Project description for the Research Project:

Non-pharmacological sleep-treatment in groups for people with psychiatric illness: Sleep in Psychiatric Care (SIP)

NCT-numbers: NCT04463498 and NCT05177055

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1. Excellence

1.1. State of the art, knowledge needs and project objectives

Sleep has been underrated for decades in medicine [1] despite the fact that improved sleep reduces psychiatric symptoms [2] and poor sleep is longitudinally linked to impaired somatic health [3]. In 2017, the Nobel Prize for Medicine or Physiology was awarded to scientists who showed that humans have a network comprising of timekeeping genes that are repeated in a daily cycle. These timekeeping genes are associated with timing of sleep and wakefulness as well as mental disorders such as depression, bipolar disorders, and other mood disorders. This important acknowledgment of sleep and circadian rhythms` relation to mental health, has turned the wheel towards increased focus on sleep-related scientific knowledge [1]. The main idea behind this project is to bring a focus on sleep into psychiatric care (SIP) and to provide an evidence-based approach of delivering non-pharmacological sleep-treatment to people with psychiatric illness.

The projects in this proposal are based on several important theoretical findings. First, disrupted and poor sleep are associated with the development, relapse, or worsening of mental disorders and also increased suicidal ideation [4]. Polysomnography studies on sleep and mental disorders show that problems with maintenance of sleep are observed in most mental disorders while sleep architecture alterations compared to normal sleep are observed in all mental disorders except for ADHD and seasonal affective disorder [5]. Sleep and mental health have a bidirectional relationship, but there is a knowledge gap on whether interventions to improve sleep also improve mental health in patients with moderate to severe psychiatric illness [2]. About 50% of patients visiting their general practitioner fulfil the criteria for chronic insomnia [6] and 45-70% of patients with depression, bipolar disorder, anxiety disorder, and PTSD have been shown to have significant sleep disruption [7, 8]. Cognitive behavioural therapy for insomnia (CBTi) is the recommended treatment option for chronic insomnia disorder worldwide, but its effect on patients with comorbid moderate to severe psychiatric illness is mainly documented in single-disorder randomized controlled studies (RCTs) [6]. A recent feasibility study from Sweden showed that CBTi delivered in groups is a clinically feasible treatment option for insomnia in an outpatient setting among patients diagnosed with depression, bipolar disorder, anxiety disorders, and PTSD [7]. In a recent series on sleep and sleep disorders in the Lancet, the authors point out that very few high-quality intervention studies exist and that treatment for circadian rhythm disorders are hindered by a scarcity of tools for measuring sleep and circadian physiology [9]. Chronotherapy (e.g., sleep hygiene, timed light exposure, and the use of chronobiotic medications), shows promising effects within psychiatric treatment [9]. Also, a high prevalence of personality disorders has been found decades ago in circadian rhythm sleep disorders, though the focus on this comorbidity seem to have gotten increased attention in later years [10]. Transdiagnostic interventions, which are based on the assumption that many differential disorders share common etiological and maintenance process [11], targeting sleep in psychiatric illness has received increased attention in the past decade [9, 12-14]. Also, disturbances of the circadian system have been

implicated in the development of several somatic illnesses such as cancer and cardiovascular diseases as well as in neuropsychiatric disorders [9]. Hence, sleep plays a pivotal role for health in the entire organism.

In this project the objective is to investigate the effects of two non-pharmacological group-based treatments for patients with insomnia and the most common circadian rhythm sleep-wake disorder; delayed sleep-wake phase disorder (DSWPD), respectively, in which both sleep disorders are comorbid with moderate to severe mental illness. We will investigate the effect on subjective and objective sleep measures and on symptoms of psychiatric illness. By treating the sleep disorders adjacent to their mental illness, we will be able to fill the gaps of the abovementioned knowledge needs. We will examine the potential benefits of sleep-treatment on a wide array of symptoms and areas of human functioning, because sleep plays a role in all aspects of the human body.

1.2. **Novelty and ambition**

The current project is highly innovative and underlines the importance of cross-disciplinary - including user-representative - collaboration. Findings from this study will improve our understanding of the development, relapse, and remission of moderate to severe mental disorders, the importance of sleep and the sleep-wake cycle including neurophysiology in health and illness and could change the way we design future package sequences in the mental health care sector. This could lead to new scientific discoveries and improved treatment interventions. The results have the potential to change the way we think about, teach new therapists (medical doctors, psychologists, psychiatric nurses, and other health personnel), and not the least the way we treat patients with mental illness and comorbid sleep disorders. This project is to our knowledge the first to combine state-of-the-art knowledge about chronotherapy with knowledge from the extensive research on the benefits of CBTi on sleep and psychiatric symptoms. It is also the first to examine the potential benefits of non-pharmacological sleep treatment in moderate to severely mentally ill patients on a wide array of functionalities.

