Plan Overview

A Data Management Plan created using DMPonline

Title: DIRECT-study

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Project abstract:

Targeted surveillance of at-risk relatives in families with confirmed hereditary cancer is a proven effective method for cancer prevention. Current clinical practice in Sweden, and most other countries, involves asking the patient herself to inform at-risk relatives. As this type of family-mediated disclosure is not very effective less than half of at-risk relatives actually receive information - effectively stopping those affected from making informed decisions about their health. This study is evaluating two alternative protocols for disclosure of genetic information in high-risk families; the current family-mediated pathway and a healthcare-assisted disclosure pathway with personalised letters sent directly to at-risk relatives. The research results will help us answer if an intervention with direct letters addressed to at-risk relatives influence the proportion of relatives contacting a Swedish cancer genetics unit within 12 months, as compared with standard family-mediated disclosure?

The study’s main component is a randomized controlled trial (RCT). It will be conducted at four Swedish cancer genetics units involving families with increased hereditary risk of developing breast, ovarian or colorectal cancer.

Besides the described intervention, a mixed method follow-up study will measure qualitative and quantitative outcomes through questionnaires and in-depth interviews.

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DIRECT-study

General Information

Project Title

Direct letters to at-risk relatives –A randomized controlled trial on healthcare-assisted versus family-mediated risk disclosure in families with hereditary cancer in Sweden (The DIRECT-study)

Project Leader

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Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

Data regarding participants/families will be collected by trained professional healthcare staff in the participating clinics according to the study protocol instructions, utilizing pre-defined Case Report Forms and pre-defined variables.
Recruitment, eligibility assessments, inclusion and randomization of research participants at pre-defined time points is integrated in the clinical care at the cancer genetic clinics involved in the study (4 sites in Sweden: clinical genetic clinics in Lund, Gothenburg, Stockholm and cancer genetics clinic in Umeå).
Most documentation will be done by the assigned research nurse/ collaborating staff at each unit who is conducting the genetic counselling with the participating patients, and research data is handled with the same security level as any other patient data on the clinic before being handed over to the national secretariat.

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

The four cancer genetic clinics involved in the study will collect and document necessary data points related to the study outcomes. Our research study will collect:

1. **Personal patient data** including name, birthdate, local clinical identifier, address, preference on communication channel and compliance with each of our inclusion criteria. During the recruitment medical data is added once available – i.e results from

genetic diagnosis.
2. **Outcome data** in the form of family data and genetic investigation results as well as information about number of at risk relatives for each study participant, and whether these have made contact with a cancer genetic clinic at the time of outcome summary (T=12).
3. **Patient Reported Outcome Measures** regarding wellbeing, stress, anxiety etc. (through validated instruments at time points T=0 and T=6 months following initial risk disclosure to the participant.
4. **Screening log and inclusion log** will be kept locally as temporary documents to enable invitation, recruitment and inclusion.

The research database designed in the Access Software environment will contain transferred variables from CRF1 and CRF3 as well as questionnaire data to enable analysis, sub-group analysis and comparison of study groups in regard of the pre-defined outcome measures. The Research Database will only hold variables in relation to the specific individual study participant number (for personal identification one would need the data key kept locally at the study clinics or in the raw data CRF1). These data keys will be destroyed as soon as the analysis in the project is complete, checked and verified (current estimated storage 15 years).

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

Personal data will be collected on paper format in Case Report Forms mailed to the national secretariat. Data will then be transferred to data points in an Access Database File format. Our data manager/statistician manage the database.

Survey data (patient-reported outcome measures) will be collected with both mailed paper surveys and the national electronic survey instrument module "formulärtjänst" from INERA. Electronic survey data will be exported to a safe IT-folder with limited access at G:/RCC/DIRECT within the Region Västerbotten IT-environment and then moved to the "skyddad filyta". The analog survey data will be transferred to the database manually and controlled to ensure good data quality.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

Recurrent audits are conducted as part of the follow-up of data from the study sites. Standard protocol built-in data control also occurs continuously as analog CRF:s arrive at the secretariat and data is digitalised. Thus, the compilation of data includes manual data checks. The responsible researcher audits the incoming case report forms 1 and 3, ensuring that all incoming data is of good quality before inclusion in the research database. Once transferred to the DIRECT Access Database, recurrent controls are carried out by the datamanager to check if data is complete and all variables are in place.

