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Type 2 diabetes self-management using continuous glucose monitoring

Submission date
16/04/2021

Recruitment status
No longer recruiting

Registration date
22/04/2021

Overall study status
Completed

Last Edited
26/08/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People living with diabetes are required to self-manage their condition through a variety of self-care activities such as eating a healthy diet, exercising regularly, taking medication, and monitoring their blood glucose levels. Individuals living with Type 2 Diabetes who receive support from specialist diabetes teams typically have complex health care needs and multiple chronic conditions for them to self-manage. This requires continuous effort and can be physically, emotionally, intellectually, and socially demanding.
Continuous glucose monitors (CGM) have been developed to give people with diabetes real-time readings of their blood glucose levels. It has been shown that using CGM can help some people with diabetes manage their blood glucose levels and improve their quality of life.
The aim of the study is to determine whether being able to see blood glucose levels using CGM for 12 weeks will help support people with complex Type 2 Diabetes to self-manage their diabetes.

Who can participate?
Adults with established Type 2 Diabetes (for over 1 year) and under the care of specialist hospital diabetes teams (Outpatients) will be invited to take part.

What does the study involve?
The study will compare the short-term use (12 weeks) of CGM on self-management behaviour compared to usual care. All participants will use a continuous glucose monitor as part of the study. Participants will be asked to attend 6 study visits over 36 weeks and will also receive 2 phone calls from the study nurse during the 12 week period that they are using the CGM device.

Participants will be allocated to recieve either CGM or usual care for 12 weeks, with an equal chance of being in either group (like tossing a coin) for the first period of the study. In the second period of the study, participants will receive the intervention that they did not receive in the first half of the study. In the third 12 week period of the study, no participants will have access to the CGM device.

Participants will wear the CGM device for 3 separate periods throughout the study. Two of the periods will last for 10 days each and during this time the participant will not be able to see their

blood glucose readings. The third period will last for 12 weeks when the participant will be able to use the CGM device fully to help them self-manage their diabetes. All participants will wear the CGM device for 12 weeks followed by a period of 12 weeks when they will receive usual care and not wear the device.

Throughout the study participants will be asked to complete the following questionnaires:
1. Diabetes Self-Management Questionnaire at randomisation, 12, 24 & 36 weeks;
2. Patient Activation Measure at screening, randomisation, 12, 24 & 36 weeks;
3. Audit of Diabetes Dependent Quality of Life Questionnaire at randomisation, 12, 24 & 36 weeks;
4. Problem Areas in Diabetes (PAID-5) questionnaire at randomisation, 12, 24 & 36 weeks.

The clinical measurements of HbA1c (glycated haemoglobin, which is a marker from blood samples of how well-controlled blood sugar has been the previous few months), total cholesterol, weight, BMI, and waist circumference will also be recorded.

What are the possible benefits and risks of participating?
The aim of the study is to determine whether CGM can help support people with complex Type 2 Diabetes manage their diabetes so possible benefits of taking part in the study could include a better understanding of Type 2 Diabetes, an improvement in diabetes self-management skills, an improvement in diabetes-related quality of life, and a reduction in diabetes-related distress. There could also be an improvement in an individual's blood glucose control and other clinical outcomes such as weight, reducing their risk of developing the complications of diabetes.

However, there may be no clinical benefit to taking part in the study and the use of a continuous glucose monitor may result in some discomfort, irritation, and redness at the site where the sensor is inserted. It may also increase anxiety or diabetes-related distress by providing regular blood glucose readings. Blood samples will be taken as part of the study which may cause some discomfort or bruising, however, this does not usually cause serious problems.