Particularly innovative aspects of this project:

- We focus our attention on a patient group otherwise often excluded from research protocols, even though a vast amount of time and money is invested every day to treat this patient group.
- We treat sleep disorders co-jointly with psychiatric disorders in a psychiatric setting.
- The broad outcome measures and the combination of self-report and objective measures.
- We will study a treatment already implemented as a treatment in a clinic, making it easier and more feasible to implement in other clinics. The project is hence based on clinical practice that already is experienced as effective and appreciated by therapists and patients. We now plan to test this clinically successful model with gold-standard evidence-based methodology.
- The sleep-treatment in groups is a cost-effective way of delivering sleep-treatment and we do it in a slow open fashion where patients can be referred anytime. After the pre-consultation with a member of the sleep-team, a date of sleep-treatment initiation is given, regardless of waitlists. This is a flexible format and does not require a lot of resources in the clinic.
- We will study the psychophysiology (such as blood pressure and heart-rate-variability; HRV) in patients with sleep- and psychiatric disorder. This may lead to new insights into the interconnection between sleep-wake regulation, psychophysiology, and psychiatric symptoms.
- We will investigate whether personality traits become changed in 12 months in patients with sleep disorders and psychiatric illness after successful treatment, which has not been investigated before, only suggested by several researchers in the field.
- We evaluate personality disorders (using a diagnostic manual, the SCID-5-PF) in all patients with DSWPD, which has been documented in the 1990`s to be prevalent in circadian rhythm sleep disorders. This has not been taken further scientifically for two-three decades. The knowledge we

will gain from this, will not only be important in the field of sleep and circadian rhythm sleep disorders, but also in the field of personality disorders.
- We will study work attendance, welfare benefits, medication use, suicide attempts and admittances in psychiatric care before, during and after the non-pharmacological sleep-treatment.
- We are conducting two RCTs in a more naturalistic setting than what is often the case since the intervention group and control group are in outpatient psychiatric treatment during the experimental period. This improves the generalizability to clinical settings, which often is a limitation in RCTs.
- We build on the new and innovative research that indicates dark-therapy (in our project by using blue light blocking glasses (bb-glasses) as a promising treatment for mental illness and sleep disorders, for the first time investigating this as an additive treatment to more established treatment protocols in a group of patients with identified sleep disorders comorbid to moderate to severe mental illness. This along with non-pharmacological, psychological and behavioral treatment, represents a much desired alternative to the use of hypnotics to mend sleep problems.

Although the treatment basis in this project is not new, this is the first study to use the research in treatment for insomnia and DSWPD without excluding moderate to severe mental illness. It is also the first RCT to our knowledge to study the effect of treatment for insomnia and DSWPD on such a wide array of functionalities as planned here, in a group setting, in a naturalistic context. We use state-of-the-art treatment and implement it in an outpatient psychiatric clinic. The treatment has so far mainly shown effect for patients with sleep disorders only or just mild to moderate specific mental illnesses such as depression, bipolar disorder, or ADHD. Our ambition is to investigate - and if the results do not contradict our hypotheses - later develop a model and manual for non-pharmacological sleep treatment in groups for people with psychiatric illness into a recommended standard, first-choice treatment for comorbid sleep disorders in moderate to severe mental illness. We plan to develop treatment manuals which ease the transferability to other psychiatric settings. The model is designed to fit the government-regulated package sequences all patients in psychiatric care are required to receive. We argue that the project also has an innovative side where established treatment is being used in a new manner, in a new setting and where it is possible to test the treatment digitally (or hybrid with face-to-face and digital follow-up) in later studies.

1.3. Research questions and hypotheses, theoretical approach and methodology

We will test the following hypotheses in two work-packages (WPs):

1. An RCT with 60 psychiatric outpatients with comorbid insomnia and moderate to severe mental illness to investigate the positive impacts of an additive group-based treatment for insomnia compared to treatment as usual in psychiatric care while on a wait-list for non-pharmacological sleep-treatment in groups.
2. An RCT with 60 outpatients with comorbid DSWPD and moderate to severe mental illness to investigate the positive impacts of an additive group-based treatment for DSWPD compared to treatment as usual in psychiatric care while on a wait-list for non-pharmacological sleep-treatment in groups.

