
Exploring the impact and experience of diabetes management technologies (using flash glucose monitoring (flashGM) as an exemplar) of adults living with type 1 diabetes mellitus (T1D), in the North of England

A Data Management Plan created using dmproadmap

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Project abstract:

The aim of this study is to investigate the impact of wearable blood glucose management technologies on people living with type 1 diabetes who are eligible to receive such devices, through standard NHS prescription. For the purpose of this research, that will mean people using flash glucose monitoring (flashGM) devices. Eligible participants will be adults living with type 1 diabetes who do not currently use any form of wearable glucose monitoring technology and who meet NICE criteria to receive funding for this device. Participants will be recruited via local diabetes centres with an aim to recruit from two different sites. The objective of the first phase of the study is to gather information in relation to changes in physiological parameters related to overall glucose control. Data related to changes in body weight and composition will also be gathered. Questionnaires to explore changes in health status, psychological well-being, treatment satisfaction and quality of life will also be administered. Further, self reported scanning frequency and low blood glucose data will also be collected. Data collection will take place before the device is started and then at 3 and 6 months post initiation. Participation in the first phase is 6 months. Results from phase 1 will be analysed to identify trends but also interesting or outlier results which warrant further exploration. These findings will then influence the second phase of the study where more in-depth questions and discussion will take place during focus group sessions, to explore experiences of flashGM use. Not all participants from the first phase will return for group interviews as participants will be selected based on their characteristics and the themes that become

apparent during data analysis. Phase 2 will be a single visit and is planned to take place approximately 6 months after the end of the participation in the first phase.

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Data Collection

Participants will consent to the following data collection at baseline. A copy of the draft case report form is attached to this application.

- o Age
- o Gender
- o Ethnicity
- o Socioeconomic data
- o Diabetes duration
- o BMI (closest reading at sensor start)
- o Current HbA1c (closest level at time of sensor start)
- o Data regarding previous use of diabetes technologies (meters / CGM etc)
- o Current diabetes medications
- o Average number of hypos per month (classified as <4mmol/l) – self reported
- o Number of blood finger prick glucose tests per day – self reported
- o Clinical contact time in addition to planned usual care (unplanned hospital admissions / clinical visits due to acute and chronic complications of diabetes).
- o Perception of diabetes control

Participants will complete quantitative questionnaires in relation to diabetes PRO's prior to sensor initiation. Patient reported outcomes will include questionnaires which address health status, psychological well-being, treatment satisfaction, and QoL as follows:

The researcher has been given full permission by the authors to utilise these measures:

(Online) quantitative questionnaires proposed include the following validated tools:

- o EQ-5D – 5L – EuroQol (health status) – (Herdman et al., 2011)
- o PAID (Problem areas in diabetes) (Reddy, Wilhelm and Campbell, 2013) (well-being)
- o Impaired awareness hypoglycaemia scores (Clarke et al., 1995, Gold, Macleod and Frier, 1994) (well-being)
- o GMSS-T1D – glucose monitoring system satisfaction survey (Polonsky et al., 2015) (Satisfaction)
- o ADDQoL19 (Bradley et al., 1999), (Bradley and Speight, 2002) updated in 2010 English short form to 14 questions (QoL)

Permission has been gained from all questionnaire authors and evidence of permission / licensing agreements have been obtained where necessary.

Follow up: 6 months post sensor initiation:

- o Changes in HbA1c, BMI, frequency of hypoglycaemia and frequency of scanning / finger prick blood glucose testing (self-reported), and perception of diabetes control will be established.
- o Current diabetes medications
- o Clinical contact time in addition to planned usual care (unplanned hospital admissions / clinical visits due to acute and chronic complications of diabetes).
- o Participants will complete (online) quantitative assessments detailed above giving a total quantitative data collection period for the study of 12-18 months dependent on recruitment rate.

Following quantitative data collection, purposively sampled participants will be invited to focus group sessions, informed by results from quantitative data analysis. Focus groups will explore experiences of flashGM use. Quantitative data analysis will drive the creation of the interview schedule. The focus groups will be led by the researcher and will be digitally recorded. The recordings will then be transcribed.

A further group of participants, who are longitudinal users of wearable glucose monitoring

technologies, who have not participated in phase 1 of the study may be sought to take part in separate focus groups, functioning as a qualitative control. Separate ethical permission will be obtained, and this will only be explored should the PhD time-frame allow.

40-120 participants will be recruited for the online quantitative questionnaire via JISC software. Data will be intermittently downloaded to Excel and SPSS systems for analysis during the data collection phase (18 months duration) and stored within a password secured university server.

