Plan Overview

A Data Management Plan created using DMPonline

Title: SAVER Information Study

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Template: DCC Template

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Project abstract:

The SAVER Information Study will involve qualitative interviews with patients who have been invited to join the trial to systematically explore patients' experiences of recruitment and participation in the SAVER trial. We will conduct interviews with ~20 patients. We will draw on qualitative techniques to analyse the interview transcripts. The findings from the Information study will be used to help patients to make informed decisions about whether to join the trial, and to address any potential recruitment and retention issues. We will also use the Information Study findings to enhance the design and acceptability of any future phase III trial from the perspective of patients.

ID: 75557

Start date: 01-08-2020

End date: 31-12-2021

Last modified: 15-04-2021

Copyright information:

SAVER Information Study

Data Collection

What data will you collect or create?

We will collect patient contact details, including name, address, contact number, NHS site, and email. We will also collect consent forms and audio-record and transcribe approximately 20 patient interviews.

How will the data be collected or created?

Health professionals at NHS sites involved in the trial will record patient contact details using a proforma with patients who are eligible for interview and provide written consent for their contact details to be shared. The study researcher will obtain consent from the patient to complete the an interview. Written consent will be obtained for face-to-face interviews, and telephone consent (i.e. audio-recorded) consent will be obtained for telephone/video call interviews. The researcher will also audio-record the patient interviews, which will then be transcribed by a professional agency and pseudoanonymised.

Documentation and Metadata

What documentation and metadata will accompany the data?

We will create a spreadsheet, which will include participant ID numbers and participant characteristics (e.g. age, gender, trial participation status, ethnicity, NHS site codes, year of interview). The spreadsheet can be used to contextualise the interviews for further secondary analysis. The interview transcripts (Word documents) will be pseudoanonymised and marked with a participant ID that links to the spreadsheet. Pseudo-anonymised data will be available upon reasonable request to the study lead (Professor Bridget Young byoung@liverpool.ac.uk)

Ethics and Legal Compliance

How will you manage any ethical issues?

Patients can provide consent for pseudoanonymised data to be used for future research and training purposes, which will include secondary analysis upon reasonable request for the data to the study lead (Prof Bridget Young byoung@liverpool.ac.uk). We will protect the identity of participants by pseudoanonymising transcripts (i.e. removing names, places etc from transcripts as best we can whilst preserving the integrity of the data) and an associated spreadsheet.

Sensitive data will be stored and transferred securely. Proformas for patient contact details will be

forwarded from NHS sites to the research team via a secure, encrypted data sharing platform hosted by the university (e.g. datanywhere) or posted directly to the study researcher. Written consent forms will be encrypted and stored electronically on university data storage drive, which will only be accessible to staff on the study team. Audio-recorded telephone consent and interviews will be uploaded to the university data storage drive. Recordings will also be encrypted. Interview recordings will be securely uploaded to the professional transcription agency, which is also encrypted. The study researcher will download transcripts, anonymise, password protect and store them on the university data storage drive.

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

N/A

Storage and Backup

How will the data be stored and backed up during the research?

A University of Liverpool data storage drive will be set up specifically for the project. Proformas for patient contact details, written consent forms, audio-recorded consent, audio-recorded interviews, interview transcripts, and a spreadsheet with participant characteristics will be stored on this drive. The study researcher will archive the data at regular periods (i.e. monthly where possible). The computing services department will also support the study team with recovery if there is an incident that requires retrieval of the data.

How will you manage access and security?

The raw and pseudo-anonymised data collected and stored on the university data store will only be accessible to members of the study team. Members will require log in details and will be privy to file passwords. Encryption processes will help to ensure that patient proformas and audio-recordings of patient interviews are secure.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Audio-recordings of interviews and patient proformas will be destroyed at the end of the study. Consent forms and audio-recorded consent forms will be stored for up to 15 years. A spreadsheet with participant characteristics (i.e. pseudoanonymised characteristics) and pseudoanonymised transcripts will be stored indefinitely for future research and training. Foreseeable uses of the data include secondary analysis.

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

Long term, data will be stored securely in the University of Liverpool archive.

Data Sharing

How will you share the data?

Pseudoanonymised data will be available upon reasonable request to the study lead (Prof Bridget Young byoung@liverpool.ac.uk)

Are any restrictions on data sharing required?

Pseudoanonymised data will be available upon reasonable request and a data sharing agreement will be compiled for such purposes. The data will not be fully open, as the data is pseudonoymised, so participants could potentially be identified in very specific circumstances (e.g. by members of staff working at NHS sites).

Responsibilities and Resources

Who will be responsible for data management?

Professor Bridget Young (byoung@liverpool.ac.uk)

What resources will you require to deliver your plan?

N/A