The specific aims of this project are to test the following hypotheses:

WP 1

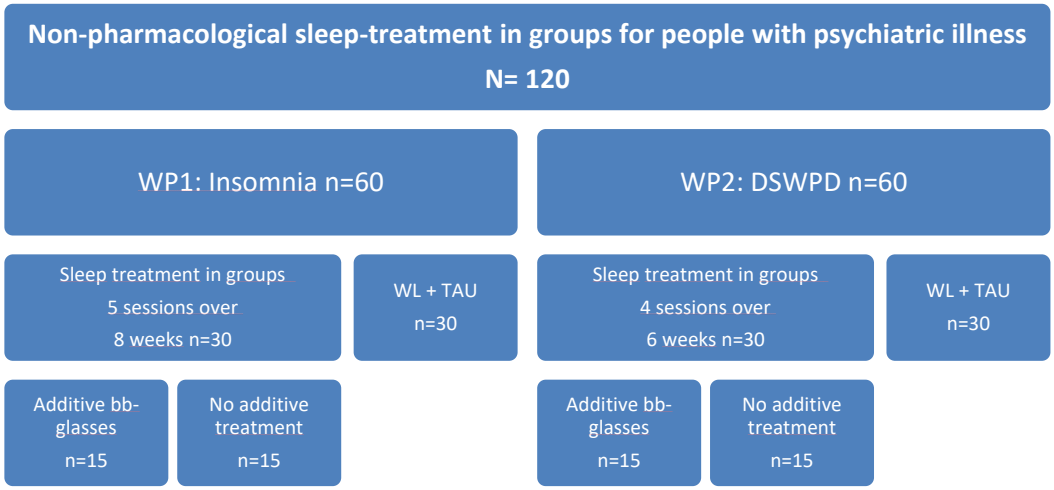
Primary hypothesis: Group-based sleep intervention based on CBTi reduces insomnia symptoms and symptoms of anxiety and depression significantly more than treatment as usual while on a waitlist for non-pharmacological sleep-treatment in groups (TAU + WL).

Primary outcome measures: Insomnia Severity Index (ISI), the Bergen Insomnia Scale (BIS), and Sleep Onset latency (SOL), Wake after sleep onset (WASO), and Sleep efficiency (SE) from sleep diaries, Becks Depression Inventory (BDI-II) and Becks Anxiety Inventory (BAI).
Secondary hypothesis: Group-based sleep intervention based on CBTi reduces symptoms in a range of areas including fatigue, sleep, attention deficits, dysfunctional beliefs about sleep, and improves well-being, attention, and daytime function significantly more than treatment as usual while on a waitlist for non-pharmacological sleep-treatment in groups (TAU + WL).
The use of bb-glasses enhances the effect of the group-based treatment for insomnia on SOL.

WP 2

Primary hypothesis: Group-based sleep intervention with light therapy at gradually advanced timing advances sleep timing and reduces symptoms of anxiety and depression significantly more than treatment as usual while on a waitlist for non-pharmacological sleep-treatment in groups (TAU + WL).
Primary outcome measures: Measured subjectively and objectively by sleep diaries, Genactiv actigraphy, and saliva samples (intraindividual variation of rise time (IIV), dim light melatonin onset (DLMO), rise /wake up-time), Becks Depression Inventory (BDI-II) and Becks Anxiety Inventory (BAI).
Secondary hypothesis: Group-based sleep intervention with light therapy at gradually advanced timing reduce symptoms in a range of areas including fatigue, sleep, attention deficits, dysfunctional beliefs about sleep and improve well-being, attention, and daytime function significantly more than treatment as usual while on a waitlist for non-pharmacological sleep-treatment in groups (TAU + WL).
The use of bb-glasses enhances the effect of the group-based treatment for DSWPD on SOL.

Figure 1. Overview of the project and the two WPs.



