1. Project title: The impact of the coronavirus disease (COVID-19) outbreak on people with concurrent mental health and substance use disorders

2. Introduction

In this project, we aim to study the impact of a pandemic outbreak on persons with concurrent mental health disorders (MHD) and substance user disorders (SUD), who are among the most vulnerable individuals in modern welfare states, such as Norway. The lockdown due to the COVID-19 outbreak touched the daily life of most people in our society. Arguably, the situation of persons with MHD/SUD, who are already marginalized and often dependent on health care services, will be particularly affected by the pandemic. To our knowledge, current research only focuses on persons who develop an MHD/SUD as a consequence of a pandemic outbreak [1, 2], whereas our study will fill the research gap of how the pandemic affects the lives of persons with an existing MHD/SUD.

If everyday social life becomes difficult due to a pandemic outbreak for citizens with economic and cultural capital, it becomes even worse for vulnerable groups such as persons with MHD/SUD, who are particularly subject to social exclusion [3]. Statistics from "Service User Plan 2018" have identified approximately 26 000 persons in Norway with addiction and mental health problems with low levels of functioning in important areas of life, such as poor living conditions, financial problems, social problems, and weak integration in their communities [4]. Their living index has shown gradual deterioration over a period of four years. About 12% have little or no contact with social networks of any kind, are isolated or have only marginal social relationships. About 13% show very poor social functioning, 60% have little or no meaningful activity and 17% are homeless. They are often referred to as the "clients in greatest need", with a wide range of needs [5]. Due to the split organization of health and social services in Norway, it is challenging to provide comprehensive, integrated and coordinated services for people in this target group. Barriers to accessing health care during pandemic outbreaks places people with MHD/SUD at greater risk, as the health care services are pushed to their capacity. People with MHD/SUD, already stigmatized and underserved by the healthcare system [6], might experience even greater barriers to treatment for COVID-19 and other diseases. These barriers might also apply to testing, implying a greater risk of spreading the virus among people with MHD/SUD. Further, the prospect of lockdowns and other public health measures may also disrupt access to syringe services, medications, and treatment and support services. This may have a major impact on persons with MHD/SUD, as they are dependent on continuity of care and support measures with people they trust [7]. As a consequence of infectionprevention measures implemented at population level due to the COVID-19 outbreak, low-threshold measures for persons with MHD/SUD are closed and many MHD/SUD patients admitted to long-term inpatient care are being discharged. According to the Church City Mission and several other NGOs in the field of mental health and substance abuse, these measures will have major consequences for the relapse rate and further reduce quality of life for persons with MHD/SUD[8]. As pre-existing MHD and SUD are likely to worsen in the face of fear and distress as in a pandemic outbreak, lockdowns imply an even greater burden for persons with MHD/SUD [9].

As the coronavirus attacks the lungs, people who smoke or inhale drugs are at particular risk. The Chinese Centre for Disease Control and Prevention reports that the case fatality rate (CFR) for COVID-19 was 6.3% for persons with chronic respiratory diseases, compared to a CFR of 2.3% overall [10]. As the rate of smoking is much higher among persons with MHD/SUD than in the general population, our target group may be expected to have an increased CFR if infected [11]. While data are preliminary, they do show the need for further research to clarify the role of underlying factors in susceptibility to COVID-19 and its course, especially in those who suffer from co-occurring disorders such as MHD/SUD.

Little is known about COVID-19 and even less about its relationship to MHD/SUD. However, experience suggests that people with compromised health due to MHD/SUD find themselves at increased risk of COVID-19 and its more severe complications, for multiple physiological, social and environmental reasons.

