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Digitally deployed, GP remote consultation video intervention that aims to reduce opioid prescribing in primary care: protocol for a mixed-methods evaluation

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ABSTRACT

Introduction Opioid prescribing rates are disproportionately high in the North of England. In addition to patients' complex health needs, clinician prescribing behaviour is also a key driver. Although strategies have been initiated to reduce opioid prescribing nationally, the COVID-19 pandemic has interrupted service provision and created challenges for the system and health professionals to tackle this complex issue. A pilot intervention using smartphone video messaging has been developed to remotely explain the rationale for opioid reduction and facilitate self-initiation of support. The aim of this study is to evaluate the potential benefits, risks and economic consequences of 'at scale' implementation.

Methods and analysis This will be a mixed-methods study comprising a quasi-experimental non-randomised before-and-after study and qualitative interviews. The intervention arm will comprise 50 General Practitioner (GP) Practices using System 1 (a clinical computer system hosting the intervention) who will deliver the video to their patients via text message. The control arm will comprise 50 practices using EMIS (a different computer system) who will continue usual care. Monthly practice level prescribing and consultation data will be observed for 6 months postintervention. A general linear model will be used to estimate the association between the exposure and the main outcome (opioid prescribing; average daily quantity (ADQ)/1000 specific therapeutic group age-sex related prescribing unit). Semi-structured interviews will be undertaken remotely with purposively selected participants including patients who received the video, and health professionals involved in sending out the videos and providing additional support. Interviews will be audio recorded, transcribed and analysed thematically.

Ethics and dissemination Ethics approval has been granted by the NHS Health Research Authority Research Ethics Committee (22/PR/0296). Findings will be disseminated to the participating sites, participants, and commissioners, and in peer-reviewed journals and academic conferences.

Trial registration number NCT05276089.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A rapid evaluation through a mixed methods approach comprising a quasi-experimental non-randomised before-and-after study and qualitative interviews will provide a comprehensive evaluation.
⇒ The intervention fidelity will be monitored by quantifying the extent of engagement with the video message.
⇒ Practice level prescribing data may be recorded inconsistently, and the data does not include prescriptions that are issued but never dispensed.
⇒ The unavailability of individual patient-level data and the impossibility of random allocation are limitations.
⇒ Collecting views from patients and professionals might be affected by responder bias.

INTRODUCTION

Opioids may be beneficial for acute pain or pain at the end of life but there is little evidence that they are helpful for long-term pain.[1] Instead, prescribing opioid pain medicines for longer than 90 days is associated with dependence and a higher risk of overdose.[2] High doses of opioid use can lead to a substantially increased risk of harm associated with greater mortality and morbidity.[3] Seventy per cent of deaths from a drug overdose worldwide are related to the harmful use of opioids.[4] Higher healthcare costs and usage are also found in patients with high-dose opioid use.[5]

Despite this, opioid prescribing increased by 34% in England during the decade between 2008 and 2018.[6] Opioid-related admissions increased by almost 50% with total treatment costs of £137 million.[7] More than 231 million opioid prescriptions were dispensed in primary care in 2018–2019

alone.[8] Research also shows a variation in prescribing patterns across geographical locations and socioeconomic factors. The majority of the highest prescribing areas are located in the North of England and deprivation is strongly associated with opioid prescribing when accounting for population demographics and disease prevalence.[6 9 10] For instance, regional prescribing is 1.2 times higher than the national average for areas with similar deprivation and 3.3 times higher than the most deprived areas in London.[8] In addition, evidence suggests that patients in primary care are likely to be prescribed stronger opioids regardless of the diagnosis of painful conditions. Instead, longer-term and stronger opioids are often found in those with multimorbidity, frequent primary care visits and referrals to specialist pain services (up to sixfold).[11] This indicates that practice team and individual clinician behaviours are also largely accountable for variations in opioid prescribing.[12]

