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## PROTOCOL FOR A PARTICIPATORY SURVEY TO INVESTIGATE THE LONG-TERM EFFECTIVENESS OF ADULT PSYCHIATRIC SERVICES (PSILEAPS): A PROSPECTIVE EXPLORATORY COHORT STUDY

### ABSTRACT

*Mental health research and practice is currently moving beyond a focus on group-level symptom reduction models. Hence, research and treatment increasingly emphasize the real-life individual needs of service users and their social networks. One example is the Open Dialogue approach (OD), which has demonstrated promising outcomes in the Finnish Western Lapland (WL) catchment area. Nevertheless, it is unclear how OD-based services have so far been maintained in WL. It is also unclear how the experiences of multi-disciplinary care teams, service users and their social network members differ, with regard to differing approaches to mental health treatment. More generally, there is a global need for information on factors associated with the long-term treatment outcomes of real-world mental healthcare. This project – a participatory survey to investigate the long-term effectiveness of adult psychiatric services (PSILEAPS) – aims to address these questions. The survey will take place over a two-week period. It will be aimed at all five WL catchment area adult mental health units, and will cover care team members, service users and members of their social network. These will be asked to share their thoughts on (i) why mental health services have been needed in the case in question, and (ii) what factors in the treatment have been helpful or unhelpful. The service users who participate will form a research cohort, which will be followed over five years. Information on demographic and clinical characteristics will be obtained from social and healthcare registers at baseline, and at two- and five-year follow-ups. The primary outcome variables at follow-up will be treatment contact at follow-up, disability allowance at follow-up and death during follow-up. Exploratory statistical analyses will be used to study how different variables (including the main principles of OD) are associated with different outcomes. The information can be used to create new hypotheses to guide future research, and to develop mental health services. The participatory design will enable service users to join in the co-production of knowledge. This has the potential to immediately guide and improve their mental healthcare.*

**KEY WORDS:** COMMUNITY MENTAL HEALTHCARE; COST-BENEFIT ANALYSIS; LONG-TERM FOLLOW-UP; NEED-ADAPTED APPROACH; OPEN DIALOGUE APPROACH; PATIENT INVOLVEMENT; SERVICE USERS; TREATMENT OUTCOME

## BACKGROUND

In evidence-based psychiatry (EBP) the aim is primarily to produce group-level information in order to guide general treatment procedures (1). The main focus in EBP is usually on measurable symptom reduction, with the possibility of subsequent confirmatory efficacy studies on specific and predefined treatment methods via randomized controlled trials. Nevertheless, although EBP has indeed produced generalizable information to support medical decision making, in practice the way in which it is sometimes (mis) understood and applied may neglect the more existential factors in mental healthcare, including long-term social functionality, personal causal beliefs regarding mental distress, service users' own treatment preferences and the real-world effectiveness of mental health treatment (1,2).

The World Health Organization (WHO) (3) and the United Nations (4) have recently expressed concern regarding the current state of global mental healthcare. There has been no improvement in long-term treatment outcomes, and many countries have witnessed a significant growth in mental health disabilities (3). Moreover, in many countries the longevity gap between people with severe mental disorders and the general population has been widening (3,5,6). WHO (3) has urged radical changes in the global practice of mental health treatment and research. It takes the view that in addition to EBP group-level symptom reduction models, research should pursue methods that take better account of the actual causes of human suffering, and the individual needs of both patients and their social networks.

One example included in the WHO (3) guidance is the *Open Dialogue approach* (OD), which originated in the Finnish Western Lapland (WL) catchment area (Länsi-Pohjan sairaanhoitopiiri). Within this area, on the basis of naturalistic research integrated with everyday clinical practice, a new way to organize and practise mental health treatment was introduced (7). Thus, instead of structured diagnostic procedures and predetermined standardized treatment methods (aimed at immediate symptom reduction), the mental health services in the WL catchment area aimed to gather all relevant people together as soon as possible, in order to create a shared understanding of each situation within reciprocal dialogue (7). After a dialogical response to the mental health crisis, various treatment approaches were integrated, according to the actual and current needs of each individual and their social networks, crossing organizational boundaries as necessary (8).

In naturalistic studies, OD has demonstrated improvements in mental health treatment outcomes and in social functioning in comparison with standard care (7,8,9,10,11,12,13,14). However, uncertainty remains concerning the elements of OD that are beneficial in different situations (15), and the extent to which the treatment approach has been maintained in WL mental health services after the original research projects (8). Moreover, there is a lack of information on how clinicians, service users and their social network members experience different treatment approaches, including the main principles and other characteristic features of OD. More generally, there is a global need for information on how different baseline characteristics, treatment strategies and personal treatment preferences are associated with long-term outcomes in real-world clinical settings.

