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Flash glucose monitoring in older patients with memory problems

Submission date
18/12/2017

Recruitment status
No longer recruiting

Registration date
09/01/2018

Overall study status
Completed

Last Edited
15/01/2020

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
Diabetes and dementia are common illnesses that can occur together in older people. In the next 10 years, about 5 million people will have diabetes, and more than a million people will have dementia. Currently, 1 in 5 patients with dementia also have diabetes. Patients with memory problems can have major difficulties in managing and monitoring diabetes. Medication for diabetes can provoke excessively low blood sugars (a dangerous, but potentially avoidable side-effect commonly known as 'hypos') needing urgent recognition and treatment. Research has shown that hypos are a particularly serious problem in patients with diabetes and dementia. These patients face a far greater risk (60% higher) of hypos than those with diabetes alone. Those who were troubled by hypos then had a 68% greater risk of dementia becoming even worse. New continuous glucose monitoring (CGM) technology relies on small (coin-sized) sensors (fitted for 1-2 weeks) to constantly record sugar levels. Patients (or carers) do not need to remember, or recognize when to do finger prick testing because alerts/trends can be sent to smartphones or computers. This creates a detailed picture of sugar levels, and allows identification of problem areas. A promising study with earlier CGM devices in 40 older adults (without dementia) picked up 102 hypos, 95 of which had not been detected on usual monitoring (using finger prick and/or symptoms). So far, no one has tested this technology to help patients with dementia and diabetes. The aim of this study is to explore whether people aged 65 and older with memory problems and diabetes can tolerate wearing the flash glucose monitoring system for two weeks to help monitor blood sugar levels.

Who can participate?
Adults aged 65 and older who have dementia and diabetes.

What does the study involve?
Potential participants are identified and invited whilst they are in hospital. Those who agree to take part are given the CGM device one month after discharge to use at home (so that they have time to recover from the hospital admission). The research team arranges to visit the participants at home to hand out the flash glucose system, fit the sensor, provide refresher training and answer any questions. The participants wear the sensor for two weeks (the lifetime of one sensor), which will typically need to be swiped with a reader three times a day (for instance, before or after meals). After one week, the research team will telephone the

participants to check how they are getting on with wearing the device and whether issues /questions have arisen. After the two weeks, the research team contacts the participants to arrange a convenient place and time to pick up the device and speak to them about their experiences. This meeting should last no more than one hour. The research team makes audio recordings of the study visits and telephone follow-up to ensure that any concerns, questions and adverse events are documented. During the time when participants wear the device, the research team would like them to continue with the management of their diabetes as per normal and not to make any changes (unless advised to do so by a healthcare professional).

What are the possible benefits and risks of participating?
Participants will potentially be able to get detailed information about blood sugar levels over a two-week period. Medical professionals will be able to analyze the information collected and make decisions on treatment plans, if need be. Participants may be able to pick up trends of high or low sugars, that can be used to inform doctors so that they can any adjustments to the treatment as they see fit. The research team will visit twice for up to an hour on each visit. Participants may feel worried about being able see blood sugar readings all the time. Participants may experience discomfort when the sensor is fitted. Participants may experience a mild skin reaction where the sensor is fitted.

Where is the study run from?
Norfolk and Norwich University Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
Alzheimer's Society (UK)

Who is the main contact?
Dr Katharina Mattishent

Contact information

Type(s)
Scientific

Contact name
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Protocol serial number
36128

Study information

Scientific Title
Flash glucose monitoring in older patients with memory problems and diabetes: A feasibility study

Study objectives
It is feasible for older people with diabetes and cognitive impairment to use a flash glucose monitoring system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge Central Research Ethics Committee, 04/12/2017, ref: 17/EE/0388

Study design
Non-randomised; Both; Design type: Diagnosis, Device, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
This study is a single-centre medical device study to determine the feasibility and acceptability of the use of a flash glucose monitoring system for up to two weeks in older patients with memory problems and diabetes.

The introduction of flash glucose monitoring using the factory-calibrated meter has emerged as a novel method to study glycaemic patterns. The system that is currently publicly available for patients to purchase is the FreeStyle Libre Flash Glucose Monitoring System-Abbott. The website also provides video tutorials on the use of the system (https://www.freestylelibre.co.uk/libre/).

The use of the flash glucose system provides ambulatory glucose profile, giving graphic and quantitative information on 24-hour glucose patterns. This can enable patients, carers and clinicians to identify patterns in glycaemic control and when they are occurring. The system consists of a reader (although Android phones can download an app, which replaces the need for a reader) and a sensor.

Patients aged 65 and over with diabetes and cognitive problems (or established dementia) will be invited to take part, whilst they are inpatients at the Norfolk and Norwich University Hospital Trust. The use of the flash glucose monitoring system takes place around one-month after discharge from the acute setting, to ensure that the participants have had a chance to fully recover from their hospital admission and are settled back into their usual routine at their usual place of residence. The aim is to recruit up to 20 participants.

The flash glucose monitoring system is given to the participants to use for up to two weeks (the lifetime of one sensor). At the first home visit, the researcher will fit the sensor and provide training on how to use the device. The research team contacts the participants one week after the first home visit (telephone call) to check whether any questions have arisen and whether the participant is still happy to be part of the study. At the end of the study period, participants and /or their carers take part in an in-depth interview to explore the acceptability of the medical device.

Intervention Type
Other

Primary outcome(s)
1. Numbers of potentially eligible patients who meet the selection criteria
2. Number of participants subsequently recruited into the study at 12 months
3. Extent of capture of blood glucose readings
4. Attrition rate and reasons for withdrawal
5. Adverse events

Key secondary outcome(s))
The following patient outcomes will be collected by means of a qualitative interview at the end of the study period (after wearing the sensor for two weeks)
1. Acceptability of ambulatory glucose profile system to patients
2. Acceptability of ambulatory glucose profile system to family and carers (both informal and formal)
3. Patient and carer experience

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Patients aged 65 and older (male or female)
2. Type 1 or Type 2 diabetes mellitus
3. On glucose-lowering medication
4. Abbreviated Mini-Mental Test (AMT) score equal or less than 8 (out of 10) or already has formal diagnosis of dementia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
17

Key exclusion criteria
1. Treatment with metformin only
2. Not willing to participate
3. Terminal illness (less than one-year life expectancy)
4. AMT>8
5. Evidence of bruising, bleeding, cellulitis and/or skin tears on the upper arms

Date of first enrolment
01/02/2018

Date of final enrolment
01/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospital
Norfolk and Norwich University Hospital Foundation Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Alzheimer’s Society

ROR
https://ror.org/0472gwq90

Funder(s)

Funder type
Charity

Funder Name
Alzheimer's Society

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/11/2019	15/01/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes