1. Project title
Towards an applicable substance use disorder treatment for inpatients with mild to borderline intellectual disability – the development and feasibility/piloting of a new intervention package.

2. Introduction
Studies indicate that up to 39% of inpatients in facilities offering substance use treatment (SUD) have an unidentified mild to borderline intellectual disability (MBID) (Braatveit, et al. 2018a; Luteijn, et al. 2017; Juberg, et al. 2017). Existing assessment and treatment recommendations for SUD treatment are cognitively demanding for patients. The interventions presume a level of intellectual and cognitive functioning that these patients only partly possess. Their cognitive challenges comprise a barrier for treatment effects of the treatment offered (Kiewik, et al. 2017). In addition, these patients often portray a complex health and social situation that require simultaneous and coordinated services from several health and care services before, during, and after SUD treatment to ensure that all their in-treatment and follow-up needs are met. Currently, there is a lack of adequate system integration and interdisciplinary collaboration for these patients, resulting in them falling between chairs (van Duijvenbode & VanDerNagel, 2019).

SUD is a complex and multifaceted condition that demands specialized services (vanDuijvenbode, et al. 2015). In order to make mainstream SUD treatment more accessible to patients with MBID, meeting both their level of functioning and their total treatment needs, adjustments are required in several areas (van Duijvenbode & VanDerNagel, 2019). **As the field currently stands, studies from SUD treatment is encouraged to focus on 1) MBID identification, 2) cognitively adapted and tailored treatment, and 3) system integration and interdisciplinary collaboration** (van Duijvenbode & VanDerNagel, 2019). The present study is the first to address all three of these areas through development and piloting of an intervention package for adapted treatment for SUD inpatients with MBID. In addition, the present study will be the first to use the new national quality register for harmful use or addiction to substances (Kvarus) as a measure of outcomes for the targeted group.

Identification of MBID in SUD patients
Previous studies have reported that individuals with MBID may have negative experiences with mainstream SUD treatment (Taggart, et al. 2007), have higher drop-out rates from mainstream SUD treatment (Chapman & Wu, 2012; Slayter, 2010), experience barriers to SUD treatment (Chapman & Wu, 2012; Slater, 2010; Slater, 2008), and have higher rates of relapse to substance use during treatment (Braatveit, et al. 2018a). It is further reported that individuals with MBID do not benefit sufficiently from mainstream addiction treatment in its current form. A number of challenges are associated with cognitive impairments in relation to their ability to receive and follow up treatment of substance use disorders, such as: limited attention span, limited vocabulary, exhibit short- or long term memory problems, quickly forget what they did understand at the beginning of the conversation, difficulties discriminating between relevant and irrelevant information, problems with planning and attention, impaired abstract reasoning and low self-insight (Kiewik, et al. 2017). These findings suggests the need for early recognition of MBID in SUD treatment as this may have significant impact on the SUD treatment outcome. Although screening methods for MBID identification has been found valid for the SUD population (Braatveit, et al. 2018b; To, et al. 2015), these are not implemented in the clinical setting (van Duijvenbode & VanDerNagel, 2019). The percent study aims at developing an adjusted SUD treatment, where MBID identification is a part of a larger audit.

Adapted and tailored SUD treatment for individuals with MBID
The cognitive challenges faced by individuals with MBID, calls for an adapted SUD treatment to the limitation MBID introduces. While buildings are universally designed to give e.g wheelchair users

access, SUD treatment in its current form, has a lack of cognitively accessibility for patients with MBID.

A number of adaptions to empower people with intellectual disabilities' participation and benefit of health services are known, such as simplicity of the language used, short and repeated instructions, use of visual materials to support understanding of complex or unfamiliar concepts ect. The application of this knowledge is scares in SUD treatment. There is evidence that interventions such as those based on motivational interviewing and mindfulness, with minor adjustments, can have some effect on SUD related topics in individuals with MBID, but the available research is of poor to moderate quality, on a pilot level, simple in nature and disregards comorbid psychiatric disorders and psychosocial problems (vanDuijvenbode & VanDerNagel, 2019; Didden, 2017). More research on the application of established knowledge about adaption of psychological treatment to the SUD field is needed.

