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STUDY PROTOCOL

Continuous Glucose Monitoring in the Management of Medication in Care Home Residents with Type 2 Diabetes (eDMED): A Protocol for a Feasibility Study

Anneka E. Welford · James Ridgeway · Clare Gillies · Pratik Choudhary · Vidya Hegde · Kamlesh Khunti · Samuel Seidu

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ABSTRACT

***Aims*:** Overprescribing is common in older adults with diabetes, potentially leading to hospitalisation and reduced quality of life. Additionally, diabetes care in older adults is often complicated by multiple interacting conditions and cognitive impairment, resulting in challenging self-management. Although evidence suggests that de-intensification of medications is safe in older adults, there are no data evaluating glucose ranges during this process.

***Methods*:** eDMED is a 12-week feasibility study including 49 adults, aged ≥ 65 years with type 2 diabetes and residing in care homes. All eligible participants will receive medication de-intensification and continuous glucose monitoring (CGM). Primary healthcare professionals (HCPs) will undergo structured training on a de-intensification algorithm and CGM, while care home staff will receive tailored education on diabetes management and CGM application to ensure safe and effective implementation.

***Planned Outcomes*:** The primary outcome is the percentage of participants achieving a composite of > 50% time in range and < 1% time below range at 12 weeks, measured via CGM. Secondary outcomes include trends in time above and below range (quantified by level of hyper- or hypoglycaemia), change in quality of life (EQ-5D-5L), percentage of data captured to indicate adherence to the CGM and the acceptability of the intervention to participants, their consultees and carers (Theoretical Framework of Acceptability questionnaire).

***Trial Registration*:** International Clinical Trials Registry Platform (ID: ISRCTN 69024008).

Keywords: Care home; Continuous glucose monitoring; De-intensification of medications; Frailty; Hypoglycaemia; Primary care; Type 2 diabetes

A. E. Welford (✉) · P. Choudhary · V. Hegde · K. Khunti · S. Seidu
Leicester Diabetes Centre, Leicester General Hospital, University of Leicester, Gwendolen Rd, Leicester LE5 4PW, UK
e-mail: aew32@le.ac.uk

A. E. Welford · K. Khunti
National Institute for Health and Care Research (NIHR), Applied Research Collaboration East Midlands (ARC EM), Leicester, UK

J. Ridgeway · K. Khunti
EDEN, Leicester Diabetes Centre, General Hospital, Leicester, UK

C. Gillies · K. Khunti
Leicester Real World Evidence Unit, University of Leicester, Leicester, UK

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Key Summary Points
By 2030, an estimated one in four care home residents in Europe will be living with diabetes.
Polypharmacy and overprescribing are common in this population and can potentially lead to hospitalisation and reduced quality of life.
This is the first UK-based study utilising advanced continuous glucose monitoring (CGM) technology to monitor the medication de-intensification process in older adults with diabetes residing in care homes.
By assessing how CGM informs medication de-intensification decisions and improves time in range for older adults with type 2 diabetes, this study seeks to provide valuable data to refine treatment protocols in this population.
The findings are expected to offer evidence-based recommendations for safe glucose management during medication de-intensification.

INTRODUCTION

By 2030, an estimated 20% of adults aged 65 and older in Europe will have diabetes, rising to 25% among care home residents [1, 2]. Approximately 50% of patients with diabetes are living with inadequately controlled glycaemic levels, as recommended by the National Institute for Health and Care Excellence (NICE) [3]. Upwards of 70% of care home residents have dementia or severe cognitive impairment [4], further complicating glyacemic control. In England, significant increases in hospital admissions have resulted from hypoglycaemia [5], with older patients [6] and those with dementia at significantly higher risk [7]. Hospitalisation for hypoglycaemia is associated with cardiovascular events, falls and fractures, death, cognitive complications, reduced quality of life, and poor prognosis [5, 8, 9].

