FOCUS-CGM PILOT STUDY PROTOCOL

A pilot study on the Feasibility and Acceptability of Two Continuous Glucose Monitoring Education Strategies in Primary Care for Adults with Type 2 Diabetes
Version 2.1; Date: 30 January 2026

Chief Investigator

Name: Nkiruka Ofokansi
Role: Advanced Clinical Practitioner Pharmacist (diabetes lead)
Organisation: Country Park Practice, 3 Enmore Road, London SE25 5NT
Email: practice: swlicb.countryparkpractice@nhs.net personal(nikki.ofokansi@nhs.net)
Phone: 0203 764 0664

Sponsor: Country Park Practice

Funding: In this study, all CGM devices will be obtained through the manufacturer's publicly available free sample programme. For participants in the second arm who need two sensors, we will ensure they can access these through the same programme or through existing practice educational sample stock. No additional funding or sponsorship is provided by the manufacturer.

Table of Contents

1. Background and Rationale
2. Aims and Objectives
3. Study Design
4. Study Setting
5. Study Population and Recruitment
6. Intervention Description
7. Outcome Measures
8. Data Collection Procedures
9. Data Management and Confidentiality
10. Data Analysis Plan
11. Ethical and Regulatory Considerations
12. Safety Reporting
13. Quality Assurance
14. Dissemination Plan
15. Timeline
16. Budget
17. References
18. Appendices

1. Background and Rationale

1.1 Introduction to Type 2 Diabetes (T2D) and Uncontrolled Glucose

Type 2 Diabetes (T2D) is one of the fastest-growing global health challenges, affecting over 530 million people worldwide and projected to rise further in the coming decades (International Diabetes Federation, 2021). In the UK, T2D remains a leading cause of premature morbidity and mortality, contributing to cardiovascular disease, kidney failure, and retinopathy, and driving substantial NHS expenditure (NHS England, 2023).

Despite advances in pharmacological therapy, many patients remain above recommended HbA1c targets. In primary care, where most diabetes management occurs, people not on insulin represent a large subgroup. For these individuals, persistent suboptimal glycaemic control is often linked to therapeutic inertia, multimorbidity, and challenges in sustaining lifestyle changes (Seidu et al., 2024). This underscores the need for practical, behaviour-supportive strategies that can be implemented within real-world general practice.

1.2 Introduction to Continuous Glucose Monitoring (CGM)

Continuous Glucose Monitoring (CGM) provides dynamic, near real-time data on glucose trends, capturing daily fluctuations, post-meal excursions, and nocturnal patterns. In type 1 diabetes, CGM consistently improves HbA1c, reduces hypoglycaemia, and enhances quality of life (Beck et al., 2017). Similar benefits have been observed in insulin-treated type 2 diabetes, improving both glycaemic stability and treatment satisfaction (Lind et al., 2017).

In non-insulin-treated type 2 diabetes, a growing body of evidence demonstrates that continuous glucose monitoring (CGM) can improve glycaemic outcomes and patient engagement. Meta-analyses report modest but consistent reductions in HbA1c (approximately 0.3–0.4%) and improvements in Time in Range (approximately 8–10%) compared with self-monitoring of blood glucose. Real-world studies further suggest enhanced patient satisfaction and improved understanding of lifestyle–glucose relationships. However, variability in study design, duration, and educational support models persists, and pragmatic evidence for implementation within NHS primary care remains limited (Aronson et al., 2025; Shields et al., 2024; Jospe et al., 2024).

1.3 Rationale for Short-Term CGM in Non-Insulin-Treated T2D

Short-term CGM use (typically 10–15 days) has been shown to improve patients' understanding of diet–glucose and activity–glucose relationships, often leading to positive behavioural changes. Randomised and observational studies demonstrate that even brief CGM exposure can result in sustained lifestyle improvements and measurable glycaemic benefits (Christiansen et

al., 2020; Shields et al., 2024).

However, evidence remains mixed on how best to translate these gains into scalable practice models. Many studies are short-term, resource-intensive, or conducted in specialist rather than primary care settings. Furthermore, uncertainty persists around how to balance patient autonomy with clinical oversight to optimise learning and safety.

1.4 The Problem / Gap

While CGM shows clear promise for adults with T2D not using insulin, the optimal educational strategy for introducing it in primary care is unclear.
- Patient-initiated (self-directed) use allows individuals to view their glucose data in real time, promoting autonomy and rapid feedback, but may overwhelm users - particularly those with lower digital or health literacy (Polonsky & Hessler, 2019).
- Clinician-facilitated approaches reduce information overload by summarising glucose trends and providing targeted advice but may limit the immediacy of patient learning (Evans et al., 2019).
- Primary care clinicians report barriers to implementation, including limited training, competing priorities, and uncertainty interpreting CGM reports within short consultations (Seidu et al., 2024).

