Plan Overview

A Data Management Plan created using DMPonline

Title: The Troponin-only Manchester Acute Coronary Syndromes (T-MACS) Choice Feasibility Study

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Template: University of Manchester Generic Template

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Project abstract:

Background A recent shift in how we deliver patient-centred care has brought shared decision making (SDM) to new attention. However, relatively little is known about how to apply SDM in the emergency department (ED). A US study has demonstrated that SDM can be successfully used in ED chest pain patients but used a now outdated algorithm to inform the SDM. The T-MACS Choice decision aid uses a contemporary algorithm, was co-designed with patients and now requires evaluation in clinical practice. Objectives Our primary objective is to establish if conducting a full-scale stepped wedge cluster randomised controlled trial evaluating the impact of SDM aided by the decision aid T-MACS Choice is feasible based on a composite of feasibility outcomes including eligible patient per time period of recruitment, recruitment rate, compliance with intervention and retention. Furthermore, we will collect data on the envisaged primary and secondary outcomes of the full-scale trial to evaluate if collecting the data is feasible by measuring missing data and providing some proof of concept. Those outcomes include decisional conflict, control preference, cardiac events, decision regret and physician satisfaction with the SDM training and delivering the intervention. Plan of investigation We will conduct a feasibility stepped wedged cluster randomised controlled trial using opt-out consent in adult patients presenting to the ED with suspected cardiac chest pain. The two ED's, representing the two clusters, will begin recruitment as 'controls' using standard care protocols based on T-MACS for 2 months. After a 1-month training period, the sites will then implement the SDM intervention using T-MACS Choice calculating the probability of a major adverse cardiac event and share that with patients through SDM. Feasibility data will be recorded throughout the study through different measures including the T-MACS database and a dedicated opt-out log. Clinical and study outcome data will be collected during the initial ED visit through a post-encounter patient survey measuring control preference and decisional conflict. Participants will be followed up at 30 days, considering their permission, for relevant secondary outcomes. Physician experience will be evaluated in a clinician post encounter survey and a survey following the SDM teaching session in the transition stage. A trial steering committee will decide on feasibility informed by pre-determined criteria. If shown to be feasible, we will proceed to apply for funding for a larger, definitive stepped wedge RCT.

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The Troponin-only Manchester Acute Coronary Syndromes (T-MACS) Choice Feasibility Study

Manchester Data Management Outline

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

- Funder
- 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?

- Other storage system (please list below)

Research Electronic Data Capture

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

- Not applicable

6. Are you going to be working with a 3rd party data provider?

- No

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

- 5 - 10 years

Questions about personal information

Personal information, also known as personal data, relates to identifiable living individuals. Special category personal data is more sensitive information such as medical records, ethnic background, religious beliefs, political opinions, sexual orientation and criminal convictions or offences information. If you are not using personal data then you can skip the rest of this section.

Please note that in line with data protection law (the 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 personal information will you be processing (please select all that apply)?

- Personal information, including signed consent forms
- Pseudonymised personal data

Data from NHS patients enrolled in the study including paper copies study surveys.

9. Please briefly outline how you plan to store, protect and ensure confidentiality of the participants' information.

Data will be stored on Research Electronic Data Capture (REDCap). Physicial research files during the studies will be pseudoanonymised. Once completed the physical research files will be archived according to local NHS trust policy.

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

- Yes – Funder requirement

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

- Yes - Public institutions with contractual arrangements (e.g. NHS research sites)

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?

- No

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

- No

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

Richard Body

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

2020-08-10

Project details

What is the purpose of your research project?

We will conduct a feasibility stepped wedged cluster randomised controlled trial involving adult patients with capacity presenting to the ED with suspected cardiac chest pain. Individual ED's representing clusters will start in control using standard care protocols before changing over to the SDM intervention aided by T-MACS Choice after a 1 month physician training period.
The primary objective of this feasibility trial is to assess if delivering a full scale stepped wedge cluster randomised controlled trial investigating the impact of SDM aided by the T-MACS Choice decision aid in patients with suspected cardiac chest pain in the ED is feasible. Therefore, we will conduct a pilot of the envisaged full scale trial to asses for eligible participants, recruitment, retention and missing data.
As part of the feasibility trial we will further asses the feasibility of collecting the envisage primary and secondary outcome measures. Furthermore, we will gather feedback from the physicians regarding the training they receive about delivering SDM with T-MACS Choice. The envisaged outcome measures we will collect data on are:

- Decisional conflict
- Control Preferences Scale
- Patient disposition and choice rates
- Cardiac events
- Patient decision regret at 30 days
- Physician experience with
    1. delivering SDM intervention
    2. training received on SDM