The aim of diabetes care is to manage symptoms and reduce the risk of acute and long-term complications [10]. Glycaemic control has long been considered the foundation of diabetes management, with NICE recommending specific glycated haemoglobin (HbA1c) targets for adults with diabetes [3]. Glycaemic control is achieved pharmacologically if lifestyle changes prove insufficient [3]; however, although the rigorous pursuit of HbA1c targets may reduce the risk of some long-term complications [11], the danger of harm in the form of hypoglycaemia is increased in older adults during pharmacological treatment [12].

Following recent developments of UK guidelines, the term 'therapeutic inertia' evolved to address the problem of overtreating some vulnerable patient groups, such as a frail older population [13]. Overtreatment is defined as the use of a treatment when potential harms exceed possible benefits [14]; one study reported overtreatment rates in older adults of between 10.1% and 44.3%, dependent on HbA1c level [15]. Importantly, data from 30 UK care homes showed that over 90% of residents with diabetes were prescribed at least one potentially inappropriate medication [16].

Evidence suggests that de-intensification of medications is safe in older people with type 2 diabetes, frailty and multiple long-term conditions [17] and now, de-intensification is common practice to prevent hypoglycaemia and associated complications. A recent systematic review found that older people and their carers were willing to have their medications de-intensified, with willingness increasing if de-intensification was completed by a trusted healthcare professional (HCP) followed by the promise of a period of monitoring [18].

However, it is unclear what constitutes safe glucose levels during de-intensification. In avoiding hypoglycaemia during clinically appropriate de-intensification, inadvertent rebound hyperglycaemia can ensue and lead to symptoms such as dehydration or hospital admissions, highlighting a greater need for glycaemic management in this population.

The most recent NICE guidelines recommend the use of continuous glucose monitoring (CGM) in patients living with type 2 diabetes

who also live with "a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring" [3]. Diabetes care in older adults is particularly onerous for several reasons: patients may be frail[19], have multiple and complex interacting conditions [20], including high rates of cognitive impairment [21], and therefore may not be able to self-manage their condition, making them reliant on their carers [22].

CGM presents an alternative method of glucose monitoring to capillary blood glucose monitoring (CBG), an invasive procedure which raises challenges in an older population with high rates of cognitive impairment [23]. CBG compromises patient comfort, may cause skin irritation and loss of sensation [24], resulting in fear and resistance to self-testing, reduced self-testing in some populations [25], compromising diabetes care and increasing the risk of complications [26]. Furthermore, this method provides cross-sectional data, meaning that periods of hyper- or hypoglycaemia may be missed [27]. Conversely, CGM provides continuous data, offering a precise method to monitor and mitigate risks such as hypoglycaemia during medication de-intensification. CGM has been shown to be well tolerated by both patients and their carers, increasing feelings of confidence, safety and reassurance when using CGM rather than CBG [23].

Currently, there are no studies objectively measuring the detailed glucose profile using interstitial glucose levels of care home residents during a de-intensification intervention.

The objective of this feasibility study is to evaluate time in range in older people with type 2 diabetes residing in care homes whilst undergoing the de-intensification process, where HCPs have access to a scripted medication de-intensification algorithm and clinical education.

METHODS

The primary objective of the study is 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.

Study Design

The study will take place within primary healthcare practices in Leicester, Leicestershire and Rutland (LLR), UK. Leicester City has the highest prevalence of diabetes in England (8.9%), and a large multi-ethnic population (59.2% people of colour) [28], which is important as some ethnic minorities have up to a fivefold increased risk for type 2 diabetes compared with white Europeans [29].

This is a 12-week feasibility study to assess the impact and acceptability of a scripted medication de-intensification algorithm and HCP education alongside CGM on diabetes management. For the purposes of this study, HCPs are defined as clinical staff with prescribing responsibilities for patients with diabetes, e.g. general practitioners (GPs), practice pharmacists or nurses.

All participants will receive the study intervention and the schedule of events as shown in Table 1. This protocol has been designed using the INCLUDE Impaired Capacity to Consent framework [30] and was guided by the Mental Capacity Act [31].

