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A pilot study evaluating two continuous glucose monitoring education strategies for adults with type 2 diabetes in primary care

Submission date
19/06/2026

Recruitment status
Not yet recruiting

Registration date
22/06/2026

Overall study status
Ongoing

Last Edited
22/06/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a common long-term condition that can increase the risk of heart disease, kidney disease, sight loss and other health complications if blood glucose levels are not well controlled. Continuous glucose monitoring (CGM) uses a small sensor worn on the skin to provide information about glucose levels throughout the day and night. CGM may help people better understand how food, physical activity and lifestyle choices affect their glucose levels. Although CGM is increasingly used in diabetes care, there is limited evidence on the best way to introduce and support its use for people with Type 2 diabetes who are not using insulin in primary care. This pilot study aims to assess the feasibility and acceptability of two different CGM education strategies delivered in a GP practice. The findings will help inform the design of a future larger study.

Who can participate?
Adults aged 35–70 years who have had Type 2 diabetes for more than one year, have an HbA1c between 59 and 86 mmol/mol, are not using insulin, can understand spoken and written English, and are willing to wear a CGM sensor and attend study visits.

What does the study involve?
Thirty participants will be recruited and randomly allocated to one of two groups.
Participants in Group A will wear a FreeStyle Libre 2 Plus sensor for approximately 15 days and will be able to view their glucose information in real time. They will receive standard education and attend a follow-up review appointment.
Participants in Group B will wear a CGM sensor for approximately 15 days but will be asked not to view their glucose data during this period. At a follow-up appointment, a clinician will review the data and discuss key findings with the participant. A second sensor will then be applied for a further 15 days, during which participants will be able to view their glucose information and apply the advice received.
Participants will complete questionnaires about their experiences. Some participants may also be invited to take part in an optional interview. Participants will take part for approximately 4–5 weeks (Group A) or 8–10 weeks (Group B). With consent, the research team will review routine

HbA1c results recorded in GP records approximately 12 months after enrolment. No additional visits or blood tests will be required for this follow-up.

What are the possible benefits and risks of participating?
Participants may gain a better understanding of how their daily activities, food choices and lifestyle affect their glucose levels. This may help support diabetes self-management.
The study is considered low risk. Possible risks include mild discomfort or skin irritation from wearing the sensor. Participants may also find that seeing glucose information causes temporary concern or anxiety, although support will be available from the study team.

Where is the study run from?
Country Park Practice (UK)

When is the study starting and how long is it expected to run for?
June 2026 to November 2026

Who is funding the study?
The study is sponsored by Country Park Practice. No external commercial funding is being provided for the study. Continuous glucose monitoring sensors will be obtained through the manufacturer's publicly available free sample programme or existing educational sample stock.

Who is the main contact?
Nkiruka Ofokansi, nikki.ofokansi@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
363998

Study information

Scientific Title

FOCUS-CGM: A randomised feasibility and acceptability pilot study comparing patient-initiated and clinician-facilitated continuous glucose monitoring education strategies for adults with type 2 diabetes in a UK primary care setting

Acronym
FOCUS-CGM

Study objectives
Primary Objective:
To evaluate the feasibility and acceptability of two approaches to continuous glucose monitoring (CGM) education in adults with type 2 diabetes managed in primary care: (1) clinician-facilitated structured CGM review and education, and (2) self-directed CGM use supported by written guidance.

Secondary Objectives:
1. To assess the feasibility of recruiting, retaining, and completing follow-up for adults with type 2 diabetes participating in a primary care CGM education programme.
2. To explore participant engagement with CGM data and identify behavioural changes related to diet, physical activity, medication-taking, and self-management.
3. To compare preliminary changes in glycaemic metrics, including average glucose levels and time spent within target glucose range, between the two study groups.
4. To assess participant satisfaction, confidence, and perceived usefulness of CGM as a self-management tool.
5. To generate preliminary data to inform the design and implementation of a larger primary care study evaluating CGM-supported education for adults with type 2 diabetes not treated with insulin.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/03/2026, London - Surrey Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 1048 088; surrey.rec@hra.nhs.uk), ref: 26/LO/0020

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose

Basic science, Health services research

Study type(s)

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Participants will be randomly allocated in a 1:1 ratio to one of two study groups using a simple randomisation process.

All participants will be adults with type 2 diabetes managed in primary care who have not previously used continuous glucose monitoring (CGM). Participants in both groups will be provided with a FreeStyle Libre CGM sensor to wear for 15 days.

Intervention Group (Clinician-Facilitated CGM Education):
Participants allocated to the intervention group will wear a CGM sensor for 15 days. Following completion of the monitoring period, participants will attend a structured clinician-facilitated review of their CGM data. Education will focus on interpretation of glucose patterns, the impact of diet and physical activity on glucose levels, and personalised strategies to support diabetes self-management. Following the educational intervention, participants will wear a second CGM sensor for a further 15 days to explore ongoing engagement with CGM and any changes in glucose patterns and self-management behaviours. Participants will also complete questionnaires assessing confidence, understanding, and satisfaction with CGM use.

Self-Directed CGM Education Group:
Participants allocated to the self-directed CGM education group will wear a CGM sensor for 15 days and receive written instructions on the use of the device and access to their glucose data through the associated application. Participants will review their own glucose data independently without structured clinician-led interpretation or education. At the end of the monitoring period, participants will complete questionnaires and/or a brief interview exploring their experiences, understanding, confidence, and satisfaction with CGM use.

Outcome data collected from both groups will include recruitment and retention rates, adherence to CGM use, participant feedback, questionnaire responses, and CGM-derived glucose metrics, including average glucose and time spent within the target glucose range.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate measured using the number and proportion of eligible participants recruited into the study at throughout the recruitment period and assessed at study completion

2. Study completion rate measured using the number and proportion of participants completing all study procedures and follow-up assessments, assessed at study completion

3. Adherence to CGM use measured using the number and proportion of participants completing the planned CGM wear period(s) as recorded by FreeStyle Libre sensor data, at at Day 15 and Day 30 (intervention group only)

4. Participant-reported acceptability of CGM-supported education measured using a study-specific questionnaire and/or semi-structured interview at completion of CGM monitoring (Day 15 for the self-directed CGM education group and Day 30 for the clinician-facilitated CGM education group)

Key secondary outcome(s)
1. Time in target glucose range measured using FreeStyle Libre CGM data at Day 15 and Day 30 (intervention group only)

2. Mean glucose level measured using CGM data at Day 15 and Day 30 (intervention group only)

3. Participant confidence in diabetes self-management measured using a study-specific questionnaire at completion of CGM monitoring (Day 15 for the self-directed CGM education group and Day 30 for the clinician-facilitated CGM education group)

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over
2. Diagnosed with type 2 diabetes mellitus
3. Registered at Country Park Practice
4. Not currently using insulin therapy
5. HbA1c above the individualised treatment target and considered suitable for CGM-supported diabetes education by the clinical team
6. Able to provide informed consent
7. Able to understand study procedures and participate in study activities

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
35 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Type 1 diabetes
2. Insulin therapy
3. Pregnancy
4. Significant comorbidity or cognitive impairment
5. Previous use of personal CGM
6. Inability to provide informed consent

Date of first enrolment
25/06/2026

Date of final enrolment
06/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Country Park Practice
Woodside Health Centre
3 Enmore Road
South Norwood
London
England
SE25 5NT

Sponsor information

Organisation
Country Park Practice

Funder(s)

Funder type

Funder Name
Country Park Practice

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.1		19/06/2026	No	No