The available treatment literature focuses on specific interventions, often of short term. For inpatients who live in a treatment environment and receive intensive SUD treatment over time, broader adaptions to treatment programs that include several evidence based SUD treatment elements are needed (e.g cognitive behavioural therapy and mindfulness). In addition, inpatients face challenges such as day structure, social interaction and endurance. For these SUD patients, adjustments that target the treatment environment and how to deliver treatment interventions is important. The evidence base for environmental interventions from MBID research is extensive, and includes interventions such as addressing the cognitive disability, education of staff on MBID, using activity schedules etc (National Development for Inclusion, 2017). When the treatment, or treatment environment make requirements that does not match the individuals functioning or prerequisites, a functioning gap arise (Lid, 2020). Negative consequences such as low treatment adherence and effect, preliminary treatment termination, and a general feeling of failure may be a result of such mismatch.

To enable inpatients with MBID to receive the same evidence based SUD treatment elements as no-MBID patients, and to be integrated in the normal treatment environment, receiving several interventions at the same time, the present study will develop MBID adjustments to specific interventions such as mindfulness, cognitive behavioural therapy and psychoeducation, as well as individual therapy and environmental therapy (målrettet miljøarbeid). Adjustments will be made drawing on recommendations from existing literature review, including the GreenLight toolkit (National Development for Inclusion, 2017), SUD and MBID specialists and experts by experience.

System integration and interdisciplinary collaboration

Several previous studies have pointed to the lack of system integration and interdisciplinary collaboration (Didden, 2017; Juberg, et al. 2017; VanDerNagel, et al. 2011; Slater, 2008; Taggart, et al. 2007). Individuals with MBID and substance-related problems are mainly treated by intellectual disability (ID) services (Slater, 2008; Taggart, et al. 2006). These services have reported a lack of knowledge and means of treating SUD (Taggart et al., 2006; VanDerNagel, et al. 2011). Likewise, a lack of knowledge on MBID may pose problems for clinicians in SUD services. In fact, the lack of focus on MBID has resulted in the entire field of SUD treatment being accused of ignoring the whole MBID/SUD comorbidity (van Duijvenbode & VanDerNagel, 2019). Both SUD, mental illness and ID are conditions that, by themselves, require attention from both primary and specialized SUD, ID and mental illness services. When they are percent as comorbid conditions, it is not clear who has what responsibility, and patients often fall through the crack (Slater, 2008).

In Norway, the intention of the TSB reform in 2004 was to ensure SUD treatment to all who needs it (Norwegian Ministry of Health, 2004). To reach this goal with regards to individuals with SUD and MBID, there is a clear need for a national development of the practice field, such as an extensive use

of individual care plans for interdisciplinary collaboration, and the use of flexible services (Juberg, et al. 2017). In addition to ensuring good health and social services to SUD patients with a known MBID condition, there is a need for collaboration routines when the MBID is uncovered during SUD treatment. System integration on an organizational level, with clear responsibilities is needed to ensure responsible healthcare along the entire treatment and care pathway, such as adequate referral to addiction medicine and smooth transitions between different forms of treatment and health care sectors (vanDuijvenbode, et al. 2015). The present study aims at developing an adjusted SUD treatment for MBID with routines for cross system integration and interdisciplinary collaboration in the health and care pathway for inpatients as part of a larger audit.

SUD treatment outcome measures

Recently, in Norway, the national quality register for harmful use or addiction to substances (Kvarus) has been implemented to systematically collect information on SUD patients, their health and life situation at the start of treatment, the treatment content, patients experience with the treatment, and changes through and after treatment termination. It collects information on a biopsychosocial level and includes treatment and follow up both from SUD services and others. Thus, the Kvarus might be ideal as a broad measure of the patients' situation, the treatments given, and the outcomes of biopsychosocial interventions. Outcomes on a biopsychosocial level is considered especially profitable to patients with MBID who often are in a complex health situation and require simultaneous services from several disciplines. The planned study will include the Kvarus as a measure of treatment outcome for a broad measure of outcomes and an opportunity to compare the MBID group to other SUD inpatients on standardized variables.

2.1. Impact for patient treatment

The planned study will develop an SUD intervention package that aims at identifying MBID, and reducing the functioning gap for these patients in treatment. It is expected to reduce the current SUD treatment inequity by adapting treatment to better meet the functioning of the MBID patient. As a result, these patients are expected to have more positive experiences with mainstream SUD treatment, get access to a wider variety of treatment elements, and generally profit better from the treatment offered. The intervention package will also include routines for cross system integration and interdisciplinary collaboration. This is thought to be especially beneficial to SUD patients with MBID as they often pose complex health and social situations that requires simultaneous attention from several health and care services. The package will enable simultaneous and coordinated services from several health and care services before, during, and after SUD treatment to ensure that all their in-treatment and follow-up needs are met.

