Plan Overview

A Data Management Plan created using DMPonline Test

Title: Psychiatric morbidity in polytrauma patients

Creator:S Nelen

Principal Investigator: Marijn Houwert

Data Manager: Stijn Nelen, Zita Millenaar

Affiliation: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Rationale: 20-63% of all trauma patients in the United States have some form of psychiatric illness. This is considerable higher compared to the general population. Studies have shown a negative impact of psychiatric comorbidity on outcome after trauma. So far little is known about the prevalence and impact of psychiatric comorbidity in Dutch polytrauma patients.

Objective: The primary objective of this study is to determine the regional prevalence of psychiatric comorbidity in polytrauma patients. Psychiatric consultation as well as preexisting mental health problems will be extracted from medical records. Secondary aims are to compare both inpatient outcomes (length of stay, in-hospital morbidity, in-hospital mortality) and post-operative functional outcomes (using EQ5D questionnaires) between polytrauma patients with and without a co-morbid mental illness. Finally, a tertiary aim of this study is to incorporate supplemental data from the Centraal Bureau voor de Statistiek (CBS) to better understand the role of psycho-social determinants of health after trauma.

Study population: All polytrauma patients admitted to the emergency department of the University Medical Center Utrecht between 01-01-2018 and 31-12-2019 will be included. Polytrauma patients are defined as patients with an Injury Severity Score (ISS) of 16 or higher. Patients will be identified and included through the database of the Traumazorg Netwerk Midden-Nederland.

Main study parameters/endpoints: Primary and secondary endpoints of this study will be the percentage of patients that required psychiatric consultation during hospitalization or had preexisting mental health issues. Both preexisting psychiatric morbidity as well as psychiatric consultation will be extracted from medical records. This study will compare in-hospital mortality and morbidity between patients with and without mental health problems. Post-discharge functional outcomes will be recorded using the EQ-5D questionnaire. Finally, zip codes for each patient will be collected to analyze the role of socio-economic factors that may influence outcomes after trauma.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

There is no burden for the patients included in this study since it is a retrospective cohort study. The results of this study will be beneficial for polytrauma patients with psychiatric comorbidity. Since determining prevalence and impact creates more awareness on the impact of psychiatric comorbidity, in turn this awareness might result in better (perioperative) integrated medical and psychiatric care in polytrauma patients

ID: 75064

Start date: 01-01-2022

End date: 01-01-2024

Last modified: 15-12-2021

Copyright information:

Psychiatric morbidity in polytrauma patients

1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

DMP template version	29 (don't change)
ABR number *(only for human-related research)*	
METC number *(only for human-related research)*	TBD
DEC number *(only for animal-related research)*	
Acronym/short study title	PsychTrauma
Name Research Folder	xx-xxx_PsychTrauma
Name Division	Heelkundige Specialismen
Name Department	Traumatologie
Partner Organization	n/a
Start date study	01-01-2022
Planned end date study	01-01-2023
Name of datamanager consulted*	Dax Steins, P. Ojha
Check date by datamanager	06-04-2021,15-12-2021

1.2 Select the specifics that are applicable for your research.

- Monocenter study
- Retrospective study
- Non-WMO

2. Data Collection

2.1 Give a short description of the research data.

Primary objective: to determine the regional prevalence of vital psychiatric comorbidity in polytrauma patients. The amount of patients that required psychiatric consultation during hospitalization will be extracted from medical records.
Secondary objective: to determine the regional prevalence of preexisting psychiatric comorbidity in polytrauma patients. The amount of patients that had mental health problems in their medical history and/or used psychotropic medication before hospitalization will be extracted from medical records.
Tertiary objectives: 1) to compare baseline psycho-social health information to assess if pre-injury factors influence trauma outcomes in the psychiatric population 2) to compare in-hospital morbidity and mortality of polytrauma patients with and without a mental illness 3) to compare post-operative functional outcomes as measured by EQ-5D questionnaire

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	700	EPD (Hix)	Excel	Quantitative	.xslx	0-10 GB
Human	700	Trauma registry (TZMN)	Excel	Quantitative	.xslx	0-10 GB
Human	700	Central Bureau of Statistics (CBS)	Excel	Quantative	.xlsx	0-10 GB

2.2 Do you reuse existing data?

- Yes, please specify

We will reuse existing patient data from the EPD,CBS and the trauma registry.

