Plan Overview

A Data Management Plan created using DMPonline

Title: Evaluation and effectiveness of the Dutch Family Clinic for presymptomatic cardiogenetic counseling: a randomized non-inferiority clinical trial

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Template: UMC Utrecht DMP

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Project abstract:

The DNA-poli is an online platform for pre- and post-test counseling for at-risk relatives of probands with inheritable cardiac diseases. The website consists of informative sections, decision support guidance and interaction with a virtual assistant. In this non-inferiority trial, the DNA-poli will be evaluated and compared to current clinical care during several timepoints using an online survey. In the surveys patient satisfaction, decisional conflict, knowledge, quality of genetic care and anxiety will be assessed. The trial is multi-center, although all participants in the intervention group of external centers will be referred to the UMC Utrecht to facilitate the process of online genetic counseling by the DNA-poli.

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Evaluation and effectiveness of the Dutch Family Clinic for presymptomatic cardiogenetic counseling: a randomized non-inferiority clinical trial

1. General features

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

DMP template version	30 (don't change)
ABR number *(only for human-related research)*	volgt
METC number *(only for human-related research)*	23-066
DEC number *(only for animal-related research)*	
Acronym/short study title	DNA-poli trial
Name Research Folder	eCG Clinic
Name Division	LAB
Name Department	Genetica
Partner Organization	
Start date study	23-10-23
Planned end date study	01-11-26
Name of datamanager consulted*	Jaap van Minnen
Check date by datamanager	

1.2 Select the specifics that are applicable for your research.

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

Non-inferiority trial of the intervention: DNA-poli, an online platform for genetic counseling of at-risk relatives of probands with inherited cardiac disease.

2. Data Collection

2.1 Give a short description of the research data.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	250	eCRF	Castor ECD	Quantitative	.csv	0-10 GB

2.2 Do you reuse existing data?

- No, please specify

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

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), coordinating researcher, Datamanager
Pseudonymized data	Research team, Datamanager

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

Experimental data from patients will be collected in an electronic Case Report Form (eCRF) in a certified Data Capture Tool: Castor. In the eCRF, skips and validation checks are built in. Audit trail will be facilitated by Castor. Raw data set will be saved in the research folder.

#	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.

- 3. Castor ECD will be used

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Time of datamanager		X	
2.	Design of eCRF	X		
3.	Data Capture Tool license fee		X	
4.	Questionnaire license fee	X		
5.	Storage	X		
6.	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, this is also described in the collaboration contracts with other participating centers. Our (anonymized) 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

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

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
overarching cardiac disease type in family (not specific variant, but disease group: DCM or HCM)	To tailor the information in the platform to the specific user.
Relation to proband	To indicate first or second degree relatives and to calculate average size of one family/how many families participated.

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.

1. The data are pseudonymized and the linking table to personal data is saved. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data. The procedure can be found: E_ResearchData - 1_MetaData

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 Rectification	The authorized person will give the code for which data have to be rectified.
Right of Objection	We provide study information and ask informed consent in the Castor for control group and on the DNA-poli for the intervention group. Of participants object to participation, regular care will be suggested and provided.
Right to be Forgotten	In the informed consent we state that the study participant can stop taking part in the research. Also, if relatives do not want to participate in the DNA-poli, their personal information will be deleted from the platform. 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.

1. 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.
2. We make use of a certified Electronic Data Capture (EDC) tool (Castor). To send surveys, email address will be used in the EDC, but this is encrypted for the users in such a way that users can send emails to subjects without seeing the actual email address. Also, emails addresses will only be accessible for investigators of the corresponding participating center. No personal data other than 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.

1. In case we need to transport personal data with colleagues, we use Surffilesender with encryption.
2. Whenever necessary we will arrange research agreements and/or Data Transfer Agreement with collaborators. The agreements will be stored at location our department's research folder.

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. For analysis, data will be stored in DRE.