There are guidelines and interventions that have been implemented to reduce opioids nationwide. The latest National Institute for Health and Care Excellence clinical guidance on the assessment and management of chronic pain highlights that people with chronic primary pain should not be started on opioids due to the lack of evidence of effectiveness and the high frequency of adverse effects.[13] There are also several strategies in clinical settings for opioid reduction with varying success rates.[14 15] For instance, the Academic Health Science Network in the North East and North Cumbria (NENC) had been running the Campaign to Reduce Opioid Prescribing (CROP) project[16] prior to the COVID-19 pandemic, which aims to encourage a reduction in inappropriate prescribing of high dose opiates for non-cancer pain by promoting the review of opioid analgesic prescribing within primary care and to support GP practices with this work. This intervention has been shown to be effective in reducing opioid prescribing in primary care.[16] However, the pandemic has disrupted essential health services and further created conditions undermining the progress made, leading to increased prescribing especially among the most vulnerable groups.[17] Also, it has been more challenging for GPs to dedicate the sustained clinical time needed to tackle this complex issue with individual patients, who may also be reluctant to seek help.

In response to the impact of COVID-19, a novel process was initiated to remotely communicate the rationale for reducing opioid use and invite patients to initiate support, which might be a valuable addition to routine care. A short video suitable for smartphone viewing is messaged using a two-way communication system. Patients can watch the video more than once and then request additional support by replying with a simple text response. The feasibility of this approach has already been tested in selected GP practices in a region in Northern England, targeted at patients identified as having been prescribed high levels of opioids. In the pilot work (Reducing your opioids by GP Video Library), the intervention was considered to be well received by patients and saved significant clinical time. Among 90 patients sent the intervention, 25% replied that they wanted to 'reduce or stop' their opioids.

The overall aim now is to evaluate the potential benefits, risks and economic consequences of 'at scale' implementation. Objectives are:

1. To describe the changes in practice level prescribing data following deployment of the video intervention.
2. To estimate the high-level economic consequences for stakeholders.
3. To explore patient and practitioner experiences and factors impacting on the success of the innovation.

METHODS AND ANALYSIS

Study design

This will be a mixed methods project consisting of a quasi-experimental non-randomised before-and-after study and qualitative interviews, undertaken across GP practices.

Patient and public involvement

The short video was constructed with support from GPs and consultants specialising in pain management and patients on opioids. This study has been developed with a member of the public with lived experience of opioid reduction, who has also reviewed and commented on the video scripts, patient facing documents and recruitment strategies. In addition, we will actively seek involvement from people from ethnic minorities and/or disadvantaged socioeconomic backgrounds to increase representation within the team.

A project advisory group including Integrated Care System (ICS) Head of Medicines Optimisation and leads for Medicines Optimisation and musculoskeletal workstreams will meet every 2 months to discuss key stages of the study, protocol, ethics, recruitment (ensure inclusivity and diversity), data collection and analysis, and dissemination and implementation plan to ensure that the findings are easily understandable and accessible, via various and preferred routes.

Quasi-experimental non-randomised before-and-after study

Study design and setting

This is a two-arm, non-randomised controlled before-and-after study of a GP remote consultation video intervention designed to reduce opioid prescribing. The video messaging is currently developed to integrate with System 1 (a clinical computer system used to record primary care contacts) but cannot yet be implemented by another popular clinical computer system called EMIS. Therefore, practices using System 1 will be chosen as the intervention arm and EMIS practices as the control arm.

A total of 50 practices using System 1 will send out the video message to their eligible patients, and 50 EMIS practices will continue to deliver care as usual. A convenience sampling strategy will be used to recruit GP practices. These will be identified with assistance from the Primary Care Research Network and the North of England Commissioning Support Unit. Study information will be

shared through their newsletters and Primary Care bulletins with regional GP practices.

Intervention

A 5 min video will be sent to the patient's mobile phone, where a GP describes reasons to reduce opioid use and highlights the support available. It invites patients to consider four response message options:

1. I want support to reduce my opioid medication.
2. I understand this video but want to continue my current dose.
3. I would like a phone call to discuss this further.
4. Not interested.

Option (1) will enable the GP practice to initiate existing opioid reduction support, option (2) will continue care and support as usual and option (3) will enable the GP practice to offer more information.

Participants

Patients targeted will include adults (aged 18 or over) registered at their GP practice with a mobile phone, regularly taking opioids for more than 90 days and/or at a dose equivalent to ≥90 mg equivalent of morphine a day (this varies for each opioid medication) using electronic records. Patients will be excluded if they are coded as having cancer or receiving palliative care. Eligible patients will be screened and identified by primary care staff in the participating practices.

