and associated atherosclerosis, simultaneously double the risk of acute vascular events such as myocardial infarction, stroke, and thromboembolism(205). Finally wound healing is significantly impaired increasing the risk of breakdown and infection by 50%(205). The collective effect of this substantially increased morbidity burden is a 30% increase in perioperative mortality compared to non-smokers(205). Awareness of this added risk in smokers listed for surgery may be poor(206).

The benefits of preoperative cessation are well established. Systematic reviews indicate that quitting 4-6 weeks before major surgery may halve rates of PPCs with no adverse effect of efforts to quit closer to surgery(207-209). The most effective route to preoperative cessation is a combination of a health behavioural change intervention and nicotine replacement therapy. These are the ‘gold standard programme’ (GSP)(210, 211). However, implementing this preoperatively has proven challenging. Whilst documentation of smoking status occur in 90%, provision of brief advice to quit by perioperative team members estimated at 30-60%, the final key step, referral and uptake by a GSP standard cessation programme may be as low as 5-23%(212).

Despite the focus of dedicated prehabilitation services seeking to remedy this, early data highlights that smoking status remains challenging to modify preoperatively and whilst increased rates of physical activity or lower alcohol consumption may persist

into the postoperative period, patients who quit preoperatively may return to smoking by 3-months following surgery(128).

1.6.5. Alcohol reduction

The concept of ‘hazardous’ or ‘risky’ drinking is a persisting public health problem. Adults consuming alcohol at levels above the government recommended 14 units per week face increased rates of chronic health conditions including liver disease, stroke, diabetes mellitus and cancer. Alcohol accounts for 75% of deaths due to liver disease in the UK, with mortality rates rising rapidly in exception to other major non-communicable causes of death. This is likely a reflection of the growing proportion of hazardous drinkers in the UK, estimated at 25% of adults(213).

Population trends are reflected in surgical cohorts, with rates of hazardous consumption estimated at 20-30%. Excess alcohol exacerbates the neuroendocrine inflammatory response to surgery(105), reflected in increased rates of cardiovascular, haematological and PPCs leading to increased lengths of stay and mortality(105). Notably, risk follows a dose-response pattern. Complication rates are 50% greater once consumption exceeds 14 units per week(214). Given the time period of chronic hazardous consumption required for liver injury to develop and manifest clinically(213), a large proportion of patients preparing for surgery and facing increased perioperative risk may have little outward evidence of organ dysfunction or more severe alcohol dependence.

Preoperative screening including quantification of consumption alongside tools to detect features of dependence such as the AUDIT-10 tool (215). Once detected, interventions should aim to reduce consumption below 14 units weekly. Interventions are broadly divided into ‘intensive’ and ‘brief’ programmes combining behavioural counselling and pharmacological support usually targeted at patients with significant excess consumption and features of dependency(216). A systematic review indicated that complication rates may be reduced by 50% with 4-8 weeks of reduced preoperative consumption(217). ‘Brief’ behavioural interventions have shown efficacy in reducing hazardous drinking in other healthcare settings(218).

They are more readily utilised across preoperative contact points but evidence for benefit is comparatively limited. An exception is the pre-op BIRDS study that has demonstrated feasibility of a brief intervention prior to major orthopaedic surgery(219).

1.6.6. Sleep health

The perioperative evidence-base for the impact of poor sleep health and intervention to enhance it preoperatively is extremely sparse with most published work relating to support of in-hospital sleep quality in the immediate perioperative period(220). However, the growing recognition of the importance of sufficient sleep of sufficient quality as key element of health(221) comparable to physical activity and proper nutrition offers potential to enhance prehabilitation efforts.

Whilst sleep appears minimally demanding outwardly, it is a physiologically dynamic process with distinct phases conferring profound biological effects(222). It's value is reflected in conservation across multiple species, suggesting an overriding evolutionary benefit despite rendering an organism unconscious and vulnerable for several hours at a time(223). The two key phases of Rapid Eye Movement (REM) and Slow Wave Sleep (SWS) are broadly thought to support psychological and physical recovery respectively. REM sleep supports a complex process of neuronal and synapse remodelling believed to be integral to learning and the formation of memory(224). Slow wave sleep is associated with neurohormonal and immune modulatory phenomena including maximal release of growth hormone(225). The now widespread recognition of the value of healthy sleep as a 'performance enhancing substance' for athletes is likely driven by the value of these phases in driving skill acquisition, optimising the adaptive response to training and preventing injury(226).

The deleterious effects of poor sleep health are also increasingly recognised. Of note, this broad phenomenon is distinct from and more widespread than established sleep disorders such as sleep apnoea and insomnia. A cohort study of over 41,000 adults from the UK biobank(227) suggested only 40% experienced regular healthy

sleep. The nature of poor sleep health appears to be heterogenous with overlap and interplay between issues of obtaining enough quantity (e.g., being able to fall and stay asleep) enough quality (achieving sufficient time in the restorative phases of sleep) and features of formal sleep disorders such as snoring. Once established, poor sleep tends to persist. Key risk factors include: Socioeconomic deprivation, shift working, being part of an ethnic minority and concerningly chronic physical and mental ill health(227). This suggests a potentially vicious circle given the association between poor sleep and hypertension, type II diabetes and ischaemic heart disease, driven by activation of the sympathetic nervous system, impairment glucose control, and systemic inflammation in response to sleep restriction(228, 229). In addition, the stress response to poor sleep may exacerbate and promote other health behaviours including a poor diet(230).

Patients preparing for major surgery may face acute psychological distress and other factors such as neoadjuvant treatment and pain likely to undermine even previously good sleep health. The mechanisms above suggest that efforts to tackle challenging issues such as smoking, alcohol excess, altering a poor diet and obtaining maximal benefit from an exercise training programme are likely to be hampered substantially by a state of acute or acute-on-chronic poor sleep. Sleep intervention has been shown to support efforts to manage obesity(231) and achieve smoking cessation(232) and a reciprocal relationship between increased physical activity and exercise and improved sleep health is recognised(233). Successful sleep health interventions typically seek to improve sleep hygiene(234, 235), removing factors such as late consumption of alcohol, caffeinated beverages or large meals, avoidance of stimulation such as blue light, intense exercise and encouraging behaviours that promote duration and quality of sleep such as consistent bed and wake times alongside early morning natural light exposure. Whilst preoperative sleep hygiene interventions are yet to be extensively studied, it represents a potentially simple, low-resource and low-cost addition to a multimodal prehabilitation programme that could potentially catalyse change across all other elements.

1.6.7. Prehabilitation for cancer surgery

Major elective surgery remains the key curative treatment for solid organ malignancy. People with cancer face additional challenges in preparation for surgery. The importance of structured prehabilitation to cancer care has been emphasised by publication of national guidance by Macmillan Cancer Support, The Royal College of Anaesthetists (RCOA) and the National Institute for Health and Care Research (NIHR)(101).

All of the health risk behaviours discussed so far are associated with development of malignancy(236). In addition, the socioeconomic factors that increase rates of those behaviours are also associated with higher rates of cancer. Crucially, those patients facing greater deprivation are likely to present later, with more advanced disease and subsequently require more extensive surgery(237). Even patients without pre-existing health risk behaviours may be placed at additional risk by the direct effect of their disease, such as reduced oral intake and increased protein catabolism driving a development of malnutrition or essential neoadjuvant treatments. Chemoradiotherapy profoundly undermines aerobic capacity assessed by CPET(238-240) and carries a host of side-effects that may further undermine nutritional intake(46). These treatments also take a psychological toll on the individual and family which, in addition to the impact of a frightening diagnosis and the natural anxiety associated with planned major surgery is sufficient to undermine mental health and wellbeing(101).

This situation is compounded by the imperative to treat promptly and minimise risk of local and distal metastasis for improved longer-term oncological outcomes leading to the shortest preoperative windows from diagnosis when compared to other major elective non-cancer procedures. Thus, people with cancer are frequently at markedly increased risk, are most in need of preoperative prehabilitation support, yet have the least amount of time available to access and engage with it. Prehabilitation interventions intended for people with cancer must be mindful of these unique challenges

1.7. The role for systematic intervention design and development in future studies

As discussed above, there is a growing body of evidence for the benefit of prehabilitation, with substantial improvement in perioperative outcomes from several studies. However, in addition to the specific limitations in the evidence base discussed above, several key overarching issues currently limit the definitive conclusion for some observers that prehabilitation should be a standard of perioperative care. In a comprehensive umbrella review of other systematic reviews concerning exercise training and nutrition support, McIsaac et al.(241) concluded that due to heterogeneity in included studies and methodological issues evidence was of low-to very low quality for conclusive evidence of benefit. The authors highlight diversity in screening techniques, programmes delivered, duration of support and adherence as key issues undermining synthesis of findings.

The importance of adherence to intervention success is becoming increasingly apparent. A recently published trial of remotely supervised multimodal prehabilitation from the same authors concluded no evidence of benefit overall, yet highlighted significant improvements in participants that had adhered(242). This is perhaps unsurprising yet a widespread issue driving variation in outcome in trialled interventions. McIsaac and colleagues also point out that there is little clarity in published studies around how and why interventions were designed and in some cases what was actually undertaken(241). The importance of applying a systematic approach to intervention development for cancer prehabilitation has been previously emphasised by Grimmet et al.(243) in a recent review they highlight the role behavioural science can play in development and understanding of why interventions succeed or fail.

The importance of systematic intervention development incorporating key stakeholders, existing evidence and underlying behaviour science theory(244) is already acknowledged within other allied healthcare settings including diet, activity and type 2 diabetes(245, 246). This is reflected in published guidance from the

Medical Research Council (MRC) on the development of complex healthcare interventions(247)

Notably vanguard clinical services implementing prehabilitation into routine critical care have arrived at this point from another direction, now seeking to better understand the barriers to service uptake, engagement, and adherence.

1.8. Implementation of prehabilitation within perioperative medicine pathways

Despite acknowledged flaws in the evidence-base, the success of early pilot services (126-129) and wider adoption of a perioperative medicine approach has driven emergence of a growing number of prehabilitation programmes in NHS surgical centres. The Covid-19 pandemic and its disruption of elective surgical care means current NHS waiting lists sit at approximately 7 million people(74). This has catalysed a redoubling of efforts modernise perioperative pathways and a paradigm shift from ‘waiting lists’ to ‘preparation lists’(248). Many UK surgical centres are opting not to wait for the evidence base to catch up before embarking on prehabilitation implementation. These drivers, and the experience of pilot and early adopting services has emphasised several challenges for prehabilitation delivery.

1.8.1. The multidisciplinary prehabilitation team

When considering the components and potential complexity of a multimodal prehabilitation programme, it is rapidly apparent that delivery is beyond the capability of a single healthcare professional group. A patient-centred approach able to meet a wide range of need necessitates the involvement and support of a multidisciplinary prehabilitation team. Figure 1.6 illustrates the range of team members that may be necessary.

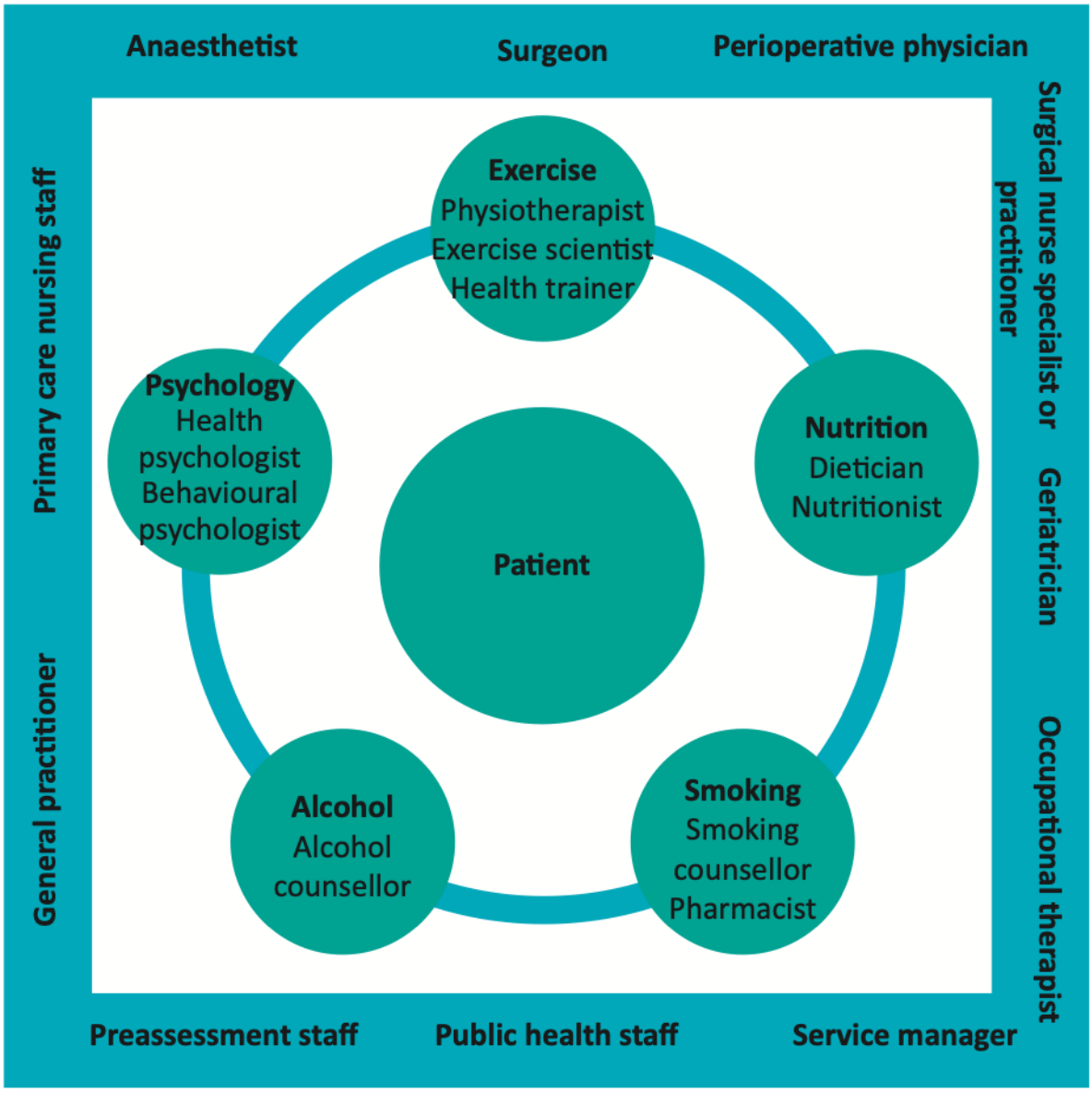

Fig 1.6. Members of the multidisciplinary prehabilitation team (not exhaustive) (97)

The role of each team member may vary dependent on the patients position on their preoperative pathway. Whilst some HCPs may be critical to promotion of a programme or service to patients, notably the listing surgeon, others may be more involved in operational delivery of programme support with patients or an advisory role for specific health risk behaviour issues such a physiotherapist and exercise scientist, dietitian, or health psychologist(83, 97).

The preoperative pathway offers multiple potential contact points where the patient may encounter one of these health professionals. Each represents an opportunity to offer, reinforce, or support a prehabilitation programme requiring consistent messaging across the wider team to facilitate programme uptake and engagement. This is the 'making every contact count' (MECC) concept for consistent and effective public health messaging endorsed by NHS England(249).

Whilst the involvement of the wider perioperative team is essential to success, the complexity of programme coordination and delivery, particularly for multibehavioural support, has necessitated dedicated staff to lead services and coordinate and manage support with input from the wider perioperative team. This reflects the established pressures on perioperative services increasingly unable to easily free staff from their routine clinical duties, now compounded by the substantial elective backlog. Efforts are underway to develop staff in these roles, notably the Macmillan ProsPer project for the delivery of prehabilitation for people with cancer(250). These initiatives acknowledge the breadth or skills and competencies required exceed that of a single HCP background, with the intent that potential future 'prehabilitation practitioners' may be drawn from multiple backgrounds. Further work is underway to include individuals with skills, knowledge, and expertise directly relevant to prehabilitation but who would fall outside of the traditional HCP categories. These individuals such as exercise trainers and health coaches may have much to offer clinical services but may be limited from a medicolegal and governance perspective to engage with NHS patients without intensive oversight from professionally registered HCPs. Work is underway to bring these groups under the same standards of accreditation, accountability and indemnity including the establishment of the CEP-UK organisation for clinical exercise professionals(251).

1.8.2. Pathway mapping and cross-sector working

A key step toward intervention implementation is a clear understanding of the preoperative pathway, allowing identification of contact points for opportune prehabilitation referral and programme promotion. There is substantial variation between surgical specialties and individual units. As outlined above, pathways

frequently do not readily support a prehabilitation approach leading to redundant preoperative time and wasted opportunity to approach and engage patients and intervene(83). The pivot towards a perioperative medicine approach is likely to make this less frequent however successful programmes have begun by obtaining a clear understanding of their local pathways and designed their prehabilitation support packages to fit. Developing interventions require a clear understanding of how they might fit within these frameworks. A clear frontier for development is closer cross-sector working and the breakdown of siloes between primary and secondary care. As discussed in more detail in chapter 2, there are huge potential advantages and equal challenges to commencing prehabilitation support earlier in preoperative pathways and closer to 'point of referral' in primary care. Any initiatives must be mindful of the unprecedented crisis currently facing primary care services(252). This reality is reflected in the difficulties many active services have encountered in extending their reach to patients outside of secondary care and earlier than 'point of listing' for surgery.

1.8.3. The 'tiered model' of prehabilitation support

This imperative to balance resource and demand has logically led to attempts to rationalise the intensity of support offered and the targeting of resources, the most precious of which is direct staff time, based on patient need. A tiered framework for prehabilitation has been proposed(101) based upon the established NHS model for comprehensive personalised care(253) encompassing 'universal' support relevant and accessible to any patient preparing for major surgical intervention moving through 'targeted' interventions to 'specialist' level care requiring the most intensive time and resource application for patients with complex needs. Figure 1.7 illustrates this concept applied to tiered provision of exercise/activity and nutritional support for prehabilitation. There is therefore scope for effective and robustly developed interventions at all levels of this framework.

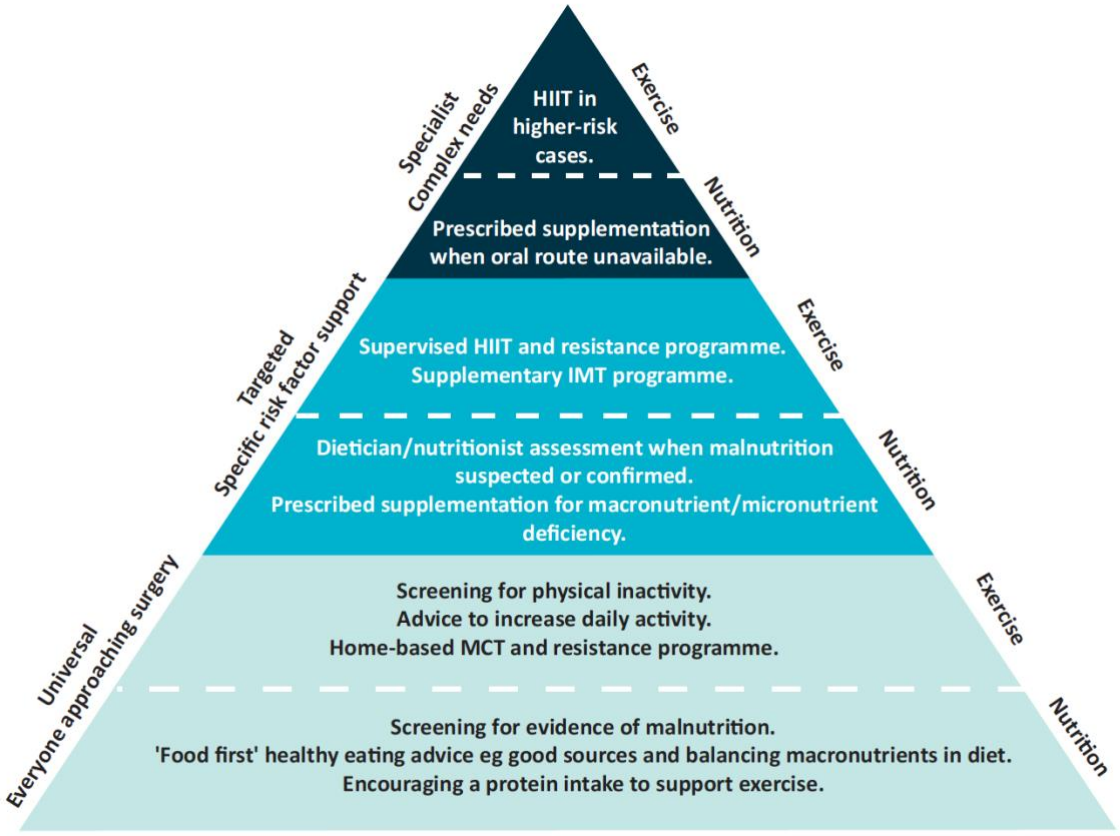

Fig 1.7. The comprehensive personalised care model applied to prehabilitation(97).

Resource need is balanced against demand. Universal interventions are generically applicable to the wider surgical population frequently requiring minimal staff oversight. Intervention intensity and resource need escalate through tailored interventions addressing more specific patient needs towards intensive interventions typically necessitating the most direct staff contact and time to support the most complex patients with the greatest care needs.

1.8.4. Learning from clinical services

Despite the acknowledged gaps in the evidence-base for prehabilitation, the rapid uptake and emergence of services across the UK has been driven by the success of longer established early-adopting services. The UK WesFit/ SAFEFit trial is a clinical service housed within a research study(126). Full trial publication is pending but preliminary results are encouraging (personal communication). The South Tees

Hospitals PREPWELL service began delivering community-based multimodal prehabilitation to patients across multiple cancer and non-cancer pathways in 2018. The service has iteratively developed with a quality improvement approach to evaluation demonstrating excellent observed rates of health behaviour change, patients adherence and programme satisfaction alongside enhancement of quality of life(128). These findings are consistent with the PREPARE programme(254) and the Medway Maritime prehabilitation programme(127).

The largest active programme with reported outcomes is the prehab4cancer initiative(129) within the GM-Cancer alliance delivering community based multimodal prehabilitation to people with cancer across Greater Manchester. A recently published wide ranging programme evaluation(255) compared the outcomes of over 1,500 patients undergoing major surgery with contemporary comparators who had declined participation. On average, prehabilitated patients experienced a 1.5-day reduction in hospital and 0.4-day reduction in critical care stay respectively releasing surgical capacity to the scale of 550 ward bed days and 146 critical care bed days. These findings were supported by improvement in functional capacity assessed by 6-minute walk test and WHODAS alongside physical frailty and quality of life.

In addition to these compelling outcomes from prehabilitation in real world clinical practice. These services have accumulated substantial ‘know-how’ in delivery of face-to-face support. A consistent experience across these services is the acknowledgement that the face-to-face model has been unable to engage the full range of surgical patients. Programme uptake is consistently around 50% across multiple services(128, 255). Therefore, around half of patients preparing for major surgical patients suitable for prehabilitation support are unwilling or unable to engage with the face-to-face model.

1.8.5. The case for remotely supervised prehabilitation

Existing prehabilitation services have identified several consistent barriers to face-to-face programme uptake, particularly for those services operating from a single community or hospital centre. Issues include: Travel time and cost, lack of flexibility around employment, family and carer commitments or discomfort in the face-to-face

group support environment(128, 255). A diversified menu of prehabilitation offers may therefore be necessary to engage a larger proportion of the surgical population. Remotely supervised or ‘home-based’ support has emerged as an appealing alternative, offering face validity for wider geographical reach and increased flexibility for both patients and staff to address the issues that may limit face-to-face participation.

This has been the driver behind development of comparable interventions in allied healthcare setting such as cardiac and pulmonary rehabilitation, where home-based programmes have shown comparable efficacy to face-to-face services(256, 257). PPI work conducted by existing services and corroborated data presented in chapter 2 confirm the appetite for this model amongst surgical patients. A discussion of remotely supervised prehabilitation necessitates consideration of the impact of the Covid-19 pandemic on prehabilitation delivery. As discussed in more detail at the opening of chapter 4, the pandemic forced existing services to rapidly reconfigure toward remotely supervised delivery, leading to rapid release of multiple remotely supervised alternatives now in clinical use(258-260).

Whilst the evidence base may be behind the leading-edge of current practice for prehabilitation overall, this is now most acute in the context of remotely supervised programmes. At the time of writing there is no published evidence around patient preferences for the format, structure, or delivery of remotely supervised support. Similarly, studied remotely supervised interventions are equally heterogenous in design preventing identification of the ‘optimal’ remotely supervised intervention components.

1.9. Summary and thesis overview

Whilst the evidence base continues to develop, supporting preoperative change in multiple health risk behaviours to prehabilitate patients for major surgery is recognised route to enhanced perioperative outcomes from the patient and wider healthcare system perspective. Learning from existing services suggests that successful face-to-face models may fail to adequately engage the full spectrum of patients in need of prehabilitation support. These services report clear patient appetite for remotely supervised alternatives. Clarity in the design and delivery of interventions is likely to enhance the evidence base to identify the most effective protocols to effect preoperative change and enhance outcomes in both direct and remotely supervised settings. Supporting uptake and subsequently adherence and intervention fidelity is emerging as a key determinant of intervention success. The importance of applying a systematic development process to complex healthcare interventions like prehabilitation programmes is well recognised. Currently, no published remotely supervised prehabilitation interventions have undergone such a process likely to optimise intervention success. This presents a clear gap in perioperative care provision now acute in the wake of the Covid-19 pandemic

This thesis presents a collection of work intended to contribute to addressing this gap. The subsequent chapters detail three studies and a final planned follow-on study approved to commence at time of writing. These include:

- **Chapter 2: An exploration of patient preferences for remotely supervised prehabilitation support utilising a discrete choice experiment.**

  This study employed conjoint analysis to explore the preferences of patients preparing for major surgery for the design and delivery of remotely supervised prehabilitation programmes.

- **Chapter 3: Systematic development of a remotely supervised, digitally facilitated multibehavioural prehabilitation programme**

Incorporating data presented in chapter 2, this study presents systematic co-design and development of a theory and evidence-informed remotely supervised, digitally facilitated multibehavioural prehabilitation programme.

- **Chapter 4: The iPREPWELL multibehavioural digital prehabilitation programme**

  This chapter presents the iPREPWELL intervention developed in chapter 4

- **Chapter 5: Feasibility testing of a remotely supervised, digitally facilitated multibehavioural prehabilitation programme**

  This chapter presents a planned and approved mixed-methods single-arm feasibility study that will evaluate the iPREPWELL intervention in patients preparing for major surgery.

- **Chapter 6: Thesis discussion**

Next, chapter 2 begins the process of determining patient preferences for remotely supervised prehabilitation support, presenting the results of a discrete choice experiment applied to the perioperative setting to explore preferences for programme design

2. Chapter 2: An exploration of patient preferences for remotely supervised prehabilitation support utilising a discrete choice experiment.

2.1. Introduction

Multibehavioural prehabilitation programmes are complex healthcare interventions comprising a package of interacting components. There is significant scope for variation between programmes. Format, mode of delivery, content, supervision, and interaction between the programme, participating surgical patients and healthcare professionals can be modified. Programmes seek to employ evidence-based approaches to support preoperative health risk behaviour change and modify perioperative risk. However, patients must first be engaged to participate, then achieve good adherence. Health behaviour change and risk reduction cannot occur if the individual is unable or unwilling to initially accept the programme on offer or subsequently engage with and adhere to its content.

Achieving these pre-requisites for all potential patients is not straightforward. Acceptability of health behaviour interventions is a complex interplay between individual patient factors and the attributes of the intervention offered(261). There is likely to be diversity across the wider population preparing for major surgery. Concerningly, several common features characterise groups less likely to accept and adhere to health behaviour interventions across multiple settings including older age groups, lower socioeconomic group, multimorbidity, multiple heath risk behaviours and social isolation(262-265). Paradoxically these hardest to reach groups may stand to benefit most from support on offer.

Longer established services providing structured health behaviour support, such as cardiac rehabilitation, recently reported uptake rates ranging from 20-50%(266).

Newly established face-to-face prehabilitation services have reported uptakes of 47%-75%(127-129). The importance of adherence to an accepted offer has been further underlined by recent randomised controlled trial evidence evaluating home-based exercise prehabilitation to improve postoperative functional recovery(242). Per protocol analysis identified that exercise capacity was only enhanced in participants with 80% programme adherence, with no benefit observed when the intervention group were compared to control group using intention to treat analysis. Designing prehabilitation interventions that promote uptake and programme adherence is likely fundamental to achieving improved perioperative outcomes.

Established face-to-face services continue to gain valuable experience delivering prehabilitation in clinical practice and aim to align programmes with patient preferences. Services have recognised that a single mode of delivery is unlikely to capture the full spectrum of patients in need of prehabilitation support. The Covid-19 pandemic has rapidly increased learning in relation to home-based prehabilitation as services rapidly reconfigured in response to national lockdowns(258), however formal research into patient preferences is lacking.

As recognised in wider healthcare settings(267), obtaining a clear picture of patient preferences for home-based prehabilitation/rehabilitation programmes is likely to support development of interventions that can engage patients, achieve good adherence and in turn produce better outcomes(247). This presents practical challenges in study design. Obtaining sufficiently detailed preference information for patients with unique individual circumstances, diagnoses and upcoming procedure would lend itself to qualitative, interview-based methods. This would allow a detailed understanding of home-based prehabilitation programme attributes that are acceptable or unacceptable for that individual. However, this approach would be time and resource intensive to scale and capture the breadth of data representative of the wider population of patients preparing for major surgery. This approach would suit a more focussed research question around a specific proposed home-based intervention. Conversely, a more quantitative survey or questionnaire-based method would be more rapidly applicable to a wider population but return less detailed data regarding individual programme attribute interaction with others in the package and the patients unique characteristics and circumstances.

Conjoint analysis (CA) presents a potential solution to explore patient preferences where very little is currently known.

2.1.1. An overview of conjoint analysis and discrete choice experiments (DCEs)

Conjoint analysis combines the comparative speed and reach of a quantitative survey but aims to obtain a fundamentally qualitative picture of individual patient and population level preferences for, and acceptability of the attributes and features of a given programme. Conjoint analysis has three broad subtypes: 'Ranking rating', 'Best-worst scaling' and discrete choice experiments (choice based conjoint analysis). The limitations of ranking-rating and best worst scaling methods in capturing the 'real world' effects of packaging levels alongside others in combination (like competing products on the shelf) has led to discrete choice experiments becoming the most widely utilised method of conjoint analysis within consumer research(268, 269)

These methods have roots in mathematical psychology and are widely utilised in commercial product design and marketing with expansion into both transport and environmental economics. Discrete choice experiments take the perspective of the individual consumer choosing whether to purchase a given product. It sits within a wider field of 'stated preference' methods, investigating what consumers indicate they would do when faced with a hypothetical scenario, rather than observation of their actual behaviour, known as 'revealed preference techniques'.

When undertaken across a larger sample, the preferences of the wider market can be obtained, allowing a single product or range of products to be optimised for acceptability and likelihood of purchase. This approach recognises that most products can be described in terms of several different attributes, that can be varied and combined (conjointly) in several different ways. The range of potential options for each product attribute are known as its 'levels'. Table. 2.1 illustrates this concept,

presenting a simple selection of product attributes and levels that could be varied and combined in the context of cars.

Table 2.1. Potential attributes and levels of a DCE concerning cars

Attribute	**Levels**
Engine size	• Litre • 1.4 Litres • 2.0 Litres
Number of doors	• Three • Five
Paint colour	• Red • Blue • Black • White

A combined selection of levels, one for each product attribute, is a ‘concept’ describing the whole package presented to a consumer considering a purchase ‘off the shelf’. A core premise of DCEs is the weighing-up the overall acceptability, or utility of the package of levels presented. Naturally, the importance of each attribute and the acceptability of a specific level will vary between individual consumers. At one extreme, consumers may be very focussed on a single product attribute, seeking to obtain, or avoid, a specific level whilst ignoring others entirely. Similarly, they may view all attributes as equally important, or unimportant, with no attribute dominating their overall decision to purchase or reject the product. All rational consumers sit at different points on this spectrum and crucially, the importance or unimportance of a given attribute and acceptability, or unacceptability of a particular level may vary depending on the range of attributes presented and which other levels are packaged within the product concept offered, leading to trade-offs to obtain or avoid particular levels.

DCEs aims to determine the degree to which each product attribute is driving consumer decision making overall and which levels are more or less acceptable to the individual and wider target market, allowing determination of which product, or

range of products would be deemed most acceptable to the target market. This is more analogous to this actual experience consumers face when choosing between products. The basis of DCEs is the 'choice task' in which two or more product concepts built from the same core set of attributes and levels and varied by one or more are presented alongside each other. An example choice set is presented in fig 2.1.

Table 2.2. Example choice set from a DCE concerning cars

	Car A (concept A)	**Car B (Concept B)**
Engine size	1.4 Litres	1.4 Litres
Number of doors	Five	Three
Paint colour	Black	Red
Parking sensors	Yes	No
Price (£)	28,000	20,000

Respondents are asked to indicate a preferred concept for each task. However, this approach indicates only which product is preferred, sacrificing detail around the strength of that preference or the ordering of the other non-preferred concepts. Completion of several structured choice tasks presenting differing concepts is required to describe which attributes are driving choices and which levels are more (or less) acceptable to the respondent. DCEs can be conducted using algorithmically generated pen and paper questionnaires or electronically and are readily accessible to a wide range of respondents.

2.1.2. DCE outputs and interpretation

There are several interrelated outputs from DCEs that allow understanding of respondent preferences:

- Level utility scores (also referred to as ‘partworths’ or ‘level utilities’)
- Attribute relative importance
- Shares of preference and market simulation

2.1.2.1. Level utility scores

Level utility scores reflect the acceptability (or unacceptability) of a given level reflecting the frequency with which it was included in preferred concepts. They are typically scaled to an arbitrary constant, frequently to sum zero within each attribute, allowing negative and positive scores.

They are an example of interval data, permitting addition and subtraction only, with each increment on the scale reflecting an equal difference in acceptability. This is analogous to the Celsius scale (^{o}C) of temperature in which ‘0’ is tied arbitrarily to the freezing point of distilled water such that, whilst it requires the same amount of heat energy to raise the temperature from 10^{o}C to 20 ^{o}C as from 30 ^{o}C to 40^{o}C, there is not twice as much heat energy in a liquid of 40^{o}C as one at 20 ^{o}C and ratio 40/20 is meaningless. Example utility scores from two attributes relating to cars are shown below.

Table 2.3. Example level utility scores of a DCE concerning cars

Attribute	Levels	Level utility
Engine size	• Litre • 1.4 Litres • 2.0 Litres	5 15 -20
Number of doors	• Three • Five	-5 5

Negative scores do not necessarily indicate 'unpopularity' or 'unacceptability' only 'less' compared to other levels within that attribute. It would be imprecise to define -20 ^{o}C as 'cold' and +20 ^{o}C as 'hot' only that +20^{o}C is hotter than -20^{o}C, and vice versa. This is particularly important in the context of 'binary' attributes with only two levels, such as 'number of doors' in table 2.3. Both levels may be acceptable (or unacceptable) to the respondent, however a preference for one will automatically result in a negative score for the other.

Crucially, level utility scores can only be meaningfully compared within the same attribute only allowing commentary on the acceptability of each level in relation to others within that attribute. In the example above, we cannot say that a 5-door car is equally acceptable as a 1L engine, in the same way that two 1kg blocks of differing metals at 5^{o}C may hold vastly different quantities of heat energy. However, the difference in acceptability of a 1.0L and 1.4L engine is equal to that between a three and five door car e.g., '10'.

The range of utility scores within an attribute is informative and indicates variation in the acceptability of the levels studied. For individual respondents, utility scores will be closer where there is greater indifference, e.g., no levels are deemed particularly acceptable or unacceptable compared to others in the same attribute. At a cohort level, where level utilities are pooled this may still indicate indifference but could also reflect a polarised cohort. For example, in a cohort of 100 respondents considering binary attribute X containing levels A and B, 50 respondents strongly favouring level A will be counterbalanced if the other 50 respondents strongly preference level B.

This attribute and its levels are clearly influencing overall concept acceptability, however there may be little difference in the utility scores of A and B when summarised for the cohort.

2.1.2.2. Attribute relative importance

The importance of a given DCE attribute to the overall acceptability or utility of the product in question, or the degree to which it is driving respondent decision making, is reported as ‘relative importance’ and allows ranking of the attributes studied. Relative Importance is an example of ratio data. Here the ‘0’ point is meaningful. An attribute with a relative importance of 100% indicates it dominated respondent decision making entirely, 0% indicates it was completely ignored. Similarly, attribute X with a relative importance of 40% is twice as important to overall product acceptability, utility and decision making as attribute Y with 20%.

Relative importance is intrinsically linked to the range of level utility scores within the attribute, a wider range suggests differing acceptability and that levels within that attribute were being actively sought or avoided. At the individual level, the range in level utility scores for each attribute can be calculated and summed with relative importance for each attribute, reported as a proportion of the total.

Relative importance also supports interpretation of utility scores at the cohort level. If multiple respondents are indifferent to the levels of an attribute that is unimportant overall, there will be a narrow range of utilities for each respondent and a low mean relative importance for that attribute overall. Conversely, a polarising attribute with wide but opposing utility score ranges across multiple respondents may also result in a narrow utility score range for the cohort when pooled, but the high relative importance at the individual level will be reflected in a high mean relative importance across the cohort.

2.1.2.3. Shares of preference and choice simulation

Level utility scores and linked attribute relative importance can be difficult to interpret and apply to 'real world' scenarios and questions, because the cohort results from a given DCE do not necessarily reflect how individuals would respond to a given concept. The 'most acceptable' concept comprising the levels with highest utility scores from each attribute estimated (highest summed utility) across the cohort, may still be completely unacceptable to an individual respondent or subgroup of responses holding preferences opposite to the majority. Choice simulation aims to predict the behaviour of individual consumers studied based upon the estimated level utilities. This is presented as 'shares of preference', the proportion of a studied population that would find that concept acceptable. This information frequently holds more 'real world' value in answering questions facing commercial organisations for example: A company with a single production line trying to determine which single product concept would give them greatest market share compared to their competitors or attempting to diversify a line of products to increase their overall market share or determining which concept would best appeal to a subgroup of their target market.

2.1.3. Limitations of traditional discrete choice experiments

Traditional DCE methods rely on multilogit regression. This requires either, multiple choice tasks to calculate individual level results or, restriction of the survey to a small number of attributes and levels. Many choice tasks are laborious for the respondent. To ensure all study levels are presented in sufficiently varied combinations, choice sets are typically designed with 'minimal overlap' concepts using orthogonal design. Given these may vary significantly from the respondents 'ideal', the survey may seem unfocussed and frustrating, repeatedly presenting choice tasks with concepts that either include unacceptable levels or omit critical levels for the respondent(269).

Traditional DCE also assumes ‘compensatory’ decision making by the respondent. i.e., whilst none of the concepts presented in the choice set may be ideal, the participant sums the individual acceptability/utility of each level in each concept and chooses the concept with the greatest utility overall, this is the weighted additive assumption of random utility theory upon which conjoint analysis is based.

Further investigation has demonstrated that this does not always hold true. Respondents may approach the process with predetermined ‘hard and fast rules’ for attributes and levels. These may wholly dictate the acceptability of the concept overall. Choices are frequently made using rapid ‘non-compensatory’ decision-making heuristics, driven by the presence or absence of specific level without an additive evaluation of the overall concept utility(269-272). This is exacerbated by overly complex, irrelevant, or uninteresting choice tasks. Respondents commonly adopt a ‘dual process’ decision making approach whereby key must-have or unacceptable levels are first screened for using simplifying non-compensatory heuristics, rapidly eliminating concepts that do not conform before the remainder are more effortfully weighed up in their entirety(269, 270).

Consequently, within traditional DCE, little attention may be paid, or information garnered about several study attributes and levels. This is supported by the recognition that, once engaged in a DCE survey, participants may spend less than 20 seconds per choice task. Further work identified that in CBC surveys of nine attribute concepts, 85% of respondent choices could be explained by consideration of no more than four attributes(269, 270, 273).

2.1.4. Adaptive choice based conjoint (ACBC) analysis

Recognition of the limitations of traditional DCE has driven development of adaptive methods that acknowledge dual process decision making and tailor DCE surveys to provide a more relevant, interesting, and engaging respondent experience. The intent is to gather richer preference information across the breadth of study attributes and levels.

Adaptive Choice Based Conjoint Analysis (ACBC) is a proprietary method developed by Sawtooth Software Incorporated (Provo, Utah, United States of America). This has emerged as a leading tool combining the advantages of 'full profile' choice tasks with additional elements approximating dual process decision making that customise the subsequent survey to the respondent. The additional stages increase survey completion time above traditional DCE, however this is traded off against reduced measurement error, improved prediction of 'holdout task' choices (274)(choice tasks not utilised in utility score estimation but included in surveys to validate the utility estimates) and better prediction of observed real world purchasing decisions Crucially, participants also report a much more relevant, engaging and less effortful experience(269, 270, 273, 275). The adaptive nature of ACBC prevents use in a pen and paper format, with surveys delivered electronically.

ACBC allows for a much wider range of potential attributes and levels to be incorporated to a stated maximum of 100 attributes and 250 levels. To obtain benefits over CBC, it is recommended when the number of studied attributes is 6-12 with no more than 7 levels per attribute. The individualised and focussed surveys generated may also allow a smaller sample size of respondents, offsetting the added completion time(270).

ACBC surveys proceed in 3 stages:

- Build your own (configurator) stage
- Screener stage
- Choice tournament stage

2.1.4.1. Build your own (BYO) 'configurator' stage

Respondents are asked to indicate their preferred level for each programme attribute, providing the combination of levels that defines their ideal concept. This provides the questionnaire with both the ideal concept for each participant and a useful indication of baseline respondent preferences similar. An example BYO question is provided in table 2.4.

Table 2.4. Example BYO question from an ACBC DCE

'Please describe the car you would be most likely to purchase. Indicate your preferred choice for each feature below.'

Feature	**Select feature**
Engine size	• 1.0 Litre • 1.4 Litres • 2.0 Litres
Number of doors	• Three • Five
Paint colour	• Red • Blue • Black • White
Sunroof	• Present • Absent
Gearbox	• Manual • Automatic
Parking sensors	• Present • Absent

This concept is used as the basis to ensure the remainder of the survey and alternative concepts presented remain related to the respondent ideal scenario and the survey remains focussed from their perspective.

2.1.4.2. Screener stage

The aim of the screener stage is to identify non-compensatory 'hard and fast rules' for each respondent early. This ensures subsequent screener questions and the choice tournament stage adapt to avoid repeatedly seeking preference information that the participant has already provided. This also allows the choice tournament to investigate attributes and levels the participant may have paid less attention to earlier, whilst concepts remain focussed on their priority attributes and levels.

Screener stage questions are typically presented with 3-5 concepts on screen simultaneously. Each concept is varied by the software from the 'ideal' BYO concept by a pre-specified number of attributes, such that every concept on screen is close to the ideal scenario. Participants are asked to indicate, for each concept presented, whether it would still be 'potentially acceptable' or 'no good for me'. An example screenshot of a screener question is provided in table 2.5. ACBC surveys typically require 7-9 screener questions.

Table 2.5. Example screener question from an ACBC DCE

'Here are four possible cars. For each one, please indicate whether it would be a possibility for you, or no good.'

	Car 1	**Car 2**	**Car 3**	**Car 4**
Engine size	1.0L	1.0L	1.4L	2.0L
Number of Doors	Three	Five	Three	Five

Paint colour	Red	Red	Black	White
Sunroof	Present	Present	Absent	Absent
Gearbox	Automatic	Automatic	Manual	Automatic
Parking sensors	Present	Present	Present	Present

Responses to several screener questions can rapidly identify participants holding non-compensatory fixed rules, e.g., a respondent totally unwilling to accept a manual gearbox might mark every concept presented with one as ‘no good’, only indicating concepts with automatic gearboxes as ‘potentially acceptable’ in the opening screener questions.

Identification of this type of response pattern triggers a targeted probe question that interrupts the screener questions, where the respondent is asked directly if a given level or levels are ‘must have’ or ‘totally unacceptable’. Labelling a level in this way ensures it is always present or absent in subsequent screener question concepts and similarly in choice tournament concepts.

This action at the screener stage weights the calculation of the utility score for the level marked as must have/unacceptable and by extension increases the relative importance of the relevant attribute.

2.1.4.3. Choice tournament

Following the screener stage, concepts marked as prior ‘possibilities’ are entered into the choice tournament. This stage mimics a traditional full profile DCE process however, all concepts will now conform to any non-compensatory rules identified by the participant and will tend to reflect their BYO ideal scenario more closely (although this specific concept will not appear in the tournament).

3-5 concepts are presented on screen per question and the respondent is asked to identify a preferred option. The preferred concept then advances to the next round. This process proceeds over 7-9 questions until a 'winning' concept is identified. To minimise the participant burden and support processing of the concepts presented, levels that are the same between concepts on screen are greyed out to allow comparison of the attributes that differ. This deliberately draws attention toward attributes of 'secondary' importance that may have been largely overlooked prior to this stage as non-compensatory rules were prioritised. An example choice tournament question is provided in table 2.6.

Table 2.6. Example choice tournament question from an ACBC DCE. Similar levels between concepts are greyed out to reduce reading burden and draw focus to other attributes and levels

'Here are three possible cars. Please indicate which is your preferred option?'

	Car 1	**Car 2**	**Car 3**
Engine size	2.0L	1.4L	1.4L
Number of Doors	Three	Three	Three
Paint colour	Red	Red	Black
Sunroof	Present	Present	Present
Gearbox	Automatic	Automatic	Automatic
Parking sensors	Present	Present	Absent

By requiring respondents to systematically weigh-up and trade-off attributes and levels in a staged approach, the eventual choice-tournament winning concept may be viewed more favourably by respondents and better fit their needs than the original concept specified at the opening BYO stage.

2.1.5. Discrete choice experiments applied to the healthcare setting

In the last 20 years, DCEs have been increasingly utilised to explore and quantify patient, service user, healthcare professional and other stakeholder preferences and valuation of many aspects of healthcare(268, 269). DCEs have now been applied to establish preferences across multiple healthcare contexts ranging from specific treatments and outcome measures to design of regional healthcare structures and payment systems(268, 269, 276). Interest continues to build in the use of DCEs to support uptake and adherence to clinical and public health programmes including prevention and treatment of chronic health conditions such as type II diabetes(277)and specific health risk behaviour programmes relevant to prehabilitation such as weight management(278) and smoking cessation(279). This acknowledges the discord that may exist between patient and system priorities and further underlines the importance of understanding patient preferences to deliver genuinely patient centred care.

A recent bibliometric analysis of over 1500 included studies(280) highlighted a rapid increase in publications since 2010 and that DCE has become a leading tool within health services research, influencing healthcare policy decision making. There is increasing focus on robust study design reflected in the publication of international guidance for design and practice by the International pharmacoeonomics and outcomes research (ISPOR) working group(281, 282).

Ryan et al.(283) highlighted that methodological issues common to CBC also apply in the healthcare setting. ACBC therefore presents a potentially more suitable method of obtaining respondent preference data that may also be more engaging for participants. The potential advantages for application to healthcare has been recognised(269) and ACBC has now been successfully utilised in this context.

A systematic review by Al-Omari et al(284) identified that DCEs have been widely utilised to explore patient preferences for osteoarthritis pharmacotherapies, in which patients must frequently trade off significant side-effects and risks against symptom benefits. An initial study incorporating an 8-attribute computer-based ACBC survey demonstrated the feasibility of the method in this population(285). The authors acknowledged prior concerns around acceptability of the method for the older age groups that typically suffer from osteoarthritis and may be less confident using digital technology. This study underlined the value of involving patient participants in survey design to minimise complexity and burden. Reassuringly, a linked study showed that individual level preference from the survey aligned with participants self-reported preferences(286).

2.1.6. Study Rationale

These successes in related healthcare fields make conjoint analysis an appealing method for rapid collection of initial preference data from surgical patients, in the context of remotely supervised prehabilitation. Where, very little is currently known beyond the predominantly anecdotal experiences of established clinical services. Building an evidence-base in this area is likely to support design of interventions that facilitate participant engagement and adherence. This is a pre-requisite for effective preoperative modification of health behaviours and improved perioperative outcomes. A discrete choice experiment utilising ACBC presents a useful method to initially explore this area, already established in allied healthcare settings.

Given the lack of prior work in this clinical area and population, identifying a specific study hypothesis, for example a specific programme attribute that may be more or less important to patients approaching major surgery is difficult. The anecdotal experience of existing prehabilitation services suggest multiple attributes could be considered. in addition, despite prior successful use in the healthcare setting, the feasibility of DCE use and specifically computerised ACBC in the preoperative population was not yet established. This study therefore opted to forgo a specific hypothesis in favour of a first exploration of surgical patient preferences in this area.

2.1.7. Study research question

What are the preferences of patients preparing for major surgery for home-based prehabilitation programmes?

2.1.8. Study aims

2.1.8.1. Primary aim

- Conduct an electronic questionnaire-based survey of patients preparing for major surgery incorporating an adaptive choice-based discrete choice experiment to explore patient preferences for home-based prehabilitation programmes.

2.1.8.2. Secondary aims

- Demonstrate the feasibility of DCE use to explore patient preferences in this clinical context
- Explore characteristic differences in patient subgroups expressing differing preferences.
- Utilise choice simulation to estimate programmes or combination(s) of programme features most likely to achieve widest acceptability to patients approaching major surgery and inform subsequent intervention development.

2.2. Methods

2.2.1. Ethical and regulatory approvals

Full ethical and regulatory approvals were obtained from an NHS REC and the HRA through submission to the Integrated Research Application Service (IRAS) to allow recruitment of NHS patient participants. Copies of approvals are available as appendix 1. following discussion with the departmental lead for research ethics, submission to a university ethics committee was waived based upon requirement for NHS ethical approval. As the recipient of competitive external funding (UK preoperative association trainee research grant 2018), the study was also registered on the NIHR portfolio for anaesthesia, perioperative medicine, and pain (APOMP) allowing study support from site clinical research teams.

2.2.2. Study overview

Study structure and participant flow is summarised in figure 2.

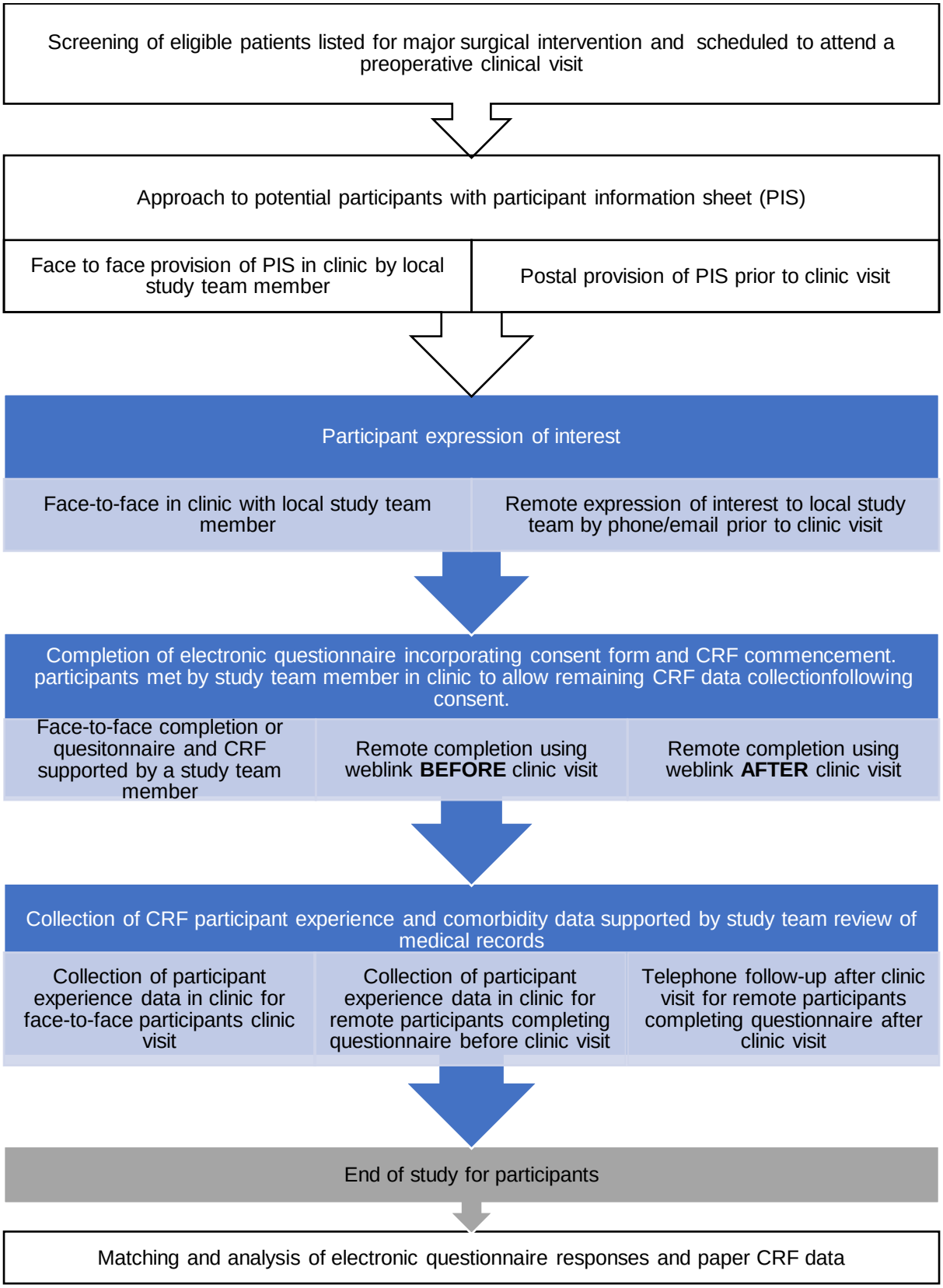

Figure 2.1. Study overview and participant involvement

2.2.3. Eligibility criteria

This study aimed to obtain representative views of adult patients preparing for major surgical intervention, the population likely to benefit most from subsequently developed remotely supervised prehabilitation interventions. It was intended that findings be applicable to wider UK surgical populations. Study inclusion and exclusion criteria with justifications are described in table 2.7.

Table 2.7. Study inclusion and exclusion criteria

Inclusion criteria	
Criterion	**Justification and rationale**
Adult patient (Age ≥18 years)	The average age of UK surgical patients approaching major surgery is 65 years(75) with rates of health risk behaviours relevant to prehabilitation support greater in older age groups. However, major surgical procedures are frequently required in younger adults, and they may also benefit from support for specific risk behaviours e.g., smoking cessation. This also allowed comparison to be made between surgical patients or different age groups. If differences exist this would be relevant for programme and service design.
Scheduled attendance at a preoperative clinical visit	This facilitated face-to-face contact with participants at a range of potential preoperative hospital visits by a study team member to allow collection of some clinical data (such as the clinical frailty score) that could not be robustly assessed remotely. This was primarily expected to be an anaesthetic preassessment clinic but also captured other visits, e.g., for neoadjuvant oncological therapy or a specialty nurse

	assessment offering flexibility in recruitment for participating sites and assisting in obtaining a wider spread of participants under the care of different surgical specialties
Scheduled NICE 'Major/complex' category procedure	As described previously, prehabilitation support is likely to be most beneficial to people undergoing major surgery, conferring the greatest perioperative physiological stress and associated risk. To ensure applicability to wider surgical populations the views of patients listed for major procedures only were sought. Major surgery is not well defined and the NICE NG45(3) document examples for 'major/complex' procedures were utilised to guide participating site screening activity. This list is not exhaustive and site principal investigators (almost all experienced consultant anaesthetists) were authorised to use clinical judgement as to what constituted a major procedure. Where there was uncertainty, local study teams were encouraged to contact the chief investigator (CI) for guidance.

Exclusion criteria

Criterion	**Justification and rationale**
Unable to provide electronic informed consent	As a non-interventional observational study, it was not felt to be necessary or practical to provide alternative consent options for participants unable to consent independently. In addition, understanding and completion of the DCE was expected to be challenging for participants in this category.

Understanding of written English does not allow completion of electronic questionnaire and questionnaire guide	Despite efforts to ensure maximum ease of understanding of both the questionnaire guide and DCE, it was expected that participation would require an understanding of written English which would present difficulties for some potential participants e.g., where English was a second language. Use of an interpreter would not have been feasible given the need to individually weigh-up choice tasks presented on screen during the DCE. In addition, there was insufficient funding to allow translation and reproduction of the questionnaire in additional languages. As the first study of its kind in a surgical population, this exclusion criterion was included for pragmatism.

2.2.4. Identification and preparation of participating sites

Potential sites local to the sponsor (South Tees Hospitals NHS Foundation Trust) were identified with the support of the NIHR Clinical Research Network (CRN) for APOMP Northeast and North Cumbria. Seven sites in the network including the sponsor site were included. To increase the wider applicability of study findings to surgical populations outside of the Northeast of England, three further sites were identified through protocol collaborators and expression of interest following registration of the study onto the NIHR portfolio.

Some participating sites recruited from more than one geographical location within their organisation. In addition to seven sites in the North East and Cumbria, the remaining three participating sites included representation from Yorkshire the South West and North West including trusts providing district general and tertiary centre services across a range of geographical and socioeconomic catchments.

Following expression of interest, local confirmation of capability and capacity and sponsor approval, a site initiation visit (SIV) was conducted with local study teams. Where possible the site principal investigator (PI) was a senior anaesthetist with experience in perioperative care to support screening decisions (see eligibility criteria above). Where this was not possible sites were encouraged to contact the CI for support. This was in-person or remote (facilitated by teleconference) depending on site preference and distance from the sponsor. This incorporated essential regulatory steps and full protocol training for local team members with particular focus on demonstration of the electronic questionnaire, use of the questionnaire guide and completion of the case record form.

2.2.5. Screening, recruitment, and consent

A participant information sheet (PIS) (appendix 2) was developed for patients in accordance with current HRA guidance (http://www.hradecisiontools.org.uk/consent/content-sheet.html). The draft PIS was piloted with a focus group of four patients enrolled in the South Tees 'PREPWELL' prehabilitation service prior to major surgery to ensure clarity and ease of understanding.

To support recruitment and facilitate pragmatic local processes for study teams and participants, a degree of flexibility was offered in the screening and recruitment process. Sites were encouraged to identify preoperative clinic lists likely to include eligible patients that could be attended, when necessary, by a study team member. In most cases these were anaesthetic preoperative assessment clinics, however some sites screened patients attending for preoperative neoadjuvant chemotherapy or other appropriate scheduled preoperative visits. Clinic lists were screened by local perioperative team members.

The PIS was provided to eligible participants either prior to the scheduled clinic visit by post or face-to-face by a study team member attending the clinic alongside the electronic questionnaire guide for participants (see below). This allowed local study teams to respond to short notice changes in clinic lists and ensure the maximum

number of potential participants could be approached. In all cases, participants were given time to read and understand the PIS.

Tick box informed consent was obtained electronically from eligible and interested patients prior to data collection, using a consent form appended to the data collection questionnaire (appendix 3). The consent form was developed and approved with reference to UK HRA guidance (https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/) and is provided as appendix 3.

Study funding was allocated to reimburse sites £15 for each participant recruited. A recruited participant was defined at SIV as an eligible patient progressing beyond the consent form of the electronic questionnaire. This was available even if patients withdrew from the questionnaire before completion which they were free to do at any time and their data withdrawn from the analysis

2.2.6. Determination of target sample size

Determination of target sample size for studies incorporating conjoint analysis is contentious and a priority area of methodological development for conjoint analysis research in healthcare. In a published review of prior work in healthcare, De-Bekker Grob et al(287) identified that of 69 prior studies (>70%) did not describe a formal sample size determination As a result, sample sizes vary widely typically ranging from less than 100 to over 1,000 respondents(276).

The authors of the above work argue that a formal minimum sample size calculation can and should be undertaken where appropriate, enhancing the credibility of findings that may influence intervention design and healthcare policy. This requires a clear initial belief about the results of interest and a specific hypothesis e.g., a difference between the relative importance of two attributes and estimation of a clinically meaningful difference.

Results from studies incorporating conjoint analysis, such as mean relative importance of attributes, are subject to two forms of error. Sampling error, deviation of the study sample from the target population and measurement error or failure to obtain 'true' results from an individual participant, resulting primarily from DCE design(288). Neither can realistically be eliminated. Measurement error is mitigated by appropriate selection of conjoint analysis method and considerations in questionnaire design (see below). Sampling error can be mitigated by an increase the sample size relative to the total target population. Consequently, it has been argued that simply maximising the sample size achieved is advisable. However, this ignores practical issues of availability of potential participants and resource constraints, both financial and in terms of staff time.(287-289)

In the study above(276) 15% referred to sample sizes utilised in prior studies and the remainder utilised a heuristic approach such as that proposed by Orme et al and others(288) in which increased statistical precision is balanced against study aims and intent, practical research constraints and the overall 'qualitative versus quantitative' focus of the study.

This study aimed to balance these positions. The limited prior work in surgical populations on this topic made prediction framing of a specific hypothesis and associated clinically meaningful difference upon which to base a sample size difficult. Within a DCE, participants make multiple comparisons between attributes, levels, and programme concepts across multiple choice sets. At this stage it was unclear which one of these would be most appropriate to focus upon. This approach would lend itself more easily to a study primarily comparing the DCE results of two distinct groups e.g., vascular, and colorectal surgical patients, rather than a first exploration of the results of a single cohort of patients attempted here. In addition, this study adopted an adaptive DCE design making specification of mechanics, such as number of choice sets undertaken difficult as these vary between respondents. Similarly, adaptive designs incorporate non-traditional DCE components (e.g., 'Build your own' and 'screener' stages) that are not accounted for in the minimum sample size estimation advised.

Despite minimum sample size calculation seeming impractical, statistical precision was a factor in determining the target sample. Based on guidance published by Orme et al 2016 (270, 288), exploratory, qualitative focussed work in new populations may require as few as 30-60 respondents. Conversely if the intent is comparison of sub-groups within the sample with the intent to detect statistically significant differences, approximately 200 responses per group is advised. If seeking robust quantitative data regarding a single cohort, a sample size of 300 is advisable

Several factors were therefore considered in selecting the study target sample size. The aims of the study were to explore the preferences of patients approaching major surgery, explore the feasibility of this method in the context of perioperative care, and provide useful information to support intervention development. Whilst multiple subgroups (e.g., surgical specialties, cancer, and non-cancer diagnosis) were deliberately included with the intent to compare results, it was not expected to produce definitive results for differences in preferences between subgroups. These study aims were balanced against practical considerations of research delivery including burden of a new type of questionnaire upon study teams and participants, number of interested research sites and availability of study funding.

Based on the above, the study sample size target was selected as 300. This was expected to be a practically achievable target allowing quantitative analysis of the cohort as a whole and initial qualitative exploration of study subgroups as a basis for later focussed work.

In addition, interim review of cohort attribute relative importance (and ranking) and level utilities was planned. This was a pragmatic check that adds reassurance around the sample size achieved. If the ranking of attribute importance and pattern of level utilities within each attribute are stable (i.e., no longer changing) between analyses with addition of further participants, it is generally accepted that the pattern for the cohort has been established though further recruitment would continue to reduce sampling error.

2.2.7. Electronic questionnaire structure and data collection

A multiple stage web-based questionnaire incorporating the following stages was systematically administered as summarised in figure 2.2.

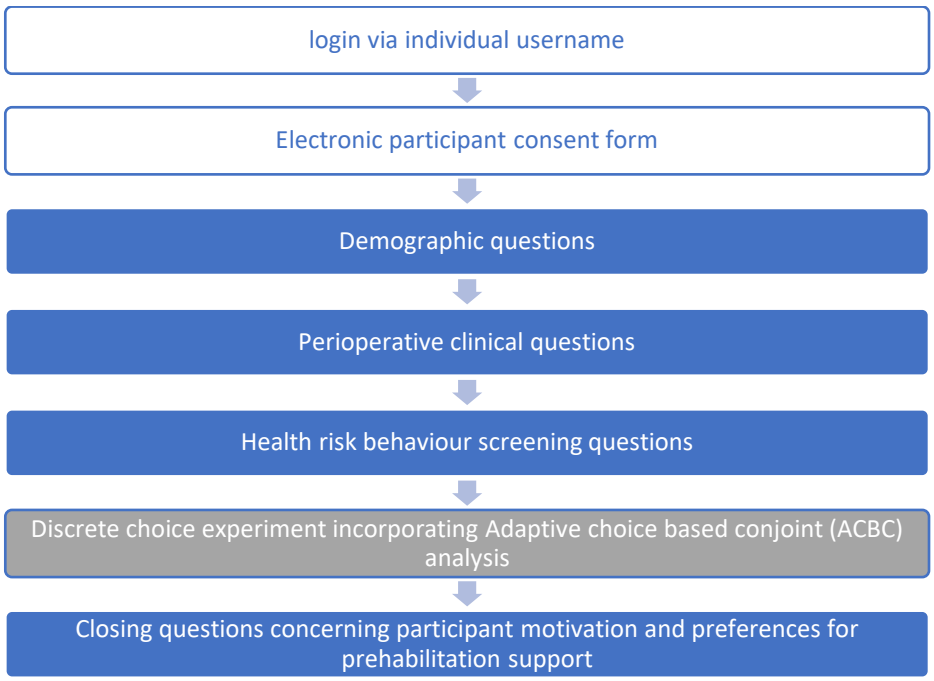

Figure 2.2. Electronic questionnaire summary structure and content.

The questionnaire and embedded DCE were built utilising the lighthouse studio software platform (Sawtooth Software, Provo, Utah, United States of America) and hosted on Northumbria University servers for access via weblink from participating NHS sites and participant personal devices. A summary of questionnaire content is provided as appendix 4 with screenshots from the live version in appendix 5.

To minimise questionnaire burden and accessibility for less digitally confident participants, check boxes were utilised wherever possible over free text entry. The questionnaire would not progress unless all data fields on screen were completed, Incomplete data fields were highlighted to the participant where needed. Progress was saved automatically against the participant username to allow later completion if required.

The electronic questionnaire could be commenced either with the support of a study team member at their clinic visit, or at home using a weblink and login details provided by the local study team. This was to maximise ease of participation for eligible patients and minimise the potential for exclusion of less IT confident participants (detailed below). The weblink and login could also be provided to eligible patients in advance of the clinic to allow prior completion. This was obtained through telephone or email request to the study team. The weblink and login could also be provided at the clinic for remote completion afterwards

The web-based questionnaire was supported by a paper case record form (CRF) for completion by study team member with reference to participant clinical records.

2.2.7.1. Demographic data

Demographic data were collected to facilitate description of the participant cohort and exploration of associations between participant demographic characteristics and expressed preferences for home-based prehabilitation support. Where relevant, demographics were recorded with reference to categories utilised by the UK Office of National Statistics (ONS). Demographic data collected included:

- Age
- Biological sex
- Ethnicity
- Marital status
- Employment status
- Home postcode for conversion to index of multi-deprivation (IMD) decile as a surrogate for socioeconomic deprivation.
- Educational attainment

2.2.7.2. Health risk behaviour data

Screening questions for health risk behaviours relevant to prehabilitation support were included to characterise the health status of the participant cohort and the applicability of study findings to surgical populations with health risk behaviours. Data were collected concerning the following:

- A subjective assessment of overall health in comparison to others of the same age using a 100mm Patient Global Assessment Visual Analogue Scale (PG-VAS)(290) in response to the question: ‘Compared to others your age, how would you rate your general health?
- Physical activity levels for moderate aerobic, vigorous aerobic and resistance activity against CMO criteria for healthy adults(131). Example activities were provided to assist participants.
- Smoking status
- Weekly alcohol intake quantified in units. Examples of unit content of alcoholic drinks were provided to assist participants

2.2.7.3. Perioperative clinical data

Perioperative clinical data were collected to facilitate description of the participant cohort and assessment of applicability of study findings to wider surgical populations. Data were also collected to allow exploration of associations between participant clinical characteristics and their expressed preferences. Perioperative clinical data collected included:

- Surgical specialty (e.g., colorectal, orthopaedic, vascular)
- Cancer status
- Planned and/or completed preoperative chemoradiotherapy treatment

2.2.8. Discrete choice experiment (DCE) design and development

The DCE component was designed and constructed with reference to both published guidance concerning utilisation in healthcare settings and technical guidance provided by Sawtooth Software. In particular, the ISPOR checklist for conjoint analysis applications in health was utilised as the benchmark design and analysis(281, 282).

2.2.8.1. Selection of attributes and levels

Potential DCE attributes and levels were identified through two routes. First, a literature review of prior healthcare studies incorporating conjoint analysis, in particular studies concerning health behaviour change interventions from related clinical contexts including general and cardiac rehabilitation programmes and smoking cessation programmes(291-293). Next, Attributes and levels were shortlisted based upon significance for the development of remotely supervised prehabilitation interventions and uncertainty around patient preferences where rational arguments could be made for preferencing different levels.

Several factors in attribute and level selection increase the complexity and duration of the process either requiring a larger number of choice sets or leading to less information being obtained for attributes and levels. Given a questionnaire of this type had not been previously utilised in surgical populations, a conservative approach was taken to refine the shortlist and avoid attribute and level selections that would result in a more burdensome questionnaire.

Firstly, programme attributes that could not realistically be aligned with expressed patient preferences in future intervention design were discarded. These programme attributes were expected to be heavily influenced by the evidence-base to support intervention efficacy e.g., ‘exercise programme type’ or healthcare system and resource constraints e.g., ‘provision of an internet enabled device to participants.

Next, attributes in which levels were sequential and could be ‘pre-ranked’ in terms of expected preference were discarded. An example would be the miles per gallon (mpg) fuel consumption of an automobile concept, in which rational participants will always logically favour the greatest mpg if available. Examples in this context were ‘number of weekly logins required’ and ‘time required per day’ expecting that participants would always prefer the minimum option and little extra information would be gained to aid intervention design.

Finally, attributes and their range of levels were ‘sense-checked’ to ensure that any conceivable combination of levels presented as a programme concept could realistically be combined in a future programme. DCEs can be designed with fixed rules that ensure ‘paired’ levels from different attributes are always presented together or that ‘mutually exclusive’ levels are never presented in the same concept.

This shortlist of attributes and levels was refined by discussion with perioperative clinicians experienced in prehabilitation delivery, then reviewed by and discussed with a focus group of 4 patients preparing for major surgery and enrolled in the South Tees PREPWELL prehabilitation service and reduced to a final list of attributes and levels. These are listed, with their accompanying rationale for inclusion, in table 2.8.

