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Feasibility study: an investigation of frailty and glycaemic control in older adults with type 1 diabetes mellitus

Submission date
10/01/2023

Recruitment status
No longer recruiting

Registration date
03/04/2023

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
We all age differently. Many people with type 1 diabetes (T1DM) worry about how they will look after their diabetes as they get older. Managing T1DM may be made harder by common things such as changes in weight, appetite, physical activity and memory which can all affect how much insulin someone needs. Some people will develop frailty as they get older. Frailty refers to a person's ability to bounce back and recover (physically and/or mentally) from illness or injury. We think that people with T1DM may have a slightly higher chance of developing frailty. We do not know if frailty affects the control of T1DM. The aim of this research is to assess whether people with T1DM and frailty have more ups and downs in their glucose levels than those without frailty. This includes whether there are more low glucose episodes in people with frailty. These are research questions that no previous studies have yet answered.

Who can participate?
Adults over the age of 65 years old with T1DM for at least 1 year

What does the study involve?
The study will involve a frailty assessment alongside a review of the individual's medical and diabetes history. The participant will wear a continuous glucose monitor (CGM) for 10 days which will be blinded, meaning the wearer cannot see the results

What are the possible benefits and risks of participating?
The benefits of taking part:
It is currently not known how the changes associated with ageing affect the control of T1DM, or how T1DM can affect the ageing process. This study will allow us to start to understand these processes better, with the longer-term aim of trying to work with older people with T1DM and their families/carers, to improve the lives and care of older adults with T1DM in the future. Understanding how CGM could be used in older adults could open up this technology more widely for example.

The risks of taking part:
1. Inconvenience at having to attend the clinic for assessment on two occasions. In order to reduce this, payment will be made for travel and parking costs to a maximum of £20. The clinic environment will be made comfortable and refreshments provided. If the participant is unable to travel to the clinic.
2. Pain and/or discomfort from wearing CGM. The device chosen is small and has been used by many people with T1DM without any pain or distress. There will be an opportunity to contact the investigator if there are any problems encountered with the device to troubleshoot issues. It will be made clear that the participant can end their involvement in the research at any point if they are finding the device uncomfortable.
3. Inconvenience at having to keep the receiver within 6 metres at all times. This is required to ensure data capture. 6 metres is a large area which should enable participants to roam their houses without needing to carry the receiver with them. Care will only need to be taken on leaving the house. There will be an opportunity to contact the investigator if there are any problems encountered with the device to troubleshoot issues. It will be made clear that the participant can end their involvement in the research at any point if they are finding this too troubling.
4. Pain or discomfort at a blood test. Blood tests will be carried out by trained personnel in a private room to ensure privacy. The protocol has been planned to ensure only one blood test is required.

Where is the study run from?
University Hospitals Sussex (UK)

When is the study starting and how long is it expected to run for?
June 2021 to April 2023

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Jonathan Golding, jonathan.golding1@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Dr Jonathan Golding

ORCID ID
https://orcid.org/0000-0003-2541-2848

Contact details
Royal Sussex County Hospital
Eastern Road
Brighton
BN2 5BE
Brighton and Hove
United Kingdom

BN2 5BE
+44 (0)1273 696955 ext 67613
jonathan.golding1@nhs.net

Type(s)
Scientific

Contact name
Dr Jonathan Golding

Contact details
Royal Sussex County Hospital
Eastern Road
Brighton
BN2 5BE
Brighton and Hove
United Kingdom
BN2 5BE
+44 (0)1273 696955 ext 67613
jonathan.golding1@nhs.net

Type(s)
Public

Contact name
Dr Jonathan Golding

Contact details
Royal Sussex County Hospital
Eastern Road
Brighton
BN2 5BE
Brighton and Hove
United Kingdom
BN2 5BE
+44 (0)1273 696955 ext 67613
jonathan.golding1@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295171

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

IRAS 295171

Study information

Scientific Title
Feasibility study: an investigation of frailty and glycaemic control in older adults with type 1 diabetes mellitus

Study objectives
Older adults with type 1 diabetes living with frailty have more hypoglycaemia than older adults with type 1 diabetes who are not living with frailty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2022, South West - Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 1048106, (0)207 104 8121; frenchay.rec@hra.nhs.uk), ref: 22/SW/0016

Study design
Cross-sectional observational study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
It is clear that in older people with type 1 diabetes (T1DM), there is a real and genuine fear of how their diabetes management will continue if/when they become less able to manage it themselves as previously. Continuous glucose monitoring (CGM) has now been well established in T1DM, and anecdotal experiences of its use by older individuals with T1DM have been overwhelmingly positive. However, few studies have specifically looked at the use of this technology in larger numbers of older adults. There are no studies with CGM that have specifically looked at individuals with T1DM and co-existing frailty issues – a patient group who could potentially benefit significantly from this technology. Flash glucose monitoring, although a form of CGM, still requires the user to intermittently scan the device in order for the data to be captured and therefore may not be the most ideal form of CGM for this patient group.

The study will investigate whether frailty impacts glycaemic control using traditional and CGM. This will determine whether increased frailty impacts overall glucose control and the occurrence of hypoglycaemia in patients with T1DM. Finally, the study will look to address the question of whether CGM is an acceptable and practical form of glucose monitoring for older adult patients with T1DM of varying degrees of frailty, and importantly those caring for them. It is hoped that the use of CGM will positively influence patient care.

This stage of the study will be a feasibility study, in order to assess the feasibility of a larger-scale project to achieve the aforementioned aims. The team plans to assess the use of CGM in 20 older adults with T1DM to explore recruitment methods, acceptability of study protocols and of the CGM device.