WL= Wait list. TAU=treatment as usual, bb-glasses=Blue-blocking glasses

Two randomized controlled trials (RCTs) will be undertaken in order to obtain an evidence-based treatment model in psychiatric outpatient care for patients with moderate to severe mental illness and comorbid sleep disorders (insomnia and DSWPD).
Choice of method: We have chosen to use the gold standard for experimental trials, RCT, as the methodological design for WP1 and 2. We want to conduct a naturalistic, yet controlled study that is generalizable to common clinical practice and outpatient psychiatric clinics. Hence, the participants will already be patients at an outpatient clinic and are not to be recruited from outside the clinic (such as from the general population). We use an RCT design to avoid confounding biases and in order to be as sure as we can that the intervention in the experimental condition represents the only difference between the groups we study. Most studies on sleep disorders exclude moderate to severe mental illness hence leaving the research results not generalizable to the patient group that may benefit from sleep interventions the most leaving a large knowledge gap regarding these patient groups. In this project, however, that is the specific

group we want to recruit and investigate, and we seek to close this gap concerning the effects of evidence-based treatment studies for sleep disorders. Since we are investigating a tormented and vulnerable group of patients that traditionally have low daytime function and tend to receive welfare, we find it particularly important to have user representatives as part of the project group to speak for the patients.

Inclusion and exclusion criteria for WP 1 and 2:
Inclusion criteria:

- Patients referred to, are offered, and who accepts attendance at the sleep-school at Bjørgvin DPS psychiatric hospital (BDPS)
- Patients fulfilling the Diagnostic Manual for Mental Disorders (DSM-V) criteria for insomnia/DSWPD
- Patients who have comorbid moderate to severe psychiatric illness operationalized as;
  1. Confirmed clinician-evaluated F-diagnosis based on the International Statistical Classification of Diseases and Related Health Problems (ICD-10/11) diagnostic system that are used in Norway
  2. and/or scores of >19 on BDI and/or scores of >15 on BAI at the time of referral to the sleep school

  Exclusion Criteria:
- Nightwork or shift work that overlaps with the patients` regular bedtime
- Not able to fill out questionnaires online even with help from others (either because of language barriers, functionality barriers or ability level)

Power analysis for the insomnia RCT

Power analysis was conducted with G*Power, version 3.1.9.2 [15]. Relevant effect sizes (Hegdes g) for power analyses were based on a recent meta-analysis of randomized controlled trials aiming at improving sleep, but that also reported an impact on mental health. The meta-analysis reported (following the removal of outliers) a large pooled effect size (g = 0.97) on sleep quality. The pooled effect size for composite mental health outcomes was g = 0.42 [16]. Another relevant meta-analysis on the effects of CBTi in patients with mental disorders and comorbid insomnia showed that effect sizes (Hedges g) for reduction of insomnia severity post-treatment were 0.50 for patients with depression, 1.50 for patients with PTSD, 1.40 for patients with alcohol dependency, 1.20 for patients with psychosis/bipolar disorder, and 0.80 for patients with mixed comorbidities, respectively. Effects on mental health symptom severity post-treatment were 0.50 for depression, 1.30 for PTSD, 0.90 for alcohol dependency (only one study), 0.30 for psychosis/bipolar, and 0.80 for mixed comorbidities [17]. Against this background an assumed effect size (Cohens d) for insomnia symptoms (primary outcome) of 0.80 was expected, whereas an expected effect size of 0.40 was deemed reasonable for the secondary (mental health) outcomes. Analyzing the data using ANOVA, setting the alpha to .05, power (1 – β) set to .80, and the correlation coefficient between repeated measures to r = .50, showed that 16 patients are needed to detect significant time (pre-post) x group (treatment vs. wait-list) interaction effects. In terms of the secondary outcomes (d= 0.40), a similar power analysis showed that a total of 52 patients are required. Taking into consideration an attrition rate of 10%, we aim, based on this power analysis, to recruit a total of 60 patients. For the sub-sample in the treatment group using additive bb-glasses, we base our power calculation on a study reporting ES of 1.6 [18]. Following the same procedure as above, we need 6 participants to show a significant time (pre-post) x group (standard care vs. treatment) interaction.

Power analysis for the DSWPD RCT

The power analysis for the delayed sleep-wake phase disorder (DSWPD) group was based on estimates of changes in dim light melatonin onset, which is one of the most important primary outcomes. Based on a previous controlled study [19] we calculated the effect size, using the Comprehensive Meta-Analysis, version 4.0, [20] in favor of the bright light intervention on this parameter to equal a Cohens d of 0.64 at posttreatment. Based on this we assumed an effect size (Cohens d) for DLMO (primary outcome) of 0.60. Setting the alpha to .05, power (1 – β) set to .80, and the correlation coefficient between repeated measures to r = .50, showed that 24 patients are needed to detect significant time (pre-post) x group