A minimum of two HCPs per practice will be required to complete the study training, which includes pre-recorded training and booster animations on the medication de-intensification algorithm (around 60 min), a 60-min pre-recorded webinar on the Dexcom ONE+ CGM and data interpretation via the Clarity platform. HCP training will be supplemented with monitoring telephone calls during weeks 2, 4 and 8 and the study team will be available with advice at any point. Additionally, HCPs will complete follow-up evaluations to assess their confidence and competency in using the algorithm and CGM. The algorithm was developed for an ongoing study (D-MED, IRAS:280971) and will guide the HCP

Table 1 Schedule of events

Location	Baseline (visit 1) day 0	Week 2: De-intensification review 10–14 days after baseline	Monitoring review (visit 2) 4 weeks after baseline	Monitoring review (visit 3) 8 weeks after baseline	End of study (visit 4) 12 weeks after baseline
	Face to face participant visit	HCP remote review	HCP remote review	HCP remote review	Face to face participant visit
Written informed consent	X				
Medical history	X				
Demographics	X				
EQ-5D-5L	X				X
Blood pressure	X			X	
Anthropometric measures	X				
Concomitant medications	X				
Receipt of Dexcom ONE+ device and set up	X				
Training for Dexcom ONE+ and hypoglycaemic and hyperglycaemic events	X				
Receipt of log of wear and events diary	X X				
Receipt of Dexcom ONE+ sensors	X		X	X	
HCP de-intensification review		X			
HCP monitoring review			X	X	
Review of CGM data and diaries for adverse or serious adverse events			X	X	X

Table 1 continued

Location	Baseline (visit 1) day 0	Week 2: De-intensification review 10–14 days after baseline	Monitoring review (visit 2) 4 weeks after baseline	Monitoring review (visit 3) 8 weeks after baseline	End of study (visit 4) 12 weeks after baseline
	Face to face participant visit	HCP remote review	HCP remote review	HCP remote review	Face to face participant visit
Record/review unscheduled visits/calls to healthcare services			X	X	X
TFA questionnaire					X
Data extraction from primary care					X

HCP healthcare professional, *CGM* continuous glucose monitoring, *TFA* Theoretical Framework of Acceptability

through the decision-making process for de-intensification [32].

Additionally, a minimum of two care home staff members will receive a 60-min pre-recorded training session which covers the Dexcom ONE+ system, high and low glucose alerts and how to respond to them, how to safely dispose of the technology and how to check for skin integrity issues. Additionally, training will cover the set-up and use of the cloud-based system, Dexcom Clarity, which gathers the glucose sensing data.

Sample Selection

We will recruit 49 participants with type 2 diabetes, aged 65 years and over living within care homes. The full inclusion, exclusion and withdrawal criteria are listed in Table 2.

Methods to recruit practices and care homes will include advertisement via the National Institute of Health Research (NIHR), direct contact, word of mouth and presentations at relevant healthcare meetings. Practices may only participate if a care home where their patients are resident also participates. NIHR ENRICH (Enabling Research In Care Homes) will distribute study information and expression of interest forms (EOI) to research-active care homes.

A database search of practice lists will be completed, and an invitation to participate, participant information sheets (PIS) and EOI forms will be mailed to eligible patients. In the event of recruitment delays, strategies such as additional outreach and extended timelines are planned.

We will recruit care home residents with and without capacity. The capacity assessment and the consent process will be guided by the Mental Capacity Act, 2005 [31] and completed by an appropriately experienced and trained research nurse or doctor.

Written informed consent will be received from participants with capacity, whilst advice will be sought, in the form of a declaration form, from consultees for participants lacking capacity. A short PIS with adaptations to language and font size is available to all participants and consultees.