2.3 Describe who will have access to which data during your study.

My division datamanager receives data from TZMN and CBS that contains direct identifying personal data(e.g. date of birth, postal code). After 4-eyes control, the dHS datamanager will encode the data with a key-linking table. This table links study specific IDs to patient IDs and is available to the datamanager and members of the research team with a care relationship to the patient. Other members of the research team receive a pseudonymized dataset and have no access to direct personal data or the key table.

Type of data	**Who has access**
Direct identifying personal data	Research team with care relationship to patient, Datamanager
Key table linking study specific IDs to Patient IDs	PI (with care relationship to patient), Datamanager
Pseudonymized data	Research team, Datamanager

2.4 Describe how you will take care of good data quality.

Research data from patients will be collected in an Excel spreadsheet. Data quality will be checked by a research member with a care relationship to the patient. Data collection will be frozen before analysis. SPSS Statistics will be used as statistical software tool.

#	**Question**	**Yes**	**No**	**N/A**
1.	Do you use a certified Data Capture Tool or Electronic Lab Notebook?		x	
2.	Have you built in skips and validation checks?		x	
3.	Do you perform repeated measurements?		x	
4.	Are your devices calibrated?			x
5.	Are your data (partially) checked by others (4 eyes principle)?	x		
6.	Are your data fully up to date?	x		
7.	Do you lock your raw data (frozen dataset)	x		
8.	Do you keep a logging (audit trail) of all changes?	x		
9.	Do you have a policy for handling missing data?			x
10.	Do you have a policy for handling outliers?			x

2.5 Specify data management costs and how you plan to cover these costs.

#	**Type of costs**	**Division** ("overhead")	**Funder**	**Other** (specify)
1.	Time of datamanager	x		
2.	Storage	x		
3.	Archiving	x		

2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.

UMC Utrecht is and remains the owner of all collected data for this study. Our data cannot be protected with IPR, but its value will be taken into account when making our data available to others, when setting up Research Collaborations and when drawing up Data Transfer Agreement(s).

3. Personal data (Data Protection Impact Assessment (DPIA) light)

Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?

- Yes, go to next question

I will process personal data. I have consulted the division datamanager and I do not have to complete a full DPIA. I therefore fill out this DPIA light and proceed to 3.1

3.1 Describe which personal data you are collecting and why you need them.

As discussed in paragraph 2.1; to fulfill the study objectives various patient, treatment and outcome characteristics will be retrieved from medical records.

Which personal data?	**Why?**
Age, gender, (abbreviated) injury severity score, substance abuse, hospitalization, trauma type, trauma mechanism, energy of trauma, ASA score	to describe our study population and eventually compare both study populations ie. patients with and without psychiatric comorbidity.
Postal code	to combine the database of the TZMN with the database of the CBS
Socio-economic factors based on postal code, such as income, social security and level of education	Psychiatric diseases and socio-economic factors are strongly related. To analyze the influence of these factors on outcome in major trauma patients in combination with psychiatric diseases.
requiring psychiatric consultation during hospitalization, reason for psychiatric consultation, preexisting mental health problems, preexisting use of psychotropic medication	To determine the prevalence of (preexisting) psychiatric comorbidity in polytrauma patients. Psychotropic medication will be used as a proxy for psychiatric comorbidity.
in hospital morbidity and mortality	To analyze if psychiatric comorbidity has an influence on morbidity and mortality.