Our statistical analysis plan (SAP) is publicly available in the officially available study record at ClinTrails.gov published ahead of study commencement.

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

Paper-based documentation (CRF’s and consent forms) are kept at each study clinic with restricted access exclusively to eligible healthcare staff. The units who use specialized patient data software (i.e. Progeny) to administer study participants do so within the IT-environment with the same patient safety levels required for any healthcare provider in Sweden. Only pre-defined data points are forwarded to the research database through mailing of CRF's to the secretariat.

Once collected, original CRF-documents are digitalised and then archived. Collected data will be stored for 15 years as required by the Swedish archive law (SFS 1990:782).

Digital screening- and randomization logs are held locally and data transferred by secure IT-solutions to the secretariat upon recurrent follow-up. Umeå university and Region Västerbotten IT-services have assisted the research project with creation of study-specific secure file folders in each IT-environment, with automated back-ups every 15 minutes up to 90 days past an erasing incident, ensuring possibilities to retrieve data in the case of accidental loss of documents.

The research data base and raw data imports are managed operationally by a qualified statistician with experience in handling of patient data, quality registries and data safety issues. Only the eligible research team involved in the project has access to the database and secure folders holding associated with the DIRECT-study.

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and

personal data, for example?

All data managed in the project is handled according to the EU general data protection act (GDPR) and Swedish patient safety standards. Data collection and handling has been pre-approved by the national Ethical Review Authority (Etikprövningsmyndigheten) and will be carried out with the legal basis of public interest.

Study related data handled in the clinical setting are protected by firewall, SITHS-identification (for healthcare staff) and logs have an additional safety level by requiring unique identifier log-in (multi-factor authentication) for research staff at the participating clinics.

All data which is shared between participating research stakeholders (utlämning av forskningsuppgift) are done through encrypted tools and safe FTP-solutions provided by the county council and university IT-services.

Final storage and archiving of research databases will be placed on a dedicated Umeå University electronic file location on local servers meeting the high safety standards for sensitive personal data "Skyddade document".

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

Legal: We will handle sensitive personal data according to GDPR-regulations, on the basis of performing a state delegated mission AND based on informed consent by participants in the study. All access to medical records is done within the clinical setting, by the healthcare staff involved in the care of the patient, and only data in pre-defined structured case report forms (CRF’s) are relayed to the research team.

IP: Instruments used in the follow-up study include the Cancer Worry Scale (CWS), RAND-36 (health and wellbeing items) and the Stait Trait Anxiety Inventory (STAI). These instruments have been chosen to cover the research questions addressed and all are in versions available from the common domain.

How is correct data handling according to ethical aspects safeguarded?

All eligible patients are invited to the study with written and spoken information and consent forms are collected for each participant. The information and consent form (forskningspersoninformation, FPI) is approved by the National Ethical Review Authority (Etikprövningsmyndigheten) and includes required items about patients’ rights to access collected data, withdraw from the study at any time, possible hazards, future dissemination or research results etc.

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and reuse of data to be considered?

The raw data in our study includes too much personal and sensitive data to effectively be anonymized with any retained research value. We have therefore been advised to keep the raw data in secure storage, with unique access retained by involved researchers, at whom questions will have to be directed.

If possible, we plan to make appropriate standard format metadata available through the Swedish National Dataservice (SND) repository after publication of the results.

Variable descriptions are included in the files and research team members contacts are available in both stored files and in public study records.

The research statistician in the team will handle any meta data indexing according to the recommended standards in the field.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

All relevant research data generated in the DIRECT-project will be stored as required by law within the appropriate IT-environment recommended by Umeå University IT-services at the end of the project period. Analog paper data (such as CRF's and consent forms) will be stored in secure archiving facilities associated with The Department of Radiation Sciences, Umeå University.

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

Only standard easy-access file formats will be used for the digital long term storage of research data in order to facilitate access if needed in the future.

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

If applicable, the repository publishing our metadata will automatically assign a Digital Object Identifier (DOI).

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

Barbro Numan Hellqvist is in charge of the databases and overall data management. Dan Harnesk has the responsibility for overall information security at Umeå University.

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

The project funds a part-time data manager statistician for the running of the project. Additional staff resources for operational management of the project will provide resources to fulfil the fair principles - in this case regarding metadata from our study. Financing of necessary IT solutions for secure storage and archiving of databases and raw data materials are covered within the budget of the project.