2.1. Needs description

Our study will focus on social dimensions of the epidemic, such as examining how vulnerable groups understand and react to the disease as well as developing strategies to combat misinformation, stigma and fear. This is a high-risk group, as many of the persons suffer from comorbidities such as hepatitis, HIV, chronic obstructive pulmonary disease and cardiovascular diseases. In addition, SUD is associated with increased susceptibility to bacterial pneumonia and other viral infections [12]. Further, individuals with MHD and SUD are particularly affected by social exclusion and often exposed to stigma, which may lead to limited utilization of physical and mental health services [13, 14], which are both of great importance in a pandemic outbreak such as that of COVID-19. Individuals with MHD/SUD are more likely to experience homelessness or incarceration [15] and with the lockdown due to the COVID-19 outbreak such persons face new unique challenges, as many of the low-threshold public meeting places are being closed and the possibility to access other forms of services is limited. There is a great need to find out more about how people with MHD/SUD cope with the COVID-19 challenges. Further, there is a need for evidence regarding diagnosis, hospitalization, treatment or cases of death (e.g. due to overdoses or suicide) among persons with MHD/SUD, in order to provide guidelines for health and social care providers. This will also ensure that persons with MHD/SUD are not discriminated against if a rise in COVID-19 cases places an additional burden on the Norwegian healthcare system.

Our project is in line with both the WHO recent research priorities to "combat stigmatization of those affected, or perceived to be affected, by the disease" [16] and the request of the US National Institute on Drug Abuse to obtain data on the risk of COVID-19 in individuals with SUD.

We plan to comply with these requests in our investigation of the impact of the COVID-19 outbreak on persons with concurrent MHD and SUD.

There is limited research on persons with MHD/SUD in general and, as far as we know, no research on the impact on this group of the COVID-19 virus, either the direct effects of infection or the effects of the various strict new regulations during the outbreak.

There is reason to believe that new pandemics or other situations that threaten the population will emerge in the future. In this context, it is essential to gain knowledge of how to care for vulnerable groups in society and how to reach them in emergencies

3. Hypotheses, aims and objectives

The overall purpose of this project is to explore the impact of COVID-19 in persons with concurrent MHD and SUD.

The sub-goals of the project are:

- 1) To explore the experiences and actions of persons with MHD/SUD as a result of the COVID-19 pandemic outbreak
- 2) To study and describe the incidence and course of COVID-19 among persons with MHD/SUD
- 3) To explore the utilization of (specialist) health care services by persons with MHD/SUD during pandemic influenza outbreaks, in addition to the prescription of psychotropic drugs

Although the effects of pandemic influenza outbreaks such as H1N1 and COVID-19 on persons with MHD and SUD have not been systematically studied, we anticipate that the COVID-19 pandemic will have major consequences, especially in view of current public reactions, and that persons with severe MHD/SUD will be especially affected. We therefore hypothesize that persons with MHD and SUD will have a lower quality of life and be even more marginalized than they already are, and experience greater susceptibility, more stigmatization and greater barriers in accessing the health care system compared to the general population as a control group.

The following research questions are addressed:

- RQ1) How do persons with MHD and SUD cope during the COVID-19 outbreak?
- RQ2) How do persons with MHD and SUD experience the different governmental restrictions due to the COVID-19 outbreak?
- RQ3) What are the concerns and perceptions of persons with MHD and SUD during the COVID-19 outbreak?
- RQ4) What characterizes the help-seeking and health service utilization behaviour of persons with MHD/SUD during the COVID-19 outbreak?
- RQ5) What are the incidence and course of COVID-19 during the consecutive waves of the pandemic among persons with MHD and SUD compared with the general population?
- RQ6) What are the specific risk factors for COVID-19 among persons with MHD/SUD?
- RQ7) Is there an increased prescription rate of psychotropic drugs during the consecutive waves of the pandemic?
- RQ8) What characterizes the utilization of specialist health care services by persons with MHD and SUD during the consecutives waves of the pandemic?

4. Project methodology

The best way to meet our objectives and to fill the existing research gaps is a mixed-method approach: In the qualitative study, we will focus on persons with MHD and SUD and collect novel data on the target group's experiences of the COVID-19 pandemic outbreak in Norway. While in the quantitative study; we will analyse existing register data to generate epidemiological evidence on influenza pandemics among persons with MHD and SUD.

