Cover page

Title:
Extreme challenges – Psychopathology and treatment experiences among extensively hospitalized, psychiatric inpatients with severe self-harming behavior in Norway.

Norwegian short title: Ekstrem selvskading

Numbers:
Clinical trials ID: 2019/FO244009

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Project number from regional ethics committtee**:** 2018/1124 Ekstrem selvskading

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Project methodology, strategy for project implementation, management and completion

Design: A cross-sectional, quantitative design is chosen for the investigation.

The target group: Inclusion criteria are based on consensus in the project group: Admissions to inpatient units (adult psychiatry, mental health centres or hospitals) are due to risk of severe self-harm. The duration of admissions are either more than 4 weeks and/or patients have had more than five admissions in the preceding year. The inclusion period will be one year.

The comparison group is a collaboration with the Norwegian Network of personality-focused treatments (the Network). It includes clinical data from 18 outpatient units (members of the Network) within regular specialist mental health services across Norway. It will include cross sectional, baseline data for 300 patients admitted to treatment during 2017-2018. The sample is chosen for comparison because it represents patients with a personality disorder eligible for outpatient treatments– one of the relevant differential diagnoses of this project. Central assessment instruments chosen in this project are currently regular Network standard.

Recruitment, sample size and statistical power: A national level of investigation is chosen to ensure a large sample, good geographical coverage and high statistical power. We expect heterogeneity within the sample and need to ensure sufficient sample size to nuance relevant subgroups with particular characteristics such as e.g. different psychopathology. Considering a) the screening investigation which identified more than 400 patients within the target group, and b) that not all patients will be willing to participate, an inclusion of N=300 patients in the target group is realistic. Based on one of the self-reports chosen in the project (SIPP-118, *see Table 2*), using SIPP-118 data from a former Network study (Ullevål personality project), power calculations indicate that subgroups with a size of n=50 are sufficient to detect relevant differences (SIPP-118 mean difference: 0.4, SD 0.7, alfa-level 0.05, two-tailed, power 0.81) (IBM SPSS sample power). N=300 target patients will thus represent high statistical power and good possibility for subgroup analyses.

Assessments: The assessment battery combines therapist administered interviews and patient self-report measures to provide a broad differential-diagnostic evaluation and information about treatment and health-service collaborations. It also includes therapist-reports. It represents a relevant high quality clinical evaluation using measures of recommended standard. Interviews and self-reports are required as data from the Norwegian Patient Registry do not reflect systematic diagnostic measures, include systematic information on self-harming behaviors, personality or cognitive functioning, and would be of insufficient standard or detail to cover aims in this project.
Psychopathology: Assessment of psychiatric disorders is based on well-established interviews for symptom disorders (MINI), personality traits and disorders (SCID-5-PD, and observer-evaluated global functioning (GAF). These will be administered in assessment of both the target and the comparison group. Assessment of the target group will additionally include a screening interview on cognitive functioning (Hayes Ability Screening Index, HASI, specific approval has been given), self-report screening of autism (Ritvo Autisme Asperger Diagnoseskjema – Revidert RAADS-R), and a detailed interview on psychosis (questions from MINI plus).
General, social and personality functioning: The assessment battery will include a combination of well-established, (no cost) self-report measures covering overall functioning and symptoms, history of severe trauma and PTSD symptoms, core aspects of personality functioning and maladaptive behaviors. These will be administered in both the target and the comparison group. Details on assessment battery can be given on request to PI.
Self-harming behaviors: Self-report on self-harming behaviors and suicide attempts last 6 months are included. Assessment of the target group will additionally include a more detailed interview of self-harming behaviors adapted for Norwegian studies (Lifetime Para suicide Count).

Service use, treatment experiences, and health service collaborations: Assessment of treatment histories include previous treatments, age first time, and contact with child/adolescent psychiatry (self-report, both the target and the comparison group), and a detailed interview on medication, treatments, primary health care and welfare services last 6 months (specially designed interview, both target and comparison group). In addition, for the target group, questions about involuntary and restrictive regimes, treatment involvement, confidence, alliance and collaboration within and across health services are included (patient and therapist reported).

Statistical analyses will include quantitative descriptive summaries of cross-sectional data (frequencies, means, and estimates of variation) and comparative analyses of data in the two independent samples (parametric and nonparametric methods). For analyses of possible nested data statistics will include multilevel analyses. Statistical support is available within the Research group Personality Psychiatry and Oslo University Hospital (Dept. for Research and Development).

Identification of risks. It is voluntary for patients to participate in the investigation. The study implements assessments instruments relevant for clinical use. Nevertheless, some patients may find the self-reports cumbersome. We have therefore designed the layout of the self-reports so that patients are encouraged to take frequent pauses. They are inpatients and hospital staff will be available to assist and support. Implementation of this project implies information and dialogue with hospital staff and flexibility with regard to datacollection procedures.

Participants, organization and collaborations

The PhD candidate will follow the PhD educationary program at the University of Oslo. Main supervisor is also Principle Investigator (E.H.Kvarstein) in this project, and co supervisor (G.Pedersen) heads the Network collaboration. The PhD candidate will join the national project group and be an associated member of the Research group for Personality Psychiatry.