These questions will be addressed via the prospective exploratory cohort study entitled *a participatory survey to investigate the long-term effectiveness of adult psychiatric services* (PSILEAPS). The study will use structured questionnaires in conjunction with actual treatment outcomes from current psychiatric services in the WL catchment area. The study design will apply a participatory research approach, including grass-roots treatment evaluation, integrated with everyday clinical practice.

## METHOD

### OBJECTIVE

The general and detailed research questions in the PSILEAPS study are framed as follows:

1. What is the nature of the mental health treatment applied in the current services of Western Lapland?
  1. How are OD principles generally applied?
  2. How are the different baseline characteristics (e.g., unit, care team characteristics, and service users' demographic and clinical characteristics) associated with different treatment strategies?
2. What is the opinion of mental healthcare *professionals* in the Western Lapland catchment area regarding mental health problems and their treatment?
  1. Do the professionals view biological, social or psychological factors as dominant in terms of causality?
  2. How are the different baseline characteristics (e.g., work experience, on-the-job-training, profession)

associated with causal beliefs?

3. In what ways are causal beliefs and other baseline characteristics associated with treatment preferences?
4. Are care team members able to work according to their own preferences? If not, what are the main obstacles to this?
3. What is the opinion of mental healthcare *service users* and their social network members regarding mental health problems and their treatment?
  1. Do they view biological, social or psychological factors as dominant in terms of causality?
  2. How are baseline variables (e.g., clinical and demographic characteristics) associated with their causal beliefs?
  3. How are causal beliefs and baseline variables associated with treatment preferences?
  4. Are there differences in causal beliefs and treatment preferences between service users, social network members and care team members?
  5. What kind of treatment have service users received, and has the treatment related to their personal treatment preferences? If not, what are the main obstacles to this?
4. What is the long-term outcome of mental health treatment, and what factors are associated with it?
  1. How are different baseline variables (e.g., unit, care team characteristics, and service users' demographic and clinical characteristics) associated with long-term outcomes?
  2. How are different treatment strategies and methods associated with long-term outcomes when adjustment is made for potential confounders (e.g., service users' demographic and clinical characteristics)?

It is anticipated that exploratory data analysis will generate new hypotheses on factors associated with (i) service users' and service providers' treatment preferences, (ii) real-life community-based mental health treatment practice, and (iii) the long-term outcomes of real-life mental healthcare. At the same time, it will be possible to obtain descriptive information on how the main premises of the Open Dialogue approach are maintained in the WL region, and the factors associated with this. The data can be used to create new hypotheses on the effectiveness of community mental health services in general, and on OD in particular.

On the basis of earlier studies, it is expected that three-year on-the-job OD training will be associated with psychosocial causal beliefs, and with an emphasis on the principles of OD, at least partially independent of the work unit and the service users' demographic and clinical characteristics. It is also expected that the service users will show a general preference towards psychosocial causal beliefs and participatory mental health treatment strategies, rather than towards biological causal beliefs and symptom reduction treatment methods. It is expected that the network-oriented treatment will be associated with more favourable long-term outcomes, and that the association will be partially independent of confounding factors, including baseline demographic and clinical characteristics.

As this is participatory research, most of the information will be immediately available to service users and care team members, with possibilities to guide the actual mental health treatment. This in itself has the potential to immediately improve the quality and effectiveness of mental health treatment. All the information gathered during the project will assist in planning the research and development of future mental healthcare services, with a view to better addressing the actual needs of service users and their social networks.

In addition to above goals and expected results, the information on care team members' experience, in-house training and treatment orientations (low threshold services, continuity of treatment and inclusion of social networks) are used to assess each mental health unit's readiness to participate in the global HOPEnDialogue project. The aim of HOPEnDialogue is to globally evaluate the effectiveness of Open Dialogue approach by following similar research frameworks and outcome evaluation as used in ODDESSI trial in United Kingdom (16).

#### DESIGN

Finland is a Nordic country with a population of 5.5 million. The Finnish mental healthcare system is publicly funded, and the municipalities are responsible for providing services to all their residents. The WL catchment area consists of the south-western parts of Finnish Lapland with a population of 61 172 in 2018. Data for the PSILEAPS study will be gathered within two-week periods from four local psychiatric outpatient units, and from one psychiatric ward.

