Plan Overview

A Data Management Plan created using DMPonline

Title: Emmetropisation of (un)corrected hypermetropia

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Emmetropisation of (un)corrected hypermetropia

Data Collection

1.1 Will you re-use existing data ?

If yes: explain which existing data you will re-use and under which terms of use.

- Yes, I will re-use existing data

For this retrospective study we will re-use existing routinely collected data from Healthcare Information eXchange of University Medical Center Utrecht (UMCU). The data include cycloplegic refractive measurements, spectacle prescriptions, age, sex, the presence of amblyopia, accommodative esotropia, and anisometropia, visual acuity and axial length. No additional examinations or measurements will be performed.

1.2 Describe your data.

Fill the table below with a brief description of the data, including the type, format and volume.

#	Data Description	Data Type	Format	Total Volume
1	Retrospective clinical patient data, including cycloplegic refractive measurements, spectacle prescriptions, age, sex, the presence of amblyopia, accommodative esotropia, and anisometropia, visual acuity and axial length. Approximately 300 patients with 2-3 visits.	Tabular	.csv/.xlsx	Estimated <10 MB
2	Pseudonymised dataset	Tabular	.csv/.xlsv	Estimated < 5 MB

Data Documentation

2.1 Describe the documentation and metadata that you will use to to make your data reproducible and interoperable.

Describe which files you will provide, along with a brief description of the information they will contain, to make your data reproducible and interoperable. Describe the information that you will provide to make the data items in questions 2.1 reusable and interoperable. If using a specific metadata standard, please mention this below.

To ensure data reproducibility and interoperability, the study dataset will be accompanied by a codebook, describing all variables, including their definitions, measurement units, coding of categorical variables and handling of missing values.

The study protocol will document the study design, inclusion- and exclusion criteria, data collection procedure and statistical analysis methods. Data processing and analysing output from SPSS syntax files (.sps) used for data cleaning, variable calculations

and statistical analyses will be retained to enable reproducibility of the analyses.
The pseudonymised dataset will be stored in a structurend tabular format using consistent variable names and coding conventions.
No specific metadata standard is planned.

2.2 Describe the folder structure you will provide to make your data reproducible and interoperable.
Describe the folder structure, naming conventions and/or version control you will use for this project.

Research files will be organised in a structured folder system, separating original data, cleaned datasets, SPSS syntax files, analysis results and study documentation.
Files will be named consistently starting with descriptive names followed by dates and version numbers. Original data will be preserved separately from processed datasets to prevent accidental modifications. Updated files will be saved with version numbers to maintain a clear record of changes.
The folder structure:

- Project Emmetropisation in corrected hypermetropia Folder
  - Original data
  - Cleaned datasets
  - SPSS syntax files
  - Analysis results
  - Study documentation
    - concept protocol_YYYYMMDD_VX
    - definitieve protocol_YYYYMMDD_VX
    - concept article_YYYYMMDD_VX
    - definitieve artikel_YYYYMMDD_VX

Data Storage

3.1. Select the storage solution(s) where you will store and back-up your data.
Select the locations where your data will be stored. You may select more than one. Please describe the storage solution and the backup strategy of your storage solution if it does not appear in the list below.

- Other (please specify below)

Research data will be collected and stored in Castor EDC, a secure electronic data capture system. Access to data will be restricted to authorised personnel.
Data security, storage and backups will be managed according to the procedures of Castor EDC and UMC Utrecht. Statistical analyses will be performed using SPSS.

Data Privacy and Security

4.1 Will you be collecting or using personal data ?

Personal data is any data which, alone or in combination with other information, can identify a living person. Such data must abide by the GDPR and requires additional safeguards and documentation to be processed lawfully.

- Yes, I will collect and/or use personal data

This retrospective study will use existing patient data obtained from electronic medical records (HiX) at the University Medical Center Utrecht. The data include demographic characteristics and clinical information, such as age, sex, cycloplegic refractive measurements and spectacle prescriptions.
The research dataset will be pseudonymised by assigning a unique study ID to each patient. Directly identifying information, such as names and patient identification numbers, will not be included in the analysis dataset.
All personal data will be processed and stored in accordance with the GDPR and applicable UMC Utrecht data protection policies.

4.2 What is the legal basis by which you are collecting and/or processing this data ?

If you are uncertain as to which legal basis applies to your type of research ; please do not hesitate to contact us at info.rdm@uu.nl or by using the "Request feedback" button and leaving a comment alongside this question.