4.1. Project arrangements, method selection and analyses

The theoretical foundation of our study is the "theory of social integration as quality of life" of Ware and colleagues [17], which describes the process of capacity development for social integration through exposure to increasingly challenging occasions for growth in the context of mental health care. Social integration is defined as a process through which individuals with mental health disabilities develop and increasingly exercise capacities for interpersonal connectedness and citizenship [18]. Persons with MHD/SUD have pre-existing capabilities to achieve progress. Current capacities are enhanced, and new ones are established, through exposure to occasions for growth. Such occasions present challenges and may be simple or complex, i.e. they consist of single interactions or of orchestrated sequences arranged in order of increasing difficulty. As challenges are handled via mechanisms such as contradiction and reinterpretation, capability is affirmed and a sense of possibility emerges, accompanied by aspiration. Aspiration and a sense of possibility promote engagement with new, more challenging occasions. Considering this theoretical framework, our project is generating data to inform measures to foster social integration for and resilience in persons with MHD/SUD affected by pandemic outbreaks, which are expected to have still broader health implications.

Qualitative study

We will use a criterion-based sampling procedure in the recruitment of a heterogeneous sample of 25 persons of both sexes with MHD/SUD with substantial impairment in the last two years, receiving local services in the municipalities of Stange and Hamar. We will conduct qualitative in-depth individual

interviews (N=10), followed by three focus group interviews (N=5 per group). The number of interviewees is based on experiences form earlier studies [26, 27] with the same vulnerable target group. We will apply both interview methods, as our target group is very heterogeneous when it comes to their impairments due to MHD/SUD. Inclusion criteria are: (a) age 18 years and above, (b) capacity to understand study information and informed consent, (c) being in contact with municipal health and social services, and (d) having a mental health and substance use problem that seriously affects everyday life, based on selfreport. Inclusion does not depend on a clinic diagnosis, as this would imply an attitude that people are unable to assess their own situation. Within the focus groups, it will be possible to discuss viewpoints and disagreements among the service users, whereas the individual interviews allow us to go much deeper and give those the possibility to participate who feel uncomfortable taking within a group. The interviews will focus on the participants' coping strategies, understanding of the pandemic, perceptions and concerns during the COVID-19 outbreak. Both individual and focus group interviews will be audiotaped. Focus group interviews will be arranged in compliance with qualitative research standards. Information will be provided and written informed consent obtained before starting the focus group interviews with support of municipal staff. Recruitment will take place in cooperation with our peer support workers, the municipal health and social services and the FACT teams (Flexibel Assertive Community Treatment) in Hedmark and Oppland. The staff ask eligible patients/service users if they are willing to participate in the study. A project employee calls those who comply to make an appointment for an interview where also the written informed consent will be obtained. Interviewees may choose whether they participate in a focus group or individual interview. To break the ice in interview situations with our target group [19] and based on our experience from earlier studies [20], a researcher will conduct the individual and focus group interviews accompanied by a peer support worker. An interview guide consisting of open-ended questions will be developed in collaboration with peer support workers. Participants will be asked to describe their personal experiences, e.g. whether they sought help and if so, what kind of help, during the COVID-19 outbreak. Individual and focus group interviews will last from 30 to 80 minutes, adjusted to the condition of the interviewees at the time.

Analysing qualitative data

Transcripts of the individual and focus group interviews will be analysed using Kvale's [21] three-step method, including coding, categorizing, and meaning-making, moving from the manifest to the latent context of the text. We will involve our advisory group, which consists of peer support workers and national and international researchers, in the analytical process, to enhance understanding of the material.