Measurements

Participant flow through the study is shown in Fig. 1. Participants will have four in-person study visits during the 12-week study period (weeks 0, 4, 8 and 12). HCPs will complete remote de-intensification or monitoring aided by the de-intensification algorithm, the CGM

Table 2 Study inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria	Withdrawal criteria
Aged ≥ 65 years	Aged ≤ 64 years old	Ineligibility (arising during the study or retrospectively having been overlooked at screening)
Confirmed diagnosis of type 2 diabetes	No confirmed diagnosis of type 2 diabetes	Significant protocol deviation, e.g. repeated purposeful removal of the CGM
Currently on tablets for diabetes control, non-insulin injectable glucose-lowering therapies, insulin or any combination of these treatments	No diabetes medication issued in the 3 months before the database search for eligible participants	Significant non-compliance with study requirements, including a period of ≥ 10 days without wearing the CGM
HbA1c < 7.5% (58 mmol/mol) in the previous 12 months prior to the baseline search	Last HbA1c reading ≥ 7.5% (58 mmol/mol) in the previous 12 months prior to the baseline search	An adverse event which requires discontinuation of the study or results in an inability to continue compliance with study procedures
Living in a care home (residential, nursing or mixed)	Participant has opted out of sharing their personal data as part of the national data opt-out policy	Consent withdrawn
Participant is willing and able to give informed consent OR a consultee is willing to complete a consultee declaration form	Receiving end of life care	
	Currently participating in a CTIMP study, or has participated in a CTIMP in the last 30 days	
	Is a temporary care home resident (i.e. < 1 month of planned transitional/respite/ residential care)	
	Planning to travel away from the care home for ≥ 2 weeks	

CGM continuous glucose monitoring, *CTIMP* Clinical Trial Investigation of Medicinal Product, *HbA1c* glycated haemoglobin

