Plan Overview

A Data Management Plan created using DMPonline

Title: Effect, Cost-effectiveness, and Usefulness of the Everyday Life Rehabilitation Intervention

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Project abstract:

People with severe psychiatric disability and impaired autonomy, living in sheltered or supported housing facilities, generally lead sedentary, solitary lives, indoors, and have significantly poorer health than others in the population, while additionally, they do not have access to equal and cost-effective health care, despite being one of the highest priority groups. Engagement in everyday activities, is important for the recovery towards a meaningful and active life. The recovery-, activity-based, and personcentred interventionmodel Everyday Life Rehabilitation (ELR), integrated in sheltered and supported housing facilities, has shown significant outcomes in feasibility studies, and thus an RCT is required, ***for the purpose of establishing the effectiveness of ELR, along with cost-effectiveness and usefulness.***

All municipalities within 270 kilometres from Umeå University, will be invited. Housing-units, with associated residents giving consent, will then be block-randomized to either receive intervention with ELR plus treatment as usual (TAU), or TAU alone for control-group. These will, after control-period, be offered ELR. Professionals involved in the ELR interventiongroup; that is occupational therapists and housing staff, will receive an educational package.

The outcomes are self-perceived recovery, quality of life, everyday functioning, and goal-attainment at 6 months, assesed using the ReQoL, RAS-DS, and GAS. ReQoL will be transformed into QALY´s.

The study has an adaptive design, including an internal pilot, in order to determine required sample sizes before continuing with the full scale RCT.

In parallell, qualitative studies and process evaluations will be conducted. Mixed methods will be applied to synthesize knowledge on usefulness.

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Effect, Cost-effectiveness, and Usefulness of the Everyday Life Rehabilitation Intervention

Administrative information about the research project

Project title:

Effect, Cost-effectiveness, and Usefulness of the Everyday Life Rehabilitation (ELR) intervention

Principal investigator:

Maria Lindström,
Dept of Community medicine and rehabilitation,
Umeå University

Contact person:

Maria Lindström,
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Responsible organization:

Umeå University.
Who is responsible for what is established in the study protocol.

Project description:

We intend to study the extent to which the intervention under study; the Everyday Life Rehabilitation (ELR), is an effective, cost-effective, and useful model for co-planned rehabilitative services in LSS- and SoL-housing facilities, aiming at supporting residents´ personalised recovery pathway.

The overall aim of the project is to investigate the usefulness, effectiveness, and cost-effectiveness of a personcentred, co-planning, recovery-, and activity-based intervention package for people with SPD living in sheltered housing facilities.

The specific research questions (RQs) are as follows 1-3:

RQ 1. What is the effectiveness of ELR intervention on recovery, quality of life, everyday functioning, symptom relief, and goal attainment, compared to Treatment as usual (TAU)?

RQ 2. What is the incremental cost-effectiveness ratio (ICER) for ELR compared to TAU?

RQ 3. How acceptable and useful is ELR to residents, occupational therapists (OTs), housing staff (HS), and housing managers (HMs) – and is it perceived different related to men and women?

We intend to study the extent to which the intervention under study; the Everyday Life Rehabilitation (ELR), is an effective, cost-effective, and useful model for co-planned rehabilitative services in LSS- and SoL-housing facilities, aiming at supporting residents´ personalised recovery pathway.

Funding:

The project is funded by the Swedish Research Council for Health, Working Life and Welfare, grant number: 2021-01391.

Other information relevant for project administration:

Data-administrator: Ulla Nygren

Statistician: Per Liv
Health economist: Lars Lindholm
Process-data: Carolina Klockmo, Maria Holknekt

Data description and collection or re-use of existing data

How will new data be collected or produced and/or how will existing data be re-used?

