An investigation into the impact of frailty on glycaemic control in older adults with type 1 diabetes: A feasibility study

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Who carried out the research?

The authors listed above carried out the research with the support of the sponsor, University Hospitals Sussex NHS Foundation Trust and with generous funding from the National Institute of Health and Social Care Research.

Public and Participant Involvement

A public and participant group of three older adults with type 1 diabetes was involved in research planning. Members of this group helped to design the study and review the information about the research which was shared with potential participants.

Introduction – why was the study needed?

Improved care is enabling people with type 1 diabetes to live longer. There are over 35,000 people with type 1 diabetes over the age of 65 in England including over 6,000 people 80.

Type 1 diabetes management in older age can be complex, and is known to be a source of anxiety for some people. The aim of this study was to assess whether people with type 1 diabetes over the age of 65, who have more of the physical and mental changes associated with aging (called frailty), have more fluctuations in their glucose levels. This feasibility study has helped in development of a larger study to investigate this further.

What were the main questions of the study?

Can we test the recruitment and study procedures for use in a larger research project, looking at glucose levels in older adults with type 1 diabetes with and without frailty?
Is there any link between frailty and glucose levels in older adults with type 1 diabetes?

The study

The study was run at the Royal Sussex County Hospital (Brighton), and Royal Devon and Exeter Hospital (Exeter) between September 2022 and March 2023. 20 adults over 65 years old with type 1 diabetes were recruited. Participants answered questions about their medical and diabetes history, questionnaires about their lifestyle, completed a cognitive assessment and standard physical frailty tests. All took part in a 10 day continuous glucose monitoring (CGM) period using a Dexcom G6 device. This device continuously measures glucose levels under the skin, relaying them to a hand-held reader. Participants could not see the glucose levels provided. Blood and urine tests were used to confirm the presence of type 1 diabetes and assess diabetes control over time.
To test the recruitment and smooth running of the study we looked at:
  ➢ How easy it would be to recruit participants and how long this might take
  ➢ How many people who were eligible to take part were actually recruited
  ➢ How many participants did not complete the study and why
  ➢ How much CGM data was captured
In addition, early insights into the relationship between frailty and glucose levels were looked at by comparing the data from the CGMs, blood tests, and frailty assessments.

Results - Recruitment

Across both sites, 20 clinical referrals were made to the research team and 10 were recruited. One person declined participation and four were found to be ineligible. Among the others, the reasons for not taking part included mobility issues, caring responsibilities and travel issues. All of these people were interested in being involved if home visits became possible in a future research study.

At Exeter, recruitment also made use of a database of people who had previously expressed interest in being part of research. 116 people on the database were eligible. 31 were contacted by email, 19 did not respond, 2 declined and ten were recruited. The research was generally well received by older adults with type 1 diabetes. 39% of eligible participants across both sites agreed to take part.

Results – Acceptability of the study procedures

For three participants, frequent loud bleeping sounds occurred due to faulty equipment. One person withdrew from the study as a result. For one participant, the sensor fell off after 6 days. All other participants completed the monitoring period. In all glucose recordings were captured 87.8% of the possible time. Some participants did not return all equipment which might slow down a larger study. The questionnaires showed participants felt comfortable with the study procedures and study documents.

The two participants who did not complete the CGM monitoring both completed the rest of the study. Even with these participants, only 10% did not complete the study, in line with what was expected.

Results – Confirmation of diagnosis of type 1 diabetes

C-peptide measurement confirmed that all participants had type 1 diabetes.

Results – frailty tests

No participants were assessed as living with frailty according to the Fried Frailty Phenotype (FFP), 14 were robust and 6 pre-frail. This is the most widely used assessment of frailty. It assesses 5 domains: weight loss, exhaustion, physical activity, walking speed and hand grip strength. A score of 3 or more out of 5 is considered frail, and a score of 1 or 2 is considered pre-frail. Two other frailty assessments were also used. 1 person was assessed as frail according to the Rockwood score, a visual global assessment. The Short Physical Performance Battery (SPPB) measures only physical ability which is only one part of what frailty means. On this measure 9 out of 20 participants were assessed as living with frailty.

Results – Frailty and glucose levels

There were not enough people in the study to assess whether frailty affected glucose levels. The study did not recruit any individuals living with frailty.

It was possible to assess individual glucose levels. Average glucose ranged between 6.3mmol/L and 12.2mmol/L. The study also looked at how often each person's glucose level went below 4.0mmol/L (hypoglycaemia). This is a key measure in older adults. Frequent hypoglycaemia is linked to falls, fractures and hospital admissions. The American Diabetes Association (ADA) recommend aiming to being hypoglycaemic less than 1% of the time in adults over 65 for this reason. Participants in this study ranged from 0 to 12.3% hypoglycaemic. 14/20 were hypoglycaemic for more than the ADA target of less than 1%.

How has the study helped?

This study is feasible and acceptable to participants. However, the need to travel to hospital stopped those with advanced frailty from taking part. Below is the key learning to take forward to the larger study:

People with frailty may have mobility problems making it difficult to travel to hospital. It is important such people are included in frailty research. We have decided to include the option of home visits in the larger study to address this. This will improve opportunity to participate for those with mobility problems or caring responsibilities.

Targeting recruitment to people who are already known to be living with frailty will help increase recruitment of those living with frailty. However, despite guidelines that suggest frailty should be routinely assessed, often this is not done. To overcome this problem, the electronic frailty index (eFI) has been developed. This score uses routinely collected data in GP practices to predict a person's frailty score – such as number of medications and medical diagnoses. To try and increase the recruitment of people living with frailty to the larger study, community diabetes team will refer people who have frailty according to their eFI. Clinicians are also able to identify frailty in individuals using professional experience, even without formal frailty scores. Asking healthcare professionals to preferentially refer such individuals should increase the chances of recruiting people living with frailty.

To address equipment issues, a newer model (Dexcom G7) will be used. The G7 is smaller, which will likely reduce the chances of it falling off. The G7 also has no need for separate transmitters so there is a lower risk of people forgetting to return equipment needed for the next participant.

Conclusion

This feasibility study has successfully demonstrated the smooth running of the protocol for use in a larger study. The improvements described should increase opportunities to participate in research for people living with frailty, reduce the number of people unable to complete the study procedures and increase the amount of CGM data recorded. This study indicates it should be possible to assess the relationship between frailty levels and glucose control in a larger study.

Identifying whether frailty is associated with more episodes of low blood glucose will be important to help devise glucose targets according to frailty level for older adults with type 1 diabetes (something that does not currently exist) and help to devise care systems that meet the needs of individuals and their carers.

This lay results summary has been reviewed by the UHSussex Research Champions, including members of the public, patients and patient representatives. A more detailed summary is available on request to the authors. The results will be submitted to relevant professional conferences to share findings and each of the participants will get a copy of this results summary.