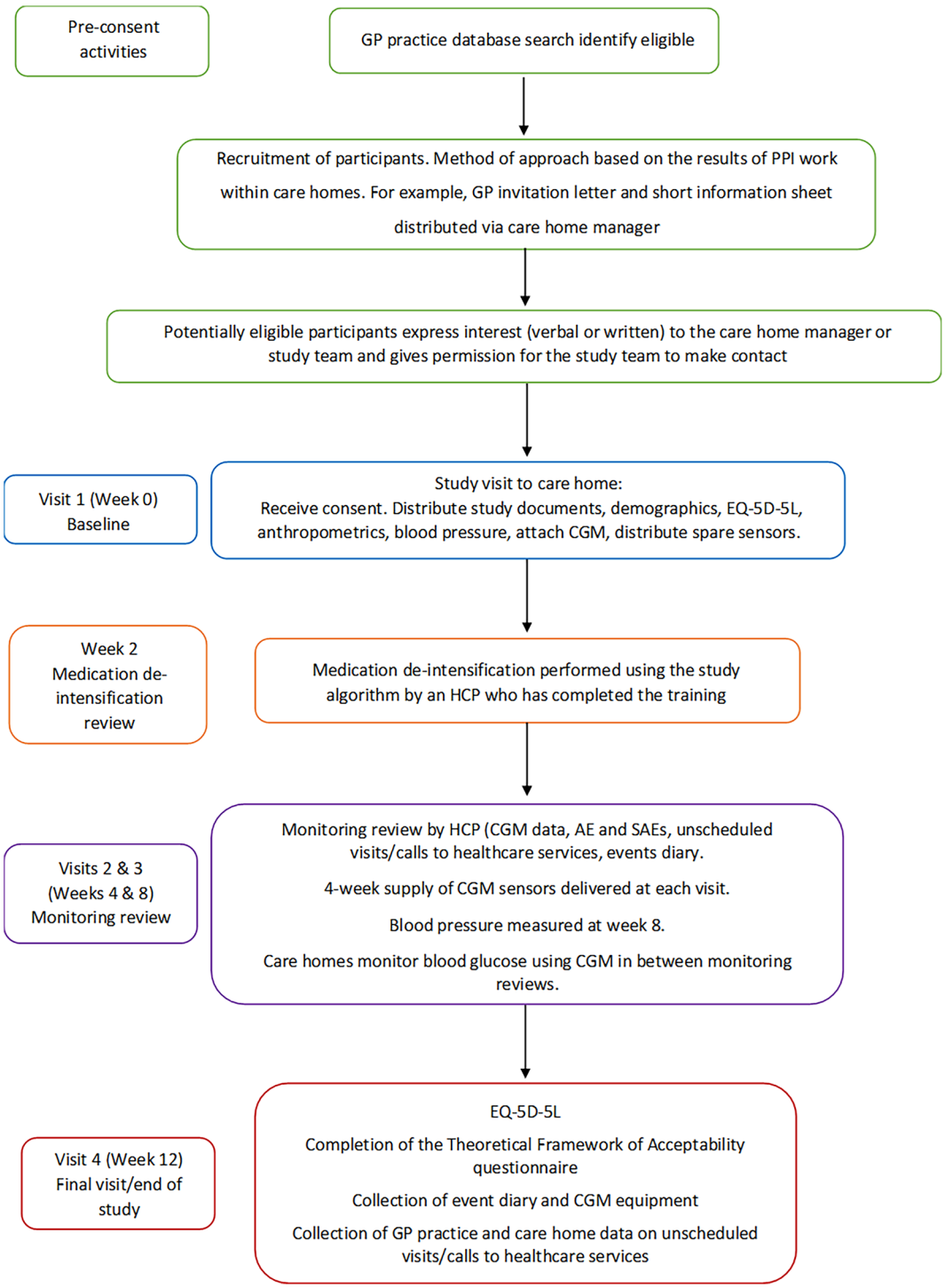

Fig. 1 Study flow chart. *AE* adverse event, *CGM* continuous glucose monitoring, *GP* general practitioner, *HCP* healthcare professional, *SAE* serious adverse event

data, self-reported hypo- and hyperglycaemic events (reported by participants or their carers and shared with the practices) and any unscheduled visits to healthcare services at three points (weeks 2, 4 and 8) throughout the study.

Briefly, data to be collected during the baseline visit will include a medical history, basic demographics (including age, sex and ethnicity), concomitant medications, anthropometrics including height and weight (body mass index (BMI) will be calculated), blood pressure and quality of life (EQ-5D-5L). These data will be obtained by a research nurse or member of the study team and will be repeated at the end of the study (week 12). An additional measurement of participant's blood pressure will take place during week 8 and an additional questionnaire (Theoretical Framework of Acceptability (TFA)) will be completed with participants, their consultees and/or care home staff during week 12.

Participants will be asked to wear a real-time CGM device (Dexcom ONE+) continuously throughout the 12-week study to aid their HCP in the safe de-intensification of their medications. The Dexcom ONE+ system includes (1) an integrated sensor-transmitter that continuously measures interstitial glucose levels, (2) an over-patch for secure placement, and (3) a reader that provides real-time glucose data. Readers were chosen over smartphones for their ease of use and to prevent barriers to participation due to a lack of digital skills.

Dexcom ONE+ sensors send real-time data from the interstitial fluid to a reader every 5 minutes which can be viewed remotely by the participant's HCP or care home staff with caring responsibilities. The sensor of the Dexcom ONE+ system needs to be changed every 10 days and will be worn on the back of participants' arms or abdomen, as per manufacturer guidelines, and to minimize accidental removal.

The monitor can be worn during everyday activities including bathing and most physical activities. Communication between the transmitter and the reader works via Bluetooth, providing they are within a 6-m distance. Therefore, the reader will be kept with participants, ideally on their person.

Alarms signifying that the user's glucose levels are too low/high will be set on the basis of Diabetes Technology UK guidance [33]. We will ask the care home to upload data with every sensor change to ensure practice staff have access to the data they require for the de-intensification/monitoring reviews. All CGM data will be stored securely on encrypted servers, and access will be limited to authorised personnel only.

Planned Outcomes

Primary and secondary study objectives are presented in Table 3.

Data Collection

The primary and majority of the secondary outcomes will be measured using the Dexcom ONE+, for which data will be collected continuously throughout the 12-week study. Time above or below range will be analysed using recent recommendations on hypo- and hyperglycaemia: levels 1–3 for hypoglycaemia and levels 1–2 for hyperglycaemia [34].