The PSILEAPS applies a participatory research design that engages community stakeholders, including mental health workers, peer experts, service users and their family members to work alongside academics in different phases of

the research process (17). The project was initiated in 2019 by arranging open community meetings for all workers and peer experts from WL mental health services. In these meetings the initial goals for the project were determined, and first drafts were made of the structured research questionnaires for care team members, service users and their social network members. The questionnaire for care team members was first piloted in Kemi outpatient clinic in December 2019. On the basis of experiences from the pilot, the questionnaire was further developed.

In the spring of 2020, the questionnaire was presented to all care team members in WL (18). At the same time, feedback on the questionnaire and on its relevance for actual clinical work was obtained. After the data collection, several new community meetings were arranged to finalize the questionnaire on the basis of the results from the pilot, paying attention to both the psychometric properties of the questionnaire and to feedback from care team members. The final version of the questionnaire was also reviewed in meetings with service users in Keropudas Psychiatric Hospital, in order to ensure that the questions were relevant and understandable from the service users' perspective.

The North Ostrobothnia Hospital District ethical committee approved the questionnaire and the participatory study design in 2020. The first pilot (19) of the participatory survey was conducted in 2020, in Keropudas hospital's outpatient clinic. Within it, all care team members gave their own responses, and also obtained responses from service users and their social network members pertaining to each treatment process within the given time frame. The pilot showed that it was possible to integrate participatory research within everyday clinical practice. Moreover, as indicated by care team members, it acted as an evaluative platform for treatment which fitted well with everyday clinical practice. However, some care team members found that the survey took too much time, especially if they had drawn up particular treatment plans prior to the outpatient meeting. The service users and their social network members found the questionnaire to be both meaningful and useful, and no harmful aspects were reported. The pilot study indicated that remote meetings associated with the COVID-19 pandemic would lead to a loss of potential candidates. Hence, the full-scale study was postponed from 2021 to 2022.

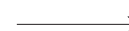
In the full-scale study, all care team members from all five adult mental health units in WL will collect the information (see above) via a questionnaire aimed at all persons who use the services within a two-week time frame. From existing case note data, it is estimated that within this two-week time

frame, there will be 200-300 treatment processes/meetings from the five adult psychiatric units in the catchment area.

During the two-week inclusion periods, the data will be gathered via structured questionnaires designed especially for this study (*Table 1*). The first part of the questionnaire is based on the biopsychosocial model of mental health problems. It consists of three questions with examples on why mental health services are needed (or not needed) for a particular service user. The second part consists of three questions on how the service users' situation should be approached. The third part includes a list of all the service and treatment approaches that currently exist in WL mental health services. Care team members, service users and their social network members will each indicate which of these treatment methods and approaches have been or may be helpful in a given treatment process. In the final part of the questionnaire, there are questions concerning the service users' current mental wellbeing, functionality and the improvement/decline in their mental health and social functioning over the last month.

Table 1. Baseline information: to be obtained for all treatment processes from each Western Lapland adult mental health unit in the two-week inclusion periods

	Demographic	Clinical	Questionnaire
Service user	Age; Gender; Education; Residence; Civil status; No. of children; Working; Sickness leave; Disability allowance	Diagnoses (ICD-10); BPRS-scores; How was treatment initiated?; How quickly was the first meeting arranged?; How frequently are meetings arranged?; Have there been changes in the treatment team members?; Is there ongoing rehabilitation psychotherapy?; Has the patient met the doctor?; No. of treatment contacts; Overall duration of mental health treatment; Drug problem; No. of re-admissions; Total duration of hospital treatment; Medical treatment (past; ongoing; type of medication(s); dose; off-label); Duration of medication (separately for each group); Medication harm? (if yes, what?); Deprescribing attempts	<p><b>Section 1: Causal belief on why I (the client) am using mental health services:</b></p> <ul style="list-style-type: none"> <li>• Psychological (e.g. emotions, thoughts/cognitions, personality) (0=disagree–10=agree)</li> <li>• Biological (e.g. functions of the brain, genes, other functions of the body) (0–10)</li> <li>• Social (e.g. interpersonal relationships, life events, and co</li> <li>• Other, what?</li> </ul> <p><b>Section 2: I (the client) may benefit if help is arranged on the basis of:</b></p> <ul style="list-style-type: none"> <li>• my subjective experiences and views (0–10)</li> <li>• other persons’ expert knowledge and opinions (0–10)</li> <li>• the influence of environmental factors (other people, living conditions, etc.) (0–10)</li> </ul> <p><b>Section 3: What helps: (0–10) (mark if the treatment method/approach has been implemented)</b></p> <ul style="list-style-type: none"> <li>• Meetings with the care team members; Continuity of care; Rehabilitation psychotherapy; Teamwork model; Psychiatric hospital care; Supported housing; Body-oriented exercise; Home visits; Electroconvulsive therapy; Occupational therapy; Medical treatment; Social work and assistance; Peer work; Expert opinion; Social network involvement; Health advice/ psychoeducation; Addiction care; An expertise network involvement; Group therapy</li> <li>• Something else? If so, what?</li> <li>• The treatment has followed my own treatment preferences (if not, what could be done differently?)</li> </ul> <p><b>Section 4: My (client’s) wellbeing</b></p> <ul style="list-style-type: none"> <li>• Current mood (low–high)</li> <li>• Current level of functioning (low–high)</li> <li>• Current social relationships (poor–good)</li> <li>• Changes in psychological wellbeing in last month (declined–improved)</li> <li>• What factors are decreasing wellbeing?</li> <li>• What factors are increasing wellbeing?</li> </ul>