Data sources and outcomes

Primary outcome

The primary outcome will be opioid prescribing at the GP practice level before and 6 months after the intervention. This is collected monthly by electronic Prescribing Analysis and Costs (ePACT2) and presented as average daily quantity (ADQ)/1000 specific therapeutic group age-sex related prescribing unit (STAR PU).

Secondary outcome

Secondary outcomes will include:

1. All opioids prescribed (including compound analgesics) recorded by the STAR PU adjusted measure on ePACT2.
2. Gabapentinoid (gabapentin and pregabalin) prescribing at the GP practice level, recorded monthly on the ePACT2, to monitor if reductions in opioids are offset by an increase in gabapentinoids.
3. Information on high-dose opioid items as a percentage of regular opioids collected from a publicly accessible dataset (OpenPrescribing[18]), which records monthly data on opioid items with a likely daily dose of ≥120 mg morphine equivalence.

Intervention fidelity will be monitored using multiple strategies. At the GP practice, the proportion of videos watched by intervention participants will be quantified. The number (proportion) of individuals who were followed up by the practice within 1 month of choosing options (1) and (3), will be quantified. Specifically for each practice, the following information will be collected:

1. The number of people sent the video.
2. The number of people who watched the video.
3. The average duration of the video watched.
4. The number of people who responded option 1.
5. The number of people who responded option 2.
6. The number of people who responded option 3.
7. The number of people who responded option 4.
8. The number (proportion) of individuals who were followed up by the practice within 1 month of choosing options 1 and 3.

To describe the primary care practice settings, data will be collected from the 2020 to 2021 Public Health England National General Practice Profiles for practice level variables in the Office for Health Improvement and Disparities's Fingertips tool,[19] including practice list size, gender ratio, Index of Multiple Deprivation (IMD), and the overall achievement in the clinical domain of the Quality and Outcomes Framework.

Intervention costs will reflect video development and deployment and participant identification. We will estimate any additional healthcare resources needed by people receiving videos who decide to reduce or eliminate their opioid use, and who may need GP practice visits to discuss this. The main economic consequences will be estimates of opioid prescription savings based on STAR PU data, plus any patient benefits from reduction or elimination of the use of opioids. For the latter, we will use published evidence on the health and societal costs of opioid addiction and the potential benefits accruing from a successful intervention.

Sample size and data analysis

The unit of analysis will be the GP practice. The targeted sample size will be 50 practices in each arm: the maximum feasible sample size given the resource constraints of the study. In a sample of 123 practices in Newcastle Gateshead, North Tyneside & Northumberland for Q4 in 2020/2021, the mean (SD) AQQ/1000 STAR PU for opioids was 515 (201), against an average for England of c. 300 units. The targeted sample size provides>80% power for the detection of an effect size (difference between arms) of 100 units at the 6 months endpoint, with 2P=0.05 and assuming a baseline to follow-up correlation of 0.5 (Analysis of Covariance (ANCOVA) model, conditioning on the baseline value of the outcome).

Descriptive statistics will be presented for all primary and secondary outcomes. The primary endpoint data will be analysed using a constrained baseline longitudinal analysis (CBLA)[20] via a linear mixed model. Monthly data across the 6 months from baseline will be analysed in a single model (7 timepoints) but the 6-month timepoint is primary. The CBLA model is equivalent to an ANCOVA (conditioning on baseline) when there is no missing data. No missing data are expected, as the monthly data for the primary outcome is extracted routinely electronically. The GP practice-level IMD will be included as a covariate as a marker of socioeconomic status, which is considered prognostic. We will use IMD tenths (from most deprived

to least deprived derived from the nine IMD deciles) as a continuous variable in this model. We are not conditioning on age and sex, as the primary outcome already accounts for the age and sex mix in the practices. The mean difference between arms will be presented together with its 95% CI, interpreted as the plausible range of effect sizes compatible with the data, model and model assumptions. In a purely exploratory secondary analysis using a study arm×IMD interaction term, we will investigate the extent to which the mean difference in opioid prescribing between arms depends on socioeconomic status. All analyses will be conducted using Stata software (version 17.0).[21]

Qualitative interviews

The aim of the interviews will be to understand patient and health professional experiences and factors impacting on the delivery and success of the intervention.