Older adults with T1DM will undergo frailty assessment and blinded CGM. The glycaemic profiles of those with and without frailty will be compared. This feasibility study will test the recruitment strategy and study procedures proposed for a definitive study. Data generated will be analysed to inform sample size calculations and refine the study protocol.

Materials:
Materials used for this study include the Dexcom G6 CGM, including sensors, transmitters and receivers. A Jamar handheld dynamometer will be used to measure hand grip strength. A stopwatch will be needed to measure walking speed and the sit-to-stand test which are part of the frailty assessments. Equipment for venepuncture and urine analysis will be required for the biochemical samples.

Procedures:
Venepuncture
Venepuncture will be performed by trained, experienced staff to obtain HbA1c level and Full Blood Count.

Continuous Glucose Monitoring (CGM)
The glucose sensor in this study is a commercially available subcutaneous glucose sensor; this is known as the Dexcom. The sensor sits just under the skin and samples interstitial glucose concentrations every 5 minutes. The sensor that sits under the skin has a maximum diameter of 1.83mm. No incision is required and it will not cause any scarring. The glucose sensor will be connected to a small (3cm in diameter) recorder. This will transmit the results to a handheld receiver. The participant won't be able to see the results of the sensor as it will be in blinded mode. The results will be uploaded in anonymous form onto Dexcom clarity - a secure online software for CGM data routinely used in clinical practice. The monitoring will occur over a 10-day period whilst the participant is doing their normal activities.

Frailty assessment
Assessment of frailty will be using the Fried frailty phenotype. This assesses 5 components. Participants will be considered frail if they fulfil three or more criteria. The five components are weakness, slowness, unintentional weight loss, exhaustion, and low physical activity.
1. Weakness: measured by hand grip strength. Grip strength will be measured using a hand-held dynamometer consecutively on both hands. The analysis will use average grip strength over both hands. Participants will be considered frail if they are within the lowest 20% by gender and body mass index.
2. Slowness: Slowness is measured using the “get up and go” test. The patient is asked to get up from a chair, walk 3 metres, turn around and sit back on the chair. If the patient takes more than 16 seconds to complete the test then they are considered to have low mobility and score a point. Participants who take less than 16 seconds are considered to have good mobility.
3. Unintentional weight loss: unintentional weight loss is measured by asking the patient the total value of unintentional weight loss in the last 6 months as a proportion of their overall weight. Participants who have lost 5% or more of their body weight score a point for this assessment.
4. Exhaustion: Exhaustion is measured by asking the patient, “In the last month do you feel that you have less energy to do the things you want?” Patients that answer “no” do not score a point for this category and patients who answer “yes”

5. Low physical activity: Patients will be asked, “How often do you practice any of the following activities (dancing, gardening, walking, farmer work).” Answers are categorised into the following groups – never/almost never, up to three times a month, once a week, and more than once a week. Patients that respond with “once a week” or “more than once a week” are considered active and do not score a point. Patients that respond “never / almost never” or “up to three times a month” score 1 point.

In addition to this, a Clinical Frailty Score will be applied to each patient. This will be based on the investigator's opinion, assisted by two scoring systems: The quality of life score EQ-5D-5L and the Lawton score for instrumental activities of daily living. This will be included as this assessment is used commonly in clinical practice

We will also complete a Short Physical Performance Battery test (SPPB). This will be used alongside the other measures of frailty as it has been shown in other studies to be sensitive to measuring a change in physical performance over 1 year. A one-year follow-up is something that we plan to include in the main study. SPPB includes measures of static balance (side-by-side, semi-tandem and full tandem balance for up to 10 seconds each), gait speed (timed 4-meter walk at a self-selected pace), and chair stand (ability and time needed to stand five times as quickly as possible with arms folded across the chest from a straight-backed chair). The walking test is already part of the Fried frailty phenotype and won’t need to be repeated for this frailty test with the time being applied to both assessments.

Intervention Type
Not Specified

Primary outcome(s)
Feasibility assessed during the study period using study records:
1. How well the recruitment strategy works in practice measured using the number of participants referred
2. What percentage of eligible participants are recruited for the study measured using the number of participants that are recruited compared to the number referred
3. Time to first and last recruitment measured using the length it takes to recruit the 20 participants
4. Attrition rate measured using the number of participants that do not complete the study after starting it
5. Adherence to the continuous glucose monitoring (CGM) device – For example how much data is lost when the receiver is out of range - measured by the percentage of CGM captured during the 10-day monitoring period

The recruitment strategy and protocol will be deemed a success if the following are met:
1. At least 30% of eligible participants recruited to the study
2. No more than a 10% attrition rate
3. At least 70% adherence to CGM

Key secondary outcome(s))
Patient experience, acceptability, and feasibility of the use of the continuous glucose monitoring device measured using bespoke questionnaires at the end of the study

Completion date
30/04/2023

Eligibility

Key inclusion criteria
Patients over the age of 65 years old with an established diagnosis of type 1 diabetes of at least one-year duration.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

Total final enrolment
20

Key exclusion criteria
Inability to understand or comply with requirements of the study, including cognitive impairment to a degree that capacity is impaired (investigator opinion).

Date of first enrolment
14/09/2022

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
University Hospitals Sussex NHS Foundation Trust

ROR
https://ror.org/03wvsyq85

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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 Jonathan Golding, jonathan.golding1@nhs.net. The type of data shared will be fully anonymised raw data and the dates of availability commence after the trial has finished (expected 01/04/2023). Informed consent was obtained from all participants.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			09/04/2024	No	Yes
Poster results			28/01/2025	No	No