3. Objectives and aims

The main aim of the study is to develop an intervention package for adjusted mainstream SUD inpatient treatment to better meet the needs and functioning of patients with MBID. The project has two objectives 1) to develop and test a SUD treatment intervention package for inpatient care adapted to the needs and functioning of inpatients with MBID, 2) investigate the feasibility of the intervention package in everyday practice. In accordance with divisions suggested by Proctor and colleagues (2010), we intend to study feasibility by exploring contextual factors that helps or hinders implementation (implementation factors), to what degree the intervention is implemented as intended and spread to all patients in need of the intervention (implementation outcomes), and the intervention`s usefulness for patients (patient outcome).

3.1 Research questions and hypotheses, theoretical approach and methodology

RQ1 - Development
#RQ1.1. What should a protocol for inpatient SUD treatment for individual with MBID include, according to existing literature, SUD and MBID specialists and experts by experience?

#RQ1.2. How can we measure compliance of this protocol?

Methods: This phase will draw on the guidance on how to develop complex interventions to improve health and healthcare by O`Cathain, et al. (2019). Based on the results of a literature review, clinical expertise of SUD and MBID specialists and experts by experience (patient representatives) we will describe the core elements of the intervention package. The intervention will include the following three main areas; 1. MBID identification 2. Adjustments to SUD treatment elements 3. Routines for system integration and interdisciplinary collaboration. Representing the main areas of the protocol, a fidelity scale will be developed to enable investigation of compliance in daily practice.

Expected results: A description (protocol) of the first version of the SUD treatment for individuals with MBID, including a scale to measure compliance to the core elements of the protocol.

RQ2 – Pilot

#RQ2.1. To what degree is the new treatment intervention package implemented, when implementation support is provided, at three and six months after onset?

#RQ2.2. What factors helps and hinders the compliance of the treatment protocol, according to the treatment providers?

Methods: An intervention study where the SUD unit receive training and consecutive audit and feedback will be conducted. Degree of compliance will be measured at baseline, 3 and 6 months using the scale developed in the previous step. Implementation factors will be explored both qualitatively and quantitatively: We will conduct semi-structured interviews with the treatment providers, and a survey on their interpretation of implementation factors using the validated Implementation Process Assessment Tool (IPAT) for insight in what promotes and what inhibit the implementation both on an individual health care worker level, and on a collective level.

Expected results: We expect to find that the intervention package is fully or partially implemented. We also expect to reveal areas for further development or change in the intervention and/or the implementation support given.

#RQ2.3: Are patients satisfied with the intervention package?

Methods: Examine patients' reactions to the intervention package through quantitative treatment evaluation with Kvarus, and through semi-structured interviews. Patients who have received the intervention will also be compared on Kvarus measures of treatment satisfaction to MBID patients who did not receive the intervention (baseline measures before the development of the intervention).

Expected results: We expect to find that patients react positively to the intervention, and more positively to treatment than MBID patients who did not receive the intervention package. We also expect to reveal areas for further development or change in the intervention.

#RQ2.4: Pre-liminary treatment effect; does the intervention seem to work?

Methods: Pre-post measures on the Kvarus will be registered for quality of life, substance use, motivation for change, and symptoms of mental illness. Patients who have received the intervention package will be compared on these measures to MBID patients who did not receive the intervention (baseline measures).

Expected results: We expect the intervention to have positive effect on the treatment outcome variables, that is, increased quality of life, reduced substance use, increase in motivation to change and reduction in symptoms of mental illness. We also expect a tendency towards more favourable results for the MBID patients who received the intervention package compared to the MBID patients who do not receive the intervention package. The results may also provide insight in areas that the intervention could be developed to further increase successful treatment outcome.

4. Execution of the study

4.1. Study design, methods and statistics

4.1.1 Design and participants

The planned project has two phases. The *first phase* will focus on the development of the intervention package and follow recommendations for development of complex interventions (O`Cathain, et al. 2019). In this phase, recruitment of participants from different stakeholders such as personnel from primary ID and SUD services, secondary/specialist ID and SUD services, and user groups will be based on convenience and willingness to participate.

The *second phase* will be a small scale (pilot) interventional non-randomised pre-post intervention study with four feasibility measures (penetration, fidelity, acceptability and preliminary treatment effects). A mixed methods design is thought to enlighten the research questions and give a deeper understanding of the results than one method alone. Such in-depth understanding is needed before a full scale study can be planned and conducted. Inpatients will be recruited from Blå Kors Haugaland A-senter. Inclusion criteria for baseline measures and the identification part of the intervention package will be all patients admitted to inpatient treatment. Exclusion criteria will be ongoing psychotic episode. For the adjusted in-treatment methods and cross-system collaboration parts of the intervention package, only patients who are identified as having MBID will be included. Exclusion criteria for this part of the study is ongoing psychotic episode and/or recent IQ test with scores in the normal range.