Study design and setting

A qualitative study with semi-structured individual interviews will be carried out with a subgroup of patients who have been sent the video message and also practitioners involved in responding to the delivery of the remote intervention in GP practices on the intervention arm. The interview will be scheduled remotely for 1–6 months, lasting less than 60 min.

Participants and sampling

All patients who have replied to the video message will be sent a subsequent message to invite them for a study interview and a link to the study information sheet and consent form. It asks patients to consider three responses:

1. Yes.
2. I would like a phone call to find out more.
3. No.

For patients who have replied (1) and (2), their contact details will be passed on to the research team. Option (1) will enable the researcher to approach the patient and make arrangements for content and study interview, and option (2) will enable the researcher to contact the patient and provide more information on this study for them to decide their participation. Patients who have agreed to be interviewed will be invited. Purposive sampling will be used to identify and select information-rich cases according to their gender, age and type of response to the video message. Participants need to be able to communicate in the English language to understand the study information and potentially have conversations with the researcher.

All healthcare professionals involved in the management of opioids and/or deprescribing of opioids in the practice would be eligible to take part including GPs, pharmacists, assistant practitioners, practice nurses and social prescribers. Embedded Clinical Research Network staff will send an email invitation to all relevant individuals, who will express their interest by responding via email directly to the research team. Purposive sampling will be used to ensure a broad representation of staff on dimensions including job titles, roles in pain management, specialty and demographics. A total of 12–15 patients and 12–15 health professionals will be targeted, which has been suggested to be sufficient to reach higher levels of data saturation within homogenous groups.[22]

Data collection

With participants' informed consent, semi-structured interviews will be conducted via telephone or online (eg, MS Teams, Zoom) for up to 60 min, using a topic guide developed according to the literature in this area and approaches from implementation science[23] to inform analysis of the interviews. The topic guide will be piloted with a public member with lived experience prior to data collection and will be continuously updated in line with emerging themes and participants' feedback. Interviews will be audio recorded with participants' consent.

Data analysis

Interviews will be transcribed verbatim (transcription function on Teams or Zoom, or a professional company if telephone) and anonymised. Data will be managed using NVivo V.12, a qualitative software programme to assist with the organisation and coding of data.

Data will be analysed using thematic analysis[24] to explore facilitators and barriers to video delivery and implementation. Interview transcripts will be read to gain familiarity with the data and develop initial ideas and codes. This will inform an overarching coding framework together with the research questions and interview topic guide. A sample of four interviews (two with patients and two with health professionals) will be double-coded independently by two researchers as a validity check to explore alternative interpretations of the data. The research project team, clinical staff members and a patient representative will discuss emerging analyses to ensure rigour, discuss differences and agree on the thematic coding framework. The reporting of the qualitative component of this study will be carried out in keeping with Consolidated criteria for Reporting Qualitative research guidelines.[25]

Ethics and dissemination

Ethics approval has been granted by the NHS Health Research Authority Research Ethics Committee (22/PR/0296).

This study builds on the CROP project by adapting, evaluating and scaling up the targeted and interactive remote care initiation approach developed during the pandemic specifically for patients taking longer-term and stronger opioids. Dissemination will be led by the research team and supported by the PPI partner and project advisory group. Findings will be disseminated to the participating sites and participants in a lay summary. A cost-effectiveness evaluation report will be produced and shared with commissioners, clinical pharmacy and primary care networks and the NENC ICS. Academic publications will be produced for clinicians

and researchers who are interested in opioid reduction. Presentations at regional and national clinical and policy meetings will also be delivered to maximise the impact.

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Contributors YF, CR and JLN conceived and developed the hypothesis and created the concept and the study design. BA developed the intervention. AMB, CP, NJ, DM, NH, EM and TF contributed to the study methods and analysis. YF drafted and revised the manuscript, and obtained the ethics approval. All independently reviewed and contributed to revising and approving the final version.

