Plan Overview

A Data Management Plan created using DMPonline

Title: Vision screening in older adults who attend hospital following a fall: an intervention development study

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Template: University of Nottingham generic Data Management Plan

Project abstract:

Background

Falls in older adults are a major public health issue and with an ageing population the number of falls is set to increase. Falls can have serious physical and psychosocial consequences for the individual and puts great financial strain on the health and social care system. The UK currently spends more than £2 billion annually on management of falls in older adults.

An ageing population also means an increase in age-related sight loss, which alone can have a similarly devastating impact on a person's independence, quality of life, the economy and can almost double the risk of falling. The majority of age-related sight loss associated with falling is preventable.

National falls prevention guidance recommends a multifactorial risk assessment in patients who present to hospital following a fall, including a vision assessment. Despite this, implementation across the UK is inconsistent. The barriers to implementation need to be understood in order to facilitate effective implementation of the guidance.

There is also evidence of a lack of engagement with eye services in the older population. It is necessary to seek the views of older adults who fall and their carers, on vision screening following a fall and their views on the priority of eye health, in order to design services which meet their needs.

This study aims to develop an intervention, used by the falls MDT, to aid the implementation of vision screening in older adults who attend hospital following a fall. Using focus groups, this study will integrate the perspectives of service users and health professionals, in order to develop a sustainable, patient-focussed intervention. A Delphi study will be used to seek consensus on the intervention. Intervention delivery and acceptability to both health professionals and patients will subsequently be assessed in a feasibility study.

Aims

- To enable implementation of vision screening in older adults who present to hospital following a fall.

Objectives

· Map the evidence regarding vision assessments in older adults who present to hospital following a fall.

· Explore the barriers and facilitators to implementation of vision screening in this population, from the perspectives of health professionals.

· Explore the views of older adults who fall and their carers on looking after their eyes.

· Develop and test the feasibility of an intervention to implement vision screening in older adults who present to hospital following a fall.

Methods

A sequential exploratory mixed-methods study is proposed, comprising four components:

Component One- Scoping review

Component Two- Focus group study on health professionals

Component Three- Focus group study on patients and carers

Component Four- Intervention development and feasibility study

Anticipated impact

The development of an evidence-based intervention will enable the implementation of national falls prevention guidance and bridge health inequalities in the management of vision impairment in this population. This could help reduce the prevalence of visual impairment that may contribute to repeat falls.

Dissemination

Results will be shared with the public by leaflets/ newsletters distributed to various services/ organisations and charities and with professionals in scientific journals and conferences.

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Vision screening in older adults who attend hospital following a fall: an intervention development study

Data description

What data will you create?

The Research Data Management (RDM) Online course was done and used to help complete this form.
Data description
This study will generate new data from two focus group studies and a Delphi study. Data description for each appears separately in the table below:

Brief description of data	File Type	Number	Size	Personal/ commercial
Focus group studies:				
Focus group recordings	.Mp4	Max 10 x 90 mins	~10GB	Personal
Transcripts	.docx	Max 10	<1GB	Anonymous
NViVo project file	.nvp	2	<1GB	Anonymous
Completed demographic questionnaires	paper/ .docx	Approx. 48	<1GB	Personal
Excel spreadsheet	.xlsx	2	<1GB	Anonymous
Delphi survey study:				
Completed Delphi surveys	.docx	40	<1GB	Anonymous
Excel spreadsheet	.xlsx	1	<1GB	Anonymous

Data collection / generation

What are your methodologies for data collection / generation? How will you ensure data quality? What data standards will you use?

I will be generating new data in this study. Existing datasets will not be used. I will be collecting the following data:

- Qualitative data from focus groups to be analysed thematically.

- Quantitative data from demographic questionnaires, without identifiable data such as name, DOB, home or work address.

- Quantitative data from Delphi surveys, without identifiable data.

All data will be anonymised before analysis. Once audio recordings have been transcribed, they will be deleted from devices. The study will comply with the General Data Protection regulation (GDPR) Data Protection Act 2018, which requires all personal data to be anonymised as soon as it is practical to do

so. A unique study ID number will be given to each participant for all study documents and electronic databases. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) to prevent miss-assignment of data.