5 qualitative focus group interviews will be digitally recorded and transcribed anonymously over a period of 6 months following the quantitative phase. Once transcribed and checked for accuracy the digital recording will be deleted. Transcription data will be held on a secured and password protected University system.

All data will be obtained and held in accordance with GDPR guidelines outlined in The Data Protection Act (2018) and as per the University of Northumbria Research Data management policy:

<https://northumbria-cdn.azureedge.net/-/media/corporate-website/new-sitecore-gallery/research/research-data-management/research-data-management-policy---version-11--01.-d-.05.-d-.2019.pdf?modified=20190502080554&la=en&hash=FC96BE9A1054394109182D39D5EA112785191099>

Research records will be named according to University of Northumbria records management policy:

<https://northumbria-cdn.azureedge.net/-/media/corporate-website/documents/pdfs/about-us-corporate/legal-services-team/guide-to-electronic-file-naming.pdf?modified=20170221102316>

For example focus group interview 1 will be file named as follow: DDMMYRFocusGrp1.doc

The date in reverse order with the name of the data file. Underscores and dashes are avoided.

Documentation and Metadata

Research data alongside files generated from analysis (SPSS / Excel / NVivo) will be stored for 7 years from the completion date of the study at the University of Northumbria as per section 10 of the Records Retention Schedule within a secured and password protected server.

Quantitative data as per the above alongside pertinent statistical tests relevant to the analysis - this is dependent on number of recruits (descriptive versus inferential statistics).

Qualitative data will also include a report of the thematic analysis, indexes in transcripts, the formulation of codes, themes and sub themes.

Data with regard to synthesis of quantitative and qualitative findings will include a follow-up joint display (Microsoft Excel) to demonstrate how the qualitative data helps to explain the quantitative results.

Ethics and Legal Compliance

Participants will be recruited via a single local NHS trust diabetes clinic.

Eligible participants (those about to commence sensor use) will be identified by the Newcastle Diabetes Centre clinical team according to their schedule for initiating patient sensors. Study information including the participant information sheet and consent form(s) will be sent to the potential participant alongside their appointment letter for sensor start in order to ensure there is sufficient time to make a decision to participate. The researcher will not require access to identifiable personal information to invite participants, as the information will be sent by the clinical team.

A poster will be created to highlight the study to eligible participants, however, this will serve as a reminder rather than a vehicle for recruitment, as all sensor start patients will be invited. Participants

will not receive payment as their baseline visit will coincide with their clinical visit and follow-up data will be collected online /via telephone

All individuals who are eligible to receive the flashGM device via NHS funded mechanisms will be invited by letter to take part when they are booked to commence sensor use, with initial study related information being provided with this appointment letter by the clinical team. This information will ask potential participants to contact the researcher to indicate their interest in participating. The researcher will attend clinic in order to provide an opportunity to recruit patients and also, check eligibility against inclusion and exclusion criteria, complete informed consent and collect baseline data, if participants have already reviewed study related information (>24 hrs to review) sent previously. Informed consent to take part and baseline data will be obtained prior to sensor start at this session. During the informed consent process, the details of the participant information sheet will be clearly explained and all questions addressed. Aligning informed consent and baseline data collection with the sensor start session (i.e.: alongside usual clinical care) will minimise disruption to the patient and maximise recruitment potential.

It is imperative that it is clearly articulated to prospective participants both verbally and via the participant information sheet that consent to take part in this study will in no way affect their access to the device or any current future treatment that they will receive, should they decide not to participate or if they later withdraw consent for participation. Further, it will be made clear to all participants that the researcher is not a member of the clinical team but a PhD candidate; any publicity, letter of invitation and/ or written information for participants will explain this arrangement clearly.

Participants will take part in this study alongside their usual standard of care.

Participants will be required to complete questionnaires in relation to their health status, psychological well being, treatment satisfaction and quality of life in relation to living with type 1 diabetes. Completion of questionnaires may be time consuming and this may be a burden to participants as there are 7 questionnaires in total to be completed on 3 occasions. Completion of questionnaires may give participants time to pause and reflect on their condition, potentially increasing anxiety or conversely, reassuring the participant by gaining a deeper understanding of how they themselves perceive their condition. In the study overview sent to Diabetes UK PPI groups, the completion of questionnaires was not deemed as onerous with regard to time or content. In order to mitigate this potential burden, the PIS will be explicit in the number and approximate timing of completion of questionnaires so participants are fully aware of the requirements. Many will have completed similar questionnaires in the past as part of their ongoing care so will potentially be familiar with the format. The researcher will offer questionnaires in a variety of formats (online, face to face, postal) in order to minimise inconvenience.

