Plan Overview

A Data Management Plan created using DMPonline

Title: Exploring prehospital practice for traumatic brain injury

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Template: University of Manchester Generic Template

Project abstract:

Background

Traumatic brain injury (TBI) is a major health burden contributing to health loss and disability worldwide. It is evident that early identification of patients with a head injury in the prehospital setting is associated with fewer serious adverse outcomes. However, identifying patients in need of trauma centre care is challenging due to the low accuracy of the existing prehospital trauma triage tools. Therefore, this study protocol aims to provide a snapshot of the current prehospital practice in the United Kingdom and explore facilitators and challenges of adopting new decision aids.

Methods

An explanatory sequential mixed-methods design consisting of two phases will be used. In the first phase, an online survey questionnaire will be distributed to prehospital care providers in clinical roles to gain a deeper insight into the current practice and obtain their thoughts about potential areas for improvement in triaging TBI patients in the United Kingdom. In the second phase, semi-structured interviews will be carried out to investigate the ambulance service personnel thoughts of introducing new measures to inform triage decisions. Survey questionnaires and semi-structured interviews will be piloted and externally reviewed to ensure content validity and reliability. Quantitative data will be summarised using descriptive statistics; qualitative data will be analysed thematically.

Impact

The findings of this study will provide a cross-sectional view of the current prehospital practice in the United Kingdom for the prehospital triage of patients with suspected TBI. Further, our findings will inform the design of future care pathways and research, identifying challenges and opportunities for future development of prehospital triage tools for TBI.

Ethics and dissemination

The NHS review and ethical approval to conduct this study is required and will be obtained from Health Research Authority (HRA). The findings of this study will be published in a relevant peer-reviewed journal and at national and international conferences.

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Copyright information:

Exploring prehospital practice for traumatic brain injury

Manchester Data Management Outline

1. Will this project be reviewed by any of the following bodies (please select all that apply)?

- Ethics

2. Is The University of Manchester collaborating with other institutions on this project?

- No - only institution involved

3. What data will you use in this project (please select all that apply)?

- Acquire new data

4. Where will the data be stored and backed-up during the project lifetime?

- P Drive (postgraduate researchers and students only)

All virtual interviews recordings will be uploaded to the cloud (according to the University of Manchester's guidelines) and transferred as soon as possible to the University of Manchester's P Drive and University of Manchester Research Data Storage Service.
Raw data will not be shared outside of the supervisory team.

5. If you will be using Research Data Storage, how much storage will you require?

- Not applicable

6. Are you going to be receiving data from, or sharing data with an external third party?

- No

7. How long do you intend to keep your data for after the end of your project (in years)?

- 5 - 10 years

Guidance for questions 8 to 13

Highly restricted information defined in the Information security classification, ownership and secure information handling SOP is information that requires enhanced security as unauthorised disclosure could cause significant harm to individuals or to the University and its ambitions in respect of its purpose, vision and values. This could be: information that is subject to export controls; valuable intellectual property; security sensitive material or research in key industrial fields at particular risk of being targeted by foreign states. See more examples of highly restricted information .

Personal information, also known as personal data, relates to identifiable living individuals. Personal data is classed as special category personal data if it includes any of the following types of information about an identifiable living individual: racial or ethnic origin; political opinions; religious or similar philosophical beliefs; trade union membership; genetic data; biometric data; health data; sexual life; sexual orientation.

Please note that in line with data protection law (the UK General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate ethical approval in order to use identifiable personal data.

8. What type of information will you be processing (please select all that apply)?

- Anonymised personal data

9. How do you plan to store, protect and ensure confidentiality of any highly restricted data or personal data (please select all that apply)?

- Other (please list below in less than 100 words)

- Use the Qualtrics survey tool to collect data with the 'anonymise' feature enabled.
- Each participant will refer to a code (Participant ID) during the interview process to maintain confidentiality.

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

- Yes – Other

Consent forms will be retained beyond the end date according to the UoM RRS.

11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?

- No

12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

- Not applicable

13. Are you planning to use the personal information for future purposes such as research?

- No

14. Will this project use innovative technologies to collect or process data?

- No

15. Who will act as the data custodian for this study, and so be responsible for the information involved?

Professor Richard Body

16. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

2022-04-17

Project details

What is the purpose of your research project?

The aim of a mixed-method study is to provide a snapshot of current practice and approaches to TBI care in the UK, as well as to explore facilitators and challenges of adopting new decision aids to

enhance prehospital triage tools.

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

- The University of Manchester Records Management Policy.
- The University of Manchester Publications Policy.
- The University of Manchester IT policies and guidelines.
- The University of Manchester Intellectual Property Policy.

Responsibilities and Resources

Who will be responsible for data management?

Naif Alqurashi - A second-year PhD candidate.
Professor Richard Body - Primary Supervisor.