In order to ensure data quality, there will be controlled organisation of the data, with naming conventions, version control and a well-structed organisation of folders. This will be maintained by the local researcher.

Topic guides, questionnaires and surveys will be developed by the local researcher (PhD student) alongside the supervisory team and PPI collaborator. They will be assessed by the research team, colleagues and PPI advisory group members for usability, face validity and content validity. To ensure data consistency, the same topic guides, questionnaires or surveys will be used for each participant relevant to the study component they were recruited to. Topic-guides will be semi-structured however. Data entry validation will be conducted by the local researcher through double checking inputted data against raw data.

Data storage and security

Where and how will data will be stored, backed-up, transferred, and secured during the active phase (short to medium term) of research?

We will use UoN-provided storage for our working data. UoN licenses Microsoft Teams, allowing for secure and controlled sharing of data among the research team. Microsoft Teams encrypts data both in transit and at rest and is approved against the University's Handling Restricted Data Policy. The service provides several layers of automatic back up and, in a disaster scenario, files can be recovered. Access to data stored in MS Teams is via secure log-in with multi-factor authentication.

Audio data will be recorded on a digital recording device, transferred to and stored on Teams using an encrypted UoN laptop. All paper-based research data will also be transferred to and stored on Teams using an encrypted UoN laptop. All paper- based research data will initially be stored in a site file at UoN in a secure cabinet. Keys to the secured cabinet will only be kept in a location known to the local researcher. Any data analysis will be performed on encrypted UoN laptops with anonymised data. Once data is transferred to Teams, it will be deleted from devices and hardcopies will be destroyed.

Data management, documentation, and curation

What are your principles, systems, and major standards for data management and creation? What metadata and documentation will you keep?

Data will be carefully organised and maintained by the local researcher. A file naming schema will be employed, which will include the data description/ title of data file, version, date [in yyyymmdd format], for ease of sorting. Spaces will not be used in file names to ensure ease of access across programs.

Folders will be organised in a clear structure. Data will be stored on Microsoft Teams supported by UoN in separate folders labelled "FocusGroups" and "Questionnaires". Each folder will contain a sub-folders for raw data, processed data and metadata. Metadata will be used for ease of understanding and use of data by others. As well as automatically generated metadata for files, metadata will also be added by the local researcher on all files in an additional page on word docs for transcribed data, an

additional sheet on excel for imported survey and questionnaire data and an annotation on NViVo for coded data. This: title, description of contents, authors, date created, format. Within files, data will be checked for clarity and ease of understanding, including: column titles, codes, units, transcribed data etc. There will also be a masterfile of metadata made on excel, with a list detailing all data files for the study. This will include details of the storage structure. Study level documentation will be available in the study protocol, thesis and any written publications, to aid the understanding, reuse and validation of datasets. Templates will be provided for all consent forms, focus group topic guides, questionnaires and surveys to aid reproducibility.

Ethics & Privacy

Are there any ethical or privacy related issues associated with your data?

Personal data will be collected during this project, and the project has considered ethical and legal implications in its data storage, as well as appropriate security of personal data. All participants will agree to data collection and to long-term retention, archiving, and sharing of their anonymised data. Research will follow standard ethical procedures of the Faculty of Medicine and Health Sciences and the University of Nottingham. Specific aspects will be considered by the Faculty ethics committee as appropriate. In particular, the creation of data from focus groups and questionnaires will require ethical approval, including consent forms outlining the storage and use for research purposes of data, including access to those data by project researchers and other researchers, both during and after the life of the project. Participants will be informed that they can withdraw their participation at any stage during or after the observations. As we will be working with personal data we will ensure that we comply with the Data Protection Act 2018, including GDPR requirements. This will include providing research participants with the relevant privacy information and ensuring appropriate safeguards for the storage and handling of data are in place. In the event of participant disclosure or incidental findings, personal data may need to be shared. In these instances, this will be discussed with the participant and informed consent will be sought prior to doing so. This procedure will be detailed in the PIS. If participants agree for their contact details to be kept for the purpose of receiving study results at the end of study, their name and preferred contact details will be stored on a separate database from study data under strict access controls.