(treatment vs. wait-list) interaction effects. No previous study has investigated secondary (mental health) outcomes of light treatment for DSPRD. Hence, we assumed a similar effect size (d= .40) as for the secondary outcomes related to CBTi for insomnia. As shown above, recruiting 60 patients should then be sufficient, also when taking attrition into account. Taken together the power analyses showed that for detecting significant improvement on the primary outcome measures for insomnia and the DSWPD-group post-treatment 16, and 24 patients need to be recruited, respectively. However, in order to be able to detect improvement in the secondary outcomes and to take attrition into account as well we should recruit 60 patients in total, in each of the two patent groups. No study has investigated the additive effect of bb-glasses to light therapy at gradually advanced timing for DSWPD.

Randomization procedures: Randomization was performed by: https://www.randomizer.org/ before inclusion. When a new patient is referred to the sleep team and meets the inclusion criteria evaluated in an individual pre-consultation before the group-based sleep-school, the patient is asked if they want to participate in the study. If they say yes, they are assigned either to Sleep-school or waitlist while in treatment as usual (TAU + WL) based on a pre-defined list. All receive a date the Sleep-school starts without being told whether or not they are assigned to a wait-list condition. They are also assigned a date for data collection at two time-points. For the Sleep-school group this is before (T1) and after (T2) Sleep-school, while for those in the TAU + WL condition are assigned T1 and T2 at least 8 (WP1) or 6 (WP2) weeks apart before they start the Sleep-school. Hence, blinding is not completely ensured, but not overt. Wait-list for specific treatments in psychiatric care is normal.

Stability in the treatment in the Sleep-school: The content (slides, hand-outs, video material) and the plan for each session in the sleep-school remains the same throughout the project. The structure has been tested over 4 years before we started recruiting and hence it is well tested. AWL and VKV has lead these groups together as co-therapists since 2017 and plan to continue until 2026 and onwards. In case of sick-leave or other unexpected circumstances, there are colleagues who can fill in for the sleep team. To ensure that the included patients receives the same treatment, we will not change the content or the structure of the sleep-school as long as we are collecting data for these projects. TAU will naturally vary with different therapists. This study is a naturalistic study in a clinic as it is, which will increase generalizability of our research.

Risks: In terms of risks and risk-mitigation table 1 below presents an overview

Table 1: Risk and risk-mitigation related to the project

Risk	Probability	Severity	Mitigating action
Problems recruiting patients	Low	High	If occurring, advertising to increase recruitment is possible and multi-cites may be established in Helse-Bergen.
Equipment malfunction	Medium	Medium	Continuously ensure data quality. Have stand-by replacement equipment
Unequal gender balance	Medium	Medium	Take this into account in the analyses and analyze for gender differences.
Adverse events	Medium	High	We can not rule out the possibility of suicide attempts or suicidal behavior occurring while participating in the study. If that happens, the clinic has procedures for such events and trained personnel available.

Ethical considerations: The two work-packages will be carried out according to the Helsinki-declaration, the Vancouver-recommendations, Good clinical practice (GCP), and CONSORT-guidelines. The project is approved by the Regional Ethics Committee of Western Norway, REK West, project number: 66304, and both WP are registered in ClinicalTrials.gov. The projects are also registered at helsenorge.no. Patients that are referred to the sleep school that decline participation in the research project or that do not meet the inclusion criteria, will still receive the treatment if considered to fulfill criteria for participating in the Sleep-

school otherwise. The wait-list group will start the active sleep school treatment immediately after the 6- or 8 weeks of waiting (waitlist guarantee), while in treatment as usual for their psychiatric illness.
Gender perspectives: We will aim at recruiting 50% men and 50% women to the studies and if we end up with unequal gender balance, we will take this into account in the analyses and analyze for gender differences.
Stakeholder considerations: Sleep problems are common, but a widespread available treatment is not common. This project may provide a feasible solution to this lack of available non-pharmacological treatment and can be implemented on all levels in the health care.