4.1.2 Instruments

Health care workers acceptability of implementation: The Implementation Process Assessment Tool (IPAT) is a questionnaire for care providers. It measures care providers perceptions of an implementation effort for a given clinical intervention, in this case the developed SUD treatment protocol for inpatients with MBID (Hartveit et al., 2019). The IPAT include four subscales representing well known implementation theories: Proceeding of phases for behavioural change, Individual activities and perceived support, Individual perception of the intervention, and Collective readiness and support (Hartveit et al. 2019). The IPAT score is found to be positive associated with implementation success.

Fidelity scale: A fidelity scale will be developed to enable investigation of compliance in daily practice.

Screening for MBID: The Hayes Ability Screening Index (HASI) consists of three short tests measuring individuals' spelling, visuospatial, and visuoconstructional abilities. It also includes four questions about known learning difficulties (Hayes, 2000). It operates with a cut-off score of 85 points for the adult population and has been found valid for the SUD population (Braatveit, et al. 2018b; To, et al. 2015).

Treatment outcome: The study will ask participant for consent to use their data from the national quality register for the treatment of harmful substance use or addiction (Kvarus) (see introduction; SUD outcome measures). All multidisciplinary specialized addiction health services (Tverrfaglig Spesialisert Rusbehandling [TSB]) in Norway have an obligation to administer the Kvarus as intended. The study will use patients Kvarus measures closest to the admission point and at the end of the residential treatment. For measurements of the preliminary treatment effects analysis of changes in quality of life, substance use, motivation for change, symptoms of mental illness will be done. For the investigation of patient satisfaction, the patient experience measures on the Kvarus will be used.

Patients' acceptability of the implementation: In addition to the quantitative Kvarus measures of patients experience with the treatment given, an interview guide will be developed to further examine patients experience with the intervention package.

4.1.3 Personnel and material

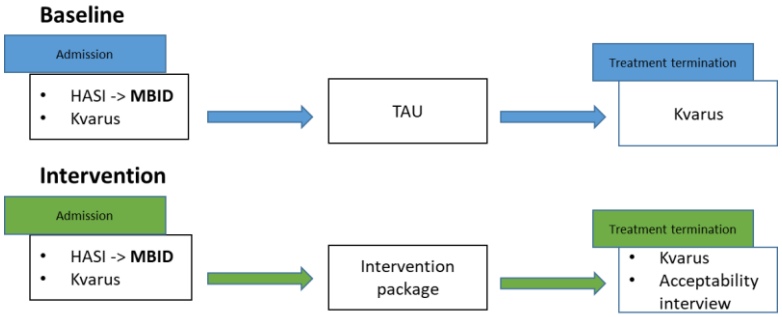
The current project relies strongly on personnel and materials already included in the normal, day to day clinical practice. Extra recourses are however needed for the organization of participation and to make sure that the data collection is of good quality. For the development of the intervention package, representatives from different disciplines and organizations working with individuals with MBID will be needed to develop the intervention package, as well as user representation.

4.1.4 Procedure

Patients: All patients admitted to treatment will be asked to participate in the study. If the patient is willing to participate, he/she will be screened for MBID by a project co-worker early in treatment, after a minimum of two weeks of abstinence from substance use. Standard procedures at the clinic for ensuring abstinence, such as urine samples and clinical observations will be checked before the screening phase to ensure that results are not influenced by recent or ongoing substance use. If there is evidence for substance use, the participant will be screened at a later time. On the baseline measures all subjects will receive treatment as usual (TAU) and Kvarus data will be collected at the start and end of inpatient treatment. The data from the HASI and the Kvarus will be linked thorough encrypted personal identification numbers.

When the intervention package is ready to be implemented, an additional consent will be presented; asking individuals with a HASI identified MBID if they are willing to receive the intervention package. If they consent, they will receive treatment in accordance with the intervention package and not TAU. They will also respond on an additional acceptability interview at the point of inpatient treatment termination. See figure 1 for design.

Figure 1. Patient measurements and treatment design



Health care workers: All healthcare workers involved in the implementation of the intervention package will receive implementation support such as education on MBID and the elements of the intervention package prior to implementation. The IPAT and the semi-structured interviews will be administered to the involved personnel prior to implementation. The fidelity scale will be administered at three and six months after onset.