Table 2.8. Discrete Choice Experiment Attributes and Levels with rationale for inclusion

Attribute	Levels	Rationale
Preoperative start point	• GP referral • Surgical listing	Identifying the optimum programme start point is key to integrating interventions with preoperative care pathways. Prehabilitation starting at GP referral the 'point of first contemplation of surgery' would offer participants the maximum conceivable time to engage with support, achieve health behaviour changes and modify their perioperative risk. Conversely, whilst waiting until surgical listing would reduce the timeframe available, by this stage patients would be certain they were planned to undergo surgery and reap the potential benefits of programme engagement.
Programme format	• Paper-based • Digital-based	Programme format is fundamental to intervention design. The capabilities and considerations of paper-

		based and digital-based resources are fundamentally different. Whilst a digital format may offer significant advantages in terms of patient and staff flexibility, tailoring of support and greater ease of monitoring and feedback, it also risks exclusion of participants without internet access or confidence in utilising information technology, for whom a paper resource would be easier to engage with and adhere to.
Start place	• Hospital • GP or community venue • Home	Interventions would require an 'on-boarding' process to establish patients on the programme including an introduction to its structure and use alongside safety assessments for exercise and the provision and use of any ancillary equipment e.g., wearable devices or exercise equipment. A hospital or community introduction may allow face-to-face HCP involvement in the process and the ability to undertake 'baseline' health risk behaviour assessments

		(e.g., of exercise capacity or physical assessment of nutritional status). This is offset by the need for patients to attend a venue to commence the programme and a fully remote introduction undertaken in the home may be preferable to minimise travel, expense, and inconvenience.
Healthcare professional review frequency	• Weekly • Fortnightly • Monthly	Remote supervision would require a minimum degree of HCP oversight and scheduled interaction participants to review progress and troubleshoot issues, alongside the ability to make unscheduled contact when participants encounter unexpected problems. The frequency of scheduled contact can be varied. patients may feel unsupported by infrequent check-ins with the supervising HCP or harassed by more frequent check-ins.
Wearable integration	• Wearable monitoring • No wearable	Wearable devices offer potential advantages to both programme participants and supervising HCPs providing opportunity for continuous biometric

		monitoring and provision of real time feedback to support programme components. Wearable devices can be readily integrated into digital programmes but could also be utilised to support paper-based interventions. However, some patients may find this intrusive or lack confidence in using this type of technology.
Local service integration	• Integrates with local services • Purely 'home-based'	Home-based programmes can be designed with instructions, activities and support intended to run purely in and around the participants home, in contrast to centre-based purely 'face-to-face' interventions requiring attendance at a hospital or community centre this would offer maximum convenience and flexibility to patients seeking remotely supervised and self-managed support for those reasons. However, hybrid designs might signpost participants to and integrate with additional local face-to-face support that would bypass some limitations of home-based support, an example would be smoking cessation

		services to allow easy access to nicotine replacement therapy or additional group exercise classes.

2.2.8.2. Questionnaire guidance document

A recognised pitfall of ACBC studies is the presentation of excessive on-screen information for each choice task(270, 288). This leads to a substantial reading burden if extensive written description and explanation of attributes and levels is provided. This must be balanced against the need to provide participants with enough information and a point of reference to make reasoned choices. This is key in the earlier stages of the survey as repeated exposure over its course allows familiarity with the presented attributes and levels to develop by later stages.

To support completion of the DCE stage, a paper questionnaire guidance document with more full lay explanations of attributes and levels than those presented on screen was produced for participant reference where needed (appendix 6). The document was piloted with a focus group of four patients attending the South Tees Hospitals PREPWELL prehabilitation service to refine language and ease of understanding.

2.2.8.3. Design and testing of ACBC stages

The DCE was opened with an introductory screen immediately following collection of perioperative clinical data. This screen was intended to orient the participant to the DCE stage. It was emphasised that the DCE was not a 'test', and they were welcome to answer honestly at all stages to obtain their individual views.

- **Selection of full or partial profile choice tasks**

The relatively conservative number of study attributes (<12) compared to the potential maximum of ACBC studies allowed full profile choice tasks to be presented in keeping with ACBC technical guidance. This had the advantage of requiring fewer DCE questions to ensure a full and balanced exposure of all study levels without presenting concepts with an overwhelming amount of detail to compare.

- **Sequence order and preference order**

As outlined above, study attributes and levels were selected to avoid those with any predetermined logical order of preference (such as a product price or fuel efficiency of a car). No attributes were therefore programmed with a level preference order.

- **Total number of programme concepts included**

The total number of programme concepts presented to the participants is the number of screener stage questions multiplied by the number of screener question concepts. The overall DCE burden increases with the total number of concepts included, as more questions and choice tasks are required, however more concepts also allow all study levels to be shown to the participant a balanced number of times, avoiding biasing of preference for a given level simply because it was seen more, or less often by the respondent.

More concepts are therefore required to present a larger number of study attributes and levels evenly. Sawtooth software technical guidance advises that surveys present each level to respondents within concepts 2-3 times and recommends numbers of screener questions and the number of concepts presented in screener stages to facilitate this, based on the number of study attributes. The survey was therefore programmed with 7 screener questions per respondent with 4 choice tasks presented on screen per screener question resulting in 28 programme concepts generated per respondent.

- **Variation of screener programme concepts from the BYO concept**

As described above, screener concepts must vary from the specified ‘ideal’ BYO concept. The degree of variation is programmed as a minimum and maximum number of attributes to vary for each programme concept generated for the screener stage. This must balance the need to keep generated screener concepts close to the BYO ideal and remain respondent focussed and prevent multiple screener

questions yet ensure sufficient variance to allow all levels to be presented to the respondent. A larger number of attributes and levels may require greater variation. In keeping with sawtooth technical guidance based on the number of included attributes, minimum-maximum attribute variation was set at 2 – 3.

- **Maximum number of probe questions**

In keeping with sawtooth technical guidance(270), the maximum number of probe questions that could be triggered was set at 4 (number of screening questions – 3) for ‘unacceptable levels’ and 3 for ‘must have levels’ (number of screening questions – 4).

- **Number of concepts in choice tournament questions and maximum number of concepts entered**

Choice tournament questions were set as triples (three concepts on screen per question) rather than (or opposed to) pairs to reduce the total number of choice tournament questions required. Any concept marked as ‘potentially acceptable’ in the screener stage was eligible for choice tournament entry. The number of triple choice tasks required would be t/2 where t=number of concepts entered. The maximum number entered was restricted to 16, just over half of the maximum 28 potentially eligible In keeping with technical guidance(270) to ensure participants would be required to complete no more than 8 choice tournament tasks and less if fewer than 16 concepts were deemed potentially acceptable from the screener stage

In addition, as all attributes and levels were available in the BYO stage and this concept should logically dominate the tournament without providing any additional preference information, it was not included in the choice tournament.

- **Design testing**

As recommended in technical guidance(270), the ACBC design was tested using computerised 'dummy' random respondents within the lighthouse studio package to assess the design, assuming target sample size of 300 was achieved:

1. **Minimum number of level appearances**: As outlined above, participants should be shown each study level at least twice and ideally three times in presented concepts to avoid bias. Design testing conformed the minimum number of level appearances was at least 3 in all cases.

2. **Mean standard error (measurement error) of level utility scores**: Published technical guidance recommends that survey designs should seek a mean standard error of measurement of level utility scores of <0.05 across dummy respondents. Testing reported a mean (SD) standard error of 0.024 (0.004)

These findings suggested a robust design likely to provide reliable individual level utility scores and allow cohort level estimates to be made. As detailed in section 2.3.3. below, the target sample size of 300 was not met and the DCE design was re-tested with the actual recruited number of respondents to ensure minimum level appearances and mean standard error remained acceptable.

- **Planned handling of misleading or contradictory responses**

It was not anticipated that patient participants voluntarily offering their time to support the study would attempt to mislead the questionnaire by providing deliberately contradictory responses, but this was acknowledged as a possibility. In addition, it was considered that participants may provide contradictory or misleading responses inadvertently through difficulty understanding or completing the DCE component. The questionnaire software was able to identify this through detection of contradictory response patterns e.g., not marking a level as 'totally unacceptable' in a triggered probe question, then continuing to mark any screener concept containing

it as ‘no good’. If these patterns were detected, the participant was brought to the normal questionnaire end screen without an explanation or further detail automatically with the questionnaire response is logged and identified. These responses would be excluded from the subsequent analysis

2.2.9. Questionnaire closing questions

Following completion of the ACBC DCE stage, closing questions were asked concerning:

- Motivation to engage with prehabilitation support for short-term (perioperative) and longer-term health benefits utilising 100mm VAS scales as previously undertaken by McDonald et al(122)
- Willingness to engage with perioperative educational content (surgery school) as part of a remotely supervised prehabilitation programme (yes/no)
- Willingness to provide their clinical information as part of a prehabilitation programme to support the preoperative assessment process (yes/no)
- An overall preference for the format/model of prehabilitation support from the options of home-based, community based face-to-face, hospital based face-to-face or no support.

2.2.10. Questionnaire pilot testing

The electronic questionnaire was tested in its entirety with a focus group of 4 patient participants from the South Tees PREPWELL service to ensure readability and understanding. Participants confirmed that the intent of the DCE was clear to them and were able to complete each stage without difficulty

Following this, several dummy test runs were undertaken taking the perspective of theoretical participants answering the questionnaire with a variety of plausible different sets of strong preferences e.g., unwilling to accept a digital programme and wearable device due to a lack of confidence with digital technology or, seeking

regular HCP contact for reassurance while utilising the programme. level utilities and attribute importance estimated by the survey for these individual responses were reviewed to ensure they reflected the predetermined preferences of the simulated respondents.

Following this development and testing process the questionnaire was deemed suitable for data collection in recruited participants.

2.2.11. Participant paper case Record Form (CRF)

A separate paper case record form was developed for completion by a study team member to be paired with the participant electronic questionnaire response. The CRF was intended to collect additional data that may have been difficult for the participant to provide accurately and obtain feedback on their experience of completing the DCE. A copy is provided as appendix 5.

Data collected via the CRF included:

- Clinical data:

  - Height
  - Weight
  - BMI
  - Clinical Frailty Scale (CFS). Sites were provided with a visual guide to the CRF validated for use in routine perioperative practice. Study team members meeting patients at their clinic attendance were instructed to undertake the CFS assessment.

- Past medical history:

  - Comorbidity profile (obtained from preoperative assessment documentation or other appropriate proformas)
  - Number of prescribed medications

- Digital device ownership and utilisation (added retrospectively following start of recruitment after team members observed that some early participants explained they had multiple devices at home but preferred paper-based programmes)
- Questionnaire experience based on that collected by Al-Omari et al(285)

2.2.12. Data handling and analysis

Pseudo anonymised electronic questionnaire responses were exported from lighthouse suite and married by participant number with an excel database of corresponding returned paper CRFs into a pseudo anonymised master study dataset with recoding to prevent any individual participant from being identifiable
This was quality checked and cleaned with data queries returned from participating sites before analysis commenced.

Non-DCE questionnaire data were analysed initially in Microsoft excel using appropriate descriptive statistics for continuous and categorical variables.

Level utility scores and linked attribute relative importance were estimated using Hierarchical Bayes (HB) via the lighthouse studio analysis module. Both HB and monotone regressions can be utilised to estimate ACBC level utilities with comparable precision(270, 288). However, HB is considered preferable for ‘group level’ estimations and comparisons with monotone regression utilised primarily for individual level analysis.

95% confidence intervals were calculated for level utility scores and attribute relative importance. Subsequent exploratory subgroup analysis was led by initial cohort analysis of level utilities and relative importance to identify groups with differing preferences. The demographic and clinical characteristics of these groups were then compared descriptively.

Shares of preference for potential programme concepts across the study cohort were estimated using the lighthouse suite choice simulator employing a first-choice model, whereby each respondent is expected to select the programme concept that holds the highest total (summed) utility for them from those presented, based on their

individually estimated level utilities. A ‘none’ option was included predict when respondents would not accept any of the specified concepts, the utility of this option for each participant was estimated from programmes labelled as ‘no good for me’ at the screener stage. ‘Randomised first choice’ (RFC) was used to increase precision. RFC adjusts for the error around individual respondent utility scores by estimating share of preference for each respondent multiple times and aggregating the result. RFC has been shown to outperform other models in predicting shares of preference(270, 288).

2.3. Results

2.3.1. Recruitment and response

Study screening and recruitment commenced in April 2019 and continued uninterrupted the until onset of the Covid-19 pandemic in March 2020. At this point, the chief investigator was redeployed to intensive care and research teams at participating sites to clinical areas or priority Covid research.

Following reassessment in August 2020, most sites were no longer able to offer capacity to support the study and a decision was taken to formally halt recruitment and commence analysis of available data. 422 potentially eligible patients had been approached across the 10 study sites. 173 patients had consented to participate (recruitment rate 40%). As detailed above, this analysis was compared to an earlier cohort interim analysis of the first 75 participants. The hierarchy of attribute relative importance and relationship of level utilities was consistent between these analyses. The achieved sample size was also within appropriate parameters for robust cohort level analysis, though offered less statistical precision (see design retesting below). This number was also expected to be sufficient to undertake exploratory comparisons between subgroups.

These factors collectively supported a decision to close recruitment at this point. Following data cleaning, queries and analysis further complicated by the pandemic during 2021 the study was formally closed via HRA/REC processes in February 2022.

Of the 173 participants, the majority (78%) completed the questionnaire face-to-face with a study team member. A total of 164 complete electronic questionnaires were obtained (completion rate 94.8%). The accompanying paper case record forms were partially incomplete for several participants. The numbers of participants affected for the relevant data fields are indicated in the tables below.

Figure 2.3. summarises recruitment and flow of participants through the study.

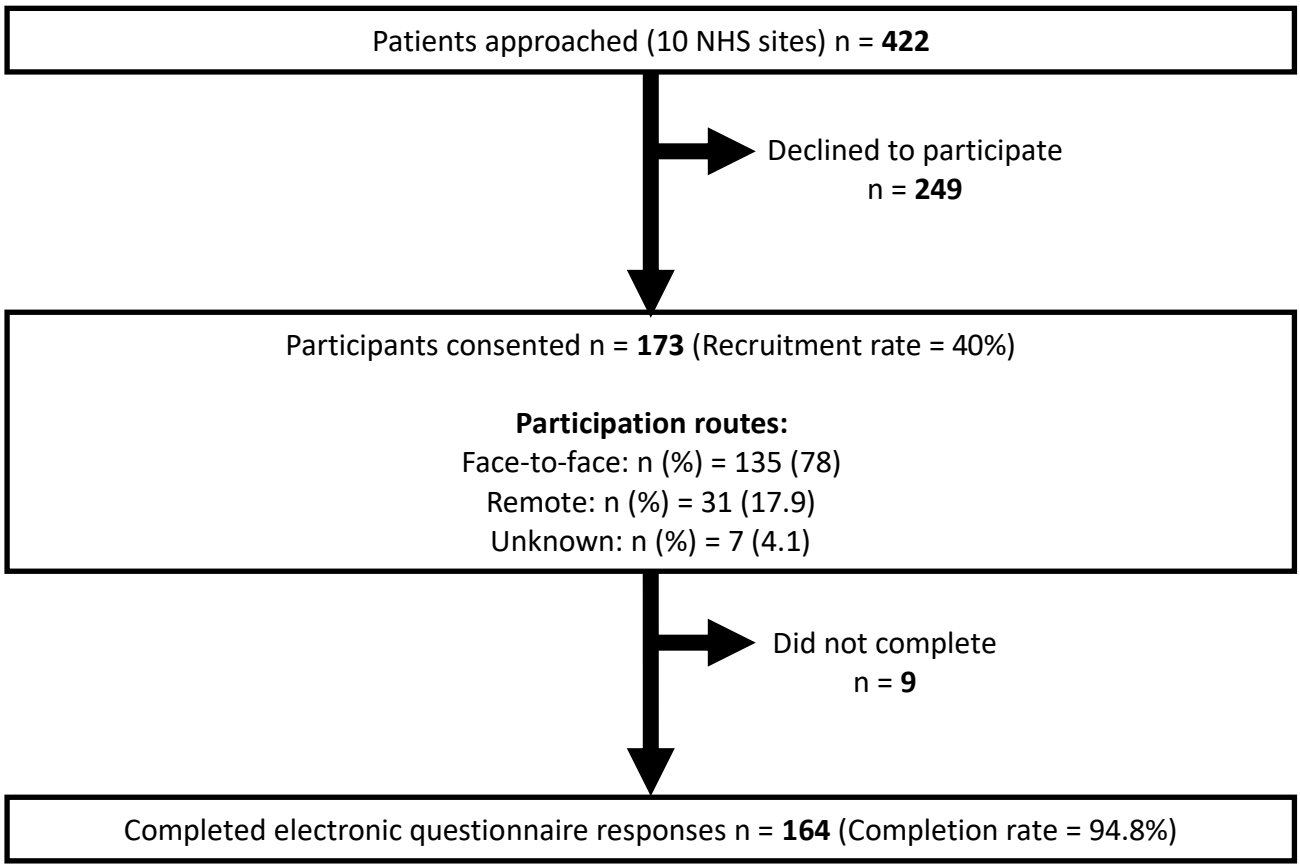

Figure 2.3. Study recruitment and participant flow chart

2.3.2. Handling and reporting of missing data

A complete participant dataset included a completed electronic questionnaire response married with a completed paper CRF. Complete electronic questionnaire responses were obtained for all 164 participants. However, paper CRFs were not complete in all cases leading to a variable to missing data. The number of participants affected ranged from 6-61 depending on the data field. This is indicated where appropriate in the relevant tables below. Where data were missing the number of participants affected are indicated as number and proportion of the. For participants with a full dataset, proportions were calculated using the reduced number of participants also indicated below.

None of the 9 participants who did not complete the electronic questionnaire component completed the DCE stage and their data were removed altogether from the analysis.

2.3.3. DCE design retesting

In response to the reduced final sample size, the DCE design was retested in keeping with the method described in section 2.2.8.3 ‘design testing’. 164 computerised respondents (rather than the original target of 300) were used to ensure each level continued to appear in choice sets frequently enough and measurement error of level utility scores remained within acceptable limits despite fewer participants. This re-testing confirmed that the design still facilitated >3 appearances of all study levels in choice sets and mean (SD) standard error of level utility score estimation was 0.034 (0.006) remaining within acceptable limits.

2.3.4. Participant characteristics

Table 1 summarises the demographics of the 164 participants. The cohort had a mean age and gender distribution comparable to other recently studied major surgical cohorts in the UK(75). Most participants were married. Only 5 participants listed their ethnicity as a group other than ‘white’. Most of the cohort were retired with one quarter in current full or part time employment. Extent of formal education was evenly spread with one third reporting degree or professional level qualifications. There was relatively even representation of all IMD deciles from 1-10.

Table 2.9. Participant demographics. Values are n (proportion) or mean (SD). No data missing.

Demographic characteristics (n = 164)		
Age	66.2	(12.1)
Gender M/F	86/78	(52/48)
Marital status		
Single	19	(11.6)
Married	107	(65.2)
Civil Partnered	5	(3.0)
Divorced	8	(4.9)
Widowed	19	(11.6)
Other	6	(3.7)
Ethnicity		
White	159	(97)
Asian	2	(1.2)
Mixed	1	(0.6)
Black	0	(0.0)
Other	2	(1.2)
Employment		
Full-time	28	(17.1)
Part-time	15	(9.1)
Retired	104	(63.4)
Volunteer	4	(2.4)
Unemployed	4	(2.4)
Other	9	(5.6)
Qualifications		
Nil formal	33	(20.1)
1-4 O-levels/GCSEs	24	(14.6)
5+ O-levels/GCSEs	27	(16.5)
2+ A-levels/VCEs	21	(12.8)
Degree/Professional qualifications	51	(31.1)
Vocational/foreign qualifications	8	(4.9)
IMD Decile		

1	17	(10.4)
2	12	(7.3)
3	13	(7.9)
4	17	(10.4)
5	15	(9.1)
6	16	(9.8)
7	23	(14)
8	23	(14)
9	20	(12.2)
10	8	(4.9)

Table 2.10. summarises participant clinical characteristics including health risk behaviour profile. A wide range of specialties were represented with the largest subgroup being major orthopaedic surgery (n= 49, 42.1%). Forty-six (27.9%) participants were preparing for cancer surgery although only 12 participants (7.3%) reported neoadjuvant chemoradiotherapy. The health risk behaviour profile of the cohort was comparable to prior studies in similar populations with high rates of physical inactivity. Sixty-six (40%) participants did not meet WHO targets for aerobic activity and 98 (59.8%) did not meet targets for resistance activity. One hundred and nine (73.6%) participants had a recorded BMI of >25kg/m^2. A wide range of comorbidities were recorded consistent with other major surgical cohorts with a mean (SD subjective general health rating of 60.9/100mm (23.9).

Table 2.10. Participant clinical characteristics and risk behaviour profile.

Values are n (proportion) or median (IQR). Missing data where indicated.

Surgical Specialty (n= 164)		
Orthopaedics	69	(42.1)
Upper GI	12	(7.3)
HPB	14	(8.0)
Colorectal	18	(11.0)
Urology	11	(6.7)
Gynaecology	13	(7.9)
Breast	4	(2.4)
Head and Neck	11	(6.7)
Vascular	10	(6.1)
Cardiac	1	(0.6)
Thoracic	1	(0.6)
Cancer surgery (n= 164)	46	(27.9)
Preoperative chemoradiotherapy (n= 164)		
None	152	(92.7)
Completed	8	(4.9)
Current	1	(0.6)
Planned	3	(1.8)
Health risk behaviour status (n= 164)		
Current Smoker	11	(6.7)
Alcohol intake >14 units per week	26	(15.9)
Physically inactive (WHO aerobic activity criteria)	66	(40.0)
Physically inactive (WHO resistance activity criteria)	98	(59.8)
BMI >25.0 (n= 148)	109	(73.6)
missing data	16	(9.8)
BMI <18.5 (n= 148)	2	(1.4)
missing data	16	(9.8)
Comorbidities (n= 159)		
Ischaemic heart disease	34	(21.4)
Heart failure	6	(3.8)
Peripheral vascular disease	6	(3.8)
Stroke/ Transient ischaemic attack	8	(5.0)
Chronic obstructive pulmonary disease	9	(5.7)
Asthma	20	(12.6)

Diabetes Mellitus requiring insulin	6	(3.8)
Diabetes Mellitus not requiring insulin	16	(10.1)
Osteoarthritis	51	(32.1)
Inflammatory arthritis	12	(7.5)
Chronic Kidney disease	17	(10.7)
missing data	5	(3.0)
Polypharmacy (n =158)		
>5 agents	43	(27.2)
>11 agents	19	(12.2)
missing data	6	(3.7)
Clinical Frailty Scale ≥4 (n= 146)	27	(18.4)
missing data	18	(11.0)
Subjective general health rating (on 100mm scale) (n=164)	63.0	(34.5)

Table 2.11. summarises the device utilisation and ownership/access profile of the cohort. Participant numbers are lower reflecting the amendment of case record form to collect these fields following commencement of study recruitment, in addition to missing data. Most participants with recorded data (n=96, 93.2%) had access to at least 1 device and were utilising a device at least a few times per week (n= 94, 69.6%).

Table 2.11. Participant device utilisation and ownership profile. Values are n (proportion) Missing data where indicated.

Frequency of device usage (n= 135)		
Daily	76	(56.3)
A few times per week	18	(13.3)
Very rarely	22	(16.3)
Never	19	(14.1)
missing data	29	(17.7)
Device Ownership or access (n= 103)		
Desktop computer ownership or access	37	(35.9)
Laptop computer ownership or access	46	(44.7)
Tablet computer ownership or access	53	(51.5)
Smartphone ownership or access	71	(69.0)
No devices owned or accessible	7	(6.8)
missing data	61	(37.2)

Additionally, responses to questionnaire closing questions indicated: Most participants were supportive of remotely supervised prehabilitation interventions that included peri-operative educational material (n= 128, 78%). The majority also supported confidential submission of clinical information to support their preoperative assessment process (n= 152, 92.7%).

Participants were also motivated to engage with prehabilitation support to obtain both short-term (peri-operative) and longer-term (post-operative) benefits; mean (SD) ratings on a 100mm scale were 85.6mm (20.2) and 86.6mm (19.9), respectively. When asked to indicate their overall preferred format of prehabilitation support, remotely supervised support was the most popular (n= 97, 59.1%), followed by Community-based (n= 42, 25.6%) and Hospital based (n=12, 7.3%). A minority (n= 13, 7.9%) indicated they would likely not engage with any prehabilitation support offered.

2.3.5. Full cohort: Questionnaire experience

Table 2.12. summarises the participant experience of completing the adaptive electronic questionnaire incorporating the ACBC choice experiment. Most participants found the questionnaire and choice experiment accessible and had a positive experience completing the questionnaire.

Table 2.12. Participant questionnaire experience. Values are n (proportion). Missing data where indicated.

Prior questionnaire and survey experience (n=135)					
	Yes		**No**		**Unable to remember**
Completed previous computerised/electronic questionnaires	72 (53.4)		57 (42.2)		6 (4.4)
Completed previous pen and paper questionnaires	97 (71.9)		32 (23.7)		6 (4.4)
Missing data	29 (17.7)				
Electronic questionnaire and choice experiment experience (n= 125)					
	Strongly agree	**Agree**	**Unsure**	**Disagree**	**Strongly disagree**
The questionnaire was easy to read	21 (16.8)	77 (61.6)	8 (6.4)	17 (13.6)	2 (1.6)
The questionnaire was easy to understand	15 (12.0)	72 (57.6)	14 (11.2)	21 (16.8)	3 (2.4)
The choice experiment was easy to understand and complete	15 (12.0)	69 (55.2)	18 (14.4)	20 (16.0)	3 (2.4)
The questionnaire was adapting to my responses	19 (15.2)	77 (61.6)	21 (16.8)	7 (5.6)	1 (0.8)
The questionnaire was enjoyable to complete	19 (15.2)	72 (57.6)	20 (16.0)	11 (8.8)	3 (2.4)

The questionnaire helped me to think about my preferences	25 (20.0)	82 (65.6)	7 (5.6)	11 (8.8)	0 (0.0)
I would be happy to complete future questionnaires like this one	29 (23.2)	69 (55.2)	13 (10.4)	11 (8.8)	3 (2.4)
Missing data	39 (23.8)				

2.3.6. Full cohort: Ideal concept selections (BYO stage results)

Table 2.13 summarises the preferences of participants when asked to indicate their 'ideal' level for programme attribute during the opening BYO stage of the choice experiment.

Table 2.13 Participant level selections at the 'build your own' stage. Values are n (proportion). No missing data.

Build Your Own (BYO) selections (n= 164)		
Preoperative start point		
GP referral	75	(45.7)
Surgical listing	89	(54.3)
Programme format		
Paper-based programme	85	(51.8)
Digital-based programme	79	(48.2)
Start place		
Hospital	50	(30.5)
GP or community venue	49	(29.9)
Home	65	(39.6)
Healthcare professional review frequency		
Weekly	49	(29.9)
Fortnightly	60	(36.6)
Monthly	55	(33.5)

Wearable integration		
Wearable monitoring	114	(69.5)
No wearable	50	(30.5)
Local service integration		
Integrates with local services	76	(46.3)
Purely home based	88	(53.7)

Participants were evenly split over the ideal preoperative start point. This was also the case for the ideal programme format. A programme that could be started at home was most popular (n=65, 39.4%), however 30% (n= 50) of participants selected a hospital and 30% (n= 50) selected a GP or community programme introduction and needs assessment. The cohort was evenly divided over the ideal HCP review frequency, approximately one third of participants opted for weekly (n= 50, 30.3%), fortnightly (n=60, 36.4%) and monthly (n= 55, 33.3%) reviews, respectively. The majority of the cohort opted for integration of a wearable device to monitor their progress (n= 115, 69.7%). Finally, the cohort were evenly split regarding integration and signposting to other local services, but a greater number of participants indicated that they preferred a programme undertaken purely in and around the home (n= 88, 53.3%).

Based on BYO stage selections alone, the most popular ideal programme concept for the cohort could be summarised as; a paper-based programme, commenced at surgical listing, undertaken purely in and around the home, structured around a home-based introduction and needs assessment with fortnightly HCP review and integrating wearable monitoring. However, this cannot fully capture the variation in preferences across the cohort.

2.3.7. Full Cohort: Screener stage results

Table 2.14. summarises the outcomes of the ‘screening’ stage indicating how frequently levels were labelled as ‘must have’ or ‘totally unacceptable’ by a participant in response to triggered probe questions. This adds context and emphasis to the choices made by the cohort in the BYO stage, indicating which

levels were actively sought/ deemed most favourable or actively avoided/ deemed least favourable. Levels attracting multiple labels of ‘must have’ and ‘totally unacceptable’ at this stage would be expected to hold greater influence over participant choices and increase the relative importance of that attribute. In the case of a binary attribute (including only two levels), labelling one level as ‘must have’ or ‘totally unacceptable’ allocates the opposite label to the other level within that attribute.

Table 2.14. Frequency levels were identified as ‘must have’ or ‘totally unacceptable’ during the screener stage. Values are n (proportion). No missing data

Programme attributes and levels (n= 164)	Identified ‘must have’		Identified ‘totally unacceptable’	
Preoperative start point				
GP referral	5	(3)	2	(1.2)
Surgical listing	2	(1.2)	5	(3)
Programme format				
Paper-based	41	(24.9)	17	(10.3)
Digital-based	17	(10.3)	41	(24.9)
Start place				
Hospital	0	(0)	15	(9.1)
GP or community venue	1	(0.6)	9	(5.5)
Home	4	(2.4)	5	(3.0)
Healthcare professional review frequency				
Weekly	2	(1.2)	23	(13.9)
Fortnightly	1	(0.6)	12	(7.3)
Monthly	7	(4.2)	9	(5.5)
Wearable integration				
Wearable monitoring	9	(5.5)	13	(7.9)
No wearable	13	(7.9)	9	(5.5)
Local service integration				
Integrates with local services				

Purely home-based	1 9	(0.6) (5.5)	9 1	(5.5) (0.6)

Only 7 participants (4.2%) designated a ‘must-have’ or ‘totally unacceptable’ level within the preoperative start point attribute. The ‘programme format’ attribute attracted the highest number of must-have or unacceptable labels from 35.2% of the cohort (n= 58). Levels appeared divisive. One quarter (n= 41, 24.9%) of participants indicated that a ‘paper-based’ format was ‘must have’ (with a reciprocal ‘totally unacceptable’ judgement for ‘digital-based’). Conversely, only 10.3% (n= 17) identified a ‘digital-based’ format as ‘must have’. Levels within ‘Start place’ were predominantly identified as ‘totally unacceptable’ (n= 39, 17.6%) rather than ‘must have’ (n= 5, 3.0%). ‘Hospital’ was identified as ‘totally unacceptable’ most frequently (n= 15, 9.1%) followed by ‘GP or community venue’ (n= 9, 5.5%) and ‘home’ (n= 5, 3.0%). This pattern was also seen within ‘Healthcare professional review frequency’; levels were identified as ‘totally unacceptable’ by 44 (26.7%) of participants versus 10 ‘must-have’ (6%). ‘Weekly’ was deemed ‘totally unacceptable most frequently (n= 23, 13.9%) followed by ‘fortnightly’ (n= 12, 7.3%) and ‘monthly’ (n= 9, 5.5%). Levels within ‘wearable integration’ and ‘local service integration’ were only identified as ‘must have’ or ‘totally unacceptable’ 22 (13.4%) and 10 (6.1%) or participants, respectively.

2.3.8. Full Cohort: Attribute relative importance

Table 2.15 summarises the estimated mean attribute relative importance for the cohort following completion of the choice tournament stage. These data are also presented in figure 2.4.

Table 2.15. Attribute mean relative importance for the full cohort. No missing data

Programme attributes (n=164)	**Estimated mean relative importance** proportion (SD)	**95% Confidence interval**
Preoperative start point	10.0 (9.1)	8.6 to 11.4
Programme format	25.1 (15.4)	22.8 to 27.5
Start place	18.6 (11.8)	16.8 to 20.4
Healthcare professional review frequency	21.2 (13.6)	19.1 to 23.3
Wearable integration	17.0 (11.6)	15.2 to 18.8
Local service integration	8.1 (8.5)	6.8 to 9.4

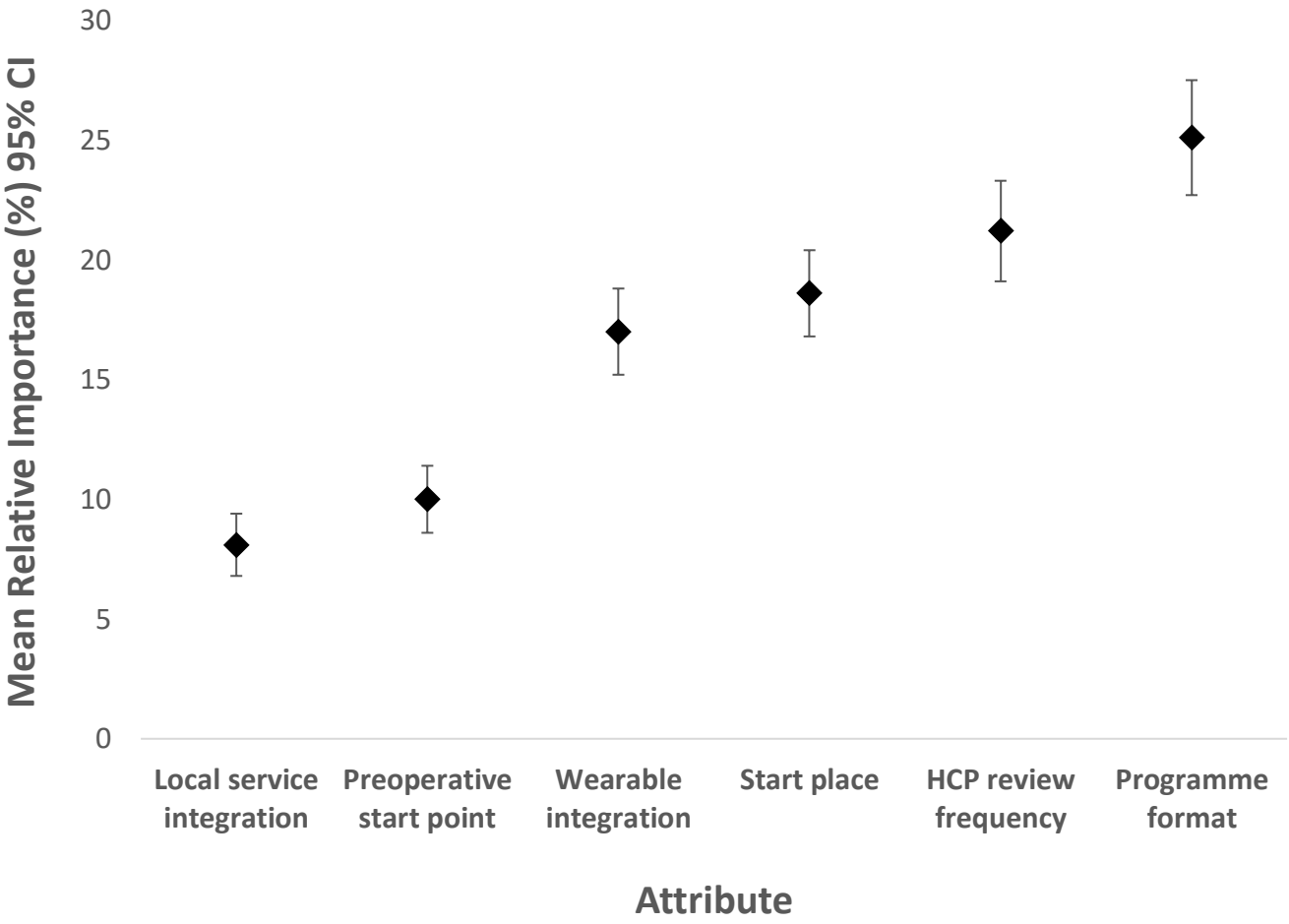

Figure 2.4. Attribute mean relative importance and 95% Confidence intervals.

Based solely upon estimated mean relative importance, the study attributes were ranked in descending order as follows:

1. Programme format
2. HCP review frequency
3. Start place
4. Wearable integration
5. Preoperative start point
6. Local service integration

However, as shown in figure 1, plotting of 95% confidence intervals for RI estimates and their overlap between the attributes suggests the following ranking may be more

precise, with a clear difference between four ‘more important’ and two ‘less important’ attributes:

- 1-4. Programme format, HCP review frequency, start place, wearable integration
- 5-6. Preoperative start point, local service integration.

These results follow logically from the ‘screener’ stage. The four attributes containing levels attracting the largest number of ‘must have’ and ‘totally unacceptable’ labels were also found to hold greater relative importance for the cohort overall on completion of the choice tournament.

2.3.9. Full Cohort: Level utility scores

Table 2.16 summarises mean utility scores for included levels. These data are also presented in figure 2.5.

Table 2.16 Mean level utility scores for the full cohort

Programme levels (n=164)	Estimated utility score (SD)	95% Confidence interval
Preoperative start point		
GP referral	-0.5 (40.6)	-6.7 to 5.7
Surgical listing	0.5 (40.6)	-5.7 to 6.7
Programme format		
Paper-based	14.6 (87.3)	1.2 t0 28
Digital-based	-14.6 (87.3)	-28 to -1.2
Start place		
Hospital	-18.7 (63.8)	-28.5 to -8.9
GP or community venue	4.4 (41.7)	-2 to 10.8
Home	14.3 (56)	5.7 to 22.9
Healthcare professional review frequency		
Weekly	-19.6 (65.7)	-29.7 to -9.5
Fortnightly	14.9 (33.1)	9.8 to 20
Monthly	4.7 (78.3)	-7.3 to 16.7
Wearable integration		
Wearable monitoring	15 (59.9)	5.8 to 24.2
No wearable	-15 (59.9)	-24.2 to -5.8
Local service integration		
Integrates with local services	-8.7 (34.2)	-13.9 to -3.5
Purely home-based	8.7 (34.2)	3.5 to 13.9

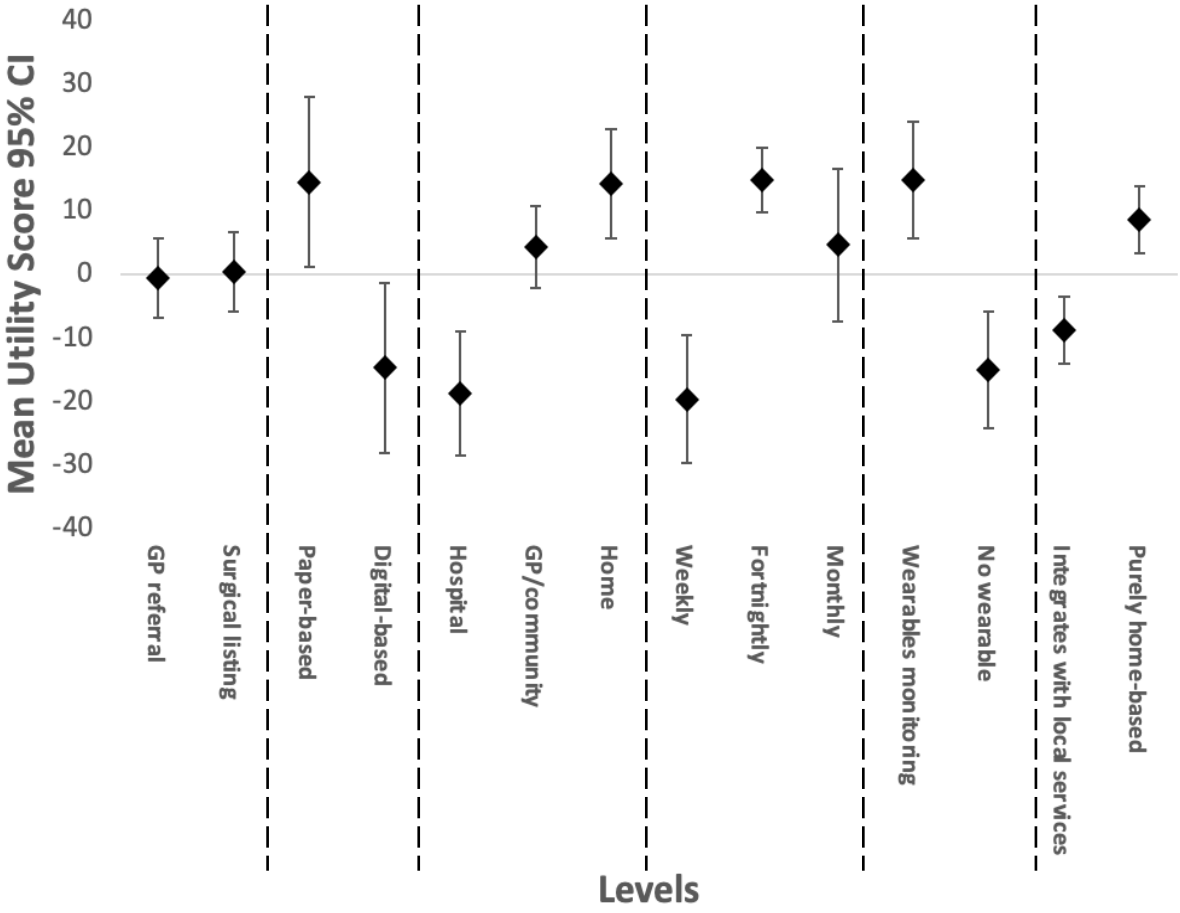

Figure 2.5. Mean level utility scores and 95% Confidence intervals. dashed lines group levels within the same attribute for comparison.

Level utilities are discussed in order of attribute relative importance. 'Programme format' carried the highest relative importance. A 'paper-based' format was deemed more favourable than 'digital-based' by the cohort overall, however both level utility scores carried wide confidence intervals, suggesting these were divisive, those strongly favouring 'paper-based' were counterbalanced by a proportion of participants strongly favouring 'digital-based'. This is in keeping with the results from the BYO stage in which the cohort was evenly split between these two levels and the findings from the screener stage in which both levels attracted comparable numbers of 'must have' and 'totally unacceptable' labels.

'HCP review frequency' showed a relatively even split between levels chosen at the BYO stage. However, utility scores indicated that a 'weekly' review was least acceptable for the cohort overall. This level also attracted more 'totally

unacceptable' labels during screening than the other two. Utility scores for 'monthly' and 'fortnightly' were similar, however a 'fortnightly' review carried both the highest utility score and a narrower confidence interval, suggesting less division in opinion over this level within the cohort and the broadest acceptability to the cohort overall.

Programme 'start place' demonstrated a similar pattern of even spread at the BYO stage that was not reflected in final utility scores. A hospital-based needs assessment and introduction to the programme was least acceptable to the cohort and attracted the most 'totally unacceptable' labels at screening. Utility scores for 'GP/community' and 'Home-based' start were similar with 'home-based' more favoured overall.

The cohort showed an overall preference for integration of a wearable device however, confidence intervals and standard deviations attached to these estimates would suggest that for a proportion of the cohort, this was unfavourable.

Preoperative start point and local-service integration were less important attributes overall. Minimal difference was seen in level utilities within 'preoperative start point'. The cohort seemed indifferent over whether programmes should commence at referral or listing. The cohort showed an overall preference for a 'purely home-based' programme, but this must be considered in the context that 'local service integration' was the least important attribute overall.

2.3.10. Subgroup analysis: Participants preferencing Paper-based and digital-based programme formats

Programme format held the highest attribute relative importance across the cohort. BYO selections, screener stage probe questions, responses and level utilities suggested that the cohort were divided over whether a paper-based or digital-based format was the more acceptable level. This divide in the cohort was explored further by analysing participants preferencing ‘paper-based’ and ‘digital-based’ at the BYO stage in terms of attribute relative importance, level utility scores and participant characteristics:

2.3.10.1. Attribute relative importance

Table 2.17. summarises the estimated attribute relative importance for patients preferencing a digital or paper-based programme format in comparison to the cohort overall. These data are also presented in figure 2.6.

Attribute relative importance followed a similar hierarchy for the two subgroups in keeping with the cohort overall. However, for patients preferencing a digital-based format, HCP review frequency had greatest relative importance with programme format moving to second. This is reflected in a significantly greater mean relative importance (SD) of programme format for the paper-based group (31.2 (17.7)) compared to the digital based group (20.8 (9.5)). This indicates that the cohort level importance of programme format is being driven largely by the subgroup preferencing paper.

In keeping with the full cohort findings, the paper-based group identified four ‘more important’ and two less important attributes. This separation was less distinct for the digital preferencing group.

Table 2.17. Attribute mean relative importance for subgroups preferencing paper and digital-based programme formats in comparison to the full cohort.

No missing data.

Programme attributes	Full cohort (n= 164)		Preference paper-based (n= 85)		Preference digital-based (n= 79)	
	Estimated mean RI (SD)	95% CI	Estimated mean RI (SD)	95% CI	Estimated mean RI (SD)	95% CI
Preoperative start point	10.0 (9.1)	8.6 - 11.4	7.5 (6.5)	6.1-8.8	12.6 (10.3)	10.3-14.9
Programme format	25.1 (15.4)	22.8 - 27.5	31.2 (17.7)	27.4-35.0	20.8 (9.5)	18.7-22.9
Start place	18.6 (11.8)	16.8 - 20.4	18.5 (12.0)	16.0-21.1	17.8 (10.2)	15.6-20.1
Healthcare professional review frequency	21.2 (13.6)	19.1 - 23.3	19.1 (14.1)	16.1-22.1	22.6 (11.5)	20.0-25.1
Wearable integration	17.0 (11.6)	15.2 - 18.8	16.7 (10.7)	14.4-19.0	16.8 (11.4)	14.3-19.3
Local service integration	8.1 (8.5)	6.8 - 9.4	7.0 (7.7)	5.4-8.7	9.4 (9.0)	7.4-11.4

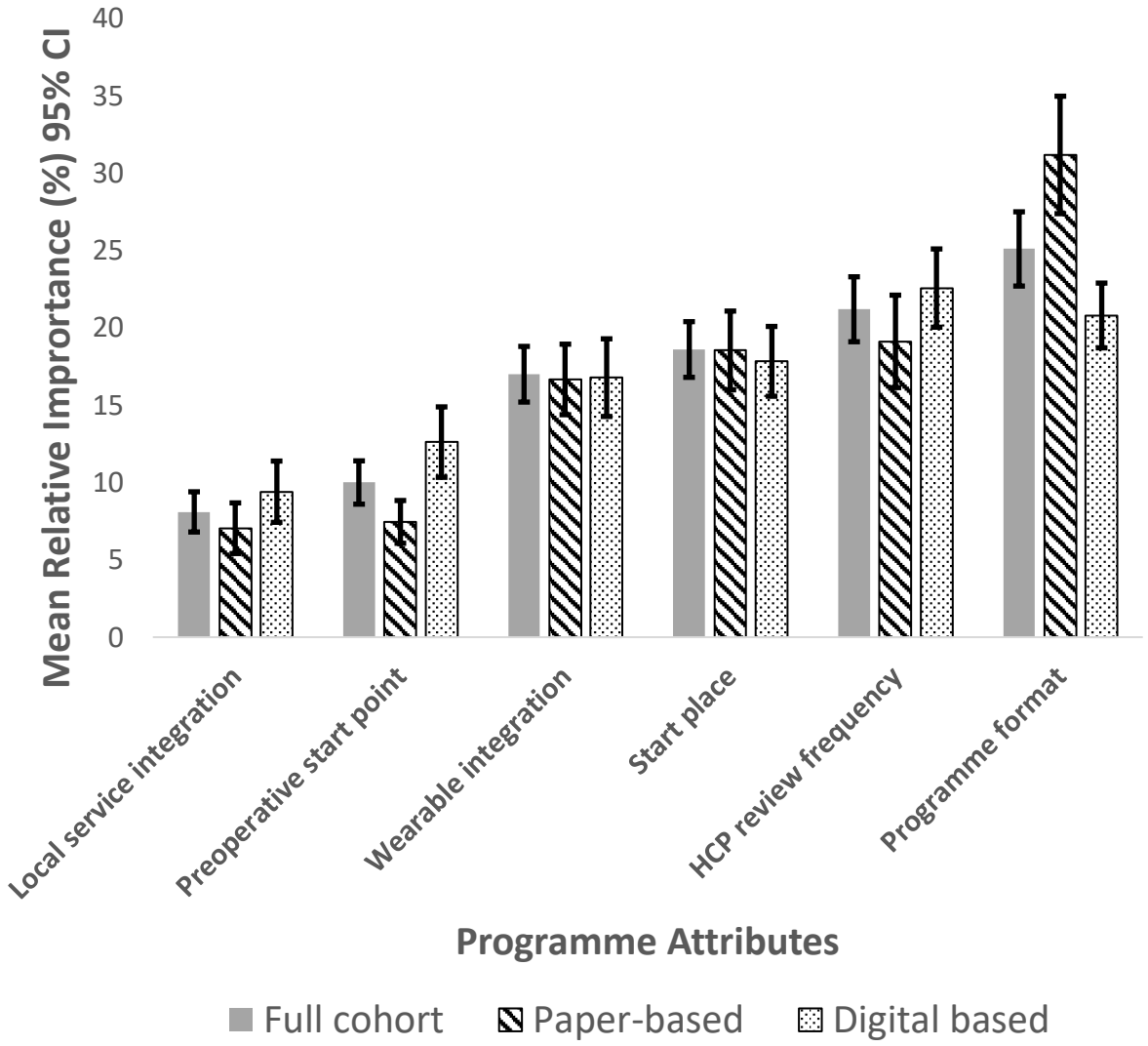

Figure 2.6. Attribute mean relative importance for subgroups preferencing paper and digital-based programme formats at the BYO stage in comparison to the full cohort.

2.3.10.2. Level utility scores

Table 2.18. presents the estimated level utility scores for the subgroups against the full cohort results.

Table 2.18. Mean level utility scores for subgroups preferencing paper and digital programme formats at the BYO stage in comparison to the full cohort. No missing data

Programme levels	Full cohort (n=164)		Preference paper-based (n= 85)		Preference digital-based (n= 79)	
	Est. utility score (SD)	**95% CI**	**Est. utility score (SD)**	**95% CI**	**Est. utility score (SD)**	**95% CI**
Preoperative start point						
GP referral	-0.5 (40.6)	-6.7 to 5.7	-2.2 (29.7)	-8.5 to 4.1	0.7 (49.1)	-10.2 to 11.5
Surgical listing	0.5 (40.6)	-5.7 to 6.7	2.2 (29.7)	-4.1 to 8.5	-0.7 (49.1)	-11.5 to 10.2
Programme format						
Paper-based	14.6 (87.3)	1.2 to 28	92.2 (55.9)	80.3 to 104	-62.4 (28.5)	-68.7 to -56.1
Digital-based	-14.6 (87.3)	-28 to -1.2	-92.2 (55.9)	-104.1to -80.3	62.4 (28.5)	56.1 to 68.7
Start place						
Hospital	-18.7 (63.8)	-28.5 to -8.9	-24.1 (59.9)	-36.9 to -11.4	-10.1 (62.7)	-24.0 to 3.7
GP or community venue	4.4 (41.7)	-2 to 10.8	7.7 (40.1)	-0.9 to 16.2	0.0 (43.4)	-9.5 to 9.6
Home	14.3 (56)	5.7 to 22.9	16.5 (58.1)	4.1 to 28.8	10.1 (49.3)	-0.8 to 21.0
HCP review frequency						
Weekly	-19.6 (65.7)	-29.7 to -9.5	-17.5 (59.4)	-30.1 to -4.9	-22.5 (68.3)	-37.5 to -7.4
Fortnightly	14.9 (33.1)	9.8 to 20	8.5 (38.4)	0.4 to 16.7	20.0 (30.5)	13.3 to 26.7
Monthly	4.7 (78.3)	-7.3 to 16.7	9.0 (75.5)	-7.1 to 25.0	2.5 (76.4)	-14.4 to 19.3
Wearable integration						
Wearable monitoring	15 (59.9)	5.8 to 24.2	-2.8 (59.6)	-15.4 to 9.9	34.4 (50.3)	23.3 to 45.5
No wearable	-15 (59.9)	-24.2 to -5.8	2.8 (59.6)	-9.9 to 15.4	-34.4 (50.3)	-45.5 to -23.3

Local service integration						
Integrates with local services	-8.7 (34.2)	-13.9 to -3.5	-6.8 (30.6)	-13.4 to -0.3	-10.7 (37.6)	-19.0 to -2.4
Purely home-based	8.7 (34.2)	3.5 to 13.9	6.8 (30.6)	0.3 to 13.4	10.7 (37.6)	2.4 to 19.0

As expected, paper and digital formats were most acceptable to those participants that had indicated them as their ideal level for programme format at the BYO stage. Notably, the range in utility scores was greater for the paper-based subgroup, indicating a stronger preference for paper in comparison to the preference for a digital-based format in the digital subgroup. These strongly contrasting results from these two large subgroups explain the narrower utility scores are reflected in the narrower utility range for this attribute at the cohort level. Both subgroups indicated that a weekly HCP check-in was the least acceptable level for scheduled review frequency. In the paper-based subgroup, the alternatives of fortnightly and monthly check-ins had similar acceptability. In the digital-based subgroup there was a much clearer preference for a fortnightly review over monthly and weekly respectively. Subgroups aligned in a clear preference for a home-based programme introduction over a community/GP based start place followed by hospital based as the least acceptable level. However, the preference for a home-based start point was most pronounced in the paper-based subgroup indicated by a wider range of utility scores. The digital-based subgroup was clearly in favour of an integrated wearable device. The paper-based subgroup showed a much narrower range of level utilities indicating more indifference to this attribute. Both subgroups were relatively indifferent to programme start point and local service integration, reflected in their positions as the attributes with least overall relative importance.

2.3.10.3. Paper-digital subgroup characteristics

The demographic characteristics of participants preferencing paper-based and digital-based programme formats are summarised in Table 2.19. Participants preferencing a paper-based programme format tended to be older with mean age (SD) 70.3 (8.5) years, were more frequently male (58.8%), no longer in full or part-time employment and reported leaving full-time education at an earlier stage. In contrast, participants preferencing a digital programme format were younger with mean age (SD) 61.7 (13.8) years with a more even male/female split. Over one third (35.4%) were still in full or part-time employment compared to 17.6% of the paper-based group. Forty three percent of this group reported a professional or degree level qualification in comparison to 20% of the paper-based group

Table 2.19. Demographic characteristics of participants preferencing paper and digital-based programme formats. Values are number (proportion), mean (SD) or Median (IQR). No missing data

	Preference paper-based format (n=85)		**Preference digital-based format (n=79)**	
Age	70.3	(8.5)	61.7	(13.8)
Gender M/F	50/35	58.8/32.2	36/43	45.6/54.4
Single	9	(10.6)	10	(12.7)
Married	58	(68.2)	49	(62.0)
Civil Partnered	3	(3.5)	2	(2.5)
Divorced	1	(1.2)	7	(8.9)
Widowed	12	(14.1)	7	(8.9)
Other	2	(2.4)	4	(5.0)
Ethnicity				
White	82	(96.5)	77	(97.5)
Asian	2	(2.4)	0	(0.0)
Mixed	1	(1.2)	0	(0.0)
Black	0	(0)	0	(0.0)
Other	0	(0)	2	(2.5)
Employment				
Full-time	8	(9.4)	20	(25.3)
Part-time	7	(8.2)	8	(10.1)
Retired	64	(75.3)	40	(50.6)
Volunteer	2	(2.4)	2	(2.5)
Unemployed	1	(1.2)	3	(3.9)
Other	3	(3.5)	6	(7.6)
Qualifications				

Nil formal	22	(25.9)	11	(13.9)
1-4 O-levels/GCSEs	16	(18.8)	8	(10.1)
5+ O-levels/GCSEs	16	(18.8)	11	(13.9)
2+ A-levels/VCEs	9	(10.6)	12	(15.2)
Degree/Professional qualifications	17	(20)	34	(43.0)
Vocational/foreign qualifications	5	(5.9)	3	(3.9)
IMD Deciles				
1	9	(5.5)	8	(10.1)
2	6	(3.7)	6	(7.6)
3	4	(2.4)	9	(11.4)
4	8	(4.9)	9	(11.4)
5	11	(6.7)	4	(5.1)
6	10	(6.1)	6	(7.6)
7	10	(6.1)	13	(16.4)
8	8	(4.9)	15	(19.0)
9	15	(9.1)	5	(6.3)
10	4	(2.4)	4	(5.1)
Median IMD	6	(4)	6	(5)

Table 2.20. compares the clinical characteristics of the programme format subgroups. Participants preferencing paper-based and digital formats were similar in terms of their clinical and risk behaviour profile.

Table 2.20. Clinical characteristics of participants preferencing paper and digital-based programme formats. Values are number (proportion) or mean (SD). Missing data where indicated.

	Preference paper-based format (n=85)		**Preference digital-based format (n=79)**	
Surgical Specialty				
Orthopaedics	38	(44.7)	31	(39.2)
Upper GI	8	(9.4)	4	(5.0)
HPB	7	(8.2)	7	(8.9)
Colorectal	11	(13.0)	7	(8.9)
Urology	3	(3.5)	8	(10.1)
Gynaecology	7	(8.2)	6	(7.6)
Breast	1	(1.2)	3	(3.8)
Head and Neck	4	(4.7)	7	(8.9)
Vascular	5	(5.9)	5	(6.3)
Cardiac	0	(0.0)	1	(1.3)
Thoracic	1	(1.2)	0	(0.0)
Other	0	(0.0)	0	(0.0)
Cancer surgery	26	(30.6)	20	(25.3)
Preoperative chemoradiotherapy				
None	76	(89.4)	76	(96.2)
Completed	6	(7.1)	2	(2.5)
Current	1	(1.2)	0	(0.0)
Planned	2	(2.4)	1	(1.3)
Health risk behaviour status				
Current Smoker	5	(5.9)	6	(7.6)
Alcohol intake >14 units per week	11	(12.9)	9	(11.4)
Physically inactive (WHO aerobic activity criteria)	33	(38.8)	33	(41.8)
Physically inactive (WHO resistance activity criteria)	50	(58.8)	48	(60.8)
BMI >25.0	58	76.3)	54	(75.0)
missing data	9 (n= 76)	(10.6)	7 (n= 72)	(8.9)
BMI <18.5	2	(2.6)	0	(0.0)
missing data	9 (n=76)	(10.6)	7 (n=72)	(8.9)
Comorbidities (n = 84)				
Ischaemic heart disease	20	(23.8)	14	(18.7)
Heart failure	6	(7.1)	0	(0.0)

Peripheral vascular disease	3	(3.6)	3	(4.0)
Stroke/ Transient ischaemic attack	4	(4.8)	4	(5.3)
Chronic obstructive pulmonary	5	(6.0)	4	(5.3)
disease	9	(10.7)	11	(14.7)
Asthma	4	(4.8)	2	(2.7)
Diabetes Mellitus requiring insulin	13	(15.5)	3	(4.0)
Diabetes Mellitus not requiring	32	(38.1)	19	(25.3)
insulin	5	(6.0)	7	(9.3)
Osteoarthritis	8	(9.5)	9	(12)
Inflammatory arthritis				
Chronic Kidney disease	1 (n= 84)	(1.2)	4 (n= 75)	(5.1)
missing data				
Polypharmacy	24	(28.9)	19	(25.3)
	8	(9.6)	11	(14.7)
>5 agents				
>11 agents	2 (n= 83)	(2.4)	4 (n= 75)	(2.4)
missing data				
Clinical Frailty Scale ≥4	17	(22.1)	10	(14.5)
missing data	8 (n= 77)	(9.4)	10 (n= 69)	(12.7)
Subjective general health rating (100mm scale)	61.7	25.2	60.1	22.4

Table 2.21 compares the device ownership and utilisation profile of the paper and digital programme format subgroups. Rates of device ownership and access were high in both subgroups. Participants reported ownership of a range of devices. No participants in the digital-based group lacked access to or ownership of a device. Only 7 participants (13%) of participants in the paper-based group did not have acces

Table 2.21 Device utilisation and ownership profile in participants preferencing paper and digital-based prehabilitation programme formats. Values are n (proportion). Missing data where indicated.

	Preference paper-based format		**Preference digital-based format**	
Frequency of device usage				
Daily	16	(23.2)	3	(4.5)
A few times per week	16	(23.2)	6	(9.1)
Very rarely	11	(15.9)	7	(10.6)
Never	26	(37.7)	50	(75.8)
missing data	16 (n= 69)	(18.8)	13 (n= 72)	(16.5)
Device Ownership or access				
Desktop computer ownership or access	*12*	*(22.2)*	25	(51.0)
Laptop computer ownership or access	20	(37.0)	26	(53.1)
Tablet computer ownership or access	25	(46.3)	28	(57.1)
Smartphone ownership or access	33	(61.1)	39	(79.6)
No devices owned or accessible	7	(13.0)	0	(0.0)
missing data	31 (n= 54)	(36.4)	30 (n= 49)	(38.0)

In response to questionnaire closing questions, both paper and digital subgroups indicated high levels of motivation on a 100mm scale to obtain short-term perioperative (82.4mm and 88.1mm) and longer-term health benefits (82.5mm and 90.0mm) from prehabilitation support. However, the digital-based format group were marginally more motivated. The majority of both groups (paper 91.8% and digital 93.7%) were also supportive of providing information to support their preassessment process using a programme. Whilst both groups were interested in preoperative educational material, a greater proportion of the digital-based group (82.3%) were interested than the paper-based group (74.1%). Home-based prehabilitation was most the preferred mode of delivery for over half of both subgroups, with similar numbers preferencing community and hospital formats or no support in both groups

2.3.11. Choice simulation and shares of preference

The choice simulator was used to estimate shares of preference for potential home-based prehabilitation programmes built from the levels studied and utilising the utility scores estimated for each individual participant. For each programme or programmes, the number of participants that would accept or reject each programme was estimated as a proportion of the 164 study respondents.

2.3.11.1. Base-case scenarios

Based on the full cohort and utility score results, a series of programme offers were simulated to estimate their likely market share if they were the only programme offered. It was estimated whether, based on their individually estimated level utilities, each participant would accept this programme or choose 'none' i.e., reject the programme offered. These scenarios reflected a prehabilitation service with sufficient resources or choosing to allocate resources to a single remotely supervised offer.

- **Scenario 1- 'The cohort ideal programme'**

A programme was simulated comprising the levels with the greatest utility at the cohort level, in theory the programme with the greatest total (summed) utility across the cohort.

- **Scenario 2- 'The ideal paper-based programme'**

A programme was simulated comprising the levels with the greatest summed utility based on/(or) using the results from the sub-group that preferred a paper-based programme format.

- **Scenario 3- ‘The ideal digital-based programme’**

A programme was simulated comprising the levels with the greatest summed utility based on/(or) using the results from the sub-group analysis that preferred a digital-based programme format.

Table 15 summarises these programmes and their estimated share of preference, the proportion of the study cohort predicted to either accept or reject it. No scenarios resulted in a share of preference exceeding 50% of the study cohort. Each programme modelled achieved comparable shares of preference around 45% of the study cohort.

Table 2.22. Programme shares of preference across study cohort in ‘base-case’ scenarios. Values are proportions (95% CI). No missing data.

Programme attribute	***Scenario 1*** ‘Cohort ideal’ versus ‘none’	***Scenario 2*** ‘Ideal paper-based’ versus ‘none’	***Scenario 3*** ‘Ideal digital-based’ Versus ‘none’
Preoperative start point	Surgical listing	Surgical listing	GP referral
Programme format	Paper-based	Paper-based	Digital-based
Start place	Home	Home	Home
Healthcare professional review frequency	Fortnightly	Monthly	Fortnightly
Wearable integration	No wearable	No wearable	Wearable monitoring
Local service integration	Purely home-based	Purely home-based	Purely home-based
Estimated share of preference (n= 164) (95% CI)	45.1 (39.1-51.1)	45.4 (39.3-51.5)	45.9 (39.2-52.5)
Proportion of respondents rejecting programme (n= 164) (95% CI)	54.9 (48.9-60.9)	54.6 (48.5-60.7)	54.1 (47.5-60.8)

2.3.11.2. Competition scenarios

Scenarios were next modelled simulating the availability of two programmes from the base-case scenarios in addition to a 'none' option where the respondent was predicted to reject both available programmes. These scenarios modelled services aiming to offer a more diverse range of remotely supervised offers to their populations and approximate the real-life approaches being taken by active prehabilitation services. Table 2.23 summarises the estimated shares of preference attained.

Table 2.23. Programme shares of preference across study cohort in 'competition' scenarios. Values are proportions (95% CI). No missing data.

Programme attribute	***Scenario 4*** 'Cohort ideal' versus 'ideal paper-based' versus 'none'	***Scenario 5*** 'Cohort ideal' versus 'Ideal digital-based' versus 'none'	***Scenario 6*** 'Ideal digital-based' versus 'ideal paper-based' versus 'none'
Cohort ideal programme estimated share of preference (n= 164) (95% CI)	28.2 (24.3-32.1)	29.8 (24.7-34.9)	
Ideal paper-based programme estimated share of preference (n= 164) (95% CI)	26.0 (22.1-29.9)		31.8 (26.2-37.3)
Ideal digital-based programme estimated share of preference (n= 164) (95% CI)		37.6 (31.6-43.6)	39.2 (33.0-45.4)
Proportion of respondents rejecting any programme (n= 164) (95% CI)	45.8 (41.1-50.5)	32.7 (27.9-37.4)	29.0 (24.3-33.7)

All three scenarios led to a reduction in the share of preference achieved by a single programme in comparison to base-case scenarios. However, availability of a second programme decreased the proportion of respondents predicted to reject any

programme. This was most evident when an ideal digital based programme was offered alongside one of the other paper-based options.

2.3.11.3. Shares of preference in subgroups

Scenario 6 was predicted to achieve greatest total share of preference (i.e., fewest participants rejecting a programme altogether). This scenario was the ideal digital programme versus ideal paper-based programme versus no programme. Scenario 6 was then remodelled in further scenarios for study respondents in demographic/clinical subgroups to explore differences in estimated share of preference. These are summarised in Table 2.24 alongside scenario 6 for comparison to the full cohort result.

- **Scenario 7- 'Participants preparing for cancer and non-cancer surgery'**

Key clinical differences exist between patients preparing for cancer surgery and non-cancer surgery (largely orthopaedic surgery in this study). These include available preoperative time frames, neoadjuvant treatments and the psychological impacts of cancer diagnoses and therapy. Scenario 7 was modelled to assess if these groups differ in their preferences regarding home-based prehabilitation support. Shares of preference results were consistent with the whole cohort results in scenario 6.

- **Scenario 8- 'Participants who, all things considered, preferred alternative prehabilitation models'**

The final questionnaire item asked participants to identify, all things considered, whether home-based prehabilitation would be their preferred option overall versus alternative face-to-face, community-based or no support. This scenario explored differences between these subgroups, on the basis that the share of preference obtained in those who would actively seek home-based support, may be more meaningful than the preferences of patients who would ideally seek other support options, reflecting a 'truer' target population for the programmes modelled. Shares of preference results were consistent with the whole cohort results in scenario 6

Table 2.24. Programme shares of preference across study cohort in 'subgroup' scenarios. Values are proportions (95% CI). No missing data.

Programme attribute	***Scenario 6*** 'Ideal digital-based' versus 'ideal paper-based' versus 'none'	***Scenario 7*** 'Participants preparing for cancer and non-cancer surgery'		***Scenario 8*** 'Participants who preferred different prehabilitation models'			
	Full cohort (n= 164)	Cancer surgery (n= 46)	Non-cancer surgery (n=118)	Home-based (n= 97)	Community based (n= 42)	Hospital-based (n=12)	No support (n= 13)
Ideal paper-based programme estimated share of preference (95% CI)	31.8 (26.2-37.3)	26.9 (16.2-37.7)	33.6 (27.1-40.1)	35.6 (26.2-37.3)	24.6 (14.1-35.2)	5.0 (0.0-10.2)	50.5 (28.1-72.9)
Ideal digital-based programme estimated share of preference (95% CI)	39.2 (33.0-45.4)	43.8 (31-56.6)	37.4 (30.2-44.6)	39.2 (33.0-45.4)	43.9 (30.8-57.0)	40.2 (14.8-65.6)	26.9 (4.0-49.9)
Proportion of respondents rejecting any programme (95% CI)	29.0 (24.3-33.7)	29.3 (19.4-39.1)	28.9 (23.6-34.3)	25.7 (19.8-31.5)	31.4 (21.3-41.6)	54.7 (32.1-77.4)	22.6 (11.0-34.1)

2.4. Discussion

2.4.1. Overview and key findings

This study successfully obtained the preferences of 164 patients preparing for major surgery regarding remotely supervised ‘home-based’ prehabilitation programmes. It is currently the only study of its kind undertaken to explore the preferences of a perioperative patient population. Participants had characteristics representative of wider UK major surgical populations and we able to engage effectively with the questionnaire with good completion rates. Participant experience was positive overall demonstrating the feasibility of utilising DCE in the context and forming a basis for further work.

Cohort level results indicated that four programme attributes held greatest relative importance namely: Programme format, healthcare professional contact frequency, programme start point and wearable integration. Utility score analysis demonstrated a preference for a paper-based programme, with fortnightly HCP review, commenced at home and incorporating a wearable device.

The pooled cohort results however masked division between respondents, notably regarding format of programme delivery. Here the cohort could be evenly divided by strong opposing preferences for paper or digital delivery. Exploration of characteristics of these two subgroups identified more observed demographic than clinical differences. Participants preferencing a paper-based programme appeared to be more frequently male, older, and likely to have left formal education at an earlier stage.

This divide was reflected in the results of choice simulation estimating the shares of preference across the study cohort that differing programmes might be expected to achieve. No single programme built from attributes and levels studied appeared able to exceed 50% uptake when offered alone. Further scenarios indicated that offering

a plausible digital and paper-based offer in parallel would lead to greatest uptake across the cohort. These findings appeared consistent in subgroups preparing for cancer surgery and those favouring different models of prehabilitation delivery overall.

2.4.2. Cohort characteristics

Overall, participant characteristics were comparable to other recently studied UK major surgical cohorts(75). Participants were drawn from multiple surgical centres covering diverse areas from a geographical and socioeconomic perspective. Mean age and sex split reflected patients enrolled in UK Perioperative Quality Improvement Programme (PQIP)(75) with a range of marital statuses, employment statuses and educational attainment represented. Comorbidity profile was consistent with previously studied cohorts with multiple chronic health conditions reported(54, 55, 75). High rates of health-risk behaviours amenable to prehabilitation were observed, with prevalence comparable to previous related studies(122, 127, 128, 255). A range of surgical specialties were represented with the largest subgroup undergoing major orthopaedic surgery, which forms a large proportion of the UK major elective surgical workload. Patients listed for total arthroplasty may also face the most prolonged waiting times in the wake of the Covid-19 pandemic. Over one quarter (27.9%) of participants were undergoing surgery for cancer. The study findings can therefore reasonably be applied to other UK surgical cohorts.

2.4.3. Questionnaire feasibility and participant experience

This study demonstrated the feasibility of a computerised survey incorporating an adaptive discrete choice experiment in a preoperative population, in keeping with prior work in similar populations of older adults(285). Most respondents reported a positive experience of taking part. Notably the survey was found to be accessible, adaptative to their responses and encouraged consideration of preferences. Whilst several participants found the questionnaire more difficult to understand and engage

with, only 9 recruited participants were unable to complete the questionnaire. This finding both adds credibility to the results observed as a true reflection of participant preferences and supports the further use of adaptive choice based conjoint analysis as a tool to investigate and understand the preferences of patients undergoing major surgery surrounding both prehabilitation and other linked elements of perioperative care.

2.4.4. Full cohort attribute relative importance, level utilities and implications for intervention design

Four studied attributes held greater relative importance in driving the acceptability of programmes presented to the study cohort with two study attributes less important overall. Each attribute and the utility scores of their component levels are discussed in order of raw relative importance.

2.4.4.1. Programme Format

This attribute held the greatest estimated relative importance for the study cohort. Selecting a paper or digital based programme format is a fundamental design decision with wide-ranging implications for both patient experience and interaction and intervention delivery for the healthcare system. This is reflected in the high relative importance awarded by the study participants.