Quantitative register study

In the quantitative part of the project, we will utilize a data file constructed by linking individual-level information from the Norwegian Patient Register (NPR), the Norwegian Prescription Database (reseptregister NorPD), the Norwegian Surveillance System for Communicable Diseases (MSIS) and register data managed by Statistics Norway. The register data administered by Statistics Norway include a wide range of socio-demographic information such as age, gender, country of birth, educational level, labour market participation, disability pension and mortality [22]. NPR (www.npr.no) collects data about all contacts and admissions to specialist health care in Norway, such as date of referral, length of stay, diagnosis, whether the hospital admission was acute or planned, treatment codes, and whether the outcome was discharge or death. We analyse register data from 2019-2021 and focus on the consecutive COVID-19-waves in Norway during 2020 and 2021. The ICD-10 main diagnosis, chapter V will be used to identify persons with MHD/SUD who will then be compared with the general population: Persons who

are registered with F10-19 as a main or secondary diagnosis with any other concurrent main or secondary F diagnosis will be defined as a person with MHD/SUD. Laboratory-confirmed influenza cases within the two periods of pandemic outbreaks will be obtained from the MSIS.

Merging register data is a time intensive process and demands epidemiologic competence. This is why we have set up three quarters of a year for preparing the final dataset and enriched the project team with experienced epidemiologists who will support the post doc-candidate.

Analysing quantitative data

The in the merged register identified persons with MHD/SUD will be matched after gender, age-group and health region (HF) with a sample from the general population as a control group. Principal factor analysis using the ICD-10 codes will be applied to identify and determine the types of patterns in COVID-19 during the consecutive waves of the pandemic in 2020-2021 among persons with MHD/SUD, while conditional logistic regression will be used to determine differences in patterns of outcomes between the general population and persons with MHD/SUD. With help of Cox regression analysis we will assess survival compared with the general population. Moreover, we will study the prescription of psychotropic drugs during the consecutive waves. All analysis will be stratified by gender.

This type of research design is highly recommended by Norwegian health authorities [23], who wish to draw on health care utilization research for health policy and planning.

4.2. Participants, organization and collaborations

The initiative for this research project comes from the Norwegian National Advisory Unit on Concurrent Substance Abuse and Mental Health Disorders (NKROP), which has which established a research group in cooperation with user representatives and international partners from the University of Strathclyde (Scotland) and Bangor University (Wales). NKROP has around 20 PhD students, five post-doctoral fellows and six senior researchers.

In the qualitative study we will build on existing solid partnerships with municipal health and social services in Stange and Hamar.

At the initial stage of the project, an international advisory board with national members will be established in order to guide and support the project. An advisory board meeting will be held twice a year via Skype. The project is scheduled to start on 01.03.2021 and to finish on 31.12.2026.

Marja Leonhardt will be in charge of obtaining ethical approval from REK, briefing the peer support workers and conducting the individual and focus group interviews. The peer support workers will be involved in conducting the individual and focus group interviews and will recruit participants with Marja Leonhardt. The municipalities of Stange and Hamar support the researchers with recruitment. Marja Leonhardt will perform all analysis, supported by the researchgroup. Register data will be stored, using the server for sensitive research data owned by Innlandet Hospital Trust. Mainly the leading institution (NKROP) with the help of peer support workers will carry out cross-project tasks. The status of the study will be presented and discussed twice a year at the meetings of the service user board.

4.3. Plan for activities, visibility and dissemination

From the beginning of the project, we publish information, progress and results of the study on the website of NKROP (www.rop.no) and our biweekly newsletter which serves as the main internet location for information on MHD/SUD in Norway and has a high profile on recovery research. Further, we provide an internet banner to our project partners — especially the municipalities Hamar and Stange, which enables them to link in an attractive way to our study website. Our study approach provides service user involvement form the design of the study to dissemination of the results: The Norwegian servicer user board — founded by NKROP since 2012 — advanced and approved the final study protocol. We use these service users as multipliers; they disseminate the project into their associations and peer communities. Service users and peers with training in research will be invited to co-author articles and take part in conferences, and planning community meetings on the project's results. We use national conferences,

such as the annual ROP-day, ISPS Norge, Psykiatriveka which are directed not only to researchers but also practitioners to report continuously about our project. Established features such as NKROPs newsletter, Facebook and twitter posts and ROP-TV (TED-talks), embedded in YouTube, will communicate our study to the general public. Bylines in daily newspapers and popular science journals such as "Dagens Medisin", "Sykepleien", and "Tidsskrift for psykisk helsearbeid", will be also part of our public communication strategy. In the last project year we will arrange a dialog-conference with service users, health and social care workers and researchers, which is a method of user involvement and a way to organize learning processes within organizations, and between organizations and their users.