The national project group is central in all phases; design, preparations, implementation procedures, evaluation, and presentations of results. It covers all health regions (*HR*), relevant research environments, clinicians and users. It includes: *Middle HR*: T.Torgersen, PhD, *Western HR*: T.Tveit, MD. *Southeastern HR*: P.A.Ringen, PhD, P.Danielsen, MA, C.A.Sveen (MA), Tore Buer (MD). *Northern HR*: H.Tvete, MD, T.Høifødt, PhD. *National Centre, Suicide Research and Prevention*: F.Walby,MA, R.K.Ramleth, MD (BUP). *Regional Centre, Violence and Traumatic Stress*: I.Lunde, MA. *Early intervention Psychosis*: K.L.Romm, PhD. *Personality Psychiatry National Advisory Unit*: Ø.Urnes,MD. *User experience*: T.Røstbakken, M.Pettersen, A.Holst. *Project member in phase I*: *Screening interviews* F. Holth, MD. *Principle researchers/PhD supervisors*: E.H.Kvarstein, PhD, G.Pedersen, PhD. The group is headed by EHKvarstein.

The Research group for personality psychiatry (University of Oslo/Oslo University Hospital) specializes on personality pathology and clinical research.

The principle investigator (PI) and main supervisor of this project, E.H.Kvarstein, associate professor, University of Oslo/ Head senior consultant, Section for Personality Psychiatry, Oslo University Hospital, is head of the Research group of personality psychiatry.

The Norwegian Network for personality disorders (the Network) is a well-established collaboration aiming to ensure clinical quality, systematic treatment evaluation and generate data for clinical research (anonymous data collection). The Network was established in 1993 and currently includes 19 outpatient treatment teams across Norway for patients with personality disorder. Approximately 400 patients are admitted to treatments within the Network each year (mean treatment duration: 2 years). The Network provides systems for patient assessment and progress evaluation, systematic feedback reports on clinical outcomes and supervision/seminars on

diagnostic assessment and treatment. The main (ongoing) research project in the Network is a multi-centre feasibility investigation of evidence-based treatment for personality disorder (started in 2017) aiming to include longitudinal treatment data for 500 patients. "*Extreme challenges*" is a research collaboration between the national project group and the Network. Baseline data from the multi-centre project constitute the outpatient comparison group in "Extreme challenges" (300 patients, admitted to outpatient treatment in 2017-18, data available in 2020).

Cosupervisor in the PhD project, head of the Network, is senior researcher Geir Pedersen [60, 61]. He is affiliated within the Section for Personality Psychiatry, Oslo University Hospital and the University of Oslo. He is a member of the research group, and will be a central researcher in this project.

Norwegian National Advisory Unit on Personality Psychiatry (NAPP). NAPP is the initiator of the current project and the organizer of the national project group. With the establishment of an expert user panel (recruiting users from the whole country), NAPP has also had an active role establishing user engagement in this project.

Budget Extrastiftelsen has granted funding for a PhD candidate equivalent of 3 years from 2019, starting late spring 2019, affiliated to the Section for Personality Psychiatry, Oslo University Hospital.

Plan for activities – practical implementation of the cross sectional investigation

A national project group has already completed a preliminary screening investigation, first publication, and designed the current project. The project group is currently starting to prepare practical implementation of the project (mobilizing regional collaborators, local resource groups and finalizing ethic approvals and systems for data collection). The PhD candidate will be an active member of the project group, involved full time from autumn 2019.

2018/19: Preparation: Regional seminars to prepare local clinicians and all collaborators precede the cross sectional investigation and are scheduled for the autumn 2019. These are a crucial part of the preparations providing updates on differential diagnostics, assessment instruments, and bilateral project-relevant information. The PhD candidate has a central role, arranging and participating in the seminars together with key members of the projectgroup and NAPP.

2019/2020: Data collection: Assessments of the target population will be performed at the inpatient institutions by local clinicians qualified for diagnostic procedures. During data collection possibilities for feedbacks/clinical discussion of individual cases will be offered. The PhD candidate, supported by principle investigator and supervisors, will have a central role in the administration of this project phase. In addition, key members of the projectgroup will be active collaborators. The PhD candidate will also complete obligatory PhD courses including elementary statistics, within 2020.
Assessments in the comparison group involve measures already implemented (from June 2017). Diagnostic interviews (MINI, SCID-5-PD) and self-reports are the recommended quality standard regularly used in outpatient units within the Network by local therapists trained for the procedures. Self-reports on personality functioning and the specially designed interview covering treatment/health services/medication/ disability are also current standard (from 2017). A recent quest-back within the Network (April 2018) indicated good compliance; 88% of the clinicians followed the recommended standard consistently for patient evaluations, 97% confirmed clinical utility of this evaluation package.

2021: Dataanalysis, discussion and presentation of results: Datacollection will be concluded and analyses of results proceeds. PhD candidate will be first author of all three publications.

Dataanalyses will be supported by supervisors, the research group and the project group. Results will be discussed within the project group.

2022: Project conclusion: The final half year of the PhD period will be confined to concluding the project, evaluation and thesis writing.

Plan for dissemination of results & implementation / translating results into practice

Running information about the project with Norwegian summaries, key researchers and references to all publications will be available at the internet home site of the Research group for Personality Psychiatry in all phases of the project.
Three research publications (Papers 1-3) are scheduled. Manuscripts will be submitted to international peer reviewed journals (open access publication). Research results will also be presented in relevant international and national conferences (symposia focusing on self-harm).
When the project is concluded, the project group will arrange a conference for participating clinicians/institutions/organizations, evaluating the investigation, implications and further developments.
The project has a broad geographic participation and several possible channels for conveying research results to relevant clinical environments. Dissemination of results therefore includes arenas available to collaborators within the health regions and participators in the project group. Central channels are also clinicians within the Network and communications via NAPP.

User involvement:

The project-group includes three members with relevant user experience, Thea Røstbakken, Mona Pettersen and Andrea Holst. They all have contact with other relevant users through membership in a national Expert user panel initiated by NAPP.

Ethical considerations

The regional ethical committee (REC) has approved our application for ethical approval. REC reference number is: 2018/1124 A (REC South East).