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Continuous glucose monitoring in the management of medication in care home residents with type 2 diabetes: a feasibility study

Submission date
09/08/2024

Recruitment status
Recruiting

Registration date
25/09/2024

Overall study status
Ongoing

Last Edited
09/05/2025

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
By 2030, one in five adults aged 65 years and older in Europe are expected to be living with diabetes; this figure is increased to one in four people when considering care home residents. Around half of people living with diabetes have inadequately controlled glucose levels, as recommended by the National Institute for Health and Care Excellence (NICE) guidelines. The fact that a reported 70% of care home residents have dementia or severe cognitive impairment further complicates glucose control in this population. In England, there have been significant increases in hospital admissions as a result of high glucose levels (hypoglycaemia), with older patients and those with dementia found to be at a significantly higher risk of low blood glucose (hypoglycaemia). Hospitalisation for hypoglycaemia is associated with cardiovascular events, falls and fractures, death, cognitive complications, reduced quality of life, and a poor prognosis. Over-treatment with certain diabetes medications increases the risk of hypoglycaemia and data from 30 UK care homes showed that over 90% of residents with diabetes had at least one potentially inappropriate medication prescribed. Although evidence suggests that de-intensification of treatment is safe in older people with type 2 diabetes, it is unclear what the safe levels of blood glucose should be during this process of de-intensification. The aim of this study is to investigate if an intervention aimed at improving diabetes control increases the percentage of participants achieving a composite of more than 50% time in blood glucose range and less than 1% time below range during the 12-week follow-up period (essentially improving time in range).
As this is a feasibility study, the aim is not to establish whether the intervention is effective, but instead the aim of is to determine if the different elements of the intervention can be delivered, whether residents and health care practitioners will take part and if the data can be collected. The results will be used to inform the design of a randomised controlled trial.

Who can participate?
Patients aged 65 years or older with type 2 diabetes who are currently on tablets for diabetes control, non-insulin injectable glucose-lowering therapies, insulin or any combination of these treatments, and are currently living in a care home setting (residential, nursing or mixed)

What does the study involve?
The intervention comprises two elements.
Stage 1: Firstly, GPs and/or appropriately qualified healthcare professionals (HCPs) with prescribing responsibilities will be asked to complete a deprescribing review of the resident's medications using a scripted algorithm which aims to reduce unnecessary medications which may induce hypo- or hyperglycaemia. This will occur during week 2 of the study.
Stage 2: Care home residents will be asked to wear a continuous glucose monitor (Dexcom ONE+) for 12 weeks (continuously) with this data fed back to HCPs electronically. HCPs will review this data, alongside self-reported hypo/hyperglycaemia (collected via a log) and medical record data (unscheduled use of healthcare services), adverse events and serious adverse events are collected on a monthly basis (during week 4 and again at week 8) to determine whether additional changes in medication are required. Care home staff will be asked to change the sensors of the monitors every 10 days and upload the data weekly to the Dexcom platform Clarity using the care home computer for HCPs to view. This process will take around 5 minutes and training will be provided, although the research team will be available for support (remotely or in-person).

What are the possible benefits and risks of participating?
People taking part in the study will be provided with the monitoring device and instructions for use. Participants and their carers will be able to see the participant's blood sugar levels continuously throughout the study. A healthcare professional will be able to monitor participant's blood glucose levels in order to adjust any inappropriate medication they may be taking. This should help maintain safe blood glucose levels and may improve overall health.
The use of a continuous glucose monitor can significantly reduce or remove the need for finger prick testing to check blood glucose levels. Research has also shown that using a continuous glucose monitor significantly reduces the number of episodes of high and low blood glucose and the risk of hospitalisation and helps manage diabetes.
The continuous glucose monitor wirelessly sends glucose level readings to the receiver every 5 minutes. This is valuable information about a participant's diabetes, which can help their care team to identify patterns in glucose levels, making their care easier and more precise. In addition, as this is a research study the results may inform ways to prevent older people with diabetes from being admitted to hospital in the future.
There are minimal identified risks to taking part in this study. The main risk for participants is the potential of an adverse reaction to changes in medication, for example, hypoglycaemic and hyperglycaemic events. This risk is an unavoidable possible consequence of changing medication. However, participants will be monitored closely by the healthcare professionals at their general practice, who will review and consider the data from the continuous glucose monitor worn. To help minimise this risk, participants and the clinical staff caring for them will have access to discuss any issues and concerns with a clinical advisor to ensure that participants' blood sugar levels stay within a safe range.
As the continuous glucose monitor contains a fine filament and is attached using an adhesive dressing, there is a small risk of skin complaints such as irritation or rashes. To reduce this risk, the care home staff attaching and removing the monitors will be fully trained to do so by the study team. Additionally, products such as baby oil can be used to make the removal of the device easier, as recommended by the manufacturers of the device.