Level utility scores indicate that paper-based programmes were more acceptable for the cohort overall. This is an important finding given wider initiatives driving the use of digitally facilitated remote healthcare solutions across the NHS, given the numerous advantages these solutions offer in terms of flexibility, scalability, and cost. This study suggests that for many patients approaching major surgery, these initiatives may not be readily acceptable. However, the confidence intervals attached to utility score estimates indicate the underlying division in the cohort, with almost half of respondents strongly preferencing a digital programme format. This subgroup analysis is discussed in greater detail below. This observation aligns with the most recent national audit of

cardiac rehabilitation services (NACR) concerning a comparable group of patients in terms of age, comorbidity, and health risk behaviour profile(294). Whilst remotely supervised modes of delivery are utilised by a minority of cardiac rehabilitation patients there is an even split between digital and paper (manual) based programmes. Though the report also notes an uptick in digital programme participation in the wake of the pandemic. Observed uptake rates in the setting of prehabilitation are anecdotal at this stage.

2.4.4.2. HCP review frequency

The frequency of planned HCP contact directly affects intervention cost and ease of implementation within preoperative care pathways by influencing the staff time required to deliver. Scheduled contact points are opportunities for participants to review progress and raise issues with supervising HCPs. Whilst scheduled contact points are not the only way to deliver participant-HCP interaction within a programme, they can support intervention engagement and adherence, capturing some of the beneficial elements of a face-to-face consultation. It must also be borne in mind that more opportunistic, participant-initiated contact mechanisms would need to be in place to deal with urgent problems or queries, and staff time would also need to be allocated to manage this workload. Contact frequency is likely to be a key determinant of how well supported participants feel. Remotely supervised programmes immediately have more opportunity for some participants to feel isolated in comparison to face-to-face services. This potentially explaining the relative importance attributed by the cohort. Indeed evidence from cardiac tele-rehabilitation suggests that a perceived lack of remote clinician contact is a key factor undermining programme adherence(295).

A fortnightly check-in frequency was most acceptable to the cohort overall with a monthly frequency less acceptable and weekly least acceptable. These results could reflect subgroups of participants who felt a weekly check-in would be too burdensome or intrusive and another group who may have felt under supported with only monthly scheduled contact. This finding is useful to support intervention design. Fortnightly scheduled contact is likely to be acceptable to most programme participants and is also likely to be feasible to deliver for supporting clinical teams dependent on staff and

patient numbers. This is supported from qualitative data from a recently published quality Improvement study delivering tele-prehabilitation during the pandemic indicating a weekly-fortnightly check in frequency was acceptable to patient participants(259).

2.4.4.3. Programme start place

All potential programmes would logically require an introductory and onboarding process for new participants. This should incorporate an initial health risk behaviour screening and baseline needs assessment process to facilitate targeting of support and assessment of change through programme participation. Where this process is undertaken has wider implications for the logistics of programme delivery and the feasibility of utilising an initial in person meeting with HCP. This also influences how participant instruction and information material is structured, to ensure participants are adequately informed to utilise the programme.

A fully home-based introduction was most acceptable to the cohort. This is unsurprising given it offers maximal convenience and flexibility from the patient perspective and the study cohort indicated they would, all things considered, generally choose home-based prehabilitation support over other models. Sending a clinical team member to every participant's home is unlikely to be feasible. This position would restrict an initial participant assessment, limiting use of some objective tools such as tests of exercise and functional capacity. Needs assessment and monitoring of health risk behaviour change would rely upon more subjective methods such as questionnaires. However, a web-based programme format with incorporation of wearable technology would likely offer more scope for objective monitoring in this area.

A community-based introduction was less favourable. This would allow participants to undergo programme induction at a community location close to home (e.g., GP surgery) with a healthcare professional. This would raise additional questions around primary care involvement in programme delivery. Primary care staff could readily be trained to remotely supervise and facilitate programmes and are likely to

possess links to locally available supporting services for health behaviour change as part of their primary health prevention role. However, in the UK to date, the overwhelming majority of prehabilitation activity has been secondary care driven and delivered, reflecting the current service pressures facing primary care(252) and a failure to successfully include primary care clinicians as members of the wider perioperative team.

Attending a hospital introduction was the least acceptable option. This is unsurprising and reflects the experience of face-to-face services that have identified travel time and cost and the need to attend multiple routine preoperative appointments already as key barrier to participation(127, 128, 255). Tertiary surgical centres in particular frequently cater for populations across a wide geographical catchment. Wider NHS drivers also continue to focus on providing decentralised and community-based care wherever possible. This patient position is unfortunately least convenient from a service perspective, with relevant resources including staff, space and equipment usually concentrated at hospital sites, offering maximum scope for objective assessment and monitoring.

2.4.4.4. Wearable integration

The cohort overall identified integration of wearable technology to facilitate progress monitoring and feedback as an acceptable programme feature. This is an important finding in the context of the above discussion, offering a route to more objective monitoring techniques if face-to-face visits to a community or hospital venue are unappealing. The scope of what wearable technology can achieve in terms of biometric tracking continues to rapidly advance, however commercially available devices are yet to be shown to reach the exacting standards of clinical monitoring tools(296). The scope for use in healthcare is enormous, however, commercial providers face competing interests around open sharing of their proprietary technology and data collection and processing methods to allow robust analysis and the need to protect those assets from competitors(297). ‘Clinically focussed’ wearables, designed for use in patient populations, with comparable suites of functions and open-source designs allowing independent scrutiny are not yet

available. Despite these important limitations, ‘off the shelf’ commercial devices have been increasingly utilised in clinical interventions, notably to increase physical activity and exercise(298). This technology also offers opportunities to monitor patients in the extended perioperative period, providing a clearer understanding of the longer-term impacts of surgery, with large feasibility studies ongoing notably the EMBRACE-GM trial.

Acceptance of wearable technology by study respondents was also surprising given the clear division over ‘programme format’. Intuitively, we might expect participants who are averse to a digital-based programme to be equally reluctant to accept wearable use. These levels are readily combined and whilst either combination would be possible, a digital programme would offer far greater scope for wearable integration than a paper-based intervention, in particular the use of wearable data within a digital programme. The willingness of patients strongly preferencing paper to accept wearable use might indicate a desire for passive monitoring and feedback from the supervising team, without the need or desire to necessarily engage actively with the technology. The appetite for feedback from participants has been an important finding from the experience of face-to-face services(127-129). This requires further exploration as a purely passive monitoring role may prevent a wearable device from supporting health behaviour change, any device utilised must provide the participants with insights about them that are actionable toward their preoperative behaviour change goals.

2.4.4.5. Preoperative start point

From the patient perspective, this attribute held low relative importance with level utilities suggesting that neither a ‘point of referral’ or ‘point of listing’ start point was more acceptable to the cohort overall. This is an interesting finding given the substantial implications this attribute has for real-world delivery of a given programme from the system perspective.

There is huge scope for closer cross-sector working to facilitate prehabilitation support from ‘point of referral’ in primary care, maximising the time available to

patients and facilitating use of existing community-based services that can support preoperative health behaviour change. Indeed, 'the perioperative period' has been defined as commencing at first contemplation of surgery(83), which will likely occur at a primary care contact. However, as outlined above most established services currently adopt a 'point of listing' referral model, acknowledging the difficulties in engaging pressurised primary care services with prehabilitation support.

An argument can also be made for awaiting a decision to proceed to surgery before commencing prehabilitation, however there is widespread recognition that this activity may also benefit patients who undergo equally demanding neoadjuvant cancer treatments without proceeding to surgery(101). In addition, a public health perspective would support health behaviour change for longer-term health and wellbeing regardless of whether that person undergoes an operation.

2.4.4.6. Local service integration

Whether local services are involved in programme delivery held the lowest relative importance across the cohort, with participants indicating a preference for 'fully' home-based support at the cohort level.

A fully 'self-sufficient' programme design participants can utilise wholly in and around their home environment would seem intuitively more appealing to a population that would predominantly opt for home-based prehabilitation support overall and would also align with preferences around programme start place, indicating a preference to avoid additional visits to other venues (community or hospital sites) for maximum convenience.

This may limit the scope of component health risk behaviour interventions within programmes that need to be considered. For example, it would become challenging to incorporate nicotine replacement therapies to a preoperative smoking cessation intervention for maximal preoperative effectiveness or offer a wider range of activity and exercise options to participants (such as access to a swimming pool or community exercise facility).

2.4.5. The paper-digital divide

A clear signal from the cohort results was the emergence of programme format as a leading attribute in terms of importance and a split regarding a paper-based or digital-based format as the more acceptable level. This attribute also has arguably the greatest implications for intervention design of those studied. Design, delivery, and monitoring of a paper-based programme would be significantly different than a digital-based intervention from the perspective of the individual patient, supervising healthcare team and wider supporting system. Choosing one format or the other is a fundamental design decision with downstream implications for other interventions including: information and content provision, ease and scope of monitoring and remote support options including integration of wearable technology, flexibility of patient-professional and patient-patient interactions. These subgroups were therefore explored in more detail.

2.4.5.1. Differences in subgroup attribute relative importance and level utilities

The hierarchy of attribute relative importance in participants favouring a paper-format mirrored the cohort results. Notably, programme format clearly separated itself from the other four ‘more important’ attributes. As a binary attribute, and as reflected in the wide level utility scores, this can be interpreted as either a stronger preference for the favoured level than the cohort overall, or a stronger aversion to the alternative (digital format). In contrast, for the subgroup preferencing a digital format at the BYO stage, programme format moved to second place behind HCP contact frequency although, as with the cohort results, the top four more important attributes could not be clearly separated. This might suggest that the strength of preference of the digital-format group for digital was less than that of the paper-based group for paper. Numerous factors may be driving the paper-based group position. This may reflect both a preference for paper resources and an active avoidance of digital alternatives. A previous scoping review(299) highlighted several barriers that might explain the

strength of this aversion to digital offers: Fear of technology, lack of confidence, cognitive impairments and older age.

There were several differences observed in level utilities between the subgroups. HCP review frequency held the greatest relative importance for the digital group, and utility scores followed cohort results with fortnightly, monthly, and weekly check-ins in a clear order of greatest to least acceptability. For the paper-based group however, whilst a weekly check-in remained least acceptable, monthly, and fortnightly check-ins held comparable utility. Participants opting for a paper-format were therefore more divided as to whether a fortnightly or monthly check-in was preferable over weekly. For programme start place, level utilities matched the cohort findings in both subgroups, notably, the difference in utility scores was wider in the paper-based group indicating a stronger preference for a home-based introduction or aversion to a hospital-based design in comparison to the digital group. Differences were also evident in wearable integration. Unsurprisingly, participants preferencing a digital format were also in favour of inclusion of a wearable device with these two levels intuitively aligned. As discussed above, we might have expected the inverse to be true in the paper-based group, level utilities here were very similar, indicating that some participants with a paper-based preference were also able to accept inclusion of a wearable device. The feasibility of wearable use in older age groups has been demonstrated in recent work aiming to increase physical activity (300). This may reflect a consistent desire for monitoring and feedback across the cohort indeed a contemporary study showed that adherence to wearable use in older adults seemed to rely upon paired clinician contact(301). Level utilities for the two less important attributes (programme start point and local service integration) were comparable across both subgroups.

2.4.5.2. Differences in subgroup characteristics

A descriptive analysis of the demographic and clinical characteristics aimed to describe these differing groups and aid explanation of their differing preferences. Participants in the paper-based group were generally older. This is unsurprising and reflects wider although rapidly changing trends in technology confidence and

utilisation which is usually greater in younger demographics. Interestingly, this subgroup was also more likely to be male. Participants preferencing paper-based programmes were also less frequently in full-time employment, this is likely strongly linked to age, however it may also suggest participants with ongoing work-commitments sought a digital format as a potentially more flexible mode of delivery that could be more readily accessed at their convenience. In addition, participants preferencing paper had more frequently left formal education at an earlier stage. This may have led to less opportunity for exposure to information technology as an element of education or prevented access to an occupation typically requiring information technology skills and confidence.

Notably, subgroups were very similar in terms of their clinical characteristics with few differences in terms of surgical specialty, health risk behaviour and comorbidity profile. Suggesting that demographic factors were more likely to be driving preference around programme format. We might also logically have expected far greater differences in device ownership and utilisation than those observed. Only a very small proportion of the cohort overall did not have an internet-enabled device available to them. Whilst these participants were clustered in the paper-format group, much of this group were in possession of a device and utilising it regularly. This is important from a 'digital-exclusion' standpoint if the wider healthcare system would favour a digital-format. In this study, those participants unwilling or unable to accept a digital-format programme were prevented from doing so for reasons other than lack of a device or an internet connection, suggesting other barriers identified as drivers of exclusion such as IT confidence and skills were more important. As the review referenced above indicates (299) a wide range of barriers to digital interventions, beyond simply device access, can be identified. Crucially this suggests that careful intervention design of a 'patient-friendly' programme may be able to change this position for an important group of patients without a requirement to provide devices or provide other IT infrastructure.

Reassuringly, questionnaire experience was also consistent between the subgroups. For the same reasons outlined above, we might have expected participants favouring paper-based programmes to be less confident participating in a digitally facilitated questionnaire study such as this one. Whilst more participants in the

paper-group had a more negative experience of participation, for the vast majority this was not the case.

2.4.6. Choice simulation and implications for intervention design

From a perioperative care standpoint, our goal should logically be the engagement of the maximum number of appropriate patients in appropriate prehabilitation support. This is analogous to the commercial organisation seeking the widest possible market share for their product or line of products. The cohort and subgroup results discussed above provide useful insight here but can fail to identify and describe the diversity and nuances in individual responses and ultimately, how many patients are likely to find the offer of a given programme acceptable as the critical first step to engagement and intervention adherence. The choice simulation findings shed greater light in this area.

The three base case scenarios illustrate the limited reach a single programme may have. The cohort ideal programme, in theory holding the greatest mean utility across the participants, was estimated to be accepted at the individual respondent level, by less than 50%. Similarly, programmes designed to appeal specifically to the large paper-based and digital-based subgroups failed to achieve a share of preference >50% reflecting poor acceptability with the other subgroup. Based on these findings, it appears that ‘remotely-supervised’ prehabilitation as a mode of delivery distinct from ‘face-to-face’ models in the wider ‘menu’ of prehabilitation options, will require further subtypes to fully engage the widest spectrum of surgical patients. This echoes the experience of national cardiac rehabilitation services, who despite a suite of models of delivery continue to strive to engage a wider population of eligible patients, with no single model of delivery able to achieve this alone(294).

The value of providing wider choice is seen in the competition scenarios modelled. Scenario 4 illustrates the impact of offering the cohort ideal programme alongside a programme designed specifically to appeal to the paper-based subgroup. Neither offer obtains a share of preference more than that when offered alone, however the

proportion of participants accepting either programme increases overall. This indicates that these offers are competing for the attention of similar participants, unsurprising given both are paper based. In contrast scenario 6 simulated a more diverse range of remotely supervised offers, achieving the widest total share of preference by offering an 'ideal' paper-based programme alongside a digital alternative, capturing the diverse subgroups within the cohort leading to fewer participants rejecting both programmes offered.

In the key clinical subgroups of cancer and non-cancer surgery (scenario 7) the programmes offered in scenario 6 achieved similar share of preference results. This is an important finding given the acknowledged differences that do exist in providing prehabilitation support to these subgroups, in keeping with earlier findings indicating that participants favouring paper and digital formats differed largely in demographic, rather than clinical characteristics. Finally, these results were also replicated in the subgroup of participants who identified that a home-based, remotely supervised option would be their prehabilitation option of choice (scenario 8). The views of these participants as the 'real' target population may ultimately hold greater value than those who would choose a face-to-face hospital or community alternative.

2.4.7. Study limitations

The study has several limitations. As outlined above, whilst ACBC offers numerous advantages over CBC it is not immune to the effects of non-compensatory decision making and fatigue or boredom of participants facing multiple choice sets. As indicated in the feasibility data, a minority of participants did not find the questionnaire wholly accessible, intuitive, or enjoyable and this must be taken into consideration in introducing potential measurement error to the results. Nine participants were unable to complete the questionnaire. In addition, due to unusual circumstances resulting from the pandemic, the study did not recruit to its initial sample size of 300. This number would have been 'ideal' for an initial exploratory study incorporating conjoint analysis of this kind and retesting of the DCE design with the achieved sample size indicated that the design retained an acceptable degree of error. This in part, was due to the inclusion of a relatively small number of

attributes and levels when compared to the full capabilities of the ACBC method. It could be argued that the study has 'under-reached' in this regard and could reasonably have been conducted using CBC alone or with an expanded range of attributes and levels included to glean more preference information. However, as described above, the choice of and ACBC design was to optimise the participant burden and experience given the study aim of exploring feasibility in this population.

The study sample were largely comparable to other major surgical cohorts recently studied, however the concentration of study centres in the North of England may limit wider applicability. Ethnicities other than 'White/Caucasian' were under-represented, potentially compounded by the decision to include good understanding of written and spoken English as a criterion for participation. There are fewer minority ethnic residents at a population level in the North East compared to other areas of the UK. The decision to deliver the questionnaire in a web-based format may also have biased toward participants more comfortable with information technology. This was a necessary trade-off to allow an ACBC design and mitigated against by offering dual routes of participation with an option for study team member support. In addition, a large proportion of the study population were still able to emphasise a clear preference for paper-based intervention formats. Finally, with the exception of orthopaedic surgery who made up the largest single specialty subgroup, it is difficult to draw conclusions about other surgical specialties from these results, which may be desirable to tailor interventions to specific preoperative pathways

2.4.8. Summary of study findings against stated aims

2.4.8.1. Primary aim

1. Conduct an electronic questionnaire-based survey of patients preparing for major surgery incorporating an adaptive choice-based discrete choice experiment to explore patient preferences for home-based prehabilitation programmes.

The study successfully obtained preferences from 164 patients preparing for major surgical information as the first of its kind in this population. Patient preferences for

programme attributes and levels were obtained with relevance to future intervention design. Inevitably, patient preferences must be balanced against system needs and resource constraints however this study suggests those programme attributes such as programme format that should be aligned more closely with patient preferences and those that can more easily be adapted to fit system constraints such as preoperative start point.

2.4.8.2. Secondary aims

2. Demonstrate the feasibility of DCE use to explore patient preferences in this clinical context.

The study demonstrates the feasibility of DCE to obtain patient preferences in the context of perioperative care and prehabilitation specifically. Obtaining a good profile of patient participation, engagement, and questionnaire experience. The findings lay groundwork for further work incorporating DCE to explore related areas or further work in this area potentially incorporating a more ambitious suite of attributes and levels or focussed on specific surgical subspecialties.

3. Explore characteristic differences in patient subgroups expressing differing preferences.

Attribute relative importance and utility scores revealed a key divide between participants preferencing paper and digital-based programme formats, with key demographic differences suggested between these groups. Of note, these groups were consistent in terms of their clinical characteristics. These findings suggest the possibility of targeting programme offers to patients with particular characteristics to enhance likely acceptability

4. Utilise choice simulation to estimate programmes or combination(s) of programme features most likely to achieve widest acceptability to patients approaching major surgery and inform subsequent intervention development.

Choice simulation identified that a paper-based and digital-based programme offer would be viable in the population of interest. Based on study responses, both would need to be offered to maximise total share of preference and provide at least one offer acceptable to most study respondents. This reflects the experience of face-to-face services that are acknowledging the need to provide a 'suite' of prehabilitation offers including direct and remotely supervised options to maximise engagement. Notably, even in this scenario, just under one third of respondents were predicted to reject both programmes modelled, indicating the need for further work to understand the barriers to acceptance and other attributes not studied here that may hold significance for the population. In addition, whilst these findings provide a useful steer toward programme concepts that may enjoy success, a face-value acceptance modelled here is only a first step toward achieving high levels of engagement and adherence and a full development process is necessary to produce an intervention likely to achieve this and downstream clinical effectiveness.

3. Chapter 3: Systematic co-design and development of a remotely supervised, digitally facilitated multibehavioural prehabilitation programme

3.1. Introduction

The results of the discrete choice experiment conducted in chapter 2 highlighted demand for a digitally facilitated prehabilitation option amongst patients preferencing remotely supervised support. Provision of a digital offer, alongside other remotely and directly supervised alternatives, would appear necessary to engage a full range of surgical patients who may benefit from prehabilitation support. This chapter describes the systematic co-design and development of a remotely supervised, digitally facilitated multibehavioural prehabilitation intervention utilising recognised health-behaviour change theory.

3.1.1. The expanding role of digital technology in perioperative care

Evidence continues to build for the utility of digital technologies in the care of patients undergoing major surgery. The widening scope and likely future role of these interventions is reflected in recent guidance from the UK Centre for Perioperative Care (CPOC) on preoperative assessment and optimisation(93).

3.1.1.1. Preoperative screening and assessment

Digital technology is suited to remote screening, assessment and streaming of patients prior to surgery. UK case studies have identified substantial cost savings from the implementation of electronic health screening questionnaires(302). It may

be feasible to shift elements of the preoperative assessment process online (ePOA) substantially offloading POA clinical staff time and space when both are currently at a premium(93). This may be particularly suited to 'higher volume, lower risk' patient groups where preassessment processes can be more easily protocolised. Questions remain around how the depth and rigour and clinical assessments necessary for preoperative assessment of the higher risk patient and those undergoing major surgery can be replicated or partially facilitated by ePOA systems. Nevertheless, widespread uptake of these systems in response to national guidance will likely lead to ever greater numbers of patients engaging with these tools as an early step in their perioperative journey with scope to transition into digitally facilitated prehabilitation support. This is supported by a recent systematic review and meta-analysis indicating feasibility of these services across 15 studies with high rates of patient satisfaction, reduced costs and crucially, comparable day-of-surgery cancellation rates to face-to-face POA(303).

3.1.1.2. Preoperative education and surgery schools

Preoperative education of patients is a recognised component of enhanced recovery pathways and a gateway to prehabilitation support. This has led to the emergence of the 'surgery school' concept as a key component of perioperative care pathways and now a formal CPOC recommendation for major inpatient surgical intervention(93). In-person, remote and hybrid designs are encouraged utilising video conferencing packages and online hosted resources. A recent UK survey(194) identified 28 established and 4 planned surgery school programmes across multiple specialties. Of these respondents, 47% reported routine signposting to relevant resources with 4 schools reporting regular signposting to mobile applications. Several centres have demonstrated feasibility across multiple surgical pathways including major cancer(304) and orthopaedic surgery(305) alongside substantial reductions in complications, lengths of stay and excellent participant satisfaction rates.

3.1.1.3. Postoperative care

In the postoperative phase, interest is growing in the use of digital tools and particularly wearable technology to objectively monitor and optimise the enhanced

recovery process. This includes inpatient biometric monitoring to detect complications developing (306). Increasingly, this role is extending beyond hospital discharge to support the longer-term recovery phase(307) with the feasibility of postoperative remote-monitoring to support telerehabilitation demonstrated within an ongoing randomised trial following cardiac and vascular surgery(308, 309). This move toward objective monitoring has been driven by concern around discrepancies with subjective patient reported outcome measures (PROMS) (310). Beyond passive monitoring, initial feasibility studies have paired wearable technology with mobile and web applications to deliver remotely supervised rehabilitation, support pain management and improve functional status following major orthopaedic surgery(311) with randomised trials now underway(312).

3.1.2. Digitally facilitated remotely supervised prehabilitation

Alongside these other elements of the perioperative pathway, digital technologies have strong face validity in facilitating delivery of remotely supervised prehabilitation support with the Covid-19 pandemic forcing a rapid expansion in their use across UK prehabilitation services(258-260).

3.1.2.1. The case for digital prehabilitation support

World Health Organisation (WHO) guidance on use of digital technology to strengthen health systems strengthening acknowledges their numerous advantages from both a patient and system perspective(313). Interventions can be flexibly delivered, at scale, across a range of internet enabled devices as mobile applications delivered by smartphone or tablet devices (m-health) or adaptive browser-based applications designed for flexible use across mobile devices and be utilised on personal computers.

They offer scope to easily incorporate a broad range of audio-visual media content alongside the facility to responsively tailor and adapt interventions to patient needs and progress. Digital formats also offer multiple facilities for patient-patient and patient-staff interactions by email, text messaging or other conferencing mechanisms

(telemedicine) and logistical advantages for facilitating teams through agile, rapid data collection, monitoring and feedback to participants. This is acknowledged further in WHO guidance for implementation into health services(314).

From the UK perspective, use of these tools align with recent National Health Service (NHS) drivers toward more remotely supervised digitally facilitated healthcare and telemedicine including the 2014 forward view(315) and 2019 long-term plan(316) alongside the 2019 Topol review(317) that emphasised the need to enable NHS staff to utilise digital technology to support their patients. These findings have been echoed in subsequent reports from the Kings Fund(318) and the 2016 Wachter review(319).

Remotely supervised, digital health-behaviour change interventions are well-established in range of allied healthcare settings supporting patients with comparable age, comorbidity, and health risk behaviour profiles to current UK surgical cohorts. This includes self-management of chronic health conditions such as cardiac rehabilitation programmes. Here, digital interventions have shown comparable efficacy to face-to-face programmes in improving health related quality of life and exercise capacity(320) and, aligning with prior DCE findings, have successfully engaged patients who would otherwise have turned down alternative rehabilitation formats(321). Digital pulmonary rehabilitation programmes have achieved comparable success in the context of chronic obstructive pulmonary disease (COPD)(322, 323) and Interventions have also successfully supported improved glycaemic control in Type 2 diabetes(324). In addition, digital interventions have been utilised to support specific health behaviour change including smoking cessation(325), alcohol reduction(326) and physical inactivity(327).

3.1.2.2. Wearable technology and activity trackers

Wearable technology and activity trackers are a form of digital technology able to support health behaviour change independently or integrated within a larger telemedicine, m-health, or browser-based programmes(297). These devices continue to develop in scope and sophistication offering unique functionality to digitally facilitated interventions via two main routes. Firstly, as ‘passive’ monitoring

tools with cutting edge devices able to undertake continuous biometric monitoring and collect exceptionally detailed data over significant time periods. It is here that links are being made between the capabilities of 'big data' approaches utilising machine learning to enhance healthcare(328). A leading example in the perioperative context is the EMBRaCE-GM study (ClinicalTrials.gov Identifier: NCT05099237), exploring the feasibility of continuous perioperative monitoring around cancer surgery and the physiological patterns that characterise the perioperative period. This expands the scope of prior work employing in-hospital biometric monitoring to detect complications within the immediate postoperative period outlined above. Studies have demonstrated significant potential to enhance perioperative risk assessment and predication and to evaluate the impact or perioperative interventions in the extended preoperative and postoperative period(329, 330).

Secondly, wearables can be utilised in a more active role within health behaviour change interventions, offering a unique vehicle for participant prompting and feedback mechanisms. Examples of these include the guiding of intensity of exercise sessions, tracking progress toward an activity target or feedback on the duration and quality of sleep. This presents facilitating healthcare professionals with a window on participant intervention adherence and engagement and the participant with rapid feedback on their activity within a programme. As identified in chapter 2, this appears to have widespread acceptability to patients preparing for major surgery. Their success in facilitating health behaviour change outside of the perioperative setting is less clear, systematic reviews have concluded benefit to increased physical activity levels in the context of chronic cardiometabolic disease (331) but debateable impact on other disease markers such as cholesterol and HbA1c levels(332).

Despite clear potential, several issues exist in the use of currently available devices(40). Leading examples with the widest suite of capabilities are commercial products intended for 'off the shelf' general purchase and utilisation. Few devices feasible for use in the outpatient setting hold the required medical device accreditation expected of other clinical monitoring tools(298, 333, 334). This feeds into wider concerns around accuracy of data collected by these devices, complicated in part by competition between commercial manufacturers leading to proprietary

restrictions on methods of data collection and analysis with few ‘open source’ devices readily available. This in turn compromises efforts to systematically review and meta-analyse data from studies utilising differing devices. Finally, most of these devices require the consent of users to collection and holding of data by the manufacturer, often outside of the United Kingdom, adding to potential issues around data governance and potentially fuelling patient concerns around safety of their information(298). Despite concerns, the potential for these devices to enhance care is widely accepted and likely to expand further as device quality continues to improve and solutions between healthcare providers and manufacturers are found(335, 336).

3.1.2.3. Covid-19 and the digital prehabilitation revolution

The parallels, promise and potential applications of digital technology to prehabilitation were already clear at the onset of the Covid-19 pandemic. Existing services had anecdotal demand from their patients for digital alternatives(128, 129). However, the unique circumstances imposed by the pandemic catalysed the use of digital resources in prehabilitation delivery.

The social-distancing measures imposed in response to the Covid-19 pandemic forced existing face-to-face services to rapidly reconfigure and implement remote solutions to continue supporting their patients preparing for major surgery. These were challenging circumstances, with national lockdown measures driving up rates of health risk behaviours in isolated and already vulnerable populations. Digital technology played a key role in facilitating this response with rapid deployment of innovative solutions across several specialties frequently in collaboration between NHS services and industry partners(258-260). The impact of those societal measures on perioperative care continues. The elective surgical backlog now facing the UK(74) and the move from waiting lists to preparation lists(248) is simultaneously an unprecedented challenge and unique opportunity to implement prehabilitation solutions within larger modernised perioperative care pathways.

A legacy of this period is the rapid gain of experience and expertise amongst prehabilitation services in using these technologies with patients. Several have experienced anecdotal success leading to adoption by their services. It is unlikely

that these newly developed and ‘road-tested’ models of delivery will now be abandoned. However, few have been rigorously evaluated and consequently, in keeping with prehabilitation practice overall, the evidence-base for digitally facilitated prehabilitation base now lags behind the leading edge of clinical practice in the UK(258).

3.1.2.4. The evidence-base for digitally facilitated prehabilitation support

A initial scoping review by Asberg et al (337) highlighted 11 studies employing digital interventions to facilitate perioperative health behaviour change including a heterogenous group of interventions encompassing text messaging, smartphone apps and one web application. These were conducted in varied surgical populations and employed both pre and postoperatively. Participant engagement rates ranged from 40 to 90%. Only a single identified study was a full-scale randomised trial of preoperative text messaging to enhance activity levels prior to bariatric surgery. This showed no evidence of benefit in terms of adherence to preoperative exercise advice. In keeping with the wider evidence for prehabilitation, the authors highlight issues with study size preventing robust conclusions around perioperative benefit.

A more recent systematic review by Robinson et al(338) sheds additional light on factors that may influence intervention success. This review included seven browser-based programmes (employing telemedicine, emails, and online educational content) four mobile-based (m-health) programmes (text-messaging and applications) and one study utilising wearable devices to track physical activity by step count. Five additional studies utilised combination interventions. Studies included feasibility and experimental designs in populations undergoing major elective bariatric, orthopaedic, and oncological general surgery. In keeping with experience in wider healthcare setting, participant retention rates across included studies were good, supporting acceptability in supporting perioperative health behaviour change.

Success in supporting behaviour change varied substantially with several trends identified: Firstly, interventions incorporating ‘interactive’ elements such as text

messaging, self-monitoring tools and wearable technology may be more effective. The authors noted the absence of any 'peer-support' interaction within included studies despite evidence for their benefit in digitally facilitated interventions elsewhere(339). Secondly, interventions commenced preoperatively may enhance the duration of postoperative behaviour changes. Finally, the eight studies underpinned by behavioural change theory in their design and delivery appeared to be more successful. However, all of these studies were postoperative interventions.

3.1.2.5. Digital exclusion

As demonstrated clearly in chapter 2, whilst digital prehabilitation is an acceptable, appealing, and accessible concept for many patients approaching major surgery, for an equally large group the opposite is true. The potential for lack of equitable access to digital prehabilitation interventions is representative of wider phenomenon of 'digital exclusion'(258). Patient may find digital interventions both hard to reach and hard to grasp. This may go some way to explaining the variation in outcomes observed and why application of theory-informed intervention design may help.

The reasons behind digital exclusion are multifactorial and may vary between individual patients. Key interlinked barriers are age, socioeconomic deprivation, and poverty with associated issues of internet and device access, poor health literacy and membership of a minority ethnic group. These are factors common to both poorer perioperative outcomes as outlined on chapter 1 and long-recognised drivers of poorer health outcomes overall(340). The sudden reliance on digitally facilitated healthcare during the pandemic threw these existing disparities into focus highlighting the challenges of engaging more elderly and minority ethnic groups. Paradoxically, UK data would suggest that rates of internet access and utilisation are on the rise in older age groups and that the pandemic has accelerated this trend. However, this was not universal(341). As suggested in chapter 2, lack of access in terms of physical possession of a device or an internet connection may be less frequent than a perceived lack of 'digital ability'(342), a reflection of overall confidence and comfort in IT usage. Countering the socioeconomic drivers of digital exclusion, such as ensuring access to broadband internet, may be beyond the scope of health systems alone to solve. However, design of patient-centred interventions

tailored to needs and current ability may be a route to widening access and promoting uptake and engagement.

3.1.2.6. Summary

Development of a digital prehabilitation intervention aligns with the preferences of a significant subgroup of patients outlined in chapter 2. This in turn follows larger trends in perioperative and wider healthcare. Evidence currently suggests that use of a preoperative health behaviour change intervention would be feasible. A patient-centred design that facilitates uptake, adherence and wider access is likely to increase success in effecting preoperative health behaviour change and by extension, influence postoperative outcomes. A theory-informed approach to design and development is likely to support this aim.

3.1.3. Underpinning health behaviour change theory and systematic intervention development tools

A wide and complex range of interacting factors may be involved in facilitating or impeding positive change in a given behaviour or behaviours(343). These range from specific individual factors to broader environmental and societal factors. Failure to understand these relationships as determinants of the behaviours of interest, and to systematically develop interventions informed by that understanding is an acknowledged pitfall leading to failure to achieve clinical effectiveness. These omissions also inhibit a full understanding of 'why' an intervention works or may have failed(344).

At a fundamental level the systematic approach to development of interventions necessitates: Firstly, obtaining a clear understanding of what the target behaviours are, including the facilitators and barriers to changing those behaviours; secondly, identifying techniques likely to positively influence those behavioural determinants and overcome barriers, and; finally, developing and implementing components of interventions that are acceptable to the target population(109, 344, 345). Whilst it is reflex to automatically think about this from the perspective of the patient preparing

for surgery, these principles must simultaneously be applied to the healthcare professionals in the perioperative team who are required to promote and deliver an intervention within their already complex roles, and the wider stakeholders involved in implementation within perioperative pathways. An elegantly designed intervention from the patient perspective will be unsuccessful if the healthcare system cannot deliver it in practice.

Several frameworks, theories, models, and tools exist to facilitate this process. The Medical Research Council (MRC) framework for the development and evaluation of complex interventions emphasises the value of theory-based intervention design but offers limited direction in terms of what should be used and why(247) The Behaviour Change Wheel (BCW) offers a means of overcoming this issue, and provides a systematic framework for intervention development. At the centre of the BCW is a behavioural system referred to as the Capability, Opportunity, Motivation, Behaviour (COM-B) model. Finally, the theoretical domains framework (TDF) is utilised to help bridge the gap between behavioural science and intervention implementation(346).

3.1.4. The Behaviour Change Wheel (BCW): An overview

The BCW is a synthesis of 19 prior frameworks and associated theories of behaviour change. These were deemed individually insufficient to capture the breadth of factors and contributors to behaviour change from the individual to wider environmental perspective(345, 347). The BCW is intended to be applicable to any behaviour of interest in a population or any size and related structures, organisations, and groups. The Behaviour change wheel (BCW) builds upon a behavioural analysis obtained using the COM-B and TDF. The behaviour system described by this analysis sits at the core. From here, the model extends outward to identify potential intervention functions that are likely to enhance identified capability, opportunity, and motivation needs and then to wider policy categories that will facilitate those functions. The BCW is described in figure 3.1.

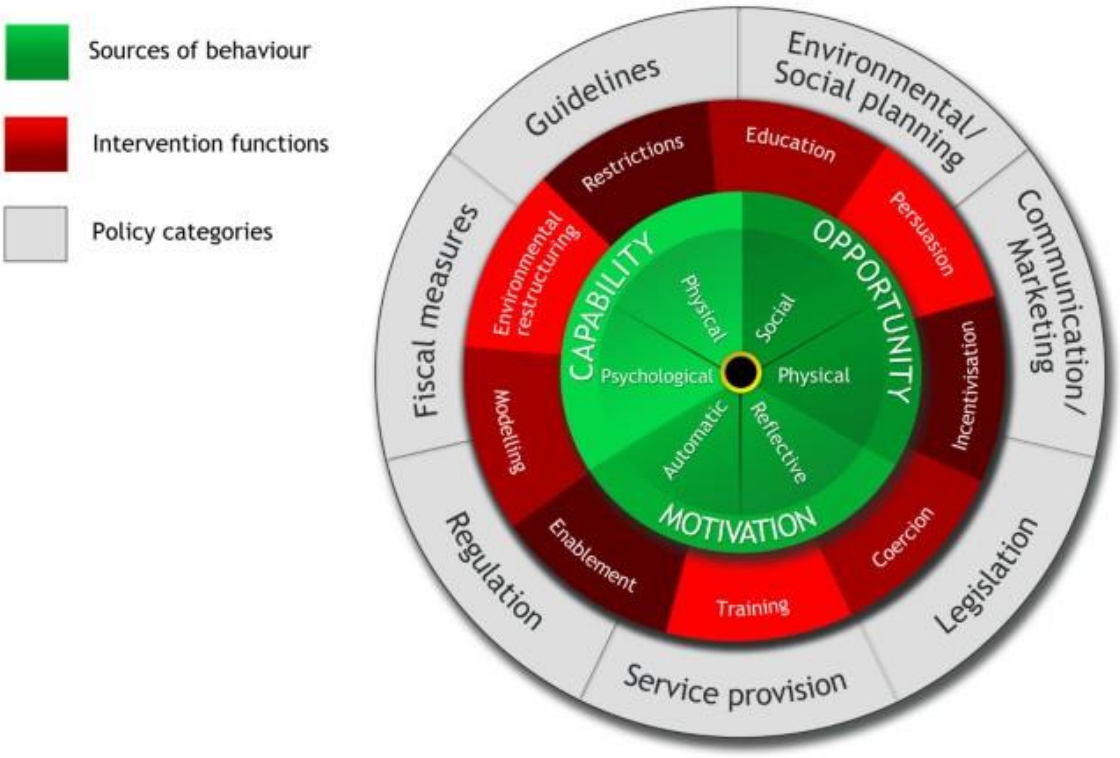

Figure 3.1 The Behaviour Change Wheel (BCW)(345, 347).

The BCW comprises three layers. A behavioural analysis using the COM-B model sits at the core. The identified change needs are linked to 9 potential intervention functions. These in turn are linked to 7 broader enabling policy categories that lead designers to appropriate behaviour change techniques (BCTs) to incorporate within the intervention.

Utilising the BCW systematically results in interventions that are well characterised in terms of their behavioural content and predicted mechanisms of action. This may be particularly important in the context of digital interventions(348). An international consensus statement on their design and evaluation emphasised that digital behaviour change interventions frequently lack clarity in their mechanisms of action or use of systematic methods to specify their component parts and mode of delivery(349). This creates problems for replicability and robust evaluation.

The BCW encourages intervention designers to avoid narrow focus on single avenue such as ‘education’ or ‘financial incentives’ and think broadly about the range of

influences involved and where an intervention might act within the described behaviour system to achieve its aims(345). In particular the model is a step forward from the intervention mapping approach(350), itself an important step toward systematic identification of opportunities to intervene but lacking in scope to identify a fuller range of influencing factors within the wider behaviour system. Whilst success of the resulting intervention is not guaranteed, applying the BCW makes understanding the behavioural reasons behind success or failure clearer.

3.1.5. Utilising the BCW in intervention design

Michie et al advocate a stepwise approach to utilising the BCW in design. This is summarised in figure 3.2

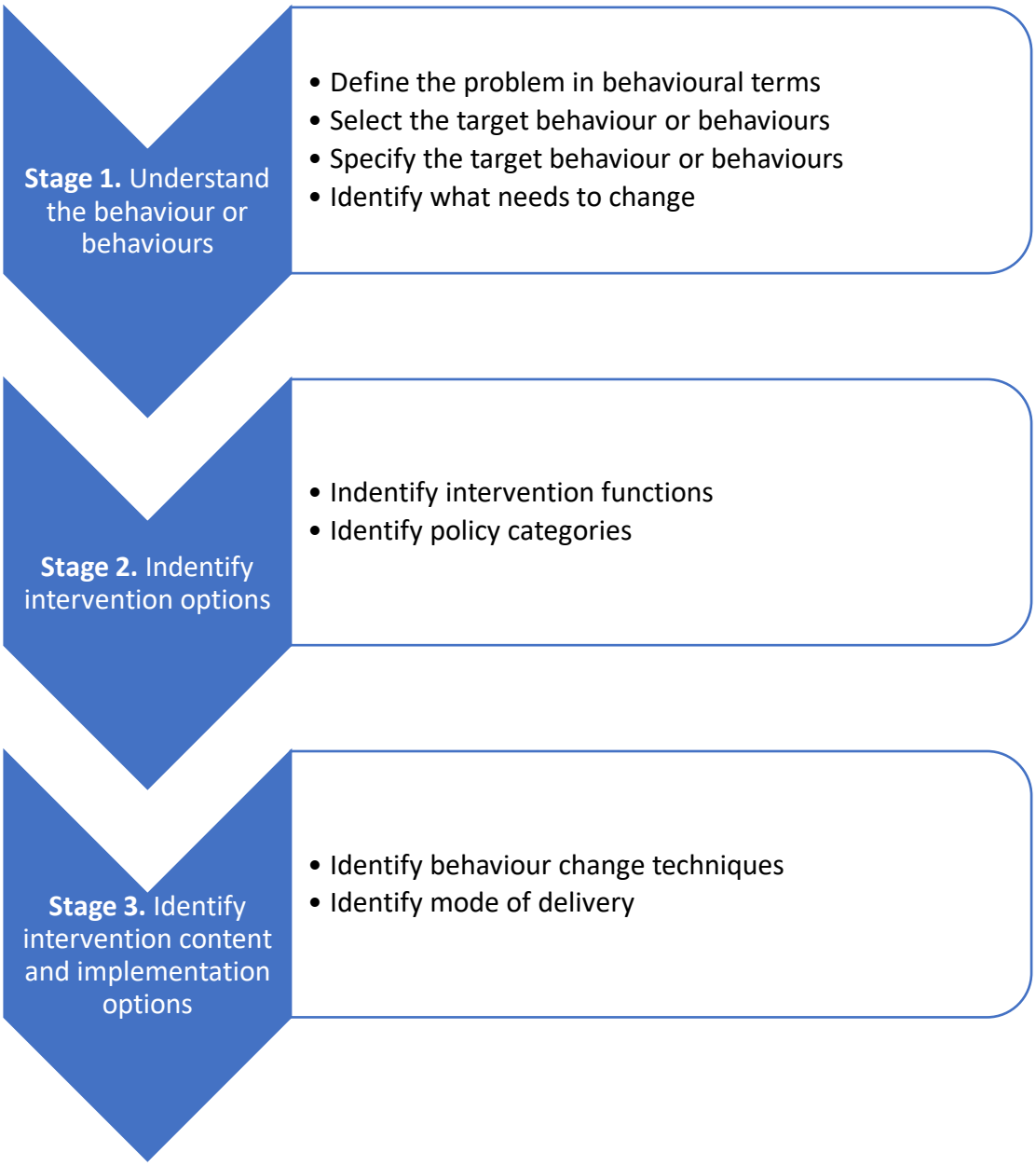

Figure 3.2 Application of the BCW to intervention design(344, 347)

3.1.5.1. Stage 1. Understand the behaviour or behaviours

The selected behaviour or behaviours of interest are defined in terms of the population involved and the behaviour itself. This acknowledges that these do not exist in a vacuum and are linked to other behaviours of the individual or others. For example, the behaviour of increasing physical activity in a patient preparing for surgery is linked to those of a healthcare professional broaching the subject and offering support. The specified behaviours should be targeted with consideration of impact, likelihood of effecting change, spill over effects and ease of

measurement(347). Once the target behaviour or behaviours are specified, the behavioural analysis is conducted utilising COM-B and responses explored in greater detail using the TDF that enabled identification of barriers, facilitators, and targets for intervention.

3.1.5.2. Stage 2. Identify intervention options

Once the behavioural analysis is complete and the needs for change identified with reference to the COM-B model constructs, these can be linked to one or more of the corresponding 9 candidate intervention functions. Each function offers a potentially viable route for an intervention to address those needs. Table 3.1. illustrates the 9 functions and their linked COM-B constructs to allow matching of needs to functions. With reference to the BCW, candidate functions should then be evaluated for inclusion based on the APEASE criteria(344, 347). These consider the suitability and likelihood of successful implementation within the intervention within its wider context. The APEASE criteria are presented in table 3.2.

Table 3.1. BCW Intervention functions and linked COM-B constructs(344, 347). Needs for change (linked to constructs of the COM-B model) identified by the behavioural analysis can be linked to a corresponding intervention function that is likely to be effective in addressing each need.

Intervention function	Definition	Linked COM-B constructs and identified intervention needs					
		Capability		Opportunity		Motivation	
		Physical	Psycho-logical	Social	Physical	Reflective	Automatic
Education	Increasing knowledge or understanding						
Persuasion	Using communication to induce positive or negative feelings or stimulate action						
Incentivisation	Creating an expectation of reward						
Coercion	Creating an expectation of punishment or cost						
Training	Imparting skills						
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase						

	the target behaviour by reducing the opportunity to engage in competing behaviours)						
Environmental restructuring	Changing the physical or social context						
Modelling	Providing an example for people to aspire to or imitate						
Enablement	Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring)						

Table 3.2. The APEASE criteria for evaluating candidate intervention functions(344, 347).

Criterion	Key question
Affordability	Is there an implicit or explicit budget that would make this function unaffordable?
Practicability	Is this function practically deliverable in routine clinical practice?
Effectiveness and cost-effectiveness	What is the likely effectiveness and cost-effectiveness of including this function compared to alternatives?
Acceptability	Is this function acceptable to all relevant parties e.g., participating patients, facilitating healthcare professionals and wider stakeholders?
Side-effects/safety	What are the potential side effects or unintended consequences of including this function?
Equity	How might this function influence the disparities in standard of living, wellbeing, or health between different sectors of society.

These criteria are used to determine the suitability of candidate intervention functions and policy categories for the intervention in context. For example, incentivisation may not be affordable in the context of an explicit budget and a coercive function may not be acceptable to facilitating healthcare professionals or lead to greater inequity.

Selection of intervention functions is followed by identification of supporting policy categories. In the same manner that COM-B needs are linked to suitable intervention functions, these are also linked to wider policy categories likely to support their implementation. Candidate policy categories and their linked intervention functions are presented in table 3.3. The APEASE criteria are also be applied to select the most suitable matched policy functions to incorporate.

Table 3.3. BCW policy functions and linked intervention functions(344, 347). Selected intervention functions to address COM-B identified needs for change are likely to be facilitated by a corresponding policy function

Policy function	Definition	Linked BCW intervention functions								
		Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Communication/ marketing	Using print, electronic, telephonic, or broadcast media	■	■	■	■				■	
Guidelines	Creating documents that recommend or mandate practice. This includes all changes to service provision	■	■	■	■	■	■	■		■

Fiscal measures	Using the tax system to reduce or increase the financial cost									
Regulation	Establishing rules or principles of behaviour or practice									
Legislation	Making or changing laws									
Environmental/ social planning	Designing and/or controlling the physical or social environment									
Service provision	Delivering a service									

3.1.5.3. Stage 3. Identification of intervention content and implementation options: Behaviour change techniques and the behaviour change taxonomy

Intervention functions and facilitating policy categories can be thought of as the levers of change. Stage 3 links these to their actual mechanisms of action in the form of behaviour change techniques (BCTs). BCTs can be defined as the smallest replicable active components of an intervention designed to support change in the way participants think, feel and react.(344, 347). They can be used in isolation or in combination with other BCTs. The options are numerous and a key step in further systematising design was the 2013 publication of a consensus, hierarchically structured taxonomy of these techniques(351). This tool facilitated moves toward clearer reporting and replicability of behavioural interventions and facilitates the synthesis and meta-analysis of outcome data from similar trialled interventions utilising the same BCTs. Similar to prior stages, the BCW links the selected intervention functions to appropriate BCTs that can implement through a policy category. A single BCT may be appropriate for more than one desired function. The potential BCTs are also evaluated using APEASE criteria for inclusion. Table 3.4. presents the taxonomy BCTs most frequently linked to each intervention function. The final step in design is defining mode of delivery for each BCT, once again the APEASE criteria provide a useful framework for decision making.

Table 3.4. BCT Taxonomy v1 techniques and linked BCW intervention functions. Those techniques listed are most frequently suitable, other linked techniques can also be utilised(347, 351)

Intervention function	Most frequently suitable individual BCTs
Education	• Information about social and environmental consequences • Information about health consequences • Feedback on behaviour • Feedback on outcome(s) of behaviour • Prompts/cues • Self-monitoring of behaviour
Persuasion	• Credible source • Information about social and environmental consequences • Information about health consequences • Feedback on behaviour • Feedback on outcome(s) of behaviour
Incentivisation	• Feedback on behaviour • Feedback on outcome(s) of behaviour • Monitoring of behaviour by others without evidence of feedback • Monitoring of outcome of behaviour by others without evidence of feedback • Self-monitoring of behaviour
Coercion	• Feedback on behaviour • Feedback on outcome(s) of behaviour • Monitoring of behaviour by others without evidence of feedback

	• Monitoring of outcome of behaviour by others without evidence of feedback • Self-monitoring of behaviour
Training	• Demonstration of the behaviour • Instruction on how to perform a behaviour • Feedback on the behaviour • Feedback on outcome(s) of behaviour • Self-monitoring of behaviour • Behavioural practice/rehearsal
Restriction	No linked BCTs as this function relates to how the external environment limits behaviour
Environmental restructuring	• Adding objects to the environment • Prompts/cues • Restructuring the physical environment
Modelling	• Demonstration of the behaviour
Enablement	• Social support (unspecified) • Social support (practical) • Goal setting (behaviour) • Goal setting (outcome) • Adding objects to the environment • Problem solving • Action planning • Self-monitoring of behaviour • Restructuring the physical environment • Review of behaviour goal(s) • Review of outcome goal(s)

3.1.6. The COM-B model of behaviour

The COM-B model (343) facilitates the capture and categorisation of factors that may facilitate or present barriers for change. The model premise is that behaviour change (B) requires the simultaneous presence of three constructs: Capability (C), Opportunity (O) and Motivation (M). Any factor influencing the likelihood of change occurring (increasing or decreasing it) can be viewed in terms of contribution to or detraction from these three precursors for change. Table 3.5. presents definitions of included terms. Figure 3.3. presents an overview of the model and a summary of potential COM-B interactions.

Table 3.5. Definitions of COM-B model terms (343)

Term	Definition
Capability	An attribute of a person that combined with opportunity makes behaviour possible or facilitates it. This is sub-divided divided in to physical and psychological capability
• Physical capability	Capability involving a person's physique and musculoskeletal functioning (e.g., balance and dexterity).
• Psychological capability	Capability involving a person's psychological function (e.g., understanding and memory).
Opportunity	An attribute of an environmental system that combined with capability makes behaviour possible or facilitates it. This is sub-divided into physical and social opportunity.
• Physical opportunity	Opportunity involving inanimate parts of the environmental system (e.g., financial, or physical resources).
• Social opportunity	Opportunity involving other people and organisations within the environmental system (e.g., social, and cultural norms
Motivation	An aggregate of mental processes that energise and direct behaviour. This is sub-divided into reflective and automatic motivation.
• Reflective motivation	Motivation that involves conscious thought processes (e.g., plans and evaluations)
• Automatic motivation	Motivation that involves habitual, instinctive, drive-related, and affective processes (e.g., desires and habits)

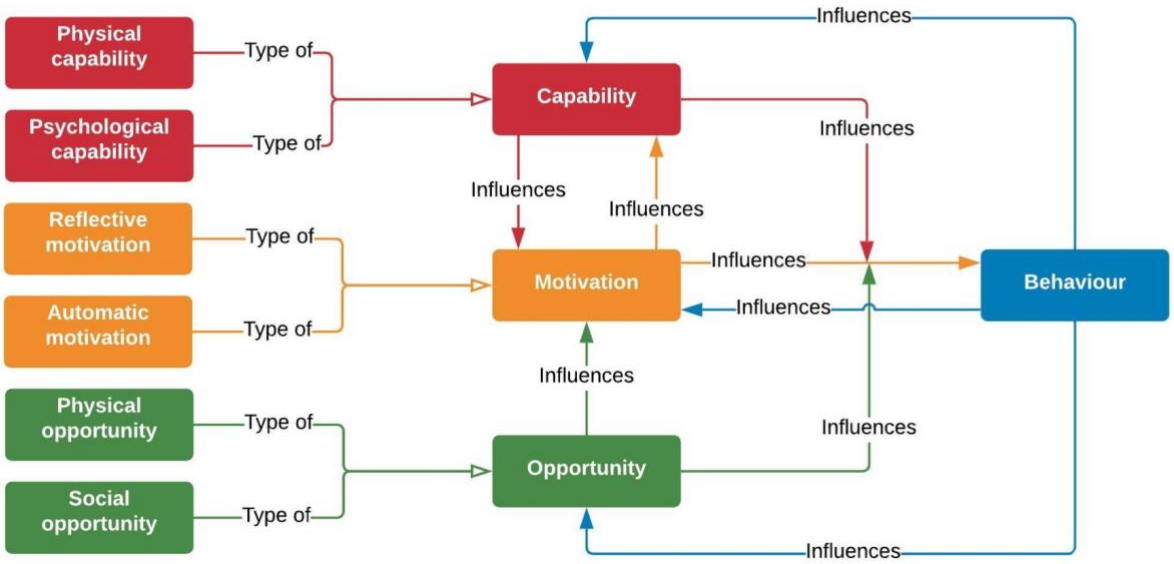

Figure 3.3. The COM-B model of behaviour(343).

A given behaviour necessitates the presence of capability, opportunity, and motivation. These constructs are each considered in terms of two subcategories (e.g., capability can be considered physical or psychological). Motivation varies from moment to moment and is essential to trigger a behaviour directly. Capability and opportunity acting like 'logic gates' to facilitate the behaviour when motivation develops. Presence or absence of capability and opportunity also influence the availability of motivation, an individual will be more motivated toward a given behaviour if they believe they are capable and possess the opportunities to undertake it, and vice versa. The relationship between motivation and capability is also reciprocal, presence of motivation will also affect the likelihood of building capability to undertake a behaviour. Finally, the behaviour itself creates feedback loops, positive and negative, to its three precursors. Undertaking a behaviour that requires learning and skill may reciprocally build capability and motivation to repeat it (such as broaching physical activity in a patient consultation). Behaviours that meet homeostatic drives, like eating, may reduce the likelihood of doing so again in the short term.

The COM-B model allows intervention designers to acknowledge and understand the full range of factors within a complex behaviour system that influence likelihood of a behaviour occurring. The model has demonstrated accuracy in identifying components of capability, opportunity and motivation that predict the likelihood of

adults undertaking physical activity(352) and smoking cessation(353) and undertaking self-management of chronic health conditions including heart failure(354) and diabetes(355).

The COM-B model is utilised within the BCW to conduct the behavioural analysis. There are several approaches, including structured interviews, focus groups and questionnaires(344). Self-evaluation questionnaires adapted to the behaviour and population of interest with questions mapped to the COM-B constructs have been used successfully to identify potential targets for intervention. Research has highlighted the acceptability, reliability and validity of these brief measures for self-evaluation of the COM-B constructs(356). Responses can then be explored in greater detail using the TDF.

3.1.7. The Theoretical Domains Framework (TDF)

The Theoretical Domains Framework (TDF) is a validated framework that synthesises 33 overlapping theories containing 128 individual explanatory behavioural constructs, distilling them into 14 theoretical domains(346). It allows a more detailed exploration of factors identified during an initial behavioural analysis. The TDF was developed to help bridge a divide between underlying behaviour change psychological theory and the specific knowledge required by implementation science(347). Table 3.6. presents the TDF domains mapped to the COM-B model.

Table 3.6. The Theoretical Domains Framework (TDF) and associated COM-B constructs(347)

TDF domain and definition	Incorporated theoretical constructs (TDF constructs)	Linked COM-B construct	
Knowledge An awareness of the existence of something	• Knowledge of condition • Scientific rationale • Procedural knowledge • Knowledge of task environment	Psychological capability	Capability
Skills An ability or proficiency acquired through practice’	• Skills • Skills development • Competence • Ability • Interpersonal skills • Practice • Skill assessment	Physical capability	
Memory, Attention and Decision processes	• Memory • Attention	Psychological capability	

The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives	• Attention control • Decision making • Cognitive overload • Tiredness		
Behavioural regulation Anything aimed at managing or changing objectively observed or measured actions	• Self-monitoring • Breaking habit • Action planning	Psychological capability	
Social/professional role and identity A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting	• Professional identity • Professional role • Social identity • Identity • Professional boundaries • Professional confidence • Group identity • Leadership • Organisational commitment	Reflective motivation	Motivation
Beliefs about capabilities	• Self-confidence • Perceived competence	Reflective motivation	

Acceptance of the truth, reality or validity about an ability, talent, or facility that a person can put to constructive use	• Self-efficacy • Perceived behavioural control • Beliefs • Self-esteem • Empowerment • Professional confidence		
Optimism The confidence that things will happen for the best or desired goals will be attained	• Optimism • Pessimism • Unrealistic optimism • Identity	Reflective motivation	
Beliefs about consequences Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation	• Beliefs • Outcome expectancies • Characteristics of outcome expectancies • Anticipated regret • Consequences	Reflective motivation	
Intentions	• Stability of intentions • Stages of change model	Reflective motivation	

A conscious decision to perform a behaviour or act in a certain way	• Transtheoretical model and stages of change		
Goals Mental representations of outcomes or end states that an individual wants to achieve	• Goals (distal and proximal) • Goal priority • Goal and target setting • Autonomous and controlled goal • Action planning • Implementation intention	Reflective motivation	
Reinforcement Increasing the probability of a response by arranging a dependent relationship or contingency between the response and a given stimulus	• Rewards (distal and proximal) • Valued and unvalued rewards • Probable and improbable rewards • Incentives • Punishment • Consequences • Reinforcement	Automatic motivation	

	• Contingencies • Sanctions		
Emotion A complex reaction pattern involving experiential, behavioural and physiological elements by which the individual attempts to deal with a personally significant matter or event	• Fear • Anxiety • Affect • Stress • Depression • Positive and negative affect • Burn-out	Automatic motivation	
Environmental context and resources Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour.	• Environmental stressors • Resources • Material resources • Organisational culture • Climate • Salient events • Critical Incidents • Person-environment interaction	Physical opportunity	Opportunity

	• Barriers and facilitators		
Social influences Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours	• Social pressure • Social norms • Group conformity • Social comparisons • Group norms • Social support • Power • Intergroup conflict • Alienation • Group identity • Modelling	Social opportunity	

3.1.8. BCW limitation and application to perioperative care

Since first publication in 2011, the BCW and its associated tools have gained widespread prominence in both understanding the sources of behaviours of interest and the design and delivery of interventions within healthcare and other public service contexts. At time of writing the original model has been cited over 7700 times.

The BCW is not without potential limitations. Michie et al emphasise that whilst it is the most comprehensive synthesis of prior existing behavioural theories and frameworks currently available, its development process utilising a systematic review may have missed potentially important components(345). In addition, at each stage intervention designers ultimately have to exercise (potentially biased) judgement around the intervention functions, policy function and BCTs incorporated.

In addition, the designers note it may bot be easily applicable to all conceivable behavioural questions. However, recent systematic reviews have supported its utilisation to support both patients and healthcare professionals in achieving behaviour change in both primary(357) and secondary care(358). In the previously cited review of digitally facilitated perioperative health behaviour interventions by Robinson et al(338), only one of the included studies reporting a theory-informed design had utilised the BCW(359). Lauti et al undertook a randomised controlled study of a postoperative text messaging intervention to prevent postoperative weight regain following bariatric surgery. To date there have been no attempts to utilise the BCW in design of a mutlibehavioural preoperative intervention.

3.1.9. Study aims and objectives

The study sought to address an evident gap in perioperative care and meet demand for a digitally facilitated systematically co-designed and developed multibehavioural prehabilitation intervention for patients preparing for major surgery. The Behaviour

Change Wheel and its linked tools were utilised as the leading framework for intervention design with limited application thus far within perioperative care.

3.1.9.1. Study aim

This aimed to conduct a mixed-method systematic intervention development process with reference to the BCW leading to co-design of a digital multibehavioural prehabilitation programme (iPREPWELL)

3.1.9.2. Study objectives

This study had the following objectives:

- Identification of target behaviours (BCW stage 1)
- Identification of barriers and facilitators to change (BCW stage 1)
- Identification of candidate BCTs and mechanisms of action (BCW stages 2 and 3)
- Co-design of intervention components and content (BCW stage 2 and 3)

The resulting programme design is described in chapter 4. In keeping with the MRC framework (247), this development work is to be followed by a planned feasibility study of the programme assessing acceptability, feasibility and fidelity of the programme. Planned methods are described in chapter 5.

The protocol manuscript (in press) encompassing the full development and feasibility testing process is included as appendix 7

3.2. Methods

3.2.1. Ethical and regulatory approvals

Full ethical and regulatory approval was obtained from an NHS REC (North West-Preston 21/NW/0219). and the HRA through submission to the Integrated Research Application Service (IRAS 300425) to allow recruitment of NHS patient and healthcare professional participants. Copies of approvals are available in appendix 8. Following discussion with the departmental lead for research ethics, submission to a university ethics committee was waived based upon requirement for NHS ethical approval. As the recipient of competitive external funding, the study was also registered on the NIHR portfolio for anaesthesia, perioperative medicine, and pain (APOMP) allowing study support from site clinical research teams.

Both parts of the intervention development process were prospectively registered on ISRCTN (ISRCTN17788295 https://doi.org/10.1186/ISRCTN17788295).

3.2.2. Composition of the intervention co-design group

The intervention co-design process described in this study was a collaborative process reliant on contribution from both research and design team members and recruited patient and healthcare professional study participants. These collectively comprised the intervention co-design group that developed the programme prototype. The research and design team included: Perioperative clinicians experienced in prehabilitation research, health psychologists experienced in behavioural science, health behaviour change and intervention development, clinical and academic team members with health risk behaviour expertise including exercise scientists, smoking cessation practitioners, dieticians, and sleep medicine specialists alongside a health economist. The programme prototype was iterated with co-design workshop findings by web developers experienced in building digital lifestyle interventions for the Healthcare sector (Hark 2 ltd, Leicester, UK, https://www.hark2.com)

3.2.3. Overview of the systematic co-design and development process using the BCW.

Figure 3.4. provides an overview of the development process with reference to the stages of the BCW.

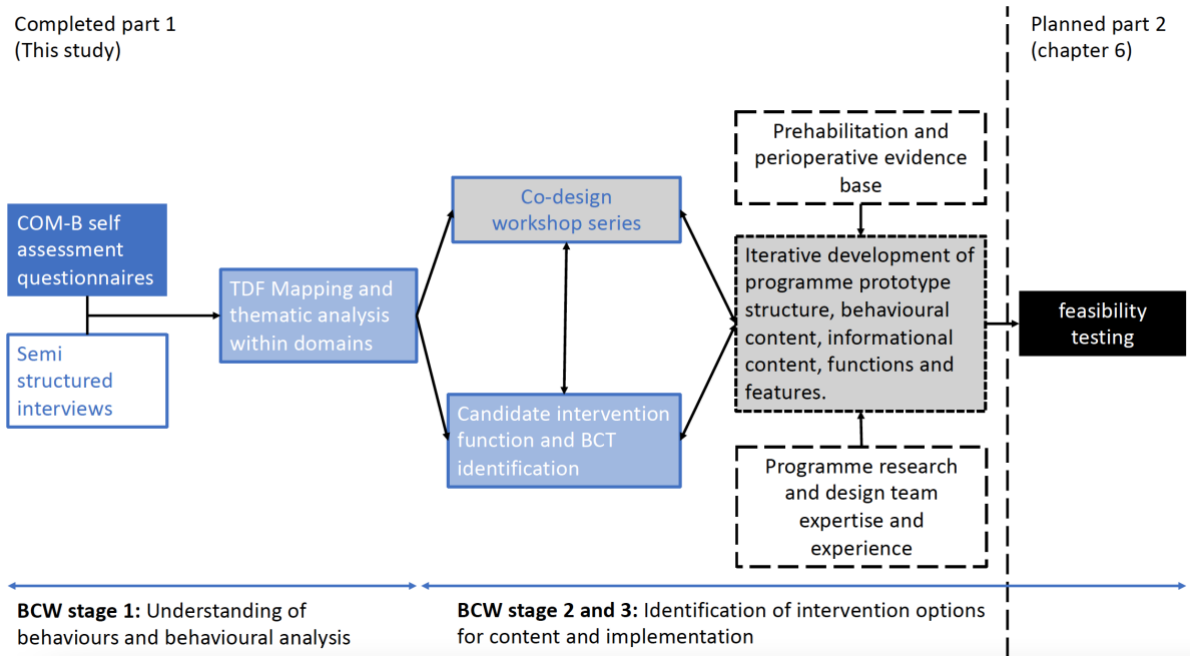

Figure 3.4. Overview of systematic intervention development process

The development process included several interdependent steps. Data were systematically collected from patient and HCP study participants using the COM-B self-evaluation questionnaire and semi-structured interviews with data analysed using the TDF. The findings generated allowed identification of behaviour change techniques (BCTs), and candidate intervention functions.

These findings informed the conduct of co-design workshops. These workshops involved exploring participant preferences for intervention content representing each of the BCTs selected (e.g., informational content, functions, and features of the programme) supported with reference to the existing perioperative evidence base for health risk behaviour intervention and the subject experience and expertise of the research and design team members of the co-design group. These inputs allowed

application of APEASE criteria from the perspective of multiple stakeholders. The resulting prototype will be tested in the study described in chapter 5.

HCP data were used to determine the barriers and facilitators with respect to COM-B that would lead to the target behaviours of promotion and support of the programme. This informed the requirements of an accompanying dedicated training resource to increase knowledge and skills for promoting uptake of the programme by patients, and ongoing support thereafter that would facilitate implementation and delivery of the developed intervention.

3.2.4. Study participant journey overview

Figure 3.5. presents an overview of the process for patient and HCP participants.

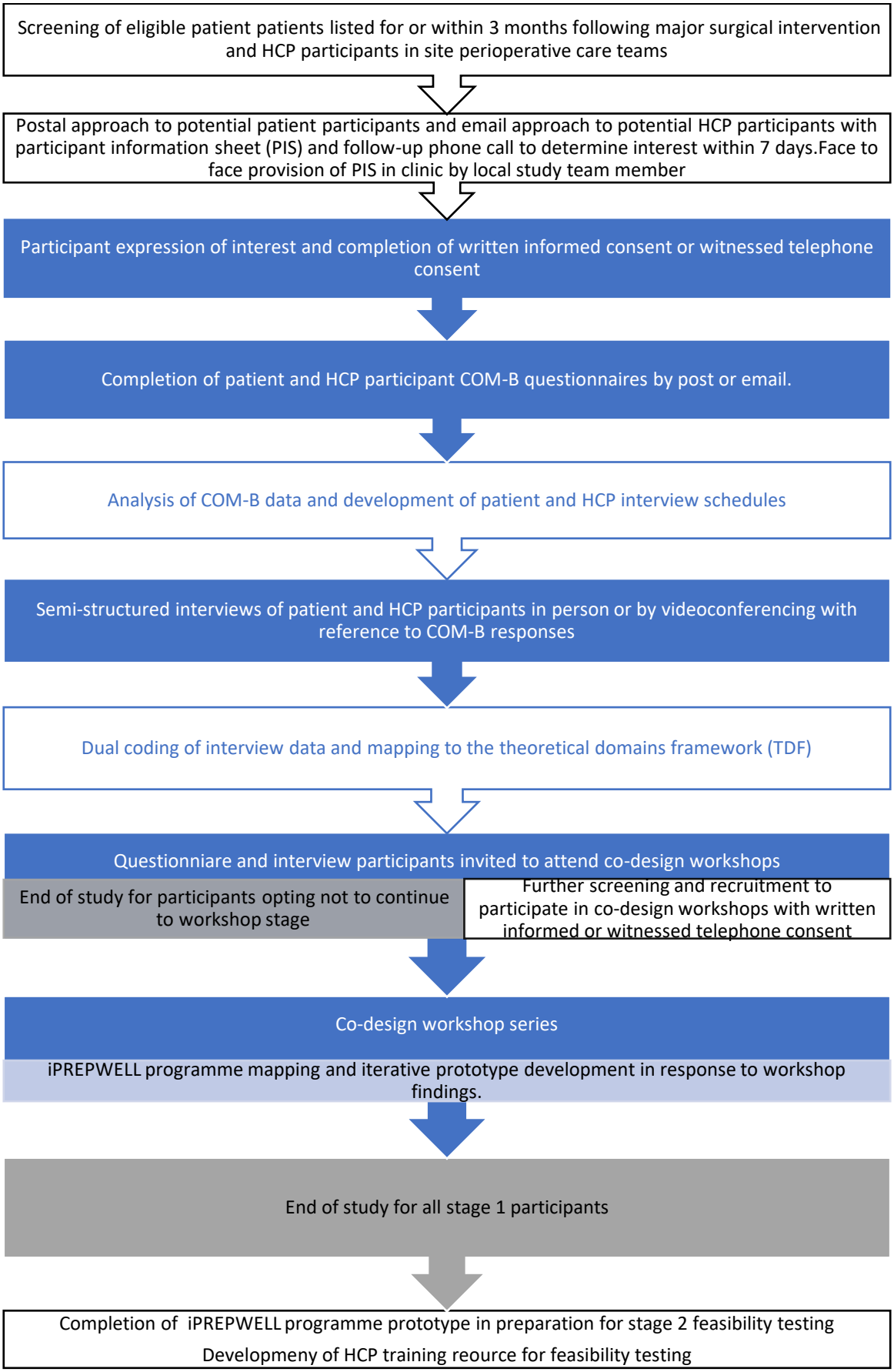

Figure 3.5. Study overview and participant involvement

3.2.5. Eligibility criteria

This study sought the views and perspectives of a sample of patients representative of those who might utilise the programme in part 2 and healthcare professionals representative of the multidisciplinary team working across major surgical pathways at the participating sites. Study inclusion and exclusion criteria are listed with justification in table 3.7.

Table 3.7. Study inclusion and exclusion criteria for patient and healthcare professional participants

Patient participant inclusion criteria	
Criterion	**Justification and rationale**
Adult patient (Age ≥18 years)	In keeping with the DCE study in chapter 2, a representative age range of patient participants that reflect those undergoing major surgery in the UK was sought. Younger adults were not excluded both due to their potential to still benefit from use of a digital prehabilitation programme and the logical expectation that they may have differing viewpoints on the use of a digital intervention than older patients. Obtaining both perspectives was deemed important to support development of an intervention suitable for a broad spectrum of patient age groups
Scheduled for or within 3-months of a NICE 'Major/complex' category procedure in one of the following specialties:	As previously described, NICE NG45(3) was used to guide identification of a 'major/complex' procedure. Patients listed for these operations would be the future target population for the developed program.

