# Real world impact and experience of Abbott Freestyle Libre Glucose Monitoring

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## Work in Progress

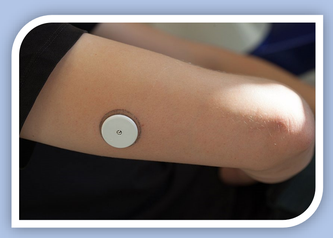
Northumbria University NEWCASTLE

NHS The Newcastle upon Tyne Hospitals NHS Foundation Trust

DIABETES UK KNOW DIABETES. FIGHT DIABETES.

### Introduction:

Abbott Freestyle Libre (FSL) is a form of 'wearable' glucose sensor which enables the monitoring of blood glucose levels without finger-prick testing; FSL has been shown to safely and significantly reduce HbA1c levels in people living with type 1 diabetes who have high levels of HbA1c (Lelarathna *et al,* 2022)



### Aim:

To investigate the real-world impact of Abbott Freestyle Libre glucose monitoring (FSL) on physiological, psychological and social measures and how this relates to the lived experience of people living with type 1 diabetes (T1D) using these devices, using a mixed methods approach

### Objectives:

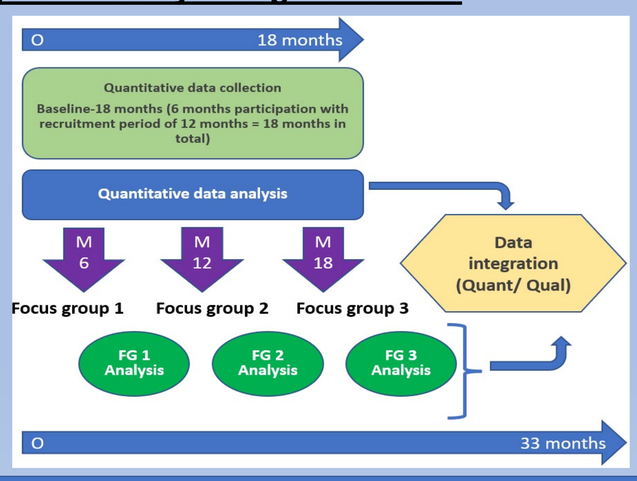
- To obtain quantitative data related to changes in physiological parameters before and after 6 months use of FSL
- To obtain quantitative data related to changes in participant reported outcome (PRO) measures before and after 6 months use of FSL
- To utilise results of quantitative data analysis to purposively sample participants for qualitative focus groups
- To utilise results of quantitative data analysis to guide exploration of pertinent themes within qualitative focus groups
- To integrate quantitative and qualitative data sets, to understand how qualitative data explains quantitative findings to develop a comprehensive picture of the impact of wearable diabetes management technologies in participant self-management

### Design:

Mixed methods can provide a depth and breadth of understanding, yielding more complete evidence mixing inductive and deductive perspectives. Combining statistics with thematic approaches ensures views and experiences of complex situations are captured (Jogulu and Pansiri, 2011)

Explanatory sequential design begins with a quantitative strand. A second, qualitative strand explains and draws inferences about the quantitative results (Cresswell, 2015). Questions which may emerge during the quantitative data collection can be resolved with additional qualitative data (Small, 2011)

**Figure 1: Study Design Overview**




### Patient and Public Involvement (PPI):

- PPI networks within UK diabetes charities (Diabetes UK and JDRF) were approached to comment on the research study with reference to acceptability, design and management of the research. Response was positive, the research question deemed well designed with appropriate aims and objectives
- A pilot of the online site to capture quantitative data was circulated via PPI networks; 4 experts by experience responded to this request and made suggestions for improvements with regard to the content, length and presentation of the survey which were incorporated into the final version

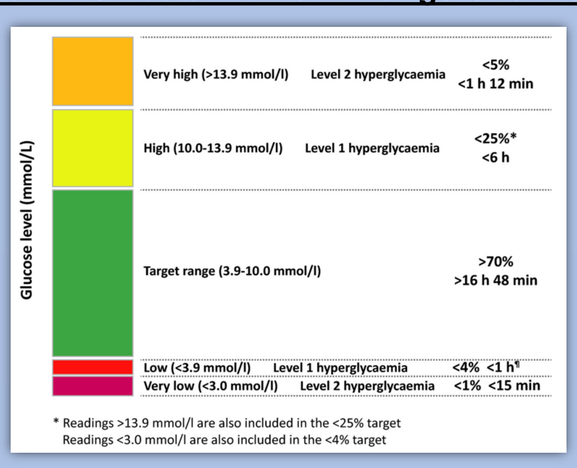
### Methods:

40 participants to be recruited during FSL sensor start appointments / within 7 days of commencing FSL, as part of their standard clinical care