Other secondary outcomes include quality of life, which will be measured at baseline (week 0) and at the end of the study (week 12) using the EQ-5D-5L [35], a valid measure for older people living in residential care [36]. Acceptability of the intervention to participants/consultees and care home staff will be assessed using the TFA questionnaire [37] at the end of the study (week 12). The TFA assesses seven domains of acceptability including affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy. Answers are given on a scale of 1–5, with optional free text entries.

Care home staff will record hypo- and hyperglycaemic events throughout the study in a log book to include date, time and details of the event, symptoms and their estimated duration, recovery time and any action taken. Baseline demographic and medical history data will be extracted from patient medical records within the year preceding the baseline visit by a member of the practice staff at 12 weeks. Adverse

Table 3 Primary and secondary study objectives

Primary objective	To assess the feasibility of using of CGM, in conjunction with a scripted de-intensification algorithm and HCP education to achieve a composite outcome of > 50% time in range and < 1% time below range over a 12-week period
Secondary objectives	The percent of data captured to indicate adherence to the Dexcom ONE+
	The trend in time in level 1 hyperglycaemia (glucose > 10.0 to 13.9 mmol/l) across the 12-week study
	The trend in time in level 2 hyperglycaemia (glucose > 13.9 mmol/l) across the 12-week study
	The trend of prolonged extreme hyperglycaemia (glucose > 16.6 mmol/l) for over 4 h across the 12-week study
	The change in mean glucose and glucose variability across the duration of the study
	The frequency of technical problems
	The trend in time in level 1 hypoglycaemia (glucose 3.9 to ≥ 3.0 mmol/l across the 12-week study
	The trend in time in level 2 hypoglycaemia (glucose < 3.0 mmol/l)
	Number of episodes per week of level 1 (3.9 to ≥ 3.0 mmol/l), level 2 (< 3.0 mmol/l) and level 3 (a severe event categorised by altered mental and/or physical status requiring assistance) hypoglycaemia
	Change in quality of life at week 12 compared to baseline
	Self-reported hypo- and hyperglycaemic events
	The acceptability of the intervention to participants, their consultees and/or care home staff (TFA questionnaire)

CGM continuous glucose monitoring, *HCP* healthcare professional, *TEA* Theoretical Framework of Acceptability

events will be reported throughout the study and be responded to by members of the clinical team (e.g. GPs, diabetes specialists, or the study's designated clinicians).

Data Analysis

On the basis of a previous study [38], we found 37.5% of the recruited population met the primary outcome. However, the objective measures of the CGM readings, coupled with the alarms that indicate readings are out of range, means that the remaining 62.5% who are not in range at baseline will have medications reviewed to improve the time in range. It is plausible that 100% of participants will have the review of their medications with the algorithm if their blood glucose readings are out of range, but as a result of other complexities and availability of eligible participants for recruitment, 100% is not feasible.

Therefore, a more conservative effect size estimate of increment of the achievement of the primary outcome from 37.5% to 70% was chosen. Assuming 37.5% of the recruited sample will meet the primary outcome at baseline and an increase to 70% at follow-up, we will need to recruit 49 participants to show a statistically significant effect. The sample size was calculated with 90% power at a 5% significance level. The sample size was calculated in Stata using the clustersampsi command.

Participant disposition will be presented with respect to completion status, reason for non-completion, protocol deviations, and length of stay in the study. Demographic and baseline characteristics will be summarised by group.

Continuous variables will be summarised as mean and standard deviation or median and interquartile range, and categorical variables will be given as counts and percentages.

For the primary outcome, a McNemar test will be used to assess the difference at baseline and week 12 in categorical variables; a paired *t* test will be used otherwise. Potential confounding factors will be investigated and adjusted for. All analyses will be carried out in Stata (version 15.0). No subgroup analyses or interim analyses are planned. Missing data will be managed using multiple imputation techniques. Sensitivity analyses will test the impact of missing CGM data on the primary and secondary outcomes.

STRENGTHS AND LIMITATIONS

There is a clear need to address the issue of therapeutic inertia in older adults [13] who are particularly affected by multiple long-term conditions and polypharmacy [16], which is harmful to the individual and results in costly downstream medical costs.