2. Impact

The results can provide valuable knowledge on the association between sleep disorders and psychiatric illness and inform on the impact of an effective and time-efficient treatment for the most common comorbidity in psychiatric care. If the results show that group-based sleep-interventions can reduce both sleep problems and psychiatric symptoms to a larger extent than treatment as usual, we will recommend a change in clinical practice. Therapists are often overloaded with patient work and may then be relieved of treating patients with comorbid sleep and psychiatric illness - and focus on patients and treatments that require individual therapy. This can lead to shorter successful treatment for those where sleep is their main problem and can lead to cost-effectiveness in the health-economy. The structure of this group-based treatment is possible to implement in district psychiatric centers (DPS) nationally and can potentially improve public access to sleep treatment, which is highly beneficial since insomnia is a predictor of subsequent work disability [21]. This can also give GPs a highly welcomed non-pharmaceutical treatment option to refer patients to instead of giving them hypnotics or antidepressants for their sleep problems [22]. The results from this project can be the beginning of the important task of closing the knowledge gap between state-of-the-art science within the sleep area and the need for improved interventions and models in psychiatric clinics.

2.1. Potential impact of the proposed research

When the project is completed, we have a vast amount of new knowledge that can be used in optimizing treatment at BDPS and other DPS`s nationally and similar outpatient clinics internationally. If the results from this project show that a group-based sleep school over 6 / 8 weeks improves not only sleep measures but also psychiatric symptoms, reduce medication use and reduces the length of treatment, we will manualize the treatment and train therapists to become sleep school leaders based on the protocol and organization used in this project, hence manualizing this model. With the knowledge obtained from this project, it might be possible to tailor treatment and offer it to those who most likely will benefit from it. Hence, this project can potentially increase the effectiveness of the treatment in psychiatric health care.

In the field of psychiatry, the results from this project might be of great importance because sleep disorders in many cases are an obstacle to other treatment (the client has DSWPD and sleeps from 8 am to 16 pm, making attendance to therapy sessions difficult or a patient with comorbid insomnia cannot benefit from psychotherapy because of issues with fatigue and attention). One–on–one talk therapy can be very time-consuming and if this project shows significant improvement also in psychiatric symptoms, patients and therapists can be saved from many time-consuming treatments that otherwise may not be very successful. The treatment in this project may in some cases be all the patient needs, work as a pre-treatment before other protocols (i.e. trauma-treatment) and in some cases be adjacent to individual therapy, enhancing its effects.

2.1 Potential for societal impact of the research project (optional)

This project has the potential to address the UN sustainable goal number 3: Good health and well-being. Sleep problems are common and can be treated relatively quickly, hence SIP has the potential to target good health and well-being wherever the treatment is implemented.

2.2. Measures for communication and exploitation

Communication with other stakeholders: Summaries of results and interpretations with interest for a wider audience will be disseminated in appropriate outlets (e.g., the web pages at the University of Bergen and Helse-Bergen). In addition, the findings will be communicated to user groups, policymakers, and practitioners within medical and mental health services through lectures and the media, as well as the general public. The project group has a long experience in cooperation with national media channels and public outreach that will allow us to implement an effective communication and dissemination plan for this project. Throughout the project, preliminary results will be presented at national and international research conferences.

Scientific results: Results will be published in internationally acknowledged peer-reviewed open-access journals within medicine, psychiatry, and psychology. We expect to publish at least 8 international publications based on the findings from the current project within the project period. Working titles for the articles are:

1. Comorbid insomnia and moderate to severe psychiatric illness: A treatment protocol for a naturalistic, randomized controlled trial (manuscript is almost ready as first draft)
2. Comorbid delayed sleep-wake phase disorder and moderate to severe psychiatric illness: A treatment protocol for a naturalistic, randomized controlled trial
3. Group-based cognitive behavioural therapy for insomnia in a transdiagnostic sample at a psychiatric outpatient clinic: A randomized controlled trial
4. Group-based chronotherapy for delayed sleep-wake phase disorder in a transdiagnostic sample at a psychiatric outpatient clinic: A randomized controlled trial
5. Personality disorders and Delayed sleep-wake phase disorder in a transdiagnostic psychiatric sample
6. Psychophysiological changes after treatment for insomnia in a transdiagnostic psychiatric sample
7. Executive functions and attention deficits in patients with sleep disorders comorbid to psychiatric illness
8. Changes in work attendance after treatment for sleep disorders comorbid to psychiatric illness

3. Implementation

3.1 Researcher and project group

Project manager: **Ane Wilhelmsen-Langeland** (AWL), specialist in clinical psychology, PhD and certified somnologist at BDPS, a general psychiatric outpatient clinic. Leader of the sleep team at BDPS. Member of the research group Bergen Sleep- and Chrononobiology network (BeSCN) at the University of Bergen (UoB). Has lead the sleep school at BDPS clinically since the spring of 2017 together with psychiatric nurse VAV. AWL will lead the clinical part of the group based sleep school and manage the data collection, scoring and plotting, analysis and interpretation of data, write articles based on the results and disseminate the results in relevant academic fields as well as to the general public. She has experience doing all of this. We apply for free purchase of her time 50% from other clinical duties in order to be able to handle the data load and write the articles from SIP in close collaboration with the project group members.