**Quantitative data** – Baseline and Month 6 data is collected online / on paper depending on participant preference

- Demographics
- Body mass index (BMI)
- Diabetes history and treatment (duration of diabetes, diabetes medication, hypoglycaemia frequency, average number of finger-pricks / scans per day, additional clinical contact time
- Perception of diabetes control
- Previous use of wearable glucose monitoring
- FSL data (summarised in figure 2):
  - Time in range
  - Time below range
  - Time above range
  - Glucose variability (target ≤36%)
  - Glucose management indicator (% / mmol/mol)

**Figure 2: FSL data - Time in Range Overview**




(Wilmot *et al*, 2021)

Participant reported outcomes (PRO questionnaires):

1. PAID - problem areas in diabetes scale (wellbeing)
2. GMSS – Glucose monitoring satisfaction survey (treatment satisfaction)
3. Modified Clark-Gold Score (hypoglycaemia awareness)
4. ADDQoL – Audit of Diabetes Dependent Quality of Life

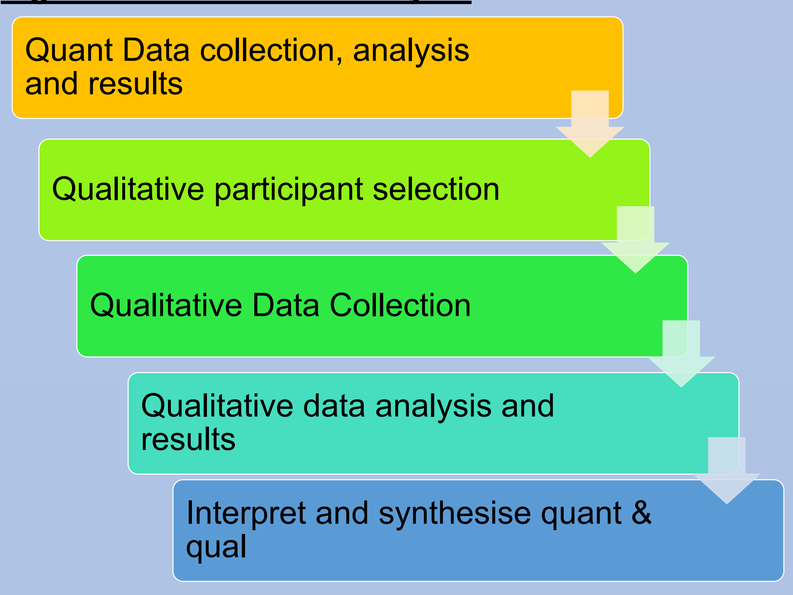
**Qualitative data** –

- Focus group discussion x 3 online / face-to-face

### Planned analysis:

- **Quantitative data** will be analysed descriptively to identify trends and outliers and to explore changes in group mean scores at baseline and following 6 months of sensor use
- **Qualitative data** will be subject to thematic analysis, to explore and understand explicit or conceptual patterns of meaning
- **Synthesis -** Integration of the data sets will enable explanation of the quantitative data with reference to the qualitative findings

**Figure 3: Overview of Analysis**




(Edmonds and Kennedy, 2019)

### Progress to date (as of November 2022):

- **Recruitment commenced in April 2022**
- **15 participants recruited to date**
- **8 participants have reached month 6 data collection point**
- **Scoring of questionnaires to date, completed via standardised auto formulae to ensure data accuracy**
- **Expert external supervisor appointed**
- **Second Participant Identification Centre in set up to enhance recruitment and diversity of the participant sample**
- **National promotion of the study via Diabetes UK in set up**

**References:**

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Edmonds, W., Kennedy, T. (2017). *An applied guide to research designs.* SAGE Publications, Inc, https://dx.doi.org/10.4135/9781071802779

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Wilmot, EG, Lumb, A, Hammond, P, *et al* (2021). Time in range: 'A best practice guide for UK diabetes healthcare professionals in the context of the COVID-19 global pandemic'. *Diabetic Medicine*, 38:e14433. https://doi.org/10.1111/dme.14433

### Expected Outcomes:

- ✓ This study will provide an overview of the impact of FSL over 6 months on physiological parameters observed via Libre view data
- ✓ May enable a deeper understanding of the lived experience of FSL to manage T1D
- ✓ Will offer an insight into relationships between the perceived efficacy of FSL, and the impact this has on:
  - Well-being
  - Treatment satisfaction (glucose monitoring devices)
  - Hypoglycaemia (low blood glucose) awareness
  - Quality of Life
- ✓ This research is a novel insight in a cohort of real-world NHS patients, situated outside of the clinical trial setting. These insights may deliver benefits to both the NHS and med-tech organisations in tailoring the development and provisions of wearable technologies more effectively.
- ✓ Recommendations for best practice in relation to future adoption and development, may be elucidated.