4.1.5 Analyses

Quantitative analyses

The statistical analyses will be planned in detail when the measurements for compliance is developed in the first step of the study. The eligible sample of patients in each MBID group (with or without intervention) is expected to be 40, whereas we expect 80% contenting to participate.

To understand the potential impact of contextual factors for implementation, the associations between IPAT scores and score on compliance (fidelity) will be explored.

A general linear model will be used to test our hypothesis in RQ2.4, using one-way MANOVA (post-hoc test) with group affiliation as independent variable (two groups), and the four dependent variables: Quality of life, Substance use, Motivation and Symptoms of mental illness. As for sample size estimates, the knowledge about treatment effect of our package are not known as this is a new intervention. The pilot study will be used to inform future power estimates in a multi-centre study. For pilot studies, one may use the formula (Dattalo, 2013) N=C/.1 + (J-1)/.1, where C=number of covariates, J=number of groups and N=sample size, 50 participants are needed in a study with two groups and three independent variables. In our study, we expect 64 participants with MBID, which is within the sample size needed.

Qualitative analyses
For the semi-structured interviews with treatment providers and patient satisfaction, interview transcripts will be analyzed using Nvivo v20.5.2. Qualitiative data will be coded using a priori and emergent themes.

4.1.6 Risk management:
One of the main risks of the planned project is the time schedule for the developmental phase. With many collaborating stakeholders and an expectation of several rounds with design and redesign, this phase may take longer than anticipated. Action will be taken to carefully plan the process and follow-up milestones to minimize the risk and stick to the schedule. Another risk factor is that the intervention package is not implemented as intended, and that the results may therefore not be interpretable as to effect. Although implementation support is thought to reduce this risk, additional close monitoring and implementation support will be provided through the whole implementation process.

4.2. Project organization and management
The project is anchored in Helse Fonna HF, administrated by the Research and Innovation department and carried out in collaboration with Blå Kors Haugaland A-senter (BKHAS). The main research group includes the following individuals form the Research and Innovation department:

The project manager **Kirsten Braatveit**, is a clinical psychologist, specialized in addiction psychology. She has held several positions in the field of addiction treatment and is experienced in both inpatient and outpatient treatment for patients with SUD. In addition she has work experience from child and adolescent psychology and a specialized mental health outpatient clinic for adults with intellectual and developmental disabilities. In 2018 she achieved the PhD degree with the thesis: «Intellectual disability among in-patients with substance use disorders». Currently she is employed as a researcher in Helse Fonna HF, and as leader for an outpatient SUD treatment department at BKHAS.

Oddbjørn Hove is a clinical psychologist/PhD, specialized in developmental disorders, and is the founder and project manager of the iSpe-project. He is head of office for an outpatient clinic for people with developmental and cognitive impairments in Helse Fonna HF. He has in depth knowledge of both the clinical and research field of mental health in people with cognitive impairments, and the implementation of research results in clinical practise. Hove will contribute in the development of the intervention package, with statistical analysis, interpretation of results and writing of all the papers in the project.

Miriam Hartveit (MSc, PhD) is a researcher at the department of research and a first amanuensis at the institute of Public Health at the University of Bergen. Hartveit has worked with quality improvement in hospitals for over 20 years, the last 10 with research in the same area. In 2016, she

received the «Helse Vest kvalitetspris» for this work. She is a collaborator in many regional, national and international implementation studies from different disciplines. In the present study, she represents the research project «Implement it». Implement it is founded and lead by professor Eirik Søfteland (Haukeland U.hospital), professor Stig Harthaug (Haukeland U.sykehus) and Hartveit. The aim of the project is to make the implementation of new work methods more efficient, in this respect, also the conduction of feasibility studies. Implement it will be a collaboration partner in the present study through Hartveit.

Regional collaboration

Centre for Drug and Alcohol Resarch (KORFOR): KORFOR manages the National Quality Register for the Treatment of Harmful Substance Use or Addiction (Kvarus). **Ole Bergesen** is register manager for Kvarus. Bergesen is PhD-candidate in industrial economics with experienc from research on register data. In the planned project, Bergesen will contribute to the practical solution and the transfer of Kvarus data to the project.

Jörg Assmus at the Kopmpetansesenter for Klinisk Forskning (KKF), Helse Bergen HF, is a biostatistician with vast experience in the social sciences. In the current project, Assmus will contribute to the planning, conduction of statistical analysis, as well as interpretation of results.