• Colorectal surgery • Upper gastrointestinal surgery • Vascular surgery • Urological surgery • Gynaecological surgery • Orthopaedic surgery • Head and neck/maxillo-facial surgery	The programme was intended to be 'multi-specialty' allowing integration into several pathways and offering potential for later tailoring and optimisation for subspecialty groups if feasibility and 'proof of concept' were demonstrated in stage 2. Consequently, a range of specialties were included representing a broader 'major non-cardiac' group of specialties. Notable exclusions were: Cardiac surgery where, despite a growing body of evidence for the safety of preoperative exercise in the context of significant coronary artery and valvular pathology, the need for remotely supervised exercise in the developed programme was felt to carry too high a risk. Thoracic, neurosurgical and breast surgery patients were also excluded due to anticipated short preoperative timeframes for future intervention use. It could be argued that an exclusively 'preoperative' group of patient participants would have best represented future programme users. However, this was not expected to be practicable to both allow participants to contribute to all 3 elements of the co-design process (questionnaire, interview, workshops) within their preoperative window. By extending this criterion to 3-months post-operatively participants would be able to undergo surgery without leaving the study should the choose and patients could also take part after surgery where, with hindsight they may have gained important new viewpoints and perspective on how a programme might have better assisted them preoperatively.

Able to understand spoken and written English.	The linguistic requirements of COM-B Questionnaire completion, participation in a semi-structured interview and participation in the co-design workshop setting necessitated pragmatic exclusion of participants without an adequate understanding of written and spoken English. Provision of appropriate translator support at all stages was not felt to be feasible within the scope of this study. This acknowledged that the resulting programme may be inadequately developed initially for non-native English speakers and as a linked consequence, not meet the cultural needs of patient subgroups. This limitation was accepted given the ability for future work to understand these requirements better and adapt the base programme to improve wider acceptability if feasibility of the prototype was demonstrated. Efforts were made to offset this by diversifying the ethnicities represented through the purposive sampling strategy detailed below.

Patient participant exclusion criteria

Criterion	**Justification and rationale**
Unable to provide informed consent	As a non-interventional observational study, it was not felt to be necessary or practical to provide alternative consent options for participants unable to consent independently. In addition, participation in the co-design process was expected to be challenging for participants in this category.

Discharged postoperatively to a destination other than their own home or commenced on end-of-life care	Participation in this study was expected to be inappropriately burdensome and logistically infeasible for potential participants in these groups.
Healthcare professional participant inclusion criteria	
Perioperative team members employed by participating Trusts from a medical, nursing, or allied healthcare professional background or a wider stakeholder in perioperative care (e.g., an individual with management or commissioning responsibility for perioperative services)	This criterion acknowledged the wide range of multidisciplinary team members necessary in the modern perioperative care of the patient undergoing major surgery. It is acknowledged that patients encounter several professionals preoperatively with opportunity to promote, support and facilitate a digital prehabilitation programme. It was also anticipated that prehabilitation teams delivering the programme in future may also require the support of 'subject specialists' for target risk behaviours e.g., dietetics for nutritional support and obtaining their views was deemed necessary. A wider group of stakeholders were also eligible to take part, acknowledging the objective of taking steps towards an implementation strategy for the future programme.

3.2.6. Participating sites

This study was undertaken across two NHS surgical centres: The James Cook University Hospital, South Tees Hospitals NHS Foundation Trust (Study sponsor) and York Teaching Hospital, York, and Scarborough Teaching Hospitals NHS Foundation Trust. These centres offered experienced perioperative research teams with track records in prehabilitation studies caring for patients across a range of

surgical specialties across diverse geographical and socioeconomic catchment areas. Extension of the study beyond two sites to further improve wider applicability of findings was limited by the logistical needs of supporting patients to attend the co-design workshops.

Following local confirmation of capability and capacity, a site initiation visit (SIV) was conducted with at York Teaching Hospital. The site principal investigator (PI) was a senior anaesthetist with experience in perioperative care and prehabilitation to support screening decisions against eligibility criteria. Steps following screening and expression of interest from York Hospital patients were coordinated by team members at the sponsor site with logistical support for the co-design workshops by the York Hospital study team.

3.2.7. Sampling strategy

A purposive sampling strategy was adopted with the underlying aim of recruiting a participant group maximally varied in terms of age, gender, ethnicity, socioeconomic deprivation, surgical specialty, and experience/confidence with digital technology. Patient participants were sought via screening exhibiting the health risk behaviours targeted by the programme. The intent was a patient participant group that would provide a relevant range of views and perspectives that reflect wider UK major surgical populations. From the healthcare professional standpoint, variance was sought in terms of age, gender, ethnicity, professional background, number of years in role and experience with provision of prehabilitation support and digital healthcare interventions participants. The intent was for HCP participants to reflect the spectrum of professionals forming the modern multidisciplinary perioperative care team and delivering perioperative services at NHS surgical centres.

It was intended and encouraged that participants were involved in as many study elements as possible however in anticipation of practical difficulties in doing so (e.g., undergoing surgery or workload) and expected dropout, participants were able to participate by three main routes:

- Completion of COM-B questionnaire and a paired semi-structured interview.
- Completion of questionnaire, paired interview, and attendance at co-design workshops
- Attendance at co-design workshops only.

Sample size was determined with reference to published guidance on data saturation for theory-informed interview studies(360). An initial 10 patient and 10 HCP participants (20 in total) completed COM-B questionnaires and interviews. Interim analysis was conducted confirming ongoing emergence of new themes prompting recruitment of a further 3 patients and 3 HCPs until data saturation was reached. This approach also facilitated regular review of the sample characteristics and adjustments to potential participants approached in line with the purposive strategy. These participants were encouraged to also attend the co-design workshops, but this was not desirable or pragmatic for all questionnaire and interview respondents prompting additional patient and HCP participant recruitment to support at least 6-12 attendees at each workshop guided by the individual session focus and requirements.

3.2.8. Screening, recruitment, and consent

Separate patient (appendix 9) and healthcare professional (appendix 10) participant information sheets (PIS) were developed in accordance with current HRA guidance (http://www.hradecisiontools.org.uk/consent/content-sheet.html).

3.2.8.1. Patient participants

Patients were screened by site perioperative clinical and study teams using preoperative clinical and surgical lists to identify eligible preoperative and postoperative patients. A patient participant information sheet (PIS) was sent by post, with a follow-up call within seven days by a study team member to confirm receipt and determine interest in participation. Patients keen to participate provided either witnessed informed consent by telephone or written informed consent (if beginning their participation at the co-design workshop stage) utilising a patient study consent form prior to data collection (appendix 11). This was prepared with

reference to HRA guidance for best practice (https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/). Patients declining participation were asked to provide a brief reason for doing. This was expected to yield potentially valuable information toward intervention development. No further data were collected beyond screening information.

It was acknowledged that patient partners, friends and family members were likely to play a key role in supporting programme engagement and helping patients effect preoperative health behaviour change. Patient participants were able to undertake their interview or attend workshops with one other person. In order that their companion's contribution could be recognised and incorporated into analysis this individual was also asked to complete the study patient consent form, but they were not counted against recruitment totals.

3.2.8.2. Healthcare professional participants

Support from perioperative services at each site were obtained by the study team to facilitate HCP time in taking part. Eligible HCPs were identified by clinical study team members with knowledge of relevant surgical pathways at the participating sites. A copy of the HCP PIS and invitation to participate was provided by email. HCPs keen to take part provided written informed consent prior to data collection. This form (appendix 12) was also prepared with reference to HRA guidance for best practice (https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/). A reason for non-participation was also recorded.

3.2.9. Data collection

3.2.9.1. Case record form and baseline data collection

A paper case record form (CRF) was completed for patient and HCP participants to allow characterisation of co-design group members contributing to the development process. Data collected are summarised in table 3.8.

Table 3.8 Participant CRF data collection

Patient participant CRF data collected	
Demographics	• Age • Biological sex • Marital status • Employment status • Qualifications
Perioperative clinical details	• Surgical specialty • Perioperative timepoint e.g., preoperative/postoperative • Procedure/planned procedure and date • Cancer status
Risk behaviour and comorbidity status	• Smoking status • Alcohol intake (units per week) • BMI (kg/m^2) • Activity status (WHO criteria for healthy adults) • Current or preoperative prehabilitation activity or support • Comorbidity profile
Information/digital technology experience	• Device ownership • Frequency of internet access/utilisation
HCP participant data collected	
Demographics	• Age • Biological sex

Professional background	• Clinical role and time in role • Experience in prehabilitation delivery • Experience in use of digital healthcare interventions with patients

3.2.9.2. COM-B questionnaire preparation and administration

The study commenced with administration of COM-B self-evaluation questionnaires. Dedicated questionnaires were developed for patient (appendix 13) and HCP (appendix 14) participants. The standard questionnaire was contextualised for prehabilitation with provision of brief instructions. For patient participants, the questionnaire aimed to explore barriers and facilitators for personal preoperative behavioural change in terms of capability, opportunity, and motivation as categorised by the COM-B model. For HCPs, barriers, and facilitators for the remote support of patients to achieve preoperative behaviour change in their clinical role were explored. Questionnaires were offered to participants with accompanying reinforcement of the relevant instructions for completion alongside contact details for the study team for questions or problems. Participants received phone or email reminders if a completed questionnaire was not returned by post or email to address any issues.

3.2.9.3. Semi-structured interview topic guide development and interview conduct

Participants who had completed questionnaires were then invited to undertake a paired semi-structured interview based on their questionnaire. Dedicated draft interview topic guides were developed for patient (appendix 15) and HCP (appendix 16) participants. These were created by a team of three researchers (two health psychologists and one perioperative clinician) with reference to the COM-B model and refined following interim analysis of returned COM-B questionnaire responses. Topic guides were piloted for usability and ease of understanding prior to commencement of semi-structured interviews.

All participants returning a completed COM-B self-evaluation questionnaire were invited to undertake a semi-structured interview lasting approximately 60 minutes with a single researcher, led by the topic guide. A single researcher (health psychologist) undertook all interviews. Before the interview they reviewed the participants COM-B questionnaire prior to tailor and explore corresponding areas of the topic guide. Participants were interviewed in person or by video-conferencing dependent on their preference. All interviews were audio recorded using a digital dictaphone for subsequent transcription and analysis.

3.2.9.4. Co-design workshop development and conduct

Workshops commenced following completion and analysis of all questionnaire and interview data. Workshops were facilitated by at least two members of the multidisciplinary research and design team. At least one health psychologist and one perioperative clinician facilitated all workshops with additional facilitators invited based on logistic requirements and relevant expertise. At least 6 and no more than 12 participants were invited to attend each session. Sessions were attended by both Patients and HCPs. No minimum session attendance was prespecified with participants able to attend all sessions if they chose. Patient participants were re-imbursed for reasonable travel expenses required to attend face-to-face.

Sessions were conducted face-to-face at both participating sites and a remote-participation option was available by video conferencing. Each session was scheduled to last up to 2 hours and began with a brief overview of development progress to date and the aims and objectives for the session. Workshop data were collected by detailed note taking by facilitators. Each session aimed to obtain the information needed from participants to advance the prototype development between sessions with parallel input from research and design team members (including the partner web development team) and reference to the evidence-base for perioperative health behaviour change interventions and other related interventions from allied healthcare settings that could be utilised as examples to obtain feedback from workshop participants at subsequent sessions.

3.2.10. Data handling and analysis

Data for each study element were analysed contemporaneously to the inform the next stage in the BCW process.

3.2.10.1. COM-B questionnaires and semi-structured interviews

COM-B questionnaire responses were reviewed prior to the paired semi-structured interview to inform the topic guide and assist the interviewer in exploring relevant areas relating to the COM-B model during the interview.

Semi-structured interview audio recordings were pseudo-anonymised prior to verbatim transcription by a 3rd party provider for academic transcription (TypeitWrite, Newcastle, UK).

Interview transcripts coded by identification or relevant text segments and mapping against appropriate domains of the theoretical domains framework. Two researchers one health psychologist who conducted the interviews and one perioperative clinician independently pilot-coded the 1st patient and 1st HCP transcripts to make use of their complementary background knowledge and insight on participant responses. This analysis was then reviewed with a 3rd researcher (health psychologist experienced in use of the BCW and TDF) to refine the coding strategy. A further 2 transcripts were then dual coded confirming a good level of agreement. Dual coding was then applied to 50% of all subsequent transcripts.

Text segments mapped to the TDF were then thematically analysed within each framework domain to identify key barriers and facilitators of engaging with (patients) and delivering (HCPs) digitally facilitated, remotely supervised health behaviour change prior to major surgery. New themes continued to emerge following the 10th patient and 10th HCP participant interview analysis. Recruitment of participants continued in keeping with the purposive sampling strategy with questionnaires

administered and paired interviews continued until a varied sample was achieved (e.g., surgical specialties and HCP backgrounds) and data saturation was reached.

The thematic analysis of patient and HCP responses mapped against TDF domains and COM-B constructs formed the initial behavioural analysis comprising BCW stage 1. From here, the highlighted COM-B constructs were linked to potential intervention functions commencing BCW stage 2. This also allowed initial progress toward BCW stage 3, allowing identification of candidate behaviour change techniques for the programme, based upon those proposed intervention functions and the underlying TDF domains. This allowed BCW stage 2 and 3 to continue through the co-design workshop series and iterative programme prototype development.

Given the need for part 2 study findings (chapter 6) and demonstration of feasibility of the developed programme prior to engagement of the necessary stakeholders (e.g., service managers and commissioning groups) evaluation of policy functions linked to candidate intervention functions was deferred at this stage.

3.2.10.2. Co-design workshops and iterative programme prototype design and development

The COM-B/TDF behavioural analysis of questionnaires and interviews underpinned the subsequent co-design workshop series, guiding workshop aims and objectives toward the completing the BCW stage 2 and 3 objectives.

Workshops aimed to refine intervention functions (BCW stage 2) and the candidate BCTs for the overall programme already identified (BCW stage 3). Workshop notes were reviewed between sessions and combined with input from the study design team and the perioperative evidence base to update an evolving map of the overall programme with detailing of specific behavioural content (BCT) and mode of delivery relating to each of the target health risk behaviours including a functions and features. Final workshops concluded with usability testing of the intervention prototype in readiness for part 2 feasibility testing.

Whilst potential candidate policy categories to facilitate the intervention were identified. It was anticipated that the findings of the part 2 study, with the attempt to implement it in practice, would be necessary to refine this further

3.3. Results

3.3.1. Screening, recruitment, and co-design group characteristics

Figure 3.6. summarises the screening and recruitment process for patient and HCP study participants.

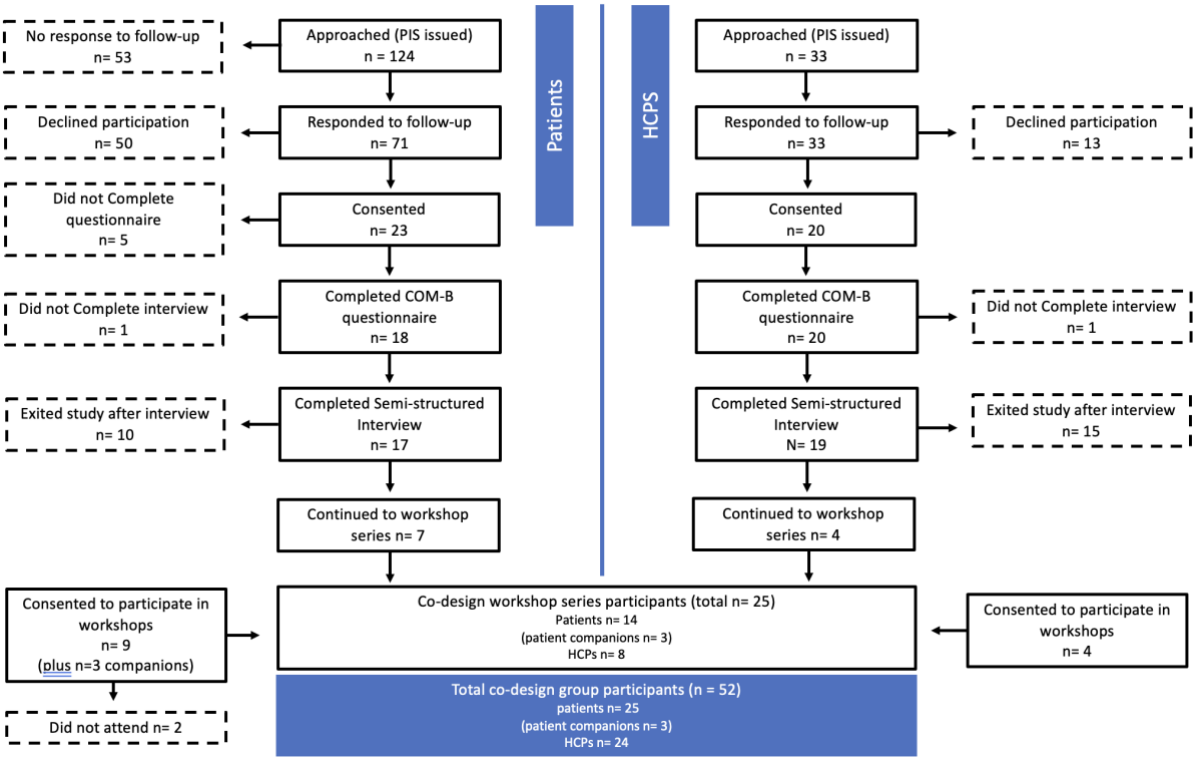

Figure 3.6. Study participant recruitment

Uptake was 32.4% amongst patients issued with a PIS who responded to follow-up. The key reasons for non-participation were lack of interest, limited time available before surgery and feeling overwhelmed prior to surgery. Five patient participants did not complete a COM-B questionnaire and did not respond to further follow-up. One patient who completed a questionnaire was unable to undertake a paired interview due to lack of time. This questionnaire was not included in the thematic analysis. Further interviews beyond the 17th patient were not required as ongoing

thematic analysis indicated data saturation had been reached. As anticipated, a further round of recruitment for the workshop stage was necessary due to the time lag between interview conduct and analysis and the workshop stage. Nine further patients were recruited with seven of those going on to attend a workshop session. seven patients participated in all three elements (questionnaire, interview, and workshop)

Uptake was greater among HCPs with 60.6% of the 33 HCPs approached consenting. The remaining HCPs declined due to lack of time. Of the 37 participants consenting, the majority completed the COM-B questionnaire and interview stages. One HCP participant opted to remove themselves from the study due to a family bereavement after questionnaire completion. This questionnaire was also not included in the thematic analysis. All other HCP participants completed an interview with saturation reached by the 19th HCP participant interviewed. An additional 4 HCPs were recruited to attend the workshop series

The characteristics of the patient and HCP co-design participants are presented in table 3.9. Some participant CRFs were partially incomplete. This is indicated against each characteristic where relevant

Table 3.9. Study co-design group participant characteristics. Values are mean (SD) or n (proportion). Missing data where indicated.

Patient participants (n= 25)		
Demographic characteristics		
Age (years)	60.3	(16.5)
Missing data	3	(12)
Gender M/F	13/9	(52/36)
Missing data	3	(12)
Marital status		
Married	17	(68)
Civil partnered	1	(4)
Widowed	1	(4)
Single	1	(4)
Other	1	(4)
Missing data	4	(16)
Employment status		
Full time	8	(32)
Part time	4	(16)
Retired	8	(32)
Missing data	5	(20)
Highest educational attainment		
Degree/professional	12	(48)
Vocational	3	(12)
Nil formal	5	(20)
Missing data	5	(20)
Clinical characteristics		
Preoperative/postoperative (at enrolment)	15/5	(60/20)
Missing data	5	(20)

Surgical specialty		
Upper gastrointestinal	4	(16)
Lower gastrointestinal (colorectal)	3	(12)
Urology	3	(12)
Vascular	1	(4)
Orthopaedics	5	(20)
Gynaecology	4	(16)
Maxillofacial	1	(4)
Missing data	4	(16)
Cancer surgery	8	(32)
Missing data	7	(28)
Comorbidity profile		
Ischaemic heart disease	1	(4)
Heart failure	1	(4)
Hypertension	1	(4)
Diabetes mellitus (insulin dependent)	1	(4)
Osteoarthritis	1	(4)
COPD	1	(4)
Asthma	1	(4)
Missing data	5	(20)
Health risk behaviours		
Smoking status		
Ex-smoker	4	(16)
Never smoked	16	(64)
Missing data	5	(20)
Alcohol intake >14 units per week	2	(8)
Missing data	5	(20)
Physical activity		
150 mins moderate activity/week	12	(48)
75 mins vigorous activity/week	4	(16)
Twice weekly resistance activity	5	(20)
Missing data	5	(20)

Offered/engaged with Prehabilitation support	5	(20)
Missing data	5	(20)
Healthcare professional participants (n=24)		
Demographic characteristics		
Age (years)	42	(8.3)
Missing data	3	(12.5)
Gender M/F	9/14	(38/58)
Missing data	1	(4.2)
Professional characteristics		
Clinical role		
Consultant surgeon	5	(20.8)
Consultant anaesthetist	3	(12.5)
Preassessment nursing staff	3	(12.5)
Nurse specialist	3	(12.5)
Physiotherapist	1	(4.2)
Dietician	1	(4.2)
Specialist surgical practitioner	4	(16.7)
Missing data	4	(16.7)
Time in role (years)	9.1	(5.9)
Missing data	9	(37.5)
Prior prehabilitation experience	11	(45.8)
Missing data	5	(20.8)
Prior experience in digital patient interventions	7	(29.2)
Missing data	5	(20.8)

Patient participants were predominantly married with over half reporting professional or vocational qualifications. A wide range of surgical specialties were represented with one third of participants undergoing surgery for a cancer diagnosis. 60% of participants were consented and began participation preoperatively. Only 7 patients demonstrated an established comorbidity. No participants were actively smoking at consent although 16% had done so previously. Only two participants reported alcohol consumption above 14 units per week and less than 50% reported activity rates in keeping with WHO targets for healthy adults. 5 participants reported having been offered or engaged with prehabilitation activity as part of their care.

HCP participants represented a range of surgical specialties and roles across the wider perioperative team. The group had been in role for an average of 9.1 years although this ranged from less than 6 months to 21 years.45.8% reported prior involvement with delivery of prehabilitation support and 29.2% had utilised digital health interventions with patients previously.

3.3.2. Specification of target behaviours

For patients, target behaviours were specified based on known health risk behaviours that elevate perioperative risk and the evidence for benefit resulting preoperative intervention discussed in chapter 1. For healthcare professionals, target behaviours were based upon anticipated roles in the facilitation of the intervention within perioperative pathways. Target behaviours are presented in 3.10.

Table 3.10. Specification of patient target behaviours. It was not possible to initially specify a behaviour relating to psychological wellbeing despite enhancing this being a programme aim. The views of participants on this area were sought during semi-structured interviews to narrow the programme focus.

Target behaviour	Who needs to perform it?	What do they need to do differently to achieve the desired change?	When do they need to do it?	Where do they need to do it?	How often do they need to do it?	With whom do they need to do it?
Patients						
Increasing levels of physical activity	Patients preparing for major surgery	Increase daily levels of physical activity to minimise time spent sedentary	No specific time	No specific location but likely in and around their home	Daily until surgery	Independently or with companions
Undertaking structured aerobic exercise training	Patients preparing for major surgery	Undertake exercise sessions at an intensity likely to improve aerobic fitness	No specific time	No specific location but likely in and around their home	At least 2-3 sessions per week until surgery	Independently or with companions
Undertaking structured resistance exercise training	Patients preparing for major surgery	Undertake exercise sessions containing movements against resistance to improve muscular strength and stamina	No specific time	No specific location but likely in and around their home	At least 2 sessions per week until surgery	Independently or with companions
Undertaking inspiratory muscle training	Patients preparing for major intrabdominal surgery	Undertake sessions using an inspiratory muscle trainer to improve strength and stamina of the muscles of breathing	No specific time	No specific location but likely in and around their home	At least 2 sessions daily until surgery	Independently
Stopping smoking	Patients preparing for major surgery who smoke	Stop smoking	No specific time	No specific location	As soon as possible before surgery	Independently
Reducing alcohol intake to within 14 units per week	Patients preparing for	Reduce alcohol intake to less than or equal to 14 units per week	No specific time	No specific location	As soon as possible before surgery	Independently

	major surgery who drink alcohol					
Eating a healthy diet	Patients preparing for major surgery	Match current diet to align with principles of healthy eating to provide nutritional support for the body before surgery	No specific time	No specific location	Daily until surgery	Independently
Increasing sleep duration and quality	Patients preparing for major surgery	Undertake a sleep hygiene practice to optimise duration and quality of sleep	No specific time	No specific location	Daily until surgery	Independently
Healthcare professionals						
Promoting the intervention	Any perioperative team member with preoperative patient contact	Begin offering and promoting the intervention to appropriate patients	During routine preoperative patient contact points	Their normal place of work	Opportunistically	Independently
Supporting patients using the intervention	Any perioperative team member with preoperative patient contact	Begin taking opportunities to encourage and support patients using the intervention	During routine preoperative patient contact points	Their normal place of work	Opportunistically	Independently
Facilitating the intervention with patients	perioperative team members able and willing to facilitate the intervention with patients	Take on an intervention facilitator role and remotely-supervise and support patients using the intervention	No specific time (guided by patient need and scheduled contacts)	Their normal place of work	As a component of their clinical role	With a team of facilitator colleagues, within the wider perioperative team

3.3.3. COM-B/TDF thematic analysis of questionnaire and semi-structured interviews

3.3.3.1. Patient participants

The thematic analysis of patient participant COM-B questionnaires and paired semi-structured interviews, organised by relevant COM-B construct is presented in table 3.11 Themes emerged across all 3 COM-B constructs (and 6 subconstructs).

In terms of capability, patient respondents emphasised a need for clear provision of information to underline 'why this matters' in the approach to surgery. This would carry added weight if delivered clearly by credible sources within their perioperative care team. In terms of making changes to lifestyle behaviour, a need for clear instruction on 'how to' in addition to 'what to do' emerged. Patients were clear that this should be sensitive to their individual circumstances and limitations, varied information technology skills and the added physical and psychological burdens of the preoperative period, notably the impact of a cancer diagnosis and treatment. In summary, the programme design and support must be able to meet patients where they are and without judgement. The need for goal setting, self-monitoring, and progress tracking mechanisms and a 'dual effort' between the patient and HCP facilitators to achieve this was also clear.

From an opportunity perspective, there was a clear signal from some respondents emphasising the need to capture the social support elements more readily associated with face-to-face programmes. This emphasised the role, value, and power of HCPs in this process alongside the need to involve a patient's own support network e.g., family and friends in these efforts. For some patients, these functions extended to peer-support mechanisms. Again, the need for this to support patients facing numerous demands and stressors on their physical reserves and cognitive bandwidth before surgery was emphasised. Patients underlined the need for a compassionate social support approach. In keeping with the findings in chapter 2, patients suggested that the programme should be available and offered as soon as

possible following surgical listing. In relation to environmental context, some patients described facilitatory factors for programme use, including a simple, intuitive platform that is easy to use and to be introduced to the programme at an early point in their preoperative treatment.

In terms of motivation, the need to help patients build a sense of control was emphasised. Indeed, there was a sense that patients should be driving their programme not vice versa. Dependent on patients' beliefs about their capability and their individual needs for prehabilitation, potential programme features were considered more conducive than others (habit formation, goal setting, planning and self-monitoring). There was significant overlap with the capability themes identified as simultaneous drivers of motivation. The value of clear messaging, emphasising the 'why' and the 'how' of preoperative change was demonstrated again as central to targeting patients' beliefs about consequences and their reflective motivation to engage with such a programme. The need for prompting functions, as a form of reinforcement, was also clear, once again with the caveat that these should be designed with the intent to support and encourage not to pressurise.

The importance of psychological wellbeing and how this can be threatened in the preoperative period was clear from patient respondents. A theme emerged around stress and anxiety as key issues in this area and a need for help in managing this preoperatively. As a result, the psychological wellbeing element of the programme was subsequently focussed on stress and anxiety management.

Table 3.11. COM-B/TDF thematic analysis of patient responses to COM-B self-analysis questionnaires and semi-structured interviews.

TDF domain	TDF constructs	Theme
Capability		
Physical Capability		
Skills	• Skills • Competence	• **Physical limitations (Fatigue and exhaustion)** ○ Feeling too tired, depleted, and exhausted to engage in physical activity ○ Chemoradiotherapy leading to feeling too unwell or fatigued to engage in activity. (Compounds with successive treatments)
		• **Physical limitations (inability to perform some exercises)** ○ Exercises may appear too strenuous ○ Comorbidities may limit engagement ○ Pain and poor mobility can limit engagement ○ Feeling 'I would If I could'.
	• Skills • Competence • Skills development	• **Limitation by information technology skills** ○ A programme should only require basic IT skills ○ Training, help and support will be required to use a programme

Psychological Capability		
Knowledge	• Knowledge (condition and scientific rationale)	• **Desire to learn more about other behaviours relating to prehabilitation (beyond exercise and nutrition)** ○ Sleep health and alcohol consumption ○ Managing pain
		• **Valuing information from a 'credible source'** ○ Valuing expert knowledge and scientific information ○ Credibility would depend on the subject
		• **Wanting to know 'why' making changes are important before surgery** ○ What are the benefits to me? ○ Why do these behaviours matter before surgery? ○ The importance of messaging this clearly Overlap with Capability-behavioural regulation-self monitoring Overlap with Motivation-beliefs about consequences

	• Procedural knowledge	• **Wanting to know what will help rehabilitation after a specific procedure** ○ Procedure specific exercises (e.g., pelvic floor training for gynaecological surgery or upper body resistance training for upper gastrointestinal surgery)
		• **Needing information on what to expect during the recovery period to help planning and develop a feeling of self-control** ○ Expected physical limitations ○ Expected emotional and psychological impact ○ Expected recovery time (and how prehabilitation might influence this)
		• **Needing information and lifestyle advice specific to cancer and cancer treatment (in addition to the surgical procedure)** ○ Are any diets or exercises beneficial or unsafe? ○ Not having reliable information on what is appropriate, safe, or beneficial when living with cancer is a source of anxiety. Overlap with Motivation-emotion Overlap with Opportunity-social influences-expert power

		• **Needing information on how to make lifestyle changes using a programme** ○ A programme would require a detailed introduction and 'how to' elements ○ How to make 'small changes' in behaviours ○ Hints and tips to changing behaviour ○ How to keep going and sustain motivation ○ What are the expected challenges in making changes? Overlap with Opportunity-peer support-overseer support
Memory, attention, and decision-making processes	• Attention • Cognitive overload/tiredness	• **Difficulty processing information and feeling overwhelmed** ○ Information overload at time of cancer diagnosis ○ Prompting and reminders would be helpful Overlap with Motivation-emotion
Behavioural regulation	• Self-monitoring	• **Self-monitoring of progress would be enhanced by joint monitoring with supporting healthcare professionals** ○ Prompting from HCPs would be needed to support self-monitoring

		Overlap with Opportunity – Social pressure/Social support
		• **Self-monitoring would be enhanced by 'digital' prompts (e.g., text messages, emails, notifications)** Overlap with Motivation-reinforcement
		• **Self-monitoring would be enhanced by forming a plan with linked goals** ○ Planning should be flexible. 'A plan I can tailor to me'.
		• **Self-monitoring would be enhanced by the ability to log and record progress** Overlap with Motivation-reinforcement-incentive seeing progress
Opportunity		
Social opportunity		
Social influences	• Social pressure • Social support	• **Need for someone to promote, explain, and demonstrate the programme ('promoter role')** ○ Value of someone taking the time to go through the programme and assist if IT skills are more limited.

		• **Needing to be supported rather than pressured by HCPs** ○ Presentation of the programme and messaging throughout is key ○ Feeling pressured is likely to be detrimental ○ Wishing not to feel 'judged' regarding health behaviours ○ 'it's okay' messages for days when things aren't going well, or it is difficult to make progress
		• **Needing a clear HCP point of contact (the 'prompter/overseer role')** ○ Feeling of regular 'human contact' is valuable ○ Feeling of being monitored and supported ○ Source of reassurance about doing the right things ○ Accountability to an external person Overlap with Capability-behavioural regulation Overlap with Motivation-Beliefs about capabilities-Empowerment, reinforcement
	• Social support • Group identity • Group norms	• **Not wanting to engage with other patients (not wanting peer support)** ○ Some patients may not wish to engage with other ○ They may not need interaction to achieve their goals

	• Modelling • Social comparisons	
		• **Wanting to engage with other patients (wanting peer support)** ○ Sharing the experience ○ Finding a 'digital buddy'
		• **Obtaining experiential knowledge from others** ○ Knowing others are in or have been in the same boat and learning from others experiences (patient stories and testimonials) ○ The value of the endorsement of other patients ○ Not necessarily direct interaction
	• Social support • Group identity • Group norms • Modelling • Social comparisons	• **Needing support for my supporters and advice for family, partner, friends, and carers on how to help me**
		• **Needing support from my supporters** ○ Involving supporters in programme activity e.g., doing exercise or eating differently together ○ Encouraging and allowing supporters to access the programme too. ○ Source of emotional support Overlap with Capability-behavioural regulation

		• **Importance and need for social support while using programme** ○ Needing social support and encouragement from HCPs and potentially other programme users ○ Preventing feeling alone while using the programme ○ Sharing problems and issues with others Overlap with Motivation-emotion
	• Power • social pressure	• **The influence of HCPs** ○ The importance of HCPs emphasising and re-emphasising messages in a supportive way ○ Ability of HCPs to motivate ○ HCPs emphasising the severity of consequences ○ All HCPs are influential irrespective of their role (NHS is a credible source) however some may be more influential in certain circumstances.
		• **The influence of Specialist nurses** ○ In a key and influential position to promote, prompt and facilitate ○ Valued by patients throughout their care pathway ○ Surgeons perceived to defer to specialist nurses to follow things like this up

		• **The influence of the Surgeon as a key promoter of a programme**
Physical opportunity		
Environmental context and resources	• Barrier • Environmental stressors • Person versus environment • Organisational culture/climate	• **Not having enough time before surgery to make changes** ○ 6 weeks doesn't feel like enough time ○ Impact of chemoradiotherapy shortening time available
		• **Not enough time in the day to make changes** ○ Ongoing other commitments e.g., working full time
		• **HCPs appear not to have enough time to offer support and advice**
	• Facilitator • Environmental stressors • Person versus environment	• **Finding ways to find enough time in the day** ○ Value of setting goals for change ○ Learning to make/prioritise time
		• **Finding ways to find enough time before surgery** ○ Setting goals for change

		○ Starting the programme when cancer treatment (e.g., chemoradiotherapy) commences
		• **The timing of programme promotion and offer** ○ In general, the sooner the better from the moment surgery is agreed ○ For cancer patients the time of diagnosis would be too stressful, need time to process this ○ The anaesthetic preassessment visit feels too late
	• Resources/materials	• **Supporting access to the programme with appropriate equipment and devices**
	• Barrier • Person versus environment • Salient events/critical incidents	• **Other life events and priorities as a barrier to change** ○ Feeling unable to make difficult changes because of other priorities ○ Feeling unable to establish routine ○ The Financial impact of making time for lifestyle changes ○ Other draws upon emotional wellbeing or energy (working full time and being a single parent) ○ Added anxiety of another thing to worry about Overlap with Motivation- Emotion

	• Facilitator	• **The programme needs to be tailored to the patient and provide choice to promote autonomy** ○ Tailored to physical abilities ○ Tailored to their condition ○ Tailored to their timescales and treatment ○ Tailored to their operation ○ A structured but modifiable plan ○ Balance between general advice and tailored advice Overlap with Motivation – Beliefs about consequences – expectancies
		• **Programme format and content must be simple, understandable, and easy/intuitive to use** ○ Simple, non-clinical language ○ Non-imperative language, e.g., guides not plans ○ As fun and engaging as possible ○ Minimal participant input e.g., automatic logging if possible
		• **Multimedia mode of information delivery** ○ Easy to view audio visual content where possible Podcasts to obtain information ○ Visual demonstrations e.g., of exercises

		○ Minimise use of written content to read
		• **Wider role for the programme** ○ User friendly for people with disabilities ○ Scope for it to be used post-surgery/rehab ○ Inclusion of other health behaviour support
Motivation		
Reflective Motivation		
Beliefs about capabilities	• Beliefs • Perceived competence	• **Belief in being already fit and healthy** ○ Not needing to make major lifestyle changes ○ Not requiring a programme ○ Unlikely to influence my outcomes ○ A digital programme would not motivate me to make lifestyle changes
		• **Belief in being already knowledgeable** ○ Fully understanding why and what to do ○ Being able to answer questions myself

	• Beliefs • Perceived competence • Perceived behavioural control	• **Working within my limits and doing all I can within reason** ○ Knowing and accepting my limits and taking care ○ Finding a way to do things within my limits ○ Deferring some changes until after surgery
	• Self-efficacy • Perceived competence • Perceived behavioural control • Empowerment	• **Staying in control** ○ Keeping a sense of control and autonomy is motivating ○ The need for high self-motivation to make change. ○ Being able to use the programme how I would like not how I am told
Beliefs about capabilities and social/professional role and identify	• Beliefs • Perceived competence • Perceived behavioural control • Identity	• **Routine and habits as a barrier and facilitator** ○ I Need to be in a routine to make lifestyle changes ○ Habit formation makes change less challenging for me ○ I find routine can be hard to break it would be 'difficult to change habits of a lifetime'
		• **Recording progress as both a barrier and facilitator** ○ I am someone who likes to record of goals achievements and progress

		○ I would find it Time consuming and laborious to record data into a digital plan or log
		• **Appeal of a digital programme as both a barrier and facilitator** ○ I am someone who finds digital technology appealing and am comfortable using them ○ I would not be enthusiastic about a digital programme and would prefer paper
Beliefs about consequences	• Beliefs • Outcomes • Expectancies	• **A Digital programme is a 'last resort', and it cannot substitute human contact** ○ Difficult to build a trusting relationship like you can with HCPs face to face. ○ Supporting psychological wellbeing is difficult without someone to talk to Overlap with Opportunity- Social influences- Social support
		• **A Digital programme is useful but not essential** ○ I could take it or leave it ○ This would be in an addition to the support and resources I already have

		• **Only worthwhile if it will benefit me** ○ I would need to be convinced it will help me through surgery ○ It would need to be tailored to my situation ○ The information must be of good quality and of value to me
		• **A digital programme would be beneficial** ○ It would have alleviated stress, helped me, motivated me. ○ You could access up to date information more easily
	• Beliefs • Consequences anticipated	• **Prehabilitation is required for rehabilitation and a good recovery**
		• **Consequences of not undertaking prehabilitation** ○ Messaging on consequences of not making lifestyle changes before surgery is motivating ○ Knowing ultimate consequences are very serious and wishing to avoid them ○ Needing to know the negative consequences of not making changes ○ HCPs are instrumental in communicating this

		○ Feeling more vulnerable to those consequences as an older person Overlap with Opportunity- Social influences- Social support
Goals	• Goal priority • Goal/target setting	• **Undertaking prehabilitation for my condition** ○ Making Lifestyle changes for managing cancer rather than for surgery ○ Less concerned about surviving surgery than surviving/beating cancer ○ To be as healthy as possible to address the cancer
		• **Undertaking Prehabilitation for my rehabilitation activity and recovery**
		• **Undertaking prehabilitation to reclaim control of life after surgery and resume normal activities after surgery**
		• **Undertaking Prehabilitation to be ready for surgery** ○ To be Ready to survive surgery ○ To meet requirements to be able to have surgery

		• **Setting achievable objectives and goals** ○ Setting achievable targets will help motivation ○ Small progressive objectives ○ For this programme to work for patients, it needs to be small, incremental, achievable objectives to meet capabilities
Automatic Motivation		
Reinforcement	• Incentives • Reinforcement	• **Needing recognition from others for achieving lifestyle goals** Overlap with Opportunity- Social influences- Social pressure
		• **Needing to see progression towards goals** ○ Being able to record goals and objectives ○ Seeing progress as a source of motivation ○ Achieving those goals as an incentive to engage in other efforts Overlap with Capability-behavioural regulation–planning
		• **'Sensitive' prompting** ○ The prompt takes your mood into account

		○ Appropriate messages that are motivational and sensitive – 'gentle reminders' ○ It's okay messages ○ Not being pressured if it's a bad day
		• **Prompt functions simulating social support** ○ Models the encouragement you might receive from others observing your progress
		• **Prompt functions to return you to the programme** ○ Reminders and sources of motivation, encouragement, and enthusiasm Overlap with Capability-Behavioural regulation
Emotion	• Anxiety • Stress • Fear • Positive/negative affect • Burnout	• **Anxiety about physical activity and exercise** ○ Acknowledging difficult relationships with physical activity ○ Simply disliking exercise ○ Worried about the safety of exercise and activity in the context of conditions and cancer ○ Worried about not doing enough or sufficient to yield benefit

		• **Anxiety and stress in the preoperative period** ○ Waiting for surgery is mentally/emotionally draining ○ Other treatments (e.g., chemoradiotherapy) compound this. ○ Stress is pervasive throughout prehab and preparing for surgery ○ Surgery itself is frightening
	• Stress • Positive/negative affect	• **Digital programme as an addition to social support** ○ A Mental wellbeing function would be valuable ○ A programme like this would have alleviated stress
		• **The need for emotional support** ○ The benefit of mental wellbeing support techniques to build self-esteem and cope with the uncertainty before surgery ○ The need to prepare and inform people about what's to come following surgery and allow 'mental adjustment'

The themes identified in table 3.11 were linked to appropriate intervention functions based on their related COM-B construct. Candidate behaviour change techniques were then identified by cross-linking from those intervention functions and the associated TDF Domains. Linking to BCTs is presented in table 3.12.

Table 3.12. Linking of patient TDF thematic analysis to interventions functions and BCTs

COM-B construct		Theme	TDF Domain	BCW Intervention functions	Behaviour change techniques (BCTs)
Capability	Physical capability	• Physical limitations (Fatigue and exhaustion)	Skills	• Enablement • Training • Persuasion	8.2 Behaviour substitution 8.7 Graded Tasks 15.1. Verbal persuasion about capability
		• Physical limitations (inability to perform some exercises)		• Enablement • Training • Persuasion	8.2 Behaviour substitution 8.7 Graded Tasks 15.1. Verbal persuasion about capability
		• Limitation by information technology skills		• Training	4.1 Instruction on how to perform behaviour

	Psychological capability	• Desire to learn more about other behaviours relating to prehabilitation (beyond exercise and nutrition)	Knowledge	• Education • Enablement	5.1 Information about health consequences 11.1 Pharmacological support
		• Valuing information from a 'credible source'		• Persuasion	9.1 Credible source
		• Wanting to know 'why' making changes are important before surgery		• Education	5.1 Information about health consequences
		• Wanting to know what will help rehabilitation after a specific procedure		• Education • Training	4.1 Instruction on how to perform behaviour 5.1 Information about health consequences
		• Needing information on what to expect during the recovery period to help planning and develop a feeling of self-control		• Education	5.1 Information about health consequences 5.6 Information about emotional consequences
		• Needing information and lifestyle advice specific to cancer and cancer treatment (in addition to the surgical procedure)		• Education • Training	4.1 Instruction on how to perform behaviour

					5.1 Information about health consequences
		• Needing information on how to make lifestyle changes using a programme		• Education • Training	4.1 Instruction on how to perform behaviour 6.1 Demonstration of the behaviour
		• Difficulty processing information and feeling overwhelmed	Memory, attention, and decision-making processes	• Enablement • Persuasion • Training	7.1 Prompts/cues 15.1. Verbal persuasion about capability
		• Self-monitoring of progress would be enhanced by joint monitoring with supporting healthcare professionals	Behavioural regulation	• Enablement • Modelling	3.2 Social support (practical) 7.1 Prompts/cues
		• Self-monitoring would be enhanced by 'digital' prompts (e.g., text messages, emails, notifications)		• Incentivisation • Enablement	2.3 Self-monitoring of behaviour 7.1 Prompts/cues
		• Self-monitoring would be enhanced by forming a plan with linked goals		• Incentivisation • Enablement	1.4 Action planning 2.3 Self-monitoring of behaviour

		• Self-monitoring would be enhanced by the ability to log and record progress		• Incentivisation • Enablement	2.3 Self-monitoring of behaviour 2.4 Self-monitoring of outcomes of behaviour
Opportunity	Social opportunity	• Need for someone to promote, explain, and demonstrate the programme ('promoter role')	Social influences	• Enablement • Persuasion	4.1 Instruction on how to perform the behaviour 6.1 Demonstration of the behaviour
		• Needing to be supported rather than pressured by HCPs		• Enablement • Persuasion	3.3 Social support (unspecified)
		• Needing a clear HCP point of contact (the 'prompter/overseer role')		• Enablement • Persuasion	2.2 Feedback on behaviour 3.1 Social support (unspecified) 4.1 Instruction on how to perform the behaviour 6.1 Demonstration of the behaviour 7.1 Prompts/cues
		• Not wanting to engage with other patients (not wanting peer support)		• Enablement • Restriction	7.5 Remove aversive stimulus
		• Wanting to engage with other patients (wanting peer support)		• Enablement • Modelling	3.1 Social support (unspecified) 6.2 Social comparison

		• Obtaining experiential knowledge from others		• Enablement • Modelling	3.1 Social support (unspecified) 6.2 Social comparison
		• Needing support for my supporters and advice for family, partner, friends, and carers on how to help me		• Enablement	3.1 Social support (unspecified) 6.2 Social comparison
		• Needing support from my supporters		• Enablement	3.1 Social support (unspecified)
		• Importance and need for social support while using programme		• Enablement	3.1 Social support (unspecified)
		• The influence of HCPs		• Enablement	9.1 Credible source
		• The influence of Specialist nurses		• Enablement	9.1 Credible source
		• The influence of the Surgeon as a key promoter of a programme		• Enablement	9.1 Credible source
	Physical opportunity	• Not having enough time before surgery to make changes	Environmental context and resources	• Environmental restructuring • Enablement	12.1 Restructuring the physical environment

		• Not enough time in the day to make changes		• Environmental restructuring • Enablement	12.1 Restructuring the physical environment
		• HCPs appear not to have enough time to offer support and advice		• Environmental restructuring • Enablement	12.1 Restructuring the physical environment
		• Finding ways to find enough time in the day		• Environmental restructuring • Enablement	12.1 Restructuring the physical environment
		• Finding ways to find enough time before surgery		• Environmental restructuring • Enablement	12.1 Restructuring the physical environment
		• The timing of programme promotion and offer		• Environmental restructuring • Enablement	12.1 Restructuring the physical environment

		• Supporting access to the programme with appropriate equipment and devices		• Environmental restructuring • Enablement	12.5 Adding objects to the environment
		• Other life events and priorities as a barrier to change		• Enablement • Persuasion	15.1 Verbal persuasion about capability
		• The programme needs to be tailored to the patient and provide choice to promote autonomy		• Enablement	1.1 Goal setting 1.4 Action planning
		• Programme format and content must be simple, understandable, and easy/intuitive to use		• Enablement • Persuasion • Environmental restructuring	6.1 Demonstration of the behaviour 12.5 Adding objects to the environment
		• Multimedia mode of information delivery		• Enablement • Persuasion • Environmental restructuring	6.1 Demonstration of the behaviour 12.5 Adding objects to the environment
		• Wider role for the programme		• Enablement • Persuasion	6.1 Demonstration of the behaviour 12.5 Adding objects to the environment

				• Environmental restructuring	
Motivation	Reflective motivation	• Belief in being already fit and healthy	Beliefs about capabilities	• Persuasion • Enablement • Education	5.1 Information about health consequences 15.1 Verbal persuasion about capability
		• Belief in being already knowledgeable		• Persuasion • Enablement • Education	5.1 Information about health consequences 15.1 Verbal persuasion about capability
		• Working within my limits and doing all I can within reason		• Persuasion • Enablement • Education	5.1 Information about health consequences 15.1 Verbal persuasion about capability
		• Staying in control		• Persuasion • Enablement • Education	5.6 Information about emotional consequences 9.2 Pros and cons 13.2 Framing/reframing
		• Routine and habits as a barrier and facilitator	Beliefs about capabilities Social/professional role and identity	• Enablement • Persuasion	1.4 Action planning 2.3 Self-monitoring of behaviour 15.1 Verbal persuasion about capability

		• Recording progress as both a barrier and facilitator		• Enablement • Persuasion	1.4 Action planning 2.3 Self-monitoring of behaviour 15.1 Verbal persuasion about capability
		• Appeal of a digital programme as both a barrier and facilitator		• Enablement • Persuasion	12.5 Adding objects to the environment 15.1 Verbal persuasion about capability
		• A Digital programme is a ‘last resort’, and it cannot substitute human contact	Beliefs about consequences	• Education • Persuasion	13.2 Framing/reframing 15.1 Verbal persuasion about capability
		• A Digital programme is useful but not essential		• Education • Persuasion	13.2 Framing/reframing 15.1 Verbal persuasion about capability
		• Only worthwhile if it will benefit me		• Education • Persuasion	13.2 Framing/reframing 15.1 Verbal persuasion about capability
		• A digital programme would be beneficial		• Enablement	12.5 Adding objects to the environment

		• Prehabilitation is required for rehabilitation and a good recovery		• Enablement	5.1 Information about health consequences 5.2 Salience of consequences
		• Consequences of not undertaking prehabilitation		• Education • Persuasion	5.1 Information about health consequences 5.2 Salience of consequences
		• Undertaking prehabilitation for my condition	Goals	• Incentivisation • Modelling	1.1 Goal setting (behaviour) 1.4 Action planning
		• Undertaking Prehabilitation for my rehabilitation activity and recovery		• Incentivisation • Modelling	1.2 Goal setting (behaviour) 1.4 Action planning
		• Undertaking prehabilitation to reclaim control of life after surgery and resume normal activities after surgery		• Incentivisation • Modelling	1.3 Goal setting (behaviour) 1.4 Action planning
		• Undertaking Prehabilitation to be ready for surgery		• Incentivisation • Modelling	1.4 Goal setting (behaviour) 1.4 Action planning
		• Setting achievable objectives and goals		• Incentivisation • Modelling	1.1 Goal setting (behaviour) 8.7 Graded tasks

	Automatic motivation	• Needing recognition from others for achieving lifestyle goals	Reinforcement	• Incentivisation • Modelling • Enablement • Incentivisation • Modelling • Enablement	10.4 Social reward
		• Needing to see progression towards goals		• Incentivisation • Modelling • Enablement	10.10 Reward (outcome)
		• 'Sensitive' prompting		• Incentivisation • Modelling • Enablement	7.1 Prompts/cues 15.1 Verbal persuasion about capability
		• Prompt functions simulating social support		• Incentivisation • Modelling • Enablement	3.1 Social support (unspecified) 7.1 Prompts/cues 10.10 Reward (outcome)
		• Prompt functions to return you to the programme		• Incentivisation • Modelling • Enablement	7.1 Prompts/cues

		• Anxiety about physical activity and exercise	Emotion	• Persuasion • Enablement	3.1 Social support (unspecified) 15.1 Verbal persuasion about capability
		• Anxiety and stress in the preoperative period		• Persuasion • Enablement	3.1 Social support (unspecified) 15.1 Verbal persuasion about capability
		• Digital programme as an addition to social support		• Persuasion • Enablement	3.3 Social support (emotional) 12.5 Adding objects to the environment
		• The need for emotional support		• Persuasion • Enablement	3.3 Social support (emotional)

3.3.3.2. Healthcare professional participants

The thematic analysis of HCP responses to self-evaluation questionnaires and accompanying semi-structured interviews relating to the promotion, support and facilitation of surgical patients utilising a digital prehabilitation programme are presented in table 3.13 As the behavioural needs illustrated relate to the HCP training and development intervention, rather than the digital programme itself, intervention functions were not specified and BCTs were linked directly from the relevant TDF domains to inform the accompanying training resource.

From a capability standpoint, HCPs expressed confidence in their baseline skills and knowledge relevant to delivery of a future programme. Respondents highlighted the need for a clear and in depth understanding of the programme content and features and the need to build their confidence in the benefit (evidence-base) for the programme for their patients. A specific capability requirement emerged around communication skills and strategies for dealing with more reticent patients and building resilience for these encounters alongside a substantial clinical workload.

Time concerns were a key theme in terms of opportunity. Respondents emphasised that the programme would need to become a recognised, supported, and resourced element of their work to succeed. Similarly, a ‘whole team’ approach was felt necessary for patients to receive consistent messaging and a coordinated experience preoperatively. Whilst having all HCP disciplines ‘behind’ the programme and the buy in of service leaders and managers seemed critical, respondents suggested that certain clinical roles would align well with programme roles. The need for a ‘promoter’ role to present the programme to patients initially was made clear, alongside a prompter role to support patients to use and continue engaging with the programme by providing regular contact with patients both remotely and in-clinic, where possible and manage issues once established. Finally, a need for an ‘overseer’ role, perhaps encompassing several surgical pathways, was identified, acting both as a source of advice for individual pathway promoters and prompters, managing the programmes data burden and providing remote technical support to patients using the programme.

From a motivation perspective, respondents made it clear that the intervention objectives and the intervention roles, they would be required to perform, would need to integrate with and complement their current roles rather than conflict to be successfully implemented. Central to HCPs motivation to facilitate the intervention hinged on their belief in the success or consequences of the programme. These beliefs about consequences included patient suitability (i.e., some patients being unsuitable for the intervention, such as having a brief surgery waiting time), patient receptivity (i.e., some patients being disinterested or too distracted to commit to a lifestyle programme, especially cancer patients) and patient benefit (i.e., whether the programme is able to make a markable difference to patients lifestyle).If these beliefs could be addressed and a clear benefit to patients could be achieved HCPs expressed motivation to support a programme being made available.

Table 3.13. Thematic analysis of HCP COM-B self-evaluation questionnaires and semi-structured interviews with linking of TDF domains to behaviour change techniques.

TDF Domain	TDF Construct	Themes	BCTs
Capability			
Physical capability			
Skills	• Skills development • Interpersonal skills	• **The need for Interpersonal skills training** ○ communication and negotiation skills to help persuade, motivate, and encourage resistant patients ○ Training for telephone and face-to-face interactions ○ Being able to understand patients' barriers and context	4.1 Instruction on how to perform behaviour 6.1 Demonstration of the behaviour
Psychological capability			
Knowledge	• Knowledge (condition/ scientific rationale)	• **The need for a clear understanding of what the programme is.** ○ The purpose, goals, aims and components on offer to patients, ○ The evidence-based rationale for the programme and how it will benefit patients (including health behaviour theory) ○ How does the programme progress? (Goals, objectives, outcomes, testimonials, success stories)	2.7 Feedback on outcome(s) of behaviour 5.1 Information about health consequences 5.3 Information about social and environmental consequences 9.1 Credible source

	• Procedural knowledge	• **The need to understand how the programme works** ○ Eligibility criteria, programme functions, patient access and usability functions, patient expectations. • **The need to understand how the programme will lead to patient benefit.** • **How to use the programme from the HCP perspective.** • **How to deliver the programme and to perform HCP roles?** ○ Definitions of roles: Promoter/ Supporter/ facilitator ○ How patients are followed-up ○ Support resources available for HCPs, ○ How patient questions and queries are answered • **Knowing what to say' to patients about the programme?** ○ Both scripted responses and loose scripts to use as a framework	4.1 Instruction on how to perform behaviour 5.1 Information about health consequences 5.3 Information about social and 6.1 Demonstration of the behaviour environmental consequences 9.1 Credible source
Memory, attention, and decision-making processes	• Attention • Decision-making • Cognitive overload/tiredness	○ **The need for mental capacity training** ○ Managing fatigue, exhaustion, frustration and de-motivation from workload, burnout and encountering resistant patients, instilling resilience,	4.1 Instruction on how to perform behaviour 6.1 Demonstration of the behaviour

		○ Recognising when physically and mental fatigue ○ Acquiring coping mechanisms to maintain focus and change mindset.	
Behavioural regulation	• Action planning	○ **Planning and prompting** ○ Making programme promotion a habit	1.4 Action planning 7.1 Prompts and cues
Opportunity			
Social opportunity			
Social influences	• Social support • Group norms	• **The importance of a 'team approach' ('strength in numbers')** ○ All perioperative HCPs must be supporting this programme. ○ A coordinated approach across surgical teams and speciality pathways ○ Consistent messaging to the patients across their preoperative journey • **The need for a designated programme Overseer Team** ○ Supporting individual specialty teams, source of advice and backup ○ Collecting and managing programme data • **The need for designated iPREPWELL 'champions' in specialty surgical teams** ○ Necessitates dedicated time and funding (resource)	3.1 Social support (unspecified)

		• **Drawing upon and access to the skills and expertise of other HCPs and teams to support patients** o Ability to signpost patients to a 'specialist' within the wider programme team e.g., a tricky nutrition question to a dietician.	
	• Group norms • Intergroup conflict	• **The variation in consistency and engagement between HCPs as a barrier** o Inconsistency across the team and between teams in the perioperative pathway e.g., surgical specialty team and preassessment services. o Undermined If the surgeon is not 'onboard'.	15.1 Verbal persuasion about capability [
	• Social support • Power	**The perceived Influence and proposed roles of other professionals and colleagues:** o **Surgeons** key promoters, perceived as most influential on patients in terms of offering messages on health consequences, perceived as leaders of this effort. o **Specialist Nurses** key prompters and potential facilitators following surgical promotion. able to capitalise on their on-going therapeutic relationship across the preoperative journey with patients from listing onwards	Nil specific BCTs Themes rationalise why certain HCP roles may align well with programme roles e.g., consultant surgeons in the promoter role

		○ **Anaesthetists** key advocates of 'fitness/readiness for surgery' in a prompter position, however 1st contact is felt to be late after listing. ○ **Preassessment and HCAs** also in a potential prompter position but 1st contact is felt to be late after listing. ○ **Cancer Care Coordinators and HCAs** potential for enhanced prompter roles ○ **AHPs** (physiotherapists, dieticians, occupational therapists, counsellors – prompters and sources of advice for programme team ○ **Existing prehabilitation service staff.** Natural overseers and prompters/facilitators. able to coordinate programme and manage data across multiple pathways ○ **Primary Care staff and GPs** potentially powerful promoter and prompter role	

Physical opportunity			

Environmental context and resources	• Barriers
	• Environmental stressors
	• Organisational culture/climate
	• Resources/material resources
		• **Time limitations**
		  ○ Limited time in clinical encounters
		  ○ Limited preoperative time (for patients)
		  ○ Compounded by current perioperative backlog and workloads
		• **Disconnected preoperative systems and processes leading to a varied and uncoordinated approach across and between teams**
		• **Not enough staff, space, and resources to support programme above current workloads**
			3.1 Social support (unspecified)
			4.1 Instruction on how to perform behaviour
			12.5 Adding objects to the environment
			15.1 Verbal persuasion about capability

	• Facilitators
	• Environmental stressors
	• Organisational culture/climate
	• Resources/material resources
		• **Dedicating time and a 'making time available' attitude**
		  ○ Making time for a brief, defined intervention.
		  ○ Challenging a culture of 'not enough time'.
		• **Connecting systems and processes**
		  ○ Embedding and tailoring use of the programme to surgical pathways
		  ○ Making it a habitual component of preoperative care and team culture
		• **Senior management approval and endorsement**
		  ○ Justifying allocation of time, funding, and resource
		  ○ Formally designating programme roles within a service
		  ○ Acquiring material and space to facilitate programme delivery (leaflets, IT access, posters in clinics)	

	Facilitators	• **Programme training design and delivery**
		  ○ Should be concise, simple, fun, and engaging
		  ○ Incorporate a combination of face-to-face training and written information (e.g., a reference guide or protocol)
		
		• **Promoter role timing and format**
		  ○ Must be brief, simple, easy, and direct, early introduction to programme
		  ○ Not undertaken at time/appointment of cancer diagnosis
		  ○ Initiation in primary care would be valuable
		
		• **Prompter role timing and format**
		  ○ must be simple and brief, not 'time consuming' 5-10 minutes intervention to deliver within routine contacts/consultations
		
		• **Programme format must be simple and easy to use (for patients and HCPs)**
		
		• **Mode of patient interaction: Preference for face-to-face delivery of care over telephone**
			Nil specific BCTs
			
			Themes here inform programme resources, training, and delivery

Motivation			
Reflective motivation			
Social/professional role and identity	• Professional role • Professional identity	• **Role compatibility: Programme and intervention roles align with and must remain compatible with 'normal' HCP roles** ○ **Surgeon** (promoter) ○ **Nurse Specialist** (promoter + prompter) ○ **Preassessment** (prompter) ○ **Anaesthetist** (prompter) ○ **AHPS** (prompter) • **Professional approaches** and principles ○ Prehab is within my role/duty versus not within my role/duty ○ Role conflict and the need for a programme role not to detract from other responsibilities ○ Respecting patient autonomy and responsibility/accountability for health regarding their decisions to engage and adhere ○ Retaining compassion, non-judgemental and gentle persuasion of patients	15.1 Verbal persuasion about capability

Beliefs about capabilities	• Professional confidence • Perceived competence	• **Expressed competence in supporting patients in their lifestyle choices** and not requiring prompting to perform intervention role. • **Expressed competence in communicating with and negotiating with patients** • **Expressed competence in professional role** • **Expressed competence in physical and mental capabilities for role** (managing fatigue, burnout, maintaining resilience, attention, and concentration)	15.1 Verbal persuasion about capability
	• Self confidence • Professional confidence	• **Concerns about not role modelling the lifestyle behaviours asked of patients** • **Training needs: open to training for programme delivery** • **Concerns about/needing to appear competent to patients**	4.1 Instruction on how to perform the behaviour 15.1 Verbal persuasion about capability
Beliefs about consequences	• Beliefs • Outcomes • Expectancies	• **Considering patient suitability** ○ Awareness of the patients' individual barriers, context, and circumstances • **Considering patient receptivity**	5.1 Information about health consequences 5.3 Information about social and environmental consequences 9.1 Credible source

		○ Perception of surgery as their last resort/only option ○ The teachable moment ○ Influence of HCPs over patients and type of messaging e.g., emphasising severity of consequences versus a gentler approach • **Belief in the benefit for patients** or needing to be convinced) the programme will benefit patients and the evidence base. • **Expectations of the programme** ○ Efficiently run programme ○ Respects patient autonomy ○ Focussed on health and wellbeing	
Intentions	• Stability of intentions	• **Willingness and wanting to support the programme and prehabilitation overall** • **Approval of and belief in overall programme aim (fitter, healthier patients)** • **Conditions of engagement in programme delivery** ○ Role compatibility ○ Efficiently run programme ○ Programme achieves its aims	2.7 Feedback on outcome(s) of behaviour

Automatic motivation			
Emotion	Stress Burnout	• Feeling frustrated and overwhelmed/tired (burnout) • Feeling frustrated and de-motivated (in relation to resistant patients) • Needing coping mechanisms (using supervision)	4.1 Instruction on how to perform the behaviour

3.3.4. Co-design workshops: Specification of BCTs for target health behaviours and modes of delivery

Following the behavioural analysis (BCW stage 1), identification of intervention functions (BCW stage 2) and the initially identified candidate behaviour change techniques for the programme overall (BCW stage 3) the co-design workshop series progressed BCW stage 3 further, focussing on key emerging implementation questions from the behavioural needs analysis to identify how the programme should meet those needs. The candidate list of BCTs were refined and modes of delivery determined for implementation in the programme prototype. This was undertaken for each of the 6 proposed programme target health behaviours individually.

Workshops 1-3 were structured around three broad overarching themes based on the COM-B/TDF analysis, the need for clear provision of information to patients, the need for goal setting and monitoring of progress and the incorporation of prompting and social support functions:

- **Workshop 1:** How the programme should provide information to patients about each target health behaviours

- **Workshop 2:** How the programme should support goal setting, planning, monitoring and tracking of progress for each target health behaviour

- **Workshop 3:** How the programme should prompt participating patients and how social support functions should be implemented.

Workshops 1 and 2 utilised an exhibition format, stations for each target health behaviours organised with relevant examples and concepts from other digital health behaviour change and perioperative programmes. Participants were able to circulate between the behaviour stations and encouraged by facilitators to comment on what they liked, disliked and why. This information was captured with note taking by facilitators and captured for each health behaviour in a subsequent discussion session. Workshop 2 (goal setting, monitoring and progress tracking) introduced

example wearable devices to the stations to prompt discussion about how these might be integrated. Workshop 3 had an adjusted format with a more traditional focus group to discuss the programmes prompting and social support features with questions put to the group by facilitators.

The findings of workshop 1-3 were integrated with the prehabilitation evidence-base and the input of the intervention design team to iterate the programme design. Each remaining workshop sessions were focussed on usability testing of the prototype in readiness for part 2 feasibility testing. The findings across the workshop series for each target health behaviour are presented below with the resulting programme design is presented in chapter 5.

Table 3.14. presents the refined set of BCTs and preferred modes of delivery for each programme target health behaviour that informed design of the programme components. While prompting was considered specifically in terms of individual behaviours, findings from workshop 3 relating to social support were considered in terms of the programme as whole rather than specific to each behaviour.

Findings from workshop 1 were consistent across the behaviours. Participants highlighted the need for clear presentation of the relevance of each health risk behaviour to their surgery and the benefits engaging with support could provide. This was accompanied by a need to specify how change could be achieved. The degree of detail varied between behaviours, physical activity and exercise was felt to require more specific and detailed instruction compared to other behaviours such as sleep. Consistently, participants advised an audio-visual format, presented by a healthcare professional with sparing use of written material, although accompanying written summaries of audio-visual content were deemed useful.

In workshop 2, participants conveyed that goal setting should be a collaborative process between the patient, programme and their HCP team. For some behaviours such as alcohol reduction and smoking a ‘universal goal’ (e.g., limiting intake and cessation) was deemed applicable to all patients. However for activity and exercise, it was felt that the programme should initially suggest goals to patients that they could then modify with their HCP. Planning functions followed a similar pattern

whereby the programme should suggest an initial structure that the patient would be able to adapt. Self-monitoring tools were felt to be useful in all cases. Where possible data entry requirements should be minimal and use simple mechanics to help participants track each of their behaviours. A weekly report was felt to be useful across the behaviours, allowing patients to self-monitor their progress over time and supporting HCPs performing 'prompter' roles to engage in focused conversations. For sleep and psychological wellbeing, a journaling tool was recommended as likely to be more useful in understanding changes than quantitative methods.

In workshop 3. There was also consistency in the use of positive reinforcement by both automatic programme generated, and HCP delivered prompts to encourage engagement and celebrate progress. Equally clear was the need for 'it's okay' messaging to extend support when participants encountered difficulties with any element of the programme acknowledging the challenging time they are facing and to restore motivation to continue. For sleep and psychological wellbeing, prompts may be less useful, and it was suggested the programme should take a more neutral response to inputted data, avoiding an impression of judgement which may exacerbate problems in these areas. Workshop 3 participants also emphasised the need for scheduled (fortnightly) HCP contact to review progress and act as a source of appropriate prompting and reinforcement of progress made. This workshop also identified a need for a more 'on demand' route to send queries to the facilitating team of staff within the programme. Finally, participants emphasised the value of peer-support elements, including the ability for patients to share stories with others and gain motivation from the success of others in using the programme.

Table 3.14. Co-design workshop findings by target health behaviour. Social support features are discussed in terms of the programme as whole

Increasing physical activity and undertaking structured exercise training		
Workshop 1: Provision of information to programme users		
Information needed	Mode of delivery	BCTs
• Why is it important to be physically active and to improve my fitness before surgery? • What are the specific benefits and reasons for me and my surgery? • How does becoming more active before surgery and undertaking exercise training relate to my recovery?	• Audio-visual formats as far as possible (brief engaging videos and images/figures) • Limited and focussed text, short, sharp statements (no more than 3-4 lines) • An accompanying booklet/leaflet to (e.g., a downloadable PDF online)	4.2 Information about antecedents 5.1. Information about health consequences 5.2 Salience of consequences 5.6 Information about emotional consequences 9.2 Pros and cons

• How can I increase my physical activity levels and engage in exercise training before surgery?
• How do I get started?
  ○ Starting small and aiming for incremental improvements
  ○ How much, how often and for how long?
• Which activities and exercises should I do?
	• Audio-visual formats as far as possible (videos and images/figures)
	• Video demonstrations of specific exercises with voiceover guidance and instruction
	• Limited and focussed text, short, sharp statements (no more than 3-4 lines)
	• An accompanying booklet/leaflet to (e.g., a downloadable PDF online)
		4.1 Instruction on how to perform behaviour
		6.1 Demonstration of the behaviour
		8.7 Graded tasks

○ Emphasis on keeping moving before surgery ○ 'Doing what you can' based on abilities ○ Choosing activities and exercises that are 'body aware' for my limitations ○ A range of options available for different abilities • How will I/should I progress? • Which activities and exercises might be particularly helpful for my specific surgery e.g., upper body strength training for upper GI surgery? • How do physical activity and exercise training relate to the other health behaviours in the programme?		

