Plan Overview

A Data Management Plan created using DMPonline

Title: The effect of sending advanced notification to trial participants two weeks before outcome data collection to improve retention: an embedded randomised controlled trial in the WORKWELL trial

Creator: Chris Sutton

Principal Investigator: Chris Sutton

Data Manager: Chris Sutton

Affiliation: University of Manchester

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ORCID iD: 0000-0002-6406-1318

Project abstract:

Many trials struggle with participant retention and completion of follow-up questionnaires. A recent UK study found that the median loss- to follow- up in a sample of 151 trials was 11%. Reminders are generally an effective way of increasing response rates to questionnaires and there is some evidence that pre-notification (contacting a participant to say that the trial team will be sending a questionnaire out soon) also has some evidence of benefit, although it is not high certainty evidence. There is no clear evidence as yet that pre-notification is effective for trial retention. We propose to investigate the effect of sending advanced notification to trial participants two weeks before the 6-month outcome data collection forms are sent to participants in the WORKWELL trial to investigate whether this improves retention. Data from this trial will also be combined with data from other trials of a comparable intervention, including those funded from within this MRC Project, within a meta-analysis.

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The effect of sending advanced notification to trial participants two weeks before outcome data collection to improve retention: an embedded randomised controlled trial in the WORKWELL trial

Manchester Data Management Outline

1. Is this project already funded?

- No

2. If you will be applying for funding from multiple sources who else will you be applying to?

- Not applicable

Funding is contained within the overall MRC Funded Project (REF: MR/R013748/18); this is an application to release up to £5000 as part of a sub-project - this amount of funding is under the control of the Project Management Group who allocate funding (~£5000 per sub-project, for approx. 25 project - the funding award contains £125k for such sub-projects)

3. Is The University of Manchester the lead institution for this project?

- Yes – leading a collaboration

The sub-project includes co-applicants from two other institutions; University of Salford and University of Central Lancashire (UCLan), although other institutions are involved in the overall MRC-funded project and will be involved in the meta-analysis of data for the relevant intervention, for which the data from this trial will be included as part of the sub-project funding agreement.

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

- Acquire new data

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

- Other storage system (please list below)

Data collection will be performed by the University of Central Lancashire who are collecting and managing all the data for the WORKWELL trial. The data for this sub-project data will be meta-data for the overall WORKWELL trial.

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

- < 1 TB

7. If you have a contractual agreement with a 3rd party data provider will any of the data associated with this project be sourced from, processed or stored outside of the institutions and groups stated on your agreement?

- Not applicable

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

- > 20 years

Data will be stored long-term and archived appropriately, and also made available 'open access', in line with MRC requirements.

Questions about personal information

Personal information or personal data, the two terms are often used interchangeably, 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.

- Pseudonymised personal data

Data for this sub-project will be meta-data on questionnaire returns, and related meta-data (timing of questionnaire return, number of questionnaire reminders etc.) which will be linked to personal information; however, University of Manchester will only ever receive the pseuonymised personal data and only the participating institutions (UCLan and University of Salford) will be able to link the codes to patient names or other idenitfying information.

10. Please provide details of how you plan to store, protect and ensure confidentiality of the participants' information as stated in the question above.

The data for this sub-project (Study Within A Trial [SWAT]) will all be collected as part of the main project, for which approval (and a separate DMP) has already been obtained. The data for this sub-project has no specific confidentialilty issues as it will be extracted from the database(s) in a pseuonymised form and so will essentially be secondary (meta)data from the main WORKWELL project.

11. If you are storing personal information will you need to keep it beyond the end of the project?

- Not applicable

12. Sharing person identifiable information can present risks to participants' privacy, researchers and the institution. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester? This includes using 3rd party service providers such as cloud storage providers or survey platforms.

- Yes - Collaboration with other universities

Personal data will be shared in pseudonymised form with co-applicants and staff working on the MRC project and is likely to be made open access at the end of this project; however, this sub-project will eventually become fully anonymised, but this is under the control of the overall WORKWELL project.

13. 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

But see above point regarding likely Open Access data requirement.

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

- Yes

But only subject to the points made above. None of the information stored is sensitive.

15. Who will act as the data custodian or information asset owner for this study?

Dr Chris Sutton

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

13/08/2018

0. Proposal name

0. Enter the proposal name

The effect of sending advanced notification to trial participants two weeks before outcome data collection to improve retention: an embedded randomised controlled trial in the WORKWELL trial

1. Description of Data.

1.1 Type of Study

Nested randomised controlled trial of retention intervention (pre-notification of questionnaire)

1.2 Types of Data

Quantitative data collected as meta-data for the overarching WORKWELL trial.