	Demographic	Clinical	Questionnaire
Social network members	Relationship to service user	Not applicable	Corresponding questions about service user's situation as above
Care team members	Age; Gender; Work experience; Contract type; Profession; Work unit; In-service training; OD training	Not applicable	Corresponding questions about service user's situation as above

All the predetermined questions will be measured via a visual analogue scale (rated from 0 (disagree) to 10 (agree)). It will be emphasized that the questions and responses are not mutually exclusive. All parts of the questionnaire will also include open-ended questions enabling the respondent to provide their own perspective.

If the service users are willing to participate, they, their care team members and possible social network members, will each provide their own responses via a questionnaire regarding the treatment process in question. All service users will also be offered the opportunity to go through all the responses regarding their situation in joint meetings with their care team members and/or with the principal investigator. These will offer instant feedback on the actual treatment for all persons who participated in that particular treatment process. During the data collection, experiences pertaining to this participatory treatment evaluation will be collected from care team members and service users, and these will be analysed via qualitative methods. To ensure a participatory design (20), care team members, service users and their social network members will be given the opportunity to review the analyses and to participate in compiling research articles.

Background information on demographic and clinical characteristics, including the somatic and psychiatric morbidity prior the participation, will be obtained directly from service users, and – with their informed consent – from their health and social registers. Psychiatric symptoms and their severity are also assessed via Brief Psychiatric Rating Scale (BPRS). Care team members will collect all questionnaires and background information from each treatment process, and deliver them to the principal investigator for saving and pseudonymization of the data.

The primary and secondary outcome variables presented in *Table 2* will be formed from the two- and five-year follow-ups. Secondary outcome variables are also used to evaluate the cost-effectiveness of treatment. The two- and five-year follow-up data for each participating service user will be obtained from social and healthcare registers in Finland. Aligned with the exploratory design, combined outcome variables are used to produce more comprehensive information on participants' life situation at follow-up.

Table 2. Primary and secondary outcome variables at the follow-up phases

Primary outcome variables	Treatment contact (yes: if there is ongoing treatment contact or psychiatric medication treatment at the follow-up) Disability allowance (yes: if there is an ongoing mental health disability allowance at the follow-up) Death (if participant has died during follow-up)
Secondary outcome variables	Working at the follow-up (yes/no) Income during the follow-up Time (days) to relapse after jointly ended treatment process Disability allowances during follow-up No. of hospital admissions during follow-up No. of hospital days during follow-up No. of outpatient visits during follow-up Medication treatment during follow-up Family relations (N of children, civil status, living alone (yes/no))

*PROPOSED STATISTICAL ANALYSES*

It should be noted that the envisaged survey is a non-confirmatory exploratory study, the aim of which is to create new hypotheses rather than to test them. Nevertheless, for register-based follow-up the goal is to reach adequate statistical power ( $1-\beta > 0.8$ ), in order to detect correlative trends and associations from the data sets. To this end, for the purposes of the correlation analyses, the minimum sample size has been calculated as 130 service users, and for the regression analyses 140 service users. These numbers will be sufficient to detect correlation coefficients higher than 0.5 and odds ratios higher than 1.7. As there may be loss to register-based follow-up due to death, the proposed sample size for PSILEAPS is 150 service users. If a sample size of 150 service users is not reached within the two-week periods (due to a loss of candidates or refusal), new data collection periods will be set until the sample is large enough. Note that the necessary sample sizes could differ according to the sub-question and minimum association we wish to detect.