Data preservation

How will you ensure the long term storage and preservation of data?

All anonymised research data created by the project will be deposited in the UoN research data archive (https://rdmc.nottingham.ac.uk) [Nottingham Research Data Management Repository]. UoN will retain and preserve research data in line with UoN and The Dunhill Medical Trust requirements for a minimum of 7 years, but data will be retained for longer periods of time where it is of continual value to users. [The funder’s minimum data retention period is 5 years, therefore that by UoN is to be used]. Data will be archived upon completion of each study component within the larger study project and before publication of outputs for each study component. For each published dataset, a DOI will be issued by the repository. Data will be archived with the study protocol to facilitate discoverability and reuse.

Data sharing and access

How will the data generated be shared and published?

All data for which consent to share has been obtained will be shared via UoN data archive under a CC-BY license. Any data which is deemed to be personally or commercially sensitive will be assessed on a case-by-case basis to determine whether it can be shared. There will be no need to update the data past the project period. All published outputs will contain a Data Availability Statement including the datacite DOI that directs to the relevant data set E.g. ‘all ___ data are available via the Nottingham Research Data Management Repository (DOI).”

Data will be released at the same time as any published outputs underpinned by the data or by one year from the end of the project. As per The Dunhill Medical Trust, the Grant Holder i.e. the local researcher (PhD student), will ensure that all peer-reviewed (primary) research publications arising from the Grant Project are made available via appropriate open access publishing sites (e.g. Europe PubMed Central) within six months of publication. A contribution will be provided at the discretion of the Trust towards open access fees levied by publishers who support the open access model.

Roles & responsibilities

Who will be responsible for managing data, data security, data quality, and data security both during the award and post-award?

The Chief investigator will be the custodian of the data, responsible for collecting and analysing the data. The UoN will be responsible for storing and archiving the data. All data, personal or otherwise, will only be accessed by the local investigator and other authorised representatives from UoN and any host institution for monitoring and/or audit of the study to ensure compliance with regulations. No patient identifiable information will be shared unless necessary. The participant will be informed that their information may be shared for the above reasons in the information sheet and will be required to give consent for this before taking part in the study.

Relevant policies

What are the relevant institutional, departmental or study policies on data sharing and data security?

We will ensure that our research aligns with the requirements of the University's Research Data Management Policy, Information Security Policy, Code of Research Conduct and Research Ethics. As we are working with personal data, we will abide by the University’s Handling Restricted Data Policy and Data Protection Policy. All third party commercial data or new data that may be suitable for commercial exploitation will be protected by the University's Intellectual Property policy.

IPR

Who will own the copyright and IPR of any data that you will collect or create? Will you create a licence(s) for its use and reuse? If you are planning to use existing data as part of your research, do any copyright or other restrictions determine its use?

Any Intellectual Property Rights are owned by the (host) Institution. This is confirmed in the funder's IP agreement.

Budgeting

What are the costs or funding required for capturing, processing, storing, and archiving your data?

Costs have been estimated by the R&I finance team at NUHT, the host organisation. These have been included in the funding for capturing, processing, storing, and archiving data. It is anticipated that £2,879.28 at the end of the 3 year fellowship will cover the storing/ archiving and monitoring of data and £8000 will cover open access costs for publications. These funds will be transferred from NUHT, the Host organisation to UoN, the Sponsor organisation, as part of a collaboration agreement. As per the funder, a contribution will be provided at the discretion of the Trust towards open access fees levied by publishers who support the open access model.

Further Help

Would you like your plan to be reviewed by specialists in Libraries?

Saving this plan after checking the "Yes" box will immediately notify Libraries DMP review service, please only do this when you are ready for review.

- Yes

Would you like a reminder and further guidance on depositing your data? If so, indicate when would be most useful.

Guidance is sent out twice a year, but you can contact library-researchsupport@nottingham.ac.uk at any time for further support.

- No further support