3.2 What legal right do you have to process personal data?

- No objection, please explain

There is no study-specific informed consent. Because of that, we will make use of the no-objection check prior to data collection. Additional text box to explain:

1. **Why:** The exception for obtaining informed consent according section 5 and 6 of the code of conduct for medical research is applicable, since informed consent cannot in all fairness be acquired and would cost a disproportionate amount of effort. The main argument for this is the large number of patients (ie. 700 patients) from which consent must be acquired when records will be screened based on the injury severity score to determine the eligible patients
2. **Who:** division datamanager
3. **When:** the no-objection check will be performed by the division datamanger when the data is shared by TZMN.

3.3 Describe how you manage your data to comply to the rights of study participants.

By using the no-objection check, patients are not informed on their rights. Under the General Data Protection Regulation, following rights are applicable and at risk:
- Article 15: Right of access by the data subject
- Article 16: Right to rectification
- Article 18: Right to restriction of processing
- Article 21: Right to object.

By performing a no-objection check. Patients still have an indirect right to restriction of processing and right to object. The data will be pseudonymized. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data. So a patients still has the right of access and if asked and checked by treating physician data can be changed (right to rectification). If a patient uses his right to object during the study, data will be erased.

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal data.

We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

Data will be requested from the TZMN and CBS. Zip code data will be anonymously cross-referenced with CBS statistical data by the PI, to assess for pre-injury risk factors. CBS data is entirely de identified and upheld to the strictest national privacy regulations as determined by an annual national audit. To further protect patient health information, this study will only track social details if there are several households within the specified zip-code. It goes without saying that there will be no hospital data shared with the CBS. In regard to data from the TZMN; with assistance of our local datamanager a SURFdrive will be used. This is a secure institutional cloud storage, to share data from TZMN via a encrypted URL-link. No data will be transported outside the UMCU network drives.

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

All data and documentation collected by the UMC Utrecht will be stored in the secured Research Folder Structure of the UMC Utrecht. Importantly, personal data is stored separately from other research data and adequate access and control rights are in place.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

For the data collected in Excel, we will prepare a codebook of the research database. We will not make use of any metadata standards.

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

An analysis plan will be written. In this plan it will be stated why which data will be used and which statistical analysis we plan to do in which software. The analysis plan will be stored in the project folder.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The data package (i.e. our research/project folder) will contain: the raw data, the study protocol describing the study procedures, the script to process the data, the scripts leading to tables and figures in the publication, a codebook with explanations on the variable names, and a‘read_me.txt’ file with an overview of files included and their content and use.

7.2 Describe for how long the data and documents needed for reproducibility will be available.

Data and documentation needed to reproduce findings from this non-WMO study will be stored for at least 15 years.

7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group. When the UMC Utrecht repository is available, the data package will be published here.

7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

We have not registered this study externally. As soon as we have a DOI-code or have published a dataset in a public repository we shall update this section.

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

For now, only internally, our department will be reusing all research data in the final dataset to generate new research questions.

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

- Yes (please specify)

As the data is privacy-sensitive, we publish the descriptive metadata in the data repository with a description of how a data request can be made (by sending an email to the corresponding author). In the event that peers like to reuse our data this can only be granted if the research question is in line with the original informed consent signed by the study participants. Every application therefore will be screened upon this requirement. If granted, a data usage agreement is signed by the receiving party.

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

All data and documents in the data package mentioned in 7.1 will be shared under restrictions.

8.4 Describe when and for how long the (meta)data will be available for reuse

- (Meta)data will be available after completion of project (with embargo)

8.5 Describe where you will make your data findable and available to others.

After data collection, the data will be frozen for analysis and processed as a .xlsx file. To be able to reproduce the study findings and

to help future users to understand and reuse the data all changes made to the raw data and all steps taken in the analysis will be documented in a text document. The research data will be archived on the research network drive of the division for 15 years after the study has ended

The results of this study will be published in a peer reviewed journal. Upon request and with proper arrangements, other researchers can view the dataset.