Berge Osnes (BO) is a specialist in clinical psychology, PhD, and holds a position as associate professor at the Department of Clinical Psychology, UoB. He is a member of the research group Emotion and Cognition Group (ECG). BO has taken part in the design and planning of this project and will take part in data collection and his main expertise in this project is in HRV, neuropsychology and neurophysiology. He is also an experienced clinician. He will participate in analyzing and interpreting the data.
Psychiatric registered nurse **Veronika Alice Vågenes** (VAV) is part of the sleep team at BDPS and facilitates the sleep school groups together with AWL. She will take part in leading the sleep school groups (in which she already has been for 6 years), and be a research fellow in SIP. She will collect data, organize and execute several tasks in SIP. We apply for 20% research fellow position for her to relief her of some clinical tasks. She also starts her Masters` degree this year in Collaboration and Public Health at the Western University of Applied Sciences and she will write her Masters` thesis based on SIP.
Professor **Ståle Pallesen** (SP). Department of Psychosocial Science and Norwegian Competence Center for Sleep Disorders member of BeSCN, somnologist, has led and supervised large sleep related projects. SP has taken part in the planning and design of the study.
Professor **Bjørn Bjorvatn** (BB) works at the Department of global public health and primary care, UoB, is the leader of the Norwegian Competence center for Sleep Disorders (SOVno), and the leader Center for Sleep medicine at HUS. He is a member of BeSCN, he is a somnologist and has led many large sleep related research projects. BB has taken part in the planning and design of the study.
Ingvild West Saxvig (IWS) works as a senior advisor at the Norwegian Competence Center for Sleep Disorders (SOVno), is a somnologist and Registered Polysomnography technician (RPSGT), member of BeSCN, PhD. IWS has taken part in the planning and design of the study.
Professor **Lin Sørensen** (LS) at Institute for biological and medical psychology, UoB, has her specific expertise in neuropsychology, she is the leader of the research group ECG. LS will take part in interpreting the data related to her areas of expertise.
Professor emeritus **Ole Bernt Fasmer** (OBF) works at the Clinical Institute 1, UoB. His expertise in this project is among others within mathematical analyses of timeseries, motoractivity and heart rate. OBF will take part in interpreting the data related to his areas of expertise.
User representatives: **Ove Vestheim** who works in division of psychiatry as an advisor/peer supporter has been involved in SIP since the start. **Arild Sørensen** from the patient organization **"**Søvnforeningen" will onwards be invited to all meetings in the project group. They will both visit in the groups and give us feedback throughout. They are also available for the participants in SIP. Hjernerådet will be invited to the yearly seminaries and mid-evaluation meetings with the project group.
International project group members:
Professor **Michael Gradisar** (MG) works in Sleep Cycle which is a company promoting sleep using technology and has been a Professor at Flinders University in Adelaide, Australia. He was part of the task force in the National Sleep Foundation Poll (USA, 2011). He has made important scientific contributions to the field of adolescent sleep and DSWPD. MG will advise in interpreting the data related to DSWPD.
Julian König (JK) is deputy Head of Research, University Hospital of Child and Adolescent Psychiatry and Psychotherapy, University of Bern, and Head of lab, Section for Experimental Child and Adolescent Psychiatry, Department of Child and Adolescent Psychiatry, University of Heidelberg. JK is a renowned capacity on HRV, and will take part in interpreting the data related to his areas of expertise and in the drafting of scientific articles. All project group members will take part in writing the scientific articles.

3.2 Project organisation and management

Work plan and tasks: Recruitment, data collection, scoring, plotting and analysis of data, writing, critically reviewing, submitting articles, and disseminating results will take place between the last quarter of 2021 and the last quarter of 2026 (see details in Gantt chart below). Dissemination will likely extend further than 2026. Patients are referred to the sleep school at BDPS where AWL and VKV are on-site. Data-collection is done continuously as patients are recruited to participate in the study. Because of the slow-open group-treatment, this is possible to follow up continuously. Five patients have already been to their 12-month follow up data collection. AWL and VKV assign full days every two-three months to score and plot data, hence some data have already been plotted. We will continue doing this throughout the study period when feasable.