What resources will you require to deliver your plan?

- The use of the Qualtrics tool for collecting data.
- Access to University P Drive.
- Access to University licensed program (NVivo) - for qualitative data analysis.
- To share data between supervisory research teams, Dropbox for Business access may be required.
- Training in qualitative data analysis.

Data Collection

What data will you collect or create?

This study will involve a national survey of UK ambulance services to establish the current practice, run a questionnaire with paramedics and then conduct semi-structured interviews to get their opinions about facilitators and barriers to implementing new triage tools.
Participants will remain anonymous and their information will remain confidential.

How will the data be collected or created?

We aim to run a national survey of current practice. We only need one who can represent each ambulance service to answer the survey questions. We want the ambulance service to let us know

their research lead or lead clinicians or someone who could fill out the survey on behalf of the service. The data will be collected using the Qualtrics survey tool with the 'anonymise' and 'prevent multiple responses' features.

In semi-structured interviews, We plan to invite each paramedic completing the survey to take part. If we happen to need any more, we may ask them to put a colleague in touch with us. Non-attendance and participant withdrawal from semi-structured interviews will be only the exclusion criteria. Several open questions will be asked, and follow-up questions will be asked based on the respondents' responses. Informed consent will be taken for the interviews. The PIS and consent form will be sent to participating paramedics by email. They will be asked to complete the informed consent form and return it by email.

We could offer a £100 set up fee per ambulance service and a £30 honorarium (paid in vouchers) for the person completing the survey and the person completing the interview. The email address of the participants will be shared with the University of Manchester’s Finance department who will send the voucher to you. The email address will be securely retained by the Finance department for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose.

Documentation and Metadata

What documentation and metadata will accompany the data?

- Detailed information about the methodology of the research will be presented in the thesis, including the design of data collection methods, the data collection process, and analysis and presentation of findings.
- To ensure participant privacy, all data will be pseudonymised.

I will also have an ongoing working document to maintain details of what data was collected and how dataset was created which will be added to during data collection. This will include information such as:
- Dates of data collection, number of participants and how long the interviews lasted
- The topic guide that will be used.
- A key for any abbreviations used
- Notes regarding any changes to transcripts, changes to original data in transcripts

Ethics and Legal Compliance

How will you manage any ethical issues?

This is a low-risk study.

Participants will receive PIS and consent form that includes information about the study objectives and aims before participating in the survey and semi-structured interview.

Participants will complete the survey questionnaire anonymously

All participants will be informed about the data collection process and confidentiality before

participating in semi-structured interviews.

No questions will be asked outside of their professional role. If the interviewees appear distressed, I will ask if they are ok to continue and tell them that there is no need to discuss that particular topic if it is upsetting.

A copy of a consent form will be given to potential participants, in advance of the interview, along with the PIS. Informed consent will be taken for the interviews. The PIS and consent form will be sent to participating paramedics by email. They will be asked to complete the informed consent form and return it by email.

All participants will be coded during transcriptions to ensure anonymity. It will be explained that all interview records will be stored in a safe place with restricted access to the research team for confidentiality reasons. The data collected will be anonymized and securely store. All data will be stored on the University of Manchester P Drive, University-approved Dropbox for Business account and University of Manchester Research Data Storage Service (RDS). Upon transcription and verification, the audio files will be deleted.

The study participants will have the right to withdraw from the study at any time and won't be required to give any reason for their withdrawal. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data.

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

The PhD researcher Naif Alqurashi and his supervisors will own all the copyright and intellectual property rights to the research project.

Storage and backup

How will the data be stored and backed up?

All data will be stored on the University of Manchester P Drive and University-approved Dropbox for Business account. These are backed up daily as part of University security.

How will you manage access and security?

All data will be stored on the University of Manchester P Drive. The University-approved Dropbox for Business account. Access to the data will be restricted to the student, research team and supervisory team.

Selection and Preservation

Which data should be retained, shared, and/or preserved?

The main findings from this study will be submitted to be published in a peer-reviewed medical journal.

Additionally, we will also aim to publish our findings at relevant national and international conferences. The publication link will be sent out to all participants from ambulance services centres and throughout relevant networks. We will also aim to share the study findings with policymakers and experts in the prehospital field. It is hoped that the findings from this study will inform the design of future care pathways and research and provide solid evidence to enhance future work in this area.

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

Data will be stored in the Manchester Research Data Storage Service (RDS) for 5 years after the completion of the project.

Data Sharing

How will you share the data?

For the development of the research project, analysis, and final thesis, pseudonymised data will be shared with the supervisory team.
The results of this research will be included in my PhD dissertation. It may also be published in an academic journal.

Are any restrictions on data sharing required?

All data shared will be pseudonymised. Identifiable information will not be included in the transcript.