The Sleep Clinic Outcome and Practice study: The SUP-study

Outcome and practice of non-pharmacological treatment of sleep-wake disturbances at the Sleep Clinic, St. Olavs Hospital

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Declarations
All authors declare that they have no competing interests in regard to this research project.

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Background

Sleep-wake disturbances including insomnia disorder and sleep-wake rhythm disorders disables many aspects of life and is highly prevalent. As one of few treatment options for sleep-wake disturbances, the Sleep Clinic at St. Olavs Hospital offers clinical assessments and treatment for this patient group in Norway. Although the treatment of insomnia disorder is well-described and recommended, there is still a major subgroup that to not benefit from the treatment. Additionally, treatment and outcome of sleep-wake rhythm disorders is little described in clinical settings. A study of clinical practice and outcomes of the treatments in the Sleep Clinic, would give the possibility to illuminate these knowledge gaps.

Aim

Describe the practice (timing and duration) and outcomes of the sleep treatments 1) Cognitive Behavioral Therapy for Insomnia and 2) Chronotherapy for sleep-wake rhythm disorders at the Sleep Clinic at St. Olavs Hospital.

Method

All patients referred to the Sleep Clinic will be asked to participate before the first consultation with a clinician. Patients will be clinically assessed, diagnosed and given treatment as usual. Main outcomes will be self-report questionnaires at treatment termination and the use, timing and duration of specific sleep treatment components logged by the clinician during treatment.

Potential impact

The findings from this research project provides possibilities to improve treatment for sleep-wake disturbances by tailoring the treatment different to respective subgroups. The findings will also contribute to novel knowledge on how we treat patients with sleep-wake rhythm disorders and to what degree they benefit from the treatment in a sleep clinic.

Background

The Sleep Clinic at St. Olavs Hospital is part of the public psychiatric health care service in the central region of Norway. The Sleep Clinic is one of few treatment units for sleep-wake disturbances in Norway. An underlying reason for this is that treatment for sleep-wake disruption is not prioritized in Norwegian public health care. The treatment opportunities among private clinics are also few and ad hoc as the knowledge on sleep disorder treatments is generally low among clinicians, including psychologists and physicians, although almost one out of two patients in a general practitioner's office report having a sleep-wake disruption[1]. Patients are typically referred to the Sleep Clinic by these general practitioners or other therapists working in the regional mental health care service. The mean waiting time from referral to the clinical assessment in the Sleep Clinic is over 12 months. During the recent years, the Sleep Clinic at St. Olavs Hospital has had three to six employed clinicians holding part-time positions and treated around 225 patients every year. The numbers of patients treated the recent years have been affected by the Covid-19 pandemic:

2018 317 treated patients
2019 225 treated patients
2020 145 treated patients (Covid pandemic)
2021 204 treated patients (Covid pandemic)

The two main groups of sleep-wake disturbances referred to the Sleep Clinic are insomnia disorder and sleep-wake rhythm disorders. Hypersomnic disorders (like narcolepsy) and parasomnias (like REM sleep behavior disorder) are mainly assessed and treated at the Department of Neurology.

Insomnia disorder

Insomnia disorder is a major public health care concern that affects 10-12 % of the general population in Western countries [2-4] , and the prevalence is shown to be on the rise in Norway [2]. Insomnia disorder involves subjective complaints of disturbed sleep and marked distress and/or daytime impairment [5] and is found to have strong correlations to both somatic and mental illness [6]. The diagnostic criteria for insomnia in the ICD-10 are: inability to fall asleep, waking up during the night or too early in the

morning for at least three nights a week for a month, and subsequent impairment in daytime functioning [5]. Insomnia Severity Index (ISI) is a validated questionnaire used as the primary outcome measure in insomnia disorder research [7] and is shown to have good psychometric properties [8].

Cognitive Behavioral. Therapy for Insomnia (CBT-I) is currently the best treatment option for insomnia disorder, recommended in several international reviews and subsequently acknowledged as the first-line treatment [9, 10], also when having somatic and mental comorbidities [11, 12]. CBT-I is a multi-component treatment which focus on three main domains: education, behaviors, and cognitions. Specifically, the treatment usually consists of one or more of the following interventions: psychoeducation about sleep, sleep restriction therapy, stimulus control, and challenging beliefs and perceptions of sleep. The stimulus control and sleep restriction components have been recognized as the most efficacious therapy techniques [9, 13].

