Plan Overview

A Data Management Plan created using DMPonline

Title: Delivering the digital ambition: Exploring how we can design, implement and evaluate digital technologies in healthcare.

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Project abstract:

Digital health technologies (DHT) comprise a broad range of applications such as telehealth, wearable devices and smart-phone and tablet applications (apps). However, whilst national and international policies present ambitious plans for DHT to revolutionise healthcare, there has been little consideration of how they can be successfully integrated into healthcare systems and processes. This is important as many reports show that even well designed DHT fail to be adopted or are quickly abandoned in clinical practice, meaning that their potential to transform healthcare is lost. Stroke rehabilitation presents an ideal opportunity to use DHT to improve patient outcomes. Pressures on services mean that the amount of rehabilitation that can be directly delivered by staff, particularly for the arm, falls far short of that known to be beneficial resulting in sub-optimal outcomes for many people and reduced quality of life. With the numbers of people surviving a stroke set to double in the next 15 years, DHT provides an attractive, innovative, practical and engaging way for staff to prescribe additional rehabilitation and improve recovery for people after stroke, within current service constraints. However, DHT are not widely used in rehabilitation and the factors that influence their use in clinical practice are not known. This project seeks to identify and understand the factors that will influence the use of DHT in healthcare. It will employ this knowledge to design, implement and evaluate a DHT intervention, using rehabilitation after stroke as a case example. The project has 3 initial phases. In phase 1, the evidence considering if and how DHT are used in healthcare will be reviewed, to explore the factors influencing their use. A national survey, observations of practice, questionnaires and interviews will describe current practice and explore the behaviours and beliefs of people after stroke, rehabilitation staff and service managers about using DHT. This information will be used to develop a theory about, and framework of, the factors influencing the use of DHT in healthcare rehabilitation. In phase 2, the theory and framework will be used to co-design, create and undertake initial testing of an app and intervention to supplement routine rehabilitation for the arm after stroke with rehabilitation staff, stroke survivors and DHT developers from our in-house innovation lab. In phase 3, the initial feasibility, acceptability and costs of the app and intervention to supplement stroke rehabilitation at a single NHS trust will be evaluated.

Data from interviews, questionnaires and generated by the app will investigate how it was used in practice. These findings will be used to further refine the theory and framework developed in Phase 1 and the app and intervention developed in Phase 2. In the second period of the fellowship (Phase 4), a multi-site feasibility study of the app and intervention will be conducted. The project outputs will also be used to guide and assess the use of other forms of DHT (e.g. virtual reality) in stroke rehabilitation and their transferability to support and evaluate DHT in other healthcare settings will be evaluated. This project will transform how DHT can be used in healthcare by generating a clear theory and framework and providing practical tools which detail the factors that must be considered in the design, implementation and evaluation of DHT. It will provide guidance on how patients and healthcare staff can co-design DHT and design a future trial of the effectiveness of the app and intervention. Its results will benefit technology developers and researchers by helping them design and utilise DHT to improve patient outcomes and enable healthcare organisations and policy-makers to consider the vital processes and resources required to realise the vision of a truly innovative and DHT-enabled healthcare service.

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0. Proposal name

0. Enter the proposal name

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1. Description of Data.

1.1 Type of Study

Phase 1a: Literature review only

Phase 1b: Survey, participant observation, semi-structured interviews

Phase 2a: Searches only

Phase 2b: App usability testing incorporating out-loud interviews and usability questionnaires; Case studies of app feasibility and acceptability incorporating semi-structured interviews, technology acceptance questionnaires and engagement data

Phase 3: single-arm feasibility study (n=40 stroke survivors).

Phase 4: Design of future pilot trial - no data collection

The University of Manchester PI, Dr. Sutton, is involved only as a Co-I for Phase 3 (and possibly Phase 4), as per the requirement of the grant, hence the remainder of this form will relate to Phase 3 only (as no data will be collected for Phase 4).

1.2 Types of Data

Objective quantitative data reflecting the function of the upper limb will be collected directly via questionnaire from the n=40 stroke survivors at baseline and after using the app (when stroke survivors are being discharged from rehabilitation) using wrist worn accelerometers and the action research arm test, recommended and validated tools of arm function. An embedded process evaluation will collect and examine fidelity data regarding their use of the app (e.g. dose, frequency), simple economic outcomes, engagement, sustainability, acceptability and examine any inequalities (with respect to age, gender, ethnicity and stroke severity) in the implementation of the app using 200 hours of overt non-participant observations, technology acceptance questionnaires.

Semi-structured interviews in a total of 15-20 purposively sampled rehabilitation staff, organisation managers and stroke patients who used the app will also be performed, although The University of Manchester PI will have no direct input to this aspect.

1.3 Format and scale of the data

Not applicable - it is not anticipated that the Manchester PI, Dr. Sutton, will receive any data. The data will be collected and managed by Dr. Stockley, the recipient of the award, at the University of Central Lancashire. The formatting of the quantitative data, which is the only data that Dr. Sutton is likely to see, is expected to use SPSS and will enable sharing of the data in line with MRC requirements. Dr Sutton may advise Dr Stockley on the formatting and management of these data.

2. Data collection / generation

2.1 Methodologies for data collection / generation

Quantitative data will be collected and entered into questionnaires (case report forms) from the stroke survivors face-to-face, using interview or self-completion methods; app usage data will downloaded from the app.

2.2 Data quality and standards

This is not the primary responsibility of the Manchester CI, although he will advise on data entry validation and verification methods as necessary.

3. Data management, documentation and curation

3.1 Managing, storing and curating data

No storage and backup will be performed at the University of Manchester. Responsibility for this, and for archiving, remains with the University of Central Lancashire (UCLan). All electronic data will be stored securely on the UCLan network server with restricted access to folders in which the data are stored, and using password protected files where necessary. Data will be backed up regularly, as per UCLan procedures.

3.2 Metadata standards and data documentation

Data management is not the responsibility of The University of Manchester.

3.3 Data preservation strategy and standards

Not the responsibility of the University of Manchester; UCLan will store and archive the data in line with MRC requirements.

4. Data security and confidentiality of potentially disclosive personal information

4.1 Formal information/data security standards

No personal data are planned to be received by the University of Manchester.

4.2 Main risks to data security

There are no risks to data security directly relevant to The University of Manchester given the planned approach is not to transfer the data to this institution.

5. Data sharing and access

5.1 Suitability for sharing

Yes, although The University of Manchester will not have responsibility for data sharing.

5.2 Discovery by potential users of the research data

Not applicable to The University of Manchester.

5.3 Governance of access

All data control measures will be retained by the CI at UCLan and that institution; The University of Manchester will not be involved in this governance.

5.4 The study team's exclusive use of the data

This will be led by the CI although it is not likely that the data will be made available more widely until at least 12 months after the ending of the funding (i.e. until 2029).

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Not applicable to The University of Manchester's role in this 'project'.

5.6 Regulation of responsibilities of users

The University of Manchester will have no control over data sharing.

6. Responsibilities

6. Responsibilities

Study-wide data management, metadata creation, data security and quality assurance of data are the responsibility of the CI at UCLan. Advice on these will be provided by Dr. Sutton, as requested and as appropriate to his role in Phase 3 of the study.

7. Relevant policies

7. Relevant institutional, departmental or study policies on data sharing and data security

Policy	URL or reference
Data Management Policy and Procedures	
Data Security Policy	
Data Sharing Policy	*e.g. a study policy of sharing research data*
Institutional Information Policy	
Other	
Other	

8. Author and contact details

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

Dr. Chris Sutton