Where is the study run from?
The study is run from the Leicester Diabetes Centre, based at the Leicester General Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2022 to September 2025

Who is funding the study?
1. NIHR Central Commissioning Facility (CCF) (UK)
2. The NIHR Applied Research Collaboration (ARC) East Midlands (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316085

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57694, IRAS 316085

Study information

Scientific Title
A feasibility study to determine continuous glucose monitor-derived glucose variations when preventing therapeutic inertia in potentially over-treated older people with diabetes

Acronym
e-DMED

Study objectives
This study aims to use continuous glucose monitoring (CGM) to objectively measure blood glucose in older people with diabetes living in care homes to help clinicians safely stop, change or reduce medications in those who are potentially over-treated.

The primary objective is to assess the effectiveness of using CGM aided by a scripted de-prescribing algorithm and health care professional education to assess the percentage of patients achieving a composite of more than 50% time in range and less than 1% time below range within the 12-week study period, in older people with type 2 diabetes who are potentially over-treated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/07/2024, London - Camberwell St Giles Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)2071048276; camberwellstgiles.rec@hra.nhs.uk), ref: 23/LO/0659

Study design
Non-randomized; Both; Design type: Process of Care, Device, Complex Intervention, Other, Cohort study

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
This is a feasibility study, recruiting older adults (aged 65 years and older) with type 2 diabetes, living in care homes who are suitable for de-intensification of medications.

Participants will be identified via GP practice database searches and/or via a search of care homes completed by the NIHR ENRICH team (Enabling Research In Care Homes). As participants reside in care homes, screening, recruitment and study visits will take place in the care home or remotely (e.g. telephone in the case of de-intensification reviews) to maximise comfort.

Participants will undergo four study visits in total. Each visit is described below:

Visit 1 - baseline

Data to be collected:
1. Informed consent
2. Medical history
3. Demographic information
4. Blood pressure and anthropometrics (if more appropriate, taken from the clinical observations at the time point nearest to study recruitment)
5. EQ-5D-5L (questionnaire to assess quality of life)

During this visit, a study team member or care home staff will attach the CGM to the participants. Participants will be asked to wear a continuous glucose monitor (Dexcom One+) for the duration of the study (12 weeks) and sensors on the monitors will need to be changed every 10 days by the care home staff. The research team will provide replacement sensors to be left at the care home.

Prior to the baseline visit, care home staff will have received full training in how to attach and change the sensor, how to download data from the reader and how the monitor can be used as part of the participant's routine care by a member of the EDEN (Effective Diabetes Education Now) team. All members of staff with caring responsibilities for participants will need to be made aware of the study.

Care home staff training will also contain information about hypoglycaemia (i.e., what it is, how to recognise an event and how to act in response to blood glucose levels <3.1 mmol/L). Additionally, participants or their carers will be given a log of wear for the CGM device to record

any unscheduled interruptions in device use and a hypo/hyperglycaemia diary to record any hypoglycaemic or hyperglycaemic events.

De-prescribing review

This remote review will occur approximately 10-14 days after the baseline visit.

Appropriate clinical staff (those with prescribing responsibilities to treat eligible patients, such as a GP, nurse prescriber or pharmacist) who have completed the training from the GP practice will carry out a usual standard of care medication review, using the de-prescribing algorithm, and make any resulting changes to medication prescribing.

HCPs will receive training in the Dexcom One+ system, practicalities (e.g. setting up Clarity accounts) and data interpretation from the EDEN team.
Clinical staff will have access to the participant's previous 2 weeks of baseline CGM data.