Workshop 2: Goals, planning and monitoring

Function	**Mode of delivery**	**BCTs**
• What kind of goals should the programme use? ○ Emphasis on keeping moving for prehabilitation and rehabilitation ○ Emphasis on building and maintaining fitness for surgery	• Pre-populated goal/(s) and targets • Set by text, image, or an icon • Modifiable by the participant.	1.1 Goal setting (behaviour) 1.3 Goal setting (outcome)

○ Programme should suggest goals based on abilities with ability to modify ○ Goals should be small and achievable		
• How should programme users plan for their goals? ○ Programme should offer patients plans based on physical ability (inactive, active, moderately active, very active) ○ Programme should offer options to progress (i.e., new goals as progress is made) ○ Option to adjust and personalise the suggested plan based on physical ability with support from a HCP. ○ Option to select from a range of available physical activities and exercises.	• Pre-populated plans and progressions • A range of levels to account for varied abilities • Ability to move between levels (modifiable by the participant) • HCP oversight of progression • Set by text, image, or an icon	1.4 Action planning 1.5 Review behaviour goal(s) 1.7 Review outcome goal(s) 8.7 Graded tasks
• How should the programme monitor and record progress toward goals? ○ 'Automatic' activity and exercise data collection and input (i.e., utilising wearable device where possible) ○ Step count is an appealing metric for physical activity ○ A simple logging function would be helpful (e.g., an exercise diary)	• Tracking of step count using wearable pedometer • Logging of completed exercise sessions (exercise diary) • Presentation of progress visually toward goal/next stage of plan	2.3 Self-monitoring of behaviour 2.4 Self-monitoring of outcome(s) of behaviour 2.6 Biofeedback 12.5 Adding objects to the environment

○ Progress should be visualised where possible and related to set goals and plan		

Workshop 3: Prompting

Function	Mode of delivery	BCTs
• When should prompts be used? ○ Triggered by activity and exercise e.g., completion of a goal or plan stage or logging an exercise session. ○ Triggered by lack of participation in programme ○ Motivational prompts weekly/bi-weekly ○ Messaging should return the user to and keep focus on preparation for their surgery ○ Messaging should be celebratory/motivational for accomplishments and gentle, if struggling to engage ('it's okay' messages) but aim to restore motivation to engage. • How should prompts be delivered? ○ Email, text messaging and direct notifications from programme would be options ○ HCPs should be involved in delivery (prompter/facilitator role)	• Prompts triggered both for engagement and non-engagement with activity and exercise plan • Messaging should aim to reinforce or restore motivation to continue • A combination of 'automated' delivery by email/text/notification and HCP contact.	2.2 Feedback on behaviour 7.1 Prompts/cues 10.10 Reward (outcome) 12.5 Adding objects to the environment 13.2 Framing/reframing 15.1 Verbal persuasion about capability

Stopping smoking

Workshop 1: Provision of information to programme users

Information needed	Mode of delivery	BCTs

• What are the benefits to me of stopping smoking before surgery?
  ○ Connecting smoking to surgical outcomes
  ○ Raising awareness amongst smokers of the effects
  ○ What are the benefits of quitting for my operation and my recovery?
  ○ This must be engaging as quitting smoking is difficult
• How does smoking cessation relate to the other health behaviours in the programme?
	• Audio-visual formats as far as possible (brief engaging videos and images/figures)
	• Limited and focussed text, short, sharp statements (no more than 3-4 lines)
	• Direct linking to smoking cessation services and support
		4.2 Information about antecedents
		5.1. Information about health consequences
		5.2 Salience of consequences
		9.2 Pros and cons

• How can I reduce and quit smoking before surgery?
  ○ Provide strategies and top tips
  ○ Clear identification of what progress looks like
  ○ Signposting and how to access outside support e.g., smoking cessation services
		4.1 Instruction on how to perform behaviour

Workshop 2: Goals, planning and monitoring

Function	Mode of delivery	BCTs

• What kind of goals should the programme use?
  ○ Smoking cessation in line with national guidelines
  ○ Useful to set ancillary goals relating to the main goal benefits e.g., money saving goal)
	• Pre-set main goal of preoperative cessation
	• Option to set ancillary goals
		1.1 Goal setting (behaviour)
		1.3 Goal setting (outcome)

• How should users plan for their goals around stopping smoking
  ○ Planning should focus on implementation of strategies described in informational content
  ○ Engagement with a smoking cessation service should be encouraged
	• Planning by selection of cessation strategies to implement
	• Incorporating smoking cessation service
		1.4 Action planning
		1.5 Review behaviour goal(s)
		1.7 Review outcome goal(s)

• How should the programme monitor and record progress?
  ○ Creating a sense of progress is key
  ○ Allow patients to acknowledge if they are struggling and providing reassurance (thinking about how you will feel if it is difficult).
	• Simple tracking mechanism e.g., tapping a cigarette icon
	• Clear reporting of progress toward cessation
	• Journaling tool to reflect on efforts toward cessation
		2.3 Self-monitoring of behaviour
		2.4 Self-monitoring of outcome(s) of behaviour
		12.5 Adding objects to the environment

○ Tracking smoking in real-time e.g., number of cigarettes. Simple mechanisms e.g., tapping an icon ○ A journaling tool might support identification of facilitators and barriers		

Workshop 3: Prompting

Function	Mode of delivery	BCTs
• When should prompts be used? ○ Regular positive messaging in response to progress supported by regular overview of progress made ○ Motivational messages weekly/bi-weekly, acknowledging this is difficult and that it will get easier ○ 'It's okay' messaging for difficult days • How should prompts be delivered? ○ Automatic delivery by programme (text messaging, emails, and notifications all acceptable) with reinforcement during HCP check-ins	• Prompts triggered frequently with any progress • Weekly/Biweekly motivational messaging • Regular progress report • 'It's okay' messaging if progress is challenging • A combination of 'automated' delivery by email/text/notification and HCP contact.	2.2 Feedback on behaviour 7.1 Prompts/cues 10.10 Reward (outcome) 13.2 Framing/reframing 15.1 Verbal persuasion about capability

Reducing alcohol intake to within 14 Units per week

Workshop 1: Provision of information to programme users

Information needed	Mode of delivery	BCTs

• Why is reducing drinking relevant to my surgery?
  ○ Connecting consuming alcohol above recommended levels with surgical outcomes
  ○ Raising awareness of the surgical risks
  ○ What are the benefits of controlling intake before surgery for recovery?
• How does alcohol reduction relate to the other health behaviours in the programme?
	• Audio-visual formats as far as possible (brief engaging videos and images/figures)
	• Limited and focussed text, short, sharp statements (no more than 3-4 lines)
		4.2 Information about antecedents
		5.1. Information about health consequences
		5.2 Salience of consequences
		9.2 Pros and cons

• How do I reduce my alcohol intake before surgery?
  ○ Understanding intake (how much is in standard drinks?)
  ○ Strategies to reduce intake ‘swaps and saves’
		4.1 Instruction on how to perform behaviour

Workshop 2: Goals, planning and monitoring

Function	Mode of delivery	BCTs
• What kind of goals should the programme use? ○ Reducing intake to within 14 units per week (national and perioperative guidance)	• Pre-set goal of reducing intake to within 14 units	1.1 Goal setting (behaviour) 1.3 Goal setting (outcome)

• How should users plan for their goals around reducing alcohol intake
  ○ Unit calculation mechanism needed to help users understand their current intake.
  ○ A planning function that allows users to visualise their intake over a week
  ○ Plan structured around a graded reduction
  ○ Acknowledgement and empathy that some users will find this difficult.
	• Unit calculator to determine intake
	• Visual weekly intake planner
	• Graded intake reduction
		1.4 Action planning
		8.7 Graded tasks

• How should the programme monitor and record progress?
  ○ Record intake in real time not retrospectively
  ○ Regular visualisation of progress against ‘baseline’ intake at outset.
	• Real time tracking using simple mechanism to calculate intake in units
	• Regular visual representation of progress
		2.3 Self-monitoring of behaviour
		2.4 Self-monitoring of outcome(s) of behaviour
		12.5 Adding objects to the environment

○ Needs to be simple mechanism e.g., dragging different types of drink into a box or tapping icons to calculate units day-to-day ○		

Workshop 3: Prompting

Function	Mode of delivery	BCTs
• When should prompts be used? ○ Regular positive messaging in response to progress supported by regular overview of progress made ○ 'It's okay' messaging for difficult days • How should prompts be delivered? ○ Automatic delivery by programme (text messaging, emails, and notifications all acceptable) with reinforcement during HCP check-ins ○	• Prompts triggered frequently with any progress • Weekly/Biweekly motivational messaging • 'It's okay' messaging if progress is challenging • A combination of 'automated' delivery by email/text/notification and HCP contact.	2.2 Feedback on behaviour 7.1 Prompts/cues 10.10 Reward (outcome) 13.2 Framing/reframing 15.1 Verbal persuasion about capability

Eating a healthy diet

Workshop 1: Provision of information to programme users

Information needed	Mode of delivery	BCTs
• Why does good nutrition matter before surgery?	• Video or audio content of a clinician explaining the reasons why nutrition matters	5.1. Information about health consequences 5.2 Salience of consequences

○ How will eating a better diet and better nutrition help my surgery and recovery? ○ How will eating a better diet and better nutrition help my condition ○ How does my weight affect my surgery? ○ How will good nutrition affect my recovery? • How does good nutrition affect the other health behaviours?	• Visual information for procedural knowledge (engaging and colourful figures)	9.1 Credible source 9.2 Pros and cons
• How can I improve my diet before my surgery? ○ What does a healthy diet before surgery look like? ○ Emphasis on healthy eating overweight management ○ How can I eat to build and retain muscle? ○ What if I am already seeing a dietician or have difficulty eating? ○ How can I deal with the symptoms of my condition and treatment that affect my ability to eat? ○ What other sources of information are available? ○ Tips for preparing healthy food when tired/busy	• Visual information for procedural knowledge (engaging, colourful images, tables, graphs) • Limited and focussed text, short, sharp statements (no more than 3-4 lines) • Top tips and bullet points • Non-clinical language	4.1 Instruction on how to perform behaviour 6.1 Demonstration of the behaviour

Workshop 2: Goals, planning and monitoring

Function	Mode of delivery	BCTs

• What kind of goals should the programme use?
  ○ Goals relating to health eating principles
  ○ Goals relating to weight management
  ○ Programme should steer this based on screening tools
  ○ Goals should complement not conflict with any dietetic programme
	• Screening led goal setting focussed on healthy eating and weight management	1.1 Goal setting (behaviour)
		1.3 Goal setting (outcome)

• How should users plan for their goals around eating more healthily
  ○ Tools for meal planning around (main meals and snacks
  ○ Pre-populated meal plans or example meals
	• Tools to help patients plan their meals and snacks according to healthy diet principles
	• Pre-populated meal plans to use as a guide
		1.4 Action planning

• How should the programme monitor and record progress?
  ○ Monitoring intake of food groups and portions
  ○ Daily recording against principles of healthy eating
  ○ A scanning feature for calorie tracking
  ○ Group participants divided over recording intake in more detail
	• A daily intake tracking tool based around adherence to healthy diet principles
	• Simple mechanic to minimise burden of data entry e.g., tapping an icon to indicate quantity consumed of different food groups
		2.3 Self-monitoring of behaviour
		2.4 Self-monitoring of outcome(s) of behaviour
		2.6 Biofeedback
		12.5 Adding objects to the environment

Workshop 3: Prompting

Function	Mode of delivery	BCTs

• When should prompts be used?
  ○ Celebrating progress and adherence to healthy eating principles
  ○ Reminders to record daily intake and ability to tailor these to principles e.g., enough protein or hydration.
  ○ Motivational messaging toward targets (weekly/bi-weekly)
  ○ 'It's okay' messaging if having difficulty with targets
• How should prompts be delivered?
  ○ Automatic delivery by programme (text messaging, emails, and notifications all acceptable) with reinforcement during HCP check-ins
	• Prompts triggered frequently by adherence to healthy eating principles
	• Weekly/Biweekly motivational messaging
	• 'It's okay' messaging if progress is challenging
	• A combination of 'automated' delivery by email/text/notification and HCP contact.
	• Weekly reports on progress
		2.2 Feedback on behaviour
		7.1 Prompts/cues
		10.10 Reward (outcome)
		12.5 Adding objects to the environment
		13.2 Framing/reframing
		15.1 Verbal persuasion about capability

Increasing sleep duration and quality

Workshop 1: Provision of information to programme users

Information needed	Mode of delivery	BCTs
• Why does sleep health matter for surgery?	• Video or audio content of a clinician explaining the reasons why sleep health matters	5.1. Information about health consequences 5.2 Salience of consequences

○ How does sleep health affect my general health? ○ Why should I pay attention to how much and how good my sleep is? • How will sleeping better help me tackle other health behaviours?		9.1. Credible source 9.2 Pros and cons
• How can I improve my sleep health before surgery? ○ Why am I not sleeping well? ○ How to fall asleep more easily? ○ How to get back to sleep on waking? ○ How to manage the effects of shift/antisocial working hours on sleep ○ How to manage the effects/symptoms of condition on sleep? ○ How to manage the effects/symptoms of surgery on sleep? ○ How to manage the effects of stress on sleep? • How to sleep well in hospital?	• Visual information for procedural knowledge (engaging, colourful images, tables, graphs) • Video or audio content of a clinician explaining	4.1 Instruction on how to perform behaviour 6.1 Demonstration of the behaviour

Workshop 2: Goals, planning and monitoring

Function	Mode of delivery	BCTs
• What kind of goals should the programme use?	• Overall goal of 'sleeping well or surgery'	1.1 Goal setting (behaviour)

○ Should be simple and generic ○ over-complicated or overly detailed might be counterproductive e.g., lead to stress and anxiety around sleep		1.3 Goal setting (outcome)
• How should programme users plan for their goals around sleep health? ○ Simple/generic planning to align with simple goals ○ Planning for sleep hygiene routines e.g., a checklist	• Pre-populated sleep hygiene plan/checklist	1.4 Action planning
• How should the programme monitor and record progress? ○ Detailed tracking and recording felt to be counterproductive ○ Debate over value of wearable use e.g., objective sleep data tracking and scoring. Decision that this should be optional. Detailed e.g., graphic visualisation of this data may not feel meaningful ○ A simple sleep diary/log felt to be most widely appropriate to help people identify factors that may be influencing their subjective sleep health	• Sleep diary/log to self-evaluate sleep quality and identify key individual factors • Optional use of wearable data to track progress	2.3 Self-monitoring of behaviour 2.4 Self-monitoring of outcome(s) of behaviour 2.6 Biofeedback 12.5 Adding objects to the environment

Workshop 3: Prompting

Function	Mode of delivery	BCTs

• When should prompts be used?
  ○ Use as reminders e.g., for a bedtime sleep hygiene routine or a bedtime prompt
  ○ Reinforcement messaging e.g., for achieving a' good night's sleep' not felt to be meaningful/valuable. Equally highlighting a poor night may be counterproductive even if messaging is careful
  ○ A progress report of how self-evaluation data is progressing would be useful
• How should prompts be delivered?
  ○ Automatic delivery by programme (text messaging, emails, and notifications all acceptable) with reinforcement during HCP check-ins
	• Prompts for undertaking sleep hygiene routine and other bedtime reminders
	• No reinforcement messaging in response to data entered.
	• A combination of 'automated' delivery by email/text/notification and HCP contact.
	• Weekly reports on progress (self-evaluations) messaging should be 'neutral' to avoid causing anxiety around sleep.
		2.2 Feedback on behaviour
		7.1 Prompts/cues
		12.5 Adding objects to the environment

Managing stress and anxiety (psychological wellbeing)

Workshop 1: Provision of information to programme users

Information needed	Mode of delivery	BCTs

• Why is psychological wellbeing relevant to me and my surgery?
  ○ Knowing the reasons why psychological wellbeing is important for surgery
  ○ Knowing that preoperative stress and anxiety are normal
  ○ Knowing the benefits of managing stress and anxiety before surgery
• How does psychological wellbeing relate to the other health behaviours?
	• Visual information for procedural knowledge (engaging, colourful images, tables, graphs)
	• Video or audio content of a clinician explaining
	• Limited and focussed text, short, sharp statements (no more than 3-4 lines)
	• Non-clinical language
		5.1 Information about health consequences
		5.2 Salience of consequences
		9.1 Credible source
		9.2 Pros and cons

• How to manage preoperative stress and anxiety
  ○ Coping strategies e.g., mindfulness techniques and exercises
  ○ Why and how to talk with others
  ○ Managing the added psychological burden of neoadjuvant treatments
		4.1 Instruction on how to perform behaviour
		6.1 Demonstration of the behaviour

○ Preparing psychologically for the recovery period- expectation management (surgery school) ○ 'Procedure specific' information e.g., what to expect with a stoma. ○ Signposting to more intensive support services (online and face-to-face) e.g., online CBT.		

Workshop 2: Goals, planning and monitoring

Function	Mode of delivery	BCTs
• What kind of goals should the programme use? ○ 'Improving psychological readiness' ○ Reduction in subjective stress and anxiety levels in the approach to the operation ○ Being in a better frame of mind to engage with other health behaviour support in the programme.	• An overall goal of improving psychological readiness for surgery.	• 1.1 Goal setting (behaviour) • 1.3 Goal setting (outcome)
• How should programme users plan for their goals around psychological wellbeing ○ Selecting of different activities and strategies that may help reduce stress and anxiety ○ Individually led	• Selection from suggested psychological wellbeing activities	1.4 Action planning

• How should the programme monitor and record progress? ○ Tool to track subjective mood over-time ○ A journaling tool and ability to reflect on how other behaviours might be impacting mood	• Subjective mood tracking tool • Journaling tool	2.3 Self-monitoring of behaviour 2.4 Self-monitoring of outcome(s) of behaviour 12.5 Adding objects to the environment

Workshop 3: Prompting

Function	Mode of delivery	BCTs
• Specific prompting not felt to be helpful here • Use of sensitive messaging and 'it's okay' messaging elements of other modules are likely to support psychological wellbeing by proxy.	N/A	N/A

Social support features (whole programme)

Workshop 3: Social support

Function	Mode of delivery	BCTs
• How should HCPs interact with and support programme users? ○ Scheduled contact required to review plans and progress, allow prompting, and discuss issues ○ Multiple acceptable formats (email, telephone call, videoconference)	• Scheduled fortnightly HCP check in aiming to simulate a face-to-face consultation • 'On demand 'access to HCP support for questions and queries	2.2 Feedback on behaviour 3.1 Social support (unspecified) 7.1 Prompts/cues 9.1 Credible source 12.5 Adding objects to the environment

○ This should aim to capture some of a 'face-to-face consultation' ○ Frequency should be fortnightly ○ 'On demand' contact option also needed for questions and queries e.g., 'live chat' messaging system		
• How should programme participants interact with each another? ○ Peer-interaction/support should be optional and overseen by HCPs ○ An avenue to share experiences is needed to build. Sense of community and help patients feel 'part of something' ○ Individuals may wish to share their story and others may benefit from them (this could be video or text) ○ 'Success stories' relating to the programme target behaviours e.g., quitting smoking, getting more active. ○ Family and carers should have access to the programme to get access to the same information help patients ○ Patients may optionally wish to 'buddy-up' with another programme user facilitated by HCP team.	• A 'Patient stories' feature to share content with others and access it. • Family/carer logins available • 'Digital buddy' feature • Engagement should be entirely patient led	• 3.1 Social support (unspecified) • 6.2 Social comparison • 10.4 Social reward

3.4. Discussion

This study is the first of its kind to utilise a theory-informed approach to the co-design of a digitally facilitated multi-behavioural prehabilitation programme. The study successfully obtained detailed information to guide the intervention content (informational and behavioural), structure and functions.

3.4.1. Co-design group characteristics

A co-design group was recruited representative of patients preparing for major surgical intervention and the multidisciplinary perioperative team of healthcare professional involved at two NHS surgical centres. Patient participant characteristics aligned with recently published major surgical cohorts in terms of age (75). Professionally and vocationally qualified participants were over-represented, aligning with findings of the subgroup preferencing digitally facilitate prehabilitation on chapter 2. Rates of smoking and hazardous alcohol consumption were low, whilst these are less common in wider surgical populations, the lack of active smoker may limit the findings relating to smoking cessation intervention content. A full range of professional backgrounds and perioperative clinical roles were represented among HCP participants with several participants bringing prior prehabilitation and digital health intervention experience to the study, adding additional insight to their views.

This approach to prehabilitation intervention development and application of the BCW approach was shown to be feasible with participants able to complete the tailored COM-B questionnaire, complete a semi-structured interview and engage actively in the co-design workshop series, resulting in the collection of data relevant to intervention design

3.4.2. Behavioural analysis (COM-B questionnaires and semi-structured interviews)

The TDF/COM-B behavioural analysis comprising BCW stage 1 identified several key requirements for the programme and accompanying training intervention to address.

3.4.2.1. Capability

Patient participants made clear the need for a range of information. Responses were consistent around the theme of helping patients clearly understand both 'why' pursuing health behaviour change via the programme would be worthwhile prior to surgery and 'how' this can be achieved. This aligns with prior work that patients may lack confidence around how to proceed toward change despite possessing sufficient motivation (122). Providing this information effectively will be critical to programme success. Patient participants also re-iterated a key piece of learning that has emerged from multiple prehabilitation services (127-129), the need to design support that has a continual awareness of the limitations and challenges faced by the populations they serve. These limitations coalesced around comorbidities and neoadjuvant treatment causing physical limitations, the psychological impact and overwhelm of facing major surgery and the potential lack of information technology confidence and even fear of these resources that are prevalent in older age groups. Any intervention and interface would seem to need the simplest mechanisms possible to achieve its aims and avoid exacerbating the preoperative burden patients face. Capability themes also highlighted the value of self-monitoring tools for patient respondents. This could be a recognised desire and value of patients taking ownership and regaining agency over their preoperative care acknowledged by prehabilitation services.

From the HCP perspective, there were encouraging levels of confidence in their capacity to support a digital programme. This is perhaps unsurprising. The co-design

group comprised a range of experienced and dedicated healthcare professionals working in highly pressurised services and used to supporting often vulnerable patients facing a potentially life changing health event. There was relatively little dissent over the fundamental value of prehabilitation activity and that patients ought to have access to it, however HCPs were clear around the need to fully explain to both: The programme content and mechanisms of action and the case for bringing a programme like this to their patients, given the potential to add to their preoperative challenges. Given the pressure on perioperative services, it is also unsurprising that a specific capability need did emerge around enhancing existing communication skills to effectively promote and discuss the programme with more reluctant and resistant patients in the context of a hectic working day.

3.4.2.2. Opportunity

Patient opportunity needs focussed around two main areas, provision of social support and awareness of the pressures presented by everyday life. Several themes emerged around the need for a social support network around the intervention. This includes both HCP-patient interactions and peer-peer patient interactions (see Tables 3.12 and 3.14). Patients appear to need HCP input via two main routes, scheduled and unscheduled. The importance of scheduled contact and the development of a therapeutic interaction while using the programme is not unexpected. Patients value and benefit from continuity of care (361) and preferencing remote supervision does not appear to mean desiring 'light touch' HCP involvement. There may be value in attempting to capture elements of face-to-face interaction. From a practical design standpoint, these findings support the preference for regular scheduled HCP contact outlined in chapter 2. There is also a need for on demand mechanisms to field unexpected questions and queries between scheduled contact points. This is logical to incorporate, as it provides an added safety layer and potentially reassurance to more nervous patient participants. Whilst we intuitively might expect this group of patients to be less comfortable in a group support environment, having opted for remote supervision, there is a clear appetite for peer support functions that capture some of the recognised valuable aspects of group support and help counteract feeling lonely or isolated prior to

surgery. This finding aligns well with prior work on the value of peer-support in other digital behavioural interventions that indicated availability of interactive features may replicate some of the benefits of group-base support(339)

Physical opportunity needs focussed on a preference for the programme to fit in with the patient's life circumstances and available time, respect their autonomy and ultimately be led by them. There appears to be an advantage to avoiding rigid design and accepting that users must be able to have bad, busy, or simply overwhelming days without the programme leaving them behind. This will require flexibility in design and a mindset of the patient choosing what parts and how much time they engage with the programme on a given day, rather than the programme dictating an agenda. As suggested in the capability needs above, this also supports the idea of value in restoring patients' sense of agency in their perioperative care.

HCP data also highlighted two key lessons for programme design. Firstly, success of the programme will necessitate a 'whole team' approach with all perioperative team members in each surgical pathway aligned in their intent and actions to succeed. HCPs indicated the need for three distinct roles within the wider team: The 'promoter' to initially present and engage patients in the programme, the 'prompter/facilitator' to support patients during their use of the programme, aligning naturally with the 'designated contact point' desired by patient participants, and a coordinating 'overseer' to support other HCPs, link to 'behaviour subject specialists' (e.g. dieticians or psychologists) and facilitate the managerial aspects of delivering the intervention. This framework fits well with the team structures already adopted by face-to-face services. Interestingly, HCPs had clear and potentially conflicting views over which groups of their colleagues were best placed to undertake those roles. In particular the linchpin position of senior surgeons as 'promoters' emerged. In addition it was suggested that specialist nurses may be underutilised as prompters/facilitators given their early, consistent contact points, how valued they are by patients and their unique understanding of the major surgical perioperative pathways in which they work. Preassessment staff, the cohort of HCPs we might intuitively have expected to lead an initiative like this, were consistent in their view that their current opportunity to initiate an intervention like this comes far too late. This finding suggests a 'specialty pathway based' approach to implementation and

training rather than by professional group might be most successful, whereby specific perioperative teams (e.g., vascular surgery or colorectal surgery) train on the programme together. This enables members to obtain a full understanding of the intervention and HCP roles, and to decide which of their team members are best placed to undertake each role given their local circumstances and context.

The second key HCP finding related to physical opportunity; specifically, the need for service buy-in and support of the programme. Participants were clear that successful implementation may hinge on service managers and stakeholders understanding the needs of the intervention and supporting their staff (with hours, resource, and physical space) to deliver it. This was predictable in the context of unprecedented service pressure on perioperative care. Providing this is likely to be a key focus of linked policy functions following feasibility testing.

3.4.2.3. Motivation

As predicted by the behavioural component interactions within the COM-B model, the needs and potential sources of motivation aligned with the capability and opportunity needs discussed above.

Patients indicated that reflective motivation would be enhanced by a sense of control over the programme that allowed them to engage with support that flexed to their perceived limitations or allowed them to build upon a perception of already being fit or healthy, re-emphasising the need for ‘patient led’ engagement and programme structure. This in turn may build a sense of control over their prehabilitation activity, surgery, recovery, and outcomes. Automatic motivation would be enhanced by clear presentation of progress made within the programme, regardless of the extent. Use of prompting mechanisms was emphasised as valuable to support this and developing a sense of recognition for the effort made to achieve change. Finally, the importance of a sense of social support around the programme was again highlighted to build enhanced motivation in the face of preoperative anxiety and stress.

HCP responses and themes identified a need for the programme, including the intervention roles, to complement their existing professional role and values, integrating smoothly with the overall objective of preparing the patient as well as possible for their operation. There was a clear signal that to be acceptable to HCPs the programme should respect the autonomy sought by patients and avoid coercive or pressurising methods to effect change (see Table 4.13.). HCPs again indicated the need to build belief in the value and benefit of the programme to their patients through the training programme to enhance their motivation to promote and deliver it on the ground.

3.4.3. Co-design workshops and identified programme design requirements

The behavioural analysis provided several valuable overarching principles to inform the programme and training intervention design and laid groundwork for more specific design decisions around mode of delivery, the programme health behaviour components and incorporated BCTs. These were explored further in the co-design workshops. The resulting principles identified for design and delivery of the programme overall and for each component health behaviour are discussed here.

3.4.3.1. General programme requirements

Whilst the component programme health behaviours were considered individually, there were several common findings.

Conveying information to users on the importance and personal benefit of preoperative change in each behaviour (both the ‘why’ and the ‘how’) was a key need identified above and re-emphasised in workshops. Workshop findings confirmed a clear preference for audio-visual delivery of this content across the behaviours and sparing use of written material and text. Notably, participants requested that this content be presented by a healthcare professional to enhance credibility and echo some of the experience of a face-to-face consultation. A new specific informational need also emerged around explaining how the health

behaviours within the programme inter-relate and may synergistically support one another.

Goal setting was recommended to be a joint process between the programme and participant, with a general pattern of a ‘suggested goal’ that the patient could then modify or adapt, reflecting the need for autonomy, control and ownership identified above. In the case of some behaviours this flexibility for patients was more important, notably activity and exercise, whereas for other behaviours such as smoking or alcohol intake there was agreement that a ‘standard’ goal (e.g., to quit and cut down) would be appropriate for most participants. Progress tracking mechanisms and the presentation of progress to users was emphasised across the behaviours with an overall preference for simple tracking and recording mechanics and minimal data entry. This presents an interesting design challenge with tension between meeting this patient need to support usability and acceptability and acquiring sufficiently granular information from participants to objectively assess change. Patients requested a mechanism to regularly report on their progress on a weekly to bi-weekly basis.

Prompting mechanisms were seen to be appropriate across all behaviours to varying extents. Workshop attendees identified that this should come from both the programme itself in the form of automated messaging (e.g., text, email, notifications) and from facilitating HCPs with the necessary scheduled check-in identified from the behavioural analysis providing an obvious route to delivery. Messaging here was key, with opportunities to both celebrate success and offer patients who are struggling support in a compassionate and non-judgemental way, summarised as ‘it’s okay’ messaging.

Finally, workshop participants supported the concept of both an in-built messaging system to provide the ‘on demand’ access to HCP support needed alongside scheduled check-ins by phone or videoconferencing. Peer-support settled on a mechanism for patients to voluntarily share stories and experiences for others to access and benefit or learn from should they choose. There was also the suggestion of a ‘digital buddy’ scheme overseen by HCP facilitators to pair up willing patients facing similar surgeries or having had similar experiences. Anecdotally, buddying

has been successfully utilised in face-to-face services. It is untested in the remotely-supervised setting and would raise potential issues around patient safety and governance.

3.4.3.2. Physical activity and exercise content

For this component, patients expressed a clear requirement for audio-visual informational content on ‘how to’ undertake exercises safely and effectively. The need for flexibility to patient abilities, need and willingness to participate was greatest here, presenting the challenge of designing content that can be accessed initially by all-comers, scale appropriately to their abilities, provide a sufficient stimulus to effect fitness changes and then progress with them toward surgery. This is a conundrum also faced in the design of face-to-face services but with the added complexity of remote delivery. Participants offered a solution in the form of a ‘pre-populated’ programme that could be rapidly scaled up or down in intensity to meet the patient where they are. This is the model for the ‘activate your heart’ (362)cardiac rehabilitation programme and the ‘step it up’(363) intervention focussed on increased physical activity using step count. No prior perioperative examples have attempted multimodal exercise training. There was also a requirement identified for emphasis on elements of activity and exercise training that would be valuable for particular operations. Participants supported step counts and the logging of structured exercise training sessions as mechanisms for tracking and progress reporting. Participants saw the clearest role for a wearable device here, allowing activity and exercise data to be automatically-entered and presented with minimal data entry burden on the user.

3.4.3.3. Smoking cessation content

Workshop findings echoed recognised difficulty in tackling this behaviour preoperatively (128). Whilst it was acknowledged that participants should all set quitting as a goal, the value of ancillary goals setting (e.g., money saved) was suggested. Creating a sense of momentum and progress would appear key here even if small steps were being taken. Participants also recommended tracking

tobacco intake in real time by using a simple programme mechanic, and that feedback and prompting should be mindful and compassionate toward the struggle that smokers trying to quit before surgery are facing. In alignment with the evidence-base for preoperative cessation (211), participants supported active signposting to a 'full' cessation service through the programme to expedite access to nicotine replacement therapy, to accompany the behavioural content provided by the programme.

1.1.1.4. Alcohol reduction content

In keeping with smoking cessation, a generic goal of reducing intake to 14 units or less was supported by workshop participants. A simple tracking metric incorporating automatic unit conversion to track intake in real time was advocated. Also, in keeping with smoking cessation, regular progress updates and sensitive prompting and messaging around progress were important given the potential difficulty some participants may face. The alignment between findings for these two behaviours is unsurprising, as they are both examples of restriction and reduction of an existing behaviour and, in one case, an addiction as opposed to other programme components that are aiming to enhance or create a new behaviour.

3.4.3.4. Nutrition content

This component was arguably the most complex to unpack. The range of dietary needs and limitation faced across major surgical populations is broad, making goal setting appliable to mixed surgical populations challenging. Patient attendees trended towards weight as a key metric here, however dietitians attending emphasised a need to move away from this to a focus on 'healthy eating' and by extension 'muscle preservation and building'. The potential to do harm also had to be negotiated, e.g., leading an already underweight patient to lose further weight. A focus on broad principles of healthy eating that could be easily explained to patients and that would not clash with an existing dietician plan or risk nutritional harm was the result. There was also a challenge around tracking. Intuitively, the detailed counting of calories and recording of macronutrient intake, notably protein, might

have been valuable from a clinical standpoint, but this was deemed to be overly burdensome and impractical by attendees. The idea of smartphone barcode scanning used by commercially available diet applications to facilitate this was raised then rejected on the basis that it would exclude programme users without a device like this. Goal setting and tracking therefore settled around creating a simple mechanism to measure adherence to healthy eating principles that would support readiness for surgery.

3.4.3.5. Sleep health content

Inclusion of sleep as a programme component was surprising to some workshop attendees, perhaps reflecting the low population awareness of its importance to general health and wellbeing (228). An informational need emerged around the principles of good sleep hygiene and the idea of constructing a sleep hygiene routine to follow as the core of this component. Participants were keen to know how better sleep health might impact progress with other behavioural support. Specific goal setting and detailed progress tracking here was felt to be potentially counterproductive by increasing anxiety and stress around sleep. In particular, the degree of detailed data that a wearable device could provide was not felt to be useful and potentially intimidating by participants. In keeping with other behaviours, a simple tracking mechanism was preferred, one which focussed on overall subjective sleep quality. Participants also supported a free-text journaling tool, when used to reflect on what elements of a daily routine might be influencing sleep health.

3.4.3.6. Psychological wellbeing content

Workshop findings indicated that this content may be more ‘passive’ in contrast to the structured support needed for other behaviours. Participants re-emphasised the importance of this element of wellbeing before surgery, but steered toward an avenue to observe, acknowledge, and reflect on their mood with the support of simple tracking mechanics and a journaling tool, supported by signposting to more targeted support given the range of issues patients may face e.g., online CBT. Including specific stress management support e.g., mindfulness techniques was

advocated but overall, participants advised this content should be relatively ‘neutral’ in its prompting and feedback interactions, with content aiming to help users ‘observe’ this area of health rather than attempting to comment, appraise or intervene.

3.4.4. Study limitations

Several limitations to the study findings with implications for the resulting intervention design are acknowledged. Whilst a diverse range of study participants were recruited to the co-design group, it can be argued that, from the patient standpoint, certain groups are under or not represented within the data with a bias toward more professionally and vocationally qualified participants, This is in keeping with the results of the DCE study in chapter 2 and may simply reflect the appeal of a study relating to digital prehabilitation support to patients more likely to opt for this model in reality. The decision to exclude non-English speaking participants may further limit the wider applicability of findings and resultant feasibility of the intervention for minority ethnic groups. However, it is reasonable to expect that the fundamental needs for those groups may overlap significantly and design modifications to meet their specific needs could be undertaken at a later stage.

The diversity and excellent spread of surgical specialties represented across patient and HCP respondents is an advantage, but also a drawback as it could be argued the resulting data lacks the specificity needed for the resulting design to be maximally effective in each surgical pathway. This was acknowledged at the outset, and it is also interesting that there was significant consistency in themes identified across patients experiencing different procedures. Again, this offers scope for adaptation and refinement plus addition of dedicated specialty content at a later stage if general feasibility is demonstrated.

The data coding and thematic analysis undertaken is also unavoidably open to subjectivity, although efforts were made to use coders with differing professional backgrounds and perspectives, to make it less likely that key themes were missed. In addition, it is reassuring that there was consistency and reinforcement of the

behavioural analysis by workshop findings and links to prior anecdotal and published experience of face-to-face services and other work on digital behaviour change interventions.

Finally, whilst this study provides valuable guidance to inform the intervention design presented in chapter 5, the data presented here is not a comprehensive blueprint to a working programme and both existing evidence and the experience of the design team will be required to help fill in gaps. However, many of the design challenges identified are not unique to digital prehabilitation and this presents an opportunity to adapt and incorporate elements of existing studied interventions 'off the shelf', where the co-design group here have not offered more specific detail and guidance.

3.4.5. Summary

This study has successfully obtained the detailed views of a perioperative co-design group of patients and HCPs through application of the behaviour change wheel meeting its stated aim. The data here provide robust insights to inform the design of a multi-behavioural, digitally facilitated and remotely supervised prehabilitation programme, which will represent the first systematically developed and theory-informed intervention of its kind. The findings here will allow the resulting programme to be well described in terms of both its intervention and behavioural content.

4. Chapter 4: The iPREPWELL multibehavioural digital prehabilitation programme

Chapter 3 presented the systematic co-design process of the iPREPWELL programme utilising the behaviour change wheel(347). This process identified key intervention needs from the patient and HCP perspective and introduced candidate behaviour change techniques and potential modes of intervention delivery for planned components. With reference to the MRC framework for complex intervention design (247), specifically 'development', the overall programme design was iterated with incorporating the perioperative and prehabilitation evidence base and the input of subject specialists (e.g. dietitians, exercise scientists, health psychologists and perioperative clinicians) within the intervention design team. The resulting programme prototype design is presented here. This programme is planned to undergo formal feasibility testing as described in chapter 5. This will transition the process from the 'development' to 'feasibility' stage of the MRC framework and complete stage 3 of the Behaviour Change Wheel.

4.1. iPREPWELL Programme overview

The iPREPWELL prototype is a progressive web-application designed for use by patients preparing for major surgery. It has been designed by a multidisciplinary design team as described in chapter 3 and built to specification in collaboration with an experienced web design and development company (Hark 2 ltd, Leicester, UK) with a track record in design and development of health behaviour change interventions for the NHS. Prior work includes digitally facilitated self-management interventions for cardiac rehabilitation (362), type 2 diabetes(364) and chronic obstructive pulmonary disease (COPD) (365).

The programme provides structured multibehavioural prehabilitation support to enhance physical and mental health and wellbeing. This is delivered via six 'modules' and supporting features designed based on the findings of the DCE undertaken in chapter 2 and co-design process detailed in chapter 3. Each module addresses an individual perioperative risk factor. The six components are presented in figure 4.1.

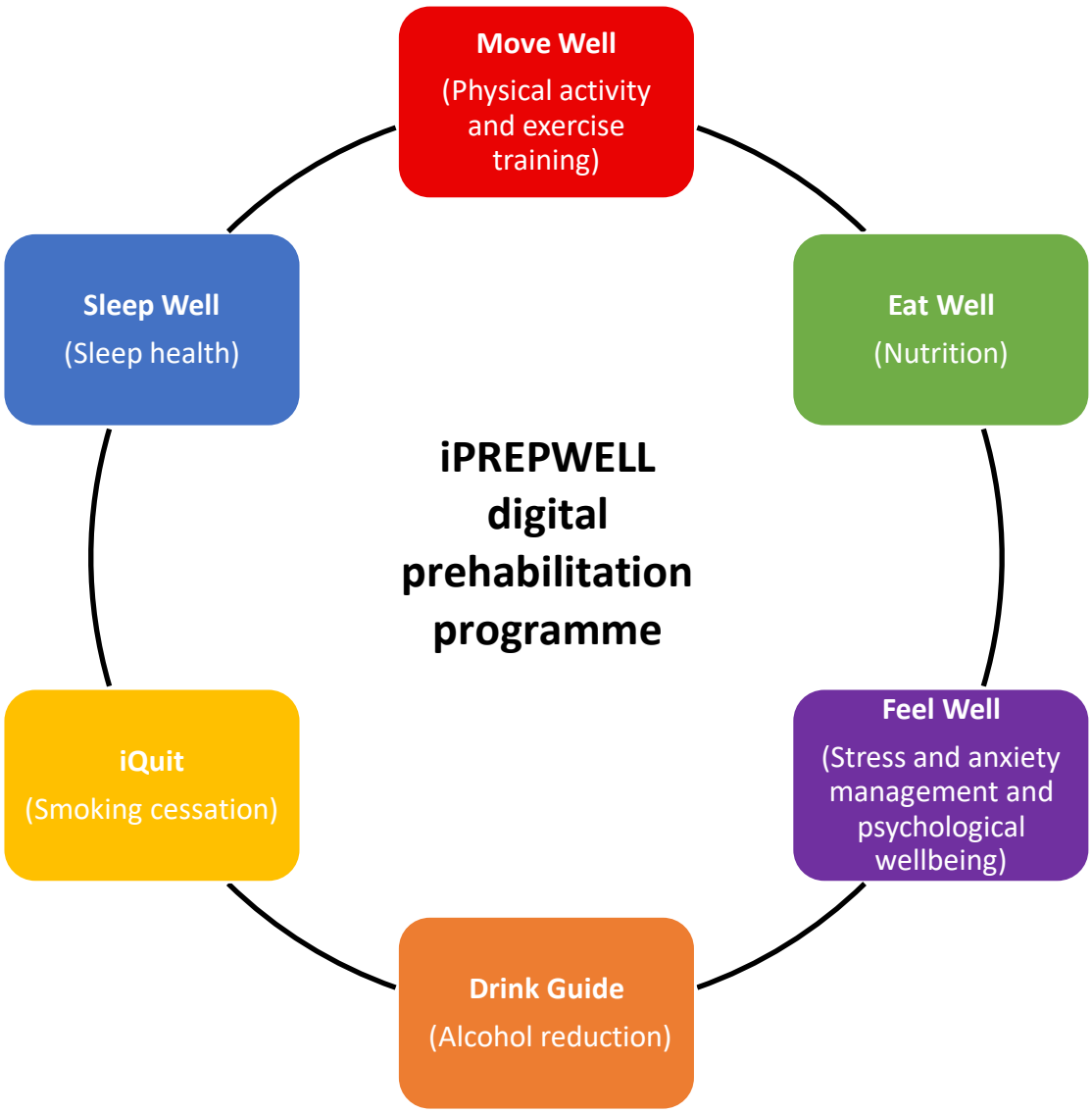

Figure 4.1. iPREPWELL programme overview

The overall programme is described utilising the TIDieR checklist in table 4.1. As the checklist is being used propectively here (i.e., prior to intervention testing), checklist items 10 'Modifications' and 11-12 'How well' are omitted in lieu of the planned feasibility study described in chapter 5. This checklist is supported by further specific

TIDieR descriptions of the 6 programme modules, including additional relevant detail. A link to the most up to date prototype design is available here (https://xd.adobe.com/view/c0fba3ea-f4be-45a0-8e06-7e1df1a29e8b-95a8)

Table 4.1. iPREPWELL programme TIDieR checklist. Items 10-12 omitted prior to feasibility testing

Checklist item	Description
1. Brief Name Provide the name or a phrase that describes the intervention.	• iPREPWELL digitally facilitated, remotely supervised multibehavioural prehabilitation programme
2. Why Describe any rationale, theory or goal of the elements essential to the intervention	• iPREPWELL is a theory and evidence informed digital mutlibehavioural prehabilitation programme co-designed with patients and perioperative healthcare professionals. • iPREPWELL was developed systematically utilsing the Behavour Change Wheel with reference to the MRC complex intervention development framework. • The overall programme aim is to enhance preoperative physical and mental wellbeing prior to surgery by addressing known perioperative risk factors: physical inactivity and poor fitness, smoking, hazardous alcohol intake, poor nutrition and poor psychological wellbeing. • Six programme components incorporate findings from the co-design process, the perioperative and prehabilitaiton evidence base and the input of subject experts within the co-design team relevant to each component. • The programme was conceived and designed to address a gap in perioperative care for a remotely supervised digitally faciliated prehabilitation option.
3. What (Materials) Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention	• The programme is delivered as a progressive web application, accessed using a browser, on any internet enabled device of the patient's choosing. • HCPs access the programme similarly via a dedicated interface. This also hosts the training programme materials (audiovisual and written materials) • The latest iteration of the programme protoype is accessible via:

delivery or in training of intervention providers. Provide information on where materials can be accessed (e.g. online appendix, URL).	https://xd.adobe.com/view/c0fba3ea-f4be-45a0-8e06-7e1df1a29e8b-95a8
4. What (Procedures) Describe each of the procedures, activities and/or processes used in the intervention including any enabling or support activities	▪ Following programme registration with a facilitating HCP, patient participants are encouraged to access the programme daily to engage with support content relevant to their health behaviours. ▪ No minimum or maximum frequency of programme access is set and participants are free to choose which programme modules they access and engage with and how often. ▪ All programme modules are designed to be completed within 4 weeks but can be utilised until surgery as required. Postoperative access is provided should the patient wish. ▪ Participants will receive a scheduled check-in with a HCP facilitator fortnightly to review progress and address issues ▪ Scheduled HCP contact is supported by an 'on-demand' in-programme messaging system for queries monitored by the facilitating HCP team. ▪ Automated SMS and email prompting is triggered with programme progress ▪ Patient interaction with programme will be supported by automated prompting to reinforce progeamme engagement and interaction and prompting delviered by HCPs during scheduled check-ins in repsonse to both engagement and non-engagement.
5. Who provided For each category of intervention provider, describe their expertise, background and any specific training given	• Supporting HCPs will be perioperative team members working across surgical pathways at delivering units. They are appropriately qualified and regulated for their professional role however experience (e.g. time in role) will vary. • All HCPs will undergo the iPREPWELL HCP training programme to develop a clear understanding of the programme intent, content and potential benefit for patients. • Three distinct roles (promoter, prompter/facilitator, overseer) are available to support programme delivery with perioperartive team members encouraged to adopt any or all roles that align most

	readily with their normal clinical role and responsibilities and service needs. The training programme will encompass all three roles to ensure programme HCPs have a good understanding of each one.
6. How Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	• iPREPWELL is delivered to patients digitally with remote HCP supervision. • Scheduled HCP check-ins, occur using telephone or video conferencing as required • Three face-to-face contact points occur at registration/baseline assessment, preoperative assessment and at 3-months postoperatively to faciliate some clinical assessments that cannot be undertaken remotely. • No mandatory group support is undertaken, however peer-peer interaction is facilitated by a 'patient stories' function allowing patients to share their perioperative experiences with others with HCP oversight.
7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	• Patients utilise the programme in and around their own home with scope to utilise other available community resources e.g. exercise classes, gym facilities and smoking cessation services should they choose to support the programme content. • Scheduled assessments (baseline, preoperative and 3-months post surgery) will occur at the patients hosptial site.
8. When and how much Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	• Patients are intended to utilise iPREPWELL over a minimum 4 weeks and continue until surgery. Postoperative access will be at patient discretion • Number and duration of programme logins and interactions will be at patient discretion but guided by vary according to individual programme modules

9. Tailoring If the intervention was planned to be personalised, titrated or adapted the describe what, why, when and how.	• iPREPWELL is tailored at two levels. Firstly, programme modules are offered guided by baseline clinical and risk behaviour assessment as follows: • All programme users: o Move Well (Breathe Well course omitted for patients undergoing orthopaedic surgery) o Eat Well o Feel Well o Sleep Well • Patients who smoke: o iQUIT • Patients who drink alcohol: o Drink Guide • Secondly, individual modules adapt according to patient progress and needs as detailed below (sections 4.4-4.9)

4.2. Patient programme journey and interaction

In keeping with the DCE findings relating to ‘programme start point’ in chapter 2, patient users are offered the programme and registered as close as possible to surgical listing to maximise available preoperative time. The programme is designed to provide at least 4-6 weeks of support prior to surgery with access maintained postoperatively should patients choose to continue use. The patient journey is punctuated by milestones facilitating assessment of physical and mental health changes and perioperative outcomes and mirrors the evaluation approach successfully undertaken by the face-to-face group-based South Tees PREPWELL programme(128). This process is summarised in figure 4.2.

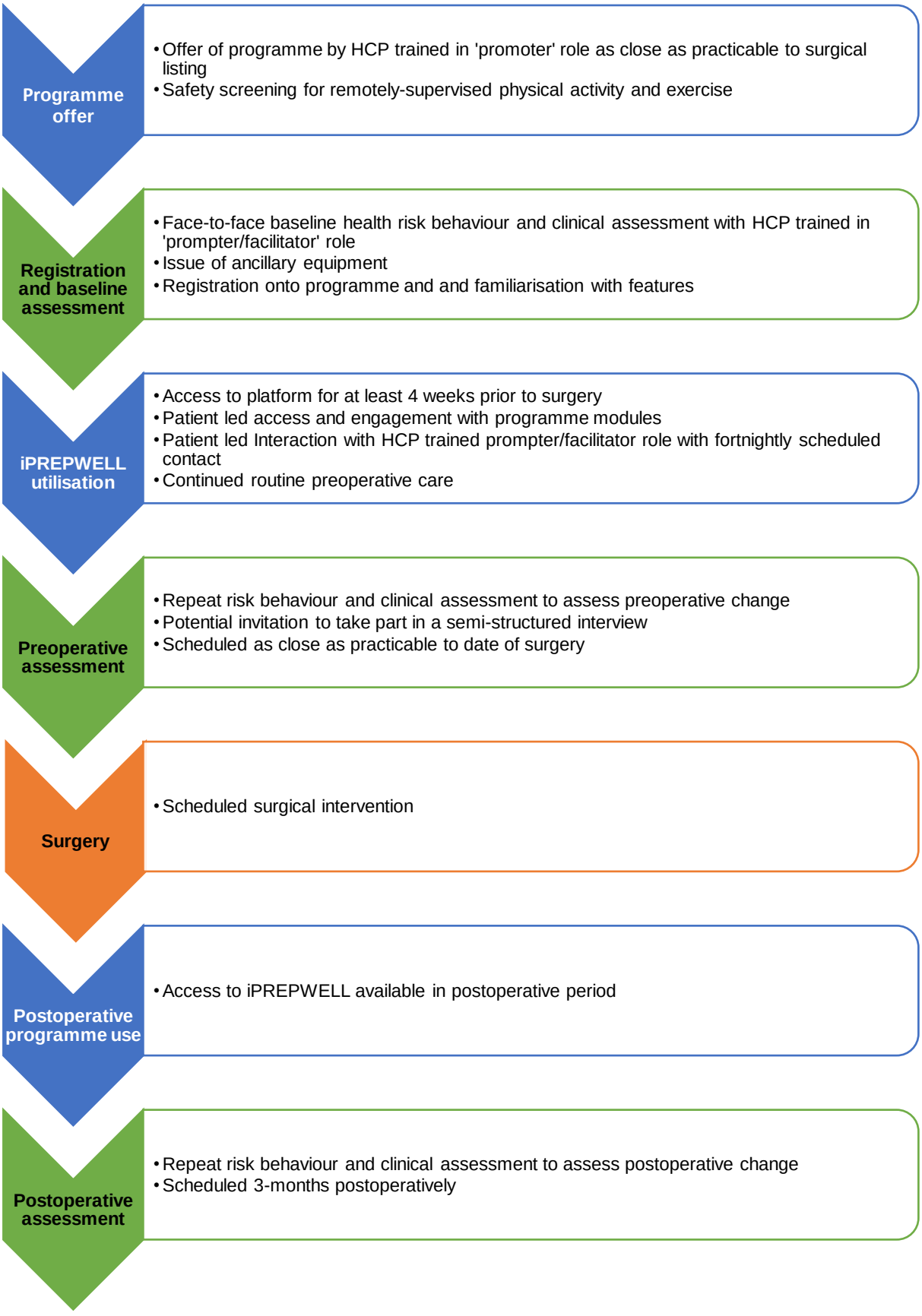

Figure 4.2. iPREPWELL patient journey overview

4.2.1. Programme offer and safety screening

iPREPWELL will be offered by a HCP promoter as soon as practicable following surgical listing. Participants will be screened for safety to undertake remotely-supervised exercise utilising the ACSM criteria for exercise testing and training(366). Patients with a contraindication will not be eligible to use iPREPWELL at present. A wealth of evidence for the safety of both maximal exercise testing and training programmes continues to build in surgical populations(102, 141). However there is a comparative paucity of for the safety of remote supervision despite individual studies supporting the safety of protocolised training in elderly and frail populations(242, 259). Post feasibility testing, there is potential scope to relax these restrictions or offer the programme without the Move Well component included to allow higher-risk patients to benefit from the other support offered.

4.2.2. Programme registration and programme data collection

Patients will undergo their programme registration and baseline assessment with a HCP trained in the 'prompter/facilitator' role. This is intended to occur at their hospital site and could occur immediately following the initial programme offer for efficiency but may require a further hospital visit. This is in direct conflict with patient preferences for the attribute 'programme start place' in chapter 2. A clear preference for a home-based introduction process was indicated by DCE respondents. However, the practicalities of undertaking face-to-face clincal assessments currently required to evaluate progress (e.g. the 6-minute walk test) necessitated this decision. This offers two avenues for potential intervention optimisation and alignment with patient preferences post-feasibility testing. Firstly, the removal of face-to-face assessments judged to be less useful or secondly the shifting of some asessments to a remotely delivered format allowing registration and onboarding to be undertaken fully-remotely. This would have the added advantage of reduced staff time to undertake the induction if the process can be appropriately streamlined.

The assessment will encompass a range of questionnaire and clinical data. Data entry will be flexible between patient and HCP entry during and following the registration visit to balance the data entry burden on both parties.

Data collection across registration and the subsequent preoperative and 3-month postoperative assessments are described in table 4.2. Data collected is divided by patient and HCP facilitator entry and by the relevant iPREPWELL component module. The breadth of metrics tracked and programme data collection were designed to align with ongoing work to define a core outcome set for prehabilitaiton interventions and studies and work by Boney et al(367) to define a wider set of outcome measures for anaesthetic and periopeative care.

This assessment will also allow ancillary equipment to be issued. Specifically the integrated wearable device (Garmin Forerunner 45, Garmin UK Ltd, Southampton, UK), resistance bands and inspiratory muscle trainer (POWERbreathe medic, POWERbreathe International Ltd, Northfield Southam, UK). This wearable device was selected following discussion with co-design workshop participants regarding then need for adequate screen size and simplicity of use and for ease of integration with the iPREPWELL programme after discussion with Hark 2. Two design team members trialled the device prior to selection to identify issues that would inhibit participant use during feasibility testing. The powerbreathe trainer was selected as the device currently being utilised in the NIHR INSPIRE trial.

Table 4.2. iPREPWELL assessment points and data collected. Subdivided by data for patient entry, HCP entry and by relevant programme module. Responses flagged on HCP dashboard for review and potential onward referral indicated in red.

Item	Baseline assessment	Preoperative assessment	Postoperative assessment
Patient or HCP entry			
Demographics (name, age, biological sex, postcode and preferred contact email)	X		
Comorbidities (tick box list)	X		
Surgery details (planned/actual date, specialty and planned/actual procedure)	X		
Chemoradiotherapy status	X		
Patient entry			
Physical activity, exercise and functional capacity (Move Well)			
International Physical Activity Questionnaire (IPAQ) short form	X	X	X
Nutrition (Eat Well)			
Dana-Faber Cancer Institute eating habits questionnaire (personal dietary assessment domains)	X	X	X
Malnutriton universal screening tool (MUST) flagged if 'high' risk	X	X	X
Patient generated subjective global assessment (PG-SGA) flagged if 'high' risk	X	X	X

Smoking (iQUIT)			
Smoking status	X	X	X
Fagerstrom score (if smoker)	X		
Alcohol consumption (Drink Guide)			
Alcohol intake (units)	X	X	X
AUDIT-10 questionnaire (if alcohol intake >14 units) flagged if 'high' risk	X	X	X
Sleep health (Sleep Well)			
Pittsburgh sleep quality index (PSQI)	X	X	X
Psychological wellbeing (Feel Well)			
Patient activation measure (PAM)	X	X	X
Hospital Anxiety and Depression Scale (HADS)	X	X	X
Quality of life			
EQ-5D-5L	X	X	X
SF-36 v2	X	X	X
HCP entry			
Bedside clinical assessment			

Stature (m)	**X**		
Body mass (kg)	X	X	X
Body mass index (kg/m^2)	X	X	X
Resting heart rate (bpm)	X	X	X
Resting blood pressure (mmHg)	X	X	X
Resting oxygen saturation (%)	X	X	X
Rockwood clinical frailty scale (CFS)	X		
Physical activity, exercise and functional capacity (Move Well)			
6-minute walk test distance (m)	X	X	X
Grip strength (kg)	X	X	X
30-second sit to stand test (repetitions)	X	X	X
Maximum inspiratory pressure (cmH_2O)	X	X	X
ARISCAT score	X		
$\dot{V}O_2$ peak ($ml.kg^{-1}.min^{-1}$) if routinely collected	X	X	
$\dot{V}O_2$ Anaerobic threshold (AT) ($ml.kg^{-1}.min^{-1}$) if routinely collected	X	X	
VE/VCO_2 at anaerobic threshold if routinely collected	X	X	
Nutrition (Eat Well)			
Body composition by bioimpedance (Fat Mass)/Fat Free Mass %)	X	X	X
Glycosylated haemoglobin (HbA1C) (recorded if routinely collected) (mmol/mol)	X	X	X

CRP (record if routinely collected) (mg/L)	X	X	X
Perioperative outcomes			
Alive at hospital discharge			X
30-day postoperative mortality			X
Comprehensive complication index (CCI) at hospital discharge			X
Days at home post-surgery (DAH_{30})			X
Length of hospital stay (days)			X
Length of critical care stay (days)			X

4.2.3. General patient programme utilisation and supporting features

Figure 4.3 presents the overall programme map for patient users.

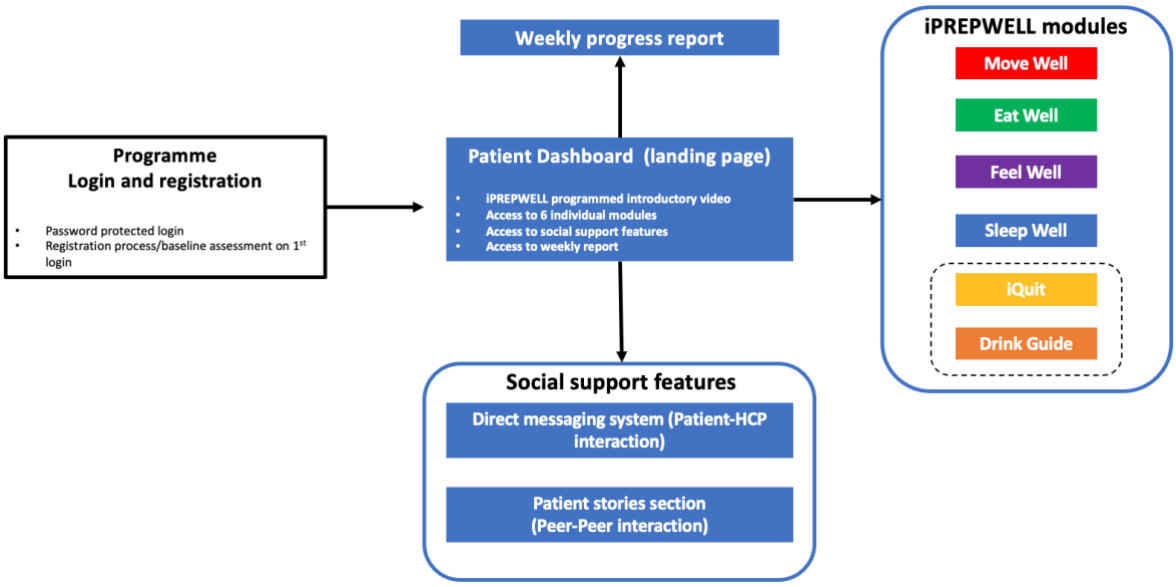

Figure 4.3. iPREPWELL patient programme map. Dotted line indicates modules available conditional on risk factors.

Participants will be free to utilise the programme and engage with content offered as they see fit from registration until surgery to align with findings of stage 1 development highlighting the need for a patient-led intervention that respected autonomy. A daily login will be encouraged however frequency and duration will also ultimately be patient led. No programme modules will be emphasised over others, however subtle visual prompting on the patient dashboard/landing page will highlight modules that are relevant to the patient but not yet accessed following registration.

Throughout, there is an emphasis on audiovisual content (video-based) to convey the information needs identified in chapter 3 with sparing use of text. As emphasised by the co-design findings, video content utilises a HCP presenter wherever possible supported with graphics. Information content is supported by goal setting and

progress monitoring mechanisms tailored for each module and based on stage 1 findings. This is discussed by module in more detail in sections 4.4-4.9.

A weekly progress report summarising all programme modules utilised so far will be generated. This is to present patients with an overview of their progress in areas of interest to them. This report will build week on week until surgery. The need for patients to visualise this clearly was emphasised for all programme target behaviours.

This is supported by a fortnightly scheduled check-in with a prompter/facilitator HCP aligining with patient preferences expressed in the preceeding DCE. stage 1 participants elaborated on this, emphasising the need for a clear line of contact with the supervising HCP team to generate a sense of outside support. The weekly progress support is a tool to guide these interactions. In additon to scheduled HCP interaction, the direct messaging system provides an on-demand HCP-patient link allowing access to support regarding unexpected queries or issues. This system will be monitored in working hours by the HCP team.

The patient stories feature aims to deliver peer-peer interaction and capture some of the benefits of peer-support seen in the group-based face-to-face prehabilitation model and desired by partcipants in the stage 1 co-design process. This feature will include curated audiovisual material from patients sharing experience of their perioperative journey and use of iPREPWELL for the benefit of others. This resource is intended to grow and develop over time allowing more procedure and specialty specific content to be provided.

4.2.4. Preoperative and postoperative programme assessments

These assessments will reflect the baseline assessment detailed in 4.2.2. with data collection as indicated in table 4.2 above. The preoperative assessment conducted as close as practicable to surgery aims to evaluate health and wellbeing change following programme use. The postoperative evaluation conducted 3 months

postoperatively aims to evaluate sustained postoperative change and collect relevant perioperative outcome data. As with the baseline assessment, they are undertaken face-to-face to allow clinical and functional assessments.

4.3. HCP programme interaction

A team of supporting HCPs will be required to deliver the programme. All HCPs will undergo the iPREPWELL HCP training programme. The co-design process findings identified several themes informing this process, notably the need to align with HCP current working roles, integrate smoothly with existing pathways and working patterns and capitalise on the potential strengths of different HCP backgrounds. Based on this, an 'in-pathway' approach will be taken to identify team members in surgical pathways willing to support the programme and undergo training together. Those HCPs will be encouraged to identify, within their teams, which programme role or roles would align best with their clincial role, capabilities and opportunity to interact with patients in their local pathway. The co-design process identified three main programme roles to populate.

4.3.1. HCP programme roles

4.3.1.1. Promoter role

Promoters are responsible for programme promotion to patients and making the initial offer at the earliest opportunity. Development work undertaken in chapter 3 indicated that the listing consultant surgeon may be best placed to successfully make this initial introduction and offer. However, this is not mandatory, indeed HCP feedback in the stage 1 process indicated that sometimes this may be an innappropriate timepoint, for example when breaking the bad news of a cancer diagnosis in the same consultation. This role is viewed as critical to achieve good programme uptake.

4.3.1.2. Prompter/facilitator role

This role is responsible for handling day-to-day programme support including registrations, baseline, preoperative and 3-month assessments, undertaking scheduled patient check-ins and monitoring the direct messaging system. Multiple HCP backgrounds could fit well with this role but stage 1 co-design findings indicated that surgical pathway nurse specialists may be particularly well placed. In addition, all HCPs with preoperative contact would be in a position to briefly encourage patients utilsing the programme.

4.3.1.3. Overseer role

Co-design work identified a clear need for an overarching coordination role to support other programme HCPs, manage referrals and data entry for the programme. HCP participants also indicated the need for a support network, Overseers would also link other programme team members to subject specialists for help with specific patient issues and queries e.g. dietitians or exercise trainers. These team members would have specific expertise relating to the programme modules but may be less comfortable facilitating the full programme with patients where the 'specialty specific' expertise of prompters/facilitators may be more applicable. This role would require a mixture of clinical and administrative input and may be best aligned with dedicated prehabilitation team members.

4.3.2. HCP training programme

The HCP training package is under development and will be hosted within the HCP interface described below. Audiovisual and written content will be bolstered by face-to-face training guided by needs identified in the co-design process. The feasibility study described in chapter 6 will also enhance this content with 'real life' experience of delivering the programme to patients. The training programme aims are:

- Provide HCPs with a clear understanding of the intention and goals of the programme intention and the structure and function from the patient perspective.
- Provide HCPs with a clear understanding of the benefits to be gained for their patients through participating
- Provide HCPs with a clear understanding of each HCP programme role and how they interact (regardless of whether they will undertake all roles within their programme team)
- Provide HCPs with role-specific training e.g communicaiton skills for resistant patients relevant to the promoter role and common queires and issues encountered for prompters/facilitators.

4.3.3. HCP programme interface

iPREPWELL contains a dedicated HCP interface for the supporting HCP team. This is presented in figure 5.4. Key features include the patient dashboard providing an overview of all registered patients and their module progress. In addition, the HCP training materials are hosted for reference and HCPs have access to the direct messaging system to monitor and respond to patient queries. There is also capability to enter and edit data against patient participant records and export participant data from the system.

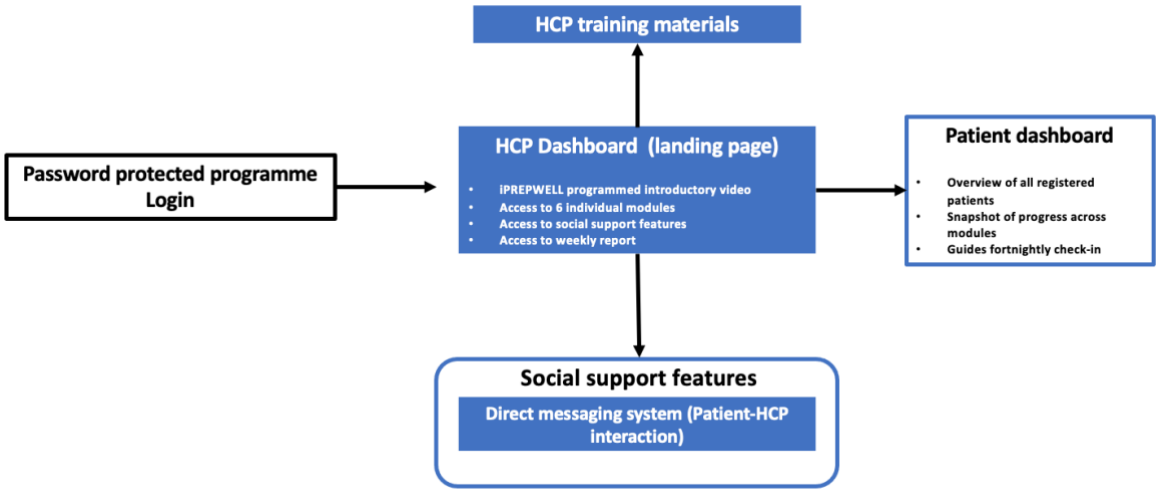

Figure 4.4. iPREPWELL HCP programme map

4.4. Move Well module

The Move Well module addresses physical inactivity and poor physical fitness. It aims to support patients to increase their general physical activity levels preoperatively and provide structured aerobic, resistance and inspiratory muscle training. This is delivered as four individual courses within the module accessed individually from the Move Well landing page: Prep Steps, Prep Fit, Prep Strong and Breathe Well. The module is mapped to the TIDieR checklist in table 5.3 presenting additional specific module detail beyond the general programme intervention description in table 5.1.

Table 5.3. Move Well module TIDieR checklist. Specific detail relevant to each component course indicated where relevant

Checklist item	Description
1. Brief Name Provide the name or a phrase that describes the intervention.	• Move Well module component of iPREPWELL digitally facilitated, remotely supervised multibehavioural prehabilitation programme
2. Why Describe any rationale, theory or goal of the elements essential to the intervention	• Move Well is offered to all iPREPWELL users with the expectation that the majority of patients preparing for major surgery will have some scope to improve an aspect of their physical fitness. • MoveWell comprises four component courses to increase preoperative physical activity levels and provide stuctured exercise training. These elements aim to enhance overall physical preparedness for major surgery. • Course are structured to meet the needs of patients with varying levels of physical fitness, provide an appropriate stimulus to achieve adaptation from this baseline and progress in line with patient ability. o **Prep Steps:** Provides support to increase general physical activity levels o **Prep Fit:** Provides structured aerobic exercise training o **Prep Strong:** Provides stuctured resistance training with an emphasis on functional and compound movements to support activities of daily living. o **Breathe-Well** Inspiratory muscle training • All component courses were developed in line with both current best-evidence for preoperative activity and exercise interventions and the findings of the iPREPWELL systematic development co-design process

	• Prep Steps is derived from the successful face-to-face ‘Step it up’ intervention utilised to increase general activity levels in primary care(363) and modified for digitally facilitated remote supervison through the co-design process. • Prep Fit, Prep Strong and Breathe Well are based upon current clinical guidance for preoperative exercise training(176). Breathe Well is additionally based upon the INSPIRE trial protocol intervention
3. What (Materials) Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention delivery or in training of intervention providers. Provide information on where materials can be accessed (e.g. online appendix, URL).	• Move Well is delivered within the iPREPWELL progressive web application as detailed in table 4.1. The module and all component course are structured around audiovisual material guided by informational needs identified in the co-design process. • The Prep Steps and Prep Fit courses are supported by an integrated Garmin Forerunner 45 wearable device provided to patients. • The Prep Strong course employs physiotherapy resistance bands provided to patients to supplement bodyweight/calisthenic movements. • The Breathe Well course utilises the PowerBreathe Medic Inspiratory muscle trainer provided to patients.
4. What (Procedures) Describe each of the procedures, activities and/or processes used in the intervention inlcuding any enabling or support activities	• Move Well is accessed from the iPREPWELL dashboard, and each component course is then accessed from the Move Well landing page. • Patients choose which of the four courses they access and engage with and how often. • Participants engage with audio-visual content covering the ‘why and how’ of Move Well and each course prior to starting. This material is available continuously for referral. • Participants using Move Well are supported by the general iPREPWELL HCP, peer support and automated prompting functions discussed above.

	• **Prep Steps:** • **Course goal setting:** Prep Steps supports patients to set daily activity goals using step count with the overarching goal of 'keeping moving and staying active before surgery'. Patients set daily step count goals in 1500 step increments. • **Course activities and procedures:** Participants are guided to avoid sedentary behaviours and consciously increase their day-to-day activity levels guided by their wearable step-count. This may include introducing more physical activity to their day to day life activities e.g. preferencing stairs or choosing to walk over transport. It may also include 'deliberate' walking sessions based on participant preference. • **Course progress monitoring:** The integrated wearable device passively records and uploads step count data to iPREPWELL. This is presented to the patient to visualise progress relating to their daily targets within the module course and in the weekly iPREPWELL report. • **Prep Fit:** • **Course goal setting:**

	Prep Fit supports patients to undertake deliberate sessions of aerobic exercise at a target intensity to enhance aerobic fitness The course is structured over 3 levels that progress under patient control (detailed below) Each level provides a weekly goal for time accumulated at the target intensity. Level goals are: Level 1: Accumulate 150 minutes at 'moderate' intensity over 1 week Level 2: Accumulate 75 minutes at 'vigorous' intensity over 1 week Level 3: Accumulate 45 minutes of high intensity interval training over 1 week • **Course activities and procedures** Participants are encouraged to undertake deliberate sessions over the week to meet their current level goal. Each session incorporates a warm-up and cool-down and participants are encouraged to build to the target intensity judged subjectively using the Borg CR-10 scale or supported by objective heart rate data from their wearable device Aerobic activities are suggested that can achieve this e.g. walking, jogging/running, cycling, or swimming. Acitivities can be mixed and matched as participants choose. On reaching level 3, a dedicated bodyweight/calisthenic HIIT training sequence is provided allowing participants to choose between this or interval training using their prior chosen activities. • **Progress monitoring**

	For each completed session, participants are encouraged to log the activity, time and their subjective intensity (Borg CR-10 rating). Prep Fit can pull wearable data to match the contemporary heart rate data to the session to log objective intensity. Use of the Borg CR-10 and wearable device are covered in the accompnaying Prep Fit audio-visual content. Accumulated progress toward the level goal is presented by Prep Fit to the participant visually. • **Prep Strong** • **Course goal setting:** Prep Strong provides structured resistance training to support postoperative functional movement and activities of daily living. Participants choose which areas to focus upon but building 'whole-body' muscular strength and stamina is encouraged • **Course activities and procedures:** Each session Prep Strong session suggests an alternating series of exercises (Series A and Series B). Each series comprises a different set of exercises across 11 general movement patterns. Each series and session incorporates lower body, upper body and core patterns. The 11 patterns are:

	○ Lower body: Squat, lunge and hip hinge (deadlift) ○ Upper body: Pressing, overhead pressing, pulling and chest opening ○ Core: Flexion, lateral flexion, extension and isometric contraction When completing the series, patients choose the exercise in each movement pattern appropriate for their fitness level and physical limitations. This is the exercise that allows 3 sets of 8 repetitions completed at a Borg CR-10 intensity of 7-8. Therabands are incorporated into higher level exercises within movement patterns. Patients are encouraged to take up to 1 minute rest between sets. Prep Strong includes dedicated audiovisual demonstration videos of each series for initial instruction and later participant reference. Videos are intended to be played during sessions. • **Progress monitoring** For each Prep Strong session and series of exercises, patients log the exercise level they performed for each movement pattern, the number of sets and repetitions completed and the intensity. Progress against each movement pattern is presented visually to the patient. • **Breathe Well** • **Course goal setting:**

	The Breathe Well course provides protocolised inspiratory muscle training with the goal of supporting patients to progressively enhance their inspiratory muscle strength and stamina. • **Course activities and procedures:** In a Breathe Well session participants aim to complete 6 sets of 5 breaths at a Borg CR-10 intensity of at least 5 utilising the powerbreathe medic IMT device. Up to one minutes rest can be taken between sets of breaths Initial resistance is set at 50% of maximum Peak Insipratory Pressure (PINSP) determined at registration • **Progress monitoring:** For each session, patients log the number of breaths completed, the resistance utilised and their perceived exertion. Number of sessions completed weekly are presented visually to the patient.
5. Who provided For each category of intervention provider, describe their expertise, background and any specific training given	• The supporting iPREPWELL HCP team will support Move Well via the mechanisms detailed above. • Physiotherapist, exercise science and clinical exercise professionals are likely to support other HCP team members in the delivery of this module.