Blå Kors Haugaland A-senter*:* The center is a treatment clinic for both in- and outpatients with SUD. The center is privately owned, but has an operation agreement with the regional health authority Helse Vest. As all publically funded SUD treatment facilities, BKHAS follows the national guidelines with recommendations for SUD treatment (Norwegian Directorate of Health, 2016). In the planned project, BKHAS will provide personnel and patients for the study. They will be involved in both the development phase and the implementation phase.

International collaboration

Prof.dr. **Robert Didden** at Radboud University is a certified mental health care psychologist, focuses as a researcher on young people and adults with a mild intellectual disability (LVB; including borderline intellectual functioning) and severe behavioural and psychological problems. His scientific and clinical interests are in risk factors, diagnosis and treatment of, among others, aggressive behaviour, addiction problems, trauma/PTSD and personality problems.

Joanneke VanDerNagel (MD, PhD) is a senior researcher at the University of Twente. Her research focus is 1) Epidemiology of dual and triple diagnosis, 2) Treatment of dual and triple diagnosis, including dual and triple diagnosis protocols, and integrated clinical pathways (IPC`s), and 3) Application of technological innovations in dual and triple diagnosis. She is affiliated with Tactus where se heads the Center for Addiction and Mild Intellectual Disability, which carries out care and treatment, research, education and method development. She has published a vast number of scientific papers on the topic of SUD and MBID. VanDerNagel has expressed her intention to collaborate by e-mail, but unfortunately, due to current sick leave, has not been available to confirm on eSøknad at the time of deadline.

In the planned project, Didden and VanDerNagel and/or their research networks will contribute with expert and cross-country inputs in the development phase of the intervention package. They will also be invited to co-author relevant papers form the study. Collaboration will aim at least one common workshop for the research networks in Norway and the Netherlands.

4.3. Budget

See eSøknad.

4.4. Activity schedule and dissemination of results

Activity	2022	2023	2024	2025	2026	2027
Preparatory activity						
Information and consent form baseline measures						
REC and DPO application for baseline measures						
Solution for transference of Kvarus data						
Baseline data collection						
Development of intervention						
Planning of/organizing process						
Create team/meetings/international networking						
Review published treatment literature						
Design intervention package						
Compliance scale						
Complete the intervention development						
REC/DPO applications and consent form						
Feasibility/pilot						
Planning						
Implementation support						
IPAT measure						
Outcome data collection						
Data analysis and preparation of papers						
Prepare data analysis						
Research group discussions/conduction of analysis						
Writing and publishing papers						
Paper 1 – Development of protocol						
Paper 2 – Feasibility of intervention in SUD facility						
Paper 3 – Patient satisfaction with new intervention						
Paper 4 – Preliminary treatment effects						

4.5. Plan for implementation

The planned project is a pilot of an adjusted intervention, and its results will be analysed with the aim of planning and conducting a larger randomized multicentre treatment study. Knowledge on adjusted SUD treatment gained in the project can be incorporated in clinical practice immediately.

5. User involvement

In the planned project both health and care workers in different organizations/disciplines who deliver services/treatment to individuals with MBID and the recipients of these services/treatments will be recognized as users. These user groups will participate actively in the development of the intervention package. User involvement is considered crucial in the project, as the aims require an elaboration of challenges from several viewpoints, solutions that affect different stakeholders, and initial acceptability from both service providers and patients. The intervention package will be a co-created product between patients, health and care providers and researchers.

6. Ethics

The Regional Ethical Committee for Medical Research in Norway (REC) will be applied for ethical approval of the study. All participation in the planned project will be based on an active, informed and voluntary consent. If the patient chooses not to participate, he or she will receive treatment as usual. All participants will be screened for MBID. The screening time will be 5-15 minutes. This is not considered especially wearing, and are in some cases included in treatment as usual. Also, the Kvarus registration will follow normal inpatient routines and no additional registration as a result of study participation will be required. The intervention package aims at delivering adjusted treatment to patients with MBID, and is intended to be better adapted to needs and level of functioning than TAU.

However, being labelled as someone in need of special treatment may be stigmatizing. On the other hand, treatment adjustments for other groups such as physically disabled, various somatic conditions or severe mental illness is a part of daily practice in the clinic. As the study is a pilot, stigmatizing aspects of the intervention may be uncovered and changed. Patients will be closely monitored, and any negative effects of the intervention will be discussed with the patient and handled by the patients treatment team. After collection, all data will be anonymized.

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