Building on NICE NG28 guidelines, this study will not only evaluate CGM's role in managing type 2 diabetes in older adults but will also explore how structured medication de-intensification aligns with these guidelines to reduce risks associated with overtreatment, such as hypoglycaemia and falls.

CGM is expected to become more widespread across the UK since the release of updated NICE guidelines [3]. The use of CGM in older adults has been found to reduce hypoglycaemic episodes [39, 40], effectively reducing HbA1c and improving time in range compared to CBG [41, 42]. Furthermore, CGM has been viewed favourably by both older adults and their carers [23], alongside improving quality of life outcomes such as well-being [43], hypoglycaemic distress and feelings of helplessness, regardless of age, gender, ethnicity, diabetes type, education level and income [39].

This is the first UK-based study utilising advanced CGM technology to monitor the medication de-intensification process in older adults with diabetes residing in care homes. The pragmatic nature of the study and the alignment of the de-intensification algorithm with current usual practice aims to reduce the burden on clinicians. Our PPI work indicated that care home staff members are receptive to using CGM and welcome the chance to upskill via training.

This protocol has been developed with various stakeholder groups, including care home nurses, managers, residents and their next of kin. The INCLUDE Impaired Capacity to Consent framework has been used to design this protocol to be inclusive for people with an impaired capacity to consent—a group who are underrepresented and often excluded from research [44]. Furthermore, the setting of this study is very relevant to the problem area addressed, since LLR has a high prevalence of diabetes and a large ethnic minority population. However, findings may need contextual adaptation for populations in different geographic or socioeconomic contexts and scalability challenges, such as resource limitations in non-research settings, will need to be evaluated in future studies.

Ethics

The study was prospectively registered at the International Clinical Trials Registry Platform (ID: ISRCTN 69024008), and will be conducted in accordance with the principles outlined in the Declaration of Helsinki. Ethical approval was granted by an NHS Research Ethics Committee flagged for research involving adults lacking capacity (23/LO/0659).

PPI involvement was sought during the development of the protocol and patient-facing documentation. Advice was enlisted from a co-investigator and PPI consultant Clare Bates (CB), who has extensive experience as a practising care home nurse. CB shared the draft protocol and documentation with residents and their next of kin, whose feedback was incorporated into the final draft. The study team attended diabetes education days for care home staff to gain insight into current diabetes care within care homes and ascertain attitudes towards the intervention. Focus groups with care home managers discussed the proposed protocol and challenges faced by care home staff, identifying

high staff turnover and lack of resources as potential barriers to participation, moreover, identifying adaptations to simplify consent processes and tailor educational materials for care home staff. The most appropriate route of accessing participants and accessible methods of communicating the study information were also highlighted.

Dissemination

Recruitment is expected to commence in January 2025. We expect results to be reported in early 2026. Study results will be disseminated in peer-reviewed clinical journals and presented at relevant scientific meetings. Authorship will be in line with the International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals [45]. Results will be shared with the participants of the study and their consultees, should they consent to further contact.

CONCLUSIONS

The manuscript does not anticipate or propose solutions for practical challenges healthcare providers might face while implementing medication de-intensification guided by CGM data.

Practical challenges, such as resistance to medication de-intensification from caregivers or limited resources in care homes, may hinder implementation. To address these, future studies should evaluate scalable training programs for caregivers and the integration of de-intensification algorithms into electronic health systems.

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Data Availability. The data sets generated and analysed during this study will be available from the corresponding author on reasonable request with appropriate institutional review board approval and data use agreement.

Declarations

Conflict of Interest. None to report for Anneka E Welford, James Ridgeway, Clare Gillies, Pratik Choudhary, Vidya Hegde, Kamlesh Khunti or Samuel Seidu.

Ethical Approval. The study was prospectively registered at the International Clinical Trials Registry Platform (ID: ISRCTN 69024008), and will be conducted in accordance with the principles outlined in the Declaration of Helsinki. Ethical approval was granted by an NHS Research Ethics Committee flagged for research involving adults lacking capacity (23/LO/0659).

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