6. How Describe the modes of delivery (e.g. face-to-face or by some other mechanism , such as internet or telephone) of the intervention and whether it was provided individually or in a group	• Mode of delivery of Move Well is that of the general iPREPWELL programme. • Patients may choose to access and engage with face-to-face group-based opportunities in their local community to supplement the programme.
7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	• Patients utilise the module in and around their own home with scope to utilise other available community resources e.g. exercise classes or gym facilities should they choose, to support the module content. Scheduled assessments are those of the main programme.
8. When and how much Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	• All four courses are intended to run with the main programme over a minimum 4 weeks and continue until surgery. Courses are structured to flex and continue with a move in surgical date. • Participants are encouraged to take a rest day between sessions in Prep Fit and Prep Strong • Prep Steps encourages daily activity towards the set step target • Prep Fit allows participants to determine how many individual sessions they wish to complete toward their weekly time target • Prep Strong encourages at least two sessions per week. • Breathe Well encourages 2 sessions of IMT daily.
9. Tailoring If the intervention was planned to be personalised, titrated or adapted the describe what, why, when and how.	• Move Well courses adapt and progress indiviudally. • Progression is utlimately patient led with oversight and review during scheduled fortnightly HCP check-ins.

	• **Prep Steps:** • Participants are prompted. To increase their step target when met for a week. They are encouraged to work toward 10000 in 1500 step increments • **Prep Fit:** • All newly registered participants commence at level 1. Once the weekly level 1 target is met (time accumlated at appropriate intensity), participants are prompted to consider progression to level 2. • Participants are able to move between levels as they choose with HCP oversight to avoid a feeling of over or under-reaching • Progression to level 3 requires HCP 'sign-off' for HIIT training suitability. • **Prep Strong:** • Participants select an exercise from each movement pattern that allows them to complete 3 sets of 8 repetitions at a Borg CR-10 intensity of 7-8 • Once achieved participants progress to 12 repetitions per set • Once 12 repetitions per set achieved they are encouraged to attempt the next exercise or utilise the next resistance level theraband, once again attempting 8 repetitions for 3 sets. • Patients can start at different exercise levels for each movement pattern and progress through the exercise progressions in each movement pattern at different rates that fit their fitness levels and limitations. • **Breathe Well**

	• Once perceived exertion falls below 5 on the Borg CR-10 scale, Breathe Well provides a new resistance setting 5% greater. • If participants cannot complete the first 30 breaths at 50% of Max PINSP they are prompted to reduce resistance to 40% of Max PINSP at the next session and progress from this point.

The Move Well component courses aim to engage patients in both increased levels of physical activity and structured exercise training. A deliberate distinction is drawn between physical activity and exercise with emphasis in video informational content on the importance of both to the surgical patient. Whilst all four course components will complement one another in building overall 'fitness' for surgery, they are able to run independently, acknowledging each patients desired choice over what and how they engaged with exercise and activity support. This was a key finding of the co-design process.

A balance was also struck across all courses between issuing patients with pre-determined goals. Given co-design indicated that patients would need guidance, yet providing ultimate control over whether that goal is upheld or changed. Flexibility is prioritised throughout. Whilst the exercise training courses are grounded in protocols likely to enhance physical fitness based on best available current evidence and guidance(174, 176), patients and their supporting HCPs can easily scale and modify them to their abilities without generating a feeling of 'failure'. Similarly, fitter patients will be able to rapidly upscale the challenge they are faced with to meet their abilities and gain a sufficient stimulus to trigger adaptations in their fitness.

The module also makes use of the integrated wearable device to passively collect relevant data and use this to track and visually represent progress for the patient. This aligns with the DCE findings in chapter 2 and implements the co-design process findings where participants saw a clear role for wearable technology to be utilised in progress monitoring for this behaviour. Also, in keeping with co-design findings a balance was also sought between detailed data collection and participant burden, with a focus on simple data entry mechanics and key detail for sessions undertaken in each component course.

4.5. Eat Well Module

The Eat Well module promotes an approach to eating that will encourage a macro and micronutrient balanced diet with a particular emphasis on protein intake sufficient to promote both readiness for the surgical insult and support adaptation to exercise training undertaken in Move Well. The Module is structured around dietary modification to align with five core 'Eat Well principles':

- Incorporating protein with every main meal to achieve intake approximating 1.2-2g/kg per day in keeping with current preoperative guidance(46, 49).
- Incorporating lower glycaemic index, minimally processed carbohydrates with main meals in favour of refined and processed sources to support a feeling of fullness, regulate total caloric intake and promote a more stable blood sugar profile(183).
- Incorporating food sources rich in polyunsaturated fats with main meals.
- Sufficient fruit and vegetable intake over a 24-hour period to promote micronutrient intake.
- Maintaining hydration

Table 4.4. Maps the Eat Well module against the TIDieR checklist.

Table 4.4. Eat Well module TIDieR checklist

Checklist item	Description
1. Brief Name Provide the name or a phrase that describes the intervention.	• Eat Well module component of iPREPWELL digitally facilitated, remotely supervised multibehavioural prehabilitation programme
2. Why Describe any rationale, theory or goal of the elements essential to the intervention	• Eat Well is offered to all iPREPWELL users with the expectation that the majority of patients preparing for major surgery will have some scope to improve their diet. • Eat Well emphasises five core principles aiming to guide patients toward a diet balanced in macro and micronutrients with sufficient protein intake to improve readiness for surgery and support adaptation to exercise in Move Well as emphasised in best available evidence for support of the surgical patient (46, 101) • The module acknowledges that patients may already be under dietitian care at registration. Supporting audiovisual material emphasises that this dietary plan should supersede that presented by the module. In addtition, dietitian participants in the co-design group vetted the advice and goals utilised to ensure they would be beneficial rather than detrimental to the nutritional health of the majority of patients presenting for major surgery. • Module mechanics were influenced directly by the systematic co-design and development process.
3. What (Materials) Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention delivery or in training of intervention providers.	• MoveWell is delivered within the iPREPWELL progressive web application as detailed in table 4.1. The module is structured around audiovisual material guided by informational needs identified in the co-design process.

Provide information on where materials can be accessed (e.g. online appendix, URL).	
4. What (Procedures) Describe each of the procedures, activities and/or processes used in the intervention inlcuding any enabling or support activities	• Eat Well is accessed from the iPREPWELL dashboard • Participants engage with audio-visual content covering the 'why and how' of EatWell. The five core principles are explained with emphasis on their contribution to readiness for surgery. • Practical information is provided on examples and sources of foods relevant to each principle, heuristics for judging portion size and managing difficulties with oral intake (e.g., the side effects of chemoradiotherapy) in addition to how the progress tracking mechanism is utilised. • Participants are encouraged to track their daily dietary intake against the five Eat Well principles that form the daily module targets. o 3 portions of lean protein daily o 3 portions of low glycaemic index minimally processed carbohydrates ('healthy carbohydrates') daily o 3 portions of polyunsaturated fat sources ('healthy fats') daily o 5 portions of fruit and vegetables daily o Drinking enough clear fluids over the day to be passing clear urine by midday • Participants are shown a visual representation of daily progress toward these goals and a weekly overview of the number of days all targets were met
5. Who provided	• The supporting iPREPWELL HCP team will support Eat Well via the mechanisms detailed above. • Dietitians are likely to support other HCP team members in the delivery of this module.

For each category of intervention provider, describe their expertise, background and any specific training given	
6. How Describe the modes of delivery (e.g. face-to-face or by some other mechanism , such as internet or telephone) of the intervention and whether it was provided individually or in a group	• Mode of delivery of Eat Well is that of the general iPREPWELL programme.
7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	• Patients utilise the module in and around their own home.
8. When and how much Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	• The module is intended to run with the main programme over a minimum 4 weeks and continue until surgery. • Daily interaction to log intake against targets is encouraged.
9. Tailoring	• Eat Well does not adapt or tailor to individual patients but they may choose to modify their indiviudal targets based on an individual dietitian programme e.g. avoiding higher fibre carbohydrate sources in the context of bowel cancer.

If the intervention was planned to be personalised, titrated or adapted the describe what, why, when and how.	

The Eat Well module presented a design challenge to meet the varying nutritional support needs of a wide range of patients preparing for major surgery without the benefit of a face-to-face dietetic consultation. One extreme considered the underweight patient with bowel cancer experiencing difficulties with maintaining a sufficient intake with an overweight patient preparing for total arthroplasty at another. The Eat Well principles were settled upon collaboratively with dietetic design team members and steered by dietetic trained participants in the co-design process. It was felt that adherence to these principles would benefit patients in both situations, particularly if combined with the Move Well programme, driving beneficial changes in body composition i.e., an increase in fat free mass. Emphasis in informational content was steered away from 'weight management' and toward 'preserving and building muscle for surgery'. It was expected that patients with the most complex nutritional needs (e.g., limited to no oral intake or a renal diet) would already be under dietetic care or could be flagged to the HCP team automatically using the relevant registration screening tools. This would allow rapid onward referral to dietetic services or a programme dietitian for assessment if available.

Module mechanics and tracking mechanisms were designed directly in response to the co-design process, allowing minimal-effort, simple daily data entry against the five principles. Whilst more granular data relating to intake would be both interesting and useful, it was clear from the co-design process that this would be potentially too laborious and off-putting for patient participants.

4.6. Feel Well module

The Feel Well module aims to allow patients to track and reflect on their mood prior to surgery and provides guidance on how to manage acute stress and anxiety that may develop in the preoperative period. It is distinct from the other iPREPWELL modules in the emphasis on more passive observation of mood and psychological wellbeing rather than intervention. This reflects the findings of the co-design process that revealed patients may find direct intervention and detailed monitoring of progress counterproductive. Table 5.5 maps the module against the TIDieR checklist.

Table 4.5. Feel Well module TIDieR checklist

Checklist item	Description
1. Brief Name Provide the name or a phrase that describes the intervention.	• Feel Well module component of iPREPWELL digitally facilitated, remotely supervised multibehavioural prehabilitation programme
2. Why Describe any rationale, theory or goal of the elements essential to the intervention	• Feel Well is offered to all iPREPWELL users with the expectation that the majority of patients preparing for major surgery are likely to experience some degree of increased preoperative anxiety or stress. • Feel Well encourages a daily mood 'check-in' and reflection on factors that may be influencing current mood. • Targeted intervention for specific psychological morbidity e.g. depression is beyond the scope of the module which instead signposts to other online resources e.g. cognitive behavioral therapy. • Techniques are provided for managing acute episodes of stress and anxiety in the form of mindfulness techniques and signposting to more extensive resources should participants find these beneficial. • Module mechanics were influenced directly by the systematic co-design and development process.
3. What (Materials) Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention delivery or in training of intervention providers.	• Feel Well is delivered within the iPREPWELL progressive web application as detailed in table 4.1. The module and is structured around audiovisual material guided by informational needs identified in the co-design process.

Provide information on where materials can be accessed (e.g. online appendix, URL).	
4. What (Procedures) Describe each of the procedures, activities and/or processes used in the intervention inlcuding any enabling or support activities	• Feel Well is accessed from the iPREPWELL dashboard • Participants engage with audio-visual content covering the 'why and how' of Feel Well. The importance of observing, acknowledging, and accepting changes in mood (good or bad) is emphasised • Audio-visual guidance is provided to undertake brief mindfulness sessions to apply in moments of acute stress and anxiety • Participants are encouraged to track their mood using simple 0-10 Likert scales derived from the Ottawa mood scales(368) considering: o Overall mood o Stress o Worry and anxiety • These scales are supported by an optional journaling tool to reflect on mood. • Participants are shown a visual representation of trends in mood in each week and over the course of the programme within the weekly report. • The module signposts to external resources that can provide more in-depth support for specific issues beyond the scope of the module and programme. E.g., more extensive mindfulness and meditation resources and online cognitive behavioural therapy.
5. Who provided	• The supporting iPREPWELL HCP team will support Feel Well via the mechanisms detailed above in table 4.1.

For each category of intervention provider, describe their expertise, background and any specific training given	• Health and clinical psyhologists are likely to support other HCP team members in the delivery of this module.
6. How Describe the modes of delivery (e.g. face-to-face or by some other mechanism , such as internet or telephone) of the intervention and whether it was provided individually or in a group	• Mode of delivery of Feel Well is that of the general iPREPWELL programme.
7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	• Patients utilise the module in and around their own home.
8. When and how much Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	• The module is intended to run with the main programme over a minimum 4 weeks and continue until surgery. • Daily interaction to track mood is encouraged.

9. Tailoring If the intervention was planned to be personalised, titrated or adapted the describe what, why, when and how.	• Feel Well does not adapt or tailor to individual patients

Feel Well aims to help participants track, acknowledge, and accept changes in psychological wellbeing before surgery in a non-judgemental and supportive manner. As a result of the co-design process, formal goals and targets for this module are omitted in favour of neutral observation. There was a clear need identified for techniques and strategies to manage moments of acute stress and anxiety with guidance for brief mindfulness techniques included. The design acknowledges that some patients will experience significant psychological distress perioperatively. This may be acute or chronic with existing psychiatric morbidity (e.g., established depressive or anxious disorders). Identifying an appropriate monitoring mechanism proved challenging with no leading tools in the perioperative context that also met the co-design requirements of speed and ease of use. The Ottawa mood scales have been validated in children undergoing surgery and their parents (368) and were adapted here to include the three items relating to overall mood, anxiety and stress most relevant to the programme needs. Mood tracking will allow facilitating HCPs to note this with reference to registration metrics relevant to the module (HADS and PAM) and signpost to more intensive support e.g., online CBT resources or onward referral to clinical psychology support. The qualitative feedback of feasibility study participants will be key to development of this module going forward and may identify routes for further ‘direct’ psychological intervention using the programme. In addition, it is suspected that engagement and progress with other programme modules may lead to synergystic improvements in psychological wellbeing.

4.7. iQuit module

iQuit aims to remotely support smoking cessation prior to surgery. As a result, it likely faces the most difficult task of the programme modules given the problems acknowledged in supporting smokers to quit preoperatively described in chapter 1. Table 4.6 presents the module TIDieR checklist.

Table 4.6. iQuit module TIDieR checklist

Checklist item	Description
1. Brief Name Provide the name or a phrase that describes the intervention.	• iQuit module component of iPREPWELL digitally facilitated, remotely supervised multibehavioural prehabilitation programme
2. Why Describe any rationale, theory or goal of the elements essential to the intervention	• iQuit is offered to iPREPWELL users actively smoking on registration. • iQuit aims to deliver the 'behavioural' element of a smoking cessation programme and link patients to local cessation services to combine this with nicotine replacement therapy providing the elements of a gold standard cessation programme(208, 210). • Module mechanics were influenced directly by the systematic co-design and development process.
3. What (Materials) Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention delivery or in training of intervention providers. Provide information on where materials can be accessed (e.g. online appendix, URL).	• iQuit is delivered within the iPREPWELL progressive web application as detailed in table 4.1. The module and is structured around audiovisual material guided by informational needs identified in the co-design process and the content of brief interventions for smoking cessation.
4. What (Procedures) Describe each of the procedures, activities and/or processes used in the intervention inlcuding any enabling or support activities	• iQUIT is accessed from the iPREPWELL dashboard • Cessation is set as the default goal for all module users • Participants engage with audio-visual content covering the 'why and how' of iQuit.

	• Content mirrors the brief intervention behavioural consultation and provides strategies for progressing to full cessation, dealing with cravings and the multiple advantages of cessation above and beyond perioperative outcomes e.g., financial savings
	• Participants use single tap/click icons to track the following metrics daily guided by the co-design process:
	  o Number of cigarettes smoked
	  o Smoke free days
	  o Whether nicotine replacement was used
	  o Whether they contacted their smoking cessation service
	• A journaling tool is also incorporated to help participants reflect on difficult days or relapses that may occur
	• Smoking cessation services are heavily signposted. iQuit allows participants to trigger an automatic referral to their local service by email within the module. This is supported by HCP facilitators/prompters on check-in.
	• Participants are shown a visual representation of progress in each week and over the course of the programme within the weekly report.

5. Who provided For each category of intervention provider, describe their expertise, background and any specific training given	• The supporting iPREPWELL HCP team will support iQuit via the mechanisms detailed above. • If participants opt for self-referral to smoking cessation they may interact with smoking cessation counsellors as part of the module.
6. How	• Mode of delivery of Feel Well is that of the general iPREPWELL programme.

Describe the modes of delivery (e.g. face-to-face or by some other mechanism , such as internet or telephone) of the intervention and whether it was provided individually or in a group	
7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	• Patients utilise the module in and around their own home. • The Patient may attend a community-based face-to-face service if they agree to self-referral.
8. When and how much Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	• The module is intended to run with the main programme over a minimum 4 weeks and continue until surgery. • Daily interaction to track smoking behaviour is encouraged.
9. Tailoring If the intervention was planned to be personalised, titrated or adapted the describe what, why, when and how.	• iQuit does not adapt or tailor to individual patients

iQUIT ultimately aims to replicate the components of a face-to-face smoking cessation consultation via its audio-visual content and link participants to accompanying nicotine replacement therapy. It is distinct from other modules in being the least self-contained and it is anticipated that encouraging participants to contact and attend their local cessation provider will be critical to success in effecting behaviour change. The module therefore conflicts with DCE findings for 'integration with local services' programme attribute in chapter 2, where participants indicated a preference for support that could be delivered fully in and around the home. However this attribute held low relative importance overall and the weight of evidence for the importance of preoperative access to nicotine replacement to support quitting attempts drove this decision(211). The evidence base also drove the decision to make cessation a default goal for all module users rather than include a progressive goal system including 'cutting down'. Full cessation is key to yielding greatest benefit in available preoperative timeframes(210).

The tracking metrics utilised are also not previously utilised or derived from and existing tool and have been designed as simple, low burden mechanics that co-design participants indicated would be acceptable to engage with daily. These metrics are intended to generate the sense of momentum and progress toward cessation that participants indicated would be necessary to help overcome setbacks and tackle this challenging health behaviour. Similarly, a journaling tool is incorporated to help participants reflect on why setbacks and relapses may have happened, supporting by non-judgemental prompting and HCP facilitator input.

4.8. Drink Guide module

Drink Guide aims to support patients who drink alcohol to maintain their weekly alcohol intake below the higher perioperative risk threshold of 14 units per week before surgery. The intervention is derived from the successful face-to-face pre-op BIRDS intervention(219) utilised to achieve the same goal in patients prior to major joint surgery and has been adapted for digital remotely supervised delivery within iPREPWELL. Table 4.7 describes Drink Guide against the TIDieR checklist.

Table 4.7. Drink Guide module TIDieR checklist

Checklist item	Description
1. Brief Name Provide the name or a phrase that describes the intervention.	• Drink Guide module component of iPREPWELL digitally facilitated, remotely supervised multibehavioural prehabilitation programme
2. Why Describe any rationale, theory or goal of the elements essential to the intervention	• Drink Guide is offered to iPREPWELL users who drink alcohol on registration. • The module aims to guide an alcohol intake of no more than 14 units per week in the approach to surgery to minimise the perioperaitve risk of alcohol consumption. • Drink Guide aims to deliver the pre-op BIRDS intevention (219) modified for digital delivery and more remote supervision 'behavioural' with module mechanics influenced by the systematic co-design and development process.
3. What (Materials) Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention delivery or in training of intervention providers. Provide information on where materials can be accessed (e.g. online appendix, URL).	• Drink Guide is delivered within the iPREPWELL progressive web application as detailed in table 4.1. The module and is structured around audiovisual material guided by informational needs identified in the co-design process and the content of preop BIRDS.
4. What (Procedures)	• Drink Guide is accessed from the iPREPWELL dashboard • Keeping weekly intake to 14 units or less is set as the default goal for all module users • Participants engage with audio-visual content covering the 'why and how' of Drink Guide

Describe each of the procedures, activities and/or processes used in the intervention inlcuding any enabling or support activities	• Content mirrors the preop BIRDS intervention and replicates the 6-step tool for goal setting and planning: 1. Step 1 – Identify good reasons for change (include pros and cons) 2. Step 2 – Set your goals 3. Step 3 – Recognise difficult times 4. Step 4 – Prepare for difficult times 5. Step 5 – Find support 6. Step 6 – Stick to your goals • Patients use single tap/click icons to record daily consumption. Icons correspond to different types of alcoholic drinks to automatically calculate unit intake per day. • Patients are encouraged to intentionally plan their intake over the week • A journaling tool is also incorporated to help patients reflect on difficult days or relapses that may occur • Participants are shown a visual representation of progress in each week and over the course of the programme within the weekly report. • A high Audit-10 score at registration is flagged to facilitating HCPs allowing signposting to more intensive support e.g., dedicated alcohol services for patients exhibiting features of dependency.
5. Who provided For each category of intervention provider, describe their expertise, background and any specific training given	• The supporting iPREPWELL HCP team will support Drink Guide via the mechanisms detailed above. • If patients require and engage with alcohol servcies they may interact with counsellors as part of the module.

6. How Describe the modes of delivery (e.g. face-to-face or by some other mechanism , such as internet or telephone) of the intervention and whether it was provided individually or in a group	• Mode of delivery of Drink Guide is that of the general iPREPWELL programme.
7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	• Patients utilise the module in and around their own home. • The patient may attend specialist alcohol sevices if they agree referral.
8. When and how much Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	• The module is intended to run with the main programme over a minimum 4 weeks and continue until surgery. • Daily interaction to track alcohol intake is encouraged.
9. Tailoring If the intervention was planned to be personalised, titrated or adapted the describe what, why, when and how.	• Drink Guide does not adapt or tailor to individual patients

Drink Guide is advantaged compared to other modules by availability of an existing similar brief intervention already validated in the preoperative setting(219). The pre-op BIRDS framework was readily adapted in line with co-design findings to structure the module. Goal setting is participant led and directed toward moving below 14 units per week. Complete abstinence from alcohol is not encouraged in favour of moderation. As with prior modules, simple tracking mechanisms were designed to help patients easily log their alcohol intake and understand their intake patterns. Content is offered to all patients who drink alcohol regardless of intake at registration as the content may be interesting and the possibility raised during co-design that increased alcohol intake may be used as a coping mechanism preoperatively. In addition, it was acknowledged that some patient with very high consumption may require more intensive support from specialist services, with the AUDIT-10 tool incorporated as a screening tool at registration and HCP facilitators able to identify patients scoring highly to signpost support.

4.9. Sleep Well module

Given the lack of specific evidence for preoperative sleep health intervention discussed in chapter 1, sleep well was designed entirely from co-design process findings aiming to help patients achieve more consistent and better-quality sleep before surgery. It is described using the TIDieR checklist in table 4.8.

Table 4.8. Sleep Well Module TIDieR checklist

Checklist item	Description
1. Brief Name Provide the name or a phrase that describes the intervention.	• Sleep Well module component of iPREPWELL digitally facilitated, remotely supervised multibehavioural prehabilitation programme.
2. Why Describe any rationale, theory or goal of the elements essential to the intervention	• Sleep Well is offered to all iPREPWELL users. There is a lack of data on poor sleep health in surgical populaitons but population prevalence is reported to be high(228) • The module aims to guide a structured approach to improved sleep hygeine and strategies for managing difficulties around sleep. • Module content and mechanics were based entirely on the systematic co-design and development process.
3. What (Materials) Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention delivery or in training of intervention providers. Provide information on where materials can be accessed (e.g. online appendix, URL).	• Sleep Well is delivered within the iPREPWELL progressive web application as detailed in table 4.1. The module and is structured around audiovisual material guided by informational needs identified in the co-design process.
4. What (Procedures)	• Sleep well is accessed from the iPREPWELL dashboard • Formal goal setting is avoided as co-design indicated this may be counter productive • Participants engage with audio-visual content covering the ‘why and how’ of Sleep Well

Describe each of the procedures, activities and/or processes used in the intervention inlcuding any enabling or support activities	• Content encompasses the principles of sleep hygiene and strategies to help fall asleep more easily, prevent wakening and how to get back to sleep on waking • Participants are encouraged to create a personal sleep hygiene protocol to follow. • Patients are encouraged to use a daily 3-item Likert scale derived from the Richards-Campbell sleep scale validated in ICU populations(369) to monitor their sleep quality. The items utilised are: o Overall quality of sleep o Difficulty getting to sleep o Amount of wakening overnight • A journaling tool is also incorporated to help patients reflect on sleep hygiene factors and their impact. • Participants are shown a visual representation of progress in each week and over the course of the programme within the weekly report.
5. Who provided For each category of intervention provider, describe their expertise, background and any specific training given	• The supporting iPREPWELL HCP team will support Sleep Well via the mechanisms detailed above.
6. How Describe the modes of delivery (e.g. face-to-face or by some other mechanism , such as internet or telephone) of the intervention and	• Mode of delivery of Sleep Well is that of the general iPREPWELL programme.

whether it was provided individually or in a group	
7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	• Patients utilise the module in and around their own home.
8. When and how much Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	• The module is intended to run with the main programme over a minimum 4 weeks and continue until surgery. • Daily interaction to monitor sleep health is enocuraged.
9. Tailoring If the intervention was planned to be personalised, titrated or adapted the describe what, why, when and how.	• Sleep Well does not adapt or tailor to individual patients

Sleep well is designed to meet the needs of patients indicated in the co-design process forming a simple sleep hygiene advice and intervention incorporating equally simple tracking metrics. The scale utilised was chosen as the closest validated tool available and modified for use in a preoperative population (e.g., removing items relating to ICU noise affecting sleep). This module was seen as the least immediately relevant to co-design participants however their views on how it should be delivered were informative. The subsequent degree of engagement with this module by feasibility study participants will be an interesting study outcome.

4.10. Summary

This chapter aimed to describe the iPREPWELL programme design resulting from the DCE findings in chapter 2, co-design process in chapter 3 and reference to the existing evidence base for prehabilitation. The programme is described prospectively using the TIDieR framework representing the intervention that will now go on to be feasibility tested. This study is described in chapter 5.

5. Chapter 5: Planned feasibility testing of the iPREPWELL multibehavioural digital prehabilitation programme

Chapter 3 presented the co-design process for a multibehavioural, digitally facilitated and remotely supervised prehabilitation programme (iPREPWELL). The programme prototype is presented in chapter 4. The next step in the systematic intervention development process is feasibility testing in two NHS surgical centres. This will be a single-arm, mixed methods feasibility study aiming to assess feasibility and acceptability of the intervention in patients preparing for major surgery and healthcare professionals promoting and supporting its delivery at those centres. This chapter presents the design, rationale, and methods of the planned feasibility study.

The planned study will fulfil dual purposes in the systematic intervention development process. Firstly, the study will contribute to implementation decisions around incorporated behaviour change techniques and modes of delivery of intervention functions, informing Behaviour Change Wheel Stage 3 (344, 347). Secondly, this study aligns with MRC guidance for complex intervention design(247), representing the necessary 'feasibility' phase between 'development' (Chapter 3) and 'evaluation'. Although the planned study is a single-arm feasibility design, it has been benchmarked and check listed against the SPIRIT guidelines for clinical trial protocols(370)

Material throughout this chapter has been reproduced from the study protocol manuscript (Durrand et al 2022)(371) This is currently an open access article that is licensed under a Creative Commons Attribution but is now in press with PLOSone, the peer reviewed submitted manuscript is presented in appendix 7.

5.1. Planned study aims and objectives

5.1.1. Study aims

1. Assess the feasibility, acceptability, and fidelity of the iPREPWELL programme for patients approaching major surgery and supporting HCPs
2. Assess adherence to, and completion of, the overall programme and the component health risk behaviour elements alongside engagement with supporting HCPs
3. Assess the feasibility, acceptability, and fidelity of delivery and receipt of programme training for supporting HCPs

5.1.2. Study objectives

1. Conduct a qualitative process evaluation with participants (patient and HCPs) to identify key determinants of programme uptake, engagement, adherence and completion.
2. Develop a set of implementation strategies with stakeholders to facilitate future implementation of the intervention should it demonstrate feasibility and acceptability.
3. Generate estimates of variability for behavioural outcomes in participants (e.g., changes in physical activity) and outcomes measures (e.g., quality of life) to inform a sample size calculation for a future randomised controlled trial should feasibility be demonstrated.
4. Undertake a preliminary cost evaluation of the intervention.

5.2. Planned methods

5.2.1. Ethical and regulatory approvals

Full ethical approval for this study has been obtained by substantial amendment to the approval obtained for the stage 1 development work presented in chapter 4. Copies of those additional approvals are presented in appendix 17. The proposed study is therefore also registered on the NIHR portfolio for anaesthesia, perioperative medicine, and pain (APOMP) allowing study support from site clinical research teams and has been prospectively registered on ISRCTN (ISRCTN17788295 https://doi.org/10.1186/ISRCTN17788295).

5.2.2. Study timeframes

Study recruitment is planned over an 8-month period with follow-up and analysis over a subsequent 4 months.

5.2.3. Study setting and participating sites

The study will be conducted at the James Cook University Hospital (South Tees Hospitals NHS Foundation Trust) and York Hospital (York and Scarborough Teaching Hospitals NHS Foundation Trust). These sites hosted the co-design process. The centres offer a diverse range of surgical specialties, serve populations across geographically wide catchments, and socioeconomically diverse catchments. Both centres are actively engaged in face-to-face prehabilitation support with prehabilitation an accepted component of several surgical pathways.

5.2.4. Eligibility criteria

The planned study will recruit patient participants preparing for major surgical intervention, and healthcare professionals from perioperative teams at the participating sites who facilitate the programme. Study inclusion and exclusion criteria for patient and HCP participants are presented in table 6.1.

Table 5.1: Study inclusion and exclusion criteria

Patient participant inclusion criteria	
Criterion	**Justification and rationale**
Adult patient (Age ≥18 years)	In keeping with the DCE study in chapter 2, a representative age range of patient participants that reflect those undergoing major surgery in the UK will be sought. Younger adults will not be excluded due to their potential to benefit from use of a digital prehabilitation programme, and because they may have different viewpoints on the use of a digital intervention compared to older patients. Obtaining a range of participant perspectives is important to support feasibility assessment across a broad spectrum of patient age groups
Scheduled for a NICE 'Major/complex' category procedure in one of the following specialties: • Colorectal surgery	NICE NG45(3) will be used to guide identification of a 'major/complex' procedure. iPREPWELL is intended to be 'multi-specialty' for integration into several pathways and offering potential for later tailoring and optimisation for subspecialty groups if feasibility and 'proof of concept' are demonstrated here. Consequently, a range of

• Upper gastrointestinal surgery • Vascular surgery • Urological surgery • Gynaecological surgery • Orthopaedic surgery	specialties are eligible for inclusion representing a broader 'major non-cardiac' group of specialties. Notable exclusions are: Cardiac surgery where, despite a growing body of evidence for the safety of preoperative exercise in the context of significant coronary artery and valvular pathology, the need for remotely supervised exercise in the developed programme is felt to carry too high a risk. Thoracic, neurosurgical and breast surgery patients are also excluded due to anticipated short preoperative timeframes for future intervention use.
American society of anaesthesiology (ASA) grade ^{3}2	This criterion aims to include participants with scope to benefit from prehabilitation support. ASA 1 patients would represent the 'fittest' subgroup of patients listed for major surgical intervention. These patients are likely to have narrow scope for enhancement of their health and wellbeing prior to surgery to modify their perioperative risk or a ceiling effect.
At least one health risk behaviour amenable to prehabilitation by iPREPWELL	This criterion ensures recruited patient participants will find the programme content relevant to their needs for improved preoperative health and wellbeing.
A minimum of 4-weeks of time available prior to surgery	iPREPWELL has been developed to support patients with this minimum time window available to effect preoperative health behaviour change. It is acknowledged the consented participants may, for clinical reasons and service pressures receive an expedited surgery date leading to a shorter period of programme use. This will be a key finding in terms of

	feasibility of programme use in ‘real’ NHS surgical pathways.
Able to understand spoken and written English.	As described in chapter 4, the co-designed programme informational content was guided by patient participants with a good understanding of written and spoken English. This is a current limitation of the programme but requires that the same inclusion criteria are applied for feasibility testing at present.

Patient participant exclusion criteria

Criterion	**Justification and rationale**
Unable to provide informed consent	As an initial feasibility study conducted with remote supervision it was felt to be potentially unsafe recruit participants unable to consent independently. Given their absence from the co-design process, it was also expected that iPREPWELL may not currently cater for their needs
Pregnancy or planned pregnancy	There is currently insufficient data around the provision of safe prehabilitation support to this patient subgroup, particularly structured exercise training under remote supervision
Severe mental illness under investigation or active treatment	This patient subgroup is likely to require a more intensive level of preoperative support and supervision to address their mental and psychological health and wellbeing than can be provided by iPREPWELL presently.

Engaging with or a preference for an alternative prehabilitation model (e.g., face-to-face service)	To avoid confounding of any observed health risk behaviour change, participants engaging in or expressing a preference for an alternative prehabilitation support model will be excluded. This is also a pragmatic decision as both participating sites offer face-to-face services. It is intended that allowing iPREPWELL to be offered and tested alongside other prehabilitation methods will add to external validity of the study findings. How this study performs in terms of recruitment and uptake of the programme when alternatives are also available is relevant to future implementation.
Healthcare professional participant inclusion criteria	
Team members employed by participating Trusts from a medical, nursing, or allied healthcare professional background involved in the perioperative care of patients preparing for major surgery willing to take part in training and support programme delivery	Reflecting the diverse group of healthcare professionals involved in programme design it is intended that the wider facilitating team of HCPs involved in surgical pathways at the participating sites can participate in training and undertake both promotion and facilitation of the programme.

Patient participants deemed unsafe for remotely supervised exercise (based on national criteria for perioperative exercise testing and training(141)), who would like to participate, will be offered access to the programme without exercise and physical activity components. This is to prevent exclusion of patients with other health risk behaviours who may stand to benefit from engaging with other programme elements.

5.2.5. Sampling strategy

As a single arm feasibility study, patient participants will be recruited consecutively from both participating sites with a target sample size of 40. This number is in line with published guidance for pilot and feasibility studies(372), is considered sufficient to address the study aims and objectives and accounts for a potential dropout rate of 20%. Individual site recruitment targets have not been pre-specified, but it is anticipated that a greater proportion of patient participants will be recruited from James Cook University Hospital, reflecting the larger volume of major surgery undertaken however no formal stratification by site will be undertaken.

A team of HCP participants will be recruited from perioperative teams at both sites to promote and facilitate the programme with the support and backing of the study team. Participants will undergo training to promote and utilise iPREPWELL with patients as part of their study involvement. A HCP participant sample size has not been pre-specified acknowledging current pressures on perioperative services illustrated and emphasised by HCP co-design group members in stage 1, however a minimum of 3-4 HCP participants are likely to be required at each site to facilitate the programme. HCP participation rate will be a key finding relating to feasibility of implementation.

5.2.6. Planned Recruitment and consent

REC and HRA approved Patient and HCP Participant information sheets and accompanying consent forms have been developed with reference to HRA guidance: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/ and http://www.hradecisiontools.org.uk/consent/content-sheet.html

5.2.6.1. Patient participants

Patients listed for major surgery will be screened for eligibility by perioperative teams utilising electronic hospital records. Potential participants will be approached by telephone to explore interest. Those interested will be given a patient PIS sent by post or email. Interested patients will receive a follow-up telephone call by a team member within 7 days allowing time to receive, read and understand the study information and consider participation. Those who would like to participate will be invited to undertake the screening and baseline assessment (visit 1) where they will be given an opportunity to ask questions and complete a consent form with a study team member. Patients who decline participation at that stage will undergo routine preoperative care and their reason for non-participation will be recorded if they elect to provide one.

5.2.6.2. Healthcare professional participants

Perioperative team members at each site will be contacted by email inviting them to take part in the study with a follow-up after 7 days providing time to consider participation. The email will provide a HCP PIS and those who are interested in taking part will complete a consent form with a study team member and be invited to begin the intervention HCP training package as the first step to engaging in programme promotion and facilitation.

5.2.7. Intervention

Patient participants will utilise the iPREPWELL programme and its health behaviour content for a planned minimum of 4 weeks or until surgery. The programme structure and content are fully detailed in chapter 4. Healthcare professionals will complete the intervention training package before promoting, facilitating and overseeing the intervention with participants as detailed in chapter 4.

5.2.8. Outcome measures

5.2.8.1. Primary outcomes

Feasibility, fidelity, and acceptability have been prioritised as primary outcome measures given the objectives of this study.

- **Feasibility:**

Feasibility will be determined through assessment of participant recruitment and retention rates, time taken to recruit to the target sample size, and rates of programme uptake and completion, including number of patients completing all relevant elements of iPREPWELL.

Feasibility of the training intervention will be determined by assessing HCP participant recruitment and retention rates, and rates of training intervention uptake and completion, including willingness to refer participants to the programme and engagement in support of patient participants utilising iPREPWELL.

- **Fidelity:**

Fidelity of delivery will be assessed by collecting data relating to intervention usage by patient participants, including when components were accessed, revisited, and for what length of time. Fidelity of receipt and enactment will be assessed qualitatively via semi-structured interviews with patient participants (see below).

Fidelity of delivery of the training intervention will be assessed by audio recording delivery of the training to ensure all intervention components are delivered per protocol using an intervention fidelity checklist(373). Fidelity of receipt and enactment will be assessed qualitatively via semi-structured interviews with HCP participants (see below).

- **Acceptability:**

Acceptability will be assessed quantitatively and qualitatively. In terms of patient participants, data will be collected on the number of logins over the intervention period and the number of interactions with facilitating HCP participants. In terms of HCP participants, data will be collected on the number of HCPs who consent to take part in the study and undertake training and who complete training. Semi-structured interviews using the TDF as an analysis framework will obtain participant views and experiences of iPREPWELL, including their experiences of interaction, perceived barriers, and facilitators to utilising it and suggestions for ways in which it could be further improved.

5.2.8.2. Secondary outcomes

Secondary outcome measures will be broadly divided into observed health behaviour change incorporating both subjective and objective assessments and perioperative outcomes measures. Measures were selected with reference to ongoing work around a core outcome set for prehabilitation studies and prior work determining measures for anaesthesia and perioperative care more widely(367). The feasibility and sensitivity of data collection for these outcome measures will be explored to identify candidate primary outcome measures for a potential future efficacy study evaluating iPREPWELL. These measures and their rationale for inclusion are presented in table 5.2.

Table 5.2. Secondary outcome measures

Physical and mental health and wellbeing outcomes		
Physical activity, exercise, and functional capacity	• International physical activity questionnaire (IPAQ) short form • 6-minute walk test (6MWT) • 30 second sit-to-stand test • Grip strength • Maximum inspiratory pressure	Acknowledging the limitations of subjective physical activity reporting as demonstrated in the METS study(374) a combination of subjective and objective measures have been selected. The IPAQ short form is a brief, easily completed and validated tool for subjective assessment of change in activity levels(375). The 6MWT is a validated(376) and pragmatic and widely utilised outcome to evaluate change in aerobic capacity, familiar to both participating sites. Cardiopulmonary exercise testing would represent a gold standard tool in this setting, however additional testing for research purposes is beyond the limit of study resources. 60 second sit to stand(377) and grip strength testing(378, 379) were included to evaluate change in muscular strength and stamina, both representing validated clinical tests readily deliverable at the bedside. Finally maximum inspiratory pressure is utilised to prescribe inspiratory muscle training and is a metric to track changes in strength of the muscles of breathing in response to IMT.
Smoking	• Smoking status	Smoking status will be recorded in a binary format and in terms of cigarettes smoked to evaluate the impact of iQUIT. The Fagerstrom score(380) will also be utilised at entry to evaluate nicotine dependence in participants who smoke.

Alcohol consumption	• Alcohol intake • AUDIT-10 questionnaire	Change in alcohol intake quantified in units will be assessed in addition to change in the AUDIT-10 questionnaire as a validated tool(381) to identify features of hazardous intake in participants who drink alcohol.
Nutritional status	• Patient guided subjective global assessment (PG-SGA) short form • Malnutrition universal screening tool (MUST) • Dana Faber Cancer Institute healthy eating questionnaire (personal dietary assessment domains) • Body mass Index • Body composition (bioimpedance)	Nutritional status is multifaceted and complex to assess requiring a combination of subjective measures and objective clinical and biochemical assessments. The MUST(382) is a validated and well-established malnutrition screening tool in UK practice, however it is predominantly utilised for inpatients and has been combined with the PG-SGA short form(383) to provide comprehensive screening and tracking. The EatWell component seeks to support dietary changes as a route to improved nutritional status. The Dana Farber eating habits questionnaire will be used to record dietary habits. Nutritional status will be objectively assessed using BMI and bioimpedance to evaluate body composition and changes in fat free body mass in response to exercise training. Finally, where routinely available, HBA1c and CRP changes will be recorded as surrogates for systemic inflammation, glycaemic control, and hyperinsulinemia.
Sleep health	• Pittsburgh Sleep Quality Index	There are no validated tools for perioperative sleep quality assessment. The Pittsburgh index is an established tool that has demonstrated reliability and validity in multiple allied clinical settings(384). Use here will allow assessment of feasibility in a perioperative population

Psychological health and wellbeing	• Patient Activation Measure (PAM) • Hospital Anxiety and Depression scale (HADS)	The key psychological health traits associated with poorer perioperative outcomes are: Low self-efficacy, Anxiety, and depression. These validated tools have been selected to track these characteristics and the impact of both the FeelWell component and use of the wider programme on psychological health. The HADS score has been utilised in multiple perioperative settings(128, 385) with the PAM now adopted by NHS England as a self-efficacy metric(190, 191)
Perioperative outcome measures		
Mortality	• Alive at hospital discharge • 30-day mortality	Mortality at two timepoints will be collected.
Morbidity	• Comprehensive Complication index (CCI) at discharge	The CCI provides a validated global assessment of incidence of perioperative morbidity to capture complication incidence and severity(60)
Length of stay	• Length of hospital stay • Length of critical care stay	Length of stay will be monitored directly as a key patient and system outcome measures and potential future primary outcome for efficacy testing.
Readmissions	• Days at home post-surgery (DAH_{30})	This is an emerging patient-centred outcome measure capturing readmission with increasing utilisation in perioperative literature(386). The DAH_{30} would also be a candidate future primary outcome.

Quality of life	• EQ-5D-5L • SF-36 v2	Quality of life is a key outcome measure and forms the basis of the exploratory health economic analysis, both tools listed are established in this role.(387, 388)

5.2.8.3. Wearable data and utilisation

Semi-structured interviews will qualitatively assess feasibility and usability of the integrated wearable device in support of programme components. Perioperative biometric data will be collected for exploratory descriptive analysis as detailed below.

5.2.9. Patient participant study activities and data collection

Following screening, enrolment and provision of informed consent, patient participants will utilise iPREPWELL until surgery, with access provided for up to 3 months postoperatively. They will receive continuous support from HCP participants and study team with scheduled fortnightly contact as a minimum, as indicated by findings in chapter 2. This will be punctuated by three schedule study visits. The patient participant journey is summarised in Figure 6.1.

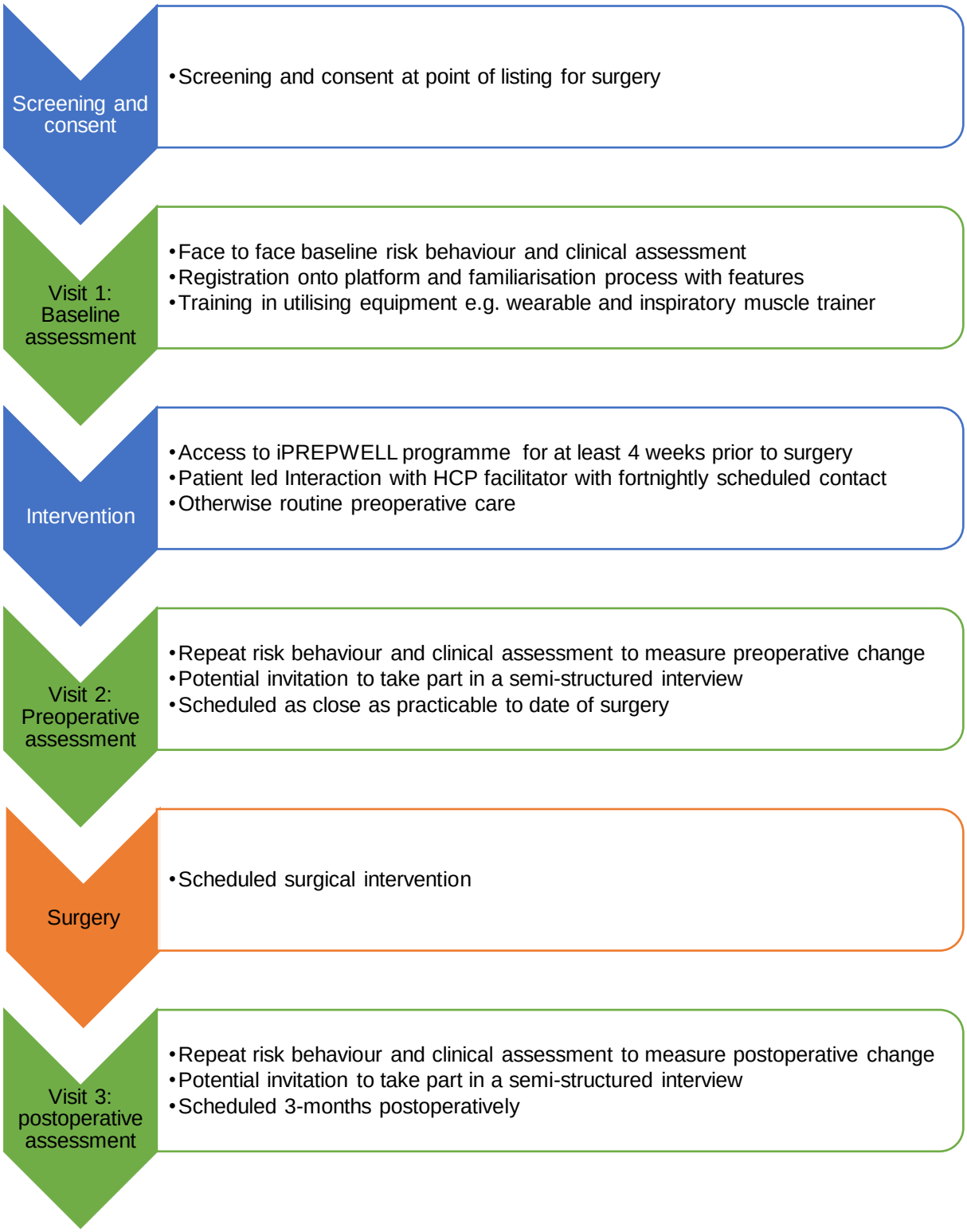

Fig 5.1. Patient participant journey

5.2.10. Summary of study visits and data collection

Planned data collection at each stage is summarised in the schedule presented in table 6.3, structured in accordance with SPIRIT guidance for clinical trials(370).

Table 5.3. Study SPIRIT schedule of enrolment, interventions, and assessments

	Enrolment	Post-allocation			Closeout
Timepoint		**T1 Post-enrolment**	**T2 Pre-operative**	**T3 3-months post-operative**	
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
INTERVENTIONS:					
Access to iPREPWELL digital prehabilitation programme (all patient participants)		♦———	———	———♦	
ASSESSMENTS:					
Safety assessment for remotely supervised exercise	X				
Demographics (name, age, biological sex, postcode, and preferred contact)		X			
Clinical assessments					
Comorbidities		X			
Rockwood clinical frailty scale (CFS)		X			
Planned/actual Date of operation		X	X	X	
Surgical Specialty		X			
Planned/actual procedure		X	X	X	

Resting heart rate (beats.min^{-1})		X	X	X	
Resting blood pressure (mmHg)		X	X	X	
Resting oxygen saturation SPO2 (%)		X	X	X	
Stature (m)		X			
Chemoradiotherapy status		X			
Health risk behaviour assessments					
Smoking					
Smoking status (number of cigarettes)		X	X	X	
Fagerstrom score		X			
Alcohol					
Consumption (units of alcohol)		X	X	X	
AUDIT (if >14 units per week)		X	X	X	
Physical activity and exercise capacity					
International Physical Activity Questionnaire (IPAQ) Short form		X	X	X	
ARISCAT score		X			
6-minute walk test (m)		X	X	X	
30 second sit-to-stand test (Repetitions)		X	X	X	
Grip strength (kg)		X	X	X	
Maximum inspiratory pressure (cmH_2O)		X	X	X	
$\dot{V}O_2$ peak (ml.kg^{-1}.min^{-1}) if routinely collected		X	X		
$\dot{V}O_2$ Anaerobic threshold (AT) (ml.kg^{-1}.min^{-1}) if routinely collected		X	X		
VE/VCO_2 at anaerobic threshold if routinely collected		X	X		

Diet and nutrition status					
Dana Faber Cancer institute eating habits questionnaire (personal dietary assessment domains)		X	X	X	
Malnutrition universal screening tool (MUST)		X	X	X	
Patient Generated – Subjective Global Assessment (PG-SGA)		X	X	X	
Body mass (kg)		X	X	X	
Body mass index (BMI)		X	X	X	
Body composition (FM/FFM%)		X	X	X	
Glycosylated haemoglobin (HbA1C) (recorded if routinely collected) (mmol/mol)		X	X	X	
CRP (record if routinely collected) (mg/L)		X	X	X	
Sleep health					
Pittsburgh sleep quality index (PSQI)		X	X	X	
Psychological health and wellbeing					
Patient activation measure (PAM)		X	X	X	
Hospital Anxiety and Depression Scale (HADS) Anxiety		X	X	X	
Hospital Anxiety and Depression Scale (HADS) Depression		X	X	X	
Quality of life assessments					
Quality of Life (EQ-5D-5L)		X	X	X	
Quality of Life (SF-36 v2)		X	X	X	
Perioperative outcome measures					

Alive at hospital discharge				X	
30-day postoperative mortality				X	
Comprehensive complication index (CCI) at hospital discharge				X	
Days at home post-surgery (DAH_{30})				X	
Length of hospital stay (days)				X	
Length of critical care stay (days)				X	
Qualitative assessments					
60-minute semi-structured interview		⟷	⟷	⟷	

Data will be collected, where possible, as an e-CRF within iPREPWELL supported by a research eCRF hosted by REDCap (www.projectredcap.org). Completion will be scheduled as part of intervention utilisation, e.g., the registration stage will populate e-CRF1 data. Data will be entered by patient participants, with additional data input by HCP participants and study team members, where appropriate. Additional data will be collected using iPREPWELL analytics on intervention utilisation, e.g., number of logins, duration of session, completion of individual intervention components, and information entered by participants during intervention usage.

5.2.10.1. Study visit 1 (screening and baseline assessment)

Patient participants will attend their recruiting site to undergo the baseline assessment process. This involves screening for remotely supervised exercise based on ACSM guidance, enrolment, and registration onto iPREPWELL and accompanying wearable technology for patients wishing to utilise it. The assessment will combine clinical, health behaviour and exercise capacity elements as detailed in table 3. It will be conducted by a facilitating HCP participant and at least one study team member. The methods for physical activity and exercise capacity assessments are detailed in table 6.4. Following visit 1, patient participants will begin utilising iPREPWELL at home with remote support by the HCP participant and study team.

Table 5.4. Clinical assessment methods and assessments of exercise and functional capacity

Clinical assessment methods	
Stature (m)	Standard outpatient clinical measurement
Body mass (kg)	Standard outpatient clinical measurement
Body mass index (kg/m^2)	Calculated as body mass (kg)/ stature squared (m^2)
Resting heart rate (beats.min^{-1})	Standard outpatient clinical measurement using pulse oximeter
Resting blood pressure (mmHg)	Standard outpatient measurement using non-invasive blood pressure cuff
Resting oxygen saturation SPO2 (%)	Standard outpatient clinical measurement using pulse oximeter
Body composition (%)	BodyStat 1500 bioimpedance device as per manufacturer instructions (BodyStat ltd, Douglas, UK)
Physical activity and exercise capacity assessments	
6-minute walk test (m)	Conducted using European Respiratory Society/ American Thoracic Society protocol(389)
30 second sit-to-stand test (Repetitions)	Conducted using Jones et al protocol(390)
Grip strength (kg)	Conducted using Trampisch et al (391) protocol using Jamar Dynamometer

	(Patterson medical, Saint Paul, Minnesota, US)
Maximum inspiratory pressure (cmH_2O)	Conducted using Silva et al protocol (392)using Powerbreathe K-series device (Powerbreathe, Southam, UK)

5.2.10.2. Study visit 2 (preoperative assessment)

Visit 2 will be scheduled prior to surgery to assess changes in secondary outcomes following platform usage. The visit will be conducted at the hospital site by at least two research team members. Data collected will mirror visit 1

5.2.10.3. Study visit 3 (postoperative assessment)

Visit 3 will be scheduled at 30 days postoperatively to assess change/maintenance of health behaviours and to collect postoperative outcome data. The visit will be conducted at the hospital site by at least two research team members. Data collected will mirror visits 1 and 2.

5.2.11. Healthcare professional participant activities and data collection

Acknowledging current service pressures at both sites and the need to recruit a viable sized team to facilitate the programme. A core team of HCP participants will be recruited from prehabilitation services at the participating sites with the support of the study team to promote and facilitate the programme. In addition, HCPs within individual perioperative pathways at the sites will be approached to join this core group and promote the study and programme to their patient groups and support participants within their specialty. Uptake and engagement of HCPs will be a key feasibility finding. All HCP participants, whether in a promoter or facilitator role (or both) will attend the structured training programme prior to engagement with the programme.

5.2.12. Qualitative data collection

Up to 40 patient participants and all participating HCPs will be invited to take part in a semi-structured interview with a study team member. This component of the study is optional. In keeping with the stage 1 development process, companions will also be included if patient participants choose and provide written consent to allow their interview contributions to be included in the analysis. All interviews will be audio recorded and transcribed verbatim.

To facilitate the exploratory health economic analysis, HCP participants will be asked to complete a diary of activity in terms of support provided to patient participants and time required.

5.2.13. Quantitative data analysis

Data will be summarised descriptively using mean and SD or median and IQR for continuous variables, and count and percentage for categorical variables. As this is a planned feasibility study, the level of missing data will be documented but no imputation undertaken.

An initial health economic analysis will be conducted supported by a study health economist to focus on costs of intervention delivery to inform design of a future efficacy study.

An initial exploratory analysis of pseudo-anonymised perioperative wearable data will be undertaken utilising machine learning techniques supported by a data informatics partner (Telstra Health UK). The intent is to characterise the changes in biometrics observed during the perioperative period for participants using iPREPWELL.

5.2.14. Qualitative data analysis

In keeping with the stage 1 development work, qualitative data will be thematically analysed using the TDF. Two members of the research team will independently code and analyse interview transcripts. The same procedure will be undertaken as described in chapter 4 to develop a coding strategy.

5.2.15. Study data handling

The iPREPWELL programme has undergone a full sponsor data protection impact assessment (DPIA). The partner web developer (Hark 2 limited) is registered with the UK information commissioner (ref: ZA435653) and hold current cyber essential certification. Hark 2 will not act as a data processor and will be unable to access participant data in a non-encrypted format.

The digital intervention will be held on a secure server with multiple security measures in place including: Following of good security practices during iterative development (e.g., OWASP top 10); all participant data encrypted at rest with AES 256 CBC cypher; all participant data encrypted during transmission via TLS; strong password policy enforced for all patient participant, HCP participant and research team member/administrator accounts; auto logout when users are idle; multi-factor authentication for admin accounts; auto locking of administrator accounts after a set period of inactivity (e.g. three months without logging in); and forced password changes at set intervals. The server provider is a 3rd party provider that currently hosts similar interventions in routine clinical use by NHS providers.

Participants will consent to utilise the integrated wearable device and accompanying smartphone application in accordance with manufacturer instructions and data protection policies. Biometric data e.g., heart rate and step count will be collected and stored by the manufacturer in accordance with those policies. The digital

intervention platform will obtain data from the device manufacturer via a 3rd party application programming interface (API). These data will be securely stored alongside other programme data.

Data held by the platform will be downloaded to secure site servers for analysis or inspection with routine access by study team members only. Direct access will be granted to authorised representatives from the Sponsor, academic institutions, and the regulatory authorities to permit study-related monitoring, audit, and inspections.

5.2.16. Planned Study management and safety considerations

A study management group (SMG) will be established prior to the commencement with representation from the sponsor (South Tees Hospitals), participating sites and institutions, patient representatives, and research partners. The group will oversee the conduct of the feasibility study and meet monthly, or as required.

Potential AEs occurring throughout the duration of stage 2 of the study, will be assessed, graded, and followed up by the research team until resolution in keeping with sponsor and Good Clinical Practice guidance.

Risk to patient participants is most likely to originate from participation in the structured exercise training programme. Other intervention components are not anticipated to lead to AEs. The overall risk of AEs relating to exercise is considered low. This is based on a growing body of evidence demonstrating the safety of structured exercise training (including aerobic, resistance and inspiratory muscle training) in surgical populations(176). This is in addition to the safety profile of several hundred maximal effort cardiopulmonary exercise tests conducted in the study target population at participating sites and nationally(141).

However, in view of the additional risk this poses in comparison to directly supervised exercise interventions, the following measures are planned to mitigate this as far as possible:

- An independent clinician will review all serious adverse events (SAEs) and report to the study management group.
- Participants will be formally risk assessed to confirm safety for participation based on international criteria for exercise training and testing as described above and the expertise of active face-to-face surgical prehabilitation services at both sites.
- Participants will undergo the baseline functional capacity assessments face-to-face with trained healthcare professionals prior to commencing remotely supervised training.
- The exercise intervention begins with clear, co-designed safety instructions relating to both undertaking physical activity safely and undertaking activity outside the home environment.
- Clear channels for participants will be provided to raise non-emergency concerns with HCP facilitators and the research team and how to access help in an emergency.
- The exercise component of the intervention scales automatically to participant capabilities and progression in intensity will be participant led and facilitator supervised.
- Wearable data collected during training sessions will allow objective intensity monitoring and adjustment as required.

5.2.17. Participant discontinuation and withdrawal

Participants will be free to withdraw from the study at any stage without providing a reason.

Participant discontinuation will occur with any of the following:

- Completion of the study protocol.
- Acute Illness requiring hospital admission.
- Death of participant or commencement of end-of-life care.

- Decision to cancel surgical intervention.
- Loss of capacity to consent to continue participation.
- Participant decision to withdraw.
- Investigator decision.
- Study management group or chief investigator decision.
- Severe non-compliance to protocol as judged by the investigator and/or sponsor.
- Safety reasons.

If a participant wishes to withdraw or is discontinued from the study, the following procedures will be observed:

- Participants will be offered the chance to take part in a semi-structured interview to provide their reasons for withdrawal from the process to allow learning. Participants will be free to decline this interview without providing a reason.
- Withdrawal of consent/ discontinuation of the study will be clearly documented in study documentation and the participant's medical record.
- No further clinical data will be collected from the participant. However, existing clinical data held will be retained and used for the research.
- Patients will continue with standard of care treatment as recommended by their treating team.

5.3. Discussion

This planned study will undertake feasibility testing of the theory-informed co-designed, multibehavioural iPREPWELL programme in people preparing for major surgery. This is the next step from the development work conducted in chapter 4 within the MRC framework and will provide valuable information to both further iterate and modify iPREPWELL.

5.3.1. Study design strengths

This study is pragmatically designed to assess feasibility of implementing the iPREPWELL intervention within surgical pathways at two NHS surgical centres. The single-arm design allows a more straightforward recruitment and follow-up process for site research teams and a focus upon the experience of intervention usage for patients and supporting HCPs within busy perioperative services. This step aligns the development process with MRC guidance where feasibility must be assessed and demonstrated prior to testing efficacy(247). Despite a non-randomised single-arm design, they study takes the opportunity to collect key information to support such a study in future. Data will be obtained on recruitment, uptake, adherence, and dropout rates alongside HCP time necessary to deliver the intervention. In addition, a wide range of secondary outcomes are piloted as potential future primary outcomes. the in-depth assessment of feasibility, fidelity and acceptability planned, combined with qualitative data collection and reference to the prior development process that describes the behavioural mechanisms behind study content will provide opportunity to fully understand where and why the programme does or does not achieve success. This is valuable data to refine the programme further in advance of a future efficacy study. This data will also take a key step beyond recent work evaluating other remotely supervised multibehavioural prehabilitation programmes highlighting the importance to uptake and adherence (242, 259) to understand what, more precisely, is driving those factors.

5.3.2. Study design limitations

There are several important limitations to the study at this stage. Firstly, conduct at two centres in the North of England (UK) limits wider applicability. Although, both centres collectively serve a mixture of urban and rural populations with socioeconomic diversity, offsetting this to some degree. The absence of a control arm at this point for reasons to allow focus on feasibility assessment, time-efficiency and reduced study cost will prevent assessment of intervention efficacy beyond observation of changes in clinical parameters and health behaviours. However as discussed this, alongside with primary feasibility, fidelity and acceptability data is key to future study design and successful application for funding.

As described in chapter 4, iPREPWELL is not currently optimised for a particular surgical pathway. This study will similarly also recruit small numbers of patient participants from any given specialty. Whilst this may limit robust conclusions about feasibility in particular surgical pathways, it may provide early evidence of disproportionate success or difficulty of use in particular pathways and highlight avenues for future tailoring to meet the needs of those pathways.

Given the experience of both prehabilitation services at the participating sites and the demand from patient groups for digital alternatives, it is anticipated that the recruitment target specified for patients is achievable but ambitious within study timeframes. HCP participants, as outlined above, may be restricted by service pressures. Reliance on the core prehabilitation teams at both sites will mitigate this to an extent and is a pragmatic approach to allow study delivery yet may limit wider applicability to NHS centres without similar services in place. Ultimately, it would be an important finding if few HCPs can engage from within perioperative pathways at the sites.

5.3.3. Summary

In summary, this planned feasibility study represents the progression from work completed in chapter 4 and lays and firm a foundation to move from toward efficacy or effectiveness testing and potential wider implementation.

6.Chapter 6: Thesis discussion

The intent of this thesis was to contribute toward the closure of an emerging gap in perioperative care. This is the provision of remotely supervised prehabilitation support to enhance the perioperative care of people undergoing major surgery. This began with the aim of developing a more nuanced understanding of patient preferences, building upon the previously anecdotal clinical experience of prehabilitation services. This was a prerequisite to development of interventions more likely to meet patient needs. These findings made the case for production of a digital solution presenting the opportunity to apply well recognised intervention development theory and methods and learning from wider healthcare to co-design a now unique programme that is ready for testing in clinical practice.

6.1. Key findings and implications

The discrete choice experiment in chapter 2 corroborates a now consistent finding from multiple prehabilitation services: The demand from patients for remotely supervised alternatives to more established face to face prehabilitation models(126-128, 255). This validates ongoing efforts by these services to diversify their range of offers to engage the widest spectrum of patients possible.

This work also highlighted stark divisions amongst those patients regarding how that support should be delivered. Despite the shift toward digital prehabilitation approaches, in line with wider trends and initiatives in healthcare, for approximately half of patients opting for remotely supervised support, paper-based models continue to hold greater value. As a result, services neglecting to offer paper-based alternatives may leave a significant proportion of their target population without a viable support option. This finding aligns with the choice simulation analysis in chapter 2, which indicated that ‘one size will not fit all. Equal attention should be paid to developing a range of prehabilitation models. Although this thesis opted to proceed toward an intervention harnessing the significant potential of digital technology and meet the evident needs of a large proportion of patients, the case is as strong for a carefully

and systematically developed paper manual. Other longer-established services, notably cardiac rehabilitation, have taken several decades to learn this lesson (266, 294). In surgical prehabilitation, we are now able to act on this far earlier. Stepping back from the prehabilitation context, this work demonstrated the feasibility of utilising DCE methods with surgical populations. Most perioperative interventions, pathways and even systems can be viewed in terms of competing and variable attributes and levels. The door is open to use conjoint analysis to rapidly gain a better understanding of patient, staff and stakeholder preferences for their better design and delivery.

The chapter 2 study also offered early clues as to the challenges a digital programme might face in engaging some surgical patients. The observed demographic differences including age, gender, and educational attainment across the 'paper-digital divide' appeared wider than the clinical differences. Traditionally cited drivers of digital exclusion such as a lack of device access(333, 349), seemed less common than might have been expected in patients strongly opting for paper, suggesting other factors were at play in driving an aversion to a digital offer. This aligned with the concept that patients can be excluded from interventions not just because they are 'hard to reach' but also because they are 'hard to grasp'. One problem requires providing the necessary infrastructure and resources, the other requires better intervention design.

This presented a clear opportunity for the qualitative work and systematic intervention co-design and development process presented in chapter 4 to better understand the barriers and facilitators for uptake of, engagement with and adherence to digital prehabilitation interventions in this patient group. Earlier work in the perioperative setting had indicated the potential value of applying behavioural theory to this problem (337, 338). The resulting data from patients shed light on what digital prehabilitation programmes need to achieve to meet the needs of their target population. In summary, programmes must be easy to access, understand and use, not overly burdensome, and continuously emphasise and re-emphasise the benefits are and how to attain them. All this must be filtered through a lens acknowledging that the patient on the receiving end is choosing to invest precious and finite physical, mental, and emotional energy in the process before a stressful and potentially frightening health event. Echoing the feedback from existing face to face services regarding the value placed by patients in regaining some control of their health before surgery (128) giving

patients ownership of the programme, a ‘patient-led’ mindset is critical. This leads to natural tension in intervention design with what current evidence suggests we would ‘ideally’ ask of patients to achieve their greatest possible improvements in their preoperative health and wellbeing (46, 176) and what they are willing or able to achieve. This work underlined programmes need to be able to meet patients where they are.

An unexpected finding was the extent to which the elements of face-to-face clinician and social support need to be captured to replicate success. Remotely supervised interventions cannot be successfully delivered as ‘light touch prehabilitation’ and require the same intensity of interest and investment from the facilitating healthcare professional team as a face-to-face service. Patients want to know their healthcare professionals are paying attention to what they are going through preoperatively, from the patient perspective this may be as valuable as enhancing their aerobic capacity or improving their nutritional state. This finding questions some of the proposed system benefits of digital interventions in this context, notably the scope for significantly reduced staff involvement and oversight in comparison to face-to-face models (317).

Indeed, the healthcare professional perspective on programme delivery is the other side of the coin and equally important to intervention implementation and success. The lessons from frontline staff were equally unambiguous in the context of perioperative care in the NHS in 2022. Staff must be convinced that the programme is worth it for their patients, believe that their patients value it and have confidence that their wider team and the system they work in values it. Echoing the patient findings, staff also categorically identified the need for the programme to respect patient autonomy, be designed compassionately and accept that what the patient chooses to do or not do with it is paramount. Equally this work suggests that if the above criteria can be met, programmes like this can be adopted within existing surgical pathways and delivered by perioperative teams. In comparison to the patient intervention, the iPREPWELL HCP training programme is still in development, but the scale of its task is clear. As recognised within wider intervention design and implementation theory(247, 349, 393, 394) designing and delivering this element of the intervention is vital to intervention success.

These findings evidence the benefit of a co-design approach. The question is raised of what we might learn if it was applied to the design or potentially re-design of other prehabilitation support models and perioperative interventions more broadly to optimise their acceptability, uptake, adherence, and impact.

6.2. Thesis strengths and limitations

This work has obtained a more detailed understanding of patient and healthcare professional views regarding remotely supervised prehabilitation than was previously available. These data provide a foundation and rationale for the design of remotely supervised prehabilitation interventions and digital interventions in particular. The data reinforce previous findings and learning from active prehabilitation services and other related healthcare settings whilst offering new perspectives unique to digitally facilitated health behaviour change before surgery. The thesis has applied recognised and robust methods to obtaining those preferences and has begun to address a deficit in currently available interventions by being the first to apply widely recognised principles of health behaviour science and development of complex healthcare interventions. This has resulted in a novel and presently unique systematically co-designed and developed multibehavioural digitally facilitated prehabilitation intervention ready to undergo robust feasibility testing in clinical practice. The iPREPWELL programme combines patient and healthcare professional perspectives with the existing evidence base and accumulated learning of current prehabilitation services to best support people preparing for major surgery to achieve preoperative improvement in their health and wellbeing.

However, the programme must now leave the drawing board and prove itself in clinical practice. As highlighted above, this will necessitate an equally carefully designed HCP training intervention to be completed. Despite this, the co-design findings offer ideal foundations upon which to design and deliver this component. In addition, as the development process has laid out how the programme is intended to work and the planned feasibility study design will monitor carefully whether it does, at the very least there will be a clear understanding of 'why' the programme should fail to achieve its aims.

The level of patient and HCP engagement achieved across the work presented, and the level of detail obtained regarding their views and preferences on this subject obtained is an improvement on that previously available. However, it is also

undoubtedly limited by the absence of the views of patients who opted not participate in this research. Whilst participation rates in this work were encouraging compared to other studies, large numbers of patients screened and approached chose not to take part. Given the potential overlap between those who do not engage with prehabilitation services and those who do not participate in prehabilitation research, this creates a difficult situation in which an 'unseen group' are most likely to both disengage with services are also least likely to express their views on why. Of even greater concern is the possibility that this group may also be at exhibit the highest rates of health risk behaviours and be at most acute perioperative risk. The necessary limits of the informed consent process make collecting information to even characterise the group of non-participants difficult. Reaching non-participants is a problem across wider prehabilitation service delivery and research and not unique to this work. However, a real risk exists that interventions and services continue to increasingly effectively meet the needs of only the patients who are able and willing to engage with them.

In addition, the co-design group were recruited from two centres the North of England. Whilst these centres cover socioeconomically and geographically diverse areas, wider applicability of findings and resulting programme design to the UK may be limited, in particular to more ethnically diverse populations. Finally, this work has been conducted in a UK NHS context, also limiting immediate application to other international healthcare contexts and systems.

6.3. Recommendations

Based on the work presented in this thesis the following recommendations are made for further research and clinical practice.

- The accompanying iPREPWELL programme healthcare professional training resource should complete design and development.
- Following planned feasibility testing, iPREPWELL should undergo further iteration with reference to study findings prior to experimental evaluation in a full-scale randomised controlled trial.
- A systematic, theory informed co-design and development process aligned with the approach taken in this work should be applied to a paper-based alternative to iPREPWELL.
- Existing services should consider taking a systematic co-design and development approach to the planning and implementation of new prehabilitation models and modification of their existing care pathways.
- Further work is urgently needed to address the ‘blind spot’ of non-participants in prehabilitation services and research, including studies designed specifically to better describe and engage this group.

6.4. Personal reflection

I embarked on this process with the expectation of significantly developing my knowledge and skills in clinical research and have not been disappointed. I have acquired new experience and expertise of research methods including conjoint analysis, qualitative research and intervention design. All areas in which I was a complete novice at the outset. This has been accompanied by a range of new experience in the practicalities and challenges of managing multiple site clinical research studies in the national health service. This includes my first experience in a chief investigator role for an NIHR portfolio adopted study and successful application for funding that has supported the projects included in the thesis. I have also learned valuable lessons from planned projects that sadly could not have been completed in the required timeframes. Significant effort was expended in designing and obtaining NHS REC approval for a planned evaluation of a primary care professional prehabilitation training resource I had previously designed (https://professional.prepwell.co.uk). As detailed in chapters 1 and 2, this was on the basis that primary care may hold a key role in supporting patients in their communities undertaking remotely supervised prehabilitation activity. However, response rates from primary care clinicians were incredibly low and despite obtaining incentive funding for their finite time, response rates did not improve leading to the project being abandoned. The failure of this project is, I believe, symptomatic of the pressures the primary care sector is facing and I continue to believe that we can do better in cross-sector working before surgery. The project was also a lesson in recognising the tipping point when perseverance and attempting differing approaches should give way to a project being abandoned.