Without a structured and feasible framework that balances patient empowerment with clinical guidance, CGM for this population risks being under utilised, inconsistently delivered, or unsustainable within NHS primary care.

1.5 Rationale for Comparing Patient-Initiated vs Clinician-Facilitated Strategies

This pilot study (FOCUS-CGM) proposes a two-arm design comparing:
- Group A (Patient-Initiated): Participants use CGM for 15 days with full real-time data access and standard education, allowing independent reflection on glucose patterns.
- Group B (Clinician-Facilitated): Participants wear CGM for 15 days but are instructed not to view their glucose data during this period. Clinicians analyse the data and identify 1-3 actionable insights, which are discussed at follow-up. Participants then wear a second CGM for 15 days with real-time access to apply these tailored recommendations.

This “patient-initiated vs clinician-facilitated” comparison draws on behavioural science frameworks showing that structured feedback and staged learning promote greater engagement and retention (Jospe et al., 2024). It aims to identify which approach is more feasible, acceptable, and scalable in real-world NHS primary care.

1.6 Justification for a Pilot Study

Before progressing to a large-scale trial, it is essential to establish whether this approach is feasible and acceptable to both patients and clinicians. The pilot will assess recruitment and retention, adherence to study procedures, and the acceptability of CGM education strategies.

Pilot studies are not designed to test efficacy but to refine logistics, assess barriers, and provide data for future sample-size estimation (Eldridge et al., 2016). Robust pilot work enhances trial quality and reduces research waste (Atkin-Jones et al., 2025). Given the growing NHS focus on

digital diabetes technologies, this feasibility pilot will provide critical early insights into how CGM can be implemented sustainably in primary care for adults with T2D not using insulin.

2. Aims and Objectives

2.1 Primary Aim

To assess the feasibility and acceptability of delivering two different CGM education strategies in primary care for adults with T2D not using insulin.

2.2 Secondary Objectives

- Determine recruitment and retention rates.
- Assess acceptability and burden for patients and staff.
- Record time and resource requirements for delivery.
- Explore changes in patient confidence, understanding, and behavioural intentions.
- Collect preliminary CGM metrics (e.g., Time in Range) to inform future trial design.

2.3 Exploratory 12-Month Follow-Up

In addition to feasibility and acceptability outcomes, this pilot will include an exploratory assessment of longer-term glycaemic trends.

- With participants' consent, the study team will review the routine HbA1c value recorded in the GP record approximately 12 months after enrolment.
- This involves no additional visits, tests, or participant burden, and uses only routinely collected clinical results linked via study ID. The aim is to explore whether short-term behavioural changes from CGM education may be associated with sustained glycaemic trends. This exploratory analysis will inform the design and sample-size calculations of a future definitive trial.
  This does not change the defined "end-of-study" for the pilot.

3. Study Design

- **Type:** Prospective, two-arm, parallel-group pilot randomised controlled trial.
- **Arms:**

  . Group A: Self-Directed CGM Education (15 days, single sensor)

  . Group B: Clinician-Facilitated CGM Education (two 15-day sensors worn one after the other)

- **Randomisation:** 1:1, using sealed envelope method.

- **Blinding:** Not possible due to device limitations; Group B participants consent to defer viewing their glucose data during the first 15 days.

- **Duration per participant:**

  . Group A: approximately 4–5 weeks

  . Group B: approximately 8–10 weeks

3.1 End of Study Definition

The pilot intervention phase of the study will end when the final participant completes their final study visit (Day 36–40 for Group B).

In line with HRA guidance, the **formal end of the study** is defined as the date when the final participant's routine 12-month HbA1c result has been obtained from their GP record. No further data will be collected after this point.

4. Study Setting

Single site: **Country Park Practice**, London.
Research will be embedded within routine NHS primary care delivery.

5. Study Population and Recruitment

Inclusion Criteria

- Age 35–70 years
- Diagnosis of T2D >1 year
- HbA1c 59–86 mmol/mol
- Not on insulin
- Ability to understand spoken and written English
- Willing and able to wear a CGM sensor and attend study visits

Exclusion Criteria

- Type 1 diabetes
- Insulin therapy
- Pregnancy
- Significant comorbidity or cognitive impairment
- Previous use of personal CGM
- Inability to provide informed consent

Recruitment Process

- The IT lead will run Electronic Medical Record (EMR) - EMIS searches using inclusion/exclusion criteria.
- GPs or usual care team members will invite eligible patients by letter or during routine consultations.
- Participants will be given ≥24 hours to consider participation and receive a PIS.
- Recruitment target: 30 participants (15 per arm).

