Plan Overview

A Data Management Plan created using DMPonline

Title: Primary care Online Emotion-regulation Treatment (POET)

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Project abstract:

Mental health problems in youth is causing incalculable suffering in youth and families. Existing treatments in primary care are not fully addressing these problems because they focus on a subset of mental health problems; are limited in efficacy, and are not provided to most youth in need. Transdiagnostic online treatments addressing mechanisms underlying mental health problems, such as emotion regulation, have been called for. We will include 388 participants aged 12-17 years and their parents in a randomized clinical trial comparing a 6-week Primary care Online Emotion-regulation Treatment (POET) to a 6-week active Supportive Treatment (ST) during 2023-2025, at several primary care clinics across Sweden. Both interventions will be delivered in blended format combining online therapist-supported treatment modules with a video-link session. Findings from our pilot randomized clinical trial (N=30) demonstrated that the trial procedures and treatment protocols are feasible and that POET are promising. The primary study aims are to examine the effects of POET vs ST at post-treatment, 3-, and 12-month follow-up on mental health problems, emotion regulation, and to test whether changes in emotion regulation mediates reduction in mental health problems. The broad long-term goal is to examine cost-effectiveness, for whom the treatment is efficacious, and to show how a brief treatment provided in youth in a primary care setting may have a positive impact on the trajectory into young adulthood.

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Primary care Online Emotion-regulation Treatment (POET)

Description of data

How will data be collected, created or reused?

- Clinical interviews with respondents
- Self-reported information
- Recording of interviews
- Registry information

What types of data will be created and/or collected, in terms of data format? Include version numbers if applicable.

- Data from clinical interviews and self-reports will be exported from Karolinska Institutet's eHealth Core Facility online data collection platform called BASS and saved in .CSV format
- Recording of clinical interviews and therapy sessions will be saved in .MP3 format
- Register data will be received in spreadsheet format and will be converted to .CSV format before analysis

What volumes of data will be created and/or collected?

- < 100 GB

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, file naming-format-versioning, etc

- Documentation will include a standardized folder structure, analysis plans, input and output files from databases and statistical software
- All files will be named according to the date of acquisition and put into folders.
- All trial details will be documented at KI ELN. We will use templates when applicable, which ensures standardized operating procedures.

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

- Data will be checked at the point of entry in BASS for double entries, completeness, missing data and unreasonable values.
- The register holder assures data quality in terms of completeness and correctness of registration.

Storage and backup

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

- KI Server

- Working datasets, and metadata will be stored on a P folder at a central IT server
- Data saved in ELN/BASS//KI servers is backed up.
- KI ELN be used for the documentation of all analyses and results.

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

- Access to the documentation stored in ELN/BASS/KI servers is restricted to group members.
- Access to data saved in ELN/BASS/KI servers requires user authentication with password.
- Data saved in ELN/BASS/KI servers is backed up.
- Access to ELN/KI servers is permitted only when on KI premises or by VPN or MFA
- For ELN/BASS/KI servers , data access is based on an individual's role in the project.
- ELN/BASS provide audit trails for tracking data changes and user activity
- We only work with pseudonymized data, with the key stored on KI server and to which only the PI, project coordinator, and research coordinator have access to.

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?

- Sensitive personal data will be handled according to GDPR. (https://staff.ki.se/gdpr).
- Data will be pseudonymized and a key will be kept separately from the data.

How is correct data handling according to ethical aspects safeguarded?

- Participant data is pseudonymized with the key stored on KI server.
- The ethical aspects will be safeguarded by the principal investigator.

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, licenses and limitations on the access to and reuse of data?

- Analysis scripts and other developed code will be stored on KI server and uploaded to Github.
- Also aggregated results will be shared in publications. Underlying raw data are considered personal data as per GDPR and can be shared with other researchers only upon drafting appropriate data sharing contracts

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

- Long-term storage will take place at the server at the Institution and in ELN. Data will be stored at least 10 years after publication. The data will include raw data and the final data analysis file.

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

- The participant data can be read by any software compatible with .csv files
- Recording of clinical interviews and therapy sessions can be opened by any software compatible with .MP3 files

How will unique and persistent identifiers for the research data, such as a Digital Object Identifier (DOI), be obtained?

Question not answered.

Responsibility and resources

Who is responsible for data management while the research project is in progress?

- Data management is performed by a dedicated PhD-student under supervision by the PI and a dedicated data manager in the research group, who is an experienced researcher with a PhD

Who is responsible for data management, long-term storage after the research project has ended?

- The PI is responsible for data management and the archive function will be responsible for long-term storage

What resources (costs, labour or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)?

- Salary for the data manager in the group is partly funded by this project

What resources will be needed to ensure that data fulfil the FAIR principles?

Because of the personal nature of data the FAIR priciples will be fulfilled on a case by case basis. All data will be shared if this is in agreement with current regulations. Possibly ethical amenments will be done to facilitate this.