Participation in the focus group interview may cause participants to identify issues about their diabetes which they may not have realised before. This may lead the participant feel vulnerable or upset. The researcher / PhD student, who will carry out the interview is a trained councillor. All patients within the diabetes centre have access to robust and timely assistance with regard to all aspects of diabetes management should issues be identified. Participants will be informed that in the unlikely event that they disclose any safeguarding issues about themselves or a relative, a referral to the appropriate services / organisation will be made.

Conversely, focus group interviews offer the opportunity for discussion in a setting which mimics real life interactions. This may present an opportunity for the participant to make new connections for on-going peer support with regard to their diabetes.

All participants will be informed that they are free to leave the study at any time without having to give a reason, without any impact to their on-going clinical care.

Access to medical records by those outside the direct healthcare team and study researcher will only be required to facilitate any regulatory body audit - this will be outlined in the PIS and participants will consent to this.

It is not anticipated that personal identifiable data will be transferred electronically. If the need arises for this, data will be encrypted and transfer will take place in accordance with GDPR compliance.

Personal identifiable data will only be utilised to maintain participant contact and will be held in the investigator site file, participant identifier sheet in a locked cabinet in a swipe access office at Northumbria University. The minimum data will be held in order to contact participants and will be accompanied by the study code key identifier.

Data will all be anonymised according to the NHS Code of Confidentiality and GMC Good Medical Practice. Participants will be assigned a study identification number in order to anonymise their information. Patient's names will not be used to identify participants. Information will be identifiable by ID codes (link anonymised).

All questionnaires will be completed online and as such will note the study identifier only. Digital

recording devices will be used to record interviews. Once downloaded and transcription and verification has taken place, the audio recording will be deleted.

Any paper based study data which is obtained (as a result of problematic access to the online database) or identifiable data will be stored in a locked and secured area accessed via swipe card access in a secured and continuously monitored facility where the research team is based at the University of Northumbria. Only members of the research team will have access to this data. Publications will not contain identifiable personal data. Any direct quotes published from the qualitative interviews will be anonymised. Original hard copies of the informed consent forms will also be kept within the site file in the secured location detailed above and a copy entered into the patients notes alongside details of study entry.

Given the above, the retention period of 7 years is adequate to address any potential ethical issues in relation to data management.

Data generated will be owned by the University of Northumbria. There is no intention to license the data for reuse. Any results generated will remain the intellectual property of Northumbria University. There is no second or third party data generated within this study.

Licensing agreements have been reached from all questionnaire authors but there is no requirement to share any IPR within these agreements. Any funder will not have IPR to the data and research findings. In both these cases, licencees and funders will be acknowledged in any relevant publications.

Charlotte Gordon will be the data guardian and the University of Northumbria will be the data controller. There will be no license or restrictions other than when the research is published.

Patenting is not foreseen within this research.

Storage and Backup

Questionnaire data will be collected via the University of Northumbria approved JISC system. Data is anonymous and storage is secure cloud based within the online questionnaire server.

Data which is download and accompanying files with regard to data analysis will be stored within the University of Northumbria secured Microsoft one-drive server which enables real time back-up of all data files. Recovery of user profiles is possible through the restore feature.

A back-up will also be made following each contact with downloaded data / data analysis files onto the secure university 'U' drive server. Support is provided for both one drive and university services by 24 hr IT support team.

University of Northumbria has sufficient data storage available to meet the needs of this study and on-going storage requirements.

Access to all storage drives and online data collection is password protected and limited to the chief investigator.

Selection and Preservation

At the conclusion of the online quantitative data capture, and once all data has been downloaded and verified, the online questionnaire platform will be deleted.

Following transcription and checking of the focus group interviews, the audio recordings will be deleted.

Quantitative and qualitative data and analysis files (excel, SPSS, Nvivo) will be retained for 7 years from the date of conclusion of the study in accordance with Northumbria University data retention guidance.

Data will be held on secured University servers as detailed above. There will be no additional cost for this data to be archived. There is no anticipated cessation to the IT infrastructure that the University provides.

Data Sharing

There is no intention to share the data. It may be possible to use an external organisation for data transcription purposes but this is dependent on grant award funding which is not yet confirmed. The Records and Information manager for the University of Northumbria would also be consulted with regard to the transfer of anonymous audio recordings outside of the organisation and Northumbria University ethics would also be informed. If this was to take place, an amendment would be made to HRA detailing the transfer of anonymous data.

Long-term sharing will be managed by the guidelines of the University of Northumbria.

Responsibilities and Resources

Charlotte Gordon will be the guardian of the generated data, including the implementation and adherence to this data management plan (DMP), data capture, metadata, quality, storage and initial archive. The University of Northumbria will maintain the storage of the data archive on One drive, 'U' drive server and future data sharing.

All resources are currently available and supported by the University of Northumbria IT services to meet the requirements of this data management plan.