Data is collected from a clinical trial with Everyday Life Rehabilitation (ELR) – a pragmatic, two-parallel-arms, cluster randomized controlled trial over two years, and simultaneous collection of process-oriented data, mostly of a qualitative nature, over three years.
Recruitment of participating municipalities, and the cluster-randomisation of housing units, precedes the recruitment, eligibility, and inclusion of participants (residents) within each participating housing facilities, at pre-defined time points, integrated in the municipal health- and social care at municipalities in northern Sweden (Västernorrland, Västerbotten, and Norrbotten).
The quantitative data consist of:
1. Recovery, quality of life, and daily functioning data, collected in the intervention- and control-group pre-post intervention, using valid and reliable paper-questionnaires with predefined variables, answered by participants(residents) of sheltered or supported housing facilities. Data will be collected by blinded testers, who are trained occupational therapy students with previous experience of the target group and context.
2. Goal Attainment Scaling; a valid and reliable method for evaluating goal attainment of intervention, using person-driven goals, predefined in different levels of expected goal-attainment before intervention and evaluated after intervention. The assessment is made by the occupational therapist (OT) and data is sent by the OT to to the research administrator. An independent person will monitor the GAS difficulty level, in order to ensure that they do not choose too easy targets or change afterwards.
The qualitative data consist of:
3. Documentation of process-data done by the housing managers (monthly follow-ups with staff), assigned occupational therapists (process-protocols) and collaborating housing staff (checklist) at each unit, who are conducting the intervention with the participants, and research data is handled with the same security level as any other patient data on the site, before being handed over to the research group.
4. Qualitative interviews will be conducted by research staff, including a smaller selection of participants (residents), housing managers, housing staff, and OTs, in close proximity to the RCT.
Data from staff can be reported to study administrator using mail if data is fully anonymised. If there is a risk for identification of research subject, they are instructed to send the data by postal system.

What data (for example the kinds, formats, and volumes) will be collected or produced?

Data formats include:
- patient/resident data (including name, address, date of birth, self-reported diagnose, and basic demographics)
- participant reported outcome data (health, recovery, and quality of life data)
- level of goal attainment data
- process-protocol data
- data from follow-up protocols with staff
- checklist data
- qualitative interview data

Data from paper questionnaires will be entered manually into Excel files. Excel files will be imported into statistical software programs, and copies of data will be stored in SPSS-format. Audio files will be transcribed into word-files, and copies will be stored in fire safe lockers.

Documentation and data quality

What metadata and documentation (for example the methodology of data collection and way of organising data) will accompany the data?

A short code book, including a variable list with an explanation for each variable will be produced and stored together with quantitative data files. Meta data will also be listed in SPSS-files, as a brief label for each variable importance for analysis.

What data quality control measures will be used?

Data validation when entering data from paper questionnaire will be performed using the internal Microsoft Excels function, to avoid registration errors. Data will be checked for unusual quantitative measurements by the study statistician Per Liv, after closing data collection after first and second study wave, respectively. Any unexpected registered values will be validated against corresponding paper questionnaire.

Storage and backup during the research process

How will data and metadata be stored and backed up during the research process?

Paper questionnaires and other outcome data in paper format, process protocols, checklists, audio recordings and transcribed interviews will be archived in fire-safe cabinets.
Databases, along with metadata, will be stored on Umeå university's servers and will be backed up continuously. Local copies of data file will be handed out to the researchers within the research group during the analysis phase of the study, to be stored password protected. After analyses, local copies of data is to be returned to the PI.

How will data security and protection of sensitive data be taken care of during the research?

All data-collection and data-handling is approved by the Swedish Ethical Review Authority, and by informed consent from the study participants. Storing of personal information and registration will follow the GDPR. Documents are saved as password protected documents.

Umeå University, and the project team, are responsible for following the Swedish Ethical Review Authority´s information on the handling of personal and sensitive data. Likewise, the main responsible operation managers at each participating municipality who have agreed to participate in the study, and thus also undertaken to follow the research scheme including all participating activities, are previously informed about the research project and the planned implementation, and the responsibility of municipality resources that guarantee the research persons´ safety and integrity in conducting the research as described and agreed.

Legal and ethical requirements, codes of conduct

If personal data are processed, how will compliance with legislation on personal data and on data security be ensured?

All data-collection and data-handling is approved by the Swedish Ethical Review Authority and by informed consent from the study participants. All data handling will follow the GDPR.
All data will be stored securely in line with local data management arrangements. Staff are informed not to email sensitive data. Personal identifiable paper records, such as informed consent, will be stored separate from anonymised paper records.
Only research staff, trial administrator (Ulla Nygren), and OTs of the municipalities will have access to the study-data during the data-collection, analyses, and publication phase. Data on paper will be stored in lockable locations, and electronic data will be stored in password-protected locations, pseudonymized, or encrypted. Research data will be stored using a trial identification code for each participant. The code-list key will be documented and safeguarded by the trial administrator (UN) during data-collection, data analyses, and publication phase. Thereafter, the code-list key will be safeguarded by the PI, according to guidelines after the completion of the study.