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

1. All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT). For analysis, data is stored on the data share(s) of one/more DRE workspace(s). DRE data shares are stored on Azure according to LRS standard, ensuring data is replicated thrice in the same Azure data center. Additionally, for version history, DRE takes daily snapshots of the data share, and retains these snapshots for 30 days rolling.
2. 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 by the UMC Utrecht backup system.

5. Metadata and Documentation

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

1. For the data collected in Castor, a codebook of my research database is available in Castor.

5.2 Describe your version control and file naming standards.

1. We will keep track of changes using descriptions of changes per datestamp for each file in a separate Word document.

6. Data Analysis

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

1. I have written an analysis plan in which I state why I will use which data and which statistical analysis we plan to do in which software. The analysis plan is stored in the project folder, so it is findable for my peers.

7. Data Preservation and Archiving

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

1. The data package will contain: the raw data, 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 codebook with explanations on the variable names, and a ‘read_me.txt’ file with an overview of files included and their content and use.
2. After finishing the project, this documentation will be stored at the UMC Utrecht eCG Family Clinic research folder and is under the responsibility of the Principal Investigator of the research group.

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

1. 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.

1. 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.

smb://dc1019.ds.umcutrecht.nl/data/LAB/lab_research/RES-Folder-GENETICA/eCG Clinic

/Volumes/LAB/lab_research/RES-Folder-GENETICA

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

I will not publish the dataset in an external repository. Therefore, I do not have a PID.

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.

The research survey data are not expected to be of interest for other researchers. The research survey data is specifically applicable to our local digital innovation (DNA-poli) that we've developed. Therefore, we do not expect the data to be of interest to other groups.
However, in future publications we will state that data are available upon request

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)

Research is not relevant to other researchers, see 8.1 However, if requested, we will make these available after approval of the Principle Investigator. The criteria and time period will be determined on a case-by-case basis.

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

Publication will be open assessable. The study protocol has been published (PMID: 41210372) and this Data Management Plan will also be available.
Along with the future publication on the results, the codebook of the data and scripts of analysis in SPSS/Matlab/R/Python will be made available upon request.

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

- (Meta)data will be available as soon as article is published

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

to be determined when data have become available

Planned Research Outputs

Publication - "Digital technologies in genetic counseling: Recommendations for a morally sound integration"

To address the increasing demand for clinical genetic counseling, digital technologies are currently being developed to increase efficiency and overcome logistical and societal barriers in genetic health care. However, it is not self-evident that genetic technologies will improve the quality of and access to genetic counseling. Moreover, several ethical questions about the appropriate tasks of digital technologies in the genetic care process have been raised, particularly when personal contact is supplemented or even replaced with digital technologies. Ethical reflections on the introduction of digital resources in genetic counseling are scarce. Here, we reflect on 3 central domains in which promises of the digitalization of genetic counseling are generally discussed: (1) promoting patient autonomy and patient-centered care, (2) increasing efficiency, and (3) increasing accessibility. We argue that the benefits of digitalization are not self-evident and are paired with challenges. We conclude by offering 4 recommendations to promote the ethically sound development of digital technologies in genetic health care: (1) specify the intended tasks and expected benefits of the digital technology, (2) identify potential challenges of digitalization, (3) consider the role of end users within the genetic care process, and (4) ensure iterative stakeholder consultation and engagement.

