Plan Overview

A Data Management Plan created using DMPonline

Title: Exploring the impact and experience of wearable diabetes management technologies (using Abbott Freestyle Libre Glucose monitoring as an exemplar) of adults living with type 1 diabetes mellitus (T1D), in the North East of England.

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Template: DCC Template

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 (or who have commenced in the last 7 days) and who meet NHS England criteria to receive funding for this device. Participants will be recruited via the local diabetes centres. 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; further data related to changes in body weight and composition will also be gathered. Questionnaires to explore changes in 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 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 focus 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 after participation in phase 1, dependent on rate of study recruitment and participants preference.

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Exploring the impact and experience of wearable diabetes management technologies (using Abbott Freestyle Libre Glucose monitoring as an exemplar) of adults living with type 1 diabetes mellitus (T1D), in the North East of England.

Data Collection

What data will you collect or create?

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 - participant reported)
o Current HbA1c (closest level at time of sensor start - participant reported)

- Libre view data (weekly average during first week of use and at month 6) including average:
- - Time in range
  - Time below range
  - Time above range
  - Glucose variability
  - Glucose management indicator
  - Scanning frequency

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 or within 7 days of sensor initiation. Patient reported outcomes will include questionnaires which address 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 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, Libre view data, 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. If focus groups take place online, there will be scope to also obtain audio / visual recordings. The recordings will then be transcribed. This may be done by an external organisation who specialise in data transcription and who are GDPR compliant– any focus group data digitally transferred to an external specialist data transcription organisation will be entirely anonymous, ensuring confidentiality. Speakers on the transcript will be identified by only a study ID which does not contain any identifiable data.

How will the data be collected or created?

40-120 participants will be recruited for the online quantitative questionnaire via JISC software. There is also an option for completion on paper for those who are digitally naive / hesitant. Anonymised study data will be intermittently downloaded / populated into to Excel (analysis database) and SPSS systems for analysis during the data collection phase (18 months duration) and stored within a password secured university server. Once quantitative data collection has been completed and downloaded, the JISC survey will be closed and response data deleted from JISC BoS. Any questionnaires completed on paper will be stored as per research data management policies.

Identifiable data, for the purpose of participant follow-up will be downloaded / populated into a separate study management database (Excel) and will be deleted once all study related activities, including participant debriefing and the sharing of study findings are completed. Paper consent forms will be stored in the site file as per the data management policies.

3 qualitative focus group interviews will be conducted during the study (participants will only take part once) will be digitally recorded and transcribed anonymously following 3 stages of interim data analysis. Once transcribed and checked for accuracy the digital recording will be deleted. Transcription data will be held on a secured and password protected University server.

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

What documentation and metadata will accompany the data?

Research data alongside files generated from analysis (SPPS / Excel / NVivo) will be stored for 5 years from the completion date of the study at the University of Northumbria as guidance from Newcastle upon Tyne Hospitals Joint Research Office advice, 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

How will you manage any ethical issues?

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 will be provided to the potential participant alongside their standard clinical information 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.

It is imperative that it is clearly articulated to prospective participants 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.

Baseline and follow-up data (at 6 months) for phase 1 (quantitative) will be collected online alongside consent data for the phase 2 (qualitative) as a standard approach.

Participants will visit the study data collection website (JISC BoS secure data collection survey tool certified to ISO 27001 standard) and complete consent and eligibility questions before accessing the online survey questionnaires. The participant will consent to

provide personal, identifiable details for the purpose of study follow up i.e: name, email address and contact telephone number.

There is also an option to complete the baseline consent and data collection at baseline and month 6 on paper for those who are digitally naive / hesitant.

Participants will take part in this study alongside their usual standard of care. Participants will not receive payment for their participation.

Participants will be required to complete questionnaires in relation to their 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 4 questionnaires in total to be completed on 2 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.

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.

Data obtained from the online JISC BoS questionnaire will be managed as follows:

1. All data periodically downloaded from JISC BoS.

2. Data separated into 2 excel spreadsheets: identifiable (study management) and non identifiable (analysis data).

3. Study code will be generated by the researcher which links identifiable study management data to analysis data.

4. Identifiable data will be retained only for the purposes of participant management and will be deleted once all study related procedures, debrief and dissemination of results is completed.

5. Analysis data will be retained for a period of 5 years

6. All data is held and managed in accordance with GDPR and University / trust data retention requirements

All data contained within JISC (BoS) online survey tool is compliant with ISO27001 - further information can be found here: https://www.onlinesurveys.ac.uk/security/

Data obtained via paper questionnaires will be managed as follows:

1. Paper copies of consent and questionnaire received. Paper consent stored to site file. Survey response data held separately to consent. All documents stored securely in locked office at university.

2. Management of study data gathered on paper proceeds as above (points 2-6)

Digital recording devices / software will be used to record interviews. Once downloaded and transcription and verification has taken place, any digital recordings will be deleted.

All study related data downloaded from JISC BoS or obtained during focus group interviews will be held on a secure University server which is accessed via a secured password protected University computer. 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.

Given the above, the retention period of 5 years is adequate to address any potential ethical issues in relation to data management.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

Data generated will be owned by the University of Northumbria. There is no intention to license the data for reuse. Any results generate 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. There are currently no external funders, any future funder(s) 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 forseen within this research.

Storage and Backup

How will the data be stored and backed up during the research?

Questionnaire data will be collected via the University of Northumbria approved JISC BoS system as detailed above (ethics and legal compliance). Data storage is secure cloud based within the online questionnaire server and compliant with ISO27001.
Data collected on paper (option for paper based completion of questionnaires) will be held within a secured locked office at the University - separated from any identifiable data.
Data which is download and accompanying files with regard to study management and data analysis are 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 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.

How will you manage access and security?

Access to all storage drives and online data collection is password protected and limited to the research team.
Files will be held in a locked draw only accessible to the researcher. Access to the secure office for paper-based documentation is limited to University members of staff via swipe access.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

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.
Any questionnaires completed on paper will be held securely for a period of 5 years.
Following transcription and checking of the focus group interviews, the digital recordings will be deleted.
Following completion of study related procedures, debrief and dissemination of results, study management, participant identifiable data will be deleted.
Quantitative and qualitative data (analysis database) and analysis files (excel, SPSS, Nvivo) will be retained for 5 years from the date of conclusion of the study in accordance with Northumbria University data retention guidance, section 10.2.

What is the long-term preservation plan for the dataset?

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

How will you share the data?

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 digital recordings outside of the organisation and Northumbria University ethics would also be informed.

Are any restrictions on data sharing required?

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

Responsibilities and Resources

Who will be responsible for data management?

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.

What resources will you require to deliver your plan?

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