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

The University of Manchester Research Data Management Policy
http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=33802%20Opens in a new window
The University of Manchester Records Management Policy
http://documents.manchester.ac.uk/display.aspx?DocID=14916Opens in a new window
The University of Manchester Publications Policy
http://documents.manchester.ac.uk/display.aspx?DocID=28526Opens in a new window
The University of Manchester IT policies and guidelines
http://www.itservices.manchester.ac.uk/aboutus/policy/Opens in a new window
The University of Manchester Intellectual Property Policy
http://documents.manchester.ac.uk/display.aspx?DocID=24420Opens in a new window
The University of Manchester Data Protection Policy
http://documents.manchester.ac.uk/display.aspx?DocID=14914

Responsibilities and Resources

Who will be responsible for data management?

Data will be captured locally by GCP trained phsicians and research nurses.
A trial coordinator and/or research nurses will input and monitor data on REDCap.
Patricia van den Berg (PI) and Richard Body (supervisor) will monitor adherence.

What resources will you require to deliver your plan?

Funding for the staff required and REDCap access have been requested.

Data Collection

What data will you collect or create?

As this is a feasibility study looking at recruitment rates, we estimate that we should collect data on 150-300 patients total .
1) Patient post-encounter survey

- collected and stored on paper (pseudoanonymised with study-ID)
- answers will be entered into REDCap
- contains validated decisional conflict scale and control preference scale

2) Physician post-enounter survey

- collected and stored on paper (pseudoanonymised with study-ID)
- answers will be entered into REDCap
- looking at physician satisfaction

3) Physician training survey

- collected and stored on paper
- answers will be entered into REDCap
- about 50-100 emergency physicians across both departments
- looking at satisfaction with training session on shared decision making

4) GP follow up case report form

- collected and stored on paper
- answers will be entered into REDCap
- collecting data on potential cardiac events

5) 30-days follow up case report form

- collected and stored on paper
- answers will be entered into REDCap
- collecting data on potential cardiac events and specified clinical outcomes

6) 30-days follow up survey

- only applicable to patients who had shared decision making (estimated 150 patients)
- collected either online directly through REDCap or captured and stored on paper with subsequent entry to REDCap
- decision regret scale

7) T-MACS Choice decision aid

- only applicable to patients who had shared decision making (estimated 150 patients)
- paper copy of completed personalised decision aid will be stored with the medical record
- choice option will be recorded on REDCap

How will the data be collected or created?

All study documents will be monitored through as study document management sheet including file names, version numbers and date and will be kept up to date throughout the study.
All study documents have an uniform design including the study name, version and date.
Data will be collected on bespoke paper surveys that will be entered into REDCap
Trial coordinator will be monitoring data entry and the study document management sheet under supervision of the PI.

Documentation and Metadata

What documentation and metadata will accompany the data?

There will be a secured file with the personal information per patient study ID. Access will be managed by the data custodian. Unless for queries relating to individual data points access to personal information is not required and a pseudoanonymised database will be used only.
A README file will be generated detailing how the study data was generated and stored in the dedicated REDCap. Where possible metadata will be recorded using the recommend metadata standards suggested by REDCaü (most commonly SNOMED CT for medical related research).

Ethics and Legal Compliance

How will you manage any ethical issues?

Ethical approval will be requested for the study reviewing any ethical issues.
Data will be pseudoanonymised using an individual study ID assigned to a patient on generation of their study document pack (equivalent to generating T-MACS risk calculator that generates T-MACS database entry). Access to the T-MACS database that is stored as excel file on NHS trust computers containing is password protected. The pseudoanonymisation key required to convert study-ID numbers to identify patients in the T-MACS database will be stored separately by the data custodian (chief investigator) on their personal drive.

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

PI and supervisor will own the copyright. Licensing of the research data is not plannned as no data sharing is considered.

Storage and backup

How will the data be stored and backed up?

Data will be stored on REDCap for the duration of the study. Physical files will be stored in a locked filing cabinet in a research office during the project. Physical files will later be archived according local NHS Trust policies.

How will you manage access and security?

Access will be regulated via accounts to REDCap. Accounts will be administered by the chief investigator.

Selection and Preservation

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

The full electronic research dataset will be stored as an encrypted electronic database using Research Data Storage through the University of Manchester.
Physical files will be archived at local NHS trust according to trust policies.

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

Physical research files will be archived according to local NHS trust policy for up to 5 years.

Data Sharing

How will you share the data?

An encrypted, pseudoanonymised database will the research data will be available to the research group members only. Data will be published in an anonymised form. Further data sharing is not planned and has not been agreed with the funder. The patient related data collected is regarded sensitive in nature prohibiting sharing.

Are any restrictions on data sharing required?

No