International conferences will be our platform for communication of the study in relevant research communities. Three to four research articles will be published in relevant international peer-reviewed journals:

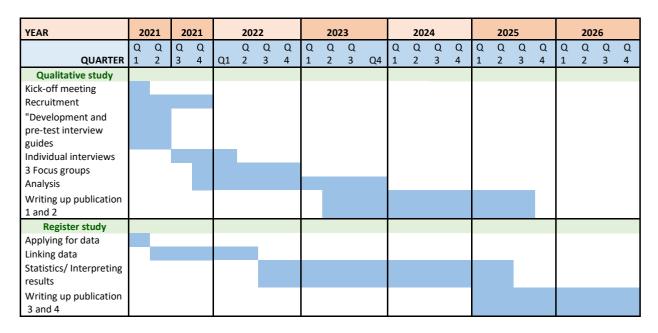
Tentative articles

| Qualitative study | Quantitative study |
|---|--|
| Article 1: Concern and perception: | Article 3: Incidence, risk factors and progression |
| Experiences of persons with MHD/SUD with | of COVID-19 among persons with MHD/SUD |
| the COVID-19 outbreak | |
| Article 2: Help-seeking & health service | Article 4: The utilization of specialist health care |
| utilization behaviour during the COVID-19 | services by persons with MHD and SUD during |
| outbreak | the COVID-19 outbreak |

4.5 Plan for implementation

Exploring the impact of COVID-19 on persons with concurrent MHD and SUD will be the first step towards the development of new intervention- and preventions programs for å vulnerable service group. There are plans for writing grant applications on the results of this study to The Research Council of Norway in 2023 and Helse Sør-Øst in 2023 for an intervention and implementation study, respectively, that may begin in 2024.

Preliminary time schedule for the planned study:



5. User involvement

Collaborative research including service users and service providers in the research process is invaluable in bringing different perspectives at all levels of accountability to the process. This inclusion is a quality-assurance safeguard that generates important questions from different vantage points that are highly relevant to municipal health and care services, and that help to improve the evidence-base used to inform

how services are both designed and provided [24, 25]. In order to substantively involve peer support researchers in a way that is both rigorous and supportive, we established a competency group consisting of individuals recruited from user groups in the NKROP national network. Members of the competency group will receive training in conducting individual and focus group interviews, and will serve as coresearchers throughout all phases of this project. NKROP has good experience in forming and running such groups [26, 27]. Furthermore, the servicer user board (Expertrådet), founded by NKROP in 2012, advanced and approved this study description.

6. Ethical considerations

Persons living with MHD/SUD are considered a vulnerable group. It is possible that certain topics during the data sampling process may be upsetting to some members of the user group. Therefore, follow-up activities and support will be planned and provided to minimize any harm. On balance, the larger risk of not interacting with individuals and groups that have been underrepresented in clinical research needs to be recognized, as it prohibits their voices from being heard and their knowledge to be incorporated into strategies for recovery. The project will only include persons who can read the information letter in Norwegian and who can provide informed consent prior to participation. Ethical procedures to incorporate autonomy, empowerment and to reduce risks will be applied at each stage of the project. Appropriate approval will be obtained for the project from the regional level by the Medical Ethics Committee for South-East Region prior to the project's commencement. Details that could identify participants will be removed before the material (qualitative study) is shown to the research group. The members of the research group will sign a declaration of confidentiality. We will obtain ethical approval and the Regional Committee for Medical and Health Research Ethics (REK). As our participants belong to a very vulnerable group, they will be offered the opportunity to get in touch with the project group after the interviews. When it comes to the quantities study (register study) necessary permission from the data owners and the Norwegian Data Inspectorate will be secured. The project will construct a data file combining information from these four sources. Precautions will be taken to prevent identification of individuals.

7. References

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