Cataract Online Refraction Evaluation: A Multi Center Randomized Controlled Trial

A Data Management Plan created using DMPonline

Creator: Janneau Claessens

Affiliation: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Rationale: Cataract is widely prevalent in especially elderly and cataract extraction surgery has thus become one of the most performed surgeries worldwide. In recent decades the safety of cataract surgery has greatly improved and it is considered one of the safest surgeries to be performed. Postoperative management consists of routine examinations within one week, to ascertain no adverse events have occurred immediately after surgery, and between 4-6 weeks, to determine the refractive error. The incidence of serious adverse events following cataract surgery is estimated to be 1%. As a result, the majority of patient visits after cataract surgery will be uneventful. Nonetheless valuable time and hospital resources are consumed. Remote monitoring could replace clinical examinations in selected patient groups. However, this practice of digital remote monitoring which the patient can use independently has not been clinically validated yet. Objective: To determine the validity, safety and cost-effectiveness of telemonitoring after cataract surgery Study design: Randomized controlled non-inferiority open trial Study population: Patients eligible for cataract surgery, without visual acuity influencing comorbidities or predisposing complicating factors.

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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)*	NL74625.041.20
METC number *(only for human-related research)*	21-061
DEC number *(only for animal-related research)*	
Acronym/short study title	CORE-RCT
Name Research Folder	21-061_CORERCT
Name Division	Division of Surgical Specialties
Name Department	Ophthalmology
Partner Organization	
Start date study	19-04-2021
Planned end date study	19-04-2023
Name of datamanager consulted*	D. Steins
Check date by datamanager	29-11-2020

1.2 Select the specifics that are applicable for your research.

- Use of Questionnaires
- Clinical study
- Prospective study
- Multicenter study
- WMO
- Interventional study

Multicenter:

1. University Medical Center Utrecht, Netherlands
2. Maastricht University Medical Center, Netherlands
3. Universitätsklinikum Tübingen, Germany
4. Augenklinik des Universitätsklinikums Ulm, Germany
5. Vienna Institute for Research in Ocular Surgery, Austria

2. Data Collection

2.1 Give a short description of the research data.

The aim of this prospective randomized controlled trial is to investigate the validity, safety and cost-effectiveness of the web-based eye test from Easee B.V. (www.easee.online/umcu-core) for telemonitoring purposes in patients (N=84/42) after cataract surgery.

The UMCU endorsed Castor EDC will be the main data capture platform to randomize eligible patients, automatically send questionnaires, and collect the clinical research data, such as sex, age, visual acuity scores, surgical complications or other ophthalmic abnormalities. The data, including data from the web-based eye test, will be manually entered into the Castor's eCRFs. Some information will be written in the consultation fields and has to be manually extracted from our EDP (HiX).

A total of 4 questionnaires will be automatically send to each study participant by Castor EDC. The outcomes/scores of each questionnaire will automatically extracted through Castor after completion.

In a semi-structured interview (3 months follow-up) we will assess the patient’s attitudes towards telemonitoring. These interviews will be recorded, transcripted and saved in the research folder on the local network drive.

All study sites will collect the same data.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	84	EPD (Hix)	Castor (eCRF)	quantitative	.csv/.sav	0-10GB
Human	84	CatQuest-9SF Questionnaire	Castor (ePRO)	quantitative	.csv/.sav	0-10GB
Human	84	EQ-5D-5L questionnaire	Castor (ePRO)	quantitative	.csv/.sav	0-10GB
Human	84	NEI-VFQ questionnaire	Castor (ePRO)	quantitative	.csv/.sav	0-10GB
Human	42	Triage questionnaire	Castor (ePRO)	quantitative	.csv/.sav	0-10GB
Human	84	Interview on telemonitoring acceptance		audio + transcripted text	.mp3 / .doc	0-10GB
Human	42	Online eye exam (Easee test)	worksheet on AWS S3 cloud	quantitative	.scv	0-10GB
Human	42	Easee exam in AWS S3 cloud	Castor (eCRF)	quantitative	.csv/.sav	0-10GB
Human	84	Adverse Events, SAE's, SUSARs	Castor (eCRF)	qualitative	.csv/.sav	0-10GB

2.2 Do you reuse existing data?

- No, please specify

For this study, we will partially collect pseudonimized data from HiX made available for research by our *Research Data Platform* (RDP). However, because of the prospective nature of this study most research data is new and not yet available to answer our specific research question. Hence, the use of Castor as DCT.

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

Direct identifying personal data, including a key-linking table to re-identify patients, will be stored in an Excel file in a secure research folder. This data is only accessible to the PI, the executive researcher and the division datamanager. Encoded research data (incremental per country & institute code) will be collected and stored in Castor EDC. As mentioned in our stuyd protocol, a participating centre will only have access to their own study records. The executive researcher and PI of the UMC Utrecht will have access to all study records in Castor EDC.

Type of data	**Who has access**
Direct identifying personal data	PI, or executive researcher on behalf of PI (per center) Datamanager
Key table linking study specific IDs to Patient IDs	PI, or executive researcher on behalf of PI (per center) Datamanager
Coded data	Research team (all centers), Datamanager

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

Research data from patients will be collected using electronic Case Report Forms (eCRF) in het UMCU's GPDR compliant Data Capture Tool: Castor EDC. In the eCRF, skips and validation checks are built-in. Data quality will be checked by an independent monitor from Julius Clinical. Data collection will be frozen before analysis.

