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Does wearing a glucose sensor and seeing your own readings help people at risk of type 2 diabetes improve their lifestyle choices?

Submission date
02/11/2026

Recruitment status
Not yet recruiting

Registration date
11/11/2026

Overall study status
Ongoing

Last Edited
11/11/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Prediabetes means blood sugar (glucose) levels are higher than normal but not high enough to be diabetes. Up to 7 in 10 people with prediabetes go on to develop type 2 diabetes in their lifetime. A continuous glucose monitor (CGM) is a small sensor worn on the arm or tummy that measures glucose day and night and shows the readings on a phone or handset. CGMs help people who already have diabetes, but we do not know whether they help people with prediabetes. This study aims to find out whether being able to see your own glucose readings, without any formal diet plan, exercise programme or coaching, helps people make their own lifestyle changes and if these changes improve their glucose levels. It will also check whether a larger future study would be possible.

Who can participate?
Adults aged 18 or over with prediabetes (an HbA1c blood test result of 42–47 mmol/mol) who have not taken part in the NHS Diabetes Prevention Programme.

What does the study involve?
At the first visit, participants come in fasted for blood tests, body measurements, questionnaires and a glucose tolerance test. In this test they drink a sugary drink and have blood samples taken over 2 hours. They then wear a “blinded” glucose sensor for 10 days. It records glucose in the background but does not show any readings. Participants are then put at random into one of two groups. The sensor group wears a real-time Dexcom G7 sensor for 12 weeks and can see their readings at any time. Anything they do with this information is up to them. The comparison group carries on with usual care and wears another blinded sensor for 10 days at Week 10. For the 12 weeks, both groups use a step-counting app and complete a short online food diary twice a week. Everyone returns at Week 12 to repeat the first visit’s tests. People in the sensor group can choose to wear one more blinded sensor at about Week 20, to see whether any changes last, and may be invited to an online interview about their experience.

What are the possible benefits and risks of participating?
Participants receive a detailed assessment of their glucose and a set of blood tests. Those in the

sensor group get access to a glucose sensor that is not currently available on the NHS for prediabetes. The possible risks are minor. The sensor can cause redness, itching or discomfort where it sits. Blood tests can cause bruising or faintness. The sugary drink can cause nausea or bloating. Some people may find watching their glucose readings worrying. The visits, app and food diaries take up some time.

Where is the study run from?
The University of Liverpool, with study visits at Aintree University Hospital, UK.

When is the study starting and how long is it expected to run for?
April 2027 to December 2028

Who is funding the study?
Dexcom

Who is the main contact?
Dr Matthew Anson, manson1@liverpool.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
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Integrated Research Application System (IRAS)
365007

Central Portfolio Management System (CPMS)
71109

Study information

Scientific Title

Real-time contInuous glucose monitoring (RT-CGM) for behaviour-only glycaemic improvement in adults with dysglycaemia: a mixed methods pilot randomised controlled trial

Study objectives
The objectives of this pilot trial are:
1. To establish the feasibility of a definitive trial, including recruitment, retention and CGM adherence
2. To explore the behavioural mechanisms of any effect through objectively measured dietary intake and physical activity, using integrated quantitative and qualitative (mixed-methods) assessment
3. To determine whether RT-CGM exposure modifies percentage time in tight range (%TITR) as a marker of impaired glucose handling in prediabetes

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/10/2026, London - Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8340; fulham.rec@hra.nhs.uk), ref: 26/LO /0770

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Abnormal findings on examination of blood, without diagnosis

Interventions
Participants are randomised 1:1 using computer-generated block randomisation with random permuted blocks of varying size, after a 10-day blinded CGM run-in (Weeks –2 to 0). Randomisation is carried out remotely and participants are told their allocation by telephone at Week 0.

Intervention: real-time CGM (Dexcom G7) for 12 weeks (Weeks 0–12), viewed on the participant's smartphone app or a study receiver. Participants receive a brief standardised orientation on sensor self-insertion and on reading the glucose display. No structured coaching, diet plan or exercise programme is provided, and any behaviour change is self-directed. Intervention participants may opt into a durability phase, wearing a further blinded CGM sensor for 10 days at Weeks 20–24, and may be invited to an online semi-structured interview.

Comparator: standard care with no real-time CGM. A blinded CGM sensor (no glucose display) is worn for 10 days at Weeks 10–12.

Both arms: standard written diet and physical-activity advice, a step-count smartphone app and repeated online 24-hour dietary recalls (Intake24) during Weeks 0–12. A fasted 75 g OGTT with paired insulin, blood tests, anthropometry and questionnaires are done at baseline and Week 12. Total duration is up to 12 weeks after randomisation for the control arm and up to 24 weeks for the intervention arm.

Intervention Type
Mixed

Primary outcome(s)
1. The feasibility and acceptability of a randomised controlled trial of real-time continuous glucose monitoring (RT-CGM), used on its own as a self-directed behavioural intervention, in adults with prediabetes, measured using study data recruitment, retention, adherence and data completeness, and participants' acceptance of the intervention, collected at the end of the study

Key secondary outcome(s)
1. Percentage time in tight range (%TITR, 3.9–7.8 mmol/L) measured using a CGM (Dexcom G7; blinded during run-in and in the control arm), over a 10-day run-in at baseline (Weeks –2 to 0) and over Weeks 10–12. The outcome is the within-arm and between-arm difference in change from baseline.