Preliminary data: As of January 2023 we did preliminary analysis where we tested Cohens` d on the first 9 participants in WP1. We found large effect sizes (ES) of 1.9 for insomnia symptoms (ISI), 1.34 for sleep efficiency (SE) and medium (0.53, 0.79 and 0.72) for total sleep time, depression and anxiety in the Sleep-school group, while in the TAU + WL group the ES were negative (-0.28) for total sleep time, and low to medium (0.57, 0.12, 0.22 and 0.29) respectively for the same variables.

Gantt chart:

Table 1. Gantt shows the project management for SIP

TASK NAME	START DATE	END DATE	Task performed by project group member(s)	2024				2025				2026			
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Work-package 1															
Recruitment	15.12.21	31.10.25	AWL, VAV												
Data collection	15.12.21	31.12.25	AWL, VAV, BO												
Scoring, plotting, analyze data	14.02.21	30.04.26	AWL, VAV, BO											KD	
Write, critically review and submit articles	01.01.23	31.12.26	All project group members												
Disseminate results	01.10.26	31.12.26	AWL, BO												
Work-package 2															
Recruitment	20.06.22	30.06.26	AWL, VAV												
Data collection	20.06.22	30.06.26	AWL, VAV, BO												
Scoring, plotting, analyze data	20.08.22	30.06.26	AWL, VAV, BO												KD
Write, critically review and submit articles	03.03.24	31.12.26	All project group members												
Disseminate results	01.10.26	31.12.26	AWL, BO												
Milestones															
Seminary for the project group		12.01.24	All project group members												
Seminary mid-evaluation		11.01.25	All project group members												
Seminary for the project group		10.01.26	All project group members												
WP1 data collection completed for RCT		31.12.25	AWL, VAV, BO												
WP2 data collection completed for RCT		30.06.26	AWL, VAV, BO												

Key Deliveries (KD): data listings for statistical analysis finalized

Probability of recruiting enough patients within the time frame: As of June 9th 2023 we have recruited 23 patients to WP 1 (recruitment started December 15th 2021) and 14 patients to WP2 (recruitment started June 20th 2022). With the current pace of recruitment, we will have recruited 60 patients for WP1 by the end of 2025 and 60 patients for WP2 by the third quarter of 2026. Referrals to the sleep-school has increased by over 30% in 2023 compared to corresponding timeline in 2022. We have not made any attempt to increase recruitment to the studies, we only recruit from patients being referred as part of clinical practice. It is possible to do more to recruit referrals if we find it necessary later on. We will do an evaluation of this by the end of 2024.

Resources:

3. Project manager AWL will lead both WPs; 2024-2026 in a 100% position. BDPS funds this as of now but free purchase from clinical duties besides the Sleep team is warranted in order to complete the projects as planned.
4. Research assistant VAV will work 20% on this project with WP1 and 2 over 3 years; 2024-2026. She will keep her clinical position at BDPS. Her Master thesis will be based on SIP.
5. BO can use some of his assistant professor position at UoB for data collection, analysis of data, writing, critically reviewing, submitting articles, and disseminating results.

6. The rest of the project group will be consulted and will take part in the project as described as part of their existing jobs with no funding from this proposal.
7. We aim to supervise psychology students who are writing their master thesis on topics related to these projects and that will provide more resources when it comes to scoring and plotting the data, as well as literature searches, and in some cases possibly also in the writing the scientific articles. Several project members hold positions at the UoB, hence access to students is ensured.

Budget: AWL received 100.000 NOK in 2020 from The Norwegian Competence Center for Sleep Disorders for research within the sleep field which was used to buy equipment necessary to start recruitment. SP, BB and BDPS has paid for Actiheart devices (to measure HRV). Data collection in itself is implementable in the current positions and organization of the WPs. However, due to the large data load, we need funding for free purchase for the project leader (50%) and a research assistant (20%) from their clinical positions in order to be able to manage the data during the recruitment period and write the scientific reports/articles. Free purchase from clinical work accounts for 2.389.000 million NOK over the 3 years. Funding for the analyses of the saliva samples (261.000 NOK), for open-access publication fees (240.000 NOK), for paid user representatives (18.600 NOK), for meeting costs (41.400 NOK) and conferences (50.000 NOK) to stay up to date and for networking, is also required in order to follow through as planned with SIP. In total we apply for 3 million NOK.

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