It is difficult to reflect on this thesis without considering the Covid-19 pandemic. Like thousands of others, it will likely remain one of the proudest and humbling moments in my career to be able to return to clinical practice alongside colleagues in intensive care when the first wave broke out in the spring of 2020. I would make the same decision again in a heartbeat. The result from the point of view of this work, however, was significant disruption and delay. On reflection I would have hoped to see iPREPWELL already into feasibility testing. In addition, the decision to prioritise

restarting and the design and development of the programme means a planned systematic review of prehabilitation intervention reporting I had hoped to include in this thesis is still underway. As well as directly impacting the work presented here, Covid has also fundamentally shifted its context, with the need to help the thousands of patients now awaiting surgical care to prepare, rather than wait for surgery now vitally important.

What I did not expect is how this PhD has influenced me as a clinician. I have, through the studies included here, felt lucky to be able sit for time with patients as they completed the electronic questionnaire, listen to their views in person during the co-design process and read and re-read the interview transcripts detailing their experiences which has given me new and valuable insight into what it means to be someone facing major surgery. I have been frequently reminded of the human being at the centre of the increasingly complex perioperative care process. It is sometimes easy to lose sight of that in the ever-hectic day-to-day business of the UK NHS and demands of clinical training in anaesthesia and intensive care. I feel lucky to now have obtained this privileged viewpoint. I hope I will be able to take it with me into better interactions with my patients in the preassessment clinic, operating theatre and critical care unit going forward.

6.5. Conclusion

In conclusion, the work presented here expands the evidence base for prehabilitation. Specifically, it deepens the understanding of patient and healthcare professional needs in engaging with and delivering remotely supervised prehabilitation at a time when the need for robustly developed interventions that can integrate into rapidly evolving perioperative care pathways has never been greater. The end-product fills a gap in perioperative care as the first systematically designed and developed, digitally facilitated multibehavioural prehabilitation intervention of its kind.

7. Appendices

Appendix 1: Chapter 2 study ethical and regulatory approvals

NHS
Health Research Authority

South Central - Hampshire B Research Ethics Committee

Level 3 Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 020 7104 8044

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

18 February 2019

Dr James Durrand
Department of Sport, Exercise and Rehabilitation
Northumberland Building, City Campus
Northumbria University, Newcastle UK
NE1 8SG

Dear Dr Durrand

Study title:	**Improving Health at Home Before an Operation: A Questionnaire Study of Patient Opinions on how to Improve Health Before Surgery.**
REC reference:	**19/SC/0038**
Protocol number:	**N/A**
IRAS project ID:	**245904**

Thank you for your letter of 11 February 2019, responding to the Proportionate Review

Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g., for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where an NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC, but you should do so at the earliest opportunity e.g., when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]		14 January 2019
Interview schedules or topic guides for participants [Questionnaire guide for participants]	5.0	17 December 2018
IRAS Application Form [IRAS_Form_11022019]		11 February 2019
Letter from funder [Letter from funder confirming grant award]		18 January 2018
Non-validated questionnaire [Mock paper questionnaire (new)]	4.0	15 January 2019
Non-validated questionnaire [Mock paper questionnaire (tracked)]	4.0	15 January 2019
Other [Email to participants requesting remote participation]	1.0	18 December 1918
Other [External grant reviewer comments]	N/A	18 January 2018
Other [Tracked version of study protocol V5]	5.0	15 January 2019
Participant information sheet (PIS) [Participant Information Sheet (new)]	6.0	15 January 2019
Participant information sheet (PIS) [Participant Information Sheet (tracked)]	6.0	15 January 2019
Research protocol or project proposal [Study protocol (new)]	5.0	15 January 2019
Summary CV for Chief Investigator (CI) [CI CV]		03 January 2018
Summary CV for student [Dr Durrand (Student and CI)]		03 January 2018
Summary CV for supervisor (student research) [Dr Tew (Lead supervisor)]		
Summary CV for supervisor (student research) [Professor Danjoux (Co-supervisor)]		
Summary CV for supervisor (student research) [Dr O'Doherty (Co-supervisor)]		
Summary CV for supervisor (student research) [Professor Doherty (Co-supervisor)]		31 October 2018

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research

Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known, please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

19/SC/0038	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

PP
Prof Chris Colbourn Chair

Email: nrescommittee.southcentral-hampshireb@nhs.net

Copy to: *Mr Joe Millar*

Mr Joe Millar, South Tees Hospitals NHS Foundation Trust

Dr James Durrand
Department of Sport, Exercise and Rehabilitation
Northumberland Building, City Campus Northumbria University, Newcastle UK
NE1 8SG

Email: hra.approval@nhs.net Research-permissions@wales.nhs.uk

19 February 2019

Dear Dr Durrand

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	Improving Health at Home Before an Operation: A Questionnaire Study of Patient Opinions on how to Improve Health Before Surgery
IRAS project ID:	245904
REC reference:	19/SC/0038
Sponsor:	South Tees Hospitals NHS Foundation Trust

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales? You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should formally confirm their capacity and capability to undertake the study. How this will be confirmed is detailed in the "summary of assessment" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g., R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set, and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements, so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Dr James Durrand
Email: jdurrand@doctors.org.uk

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **245904**. Please quote this on all correspondence.

Yours sincerely

Michael Higgs
Assessor
hra.approval@nhs.net

Copy to: *Mr Joe Millar, South Tees Hospitals NHS Foundation Trust*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	Version	Date
Covering letter on headed paper		14 January 2019
Evidence of Sponsor insurance or indemnity [Northumbria University]		16 July 2018
HRA Schedule of Events	1.0	08 January 2019
HRA Statement of Activities	1.0	08 January 2019
Interview schedules or topic guides for participants [Questionnaire guide]	5.0	17 December 2018
IRAS Application Form [IRAS_Form_19122018]		19 December 2018
Letter from funder		18 January 2018
Non-validated questionnaire [Mock paper questionnaire]	4.0	15 January 2019
Other [Email to participants requesting remote participation]	1.0	18 December 1918
Other [External grant reviewer comments]		18 January 2018
Participant information sheet (PIS)	6.0	15 January 2019
Research protocol or project proposal	5.0	15 January 2019
Summary CV for Chief Investigator (CI) [James Durrand]		
Summary CV for supervisor (student research) [Garry Tew]		
Summary CV for supervisor (student research) [Gerry Danjoux]		
Summary CV for supervisor (student research) [Alasdair O'Doherty]		
Summary CV for supervisor (student research) [Patrick Doherty]		

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging, and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/ consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments

4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used. The sponsor has confirmed that an agreement covering the sharing and processing of personal data will be in place with Northumbria University.
4.2	Insurance/ indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	External funding has been secured from the preoperative association. Resources will be provided to participating NHS organisations as detailed in the Statement of Activities
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments

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Section	Assessment Criteria	Compliant with Standards	Comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is a single type of participating NHS organisation, i.e., the research activity at all sites shall be the same.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training, and experience that PIs should meet (where applicable).

A Principal Investigator should be in place for all participating NHS organisations in England and Wales, and individuals have been identified for the sites listed in Part C of the IRAS form.

The sponsor will provide site initiation training but does not have any other study specific training expectations of local staff delivering this study. GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

As a non-commercial study undertaken by local staff, it is unlikely that letters of access or honorary research contracts will be applicable, except where local network staff employed by another Trust or researchers employed by a university are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, such researchers undertaking any of the research activities listed in A18 of the IRAS form would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 2: Chapter 2 participant information sheet

Participant Information Sheet

Improving Health at Home before an Operation

A questionnaire study of patient opinions on improving their health before surgery

We would like to invite you to take part in our questionnaire research study. We are sending you this invitation as you have an upcoming appointment at an anaesthetic preassessment clinic.

Before you decide, it is important to understand why this research is being done and what it involves. Please take time to read the following information sheet. When you attend your appointment, one of our research team can go through this information sheet with you; please ask us if there is anything that is not clear or if you have any questions. If you decide to take part, it will take you less than 30 minutes to complete

The questionnaire is completed on a computer, tablet, or other electronic device. We will provide you with any help you need to complete the questionnaire and take part.

What is the purpose of the study?

The study aims to collect patient opinions on the best way to support them improving their general health and fitness at home prior to an operation.

Your important views will help design and build new tools, improving care for patients undergoing surgery in the future.

Why is it important to improve your health and fitness before surgery?

Operations place a large strain on your body. Getting in the best health you can beforehand is important. Unhealthy lifestyle behaviours like: Smoking, being inactive, too much alcohol and being underweight and overweight are important issues to deal with before surgery. These 'risk factors' mean patients are more likely to experience complications affecting the heart, breathing, kidneys and the ability of wound(s) to heal. Any complication after surgery may keep you in hospital for longer, reduce your quality of life and slow your recovery to independence.

Research shows that improving your general health and wellbeing in the time before surgery is important. Examples of lifestyle changes include increasing activity and exercise, reducing the amount of alcohol you drink, stopping smoking and achieving a healthy diet and body weight. Improving your health and fitness in this way before surgery is called 'Prehabilitation'.

Very few hospitals in the UK are able to offer Prehabilitation support for patients before surgery. We have recently started a community based Prehabilitation support programme that patients are enjoying and find very beneficial. However, not all patients are able or wish to attend these classes. Some patients would prefer support to achieve these benefits by themselves at home.

We plan to use your responses from this study to develop a new self-help, home-based programme, improving the options for future patients. Your answers will help us design a popular self-help programme.

Why have I been invited?

It is really important that we collect views from the most appropriate group of patients for this project.

We are aiming to recruit approximately 300 patients from 5 hospitals around the UK. You have been invited to participate because you are due to attend an anaesthetic preassessment clinic to assess your readiness for a major operation. Your views are therefore exactly the ones we wish to collect.

Do I have to take part?

No, participation is completely voluntary and choosing not to participate in the study will in no way affect your medical care. If you would like to take part, you will be asked to complete a consent form before the questionnaire begins. If you decide to participate but then change your mind you can withdraw at any time without providing a reason.

What will happen to me if I take part?

You will complete a questionnaire on an electronic device such as computer, laptop, or tablet. It is expected this will take no longer than 30 minutes and is likely to be faster for some people. We will provide you with any help you need to complete the questionnaire and take part.

If you decide to take part, you have two options for completing the questionnaire:

> Option 1. At your clinic appointment: A member of our team will approach you while you are waiting for your appointment and can support you in completing the questionnaire on a device we will provide. We will help you to complete the questions, but the answers will all be yours.
>
> Option 2. In your own time before your appointment: If you have a computer or tablet at home with internet access, you can complete the questionnaire in your own time. If you prefer this option, please email your local study team for instructions at this address:

[INSERT SECURE SITE EMAIL CONTACT]

We have included some important background information alongside this sheet to help you during the questionnaire. This will be useful to read for anyone keen to take part but is especially important to read if you are taking part at home.

Either way, a member of the study team will meet you when you attend for your appointment and check that you have received and read the information sheet. They can answer any questions that you may have. You can then tell them if you have already completed the questionnaire at home, would like help completing it, or do not wish to take part at all.

What will I have to do?

We do not require anything further from you after completing the questionnaire. The questionnaire includes these parts:

1. A consent form: This will confirm you have read and understood this information sheet and any questions you have are answered. It will also confirm you are happy to participate in the study and that you are happy for members of the study team to collect some information from your records about your planned operation.

2. Questions about you and your planned surgery. Some of this information will be 'identifiable' (for example your date of birth) and will be carefully handled throughout the study (see 'will my taking part in the study be kept confidential' below).

3. Questions about your general health and any risk factors you may have, like those described above.

4. A 'choice experiment': This is the main part of the questionnaire. You will be shown a series of potential 'home-based' programmes for supporting lifestyle change before surgery. The programmes will have different features combined in different ways. The questionnaire will ask you to choose your preferred program. This helps us build a picture of which programmes are most popular.

The separate questionnaire guide we have provided gives more information about the choice experiment. It includes details about the features that could be included in the programme and their advantages and disadvantages. This will help you make decisions about your preferred program.

5. Final questions about improving health before surgery and other programme features.

Expenses and payment for participation.

Participation in the study is entirely voluntary and we are extremely grateful for your time. However, we are unable to offer payment or reimbursement of expenses for participation.

What are the possible disadvantages of taking part?

Taking the time required to complete the questionnaire is the main disadvantage. However, we expect this will take under 30 minutes. If you choose to complete your questionnaire in hospital, we will aim to complete the questionnaire with you while waiting for your preassessment clinic appointment. This is so that we do not extend your visit any more than necessary.

We also recognize that reflecting on your own health and fitness before your operation may raise some anxiety about your operation. Please feel free to speak to a study team member if this is the case.

What are the potential benefits of taking part?

Participating in the questionnaire is unlikely to lead to any direct benefits to you. However, the information we gather will be extremely valuable in developing new tools to improve the support and care for future patients getting ready for an operation.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. Please discuss this with the study team member present in the first instance or utilize the contact details below. If your issue has not been dealt with following this, you can contact your Patient Advice and Liaison (PALS) service to take this further.

[INSERT SITE PALS CONTACT]

Will my taking part in the study be kept confidential?

South Tees Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. South Tees Trust and

Northumbria University will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personal identifiable information possible.

You can find out more about how we use your information by contacting the chief investigator detailed below.

[NHS site] and Northumbria University will collect information from you and your medical records for this research study in accordance with our instructions.

[NHS site] will use your name, NHS number, date of birth and address to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from South Tees Hospitals and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [NHS site] will pass these details to South Tees Hospitals and Northumbria University along with the information collected from you and your medical records. The only people in South Tees Hospitals or Northumbria University who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, date of birth, address or other contact details.

[NHS site] will keep identifiable information about you from this study for 10 years after the study has finished.

All procedures for handling and protecting your information will meet the requirements of UK GDPR (Data Protection act 2018).

Reflecting on your own health and fitness prior to your operation may also encourage you to take action to make improvements before surgery.

What will happen to the results?

The study results will be presented anonymously at academic conferences and published in academic journals. The research is also part of PhD project, and the data will be submitted anonymously as part of a final thesis.

Who is organizing and funding the research?

Northumbria University and the South Tees Hospitals NHS Foundation Trust are conducting this study. It is supported by other NHS Foundation Trusts including:

- York Hospitals
- North Tees and Hartlepool Hospitals.
- Newcastle University Hospitals
- Central Manchester Hospitals

The study is funded by the UK Preoperative Association.

Who has reviewed the study?

The study has approval by the South Central- Hampshire B research ethics committee (19/SC/0038)

The questionnaire itself has been reviewed by patients like you getting ready for an operation.

Further information

For further information regarding the study, advice around participation or to discuss a problem please contact your local study team or the chief investigator:

Your local study team:

[INSERT LOCAL TEAM CONTACT]

Chief investigator:

Dr James Durrand:

PhD Student Northumbria University Department of Sport, Exercise and Rehabilitation, City Campus, Northumberland Building, Newcastle, UK, NE2 1UY

Research Fellow in Anaesthesia, Department of Anaesthesia, James Cook University Hospital, Marton Road, Middlesbrough, UK, TS4 3BW

Email: James.durrand@northumbria.ac.uk

Co-investigators

Dr Garry Tew, Associate Professor, Northumbria University Department of Sport, Exercise and Rehabilitation.

Dr Alasdair O'Doherty, Lecturer, Northumbria University Department of Sport, Exercise and Rehabilitation.

Dr Suzanne McDonald, Psychologist with Research Design Service, Newcastle University.

Dr Angela Bate, Health Economist and Health Services Researcher, Northumbria University.

Dr Basem Al-Omari, Senior Lecturer, Northumbria University Department of Nursing, Midwifery a
Professor Gerard Danjoux, Consultant Anaesthetist and Research Lead, South Tees Hospitals NHS Foundation Trust.
Dr Reema Ayyash, Consultant Anaesthetist, South Tees Hospitals NHS Foundation Trust.
Professor Patrick Doherty, Professor of Cardiovascular Health, University of York.
Dr David Yates, Consultant Anaesthetist, York Teaching Hospitals NHS Foundation Trust
Dr Elke Kothmann, Consultant Anaesthetist, University Hospitals North Tees, and Hartlepool
Dr Rhona Sinclair, Consultant Anaesthetist, Newcastle University Hospitals NHS Foundation Trust
Dr John Moore Consultant Anaesthetist, Central Manchester University Hospitals NHS Foundation Trust

Appendix 3: Study electronic consent form

Consent Form

Please make sure you have read and understood the **participant information sheet** sent to you by post before continuing and that any questions been answered by the study team.

Next, please confirm whether you agree with the following statements by clicking in the circles. This confirms your informed consent to continue completing the questionnaire.

'I confirm that I have read and understand the information sheet dated 18/01/19 version 6 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.'

◯ Yes I agree

'I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.'

◯ Yes I agree

'I understand that data collected during the study, may be looked at by individuals from South Tees Hospitals and Northumbria University, from regulatory authorities or from my NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.'

◯ Yes I agree

'I agree to take part in the study.'

◯ Yes I agree

Back Next

Appendix 4: Chapter 2 electronic questionnaire content

This questionnaire study will be delivered to participants electronically. This document is intended to provide an overview of the content and an example of the choice experiment (conjoint analysis) component that will be presented.

Text presented to the participant on screen is *italicized*.

1. Welcome screen

On opening the questionnaire weblink and login, a welcome screen will first appear with the following message:

'Thank you for helping with this questionnaire study. Your views are very important in developing new tools to support future patients preparing for major surgery.

The Study Team'

2. Consent form

The questionnaire will begin with the recording of informed consent as some participants may have chosen to undertake the questionnaire independently in their own time before their clinic appointment

'Please make sure you have read and understood the participant information sheet sent to you by post before proceeding and that any remaining questions have been answered by the study team. Following this, please confirm you agree with the following'

(Check boxes available to indicate agreement with statement: '*Yes I agree*')

1. I confirm that I have read and understand the information sheet dated ***X*** *version* ***X*** *for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.*

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that data collected during the study, may be looked at by individuals from South Tees Hospitals and Northumbria University, from regulatory authorities or from my NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to take part in the above study.

3. Demographic questions

Following recording of informed consent screens will collect the following demographic information. A combination of check boxes and white spaces will be used to collect responses.

Q1. Please enter your date of birth

Q2. Please enter your postcode

Q3. Please indicate your gender

- *Male*
- *Female*
- *Other*

Q4. Please enter which hospital is undertaking your operation

- *South Tees University Hospitals (James Cook Hospital or Friarage Hospital)*
- *North Tees and Hartlepool University Hospitals (North Tees Hospital or Hartlepool Hospital)*
- *York Teaching Hospital*
- *Newcastle University Hospitals (Royal Victoria Infirmary or Freeman Hospital)*
- *Manchester University Teaching Hospital*

Q5. Please indicate your marital status

- *Single*
- *Married*
- *Civil Partnered*
- *Divorced*
- *Widowed*
- *Other*

Q6. Please indicate your ethnicity

- *White/ White British*
- *Asian/Asian British*
- *Mixed/Multiple*
- *Black/ African/ Caribbean/ Black British*
- *Other*

Q7. How would you describe your current employment status

- *Full-time employment*
- *Part-time employment*
- *Retired*
- *Volunteer*
- *Unemployed*
- *Other (please specify)*

Q8. Please indicate your highest level of educational attainment

- *No qualifications.*

- *1-4 O Levels/CSE/GCSEs (any grades), Entry Level, Foundation Diploma, NVQ Level 1, Foundation, GNVQ, Basic/Essential Skills.*

- *5+ O Level (Passes)/CSEs (Grade 1)/GCSEs (Grades A*-C), School Certificate, 1 A Level/ 2-3 AS Levels/VCEs, Intermediate/Higher Diploma, Welsh Baccalaureate Intermediate Diploma, NVQ level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma; Apprenticeship.*

- *2+ A Levels/VCEs, 4+ AS Levels, Higher School Certificate, Progression/Advanced Diploma, Welsh Baccalaureate Advanced Diploma, NVQ Level 3; Advanced GNVQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Diploma.*

- *Degree (for example BA, BSc), Higher Degree (for example MA, PhD, PGCE), NVQ Level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher level, Foundation degree (NI), Professional qualifications (for example teaching, nursing, accountancy).*

- *Vocational/Work-related Qualifications, Foreign Qualifications (not stated/level unknown)*

4. Clinical questions

The following screens will collect the following clinical information. A combination of check boxes and white spaces will be used to collect responses.

Q9. Please indicate the area of your planned operation

- *Bone or joint (orthopaedic surgery)*
- *Stomach, gullet, or small bowel (upper gastrointestinal surgery)*
- *Large bowel/colon (Lower gastrointestinal surgery)*
- *Kidney, prostate, bladder, or male reproductive organs (urological surgery)*
- *Female reproductive organs (gynaecological surgery)*
- *Head and neck (ENT or Maxillofacial surgery)*
- *Aorta or other blood vessel (Vascular surgery)*

- *Other (please specify)*

Q10. Is your operation due to a diagnosis of Cancer?

- *Yes*
- *No*

Q11. Are you receiving chemotherapy or radiotherapy before surgery?

- *I am not having chemotherapy or radiotherapy before surgery*
- *I have already had chemotherapy or radiotherapy before surgery*
- *I am currently having chemotherapy or radiotherapy before surgery*
- *I will be having chemotherapy or radiotherapy before surgery*

4. General Health questions

Q12. In comparison to others your age, how would you describe your general health?

- *Good*
- *Fair*
- *Poor*

Q13. Do you smoke?

- *Current smoker*
- *Ex-smoker*
- *Never smoked*

Q14. What is your weekly alcohol intake in UNITS? The following information may help:

Pint of beer 4% = 2.3
500ml can of strong lager 6% = 3
250ml glass of wine 11% = 2.8
330ml can of cider 5% = 1.7
Single 25ml measure spirit = 1

Q15. Do you engage in regular moderate physical activity of at least 30 minutes duration on average 5 times a week? (e.g., 150 minutes over 7 days)

Examples of this include:

- *Brisk walking (5 km/hr)*
- *Leisure cycling (<16 km/hr)*
- *Leisure swimming*
- *Playing doubles tennis*

- *Line-dancing*

- *Yes*
- *No*

Q16. Do you engage in 75 minutes of vigorous exercise per week?

Examples of this include:

- *Jogging or running*
- *Swimming continuous laps*
- *Playing singles tennis*
- *Rollerblading at fast pace*
- *Playing basketball or football*
- *Skipping with a rope*

- *Yes*
- *No*

Q17. Do you engage in muscle strengthening exercises on 2 or more days per week? This is activity where your muscles work against resistance such as exercising with weights or digging a garden.

- *Yes*
- *No*

5. Choice experiment

At the point the participant will begin the choice experiment. This will proceed in 3 stages.

This is the beginning of the choice experiment. ***You will find it useful to have your questionnaire guide to hand. This will help you make informed choices during the experiment.***

Stage 1: 'Build your own'

For each of the following features of a home-based programme to support patients in improving their health before major surgery, please indicate your most preferred option.

1. When the programme starts.

- *Referred by my GP*
- *Booked for my operation*

2. How I use the programme.

- *Paper Based*
- *Digital based*

3. How I am introduced to the programme and assessed.

- *At hospital*
- *At my GP or community venue*
- *At my home*

4. How often the facilitator checks in with me.

- *Weekly*
- *Fortnightly*
- *Less than fortnightly*

5. Whether monitoring technology is used.

- *Technology used*
- *No technology used*

6. Direction to other services and support.

- *Other support involved*
- *No other support*

Stage 2: 'screening'

The patient will be shown 6-8 screens. Each screen will contain 4 differing programmes formed from the attributes and levels above. On each screen, patients will be asked to indicate any of the 4 programmes that they would consider using. The number of screens shown will vary depending on responses.

An example screen is shown:

Below are four 'possible' programmes that could be built for patients to use

Please indicate by which of the following programmes you would consider using as a patient to improve your general health and wellbeing before surgery.

	Programme 1	Programme 2	Programme 3	Programme 4

When the programme starts	Referred by my GP	Booked for my operation	Referred by my GP	Booked for my operation
How I use the programme	Paper based	Digital based	Paper based	Digital based
How I am introduced to the programme and assessed	At hospital	At my home	At my GP or community venue	By telephone
How often my facilitator checks in with me	Less than fortnightly	Weekly	Fortnightly	Weekly
Whether monitoring technology is used	Technology used	Technology used	Not used	Not used
Direction to other services and support	Other services or support involved	No other support	No other support	Other services or support involved
Might be an option for me				

Based on responses the software will insert 2-4 additional screens to confirm if participants consider some levels 'must haves' or 'unacceptable'

Stage 3: 'choice tasks'

Based on the responses to stage 1 and 2, the patient will have begun to inform the software about preferences for certain attributes and levels. They will then move onto the choice tasks stage. They will be asked to select one of two programmes on screen. The software will begin to 'lock' attributes and levels that the patient has already expressed a clear choice over. Other attributes and levels will be targeted and varied to identify their preferences and gain a full picture across all attributes. The total number of screens will vary as a result.

An example screen is shown:

Please indicate which of these two home-based programmes you would prefer to use as a patient before surgery.

	Programme 1	Programme 2
When the programme starts	Referred by my GP	Booked for my operation
How I use the programme	Paper based	Digital based
How I am introduced to the programme and assessed	At hospital	At my home
How often my facilitator checks in with me	Fortnightly	Weekly
Whether monitoring technology is used	Technology used	Not used
Direction to other services and support	Other services or support involved	No other support
I prefer this programme		

6. Final questions

Following the choice experiment, the participant will be asked final questions surrounding their motivation for preoperative health change overall and preference for their 'ideal' home-based programme versus a traditional face to face programme.

Thank you for completing the choice experiment. These are the final questions to complete the questionnaire

Q18. Programmes like these could also provide educational material to inform patients approaching surgery. This might involve videos watch or materials to read about what to expect before and after their operation. What do you think about this?

- *I would be interested in reading/watching educational content like this before my operation.*
- *I would not be interested in reading/watching educational content like this before my operation.*

Q19. Programmes like these could ask you to confidentially provide more detailed information about any long-term medical conditions you have to the team looking after you around surgery. This could help them support you better around surgery. What do you think about this?

- *I would be happy to provide this information confidentially as part of a programme*
- *I would not be happy to provide this information confidentially as part of a programme*

Q20. As a patient approaching major surgery, how motivated would you be to engage with support to improve your general health before your operation aiming to reduce the risk of complications and encourage a smoother recover?

A semantic differential slider will be provided

Not all motivated----------Extremely motivated

Q21. As a patient approaching major surgery, how motivated would you be to engage with support to improve your general health before your operation for longer-term health benefits after surgery?

A semantic differential slider will be provided

Not all motivated----------Extremely motivated

Q22. All things considered, if you were seeking support to improve your overall health before surgery what kind of support would prefer?

- *My 'ideal' home-based programme out of those described earlier.*
- *A face-to-face programme where I attended hospital 2-3 times per week for group exercise and other support sessions with patients like me.*
- *A face-to-face programme where I attended a community venue near my home 2-3 times per week for group exercise and other support sessions with patients like me.*
- *I would not be interested in any sort of programme to help improve my overall health before surgery.*

7. End screen

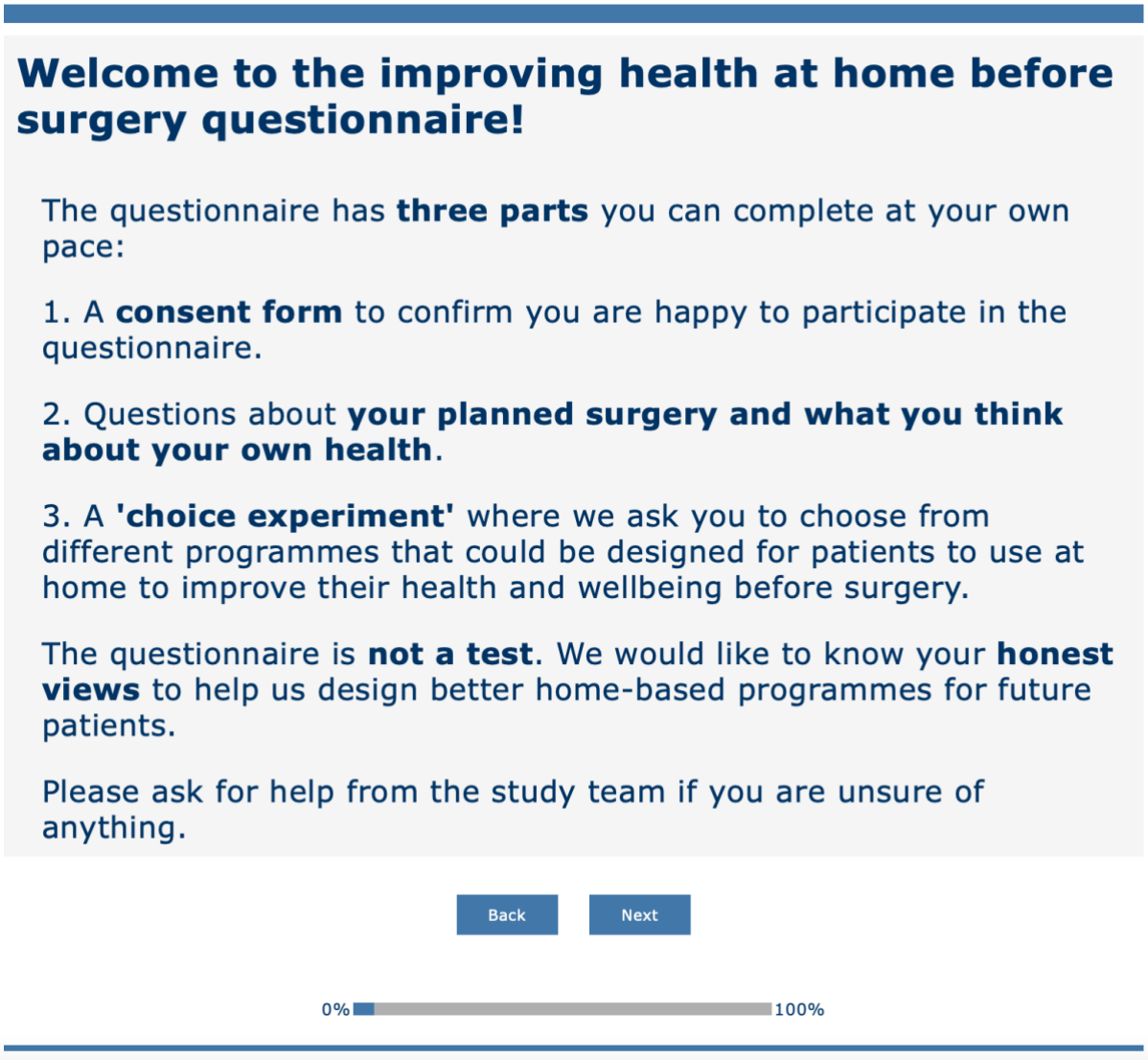
A final screen will appear at the end of the questionnaire

Thank you very much for participating in this questionnaire. Your responses have been saved and you may close the questionnaire when you are ready. This is the end of your participation in the research study

We are very grateful for your time and please contact the study team if you have any further questions.

Appendix 5: Chapter 2 electronic questionnaire screenshots

Welcome screen



Example demographics screen

About you

Please indicate your marital status?

- ○ Single
- ○ Married
- ○ Civil Partnered
- ○ Divorced
- ○ Widowed
- ○ Other

How would you describe your ethnicity?

- ○ White/ White British/ White Irish
- ○ Asian/Asian British
- ○ Mixed/Multiple
- ○ Black/ African/ Caribbean/ Black British
- ○ Other

How would you describe your current employment status?

- ○ Full-time employment
- ○ Part-time employment
- ○ Retired
- ○ Volunteer
- ○ Unemployed
- ○ Other

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Example perioperative clinical data screen

About your operation

Please indicate the body area of your operation.

- ◯ Bone or joint
- ◯ Stomach, gullet or small bowel
- ◯ Liver, Pancreas, Gall bladder or bile ducts
- ◯ Large bowel/colon
- ◯ Kidney, prostate, bladder, urinary tract or male reproductive organs
- ◯ Female reproductive organs
- ◯ Breast
- ◯ Head and neck
- ◯ Aorta or other blood vessel (not including the heart)
- ◯ Heart
- ◯ Lungs and chest
- ◯ Other

Is your operation due to a cancer?

- ◯ Yes
- ◯ No

Are you having chemotherapy or radiotherapy before surgery?

- ◯ I **am not** having chemotherapy or radiotherapy before surgery.
- ◯ I **have already** had chemotherapy or radiotherapy before surgery.
- ◯ I **am currently having** chemotherapy or radiotherapy before surgery.
- ◯ I **will be having** chemotherapy or radiotherapy before surgery.

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Example health behaviour data screen

About You

Compared to other people your age, how would you rate your general health?

About the same

Worse than others — **Better than others**

You can move the slider anywhere from 0-10

Do you smoke?

- ○ Current smoker
- ○ Ex-smoker
- ○ Never smoked

In an average week, how much alcohol do you drink in UNITS

To help you work this out:

Pint of beer (4% ABV) = 2 units
Pint of strong beer (6.5% ABV) = 4 units
Small (125 ml) glass of wine (12.5% ABV) = 1.5 units
Large (250ml) glass of wine (12.5% ABV) = 3 units
Single (25ml) measure spirit (40% ABV) = 1 unit

If you do not drink alcohol please enter 0 (zero)

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DCE introduction screen

Choice experiment

This is the beginning of the choice experiment.

We are seeking your **honest views** on the various ways a home-based programme could be designed to help future patients like you **improve their general health before surgery**

A home based programme would be different for each person but might involve:

An exercise programme to increase physical activity

Help to stop smoking

Help to reduce alcohol intake

Other support to improve general health

The choice experiment will happen in **3 parts:**

1. You will be asked to choose 6 features of a home -based programme from the options to **'build your own' ideal programme**.

2. You will be shown screens with 4 different programmes to compare all built slightly differently from your ideal programme. You will be asked **if you would consider using** each of them

3. You will be shown screens with 3 different programmes all built slightly differently and asked to **pick a favourite**.

The questionnaire will be **trying to find out which features are most important to you** by adjusting the programmes you are given to choose from.

Keep your paper 'questionnaire guide' document handy or ask a study team member for a copy to look at. This will help explain what the different programme options mean

Please ask the study team if you are unsure at any point.

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Build your own stage task

Choose your ideal home based programme

Instructions:

On the **left** are **6 features** that make up a home-based programme.

For each programme feature, **choose your one favourite** from the possible options on the **right.**

Programme features	Possible options to choose from
Whether I might be prompted to visit my GP or other appropriate local services during the programme.	◯ **I might be prompted to visit my GP or other local services and support if appropriate** ◯ **The programme works all on it's own in and around my home.**
How often the healthcare professional would check in with me while using the programme	◯ **Weekly** ◯ **Fortnightly** ◯ **Monthly**
How the programme would be built for me to use	◯ **Paper-based programme** ◯ **Digital-Based programme**
Where I would be first introduced to the programme and my needs assessed	◯ **At Hospital** ◯ **At my GP or community venue** ◯ **At my home**
When I would start using the programme	◯ **Referred by my GP** ◯ **Booked for my operation**
Whether I would wear monitoring technology to track my progress	◯ **Technology is used to track my progress at home** ◯ **Not used**

Remember, take a look at your questionnaire guide if you need more details about each option.

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Example screener stage task

Which of these home-based programme might work for you?

Instructions:

Here are **4 possible home-based programmes, each slightly different from the ideal programme you selected.**

All are built from the **same list of possible options you have already seen**.

For **each** programme, please tell us **whether you would consider using it** or not?

(1 of 7)

Whether I might be prompted to visit my GP or other appropriate local services during the programme.	I might be prompted to visit my GP or other local services and support if appropriate	The programme works all on it's own in and around my home.	I might be prompted to visit my GP or other local services and support if appropriate	The programme works all on it's own in and around my home.
How often the healthcare professional would check in with me while using the programme	Weekly	Fortnightly	Fortnightly	Monthly
How the programme would be built for me to use	Paper-based programme	Digital-Based programme	Paper-based programme	Digital-Based programme
Where I would be first introduced to the programme and my needs assessed	At Hospital	At my home	At my home	At my GP or community venue
When I would start using the programme	Booked for my operation	Booked for my operation	Referred by my GP	Booked for my operation
Whether I would wear monitoring technology to track my progress	Technology is used to track my progress at home	Not used	Not used	Technology is used to track my progress at home
	○ I would consider using this programme ○ This one won't work for me	○ I would consider using this programme ○ This one won't work for me	○ I would consider using this programme ○ This one won't work for me	○ I would consider using this programme ○ This one won't work for me

Remember, take a look at your questionnaire guide if you need more details about each option.

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Example must have/unacceptable question

Okay, it looks like you are avoiding programmes with a particular option?

Would any of the following options be **totally unacceptable** to you?

If so, mark the **one option** that is most unacceptable.

This option will stop appearing in the next programmes.

- ◯ **Where I would be first introduced** to the programme and my needs assessed - At Hospital
- ◯ **How the programme would be built** for me to use - Paper-based programme

- ◯ None of these are totally unacceptable.

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Example choice tournament task

Which of these 3 programmes is your favourite?

Instructions:

Here are **3 different home-based programmes**

Which one of these 3 programmes would you **most want to use?**

We've greyed out the **identical** features to help you **focus on the differences** between them.

(1 of 7)

Whether I might be prompted to visit my GP or other appropriate local services during the programme.	**I might be prompted to visit my GP or other local services and support if appropriate**	**I might be prompted to visit my GP or other local services and support if appropriate**	**I might be prompted to visit my GP or other local services and support if appropriate**
How often the healthcare professional would check in with me while using the programme	**Weekly**	**Monthly**	**Weekly**
How the programme would be built for me to use	**Digital-Based programme**	**Digital-Based programme**	**Digital-Based programme**
Where I would be first introduced to the programme and my needs assessed	**At my GP or community venue**	**At Hospital**	**At my home**
When I would start using the programme	**Referred by my GP**	**Referred by my GP**	**Referred by my GP**
Whether I would wear monitoring technology to track my progress	**Technology is used to track my progress at home**	**Technology is used to track my progress at home**	**Technology is used to track my progress at home**
	○	○	○

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Appendix 6: Chapter 2 participant questionnaire guidance document

Northumbria University NEWCASTLE

NHS York Teaching Hospital NHS Foundation Trust

NHS The Newcastle upon Tyne Hospitals NHS Foundation Trust

South Tees Hospitals NHS NHS Foundation Trust

NHS Manchester University NHS Foundation Trust

North Tees and Hartlepool NHS NHS Foundation Trust

Questionnaire Guide

Please read the participant information sheet before looking at this guide.

This guide will help you complete the questionnaire, especially if you are taking part at home before your appointment. A copy will also be available if you are waiting to take part at your appointment.

Important background information

Any future home-based programme to help patients improve their health before surgery will need 4-6 weeks. It would be designed to guide patients step-by-step through the process. This might include an exercise programme and support with reducing other risk factors such as smoking. All of this would be done in or around the person's home, without needing regular trips to hospital or other venue. Patients on the programme would be supervised and helped by programme staff

There are lots of different ways a programme could be designed and delivered. The opinions of people who are actually undergoing surgery are essential to help us design an acceptable and useful programme.

About the 'choice experiment'

The main part of the questionnaire is a 'choice experiment'.

The choice experiment involves a range of 'attributes' and 'levels'. You can think about it a bit like buying a car. Attributes would be things like the maker, the colour, or the number of doors. Each attribute has levels, or different ways to do it. For example, when choosing a car, the attribute might be 'colour'. The levels would then be: Red, blue, white, black, etc.

In this case, rather than a car, the experiment is about a home-based programme for patients approaching surgery. Like cars, the programme we design will have several attributes that can be done in different ways.

In this questionnaire we will show you a selection of potential programmes with different levels for each attribute and ask you to indicate which programme you prefer. This will be different for everyone but by looking at all participants together we can start to plan programmes that future patients will want to use.

The attributes and levels involved in the experiment are explained below. To help you in making your choices you can look back at these as you go through the choice experiment.

Attribute	Levels	What this means
1. When I would start using the programme At what point would I prefer the home-based programme to start before my operation?	Referred by my GP	I start using the programme when my GP refers me to see a surgeon with my problem. At this point you would have the most time before a possible operation to start making changes to your lifestyle. However, it might be decided an operation isn't needed once you have seen a surgeon later.
	Booked for my operation	I start using the programme when I am booked for an operation. At this point you have seen your surgeon and together decided an operation is definitely needed. However, you might have less time to make beneficial lifestyle changes than if it had started when you were referred by your GP.

2. How the programme would be built for me to use. How would I prefer to participate in the programme? This is how information and instructions are presented to me so I can start making lifestyle changes to improve my general health and fitness before surgery.	Digital-based programme	The programme is delivered digitally using a website that can be accessed on a home computer, tablet device or smartphone. You would follow the information and instructions to help modify your lifestyle and record progress using an online website. The website would be designed with patients like you, for patients like you to be 'user-friendly', even for those less confident with computers. You would be shown how to use the website before starting You would need a device that can connect to the internet. It would allow features such as information videos and allow patients to interact with each other and staff using message boards and 'ask the expert' options. It would allow you to have an interactive experience and feel more supported with the programme if you would like this. All exercise equipment needed would be provided
	Paper-based programme	The programme is delivered as a paper-based handbook or manual. The manual would include guidance, pictures, and details to support you to improve your health. You would follow the information and instructions to help modify your lifestyle and record your progress using the manual. The manual would be designed with patients like you for patients like you from the start to be 'user-friendly'. You would be shown how to use the manual before starting. It would not require access to the internet, or an internet enabled computer or device to use. A paper-based option would not be able to include information videos or instructions and would not be able to support interaction with other patients and staff. All exercise equipment needed would be provided

3. Where I would be first introduced to the programme and my needs are assessed. How should I be introduced and started on the programme and my needs for lifestyle change assessed?	At hospital	I go to hospital to be introduced to the programme and shown how to use it by a healthcare professional face to face.
	At my GP or community venue	I attend my GP or community venue to be introduced to the programme and shown how to use it by a healthcare professional face to face.
	At my home	A healthcare professional visits my home to introduce me to the programme and show me how to use it face to face.
4. How often the healthcare professional would check in with me while using the programme. How frequently should the healthcare professional check in with me while using the home-based programme to monitor progress?	Weekly	I have regular weekly contact with a healthcare professional, and someone is always available for problems or questions.
	Fortnightly	I have regular fortnightly contact with a healthcare professional, and someone is always available for problems or questions.
	Monthly	I have Monthly regular contact with a healthcare professional, and someone is always available if I have problems or questions.

5. Whether I would use monitoring technology to track my progress. Do I use technology to help monitor my progress during the programme?	Technology is used to track my progress	My progress is monitored with the help of wearable technology e.g., a 'fitbit' to record my physical activity. This would be provided for me, and I would be shown how to use it when starting the programme.
	Not used	No technology is used to monitor my progress.
6. Whether I might be prompted to visit my GP or other appropriate local services during the programme. Does the programme encourage me to seek help from other local supporting services such as 'stop smoking' or my GP if it might help me improve my health further?	I might be prompted to visit my GP or other local services and support if appropriate.	The programme could ask and prompt me to attend other appropriate services or my GP based on my needs. This might include smoking cessation services, alcohol reduction services or other exercise facilities available.

Appendix 7: Chapter 3 copy of study protocol manuscript in press

Systematic development and feasibility testing of a multibehavioural digital prehabilitation intervention for patients approaching major surgery (iPREPWELL): A study protocol

Short title: Study protocol for a multibehavioural digital prehabilitation intervention

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Abstract

Improving outcomes for people undergoing major surgery, specifically reducing perioperative morbidity and mortality remains a global health challenge. Prehabilitation involves the active preparation of patients prior to surgery, including support to tackle risk behaviours that mediate and undermine physical and mental health and wellbeing. The majority of prehabilitation interventions are delivered in person, however many patients express a preference for remotely delivered interventions that provide them with tailored support and the flexibility. Digital prehabilitation interventions offer scalability and have the potential to benefit perioperative healthcare systems, however there is a lack of robustly developed and evaluated digital programmes for use in routine clinical care. We aim to systematically develop and test the feasibility of an evidence and theory-informed multibehavioural digital prehabilitation intervention 'iPREPWELL' designed to prepare patients for major surgery. The intervention will be developed with reference to the Behaviour Change Wheel, COM-B model, and the Theoretical Domains Framework. Codesign methodology will be used to develop a patient intervention and accompanying training intervention for healthcare professionals. Training will be designed to enable healthcare professionals to promote, support and facilitate delivery of the intervention as part of routine clinical care. Patients preparing for major surgery and healthcare professionals involved with their clinical care from two UK National Health Service centres will be recruited to stage 1 (systematic development) and stage 2 (feasibility testing of the intervention). Participants recruited at stage 1 will be asked to complete a COM-B questionnaire and to take part in a qualitative interview study and co-design workshops. Participants recruited at stage 2 (up to twenty healthcare professionals and forty participants) will be asked to take part in a single group intervention study where the primary outcome will include feasibility, acceptability, and fidelity of intervention delivery, receipt, and enactment. Healthcare professionals will be trained to promote and support use of the intervention by patients, and the training intervention will be evaluated qualitatively and quantitatively. The multifaceted and systematically developed intervention will be the first of its kind and will provide a foundation for further refinement prior to formal efficacy testing.

Introduction

Approximately 310 million people undergo surgery globally each year [1], and requirement for surgical intervention continues to grow. Improving perioperative outcomes is an ongoing healthcare challenge. In the UK 2.4 million major surgical procedures are undertaken by the National Health Service (NHS) annually [2], with associated perioperative mortality and major morbidity rates estimated at 3.5-4% [3,4] and 15-40% respectively [5]. A single major complication such as wound infection, postoperative pneumonia, myocardial infarction, or acute kidney injury profoundly disrupts a patients' recovery and has major implications for healthcare utilisation. For example, length of hospital stay is increased up to 3-fold [6], risk of re-admission is significantly increased [7], and patients are less likely to be discharged to their home environment [8]. In the longer-term, functional status and quality of life of patients is undermined for several months following discharge, with many individuals never regaining their former independence [9].

Physically and mentally preparing patients for major surgery is one strategy to improving outcomes, a concept known as prehabilitation [10]. Patients with better physical [11], nutritional [12] and mental health [13] encounter fewer complications, leave hospital sooner and experience a faster and more complete recovery, with better preservation of their preoperative independence and quality of life [10]. Optimising the preoperative physical and mental health of individuals in this way carries considerable importance. Co-morbid disease and health risk behaviours render the body less able to tolerate the physiological demand of surgery, thereby elevating the risk of perioperative complications 2-3-fold [10]. Furthermore, anxiety and low self-esteem are also very common in preoperative patients and have shown to increase perioperative risk [13]. These risk factors frequently cluster in surgical patients with at least two evident in 40% of patients presenting for major surgery [14]. Fortunately, scheduled surgery presents a key 'teachable moment' to facilitate behavioural change [14]. Patients have been shown to be amenable to optimising their health using behavioural change interventions preoperatively. Furthermore, changes in health behaviours that can increase resilience for surgery and reduce perioperative risks are achievable within 4 weeks [15]. The main pillars of prehabilitation are physical activity and exercise, nutritional optimisation, and support for

mental wellbeing [16]. However, interventions to promote smoking cessation [17], alcohol reduction [18] and improved sleep quality [19] may be equally important and should be incorporated into multibehavioural interventions to optimize patient health in the limited time available preoperatively. Access to preoperative support is a clear patient priority. Prior work has emphasised the importance of improved postoperative functional outcomes from the patient perspective [20], the area of strongest evidence for the benefits of support [15]. At a system level, prehabilitation is now a key recommendation of several national initiatives to improve the quality of UK perioperative care [21, 22]. This shift in focus across perioperative services is now cross-specialty, underlined by the recent reframing of 'waiting lists' to 'preparation lists' driven in part by the severe impact of the Covid-19 pandemic on surgical waiting times and population health [22].

The Covid-19 pandemic has greatly influenced the delivery of prehabilitation services in the UK over the last 2 years. Several established services that were previously delivering face-to-face interventions were forced to rapidly innovate to deliver remote support to patients. This was at a time when evidence-based remote solutions, including digital interventions, were lacking. The subsequent 'explosion' of interest in digital healthcare initiatives has gone some way to help meet this shortfall with NHS organisations often working in partnership with industry to rapidly create solutions. However, the lack of evidence-informed, systematically developed interventions raises questions about effectiveness, replicability, and, of critical importance, uptake and continued engagement by patients and healthcare professionals (HCPs). Uptake and engagement were the topic of an editorial [23] that highlighted the need to address several key questions in the context of intervention development. These include determining whether a digital solution is wanted by patients and HCPs and why; to what extent they believe it would be beneficial; how a digital intervention could be used to optimise outcomes; whether it would be cost-effective; and whether is there a risk of increasing inequalities in perioperative care. The experience of face-to-face prehabilitation services pre-pandemic indicated that up to 50% of patients were unable or unwilling to engage with this model [24] Barriers include: The requirement to travel, associated cost, inflexibility in terms of time and location, and discomfort in group settings. Digital solutions offer a potential alternative and have been successfully delivered elsewhere in the context of type 2 diabetes management [25] and cardiac

rehabilitation [26], and these interventions have observed high levels of patient engagement and health behaviour changes comparable to face-to-face programmes. Given the similarities between these populations and those preparing for major surgery, in terms of age, comorbidity and health behaviour characteristics, it is reasonable to assume that uptake and engagement with a digital intervention preoperatively would be comparable. The use of digital prehabilitation interventions aligns with wider NHS drivers to incorporate digital technology into patient care [27]. The need for scalability and efficient use of staff time makes digital solutions a logical way forward and has the potential to enhance healthcare systems and service delivery.

In the context of digital health behaviour change, 'digital exclusion' is a key concern and has the potential to widen existing health inequalities [28]. Those in the most deprived socioeconomic groups exhibit the highest rates of health risk behaviours that elevate perioperative risk, yet they also face barriers to using digital interventions including access to a device and continued internet access [28]. In addition, the mean age of patients undergoing major surgery is 67 years. Whilst information technology confidence and internet usage in older age groups continues to grow, and a greater proportion of older adults have become familiar with remote services due to Covid, there are still a proportion of this population who are not confident to use digital interventions. As such, utilisation of co-design methods is key to mitigating these inequalities and optimising engagement of patients and HCPs [29]. As with all health behaviour change interventions, prehabilitation interventions are likely to be significantly enhanced by employing a systematic, theory and evidence-informed developmental process in collaboration with stakeholders to increase uptake, engagement, adherence, and overall impact [29].

Study Aims and objectives

The aim of this study is to systematically develop, and feasibility test a multibehavioural digital prehabilitation intervention for patients approaching major surgery. More specifically, the main objectives are as follows:

- To develop a theory and evidence-informed digital prehabilitation intervention to target changes in lifestyle behaviours including physical activity, exercise, nutrition, alcohol consumption, sleep, smoking and psychological wellbeing prior to major surgery
- To develop a theory and evidence-informed training resource for HCPs to promote and support delivery of the digital intervention
- To assess the feasibility, acceptability, and fidelity of the digital intervention for patients approaching major surgery and supporting HCPs
- To assess adherence to and completion of the intervention (i.e., do participants work through all components of the intervention and engage with the HCPs providing support
- To assess the feasibility, acceptability, and fidelity of delivery and receipt of the 6. training intervention for HCPs
- To conduct a qualitative process evaluation with participants (patient and HCPs) to identify determinants of uptake, engagement, continued use and completion of the intervention.
- To develop a set of implementation strategies with stakeholders to facilitate future implementation of the intervention should it demonstrate to be acceptable and feasible.

Additional objectives are to generate estimates of variability for behavioural outcomes (e.g., physical activity) and outcomes (e.g., quality of life) to inform a sample size calculation for a randomised controlled trial (should the intervention demonstrate acceptability and feasibility), and to undertake a preliminary cost evaluation of the intervention.

Materials and Methods

Study setting and design:

his two-stage study will be conducted at two NHS Hospital Trusts: South Tees Hospitals NHS Foundation Trust, Middlesbrough, UK and York and Scarborough Teaching Hospitals NHS Foundation Trust, York, UK. Stage 1 of the study involves the systematic development of an evidence and theory-informed multifaceted behavioural intervention, and stage 2 involves testing the feasibility of the intervention in practice. Figure 1 presents a SPIRIT schedule of enrolment, intervention and assessments for study stage 2 and an overview of stage 1 and 2 design and timelines is presented in figure 2.

Figure 1: SPIRIT schedule of enrolment, interventions, and assessments (study stage 2).
[INSERT figure 1]

Figure 2: Overview of the study design and timelines
[INSERT FIGURE 2]

Procedure

Stage 1 (Months 0-15):

A mixed method systematic intervention development process will be undertaken with reference to guidance for developing digital interventions [30]. The intervention will be underpinned and informed by the behaviour change wheel (BCW) [31], COM-B model, the theoretical domains framework (TDF) [32] and a person-based approach [33]. Data generated will inform the development of a logic model and selection of behaviour change techniques (BCTs) [34] for inclusion in the intervention. Subsequently, a co-design group will be recruited to collaborate with our multidisciplinary research team, including health psychologists, perioperative clinicians, exercise scientists, dietitians, and our partner web developers (Hark 2

Ltd, Leicester, UK). The group will include patient participants (those preparing for and having recently undergone major surgery), HCP participants recruited from the two participating NHS Trusts, and other stakeholders (e.g., commissioners) in order to develop a set of implementation strategies alongside the intervention [35].

Intervention

The multibehavioural digital intervention will be web-based and accessible via desktop, tablet, and mobile phone. The digital intervention and an accompanying training resource for HCPs will be co-designed with participants to facilitate changes in risk behaviours (e.g., physical activity, smoking, alcohol consumption, nutrition, sleep, and psychological wellbeing) with the overall aim to improve preoperative physical and mental health and wellbeing and reduce perioperative risk. The intervention will be designed for delivery/receipt over 4-8 weeks prior to surgery. 214

Stage 2 Overview (Months 16-24):

A single-arm mixed methods study will be used to assess feasibility and acceptability of the intervention with patients preparing for major surgery and HCPs promoting and supporting delivery of it each participating NHS Trust.

Stage 1 Sampling, eligibility criteria and recruitment

Sampling strategy

A purposive sampling strategy will be used to recruit patient and HCP participants representative of the UK major surgical population and the modern multidisciplinary perioperative team. In terms of patient recruitment, the aim will be to ensure maximal variation of age, gender, ethnicity, socioeconomic deprivation, and experience/confidence with online technology. Furthermore, we will aim to obtain a representative sample in terms of the health risk behaviours targeted by the prehabilitation intervention (e.g., smoking status). For recruitment of healthcare professionals, we aim to achieve maximal variation in terms age, gender, ethnicity,

professional background, number of years in the role and experience with provision of prehabilitation support and digital healthcare interventions. Participant numbers recruited at each site will be adjusted to reflect differing surgical caseloads and specialties. Up to40 participants (20 patients and 20 HCPs) will be recruited to stage 1of the study and asked to complete a COM-B self-evaluation questionnaire and participate in a semi structured interview. With reference to published guidance on data saturation for theory-informed interview studies [36], an interim analysis will be conducted following data collection from the 10th patient and the 10th HCP participants. If new ideas and themes continue to emerge, recruitment will continue, and sample size will be increased in increments of three. This will be followed by a further interim analysis, up to a maximum of 20 patients and 20 HCPs. Where possible, these participants will also be invited to participate in co-design workshops. 243 Recruitment of participants to co-design workshops will be guided by individual session requirements. The aim is for patient and HCP participants to attend workshops together, with no more than 12 participants present at each session. Patient or HCP specific sessions may be required depending on progress of the co-design process and/or preferences of each participant group.

Stage 1 eligibility criteria

Patients

Patients aged ≥18 years preparing for major surgery (as indicated by NICE NG45 [37]) or within 3-months of having undergone major surgery; discharged to their own home; able to communicate in spoken and written English, and able to provide informed written consent will be eligible to take part in the study. Patients receiving end-of-life-care will be excluded.

Healthcare professionals

Perioperative team members employed by participating Trusts from a medical, nursing, or allied healthcare professional background or a wider stakeholder in perioperative care (e.g.,

an individual with management or commissioning responsibility for perioperative services) will be eligible to take part. A willingness to take part in training to support promotion and/or delivery of the intervention is essential. 264

Stage 1 recruitment and consent

Patient participants

Eligible patients will be identified by screening preoperative clinical and surgical lists by perioperative teams at participating Trust sites. A patient participant information sheet (PIS) will be sent by post or email to each participant, with a follow-up call within seven days to confirm receipt and determine interest in participation. Those wishing to take part in the study will be asked to provide informed consent prior to data collection through completion of a study consent form. Patients declining participation will continue to receive usual perioperative care and a reason for non-participation will be recorded. We anticipate that patient participants may wish to involve a partner, friend, or family member during their interview or at workshops, and we acknowledge the valuable contribution these companions can make to the co-design process. As such, we will ask companions to complete a consent form to enable their contributions to be recorded, analysed and findings used to contribute to the intervention development process. Preoperative patients and patients within 3 months postoperatively are eligible to participate in the study to inform intervention development. This acknowledges that short preoperative timeframes may prevent patients participating in all stage 1 components before their operation (e.g., major cancer surgery). Patients who do undergo surgery following participation in stage1 of the study may continue to participate postoperatively if they wish. This facilitates the collation of views from patients who are approaching surgery and/or have undergone surgical intervention.

Healthcare professional participants

Eligible HCPs will be identified by clinical members of the study team and provided with a copy of the stage 1 HCP PIS by email. HCPs wishing to participate in the intervention development study will be asked to respond positively to the email invitation and subsequently provide informed

written consent with a member of the research team prior to data collection. Additional recruitment will be undertaken to offset drop-out between stage 1 components.

Stage 1 Study procedures and data collection

A case record form will be completed for all stage 1 participants to facilitate a description of individual participants and to characterise the group overall. Baseline data to be collected from participating patients are demographics (i.e., age, sex, ethnicity, marital status, postcode for calculation of Index of Multiple Deprivations, and educational attainment); clinical and health risk behaviours (e.g., Surgical stage [pre/postoperative], surgical date/planned date, specialty and procedure/planned, procedure, cancer status, Neoadjuvant chemoradiotherapy, comorbidities, Physical activity status [WHO criteria for healthy adults], smoking status, and alcohol intake [units per week]), malnutrition status [PG-SGA]; and information technology access and confidence (e.g., Frequency and availability of internet access, device ownership and utilisation). Baseline data to be collected from participating HCPs are, demographics (e.g., age, sex, and ethnicity); and occupational data (e.g., clinical role, length of time in clinical role, prior experience in prehabilitation support, prior experience in utilisation of digital clinical interventions with patients).

COM-B self-evaluation questionnaires

The COM-B behavioural self-evaluation questionnaire adapted for the content of prehabilitation [31] will be administered to perform a behavioural analysis with each participant (patients and HCPs). In the context of behavioural change, capability (C), opportunity (O) and motivation (M) will be explored in accordance with the COM-B model. COM-B self-evaluation questionnaires are provided in our supplementary document (S1). Questionnaire data will be collated and used to inform and tailor semi-structured interviews.

Semi-structured interviews

Following questionnaire completion, participants will be invited to take part in a semi-structured interview with a research team member lasting up to 60 minutes. Interview topic guides [see supplementary document S2] will be informed by the COM-B model [31] and individualised to explore COM-B questionnaire responses in more detail.

Co-design workshops

A series of co-design workshops will be undertaken and facilitated by at least two members of the multidisciplinary research and design team. Each workshop will be guided by a schedule and will last up to two hours. The first workshop will involve a summary of the initial programme concept and COM-B questionnaire and semi-structured interview findings to provide context. Subsequent workshops will begin with a brief introduction, including session aims and objectives and progress made since previous workshops. Where workshops are conducted in-person, they will be conducted in line with each current covid-19 guidelines within each site to maintain staff and patient safety. Remote participation sessions (utilising a videoconferencing platform) will be offered if required (appropriate for ongoing pandemic restrictions). Given the nature of the intervention to be developed (i.e., remote/digital), it is considered appropriate to offer a remote option to participate to overcome barriers including cost and travel. Workshops will be supported by detailed notetaking by session facilitators Individual co-design workshops will be structured in response to findings from TDF analyses (see stage 1 data analysis) and activity during earlier sessions. Briefly, workshop topics will be informed by the findings of the behavioural analysis and TDF semi-structured interview findings with reference to the BCW and BCT Taxonomy v1 [34]. Participants will be invited to attend up to six workshops with no minimum commitment beyond one workshop. Workshops five and six will involve usability testing employing 'think-aloud' techniques [33]. The digital intervention content and associated HCP training intervention will be iteratively developed in collaboration with participants during each session. Following the conduct of the final workshop, the resulting prototypes will be updated/modified, where required in preparation for feasibility testing (i.e., stage 2 of the research).

Stage 1 Data analysis

Semi-structured interviews

All interviews will be audio recorded and transcribed verbatim. Transcripts will be thematically analysed (deductively) using the TDF. The following procedure will be followed: The first participant transcript will be independently pilot coded by two team members and discussed to agree on an initial coding strategy. The same research team members will independently read, re-read and code two further transcripts. If a good level of agreement is achieved, the first researcher will code/analyse the remaining transcripts. Text segments will be assigned to relevant domains of the TDF, and a thematic analysis conducted within each theoretical domain. If specific text segments do not fall into a specific TDF domain, additional domains will be generated to ensure the entire dataset is represented. Following analyses of the dataset, domains identified, and associated themes will be used to select BCTs to include within the intervention with reference to the Behaviour Change Taxonomy v1 [34].

Co-design workshops

Audio recordings of workshops will be transcribed verbatim. Transcripts will be reviewed alongside facilitator notes to capture all key information and decisions. This will enable an audit trail and reporting of when, how, and why key development decisions were made. Following the conduct of each co-design workshop, a summary document will be prepared to enable Hark 2 to iteratively develop an intervention prototype ahead of usability testing.

Stage 2 Sampling and eligibility criteria

Stage 2 Sampling strategy

Up to 40 patient participants listed for major surgery (from a range of surgical specialties) will be recruited to take part in the study from the two participating Trusts. This target sample size is informed by published guidance for pilot and feasibility studies [38] and accounts for potential drop-out (≈ 20%). HCP participants will be recruited from each site and required to undergo training (training co-designed during stage 1) and either promote use of the digital intervention by patients or provide support to those using it. The number of stage 2 HCP participants will be guided by stage 1 findings (i.e., following consensus on who should fulfil what role).

Stage 2 Eligibility criteria

Patient participants

Patients aged ≥18 years preparing for major surgery (as indicated by NICE CG45 [36]) and available for a minimum of 4 weeks prior to planned surgery; ASA (American Society of Anaesthesiology) fitness for surgery ? grade 2; At least one health risk behaviour amenable to prehabilitation (e.g., current smoker); able to access and utilise the internet at home; able to communicate in spoken and written English, and able to provide informed written consent will be eligible to take part in the study. Participants who are pregnant or planning pregnancy; have severe mental illness (under active investigation or treatment by mental health services and/or preventing written informed consent); already undergoing prehabilitation or have a preference for an alternative mode of support (e.g., an in-person, face-to-face service); and those receiving end-of-life-care will be excluded. Where a patient participant has a safety contraindication to unsupervised exercise training based on ACSM criteria for clinical exercise testing and prescription [39], they will be excluded from the structured exercise component of the intervention but will be given access to other components of the intervention.

Healthcare professional participants

Perioperative team members currently caring for patients approaching major non-cardiac surgical intervention will be eligible to take part. A willingness to take part in training to support promotion and/or delivery of the intervention is essential.

Stage 2 Recruitment and consent

Patient participants

Patients listed for major surgery will be screened for eligibility by perioperative teams utilizing electronic hospital records. Potential participants will be approached by telephone to explore interest. Those interested will be given a patient PIS sent by post or email. Interested patients

will receive a follow-up telephone call by a team member within 7 days allowing time to receive, read and understand the study information and consider participation. Those who would like to participate will be invited to undertake a screening and baseline assessment (visit 1) where they will be given an opportunity to ask questions and complete a consent form with a study team member. Patients who decline participation at that stage will undergo routine preoperative care and their reason for non-participation will be recorded if they elect to provide one.

Healthcare professional participants

Perioperative team members at each site will be contacted by email inviting them to take part in the study with a follow-up after 7 days providing time to consider participation. The email will provide a HCP PIS and those who are interested in taking part will complete a consent form with a study team member and be invited to begin the intervention HCP training package.

Stage 2 Outcome measures

Primary outcomes

1. Feasibility:

Feasibility will be determined by assessing participant recruitment and retention rates, time taken to recruit to the target sample size, and rates of intervention uptake and completion, including number of patients completing all relevant components of the intervention. Feasibility of the training intervention will be determined by assessing HCP participant recruitment and retention rates, time taken to recruit to the target sample size, and rates of training intervention uptake and completion, including willingness to refer to the intervention and continue to promote and support patient participants with the intervention.

2. Fidelity:

Fidelity of delivery will be assessed by collecting data relating to intervention usage by patient participants, including when components were accessed, revisited, and for what length of time. Fidelity of receipt and enactment will be assessed qualitatively via semi-structured interviews with patient participants. Fidelity of delivery of the training intervention will be assessed by audio recording delivery of the training to ensure all intervention components are delivered per protocol using an intervention fidelity checklist [40]. Fidelity of receipt and enactment will be assessed qualitatively via semi-structured interviews with HCP participants.

3. Acceptability:

Acceptability will be assessed quantitatively and qualitatively. In terms of patient participants, data will be collected on the number of logins over the intervention period and the number of interactions with facilitating HCP participants. In terms of HCP participants, data will be collected on the number of HCPs who consent to take part in the study/be trained and who complete training. Semi-structured interviews using the TDF as an analysis framework will obtain participant (patients and HCPs) views and experiences of the intervention, including their experiences of using/interacting with the intervention, perceived barriers, and facilitators to using it and suggestions for ways in which it could be improved.

Secondary outcomes

Data will be collected on the following secondary outcomes: Patient activation (Patient Activation Measure [PAM]); physical activity (International Physical Activity Questionnaire [IPAQ], accelerometery data from integrated wearable device); smoking status (self-reported); alcohol consumption (units per week); nutritional (PG-SGA) and dietary status (Dana-Faber healthy eating questionnaire, modified for personal consumption); sleep (Pittsburgh Sleep Quality Index); exercise capacity (6-minute walk test [6MWT], 30-second sit to stand repetitions, grip strength, maximum inspiratory pressure); Psychological wellbeing (Hospital Anxiety and Depression Scale [HADS]); Health-related quality of life (HRQOL using SF-36v2 and EQ-5D-5L); postoperative mortality and morbidity (30 and 90 day mortality, Comprehensive Complication Index [CCI]); and length of stay and readmission (length of hospital stay, length of

critical care stay, days at home [or usual residence] within 30 days of surgery [DAH30]). The feasibility and sensitivity of data collection for these outcome measures will be explored to identify candidate primary outcome measures for a future randomized controlled trial of the intervention. In addition, semi-structured interviews will qualitatively assess feasibility and usability of the integrated wearable device in support of programme components and perioperative biometric monitoring.

The digital intervention (iPREPWELL)

The content and format of the digital intervention components will be informed by the systematic development process undertaken during stage 1 of the study. However, the intervention will have the following features and functions:

- Intervention duration – the time between participants being listed and having their surgery is between 4 and 8 weeks on average, therefore the duration of the intervention will run in accordance with this timeline. Access will be continuous during this time and up to 3 months postoperatively.
- Intervention components offered to participants will be personalised during registration, i.e.., non-smokers will not be offered content related to smoking.
- Given the tendency for clustering of health risk behaviours and limited preoperative timeframes in surgical populations, intervention components will be designed to run simultaneously. They will be delivered using textual, audio, and visual material.
- Decisions about the specific mode of delivery and format of each intervention component will be informed by findings from the systematic development process.

Additional intervention features could include:

- Incorporation of a wearable physical activity monitoring device to facilitate self-monitoring and real-time participant feedback. The most appropriate device will be agreed in collaboration with participants during phase 1 of the study.

- An online forum facilitating interaction with facilitators and other participants. Direct messaging between the facilitating HCP and participants to prompt behavioural change and provide support.
- Access to educational content in the context of the perioperative journey (e.g., 'digital surgery school').

The physical activity and exercise component of the intervention will be included for all participants reflecting the high rates of physical inactivity within this clinical population, and the potential to enhance aspects of physical fitness in surgical populations [11]. Only participants with identified contraindications to physical activity or exercise will be excluded from this component of the intervention. This intervention component will support increased physical activity and remotely supervised structured exercise before surgery including aerobic, resistance/strength and inspiratory muscle training. Specifically, this will include:

Provision and use of home-based exercise equipment, including resistance bands and an inspiratory muscle training device
Utilisation of the integrated wearable device to guide training sessions and provide feedback e.g., heart-rate guidance for aerobic training sessions

Patients will be encouraged to login throughout the intervention period to engage with the various components to promote/maintain motivation and volition to support health behaviour change. It is anticipated that patients will require a level of remote HCP support throughout the timeline of the intervention. What this involves will be determined during stage 1 of the study, the developmental process. HCP participants will take part in training prior to support patient participants.

The training intervention

The content and format of the training intervention for HCPs will be informed by the systematic development process undertaken during stage 1 of the study. Not wishing to pre-empt the outcome of stage 1 of the study, training is likely to incorporate health behaviour-specific

content to target knowledge, and skills-based training to facilitate promotion of the intervention during routine care and to facilitate the provision of support to patients throughout the intervention period. The training intervention, as with the patient intervention, will be theory and evidence-informed with reference to the BCW [31].

Stage 2 Study visits

Figure. 3 provides an overview of stage 2 of the study (feasibility study). 542
[INSERT FIGURE 3]

Visit 1 (Screening and baseline assessment)

Patient participants will attend the hospital site to undergo a baseline assessment process (incorporating a safety screen for remotely supervised exercise based on ACSM guidance [38]) and registration onto the intervention. The assessment will combine clinical, health behaviour and exercise capacity elements as presented earlier. It will be conducted by a facilitating HCP participant and at least one research team member. The methods for physical activity and exercise capacity assessments are provided in our supplementary document (S3). Following visit 1, patient participants will utilise the digital intervention at home with remote support by a trained HCP participant.

Visit 2 (preoperative assessment)

Visit 2 will be scheduled prior to surgery to assess changes in health behaviours (e.g., physical activity) following platform usage. The visit will be conducted at the hospital site by at least two research team members. Data collected will mirror visit 1 (supplementary document [S4]). 559

Visit 3 (postoperative assessment)

Quantitative data

Data will be summarised descriptively using mean and SD or median and IQR for continuous variables, and count and percentage for categorical variables. As this is a feasibility study, the level of missing data will be documented but no imputation undertaken.

An initial health economic analysis will be conducted to focus on costs of intervention delivery to inform design of a future efficacy study.

An initial exploratory analysis of pseudo anonymised perioperative wearable data will be undertaken utilising machine learning techniques supported by Telstra Health UK.

Qualitative data

Qualitative data will be thematically analysed using the TDF. Two members of the research team will independently code and analyse interview transcripts. The same procedure will be undertaken as described during stage 1 to develop a coding strategy. A detailed description of how data will be handled is provided in supplementary document (S4).

Study management

A study management group (SMG) will be established by the chief investigators prior to the commencement of stage 2 of the study with representation from the sponsor, participating sites and institutions, patient representatives recruited during stage 1, and research partners. The group will oversee the conduct of the feasibility study and meet monthly, or as required.