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Competing interests BA has developed the video intervention. The video may be commercialised for financial gain.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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REFERENCES

1 Faculty of Pain Medicine of the Royal College of Anaesthetists. Opioids aware: london. 2020. Available: https://www.fpm.ac.uk/opioids-aware [Accessed 22 Apr 2022].
2 Public Health. Dependence and withdrawal associated with some prescribed medicines: an evidence review. London: Public Health England; 2019. Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940255/PHE_PMR_report_Dec2020.pdf [Accessed 6 Jan 2022].
3 Richards GC, Mahtani KR, Muthee TB, *et al*. Factors associated with the prescribing of high-dose opioids in primary care: a systematic review and meta-analysis. *BMC Med* 2020;18:68.
4 World Health Organisation. Opioid overdose: world health organisation. 2021. Available: https://www.who.int/news-room/fact-sheets/detail/opioid-overdose [Accessed 22 Apr 2022].
5 Chang H-Y, Kharrazi H, Bodycombe D, *et al*. Healthcare costs and utilization associated with high-risk prescription opioid use: a retrospective cohort study. *BMC Med* 2018;16:69.
6 Curtis HJ, Croker R, Walker AJ, *et al*. Opioid prescribing trends and geographical variation in england, 1998-2018: a retrospective database study. *Lancet Psychiatry* 2019;6:140–50.
7 Friebel R, Maynou L. Trends and characteristics of hospitalisations from the harmful use of opioids in England between 2008 and 2018: population-based retrospective cohort study. *J R Soc Med* 2022;115:173–85.
8 Nowakowska M, Zghebi SS, Perisi R, *et al*. Association of socioeconomic deprivation with opioid prescribing in primary care in England: a spatial analysis. *J Epidemiol Community Health* 2021;75:128–36.
9 Mordecai L, Reynolds C, Donaldson LJ, *et al*. Patterns of regional variation of opioid prescribing in primary care in England: a retrospective observational study. *Br J Gen Pract* 2018;68:e225–33.
10 Chen T-C, Chen L-C, Kerry M, *et al*. Prescription opioids: regional variation and socioeconomic status-evidence from primary care in england. *Int J Drug Policy* 2019;64:87–94.
11 Foy R, Leaman B, McCrorie C, *et al*. Prescribed opioids in primary care: cross-sectional and longitudinal analyses of influence of patient and practice characteristics. *BMJ Open* 2016;6:e010276.
12 McCrorie C, Closs SJ, House A, *et al*. Understanding long-term opioid prescribing for non-cancer pain in primary care: a qualitative study. *BMC Fam Pract* 2015;16:121.
13 NICE. Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain london national institute for health and care excellence. 2021. Available: https://www.nice.org.uk/guidance/ng193
14 de Kleijn L, Pedersen JR, Rijkels-Otters H, *et al*. Opioid reduction for patients with chronic pain in primary care: systematic review. *Br J Gen Pract* 2022;72:e293–300.
15 Moride Y, Lemieux-Uresandi D, Castillon G, *et al*. A systematic review of interventions and programs targeting appropriate prescribing of opioids. *Pain Physician* 2019;22:229–40.
16 Alderson SL, Farragher TM, Willis TA, *et al*. The effects of an evidence- and theory-informed feedback intervention on opioid prescribing for non-cancer pain in primary care: a controlled interrupted time series analysis. *PLOS Med* 2021;18:e1003796.
17 Farrow L, Gardner WT, Tang CC, *et al*. Impact of COVID-19 on opioid use in those awaiting hip and knee arthroplasty: a retrospective cohort study. *BMJ Qual Saf* 2021:bmjqs-2021-013450.
18 OpenPrescribing.net. *EBM datalab*. University of Oxford, 2017.
19 Public Health. Public health profiles.: public health england. 2021. Available: https://fingertips.phe.org.uk [Accessed 29 Oct 2021].
20 Coffman CJ, Edelman D, Woolson RF. To condition or not condition? analysing " change" in longitudinal randomised controlled trials. *BMJ Open* 2016;6:e013096.
21 StataCorp. *Stata statistical software: release 17*. College Station: TX: StataCorp LLC, 2021.
22 Guest G, Namey E, Chen M. A simple method to assess and report thematic saturation in qualitative research. *PLoS One* 2020;15:e0232076.
23 Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci* 2015;10:53.
24 Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006;3:77–101.
25 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 2007;19:349–57.