2. Other CGM metrics: % time in range (3.9–10.0 mmol/L), % time above range, mean glucose, glucose variability (coefficient of variation) and the number of postprandial glucose excursions, measured using CGM (Dexcom G7) at baseline (Weeks –2 to 0) and Weeks 10–12

3. Glycated haemoglobin (HbA1c) measured using venous blood test at baseline and Week 12. This includes the proportion of participants with resolution of prediabetes (HbA1c <42 mmol /mol).

4. Glucose tolerance and insulin sensitivity measured using a 75 g OGTT with plasma glucose and serum insulin at 0, 30, 60 and 120 minutes, at baseline and Week 12. These give HOMA-IR, the Matsuda index, and 1-hour and 2-hour glucose.

5. Plasma triglycerides and non-HDL cholesterol measured using a fasting venous blood test at baseline and Week 12

6. Liver enzymes (ALT) measured using a fasting venous blood test at baseline and Week 12

7. Weight, BMI and waist circumference measured using standardised anthropometry at baseline and Week 12

8. Durability of effect (intervention arm only) measured using %TITR and other CGM metrics from blinded CGM (Dexcom G7) at Weeks 20–24, compared with Weeks 10–12

9. Dietary intake (energy, macronutrient and carbohydrate intake) measured using repeated online 24-hour dietary recalls at (Intake24) from Week 0 to Week 12

10. Physical activity measured using mean daily step count from a smartphone step-count app, at Week 0 to Week 12

11. Physical activity, sedentary behaviour and eating behaviour measured using the Recent Physical Activity Questionnaire (RPAQ), Last 7-day Sedentary Behaviour Questionnaire (SIT-Q-7d) and Self-Regulation of Eating Behaviour Questionnaire (SREBQ) questionnaires at baseline and Week 12

12. Perceived risk of developing diabetes measured using the Risk Perception Survey for Developing Diabetes (RPS-DD) at baseline and Week 12

13. Usability of RT-CGM (intervention arm) measured using the System Usability Scale (SUS) at Week 12

14. Self-reported behaviour change prompted by RT-CGM (intervention arm) measured using a study-specific behavioural survey at Week 12

15. Participant experience and acceptability of RT-CGM (intervention arm) measured using semi-structured online interviews (up to 12 participants) at after Week 24

Completion date
01/12/2028

Eligibility

Key inclusion criteria
1. Adults aged > = 18 years
2. Prediabetes defined by a screening HbA1c of 42–47 mmol/mol (6.0–6.4%, DCCT)
3. Able and willing to give written informed consent
4. Have not previously taken part in the NHS Diabetes Prevention Programme

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Clinical diagnosis of diabetes, including diabetes in remission
2. Current use of metformin, incretin-based therapies (GLP-1 agonists, dual GLP-1/GIP agonists, 2 common brands are ‘Ozempic’ and ‘Mounjaro’) or other weight-loss pharmacotherapy, including agents taken privately
3. Current or recent use of glucocorticoids
4. Planned or previous bariatric surgery
5. Pregnancy
6. Previous extensive use of RT-CGM (> = 4 sensors/past year)
7. Current or anticipated treatment with hydroxyurea during the study period
8. Renal replacement therapy (haemodialysis or peritoneal dialysis), or critical illness
9. Planned MRI or diathermy during sensor wear that cannot be rescheduled or accommodated by sensor removal
10. Known adhesive allergy, or dermatological condition, extensive scarring or tattooing at both approved insertion sites (abdomen and posterior upper arm) precluding sensor wear

Date of first enrolment
14/04/2027

Date of final enrolment
01/12/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Aintree University Hospital
Lower Lane
Liverpool
England
L9 7AL

Sponsor information

Organisation
University of Liverpool

ROR

https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
Dexcom

Alternative Name(s)
Dexcom, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Matthew Anson (manson1@liverpool.ac.uk).
Type of data: de-identified individual participant data (CGM-derived metrics, biochemical, anthropometric, dietary and physical-activity outcomes). Interview transcripts will not be shared beyond the research team.
When and for how long: from publication of the main results, for the University of Liverpool's 10-year retention period.
Access criteria: researchers with a methodologically sound proposal, subject to approval by the Chief Investigator and Sponsor, and a data-sharing agreement.
Mechanism: secure transfer of anonymised data following Sponsor information-governance approval.
Consent: participants consent to pseudonymised storage and to publication of results;
Anonymisation: direct identifiers removed; dates and other indirect identifiers removed or coarsened before sharing.
Restrictions: data are owned by the University of Liverpool as Sponsor; sharing is subject to UK GDPR and the Data Protection Act 2018.Twitter.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	REALISE-CGM research study Form v1.0. IRAS 365007. Sponsor: University of Liverpool – Fill in form		09/11/2026	No	No