- Informed consent

Patient data will be collected retrospectively from existing medical records. Patients and/or their legal representatives will be informed about the study through an existing Patient Information Form (PIF), and written informed consent will be obtained through the existing research registry before their data are included in the study.

Only data from patients for whom the required consent has been obtained will eb included in the research dataset.

4.3 Select the privacy and security measures you will employ to protect the privacy of your data subjects. Check all that apply.

- Pseudonymization
- Secure storage
- Minimization
- Aggregation/Abstraction
- Access control

Patient data will be pseudonymised using unique study identifiers, with the identification key stored separately from the research dataset. Only data necessary to answer the research questions will be collected.

Research data will be stored in a secure, instutionally approved environment, with access restricted to authorised research personnel. Results will be reported at an aggregated level to prevent identification of individual patients.

Encryption = zijn de bestanden daadwerkelijk versleuteld dan alsnog aanvinken

4.4 Who is the controller of the personal data ?

The controller of the personal data is the entity which determines what is done with the data. In most cases the controller is Utrecht University.

Utrecht university is the controller of the collected personal data. Nevertheless, the principal investigator of the research project will ensure that the data is handled and processed in accordance with the GDPR.

4.5 How will ownership and intellectual property rights of the data be managed?

Describe who controls access to the data and who determines what is done to the data.

The clinical data originate from electronic patient records (HiX) at the University Medical Center Utrecht. UMC utrecht is responsible for the managment and protection of the original patient data. Durting the project, acces tot the research dataset will be restricted to authorised members of the research team. Decision regarding data access, use and sharing will be made in accordance with UMC Utrecht policies and applicable data protection regulations. If any member wishes to grant (temporary) access to others, they should seek approval from the principal investigator.

Data Selection, Preservation & Sharing

5.1 Describe the data you will be preserving and the storage solution where it will be preserved?

Describe which data will be preserved under long-term storage. You may refer back to the data described in question 1.2 to specify which data will be preserved. Explain where you will preserve your data, and how procedures are applied to ensure the survival of the data for the long term.

The pseudonymised research data, including cycloplegic refractive measurements, spectacle prescriptions, and relevant patient characteristics, will be preserved for at least ten years in accordance with institutional guidance.

The data will be stored in Castor EDC, a secure electronic data capture system with controlled access. Access will be restricted to authorised research personnel to ensure data securityuand integrity. Castor EDC is an integrated, secure and (long-term) storage

enviroment.

5.2 Describe the data you will be sharing and the repository where it will be shared?

Describe which data you will be sharing. Select where you will make your data findable and available to others. If selecting "Other" please specify below which repository and provide a URL.

Please also write below if you will apply any conditions to the re-use of your data. (i.e. Creative commons license or Data Transfer Agreement).

- Other

The pseudonymised patient data will not be made publicly available due to privacy regulations, only the non-personal data will be shared. The research data will be stored securely in Castor EDC.

Data may be made available to other researchers upon reasonable request, subject to approval by the responsible research institution and applicable data protection regulations. No public data-sharing licence will be applied.

5.3 Are specialized, uncommon or expensive software, tools or facilities required to use the data?

Please list any specialized, uncommon or expensive software, tools or facilities that are absolutely required to obtain, use or handle your data, if any.

Castor EDFC will be used for secure data collection and managment, and IBM SPSS Statistics will be used for statistical analysis. Both require institutional access or software licences.

No additional specialised equipment or facilities are required. The research data can be exported in standard file formats, such as CSV, allowing reuse with other statistical software

Data Management Costs and Resources

6.1 What are the foreseeable research data management costs and how do you expect to cover them ?

Please specify the known and expected costs involved in managing, storing and sharing your data. Also explain how you plan to cover these costs.

No significant additional research data managment costs are expected. Castor EDC will be used for secure data collection and storage, and SPSS will be used for statistical analysis.

The costs associated with software licences and data storage are expected to be covered by existing institutional facilities at UMC Utrecht. No additional funding is anticipated.

6.2 Who will be responsible for data management?

Please specify who is responsible for updating the DMP and ensuring it is being followed accordingly.

The master student, Maaike Hoogsteder will be responsible for maintaining the DMP up to date.

The principal investigator, Dr. Ossewaarde-van Norel, J., will have responsibility for data managment, including data security, access permissions, and long-term preservation of the research data.

6.3 State if you contacted an RDM consultant from Utrecht University to help you fill out your DMP.

Please list their name and date of contact.
This is mandatory for NWO grants.

An RDM consultant from UMC Utrecht reviewed the Data Managment Plan and provided feedback.

Name: ...

Date of consultation: ...