How will other legal issues, such as intellectual property rights and ownership, be managed? What legislation is applicable?

All data-collection and data-handling is approved by the Swedish Ethical Review Authority and by informed consent from the study participants. All data handling is done in accordance with GDPR.
Co-authors of the studies own the intellectual property rights. External cooperators may be involved, by the decision of PI.

PI is given the right to the final decision about requests on data sharing.

How will possible ethical issues be taken into account, and codes of conduct followed?

The project is approved by the Swedish Ethical Review Authority (Dnr 2020-06220), where data handling also is described. We will conduct this project in such a way as to protect the human rights and dignity of participants, as reflected in the Helsinki Declaration. We will conform to Good Clinical Practice (GCP) guidelines, data protection, and freedom of information acts. Storing of personal information and registration will follow the GDPR.

The proposed trial poses small risk to the participants. The interventions offered via Everyday Life Rehabilitation (ELR) have shown preliminary evidence and do not expose the research subject to further risk or injury compared to Treatment as Ususal (TAU). Yet, the municipality delivery of and adherence to intervention is crucial. Also, the trial procedures are decisive. Therefore, the internal pilot during first wave will serve as a review, used as basis for decisions on updating the required sample size, investigating and improving feasibility, and any other need for adaptations before continuing with the full-scale RCT in the second wave.

All eligible persons are invited to the study with written and verbal information and consent forms are collected for each participant. The information and consent forms are approved by the Swedish Ethical Review Authority and include required items about participant´s rights.

Participants will receive continuous information about the study set-up and importance of follow-up. Trained, blinded testers will support data-collection.

Participants can leave the trial at any time for any reason, without consequences. The participation can also be ended by the investigator or Occupational therapist (OT), if the participant is in acute psychosis or acute suicidal risk.

In addition, the OTs are responsible for reporting adherence to the intervention and process protocol and to the checklist for collaboration. The Housing managers are responsible for reporting monthly follow-ups with staff. The leads/contact persons of the municipalities are responsible for reporting any other departure from the protocol.

Data sharing and long-term preservation

How and when will data be shared? Are there possible restrictions to data sharing or embargo reasons?

Regarding reuse of data, it will be very limited, and decided by PI, due to the character of target group and sites. The proposed research will involve relatively small samples, recruited from municipal housing facilities for persons with severe psychiatric disabilities (SPD). The rare and specific type of settings are associated with distinguished features, as well as conditions. Even if all IDs are removed, we judge that there is a risk of potential threat to integrity, and not possible to protect the identities of subjects and type of data we will collect, due to the relatively restricted area from which we are collecting data. Therefore, we are not planning to share the data with anyone other than those involved in the research group and associated co-authors.

The datasets will only be available to the research team and associated co-authors, during the trial analyses and publication phase. The datasets used, can be made available by the PI, for review upon reasonable request, and in agreement with data transfer guidelines.

How will data for preservation be selected, and where will data be preserved long-term (for example a data repository or archive)?

After the study has ended, the local copies of data are returned to PI Maria Lindström, who will archive them for a minimum period of 10 years.

Registered raw data in comma-formatted text files in read-only mode and audio files will be stored on the servers of Umeå University along with a code book containing meta data.

Umeå University is responsible of taking relevant organizational and technical measures to ensure data protection in accordance with current rules. Also, that the information is preserved in accordance with constitutional requirements.

What methods or software tools will be needed to access and use the data?

Data will be archived in text file format to facilitate reading data using any software.

How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?

DOI will not be applied.

Data management responsibilities and resources

Who (for example role, position, and institution) will be responsible for data management (i.e. the data steward)?

The independent administrator, Ulla Nygren, is responsible of the safeguarding and storage of data during data-collection and analyses phases. When data-collection is finished, PI Maria Lindström is responsible for storing and archiving data.
Per Liv is responsible for data-processing (quantitative data).
Maria Lindström is responsible for data-processing regarding qualitative data.

What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

Funding for Per Liv as a study-statistician, and Ulla Nygren as a study-administrator is available. Umeå University offers an infrastructure for storing and backing up data.