Where is the study run from?
Diabetes Research Group, Swansea University (UK)

When is the study starting and how long is it expected to run for?
From May 2020 to March 2023 (updated 25/05/2022, previously: February 2023; updated 31/03/2022, previously: December 2022; updated 19/10/2021, previously: August 2022; updated 03/08/2021, previously: July 2022)

Who is funding the study?
Dexcom (USA) and Swansea University (UK)

Who is the main contact?
Dr Sharon Parsons
S.N.Parsons@Swansea.ac.uk

Contact information

Type(s)
Public

Contact name

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Additional identifiers

Integrated Research Application System (IRAS)
290957

Protocol serial number
RIO 031-20

Study information

Scientific Title
A randomised, controlled crossover study of short-term use of continuous glucose monitoring (CGM) to support self-management behaviour in complex type 2 diabetes mellitus: the DISCO GM study

Acronym
DISCO GM

Study objectives
Visualisation of blood glucose levels through the short-term use of continuous glucose monitoring alters self-management behaviour in people with complex type 2 diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2021, Wales Rec 6 (Public Health Wales, Building 1, Jobswell Road, St David's Park, SA31 3HB; +44 (0)1267 611164; Wales.REC6@Wales.nhs.uk), ref: 20/WA/0349

Primary study design
Interventional

Study design
Single centre interventional randomized crossover trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Self-management of type 2 diabetes

Interventions
The study will be a randomised controlled crossover study of 36 weeks duration comparing:
1. Routine diabetes care plus diabetes self-management education
2. Short term use of Continuous Glucose Monitoring (12 weeks) plus diabetes self-management education.

Following diabetes self-management education, each participant will be randomised to undertake each intervention for a period of 12 weeks, followed by a 12-week follow-up period. The treatment sequence will be allocated at random. Randomisation will be performed using a computer generated list of random study sequence. Participants will be stratified according to whether they receive insulin therapy.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Diabetes self-management behaviour will be measured using the Diabetes Self-Management Questionnaire (DSMQ) at randomisation, 12, 24, and 36 weeks.

Key secondary outcome(s)
1. Diabetes-related quality of life measured using the Audit of Diabetes Dependent Quality of Life (ADDQoL) questionnaire at randomisation, 12, 24, and 36 weeks
2. Diabetes related distress measured using the Problem Areas in Diabetes (PAID-5) questionnaire at randomisation, 12, 24, and 36 weeks.
3. Patient Activation Level measured using the Patient Activation Measure (PAM) at screening, randomisation, 12, 24, and 36 weeks
4. Blood glucose control measured using HbA1c at randomisation, 12, 24, and 36 weeks
5. Glucose variability, incidence of hypoglycaemia, and time in range metrics will be measured using the continuous glucose monitoring device during the 12 week period the participant wears the device
6. Clinical outcomes such as weight, BMI, waist circumference and total cholesterol will be measured at randomisation, 12, 24 and 36 weeks

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Diagnosed with Type 2 Diabetes for over 1 year
3. Receiving care from a specialist diabetes team (hospital outpatient setting)
4. HbA1c level equal to or over 75 mmol/mol (9%)
5. Willing and able to provide informed consent
6. Willing and able to engage with continuous glucose monitoring

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Diabetes other than Type 2 Diabetes
2. Pregnancy
3. Participation in any investigational drug trial within one month prior to visit 1
4. Condition rendering the participant unable to understand the nature, scope, and possible consequences of the study
5. End-stage renal disease (existing or planned dialysis or transplantation)
6. Severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, and diabetic macular oedema
7. Blindness or severe loss of visual acuity in both eyes
8. Treatment with hydroxyurea
9. Treatment with paracetamol (acetaminophen) higher than 1,000 mg every 6 h daily

Date of first enrolment
21/06/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Clinical Research Unit, Morriston Hospital
Heol Maes Eglwys
Swansea
United Kingdom
SA6 6NL

Sponsor information

Organisation
Swansea University

ROR
https://ror.org/053fq8t95

Funder(s)

Funder type
Industry

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

Funder Name
Swansea University

Alternative Name(s)
, Prifysgol Abertawe

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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 Sharon Parsons (S.N.Parsons@Swansea.ac.uk) once all analysis and study publications have been completed. All data shared will be anonymised and released following review of the request and agreement by the Chief Investigator and all Co-Investigators

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/08/2025	26/08/2025	Yes	No
HRA research summary			28/06/2023	No	No