Non-confirmatory exploratory statistical approaches (21,22) will be used to analyse the data. The sample characteristics and group differences will be studied via descriptive statistics, chi-square test, and parametric or non-parametric tests, depending on the properties of the

data. Associations and observable trends will be studied via descriptive statistics, correlations, factor analysis and regression analysis (questions 1–3). Regression models with stabilized inverse probability of treatment and/or other adjustment will be used to study how demographic and clinical baseline characteristics are associated with the long-term outcome (question 4).

DISCUSSION

Participatory research design engaging the clinicians, peer experts and service users to work alongside academics, from problem identification to the dissemination of results, develops a community capacity to be co-producer of the research process and outcomes (17). This may in itself help to develop research-based mental health services, although more collaborative research-process also sets some challenges to the generalizability of both the research design and results. For example, as both the research questions and measurements were drafted in joint process with clinicians and peer experts in one catchment area, they may not be directly transferable to other settings. Nevertheless, the participatory design is transferable, and re-conducting the process in other catchment areas would provide information on both the participatory research



process and treatment outcomes, that could be further used to estimate the generalizability of the main outcomes of PSILEAPS project.

Even though the research will be collaboratively planned with care team members, it is possible that some workers will not be willing to participate in the data collection. There may also be uncontrollable selection in how they collect the data. To minimize this, all phases of the research will be planned and tailored together with all the care team members in each unit. The main goal is to conduct all the phases of study so that the research does not cause any extra burden on care team members. The design of the data collection is based on the co-creation of knowledge which would in any case take place in real-world treatment meetings. The differences will lie mainly in the more systematic documentation of information.

By using clinical case note data, it will be possible to conduct attrition analyses. If the attrition analyses indicate that there is loss or selection of participants as compared to the overall sample space (all the service users of the unit), it will be possible to re-conduct data collection in a different time frame. Moreover, if some care team members are unwilling to participate, there is the possibility that the principal investigator can collect data from their clients. To minimize loss and selection in follow-up, permission will be asked of all participants, so that their follow-up information can be obtained directly from social and healthcare registers.

It should also be noted that register-based variables, including the use of services and disability allowances, do not necessarily indicate better treatment outcomes in terms of, for example, life satisfaction, personally defined recovery from mental distress and general health. Nevertheless, the explorative design and the use of personal identification numbers allow us to combine and observe primary and secondary outcome variables side by side, in order to estimate more comprehensively participants' life situation at follow-up, and also the validity of singular outcome variables. To further increase the validity of main conclusions, service users and clinicians from the Western Lapland catchment area are openly invited to comment on the results and draft the research articles together with academics.

The WL hospital district has officially approved the design, and will support the research by allowing care team members to conduct the research within their working hours. As WL mental health services is part of Finnish public healthcare services, and is funded by a consortium of municipalities, this support is non-commercial. In line with the bottom-up study design, the research board of

the PSILEAPS project will include both clinicians and peer experts within the catchment area. The principal investigator (TB) of the PSILEAPS project works as a clinical psychologist in the catchment area, and the co-investigator (HM) has a position as a peer expert. These positions could allow unique insights into the actual clinical practices of WL; nevertheless, it is recognized that having these positions could bring elements of subjectivity to the topic, with vulnerability to researcher allegiance bias. These issues will be openly discussed during the project.

The overall aim of PSILEAPS is to produce ecologically valid information on real-world mental health treatment and the factors associated with different treatment outcomes. The study design is also expected to have a direct impact on the quality of care, as it will provide instant feedback on treatment and treatment preferences.

It is expected that the PSILEAPS project will function globally as an example for other mental healthcare units on how participatory research can take place within everyday clinical work, and can shape mental health services in a bottom-up manner. The project will also provide new hypotheses on the effectiveness of real-world mental health treatment. It is likely that these hypotheses will be further tested via more structured confirmatory research designs. All of these outcomes will directly assist the development of more effective and more research-based mental healthcare services and practices.

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The research protocol was approved by the ethical committee of North Ostrobothnia hospital district (EETTMK: 38/2020). All participants will be informed on the conduct of the study, and will sign the appropriate informed consent forms.

#### *Disclosure statement*

The authors have no competing interests to declare.

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