#	**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.	Data Capture Tool license fee		X	
3.	Storage		X	
4.	Archiving*		X	

*DataverseNL

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.

An agreement on the intellectual property rights is laid down in the investigator initiated study agreement between the UMC Utrecht and Easee BV.

"The parties shall jointly own the results arising directly from the clinical studies. All intellectual property rights and know how owned by or licensed to any of the parties as defined below shall remain the property of the party or its licensor:

UMCU:

- Data on technology acceptance (questionnaires)
- Patient reported outcomes (ie CatQuest)
- Patient selection (i.e. a triaging questionnaire)
- Interpretation of data on pre-operative comorbidities influencing surgical results (i.e. visual acuity, adverse events)

Easee B.V.:

- Know how on how the technology will need to be technically integrated into existing IT infrastructure and data storage, such as API's, data formats and security protocols
- Expertise and know how on user experience and user interaction to ensure users are performing the tests according to the intended use and minimize the risks of misuse, abuse and/or suboptimal user experience
- Expertise and assistance in quality assurance and quality control allowing for use of the technology accord to relevant standards and regulations
- Insights and data on the user experience and results in various demographic groups and use cases encountered during user test sessions and the use of the product outside of the study."

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.

A detailed description on why the data is collected (study objectives) can be found in the Study Protocol.

Which personal data?	**Why?**
Name and email address of participants	To be able to invite participants for taking part in the research and to send them questionnaires
Gender, age	To describe our study population
Test results of digital eye exams	For analysis of study objective
Visual acuity measurements at in-hospital consultations	For analysis of study objective
Information regarding occurrence of surgical complications	For analysis of study objective

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

- Study-specific informed consent

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

All research data are coded and the linking table to personal data is saved in a secure research folder. The key-linking table is only accessible to the PI, the executive researcher and the division datamanager. With this linking table they can re-identify study participants when necessary and deliver, correct or delete the data.

Right	**Example answers**
Right of Access	Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person.
Right of Access	Participants can have access to their own data, if requested.
Right of Rectification	The authorized person will give the code for which data have to be rectified.
Right of Objection	We use informed consents.
Right to be Forgotten	In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias.

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

We use a secure Research Folder Structure for access control. Only authorized research members have access to personal data, including the key-linking table.

For data collection, we use the UMCU endorsed Electronic Data Capture (EDC) tool Castor, which is ISO 27001 & ISO 9001 compliant. To automatically send surveys email addresses need to be added to the records. Added email addresses are encrypted for the users in such a way that users can send emails to subjects without seeing the actual email address. No other personal data besides email address will be used in the EDC.

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

There will be no sharing of direct identifying data. We will use Castor EDC as the database for collecting data.

External centers will manually add the personal data of study participants to the Castor EDC-system. The personal data will not leave the local network drives of the centers. We will use Castor EDC to anonymously send questionnaires to these study participants without seeing the actual email address.

Easee B.V. will collect data regarding the outcomes of the web-based eye exams. These data will be 'study ID'-specific and stored in a GDPR compliant cloud server with encryption (Amazon Web Services S3 bucket, data will be stored in EU). The executive researcher of the UMC Utrecht will have access to the exam results. The study-IDs will be used to link the eye exams to the study participants.

Easee will have no access to the linking tables to identify the patients based on the study IDs. These linking tables will not be transported outside of the network drives of the local centers.

We have confidentiality agreements with all participating centers and a consortium agreement and clinical trial agreement with Easee BV. These agreements are stored in the research folder on the UMCU network drive.

4. Data Storage and Backup

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

UMC Utrecht is initiator of this multicenter study. 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. In other participating sites, data and documentation will be stored accordingly.

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

During data collection, automatic backups will be made in the Electronic Data Capture Tool Castor. Upon completion of data collection, all data are exported and saved in the Research Folder Structure where they are automatically backed up 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.

We will use Castor for collection of data. There will be a data dictionary captured and for every variable this data dictionary contains an explanation of the values. Furthermore, changes in Castor will be recorded in an audit trail.
During data-analysis we will keep track of R-scripts or SPSS syntax.

5.2 Describe your version control and file naming standards.

Track of changes using descriptions of changes per datestamp for each file are stored in a separate Word document.
Furthermore, 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. Every month, we will move minor versions to a folder OLD. The major versions will be listed in a version document (projxVersDoc.txt), stating the distinguishing elements per listed version.

6. Data Analysis

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

We will be using SPSS or R, for statistical analysis of the data (will be decided later). The scripts will contain comments, such that every step in the analysis is documented and peers can read why we made certain decisions during the analysis phase.

7. Data Preservation and Archiving

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

The data package will contain: the raw data (Castor database export), the study protocol describing the methods and materials, the script to process the data, the scripts leading to tables and figures in the publication, a Castor data dictionairy 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.

In view of the regulation for Clinical Trials, I need to store all data for at least 15 years with the goal to be able to go back to patient level.

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.

We will use DataverseNL as certified repository. We will update this section later.

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

We will be using a DOI-code and will update this plan as soon as we have the code.
The trial has been registred in ClinicalTrials.gov: NCT04809402

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.

My peers 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)

Data regarding the online eye exam (its design, functioning and evaluation of the algorithms) of Easee bv will not be made publicly available. Only the test results that are relevant for the study objectives will be made publicly available through publication and a public repository.

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)

Within 1 year after completion of the project, the (meta)data will be available.

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

We will use DataverseNL to make the data findable and available to others.