Publication - "Why We Should Understand Conversational AI as a Tool"

Publication - "DNA-poli: Design and development of a digital platform for family communication support and predictive genetic counseling on inherited diseases"

By developing a digital platform ("DNA-poli") we aim to improve the uptake and efficiency of predictive genetic counseling and cascade testing for relatives at-risk of inherited conditions. This is crucial for reducing disease morbidity and mortality while meeting the growing demand for genetic counseling. We outline the design, development, and final concept and prototype of DNA-poli and discuss the challenges faced and how these were addressed.We followed an approach based on the Design Thinking and Human-Centered Design methods, which entails four stages: 1) Discover/Define, 2) Design, 3) Develop, and 4) Deliver. Stakeholders were actively involved through interviews, focus groups, and sounding board consultations. Two inherited cardiac conditions (hypertrophic cardiomyopathy and dilated cardiomyopathy) served as the first use case.The DNA-poli prototype is a digital outpatient clinic for predictive counseling on inherited conditions and cascade testing. It facilitates both pre-test and post-test genetic counseling, including information provision on specific conditions and tests, decision support, collecting medical information from a counselee, and return of results. ARRs can process relevant information online at their convenience and can request genetic tests locally after a short teleconsultation with a healthcare professional. A conversational agent is incorporated to answer questions and collect patient characteristics.DNA-poli is the first digital cardiogenetics platform to encompass the full genetic care pathway for family communication and predictive genetic counseling. Development challenges related to logistical implementation, ethical and legal considerations, and ensuring quality of care standards.DNA-poli allows timely, efficient, and flexible access to predictive counseling, supporting probands with informing their ARRs. ARRs have access to personalized information and modules to support decision-making at their convenience.

Publication - "Evaluation of DNA-poli: Study protocol of a randomized controlled trial to assess a digital platform for family cascade genetic testing and predictive genetic counseling"

ABSTRACTIntroductionThe present uptake of predictive genetic counselling among at-risk relatives (ARRs) for cardiogenetic diseases is suboptimal with 40-50% of ARRs being tested after one to three years post- disclosure. Digital technologies are increasingly proposed to improve accessibility, efficiency, and uptake of predictive genetic counselling and, if desired, predictive genetic testing. Therefore, DNA- poli was developed: a digital platform providing family communication support and pre- and post-test genetic counselling for ARRs. The online DNA-poli aims to decrease the threshold for ARRs to seek genetic counselling without compromising the quality of care while increasing the efficiency of genetic care. Here, we describe the study protocol for a randomised controlled trial evaluating DNA- poli in clinical practice.Methods and analysisA non-inferiority multicentre randomised controlled trial with parallel-group design will be conducted. The intervention group using the DNA-poli platform will be compared to a control group receiving regular counselling. Probands with hypertrophic or dilated cardiomyopathy in whom a (likely) pathogenic variant in specific genes with definitive gene-disease validity is identified, will be included like their ARRs and physicians. The primary outcome is the uptake of cardiogenetic counselling six months post-disclosure with an extended follow-up of one year and stakeholders' experiences. Secondary outcomes are informed decision-making in ARRs, empowerment, and the satisfaction of all stakeholder groups. In addition, the efficiency of consultations and the genetic care process will be analysed. Descriptive and inferential statistics will be performed to analyse data.Ethics and disseminationThis study protocol was exempted from approval by the Medical Ethical Committee NedMec because the Act of Medical Research Involving Human Subject (WMO) was not applicable (no. 23-066/C). Study findings will be shared with stakeholders, published in journals, and will be presented at both international and national conferences.Registration detailsNCT06431425ClinicalTrials.gov

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Planned research output details

Title	DOI	Type	Release date	Access level	Repository(ies)	File size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Digital technologies in genetic counseling: Recomm ...	10.1016/j.gim.2025.101370 ...	Publication	2025-04-01	Open	None specified		None specified	None specified	No	No
Why We Should Understand Conversational AI as a To ...	10.1080/15265161.2023.2191039 ...	Publication	2023-05-02	Open	None specified		None specified	None specified	No	No
DNA-poli: Design and development of a digital plat ...	10.1016/j.pec.2025.108746 ...	Publication	2025-07-01	Open	None specified		None specified	None specified	No	No
Evaluation of DNA-poli: Study protocol of a random ...	10.1016/j.gimo.2025.103456 ...	Publication	2024-11-05	Open	None specified		None specified	None specified	No	No