DMP title

Project Name My plan (Netherlands Heart Institute) - DMP title

Project Identifier 666

Grant Title 66666

Principal Investigator / **Researcher** Ricardo de Miranda Azevedo

Project Data Contact Wanda van-Ast

Funder Netherlands Heart Institute

General information

Project title

"DEpression in Myocardial Infarction patients" (DEMI)

Contact person of the project

Full name	Institution	E-mail address	Telephone
Ricardo de Miranda Azevedo	Academisch Medisch Centrum (AMC)	r.de.miranda.azevedo@amc.nl	+31 616793711

Summary of the project

Previous studies showed that depression increases the risk of post-MI mortality. However, other studies suggest that somatic symptoms (e.g. insomnia) secondary to heart disease could confound this association. The present study aims to investigate whether somatic and cognitive symptoms of depression are differentially related to post-MI mortality in a cohort of adults that suffered a MI. Participants will be yearly assesed for five years.

Is there a person responsible for data management in this project?

- Yes

Full name	Institution	E-mail address	Telephone
Wanda van-Ast	Academisch Medisch Centrum (AMC)	wanda@amc.nl	+31 6666666

Is there a back-up data manager?

- Yes

Full name	Institution	E-mail address	Telephone
Rene Minaar	Academisch Medisch Centrum (AMC)	rene@amc.nl	+31 677777777

Third-party data reuse

Did the researchers search for third-party data that could be reused in the current project? - F,A,I,R

- Yes

Yes. We searched BBMRI-NL and Zenodo for potential third-party data that could be reused. Furthermore, we browsed Re3data to find other potential repositories. Unfortunately, we could not locate data that could be integrated with the present study.

Did the researchers check whether the informed consent form used for the third-party data collection allows the researchers to reuse this data? - F,A,R

- Yes

Yes. We requested for the informed consent form used by the third-party data source. It includes a statement in the about the intention of reuse and the conditions under which the data will be made available (i.e. only for non-commercial purposes after being anonymized).

Creating and processing data

Did the authors search for metadata standards that could be used in the project? Include a description, if applicable. - I

- Yes

Yes. We will use the Reference Metadata in Euro SDMX Metadata Structure, International Code of Diseases - 10 (ICD10) and the Dutch translated version of the Beck's Depression Inventory (BDI).

List all the variables that will be measured at the study. Specify which tools/instruments will be used for measuring the data. - I,R

Demographics (age, sex, years of education, marital status): Self-report forms will be responded by the participants and later included in the database by Member 1 through RedCAP platform (data entry monitor). Depressive symptoms: A self-report questionnaire (BDI) will be filled in by participants at each of the yearly visits. Later, the data monitor will enter the data on ReCAP. Killip class: The assessment of heart failure will be performed through the Killip classification, administered by the study cardiologist. Blood pressure will be measured using a NAIS sphygnamometer during the hospital visits under the supervision of the study cardiologist.

What will be the procedure to standardize metadata for variables without standard ontologies? - F,I,R

An ontology will be created for the variables without standard ontology. Further, this ontology will be shown to other peer researchers and eventually published at biosharing.org or through a scientific report, if applicable.

Data collection and IT professionalism

How existing third-party data is going to be combined with new data? - I,R

To harmonize existing data with newly collected data we will follow the approach suggested by Rolland and colleagues (2013). First, the project members with the assistance of the data manager will define which variables are necessary to be harmonized based on the research questions to be answered. Second, data concepts will be discussed and see whether they can be harmonized. The quiestionnaires that will be used for collecting new data will be designed on the same way (i,e. using the same metadata standards) used at the third-party data collection. This issues will be discussed during monthly meetings of the research group. Third: a list of data concepts will be derived based on the third-party data and the PI will evaluate which variables are going to be eligible for being harmonized with the new data. Fourth: Common data elements will be generated based on the variables elected to be harmonized. For sake of completeness, the questionnaire items will be identical to the ones used by third-party data. Fifth: Once all the common data elements were identified and derived, the data manager will combine both data sets by using the "ADD FILES" function at SPSS version 23. The new cases will be added and matched according the common data elements. The sixth and last step will consist of quality assessment, Descriptive statistics (such as range and frequencies) will be requested for the harmonized variables in order to see whether all values are falling at the expected range.

How are data edits going to be documented?

In the current project, data edits will be registered and tracked following the recommendations by Brand and colleagues (2011). Therefore, a table will be derived and filled in every time someone includes/changes information on the database. This procedure will also be described ath the study protocol. The following information will be assessed on this table: Number of edits, to which case report form does the edit refers to, which visit it refers to, which variables were changed, a description of the change that was made, and a description of the actions that were further taken (e.g. informing the PI in case of a protocol deviation).

Is the data going to be audited/monitored?

- Yes

The guidelines of the NFU will be used for planning data audits. An independent researcher assigned by the data management team and unknown to the remaining project members will perform audits. An audit checklist will be derived, and filled in by the data auditor during each of the audits. A total of three audits will be conducted during the two first years after data collection starts.

Are there going to be strategies to prevent data entry mistakes? If so, describe.

- Yes

Yes. Validation rules will be used on REDcap. Reference values will be taken from the inclusion criteria (e.g. minimum age 18 and maximum age 75) and also typical reference values for blood pressure, glucose levels and left ventricular ejection fraction. At the mid-phase DMP, a table describing these values will be included.

How is the data going to be stored and backed-up during the data collection phase? - F,A

Data will be backed-up at figshare (provided by the university) and at BeeHub (provided by SurfSara. Raw data will be stored at B2SAFE, due to its larger content.

Privacy and integrity

Does the project needs approval by a medical ethical committee?

- Yes

Yes. The project was already approved by the Ethics Committee (AIEC) of the University of Amsterdam.

Describe the procedure that will be used to obtain informed consent of the participants.

nformed consent will be obtained through informed consent forms designed by the project members. The informed consent forms will be backed-up together with the raw data at B2SAFE. These forms can be requested for inspection upon request to the data manager of the project. A clause explaining that the data will be made available for third-party reuse was included.

Is there a committee assigned to review privacy and integrity issues of the project?

- Yes

A data safety monitoring board will be requested to the responsible UMC and contacted once data collection starts

How are privacy and accuracy issues going to be addressed for data collected using mobile devices?

o address the issue of potential loss of privacy (and the perceived potential loss of privacy by the participant), it will be described in the informed consent form how the data transmission flow is designed. Data will be recorded using an application programmed by the research team, and data will be directly transmitted to the research storage facility., not needing to go through third-party servers The storage of the data on the participant's device will be minimized by being daily transmitted. The issue of attributability will be addressed by making use of password verification and automatic notifications when the device is removed. Technology interruptions will be addressed by providing unlimited wireless data plans to the participants. Moreover, back-up devices will be immediately available in case the device gets damaged. Establish data chain of custody in contracts ï‚· Establish controls over access and minimize data stored on device ï‚· Establish data chain of custody in contracts ï‚· Establish controls over access and minimize data stored on device ï‚· Update informed consents to address general privacy concerns and outline how and where these data will be used. Users should be able to opt out of secondary uses of data that are beyond the primary goal of the protocol. This should alleviate some of the IRB/EC worries and not delay

approvals

Budget

Explain how data management will be costed in the project.

Around 5% of the total budget will be directed for data management. Data management will be costed by using the data management costing tool of the UK Data Archive. The final version will be made available upon request to the PI.