1.3 Format and scale of the data

240 records of approximately 10 fields. Data will be stored in formats suitable for long-term archiving, in CSV (or Excel) format, and also in Stata format for data analysis.

2. Data collection / generation

2.1 Methodologies for data collection / generation

Data will be collected as meta-data for the overarching WORKWELL trial and extracted from the tracker database (tracking participant responses) at the end of the 6-month trial follow-up period.

2.2 Data quality and standards

Data checking will be performed by the UCLan data management team and will be subject to validation on receipt for analysis by the University of Manchester.

3. Data management, documentation and curation

3.1 Managing, storing and curating data

The data will be collected and stored within a secure database held at UCLan used to track participants in the WORKWELL Trial. This database will be backed up regularly as is key to the management of the trial. No new data will be collected for the purposes of this trial, save the details as to whether or not each individual was randomised to receive the pre-notification card (and, for those to whom it was sent, when it was sent). A data extract (likely to be in EXCEL or CSV format) containing the relevant fields for analysis in this project will be exported at the end of this nested trial (i.e. once follow-up of the 6-month outcome data has ceased) and transported using encrypted email to the University of Manchested statistics team.

3.2 Metadata standards and data documentation

The data set is very small (in terms of number of fields/variables), so a simple, separate data dictionary will be compiled, detailing the variables, their definitions and other relevant details.

3.3 Data preservation strategy and standards

All data will be retained. The data will be archived locally but may also be made available in conjunction with any publication produced, and also will be retained by the MRC SWAT project (PROMETHEUS) team in relation to the overall project and related meta-analysis project (and its retention policy). The combined dataset (including that from this sub-project) will be stored by the University of York in a secure location. Data from individual datasets will remain the property of PROMETHEUS collaborators, in this case the University of Manchester (and collaborators at other institution).

4. Data security and confidentiality of potentially disclosive personal information

4.1 Formal information/data security standards

No additional identifiable data will be collected as part of this sub-project and there are no additional risks to the data from this project. Please refer to the WORKWELL Trial Pan-Man form for details regarding the security standards for the storage of the data for that project.

4.2 Main risks to data security

Given the nature of the fields collected (see earlier responses) and that the participant information relating to this project is all pseuonymised, there are no substantive risks to data security providing research partners adhere to processes as The University of Manchester will not receive any identifying information, nor will any of the details provided by sensitive data.

5. Data sharing and access

5.1 Suitability for sharing

Yes

5.2 Discovery by potential users of the research data

No specific arrangements for this subproject - please see DMP for the overall PROMETHESUS project which will co-ordinate the potential for discovery by users of the data from the ~25 projects, including this, funded from within the MRC funding envelope for PROMETHEUS.

5.3 Governance of access

The project team has no plans for making the data more widely available, but will work with the PROMETHEUS team leads at York to ensure that research data are made available at an appropriate point in time. (Please refer to the overarching MRC Project 'Routinely embedding recruitment and retention interventions within randomised controlled trials' Pan-Man for details of the process for implementing these plans - this study team will agree to release the data for public access once the relevant key pulbications are accepted).

5.4 The study team's exclusive use of the data

Please refer to the overarching MRC Project 'Routinely embedding recruitment and retention interventions within randomised controlled trials' Pan-Man for details of the process for implementing these plans - this study team (i.e. the WORKWELL SWAT team) will agree to release the data for public access once the relevant key pulbications are accepted, in line with the preference of the PROMETHEUS team.

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

See above.

5.6 Regulation of responsibilities of users

No.

6. Responsibilities

6. Responsibilities

Primary responsibilty is with Denise Forshaw at Lancashire CTU, UCLan. In conjuction with the PI, Sarah Rhodes will have responsibility for liaising with Denise regarding data extraction from the main WORKWELL tracker database and validating the data extracted.

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	http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=33802%20
Data Security Policy	http://documents.manchester.ac.uk/display.aspx?DocID=14914
Data Sharing Policy	http://www.library.manchester.ac.uk/using-the-library/staff/research/services/research-data-management/sharing/
Institutional Information Policy	http://www.itservices.manchester.ac.uk/aboutus/policy/
Records Management Policy	http://documents.manchester.ac.uk/display.aspx?DocID=14916
Intellectual Property Policy	http://documents.manchester.ac.uk/display.aspx?DocID=24420

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