ISRCTN11565460 https://doi.org/10.1186/ISRCTN11565460

Can unscheduled inpatient length of stay and hospital costs be reduced using 'flash' glucose monitoring?

Submission date
02/11/2021

Recruitment status
No longer recruiting

Registration date
10/11/2021

Overall study status
Completed

Last Edited
10/05/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes is a serious condition where the blood glucose (sugar) level is too high. Research shows that people with diabetes are significantly more likely to be admitted to hospital than people without diabetes and stay in hospital on average twice as long. This study is seeking to test an intervention to improve glucose monitoring for people with diabetes who have been admitted to hospital.

Who can participate?
Adults (aged 18 years and older) currently admitted to hospital with a diagnosis of diabetes

What does the study involve?
Participants will be randomly allocated into either the intervention or non-intervention group. Participants in the intervention group will wear a Flash Glucose Monitoring device for the duration of their stay in hospital. Flash Glucose Monitoring devices include small sensors worn just under the skin that measure glucose (sugar) levels continuously throughout the day and night and can be checked by simply scanning a monitor over the sensor. Participants' treatment will not be affected or changed but they are asked to check their glucose levels using the monitor to scan the sensor every 2 hours as well as having the usual fingerprick testing carried out in the ward. When they are discharged, they will be given the choice to take home the Flash Glucose Monitoring device for the remaining time left on the sensor (up to a maximum of 2 weeks).
Participants in the non-intervention group will receive routine care for their diabetes while they are in hospital and/or are discharged home as normal when they leave the hospital. All participants will fill out a short questionnaire and the researcher will collect information about their glucose monitoring and diabetes treatment from their notes.

What are the possible benefits and risks of participating?
Participants in the intervention group will have the opportunity to experience the use of technology to monitor their diabetes whilst they are in hospital, and the take-home intervention group could experience the use of this at home following their discharge also. All participants

will be given the opportunity to confidentially and anonymously share their experiences and opinions on inpatient diabetes management at their participating hospital. The researchers do not consider there to be any serious risks in taking part. Participants may feel slight discomfort when the sensor is first applied and/or mild skin irritation from the adhesive. Taking part will have no bearing on their health or medical treatment.

Where is the study run from?
Ulster University (UK)

When is the study starting and how long is it expected to run for?
October 2019 to January 2022

Who is funding the study?
Interreg European Regional Development Fund

Who is the main contact?
Kathleen Michelle Friel
friel-k5@ulster.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Vivien Coates

Contact details
Ulster University
Institute of Nursing and Health Research
Magee campus
Room G081
Derry
United Kingdom
BT48 7JL
+44 (0)28 7012 4206
ve.coates@ulster.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
266868

Protocol serial number
V2.6 15/04/2021

Study information

Scientific Title

Interreg diabetes centre for personalised medicine - unscheduled care in diabetes - study 2: inpatient study

Study objectives
Can unscheduled inpatient length of stay and hospital costs be reduced using 'Flash' glucose monitoring?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2019, North of Scotland Research Ethics Committee (1) (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; nosres@nhs.net), REC ref: 19/NS/0161

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
This is a descriptive developmental mixed-methods study using both qualitative and quantitative approaches with two phases:

Phase 2, Part B: pilot study – use of Flash Glucose Monitoring where participants will be randomised into either the active use of Flash Glucose Monitoring or the non-intervention group using individual sequential randomisation.

Intervention arm:
Participants in the intervention group will be provided with a Freestyle Libre Flash Glucose Monitoring sensor and asked to self-apply the sensor with guidance from the research nurse. Patients will be advised to scan the sensors every 2 hours during waking hours with at least one scan between 10 pm and midnight and 6-8 am. Routine capillary testing will continue to be carried out as per hospital protocol at least four times daily. All measurements will be recorded on the bedside glucose monitoring chart along with a note of any action or intervention based on the glucose result. During the inpatient stay for patients and ward staff to enhance decision making the full dataset of values will be downloaded by the researcher or research nurse daily from the monitor to 'Libre view' software and printed out in the ward for patients and staff to view. The researcher will download the full dataset at the end of the 2-week period and note any changes the patient has made to therapy if the sensor is used following discharge from the ward. All participants in the intervention group will be given the option to take the Flash Glucose Monitoring device to use at home for up to 2 weeks, if less than 2 weeks use as an inpatient, following their discharge from hospital.

Control arm:
Participants in the usual care group will receive standard POC capillary blood glucose testing according to hospital protocols. All participants' case notes will be reviewed to collect the frequency of tests, the blood glucose readings and whether any intervention was needed.

Phase 2, Part C: pilot study – evaluation interviews consisting of both patients who were enrolled into, and healthcare professionals (HCPs) who were involved in the delivery of, the pilot study Part B. Evaluation interviews will be carried out with participants from both study arms following their consent to participate in an interview.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Flash Glucose Monitoring

Primary outcome(s)
1. Clinical decision making (changes made to therapy) measured using patient medical records at 4 hourly intervals
2. Patient safety measured using patient medical records at 4 hourly intervals

Key secondary outcome(s))
Length of stay (LoS) measured using patient medical records at hospital discharge

Completion date
31/01/2022

Eligibility

Key inclusion criteria
Phase 2, Part B: pilot study – use of Flash Glucose Monitoring:
1. Adults (aged 18 years and older)
2. Diagnosed with diabetes
3. Admitted to hospital wards defined in phase 1
4. Able to read and understand the participant information sheet (PIS)
5. Able to give written informed consent

Phase 2, Part C: pilot study - evaluation interviews:
1. Patients or HCPs that have participated in phase 2, part B
2. Able to read and understand the participant information sheet (PIS)
3. Able to give written informed consent

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Phase 2, Part B: pilot study - use of flash glucose monitoring:
1. Children or young people (aged younger than 18 years)
2. Not diagnosed with diabetes
3. Admitted to hospital wards not defined in phase 1
4. Pregnancy or gestational diabetes
5. Significant intercurrent illness and/or terminal diagnosis
6. Have a condition and/or treatment known to affect variability of blood glucose, such as on kidney dialysis
7. Already using a Flash Glucose Monitoring or continuous monitoring device
8. Unable to read and understand the participant information sheet (PIS)
9. Unable to give written informed consent

Phase 2, Part C: pilot study - evaluation interviews:
1. Ongoing significant co-morbid illness
2. Unable to read and understand the participant information sheet

Date of first enrolment
19/10/2019

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Scotland

Ireland

Study participating centre
Raigmore Hospital
Old Perth Rd
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Altnagelvin Area Hospital
Glenshane Road
Derry
United Kingdom
BT47 6SB

Study participating centre
Letterkenny University Hospital
Kilmacrennan Road
Letterkenny
Ireland
F92 AE81

Sponsor information

Organisation
University of the Highlands and Islands

ROR
https://ror.org/02s08xt61

Organisation
NHS Highland

ROR
https://ror.org/010ypq317

Funder(s)

Funder type
Government

Funder Name
Interreg

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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?
Results article		28/11/2021	10/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Evaluative interview version 1.4	08/10/2019	03/11/2021	No	Yes
Participant information sheet	Intervention study version 1.5	08/10/2019	03/11/2021	No	Yes
Protocol file	version 2.6	15/04/2021	03/11/2021	No	No