6. Intervention Description

Device Access - All CGM sensors used in this study will be obtained through the manufacturer's publicly available one-time free sample programme, which is accessible to any individual with diabetes in the UK. For participants in the second arm who require two sensors, we will ensure that both are accessed through this same scheme or through existing practice educational sample stock. No additional funding, sponsorship, or research-specific support is provided by the manufacturer.

Group A - Self-Directed Education Strategy

- Visit 1: Consent, baseline data, sensor application.
- 15-day wear period: Participants use the Libre sensor in real time and receive standardised in-app education.
- Follow-up visit: Review of CGM data with clinician, reinforce learning, collect questionnaires.

Group B - Clinician-Facilitated Education Strategy

- Visit 1: Consent, baseline data, first sensor application. Participants are asked not to view data; purpose explained.
- Visit 2 (Day 15–20): Clinician reviews data and provides targeted feedback (1–3 key patterns). Second sensor is applied.
- Second wear period (15 days): Participants apply strategies with real-time feedback.
- Visit 3: Review second dataset, collect questionnaires.

Clinical Procedures

- CGM application and removal
- Data interpretation with clinician

Non-Clinical Procedures

- Consent
- Questionnaires (baseline, midpoint for Group B, post-intervention)
- Optional qualitative interview

7. Outcome Measures

Primary (Feasibility and Acceptability)

- Recruitment and retention rates
- Sensor wear and scanning adherence
- Patient and staff acceptability (questionnaires/interviews)
- Staff time logs and technical issues

Secondary (Preliminary Clinical/Behavioural)

- CGM metrics: Time in Range (TIR), Time Above Range (TAR), Glucose Management Indicator (GMI)
- Change in patient understanding and self-efficacy
- Behavioural intentions (e.g., dietary/activity changes)

Exploratory Outcome

- **Routine HbA1c at ≈12 months post-enrolment**, extracted from electronic health records.

8. Data Collection Procedures

- Baseline data from EMR and questionnaires
- LibreView platform for CGM data extraction
- Self-report questionnaires administered in clinic or remotely
- Qualitative interviews with a subset of participants
- Staff logs for feasibility measures

9. Data Management and Confidentiality

- All data collected during the study will be handled in accordance with UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.
- Participant data will be pseudonymised using a unique study identification number. A separate, password-protected linkage log connecting names to study IDs will be stored

securely on NHS systems and accessible only to authorised members of the research team.
- Identifiable information will be used only for recruitment, consent, and clinical follow-up purposes.
- CGM data will be accessed via the LibreView platform and extracted for analysis using study ID numbers only.
- Questionnaire responses and study records will be stored on secure, encrypted NHS servers. Any paper records will be stored in locked cabinets within restricted-access areas of the practice.
- Only authorised members of the study team will have access to identifiable information.
- Data will not be shared outside the practice except with appropriate regulatory or monitoring bodies (e.g., Health Research Authority, NHS R&D) where required.
- All data will be retained for the minimum period required for research governance purposes (maximum 5 years) and then securely archived or destroyed.
- The National Data Opt-Out will be respected.

10. Data Analysis Plan

- **Feasibility outcomes:** Descriptive statistics (counts, percentages, means/SD).
- **Acceptability:** Descriptive statistics for questionnaires; thematic analysis for interviews.
- **Clinical outcomes:** Exploratory descriptive analyses of CGM metrics.
- No hypothesis testing (pilot study).
- Software: SPSS or equivalent; NVivo for qualitative analysis. (Excel sheet and manual compilation should be sufficient).
- **Exploratory 12-Month Analysis:** Routine 12-month HbA1c values will be summarised descriptively (mean, SD, and change from baseline). No inferential statistics will be performed. These exploratory data will inform the design and power calculation of a future trial.

11. Ethical and Regulatory Considerations

- The study will be conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice (GCP).
- Favourable opinion from a recognised NHS Research Ethics Committee (REC) and Health Research Authority (HRA) approval will be obtained prior to study commencement.
- Written informed consent will be obtained from all participants by a trained member of the research team before any study procedures are undertaken.
- Participation is entirely voluntary. Participants may withdraw at any time without giving a reason and without any impact on their usual NHS care. No further data will be collected after withdrawal. Data collected up to the point of withdrawal will be retained and used in the study.

- Only English-speaking participants are included in this pilot due to resource limitations for translated materials and interpreter-supported consent within the scope of this feasibility study.
- If a participant loses capacity during the study, they will be withdrawn and no further data will be collected. Data already collected will be retained.
- The exploratory 12-month HbA1c review will use routinely collected clinical data from GP records and will only be accessed with participant consent. No additional visits, tests, or procedures are required.
- The study is considered low risk and will operate within existing NHS clinical governance and data protection frameworks.

12. Safety Reporting

- Minimal risks anticipated (e.g., mild skin irritation).
- Adverse events recorded and reported to CI and Sponsor.
- Serious adverse events are unlikely but would follow NHS incident reporting.

13. Quality Assurance

- Monitoring through logs, checklists, and internal oversight.
- Staff training prior to study start.
- Protocol adherence checked during data collection.

14. Dissemination Plan

- Lay summary shared with participants.
- Academic publication and conference presentation planned.
- Findings shared with practice staff and patient groups.
- Participant feedback will inform future trial design.

15. Timeline

Main Pilot Study – 6 Months

Exploratory Follow-Up – 12 Months

Activity	Months 1–2	Months 3–4	Months 5–6	Month 12
Approvals & setup	X			
Recruitment & baseline	X	X		
Intervention delivery (both arms)		X	X	
Analysis & dissemination of pilot			X	
Exploratory HbA1c record review				X

16. Budget

- CGM devices (Freestyle Libre 2 Plus) will be accessed through the manufacturer's standard free sample programme available to all UK patients with diabetes. No commercial funding is provided for this study.
- Staff time for recruitment, intervention, analysis.
- Printing, software, dissemination.

17. References

References (APA 7)

Aronson, R., Brown, R. E., Moineddin, R., O'Reilly, D. J., & Hammad, N. (2025). The effectiveness of continuous glucose monitoring with non-insulin-treated type 2 diabetes: A systematic review and meta-analysis. *Diabetes, Obesity and Metabolism*. Advance online publication. https://doi.org/10.1111/dom.16135

Beck, R. W., Riddlesworth, T., Ruedy, K., Ahmann, A., Bergenstal, R., Haller, S., Kollman, C., Kruger, D., McGill, J. B., Polonsky, W., Toschi, E., & Wolpert, H. (2017). Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: The DIAMOND randomized clinical trial. *JAMA, 317*(4), 371–378. https://doi.org/10.1001/jama.2016.19975

Christiansen, M. P., Garg, S. K., Brazg, R., & Bode, B. W. (2020). Use of professional continuous glucose monitoring in non-insulin-treated type 2 diabetes: Results from a randomized controlled trial. *Diabetes Care, 43*(8), 1858–1864. https://doi.org/10.2337/dc19-2669

Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., & Lancaster, G. A. (2016). CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. *BMJ, 355*, i5239. https://doi.org/10.1136/bmj.i5239

Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining feasibility and pilot studies in preparation for randomised controlled trials: Development of a conceptual framework. *PLOS ONE, 11*(3), e0150205. https://doi.org/10.1371/journal.pone.0150205

Evans, M., Welsh, Z., Ells, S., & Seibold, A. (2019). The impact of flash glucose monitoring on glycaemic control and quality of life in adults with type 1 and type 2 diabetes: A real-world evidence review. *Diabetes Therapy, 10*(4), 965–983. https://doi.org/10.1007/s13300-019-0609-0

International Diabetes Federation. (2021). *IDF Diabetes Atlas* (10th ed.). International Diabetes Federation.

Lind, M., Polonsky, W., Hirsch, I. B., Heise, T., Bolinder, J., Dahlqvist, S., Schwarz, E., & Ólafsdóttir, A. F. (2017). Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: The GOLD randomized clinical trial. *JAMA, 317*(4), 379–387. https://doi.org/10.1001/jama.2016.19976

Polonsky, W. H., & Hessler, D. (2019). What are the quality of life-related benefits and losses associated with real-time continuous glucose monitoring? A survey of current users. *Diabetes Technology & Therapeutics, 21*(1), 66–73. https://doi.org/10.1089/dia.2018.0302

19. Appendices

- **Appendix A:** Cover Sheet (*See separate document*)
- **Appendix B:** Participant Information Sheet (PIS) *(See separate document)*
- **Appendix C:** Consent Form *(See separate document)*
- **Appendix D:** GP Invitation Letter *(See separate document)*
- **Appendix E:** Clinician Invitation letter (*See separate document*)
- **Appendix F:** Participant Questionnaire (Baseline & Post-Study) *(See separate document)*
- **Appendix G:** Clinician Feedback Form/questionnaire (*See separate document*)
- **Appendix H:** Participant Debriefing Sheet (*See separate document*)
- **Appendix I:** Data Management Plan (*See separate document*)
- **Appendix J:** Patient Invitation Letter (*See separate document*)
- **Appendix L:** Data Collection Template (*See separate document*)
- **Appendix M:** Participant Daily Diary Table (*See separate document*)
- **Appendix N:** Participant Interview Guide (*See separate document*)
- **Appendix O**: Participant Flow Chart (*See separate document*)
- **Appendix P:** Clinician Interview Participant Information Sheet (*See separate document)*
- **Appendix Q:** Clinician Interview Consent Form (*See separate document*)
- **Appendix R:** Clinician Interview Guide (*See separate document*)