Study Safety considerations

Stage 1

Participation during Stage 1 is anticipated to present a low risk of adverse events (AEs) for participants. Potential AEs occurring during stage 1 activities will be assessed, graded, and

followed up until resolution by the study team in keeping with study sponsor and UK Good Clinical Practice (GCP) guidance.

Stage 2

Potential AEs occurring throughout the duration of stage 2 of the study, whilst the intervention will be assessed, graded, and followed up by the research team until resolution in keeping with sponsor and GCP guidance.

Risk to patient participants is most likely to originate from participation in the structured exercise training programme. Other intervention components are not anticipated to lead to AEs. The overall risk of AEs relating to exercise is considered low. This is based on a growing body of evidence demonstrating the safety of structured exercise training (including aerobic, resistance and inspiratory muscle training) in surgical populations [41]. This is in addition to the safety profile of several hundred maximal effort cardiopulmonary exercise tests conducted in the study target population at participating sites and nationally [42].

Despite this, we are mindful of the additional risk this poses in comparison to directly supervised exercise interventions. The following measures are planned to mitigate this as far as possible:
An independent clinician will review all serious adverse events (SAEs) and report to the study management group. Participants will be formally risk assessed to confirm safety for participation based on international criteria for exercise training and testing [42] and the expertise of an active face-to-face surgical prehabilitation service.

Participants will undergo several functional capacity assessments face-to-face with trained healthcare professionals prior to commencing remotely supervised training.
The exercise intervention will begin with clear, co-designed safety instructions relating to both undertaking physical activity safely and undertaking activity outside the home environment.
Clear channels for participants will be provided to raise non-emergency concerns with HCP facilitators and the research team and how to access help in an emergency.

The exercise component of the intervention will be scaled to participant capabilities and progression in intensity will be participant, rather than facilitator lead. Wearable data collected during training sessions will allow intensity monitoring and adjustment as required.

Stage 2 participant discontinuation and withdrawal

Stage 2 participants will be free to withdraw from the study at any stage without providing a reason. Participant discontinuation will occur with any of the following:

- Completion of the stage 2 study protocol.
- Acute Illness requiring hospital admission
- Death of participant or commencement of end-of-life care
- Decision to cancel surgical intervention
- Loss of capacity to consent to continue participation
- Participant decision to withdraw
- Investigator decision
- Study management group or chief investigator decision
- Severe non-compliance to protocol as judged by the investigator and/or sponsor
- Safety reasons

If a participant wishes to withdraw or is discontinued from the study, the following procedures will be observed:

- Participants will be offered the chance to take part in a semi-structured interview to provide their reasons for withdrawal from the process to allow learning. Participants will be free to decline this interview without providing a reason.
- Withdrawal of consent/ discontinuation of the study will be clearly documented in study documentation and the participant's medical record.
- No further clinical data will be collected from the participant. However, existing clinical data held will be retained and used for the research.

- Patients will continue with standard of care treatment as recommended by their treating team.

Approvals and registrations

Ethical and regulatory approval for the study has been obtained from Health Research Authority (HRA) North West Preston Research Ethics Committee (Ref: 21/NW/0219). The study is registered on the ISRCTN registry (ISRCTN 17788295) and has been adopted onto the UK National Institute for Health and Care Research (NIHR) portfolio for anaesthesia, pain, and perioperative medicine with South Tees Hospitals NHS Foundation Trust as study sponsor (contact details available via corresponding author).

Study status and timeline

Stage 1 study recruitment is underway at time of writing and commenced in October 2021. The study is planned to complete by October 2023.

Discussion

We have presented a protocol for the development and feasibility testing of a theory-informed co-designed, multibehavioural prehabilitation intervention for people preparing for major surgery at the time of writing, we are unaware of any robust developed interventions following a systematic developmental process available to target changes in multiple health behaviours simultaneously, which is an urgent unmet need in perioperative care. This study aims to develop, and feasibility test a digital multibehavioural intervention for patients and a training intervention for healthcare professionals.

We acknowledge several important limitations to the protocol for the study at this stage. Firstly, our study will be conducted at two centres in the North of England (UK) which may limit wider applicability. Although, both centres serve geographically and socioeconomically diverse populations that will offset this to some degree and this will be further mitigated by a purposive sampling strategy to ensure maximum variation in stage 1 participants. Secondly, we will develop an intervention for those approaching major surgery. We acknowledge this may result in an intervention that is not fully optimised for specific surgical populations or pathways. However, this is deliberate to produce a generic intervention that is feasible and acceptable for the majority of surgical patients and can be readily modified and adapted for specific populations going forward. Should the intervention developed demonstrate to be acceptable and feasible by participating patients and HCPs, a further study will be required to establish effectiveness and cost-effectiveness. Finally, the absence of a control arm within the feasibility study for reasons of time-efficiency and study cost will prevent assessment of intervention efficacy. However, this is not the main aim of the study and the data collected with the single-arm design will provide useful data in support of any follow-up efficacy trial. Stage 1 and stage 2 findings of this study are planned to be disseminated by peer-reviewed publication and presentation at relevant conferences. In addition, our wider study team have links to regional and national initiatives to improve the readiness of patients approaching major surgery in the wake of the Covid-19 pandemic, offering broader opportunities to evaluate and scale the developed programme if the findings of this study support this.

Study amendments will be by submission to the approving Research ethics committee in accordance with UK HRA policies and procedures. Study termination will be either planned by completion of the full protocol at both participating sites or unplanned by the chief investigators following consultation with the study management group.

Supporting information

S1: Stage 1 Patient and HCP participant COM-B self-evaluation questionnaire.

S2: Stage 1 Patient and HCP participant semi-structured interview topic guides.

S3: Methods for stage 2 physical activity and exercise capacity assessment

S4: Study data Handing

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Appendix 8: Chapter 3 copy of study ethical and regulatory approvals

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor Gerard Danjoux
Department of Anaesthesia
Cheriton House, James Cook University Hospital
Marton Road, Middlesbrough
TS4 3BW

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

22 September 2021

Dear Professor Gerard Danjoux

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Systematic development and feasibility testing of a digitally facilitated, remotely supervised, multimodal prehabilitation intervention for patients approaching major surgery.**
IRAS project ID:	**300425**
Protocol number:	**V1.0**
REC reference:	**21/NW/0219**
Sponsor	**South Tees Hospitals NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these

devolved administrations, the final document set, and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation.
The relevant national coordinating function/s will contact you as appropriate Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **300425**. Please quote this on all correspondence. Yours

sincerely,

Abitha Paimpillichalil Approvals
Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mr Joe Millar, South Tees Hospitals NHS Foundation Trust*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_01072021]		01 July 2021
Letter from funder [Sport England Funder Letter]	N/A	06 July 2021
Letters of invitation to participant [HCP invitation stage 1]	v1.0	12 June 2021
Organisation Information Document [OID]	v1.1-2	23 August 2021
Organisation Information Document [OID]	v2.0	23 August 2021
Other [Study protocol v2.0]	v2.0	23 August 2021
Participant consent form [HCP participant stage 1]	v1-2	23 August 2021
Participant consent form [HCP participant stage 1]	v2.0	23 August 2021
Participant consent form [Patient participant stage 1]	v1-2	23 August 2021
Participant consent form [Patient participant stage 1]	v2.0	23 August 2021
Participant information sheet (PIS) [Patient participant stage 1]	v2-3	16 September 2021
Participant information sheet (PIS) [Patient participant stage 1]	v3.0	16 September 2021
Participant information sheet (PIS) [HCP participant stage 1]	v2-3	16 September 2021
Participant information sheet (PIS) [HCP participant stage 1]	v3.0	16 September 2021
Research protocol or project proposal [Study protocol v1-2 tracked changes]	v1-2	23 August 2021
Schedule of Events or SoECAT	2.1	
Summary CV for Chief Investigator (CI) [CI CV]		20 June 2021
Summary CV for student [James Durrand]		20 June 2021
Summary CV for supervisor (student research) [CO-CI Avery CV]	N/A	20 June 2021
Summary CV for supervisor (student research) [Tew CV]	N/A	20 June 2021
Summary CV for supervisor (student research) [O'Doherty CV]	N/A	28 June 2021
Summary CV for supervisor (student research) [Doherty CV]	N/A	28 June 2021
Validated questionnaire [HCP participant COM-B questionnaire]		
Validated questionnaire [Example Duke Activity Status Index (DASI)]		
Validated questionnaire [Example International Physical Activity Questionnaire (IPAQ) short form]		
Validated questionnaire [Example Fagerstrom score]		
Validated questionnaire [Example AUDIT-10]		
Validated questionnaire [Example Dana-Farber Questionnaire]		
Validated questionnaire [Example Pittsburgh Index]		
Validated questionnaire [Example Hospital Anxiety and Depression Scale]		
Validated questionnaire [Example EQ-5D-5L]		
Validated questionnaire [Example SF-36]		
Validated questionnaire [Example Patient Activation Measure (PAM)]		
Validated questionnaire [Patient Participant COM-B questionnaire]		

Appendix 9: Chapter 3 study participant information sheets (patients)

Development of an online health and wellbeing programme for patients approaching major surgery

Participant information sheet

We are developing a new, online resource to help patients get ready for surgery and would like your help to build it!

Because you are about to have or have recently had a major operation, we are inviting you to join our development group to tell us what it is you need (or needed) to prepare for surgery. We will also ask you to share your experiences and views of how you have been supported so far, and whether this was useful. This will help us to build the best resource we can for patients like you who are preparing for surgery.

The resource is being designed and built as part of a research study and PhD project. Before you decide if you would like to participate, it is important that you understand why the study is being done and what taking part would involve.

What is the purpose of the study?

We know that patients who have better physical and mental health tend to have an easier journey through major surgery. They experience fewer problems (complications) afterwards and usually recover more quickly.

Helping patients to improve their physical and mental health and wellbeing **before** an operation is known as 'prehabilitation' and could involve:

- Exercising to get fitter
- Stopping smoking
- Cutting down on alcohol

- Eating well
- Sleeping enough and sleeping better
- Concentrating on improving psychological wellbeing

There are lots of ways to support patients to achieve these things. However, most NHS services need patients to attend hospitals or other venues a few times per week to get help.

Many patients have told us they would prefer a different option due to the travel, cost, and inconvenience of such visits. For example, many patients have said they would prefer support they can access when they want and in and around their own home. This has become very important during the recent Covid 19 pandemic.

This support can be provided using an online programme that is monitored by a healthcare professional. It enables patients preparing for surgery to access and use it on their home computers, tablet devices or smartphones. We plan to develop a programme like this for patient to use at home or anywhere they chose.

Involving people preparing for surgery or those who have recently been through major surgery in the development of the programme is important to ensure it is something they want and provides the information they need. It is also important that future patients can use the programme easily and that it will offer them the type of support they need to improve their physical and mental health leading up to their operation.

Why have I been invited to take part?

As someone who is preparing for surgery, or who has recently been through a major operation, you have experience of what it is like to prepare for surgery.

Getting your views during the development of the programme is vital to ensure we build something that is useful for future patients like you.

Do I have to take part?

No, joining the group is completely voluntary. Choosing not to will in no way affect your ongoing medical care.

If you would like to take part, you will be asked to complete a consent form before joining the first group session. If you decide to join but then change your mind, you can leave at any time without giving a reason.

A member of the team will telephone you around 1 week after postage of this information sheet to determine if you would like to take part if you haven't got in touch with us beforehand.

What will participating involve?

There are 3 parts to the study described below. We invite you to take part in just the 1st two or all three parts. Please speak to the study team if you would like more information or to undertake only a particular part of the research:

Part 1. Complete a brief questionnaire (15 minutes)

We will ask you to complete a brief questionnaire to collect some key information about how the online programme should be designed for patients.

Part 2. Take part in an interview (60 minutes)

You will be invited to take part in an interview with a researcher. This will last up to a maximum of 60 minutes. During this interview the researcher will ask you more detailed questions about what type of information and support you would like to receive from the new programme to enable patients to better prepare for surgery. This interview may take place face-to-face, in person at the James Cook University Hospital or York Teaching hospital or from your own home using a video conferencing system like Zoom or Microsoft Teams. The interview will be **audio recorded** to make sure we don't miss anything important that you tell us.

You may like to involve a partner, friend or family member who is supporting or has supported you around your operation in the interview. We would also like to include this person and understand their experiences of helping someone around surgery. If you have someone in mind who might like to do this, **please show them this information sheet** as we will ask them to consent to take part in the recorded sessions so their contribution can be recognised in developing the programme.

Part 3. Join the programme design group

After this you will be invited to take part in **up to six workshops but can participate fewer if you choose**. The workshops will take place either 'face-to-face' at the hospital or remotely by videoconferencing. All face-to-face meetings during the study will be organised in a Covid-safe environment.

Who else will attend the workshops at the same time as me?

Other people taking part in the workshops may include other patients who have recently had major surgery and healthcare professionals involved in the care of patients undergoing surgery. No more than 25 people will attend each workshop.

Representatives from a web development company who are helping us to build the online programme may also be in attendance at some workshops to ensure they can receive and understand your feedback. They have been involved in several projects like this one before and find this really helps them understand what patients need. The representatives will not have access to any of your personal data.

How long will each workshop last and what will it involve?

Each workshop will last up to **2 hours.** Each group will be arranged at convenient times for group members and will be led by at least two members of the research team: Research team members include healthcare professionals, researchers, health behaviour change specialists and representatives from the company who will be building the online programme

During each session we will **ask for the views of group members on how best to design the programme to provide the health and wellbeing support patients require before surgery. To do this we will present information to group members and ask for their views on it. Everything developed will be based on what group members tell us they need to improve their physical and mental health before surgery.** Group participation will involve viewing and testing out early versions of the online programme as it develops to make sure it is useful and easy to use.

Each workshop will **be audio recorded**. We do this so that we don't miss any important information you tell us about the programme. Once we write up the information from the audio recording, we delete it.

You are welcome to bring someone with you to the group sessions (e.g., a partner, family member or friend). If you would like to do this, please **give them this information sheet to read** because we will ask them to consent to taking part in the same way as we ask you.

At the end of these workshops, we plan to offer the online programme to other patients preparing for an operation. Once they have used it, we will collect their views.

Expenses and payment for participation.

We will be able to reimburse your expenses (e.g., travel costs, mileage, and parking) for every session you attend.

What are the possible advantages and disadvantages of taking part?

Giving up your time to attend and participate in group workshops should be considered.

We also recognise that you may be experiencing a difficult journey toward or recovering from your operation. Discussing issues around this may be stressful or lead to anxiety for some. Please feel free to speak to a team member if this is the case. You do not need to take part in every workshop or stay for the whole workshop if a particular topic is difficult for you.

There is unlikely to be a direct benefit to you from participating. However we hope you will find the experience interesting, informative and that you benefit from the chance to interact

with other patients who have had similar experiences to you. The information you give us may also help develop a programme for people like you in the future.

What if there is a problem?

Any complaint you have about participating in this research project will be addressed appropriately. Please discuss this with a team member in the first instance or use the contact details below. If your issue has not been dealt with following this process, you can contact the Patient Advice and Liaison (PALS) service to take this further.

[PALS CONTACT]

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against South Tees Hospitals NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

How will we use information about you?

We will need to use information from you and your medical records for this research project. People will use this information to do the research or to check your records to make sure that the research is being done properly.

This information will include your:

- Name
- Age
- Contact details including a telephone number, address, postcode, and email address if you have one
- Biological sex at birth and gender
- Marital status
- Employment status
- Your educational history
- Which internet enabled devices you own, have access to and how often you use them
- How often and for how long you use the internet
- Whether you have used programmes like the one we are building before
- Your previous or upcoming surgery and dates
- Your current physical activity level, smoking status and whether you drink alcohol
- Whether you undertook or are undertaking any activity to improve your health before surgery

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to or calling the study team under 'local study team contact below.

What will happen to the results?

The information you provide during interviews and group workshops will be used to develop the new programme. The process used to develop this programme, including the findings from each stage will be presented at academic conferences and published in academic journals. The research is also part of PhD project anonymous data will be submitted as part of a final thesis.

Who is organizing and funding the study?

South Tees Hospitals, York Teaching Hospitals, Northumbria University and Teesside University are organising the study.

The study is funded by Macmillan Cancer Support and Sport England.

Who has reviewed the study?

The study has approval by North West-Preston research ethics committee (21/NW/0219)

Further information

For further information regarding the study, advice around participation or to discuss a problem please contact the study team or the Chief Investigator:

Your local study team:

[INSERT LOCAL TEAM CONTACT]

Chief Investigators:

Dr Leah Avery
Associate Professor in Applied Health Psychology and Chartered Health Psychologist, School of Health and Life Sciences, Teesside University.

leah.avery@tees.ac.uk

Professor Gerard Danjoux

Professor of Perioperative Medicine, School of Health and Life Sciences, Teesside University and Hull York Medical School, and Consultant in Anaesthesia and Sleep Medicine at the Department of Anaesthesia and Perioperative Medicine, South Tees Hospitals NHS Foundation Trust.

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Telephone: 01462 850 850

Department of Anaesthesia

Cheriton House, James Cook University Hospital

Marton Road

Middlesbrough, TS4 3BW

Appendix 10: Chapter 3 study participant information sheets (healthcare professionals)

Development an online prehabilitation programme for patients approaching major surgery

Healthcare Professional Participant information sheet

We are developing a new, online resource to help patients get ready for surgery and would like your help to build it!

As a healthcare professional involved in the care of patients preparing for major surgery, we are inviting you to join our multidisciplinary design group to share your experience and expertise. This will help us build the best resource we can for patients preparing for major surgery.

The resource is being developed as part of a research study and PhD project. Before you decide if you would like to participate, it is important you understand why the study is being done and what taking part as a group member would involve.

What is the purpose of the study?

We know that patients who have better physical and mental health have an easier journey through surgery, encounter fewer complications and recover more smoothly

Helping patients to improve their health and wellbeing prior to surgery is known as 'prehabilitation' and can reduce perioperative risk. Prehabilitation may include:

- Exercise training
- Smoking cessation
- Alcohol reduction
- Nutrition support

- Supporting more and better-quality sleep
- Supporting psychological wellbeing

There are many ways to support patients in these areas. However, most NHS services need patients to attend hospitals or other venues a few times per week to access it.

Patients have told us they would alternative options due to avoid travel, cost, and inconvenience. Specifically, support they can access more flexibly in and around their own home. This is now urgent following the Covid 19 pandemic.

Remote support can be provided using an online programme, supervised by a healthcare professional, that patients preparing for surgery can access and use on their home computers, tablet devices or smartphones. We plan to design and build the first programme of this kind.

Involving healthcare professionals in the design of the platform is crucial to ensuring it works for patients and supporting staff.

Why have I been invited?

As someone experienced in caring for patients preparing for major surgery, **your views are crucial to ensure the resource we develop work in day-to-day clinical practice to support patients.** We also need your input to help develop the accompanying training resource for healthcare professionals.

Do I have to take part?

No, taking part is completely voluntary.

If you would like to take part, you will be asked to complete a consent form before the 1st session. If you decide to join but then change your mind, you can leave at any time without providing a reason.

What will taking part involve?

There are 3 parts to the study described below. We would invite you to participate in:

1. Parts 1 and 2 only
2. Parts 1, 2 and 3

However, if you would like to undertake a particular part only, please get in touch with the study team

Part 1: Complete a brief questionnaire (15 mins)

We will ask you to complete a 15-minute **structured questionnaire** around the facilitators and barriers to behaviour change before surgery.

Part 2: Undertake an interview with a research team member (up to 60 mins)

We will invite you to undertake an **interview** with you lasting up to 60 minutes. This is to obtain your views in more detail on how best to support patients before surgery. This will be **audio recorded** to ensure we don't miss any key details, transcribed and then the recording will be deleted.

Part 3: Join the programme co-design group

We will invite you to attend a series of design workshops alongside other HCPs and patients who have recently undergone or a preparing for major surgery. You can take part in **up to six workshops but there is no minimum**

Workshops will last approximately **2 hours**, scheduled at convenient times for the group and led by at least 2 members of our study team: These may include health psychology and behaviour change specialists and representatives from the company who will be building the online platform itself.

During each session we will **seek the views of group members on how best to design the platform and provide the health and wellbeing support, present information to patients using it and ensure it is friendly and easy to use.** This will involve viewing and testing out early versions of the platform and the staff training resource as they develop.

There will be opportunity to take part 'face-to-face' in a Covid-safe environment at the James Cook University Hospital or York Hospital or online using a video conferencing platform.

Each workshop **will be audio recorded**. This is so our team can review these later and help understand how and why decisions about the platform were made. Recordings will be deleted after they are transcribed.

At the end of this process, the online platform is planned go on to be road-tested by patients preparing for an operation.

Your taking part in the study will end when you leave your last workshop.

Expenses and payment for participation.

We are unfortunately unable to reimburse you for your time in taking part.

What are the possible advantages and disadvantages of taking part?

Giving up your time to attend and participate is the main disadvantage. There may be no direct benefit to you individually, but we hope you will find the experience interesting, worthwhile and benefit from the chance to interact with patients and other like-minded staff members intending to build something new to benefit future patients. This is also an opportunity to contribute to service development and your CPD requirements

What if there is a problem?

Any complaint about the way you have been dealt with as a group member will be addressed. Please discuss this with a team member in the first instance or use the contact details below.

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against South Tees Hospitals NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

How will we use information about you?

We will need to collect some brief information from you for this research project in addition to the audio recordings of interviews and workshop sessions. These will be pseudo-anonymised prior to any analysis, and you will not be identifiable in any future publications or presentations. This information may also be used by regulators to make sure that the research is being done properly.

This information will include your:

- Name
- Professional role
- Whether you have had any previous involvement in developing previous programmes like this or using them with patients
- Whether you are involved or have been involved in undertaking prehabilitation activity with patients

People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to or calling the study team under 'local study team contact below.

What will happen to the results?

The development group process and analysis will be presented at academic conferences and published in academic journals. The research is also part of PhD project, and the data will be submitted anonymously as part of a final thesis.

Who is organizing and funding the study?

South Tees Hospitals, Northumbria University and Teesside University are organising the study.

The study is funded by Macmillan Cancer Support and Sport England.

Who has reviewed the study?

The study has approval by North West-Preston research ethics committee (21/NW/0219)

Further information

For further information regarding the study, advice around participation or to discuss a problem please contact the study team or the chief investigator:

Your local study team:

[INSERT LOCAL TEAM CONTACT]

Chief investigators:

Dr Leah Avery

Reader in Applied Health Psychology and Chartered Health Psychologist, School of Health and Life Sciences, Teesside University.

Email: leah.avery@tees.ac.uk

Professor Gerard Danjoux

Professor of Perioperative Medicine, School of Health and Life Sciences, Teesside University and Hull York Medical School, and Consultant in Anaesthesia and Sleep Medicine at the Department of Anaesthesia and Perioperative Medicine, South Tees Hospitals NHS Foundation Trust.

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Appendix 11: Chapter 3 study consent form (patients)

Digitally facilitated multimodal prehabilitation

Stage 1 Patient Participant Consent Form

IRAS ID: 300425

Name of Chief Investigators: Professor Gerard Danjoux and Dr Leah Avery

Participant study identifier: ☐ Patient ☐ Companion

1. I confirm that I have read the information sheet dated [X] version [X] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the results of this study may be published in a medical journal and presented at conferences. ☐
4. I understand that representatives from the web design company (Hark 2) may be present at and take part in workshop sessions, but they will not have access to my personal data. ☐
5. I understand that parts of the study will be audio-recorded for later analysis, but I will not be identifiable in any publications or presentations and the recordings will be deleted once they have been converted to paper transcripts ☐
6. I understand that data collected about me during the study, will be looked at by individual members of the research team including from Northumbria and Teesside Universities, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
7. I agree to take part in the above study. ☐

Name of participant	**Date**	**Signature**
Name of researcher taking consent	**Date**	**Signature**

Appendix 12: Chapter 3 study consent form (healthcare professionals)

Digitally facilitated multimodal prehabilitation

Stage 1 Patient Participant Consent Form

IRAS ID: 300425

Name of Chief Investigators: Professor Gerard Danjoux and Dr Leah Avery

Participant study identifier:

1.	I confirm that I have read the information sheet dated [X] version [X] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3.	I understand that the results of this study may be published in a medical journal and presented at conferences.	☐
4.	I understand that representatives from the web design company (Hark 2) may be present at and take part in workshop sessions, but they will not have access to my personal data.	☐
5.	I understand that parts of the study will be audio-recorded for later analysis, but I will not be identifiable in any publications or presentations and the recordings will be deleted once they have been converted to paper transcripts	☐
6.	I understand that data collected about me during the study, will be looked at by individual members of the research team including from Northumbria and Teesside Universities, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
7.	I agree to take part in the above study.	☐

Name of participant	**Date**	**Signature**
Name of researcher taking consent	**Date**	**Signatur**

Appendix 13: Chapter 3 copy of COM-B questionnaire (patients)

When it comes to you personally changing various lifestyle behaviours (e.g., increasing physical activity levels, stopping smoking) before your operation, what do you believe you need to be able to do it?

Please circle any of the items on the list that you think apply to you. You can circle as many or as few as you think appropriate. Some of the items may look strange, but that is just because we need to cover all areas – some which may not apply to you.

For each item you circle, could you also say why you think it might be important for you in the free text box provided beneath.

I would have to....

Capability

1.	Know more about why it is important	e.g., have a better understanding of the benefits of making lifestyle changes before my operation
2.	Know more about how to do it	e.g., have a better understanding of how to effectively make lifestyle changes prior to my operation
3.	Have better physical skills	e.g., acquire/develop new skills to make lifestyle changes before my operation and overcome challenges associated with that
4.	Have better mental skills	e.g., learn how to reduce the likelihood of relapsing when attempting to make and maintain lifestyle changes before my operation
5.	Overcome physical limitations	e.g., continue to make changes to my lifestyle when feeling tired and stressed
6.	Overcome mental obstacles	e.g., overcome the urge to give up on making lifestyle changes before my operation when faced with challenges

7.	Have more physical stamina	e.g., develop greater capacity to maintain physical effort, particularly when faced with a personal challenge or obstacle
8.	Have more mental stamina	e.g., develop greater mental capacity to make lifestyle changes before my operation even when lacking in motivation and faced with challenges

I would have to....

Opportunity

9.	Have more time to do it	e.g., dedicate more time to making lifestyle changes before my operation
10.	Have the necessary materials/resources	e.g., have the equipment or resources to help me make lifestyle changes before my operation
11.	Have patients around me doing the same thing	e.g., be part of a group of patients who are also trying to make changes to their lifestyle before their operation
12.	Have triggers to prompt me	e.g., have reminders at specific times to prompt me to make the lifestyle changes I would like to, to reach my goals
13.	Have support from others	e.g., have healthcare professionals, other patients or family members supporting me to make lifestyle changes before my operation

I would have to....

Motivation

14.	Feel that I want to do it enough	e.g., feel a sense of pleasure or satisfaction from making lifestyle changes before my operation
15.	Feel that I need to do it enough	e.g., care more about the negative consequences of not trying to make lifestyle changes before my operation

16.	Believe that it would be a good thing to do	e.g., have a strong sense that I should make lifestyle changes before my operation
17.	Develop better plans for doing it	e.g., have clearer and well-developed plans for making lifestyle changes before my operation to make success more likely
18.	Develop a habit of doing it	e.g., getting into a pattern of making lifestyle changes before my operation without having to think too much about it
19.	Something else (please specify):	

Thank you for taking the time to respond to this questionnaire.

Appendix 14: Chapter 3 copy of COM-B questionnaire (healthcare professionals)

When it comes to you personally providing remote support that targets lifestyle behaviour change to patients preparing for their operation, what do you think is needed for you to do it?

Please circle any of the items on the list that you think apply to you. You can circle as many or as few as you think appropriate. Some of the items may look strange, but that is just because we need to cover all areas – some which may not apply to you.

For each item you circle could you also say why you think it might be important for you in the free text box provided beneath.

I would have to....

Capability

1.	Know more about why it is important	e.g., have a better understanding of the benefits of supporting patients to make lifestyle changes to improve the quality of their sleep prior to surgery.
2.	Know more about how to do it	e.g., have a better understanding of how to effectively support patients to make a number of lifestyle changes prior to surgery
3.	Have better physical skills	e.g., acquire/develop new skills to effectively support patients to make lifestyle behaviour changes prior to their surgery.
4.	Have better mental skills	e.g., learn how to reduce the likelihood that patients go off on tangents during discussions about lifestyle behaviour change prior to their surgery.
	Ensuring regular updates including via email, telephone and occur face to face	
5.	Overcome physical limitations	e.g., proceed to provide support to patients to make lifestyle behaviour changes prior to surgery when feeling tired.
	Adapting information to suit different patient's, e.g., upper body work at home in the chair using household items as opposed to attending a gym, continuing to use steps and stairs as part of daily exercise. E.g. Reducing weight slowly and reducing cigarette consumption	
6.	Overcome mental obstacles	e.g., overcome the urge to avoid providing support to a patient who has previously been resistant to changing their lifestyle behaviours

7.	Have more physical stamina	e.g., develop greater capacity to maintain physical effort, particularly following provision of support to a challenging patient.
	This is where teamwork plays a greater part	
8.	Have more mental stamina	e.g., increase mental capacity to discuss lifestyle behaviour change with patients, particularly following provision of support to a challenging patient.

I would have to....

Opportunity

9.	Have more time to do it	e.g., dedicate time to provide support to patients targeting lifestyle behaviour change.
	This needs to be part of any job plan	
10.	Have the necessary materials	e.g., have materials available to me to help me target lifestyle behaviour change with my patients prior to surgery.
	Multimedia choices help as well as addressing issues with a variety of scenarios and FAQ	
11.	Have colleagues around me doing the same thing	e.g., be part of a group of colleagues who are also providing remote lifestyle behaviour change support to patients prior to surgery.
	Having a sense of working in a team helps personal and team development	
12.	Have triggers to prompt me	e.g., have reminders at strategic times to prompt me to use specific strategies to support lifestyle behaviour change in patients prior to surgery.
13.	Have support from others	e.g., have colleagues/supervisors supporting me to provide lifestyle behaviour change support to patients prior to surgery.
	Peer group work with patient input is how I started our service	

I would have to....

Motivation

14.	Feel that I want to do it enough	e.g., feel a sense of pleasure or satisfaction from providing support to patients to help them make lifestyle behaviour changes prior to surgery.
	There is no greater feeling than being thanked for supporting a patient's recovery	

15.	Feel that I need to do it enough	e.g., care more about the negative consequences of not providing support to patients to make lifestyle behaviour changes prior to surgery.
	The impact on patient's lack of knowledge and skills to help themselves before surgery affects their recovery and nowhere is this more apparent than when they return to clinic post op. These appointments are always longer if the patients have not had adequate preoperative information	
16.	Believe that it would be a good thing to do	e.g., have a strong sense that I should provide lifestyle behaviour change support to patients prior to surgery.
	This is part of my ethos in working within orthopaedics, this is part of the holistic service we aim to provide	
17.	Develop better plans for doing it	e.g., have clearer and well-developed plans for providing lifestyle behaviour change support to patients prior to surgery.
	This is so important for consistency for each patient so that across all practitioners the same approach is used	
18.	Develop a habit of doing it	e.g., getting into a pattern of providing lifestyle behaviour change support to patients prior to surgery without having to think too much about it.
	This is already part of my role in supporting patients before during and after surgery	
19.	Something else (please specify):	

Thank you for taking the time to respond to this questionnaire.

Appendix 15: Chapter 3 copy of semi-structured interview topic guide (patients)

Stage One, 1:1 Interviews Patients – Topic Guide

Important to consider, prior to interview, patient's: [a] stage in surgical pathway (whether pre/post-operative) and [b] their involvement in receiving lifestyle advice preoperatively.

Before recording/scene-setting: We are designing a digital programme to help patients make lifestyle changes to better prepare for surgery. By 'lifestyle' we mean health and wellbeing advice and support to make improvements with nutrition, exercise, sleep, smoking, alcohol consumption and mental wellbeing. And by 'digital programme' we mean that the programme of support will be accessed through the internet using a desktop computer, mobile phone, or tablet-device.

Openers:

We have contacted you for an interview because we are aware that you are [due to have/have had] an operation

a. When preparing for surgery, did/have you receive/[d] any lifestyle advice/information or specific support?
b. What kind of advice/information did you receive? Who provided it?
c. Did you find the advice/information useful? Was there anything else you needed to know? Was the information you were given understandable? Was it clear? How did it inform the way in which you prepared for your operation, if at all?

Capability

1. There are many benefits to making lifestyle changes before surgery. Do/did you feel you have/had a good understanding of why it is/was important to make lifestyle changes before surgery? Could you explain your answer?

2. Based on your understanding currently/at the time before surgery, do/did you feel you [are/were] able to make the necessary lifestyle changes to help you prepare for surgery?

   Prompt: Or is/was there something else you would need/have needed? (What would that be/have been?)

3. If you were using a digital programme, like the one we are designing, what 'skills' do you think you would need to access and use the programme to help you make lifestyle changes before surgery?

   Prompt: These can be:
   a. Physical and 'technical' skills (e.g., IT literacy)
   b. Psychological or 'soft' skills (e.g., communication, asking for help)

4. Sometimes making lifestyle changes can be tiring and stressful. [Looking back] Do you think you would find/have found making lifestyle changes more or less physically tiring and/or stressful, if you were using a digital programme?

5. While using a digital programme, what additional support or skills would you need/have needed to help you overcome these kinds of 'physical limitations' or challenges when making lifestyle changes ahead of surgery?

6. Similarly, feeling tired and stressed can sometimes make us feel like giving-up on making lifestyle changes. Do you think using a digital programme would have helped with feeling emotionally drained when making lifestyle changes, or more so? Could you explain your answer?

7. While using a digital programme, what additional support or skills would you need/have needed to help you overcome any emotional or mental obstacles or challenges when making lifestyle changes?

Opportunity

8. Do/Did you feel you have/had enough time to make lifestyle changes before your operation?

   Prompt:
   - Do/did you have enough time in the day? Enough time before surgery?
   - If 'no': Is/Was it possible to make more time?
   - How do you believe you could make/have made more time to make lifestyle changes before surgery?

9. As part of the digital programme, patients will need to use a computer, mobile phone, or tablet device with access to the internet. Do you have access to devices like these? Would you need/have needed some help in accessing one? Would you need/have needed some help in using this device?

10. If you were using a digital programme, do you think you would find/have found it useful [at the time] to know of other patients who are/were also using the digital programme?

    Prompt: And would you [like/have liked] the programme to connect you with other patients while using it?

11. When using the digital programme to make lifestyle changes, do you think it would be/have been helpful to receive reminders or prompts to make lifestyle changes? (e.g., an alert or prompt to help you remember)

Prompts: What kind of reminders do you think would be/have been most helpful? [e.g., text messages, emails, phone calls]

12. Outside of the digital programme, support to make lifestyle changes can also be important for some people. What support [if any] from other people would you find/have found helpful? [e.g., healthcare professionals, other patients, family, friends etc.,]

Motivation

13. In preparation/When you were preparing for surgery, do you feel that you want/did want to make lifestyle changes?

    Prompt:
    - Why was this important to you?
    - And would a digital programme help you feel motivated to want to make lifestyle changes?

14. [At the time] Do/Did you feel that you need/needed to make lifestyle changes before surgery? Can you explain your answer?

    Prompt:
    - Can you think of/are you aware of any negative consequences of not making lifestyle changes before surgery? [e.g., social pressures]
    - Would you feel you would need/have needed to use a programme like this in order to make those lifestyle changes?

15. [At the time] Do/Did you believe it would be a good thing to make lifestyle changes before your operation? If you were offered a digital programme by a healthcare professional – would this give/have given you a strong sense of: 'making lifestyle changes is something you should be doing?'

    Prompt: Can you tell me why making some lifestyle changes might not be a good idea for you personally? [e.g., social pressures]

16. In order to make lifestyle changes before your operation, do you think [having/having had] a well-developed plan would help you to reach your lifestyle goals? If so, could you talk me through what this plan would have to include to work for you? Would you feel/have felt motivated to use a digital programme to help develop this plan?

17. Sometimes getting into a routine can help you achieve your lifestyle goals. Would you be/have been interested in using a digital programme to help you plan your lifestyle goals in a way that would help you develop a routine? Could you explain your answer?

Appendix 16: Chapter 3 copy of semi-structured interview topic guide (healthcare professionals)

Stage One, 1:1 Interviews HCPs – Topic Guide

Important to consider prior to interview that: the provision of remote support or promotion for prehabilitation uptake will be **relative to the role of HCP and therefore needs to be considered prior to interview.**

Before recording – scene-setting: **The intervention will require the perioperative team to offer and promote the programme to patients preoperatively, and this will include providing positive reinforcement to patients using it during consultations. A team of HCPs will be trained to oversee and support patients using the programme.**

Openers:

d. Can you tell me a bit about your role?
e. At what stages do you engage with patients in the preoperative pathway?
- Prompt: How much time do you usually have with each patient altogether?

f. Do you already provide lifestyle advice to patients? What does that entail?
g. What could you foresee your role being, if a programme like this were made available to patients in the preoperative pathway at your hospital?
h. Who in the healthcare team could or should have a role in promoting a programme like this to patients?
i. Who in the healthcare team could or should oversee patients using a programme like this?

Capability

2. When [remotely supporting patients to use/promoting] a digital prehabilitation programme, what additional knowledge would you need in order to understand the purpose of the intervention?

3. What specifically would you need to know about the digital prehabilitation programme to effectively [support patients to use it/promote it to patients]?

4. What additional skills and competencies would you need to effectively [remotely support patients to use/promote] a digital prehabilitation programme?

    - Prompt: What physical and technical skills would you need? (e.g., IT literacy)
    - Prompt: What psychological or 'soft' skills would you need? (e.g., communication, negotiation)

5. To what extent do you feel you need to develop skills to overcome your own physical limitations when [promoting/supporting] the use of a digital prehabilitation programme? (For example, when feeling physically tired, particularly if patients haven't responded positively)

Prompts: work, time, environment, space, being face-to-face or over telephone – physical practicalities

6. Often, we are hesitant to offer an intervention to patients who have previously been resistant. To what extent do you feel you need training on how to overcome your own mental obstacles when [promoting/supporting] use of a digital prehabilitation programme to your patients?

7. [Promoting use of an intervention or supporting patients] to use an intervention can be physically tiring. How useful would you find training on how to maintain your physical effort when promoting or supporting use of a digital prehabilitation intervention?

8. Promoting use of an intervention or supporting patients to use an intervention can be mentally draining, particularly when patients do not engage. How useful would you find training on how to increase mental capacity to [promote the use of/support patients to use a] digital prehabilitation programme to patients prior to surgery?

Opportunity
Within your working role:

9. How much time realistically do you currently have to [promote use of/support patients to use a] digital intervention?

    - Follow-up: How likely are you to dedicate more time to doing this, if it impacts positively on patient outcomes?

10. To what extent do you feel you have the necessary resources, materials, or equipment to [promote use of/support patients to use a] digital prehabilitation intervention (prompt: if needed ask for more depth to the response)?

11. <u>To help you [</u>promote/ support patients to use] a digital prehabilitation programme, to what extent would you need colleagues around you doing the same thing?

    - Prompt: Why/explain answer

12. To what extent do you feel you would need to be prompted to [promote the use of/support patients to use] a digital prehabilitation programme?

13. To what extent do you feel you require support from others to [promote use of/support patients to use a] digital prehabilitation intervention?

    - Prompt: If needed ask for more depth to the response, for example what type of support are they looking for?

Motivation

On a personal note, to what extent:

14. Do you feel that you would want to [promote use of/support patients to use] a digital prehabilitation programme?

15. Do you feel that you would need to [promote use of/support patients to use] a digital prehabilitation programme?

16. Do you believe that it would be a good thing to [promote use of/support patients to use] a digital prehabilitation programme?

17. Do you believe that you would need to develop better plans to [promote use of/support patients to use] a digital prehabilitation programme?

18. Do you feel you would need to develop a habit to effectively [promote use of/support patients to use] a digital prehabilitation programme?

Appendix 17: Chapter 5 copy of study ethical approval (substantial amendment to appendix 8)

North West - Preston Research Ethics Committee
Barlow House
3rd Floor 4 Minshull Street Manchester
M1 3DZ Tel: 0207 104 8019

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

21 September 2022

Dr James Durrand Department of Anaesthesia
Cheriton House, James Cook University Hospital Marton Road, Middlesbrough
TS4 3BW

Dear Dr Durrand

Study title:	Systematic development and feasibility testing of a digitally facilitated, remotely supervised, multimodal prehabilitation intervention for patients approaching major surgery.
REC reference:	21/NW/0219
Protocol number:	V1.0
Amendment number:	Study stage 2 amendment
Amendment date:	28 July 2022
IRAS project ID:	300425

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Completed Amendment Tool [Amendment tool]	1	28 July 2022
Organisation Information Document [OID]	1	28 July 2022
Participant consent form [Patient consent form]	1	30 July 2022
Participant consent form [HCP consent form]	1	30 July 2022
Participant information sheet (PIS) [HCP PIS]	1	30 July 2022
Participant information sheet (PIS) [Patient PIS]	1	30 July 2022
Research protocol or project proposal [Protocol (clean)]	3	30 July 2022
Research protocol or project proposal [Protocol (tracked changes)]	3	30 July 2022
Schedule of Events or SoECAT [SoE]	1	10 August 2022

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

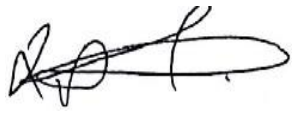
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS Project ID - 300425:	**Please quote this number on all correspondence**

Yours sincerely



PP:Professor Karen Wright
Chair

North West - Preston Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 29 August 2022

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Karen Rouse	Deputy Head of School of Dentistry	Yes	
Professor Karen Wright	Professor of Nursing	Yes	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Zainab Tauqeer	Approvals administrator

Appendix 18: Chapter 5 study participant information sheet (patients)

Feasibility testing of an online health and wellbeing programme for patients approaching major surgery

Participant information sheet

We have developed a new, online resource to help patients get ready for surgery and would like your help to test it!

As you are about to undergo a major operation, we are inviting you to test our new programme designed to help patients prepare themselves for an operation.

This resource is being tested as part of a research study. Before you decide if you would like to take part in the study, it is important that you understand why it is being done and what taking part would involve.

What is the purpose of the study?

We know that patients who have better physical and mental health tend to have an easier journey through major surgery, and experience fewer problems (complications) afterwards.

Helping patients to improve their health and wellbeing **before** an operation can lead to a smoother recovery afterwards. This is known as 'prehabilitation' and can involve:

- Exercising to get fitter
- Stopping smoking
- Cutting down on alcohol
- Eating well
- Sleeping enough and sleeping better
- Managing stress and improving psychological wellbeing

There are lots of ways to support patients to achieve these things. However, most NHS services need patients to attend hospitals or other venues a few times each week to get the support they need.

Many patients have told us they would prefer a different option due to the travel, cost, and inconvenience of such visits. For example, many patients have said they would prefer support they can access when they want it and in and around their own home. This has become very important following the recent Covid 19 pandemic.

We have developed an online programme to meet this need. The programme is designed to be accessed and used in and around your home using a smartphone, tablet or desktop computer that means you don't need to come into hospital. It will provide you with structured support to improve your general physical and mental health before your operation.

You will need to have access to at least one of these internet enabled devices at home and an internet connection to be able to take part.

A healthcare professional team will supervise you and you will be able to communicate with them regularly online through the programme.

The programme has been carefully designed by a team including: Patients like you, healthcare professionals that care for patients having major surgery, health psychologists and web developers.

We now need patients approaching surgery to try out the new programme before their operation and tell us what they think of it.

Why have I been invited to take part?

As someone currently preparing for a major operation, you are in an ideal position to test the platform. **Your feedback is vital to develop the programme further. This includes improving the content and how easy it is to use.**

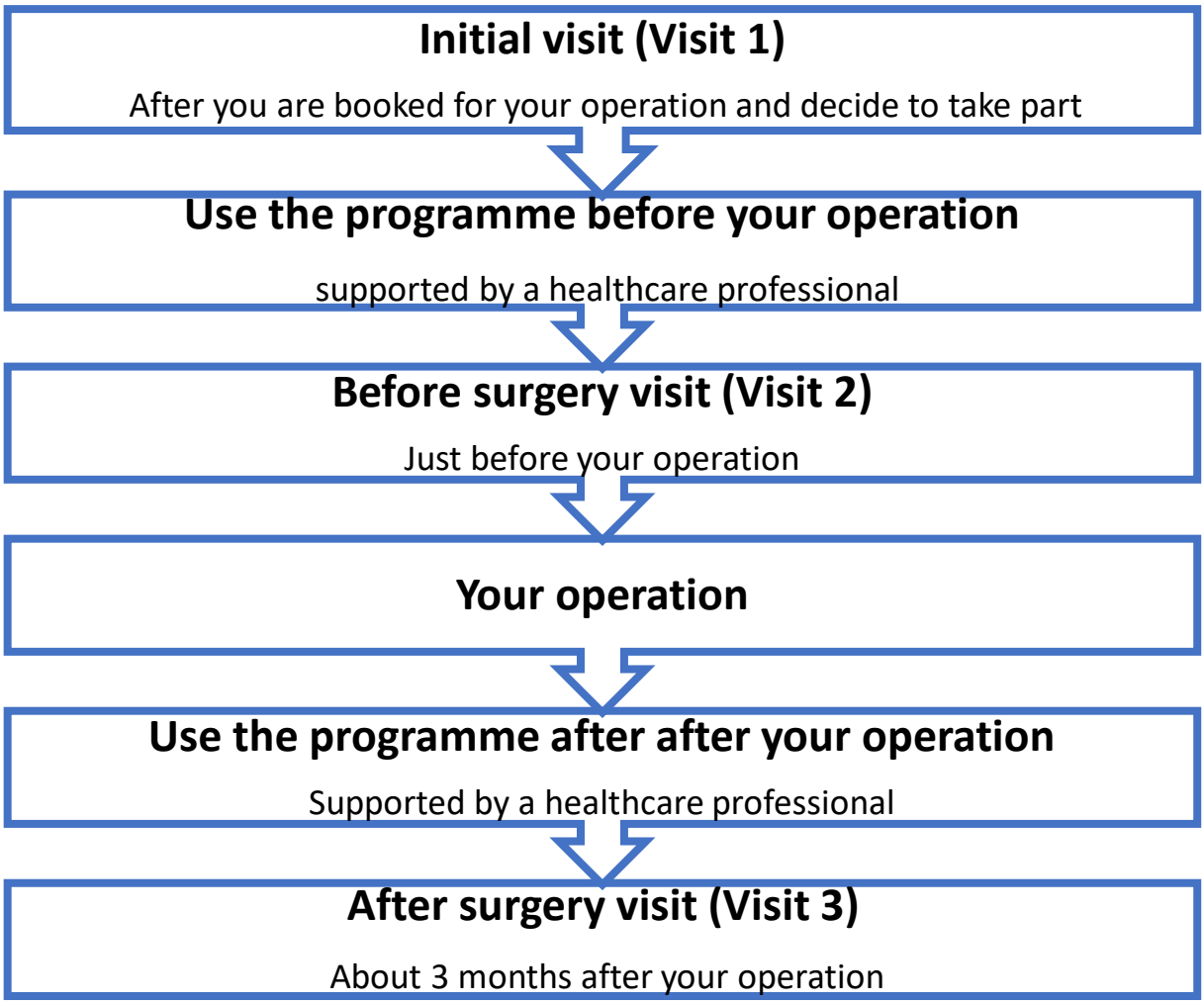
Do I have to take part?

No, taking part is completely voluntary. Whether you choose to take part or not will in no way affect your medical care currently or in the future.

If you would like to take part, you will be asked to complete a consent form. If you decide to take part but then change your mind, you can leave the study at any time without providing a reason.

What will taking part involve?

Taking part will involve the following steps. Further information about each step is provided below:



What will happen at visit 1? (After you are booked for your operation and decide to take part)

Visit 1 will last up to 2 hours and take place at hospital. The main purpose of this visit is to check you are safe to use the programme, get an idea of how it can help you and get you started using it.

If possible, we will try and arrange this visit alongside another routine visit you have booked, but if this isn't possible we may ask you to attend hospital to get you started and give you as much time as possible using the platform we can before your operation.

You will meet members of our study team and one of the healthcare professionals that will be supporting you when using the programme at this visit.

You will first be taken through the study consent form and asked to sign it if you are happy to proceed.

The rest of the visit will involve setting you up on the programme and introducing you to using it. We will collect information about you, your medical history, and your upcoming surgery information. The team and the programme will assess how to help you to improve your overall health and wellbeing. This will involve:

- Completing questionnaires about your health and wellbeing.
- Taking some basic measurements such as your height, weight, and blood pressure.

- A safety assessment to ensure you are safe to exercise in and around your home using the programme.
- Making an assessment of your current confidence exercising including things like completing a short walking test at your own pace.

You will also be given a wrist worn 'fitbit' style device you can use with the programme before and after surgery. The device will be able to communicate with the online programme using an app you will download onto your smartphone. The device will continuously collect information about your vital signs (e.g., your pulse rate) and other information to help guide your use of the programme such as your physical activity levels and how well you are sleeping. It will also be used to help guide any exercise sessions you complete. You will be able to keep this device at the end of the study.

If you are comfortable wearing the device, we will use the data it collects about you anonymously to find out more about how surgery and recovery from surgery affects people.

In addition, **you will be given equipment to use with the programme to help improve your fitness before the operation.**

Once this assessment is complete, and the information about you is entered into the online programme, you will be able to use it wherever you have access to the internet and begin using the support available to you.

What will using the programme in the weeks before my surgery involve?

We will ask you to **access the programme several times per week in lead up to your operation** in whatever way you prefer. The programme will provide you with videos to watch and information to read to help you set goals and prepare for surgery alongside instructions and support to follow that aims to improve your physical and mental health and wellbeing with tools to help monitor your progress. Exactly what the programme helps you to do will vary depending on your needs, but it may involve:

- Following an exercise programme to:
    - Improve how well your heart and lungs work to help your organs cope with the demand of major surgery.
    - Make your body stronger to work with physiotherapists more easily and get out of bed and moving more quickly after surgery.
    - strengthen the muscles you use to breathe to avoid problems such as chest infections after surgery.
- Help to reduce or quit smoking before your operation
- Help to reduce how much alcohol you drink to a recommended level before surgery
- Help to improve your diet to support your exercise training and build your reserves for surgery
- Help to manage the stress that can come with preparing for major surgery.
- Help to sleep more and better
- Interact with supporting staff members and other patients also preparing for surgery using the platform if you choose.

How much you use the platform and what you use it for will be **entirely up to you**. You will be asked to set goals to reach and record your progress along the way. Healthcare professionals will support you

using the platform itself and encourage you as you progress. You will be able to communicate with them using the platform and raise any difficulties you have.

What will happen at visit 2? (just before surgery)

The main purpose of this visit is to see how far your overall health and wellbeing has improved through using the programme.

Like visit 1, this will also **last up to 90 minutes and take place at hospital.** It will be organised just before your operation. Where possible we will try to book this alongside another routine visit you have, but we are likely to ask you to attend hospital even if you don't have another appointment arranged.

You will again be met by at least two team members. Many of the assessments performed at visit 1 will be repeated. The aim will be to see how your health and wellbeing has changed having used the programme, such as a repeat of your exercise test to see if your fitness has improved.

What will happen at visit 3? (3 months after your operation)

After your operation, the programme will be available to you once again. Support will now change to focus on helping you recover from your operation as well as possible. As before, you will be able to access and use the platform as much as you like.

The main purpose of the 3rd visit is to review your health and wellbeing after surgery. You will be asked to attend visit 3 about 3 months after your operation. We are likely to ask you to attend hospital especially for this visit.

Like visits 1 and 2 this will **last up to 90 minutes**.

You will again be met by 2 team members. Many of the assessments performed at visit 1 and 2 will be repeated. The aim will be to see how your health and wellbeing has changed following surgery during your recovery.

Your participation in the study will end after this visit.

Will anything else happen as part of the study?

After your operation, you may also be invited to take part in an **interview with a study team member** lasting up to 60 minutes. This is to seek more detailed feedback on your experiences of using the programme. This will be audio recorded so we do not miss anything important you tell us.

We recognise patients may involve a partner, friend or family member who supports them while using the platform. We would also like to invite this person to undertake an interview and understand their experiences of helping someone use the programme. If you have someone in mind who might like to do this, **please show them this information sheet** as we will ask them to consent to take part in an audio recorded interview.

Expenses and payment for participation.

We will be able to reimburse reasonable expenses incurred (e.g., travel costs, mileage, and parking) for every study visit you attend.

What are the possible risks or disadvantages of taking part?

Taking time and putting effort into to using the platform before surgery should be considered.

The programme will encourage you to exercise in and around your home. This has a very small risk associated with it. We will check that you are safe to use the exercise programme with remote supervision before starting you on the platform. You will be given clear instruction on how to make exercise and activity as low risk as possible.

Engaging in physical activity and exercise are recognised to be a safe and effective way to improve health and wellbeing in adults of all ages and is now widely used in patients preparing for surgery.

We also recognise that the time before surgery can be difficult physically and emotionally. Using the programme is designed to help you with this. You can engage with as much or as little of the programme as you are able. If doing so is adding to your stress or anxiety, please discuss this with a study team member. If necessary, you are free to withdraw from the study at any time without providing us with a reason.

What are the potential benefits of taking part?

The programme has been designed to improve your health and wellbeing and prepare you as well as possible for your surgery. We hope this is what you will experience though using it and it will lead to a recovery that is as smooth as possible for you.

We hope you will find the experience interesting, worthwhile and benefit from the chance to interact with other patients in a similar position experience and healthcare professionals that together are trying to develop the best resource we can for patients.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. Please discuss this with a team member in the first instance or use the contact details below. If your issue has not been dealt with following this, you can contact the Patient Advice and Liaison (PALS) service to take this further.

[INSERT PALS CONTACT]

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against South Tees Hospitals NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- Name and initials
- NHS and medical record number
- contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team who can direct you to the sponsor (South Tees Hospitals) data protection officer
- by sending an email to [INSERT SITE EMAIL]
- by ringing us on [INSERT SITE PHONE]

Will my taking part in the study be kept confidential and how will my information and data be handled?

South Tees Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information provided by you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. South Tees Trust will keep identifiable information about you for 10 years after the study has finished.

York Teaching Hospitals will collect information from you and your medical records for this research study in accordance with South Tees instructions as the sponsor. if you are participating in York. Your identifiable information e.g., name, date of birth and hospital number will be used to invite you to take part. York Teaching Hospitals will pass these details to South Tees Hospitals along with the information collected from you and your medical records. The only people in South Tees Hospitals who will have access to

information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, date of birth, address or other contact details.

Information about you collected by the platform will include the minimum identifiable information, be stored securely, and encrypted. It will only be accessible by study team members and the healthcare professionals caring for you around your operation. The company developing the programme will not have access to your data.

The wearable device used by the platform is freely available commercially. By using it as part of the study you will be asked to provide some personal information and consent to the device manufacturer data collection protection and storage policies which will be provided to you when registering the device using your smartphone. Data requested by the device may include your name, email address, biological sex, and date of birth. This is the same process as if you had decided to buy and use a device like this outside of the study.

The platform will access and collect this data and store it securely alongside the other data inputted to it by you, the study team and the healthcare professionals caring for you around your operation.

Data collected about you by the wearable ('fitbit' device) will be pseudo-anonymised and analysed by a data analytics company (Telstra Health UK) who are supporting the study under a secure data sharing agreement to learn more about how surgery affects people physically. No identifiable information about you will be passed to this company and you will not be personally identifiable.

Individuals from regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in South Tees Hospitals or the Partner Universities who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, date of birth, address or other contact details.

data about you will be anonymised where possible before shared and secure storage by partner institutions supporting the study: Teesside and Northumbria Universities. Audio recordings of interviews will be converted to text (transcribed) and participants anonymised by their study/group identifier. Only anonymised data will be stored long-term outside of South Tees Hospitals

All procedures for handling and protecting your information will be undertaken in keeping with Caldicott principles and meet the requirements of UK GDPR (Data Protection act 2018).

You can find out more about how we use your information by contacting the chief investigator

What will happen to the results?

The study results will be presented at academic conferences and published in academic journals. The research is also part of PhD project, and the anonymised data will be submitted as part of a final thesis.

Who is organizing and funding the study?

South Tees Hospitals, York Teaching Hospitals, Northumbria University and Teesside University are organising the study.

The study is funded by Macmillan Cancer Support and Sport England.

Who has reviewed the study?

The study has approval by North West- Preston Research Ethics Committee (21/NW/0219)

Further information

For further information regarding the study, advice around participation or to discuss a problem please contact the study team or the Chief Investigator:

Your local study team:

[INSERT LOCAL TEAM CONTACT]

Chief Investigators:

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Professor Gerard Danjoux

Professor of Perioperative Medicine, School of Health and Life Sciences, Teesside University and Hull York Medical School, and Consultant in Anaesthesia and Sleep Medicine at the Department of Anaesthesia and Perioperative Medicine, South Tees Hospitals NHS Foundation Trust.

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Appendix 19: Chapter 5 study participant information sheet (healthcare professionals)

Feasibility testing of an online health and wellbeing programme for patients approaching major surgery

Healthcare Professional Participant information sheet

We have developed a new, online resource to help patients get ready for surgery and would like your help to test it!

We are looking for healthcare professionals involved in the perioperative care of patients undergoing major surgery to support patients using the new resource.

This resource is being tested as part of a research study. Before you decide if you would like to take part, it is important you understand why the study is being done and what taking part would involve.

What is the purpose of the study?

We know that patients who have better physical and mental health tend to have an easier journey through major surgery, running into fewer postoperative complications.

Helping patients to improve their health and wellbeing **before** an operation is known as 'prehabilitation' and can involve:

- Exercise training
- Smoking cessation
- Alcohol reduction
- Nutritional support
- Sleep health support
- psychological wellbeing support

There are lots of ways to support patients to achieve these things. However, most NHS services need patients to attend hospitals or other venues a few times per week to get help.

Many patients have told us they would prefer a different option due to the travel, cost, and inconvenience this may involve. These patients would prefer support they can access more flexibly in and around their own home. This has become very important during the recent Covid 19 pandemic.

We have designed and built an online platform to meet this need alongside training materials to help HCPs use the platform with patients. The platform is designed to be accessed and used at home using a smartphone, tablet, or desktop computer without coming to hospital. It provides structured prehabilitation.

Patients utilising the platform are supported remotely by a team of healthcare professionals.

The platform has been carefully designed by a team including: Patients, other perioperative healthcare professionals, health psychologists and web developers.

We are recruiting patients approaching surgery to try out the new platform before surgery and need a team of HCPs to trial the facilitator role supported by our study team.

Why have I been invited?

As HCP caring for patients preparing for major surgery, you are in an ideal position to promote and/or support patients using the platform. **Your experience and feedback during this initial road testing are vital to develop the platform further and make it as effective as we can in supporting patients preoperatively.**

Do I have to take part?

No, taking part is completely voluntary.

If you would like to take part, you will be asked to complete a consent form. If you decide to take part but then change your mind, you can leave at any time without providing a reason.

What will taking part involve?

There are several roles for HCPs within the study as team members delivering the platform for patients. **You will receive dedicated training via a package developed alongside the programme before supervising patients using it.**

The study has the support of perioperative services at the participating sites and efforts will be made to accommodate your taking part within your contracted working hours.

Promoting the platform to patients preparing for surgery

As a healthcare professional involved in the perioperative care of patients preparing for major surgery, you will have opportunities to introduce and promote use of the platform to patients and encourage them to participate. In addition, there will be opportunity to encourage patients already using the platform as part of the study.

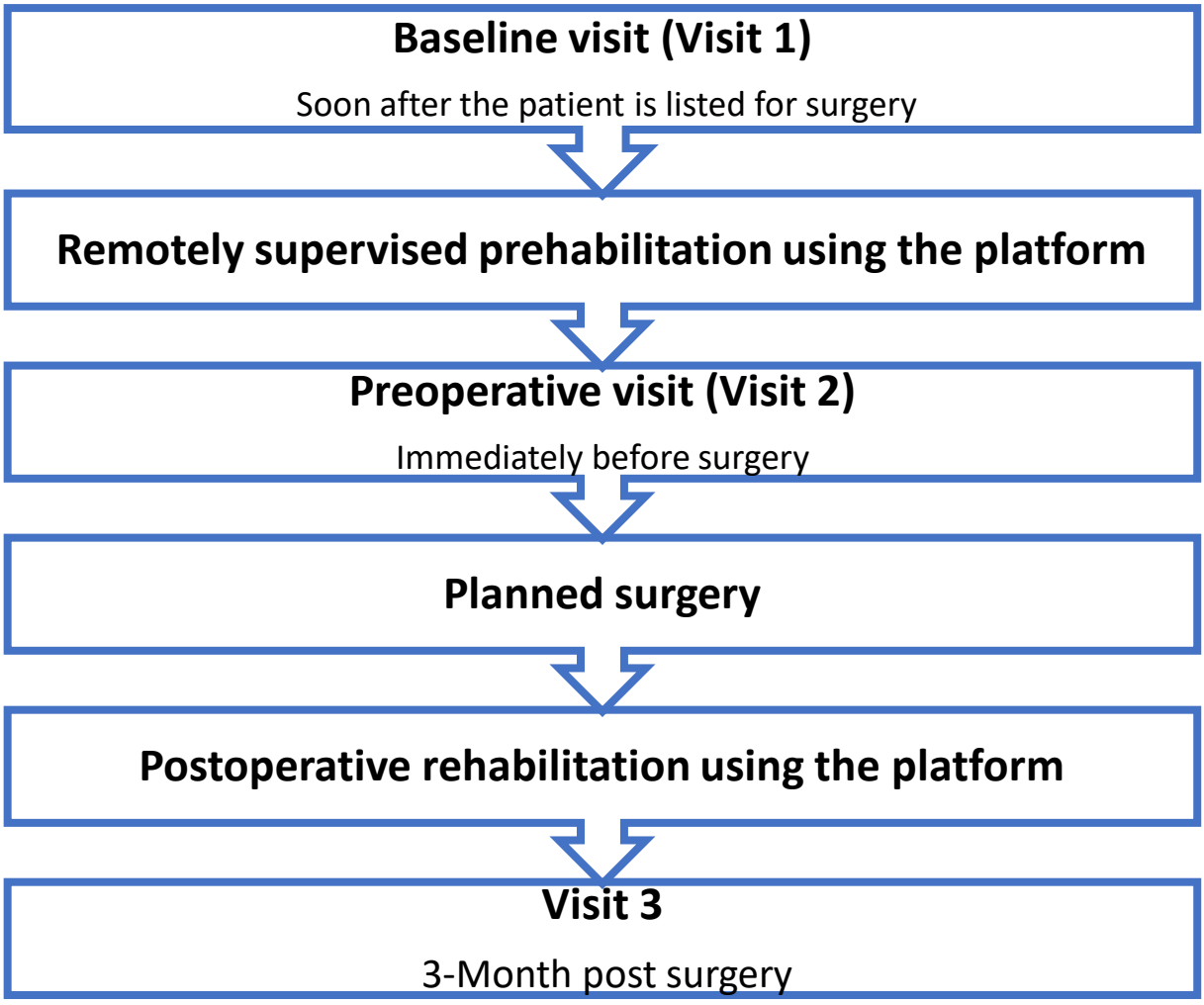
Supporting patients using the platform before surgery

Your role as a supporting HCP will involve monitoring patients using the platform using the 'dashboard' to review their progress and supporting them with prompts as needed. Patients will also be able to contact you with queries, issues, and problems although the platform support is designed to be as 'hands-off' as possible for supervising HCPs. We will ask you to log how much time you need week to week to support patients on the platform, this is a key piece of information for the study.

We recognise the pressures on preoperative clinical services and at all times the study team and prehabilitation teams will support you in this role. A key aim of the study is assessing the feasibility of using the programme in 'real life' clinical practice.

Patient participant journey

Patients using the platform during the study will proceed through the following steps:



Visit 1- Baseline assessment

This will be a face-to-face assessment with the patient supported by the study team.

The purpose of this visit is to introduce and register the patient on the programme, set them up to use it and undertake a baseline assessment of their health and wellbeing

This will involve

- Helping patients' complete questionnaires about their physical and mental health and wellbeing to ensure the programme provides the right support

- Basic clinical assessments such as height, weight, and blood pressure.
- A safety assessment to ensure patients are safe to exercise in and around their home under remote supervision
- Making an assessment of the patient's physical fitness including a 6-minute walk test

Patients will be issued with and introduced to a wrist worn 'fitbit' style device to use with the platform. The device will be able to communicate with the platform using an app you download onto their smartphone. The device will continuously collect vital sign data and other information to help guide their use of the platform such as physical activity levels and will also be used to help guide exercise training sessions.

In addition, patients will be given equipment to use with the platform including resistance training bands and an inspiratory muscle trainer.

Patients will aim to access the platform several times per week for 4-6 weeks in the lead up to their operation.

The platform will provide audio-visual material and structured support aiming to improve physical and mental health and wellbeing. Exactly what the platform provides will vary depending on patient need but may include.

- A structured exercise training programme including aerobic, resistance and inspiratory muscle training
- Smoking cessation
- Alcohol reduction
- Nutrition support
- Psychological support
- Sleep health support

Visit 2

Like visit 1 this will **last up to 90 minutes and take place at hospital.**

It will mirror the 1st visit aiming to determine the impact of platform use on patients' health and wellbeing e.g., a repeat 6-minute walk test to see if fitness has improved.

Following this, patients will undergo their scheduled operation.

Visit 3

After surgery, patients will be able to access the platform for rehabilitation support to enhance their recovery

3 months after surgery, patients will be asked to attend visit 3. Like visits 1 and 2 this will **last up to 90 minutes** and will assess their health and wellbeing in the recovery phase.

Will anything else happen as part of the study?

During the study, you may also be invited to take part in an **informal interview with a study team member** lasting up to 60 minutes. This is to seek more detailed feedback on your experiences of supporting patients using the platform. This will be audio recorded so we do not miss anything important you tell us.

Expenses and payment for participation.

We are unable to pay you for participating in the study. Participants will be supported to take part within their scheduled working hours with accommodation for their current clinical duties.

What are the possible risks or disadvantages of taking part?

Giving up your time towards supporting patients using the platform is the main disadvantage. We will seek the support of clinical service managers to accommodate staff wishing to take part in this project.

We understand you may have apprehension around supporting patients undertaking remote exercise activity. Patients will undergo a robust safety assessment based on the experiences of established prehabilitation services before taking part. You will have direct support from these services and the study team throughout the study.

What are the potential benefits of taking part?

We hope you will find the experience interesting, worthwhile and benefit from the chance to interact with others seeking to improve patient outcomes. Participating in the study is an opportunity to engage in service improvement and the training process may help you meet some of your CPD requirements. You will be amongst the 1st HCPs to trial what we hope will become a new model of perioperative care.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. Please discuss this with a team member in the first instance.

How will we use information about you?

We will need to use information from you and from you for this research project.

This information will include your:

- Name and initials
- contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team who can direct you to the sponsor (South Tees Hospitals) data protection officer
- by sending an email to [INSERT SITE EMAIL]
- by ringing us on [INSERT SITE PHONE]

Will my taking part in the study be kept confidential and how will my information and data be handled?

South Tees Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information provided by you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. South Tees Trust will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information once collected are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will collect the minimum personal identifiable information possible.

York Teaching Hospitals will collect information from you for this research study in accordance with South Tees instructions as the sponsor. Individuals from South Tees Hospitals and regulatory organisations may look at your medical and research records to check the accuracy of the research study. York Teaching Hospitals will pass these details to South Tees Hospitals along with the information collected from you. The only people in South Tees Hospitals who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you.

Individuals from regulatory organisations may look at your research records to check the accuracy of the research study. The only people in South Tees Hospitals or the Partner Universities who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you

data about you will be anonymised where possible before shared and secure storage by partner institutions supporting the study: Teesside and Northumbria Universities. Audio recordings of interviews will be converted to text (transcribed) and participants anonymised by their study/group identifier. Only anonymised data will be stored long-term outside of South Tees Hospitals

All procedures for handling and protecting your information will be undertaken in keeping with Caldicott principles and meet the requirements of UK GDPR (Data Protection act 2018).

You can find out more about how we use your information by contacting the chief investigator

What will happen to the results?

The study results will be presented at academic conferences and published in academic journals. The research is also part of PhD project, and the data will be submitted anonymously as part of a final thesis.

Who is organizing and funding the study?

South Tees Hospitals, York Teaching Hospitals, Northumbria University and Teesside University are organising the study.

The study is funded by Macmillan Cancer Support and Sport England.

Who has reviewed the study?

The study has approval by North West- Preston Research Ethics Committee (21/NW/0219)

Further information

For further information regarding the study, advice around participation or to discuss a problem please contact the study team or the chief investigator:

Your local study team:

[INSERT LOCAL TEAM CONTACT]

Chief investigators:

Dr Leah Avery

Reader in Applied Health Psychology and Chartered Health Psychologist, School of Health and Life Sciences, Teesside University.

Leah.avery@tees.ac.uk

Professor Gerard Danjoux

Professor of Perioperative Medicine, School of Health and Life Sciences, Teesside University and Hull York Medical School, and Consultant in Anaesthesia and Sleep Medicine at the Department of Anaesthesia and Perioperative Medicine, South Tees Hospitals NHS Foundation Trust.

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Appendix 20: Chapter 5 study consent form (patients)

Digitally facilitated multimodal prehabilitation

Stage 2 patient participant consent form

IRAS ID: 300425

Name of Chief Investigators: Professor Gerard Danjoux and Dr Leah Avery

Participant study identifier:

1. I confirm that I have read the information sheet dated [X] [(version)] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the results of this study may be published in a medical journal and presented at conferences. ☐
4. I understand I will be invited to utilise a commercial fitness and wellbeing tracker [insert device] as a study participant. In doing so I understand I will be asked to provide some personal information to register the device and consent for the device to collect pseudoanonymised data about me in keeping with [insert company] policies and procedures to be obtained by the web-based programme to support improvements in my health and wellbeing before surgery. ☐
5. I understand that, should I choose to use the fitness and wellbeing tracker, data collected about me by it will be anonymised and shared with an industry partner data analytics company [Telstra health UK] under a secure data sharing agreement to explore how major surgery affects patients physically. I understand that I will not be individually identifiable from the data shared. ☐
6. I understand that data collected during the study may be looked at by research team members from Northumbria and Teesside Universities. These data and my medical records may also be looked at by representatives of the research sponsor (South Tees Hospitals) or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
7. I understand that my GP will be informed of my participation in the study. ☐
8. I agree to take part in the above study. ☐

Name of participant	**Date**	**Signature**
Name of researcher taking consent	**Date**	**Signature**

Appendix 21: Chapter 5 study consent form (healthcare professionals)

Digitally facilitated multimodal prehabilitation

Stage 2 HCP participant consent form

IRAS ID: 300425

Name of Chief Investigators: Professor Gerard Danjoux and Dr Leah Avery

Participant study identifier:

1. I confirm that I have read the information sheet dated [X] [(version)] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the anonymised results of this study may be published in a medical journal and presented at conferences. ☐
4. I understand that data collected during the study, may be looked at by individual members of the research team including from Northumbria and Teesside Universities, from regulatory authorities or f from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access. ☐
5. I agree to take part in the above study. ☐

Name of participant	**Date**	**Signature**
Name of researcher taking consent	**Date**	**Signature**

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