Visit 2 and visit 3 (weeks 4 and 8)

Participants will be given additional replacement sensors.

Medication review: HCPs will carry out the medication review (remotely, from the GP practice) with the aid of the de-prescribing algorithm, following their training.

Participant's glucose data and event diary will also be reviewed by the HCP to help guide the de-intensification process. Concomitant medication, adverse and serious adverse events will be discussed with the participant and/or their carers, and unscheduled visits to healthcare services and CGM data and the event diaries will also be reviewed and recorded within the CRF (Case Report Form).

Visit 4 - final visit (week 12)

Participants will be asked to complete the EQ-5D-5L (questionnaire to assess quality of life).

Diaries will be collected or posted back to the research team in a prepaid and addressed envelope and filed with other CRFs, in each participant's unique folder (see Section 10.1). Any unscheduled visits/calls to HCP and healthcare use data will be collected from the participants' GP surgery records and/or the care home.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexcom One+

Primary outcome measure

The percentage of participants achieving a composite of more than 50% time in range and less than 1% time below range, during the 12-week follow-up period. Measured via CGM continuously across the 12-week study.

Secondary outcome measures
The proportion of participants, during the 12-week follow-up period, with any of the following outcomes:
1. Quality of life measured using the EQ-5D-5L at baseline and 12 weeks
2. Self-reported hypoglycaemic-related adverse events measured via a diary/log throughout the 12-week study
3. Self-reported hyperglycaemic-related adverse events measured via a diary/log throughout the 12-week study
4. Emergency hospital admissions for hypoglycaemic-related events, extracted from medical records and reviewed during the medication reviews (weeks, 2, 4 and 8) and at 12 weeks
5. Emergency hospital admissions for hyperglycaemic-related events extracted from medical records and reviewed during the medication reviews (weeks, 2, 4 and 8) and at 12 weeks
6. Death, extracted from medical records throughout the 12-week study

The following will be measured by extracting the data from the Dexcom One+ device (the Dexcom ONE+ collects data continuously, so these variables are measured throughout the 12-week study):
1. The change in “time above ranges” - time spent above 10 mmol/l and 13.9 mmol/l
2. The change in “time below ranges” - time below 3.9 mmol/l and 3.0 mmol/l
3. The percentage of participants recording a 4-hour sustained glucose reading >18 mmol/l at least once
4. Adherence to the Dexcom One+ sensor programme
5. The frequency of technical problems reported on a log/diary throughout the 12-week study

1. The acceptability of the study device by participants, their consultee (if applicable) and care home staff will be assessed using the Theoretical Framework of Acceptability questionnaire at week 12

Overall study start date
12/12/2022

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Aged 65 years or older
2. Confirmed diagnosis of type 2 diabetes
3. Currently on tablets for diabetes control, non-insulin injectable glucose-lowering therapies, insulin or any combination of these treatments
4. HbA1c less than 7.5% (58 mmol/mol) in the previous 12 months prior to the baseline search
5. Currently living in a care home setting (residential, nursing or mixed)
6. Participant is willing and able to give informed consent for participation OR if the participant lacks capacity, a consultee is willing to complete a consultee declaration form

Participant type(s)

Patient

Age group
Adult

Lower age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 49; UK Sample Size: 49

Key exclusion criteria
1. No confirmed diagnosis of type 2 diabetes
2. No diabetes medication issued in the 3 months before the database search for eligible participants
3. Aged 64 years old and younger
4. Last HbA1C reading >=7.5% (58 mmol/mol) in the previous 12 months prior to the baseline search
5. Participant has opted out of sharing their personal data as part of the national data opt-out policy
6. Receiving end-of-life care
7. Currently participating in a CTIMP study, or has participated in a CTIMP in the last 30 days
8. Is a temporary care home resident (i.e. less than 1 month of planned transitional/respite residential care)
9. Planning to travel away from the care home for >=2 weeks (on holiday, for example)

Date of first enrolment
01/02/2025

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
Care home sites - unknown currently
United Kingdom
-

Sponsor information

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Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
NIHR Applied Research Collaboration East Midlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/05/2025	09/05/2025	Yes	No