More than 200 treatment studies have shown that on average CBT-I is a highly effective treatment for insomnia disorder [14, 15]. On the one hand, a review of 48 treatment studies using psychological interventions showed that half of the patients had clinically significant outcomes, and one-third were considered "good sleepers" following treatment – a finding that remained consistent over time [9]. On the other hand, when compared to control interventions such as sleep hygiene advice, 30-60% of individuals offered CBT-I do not demonstrate clinically significant benefits of the treatment [16, 17], suggesting there are subgroups of patients that do not respond to treatment.

The treatment manual for CBT-I provides guidance to therapists regarding the content of treatment on a session-to-session basis[18]. However, individual adaptations of the treatment are often made to match the need of the patient, resulting in a certain level of inter-individual variation in which sub-components of the treatment patients will receive, and their order. Thus, there is a potential to explore the effectiveness of different variations of administering CBT-I. Our knowledge of the benefits of CBT-I currently exceeds our understanding of for whom and how the treatment works, and identifying the treatment components that generate change for different patient groups may also help develop and tailor the treatment to those with little or no effect of CBT-I.

Sleep-wake rhythm disorders

Sleep-wake rhythm disorders are also known as circadian rhythms disorders. Delayed sleep-wake rhythm disorder is the most common disorder and the prevalence among young Norwegian adults is estimated to be 3.3%[19]. However, the number of people seeking medical help is probably far lower. A proposed reason for this is that the knowledge of these disorders is low among both patients and health care professionals. A general feature of sleep-wake rhythm disorders is that the sleep-wake patterns are not in alignment with the societal rhythm, thus their sleep is out of sync with the majority of the public and they therefore experience major functional impairments from their condition. The patients with sleep-wake rhythm disorders referred to the Sleep Clinic are typically in their mid-twenties, making this population older than what is most often described in studies on sleep-wake rhythm disorders[20, 21]. The majority of these patients have not completed their education even at high school and have difficulties holding on to a job – something they typically have experienced over years. Subsequently, this group tends to drop out of education and working life from a young age.

The human circadian system is composed of many interconnected circadian rhythms in tissue throughout the body which follow an approximately 24-hour rhythm. The circadian system is one of the major factors driving the sleep-wake rhythm, organizing sleep and wakefulness to nighttime and daytime[22, 23]. The timing of the circadian system is coordinated and regulated by the body´s central "internal clock", the suprachiasmatic nucleus, which is located in the hypothalamus of the brain [24]. For people with sleep-wake rhythm disorders, the timing of circadian rhythms tends to be shifted either earlier or later compared with the general public, which results in interference with social, educational, or work schedules. In sleep-wake rhythm disorders there may be physiological deviations in the function of the internal clock or there may be external factors that drive the internal clock out of sync with the surroundings such as in jet lag disorders or shift work disorder. In the Sleep Clinic, we only treat internal sleep-wake rhythm disorders including 1) non-24-hour sleep-wake phase disorder, 2) irregular sleep-wake disorder, 3) advanced sleep-wake phase disorder (morning larks), but most common is 4) delayed sleep-wake phase disorder (night owls) (see figure 1). According

to the American Academy of Sleep Medicine[25], the diagnostic criteria for delayed sleep phase disorders are that the sleep phase is delayed relative to the desired or necessary time to fall asleep and to rise and that this pattern must have been present for at least 3 months and is confirmed by sleep diaries or actigraphy for at least one week. There is also a criterion that sleep quality and quantity increases when patients self-select bedtimes and risetimes. The same diagnostic criteria apply for advanced sleep-wake phase disorder, except that with this disorder, the sleep phase is advanced relative to the desired or necessary time to fall asleep and rise in the morning. Non-24-hour sleep-wake phase disorder, or free-running sleep-wake disruption, is characterized by a progressive delay in falling asleep and rising across weeks. Further, the symptoms of insomnia symptoms and sleepiness go into remission in periods when their sleep-wake cycle is in sync with their desired sleep phase. Irregular sleep-wake phase disorder is characterized by the lack of rhythm and length of sleep and wakefulness. In the most serious cases, sleep is very fragmented throughout the 24-hour period. The diagnostic criteria for this pattern of varying sleep and wakefulness is that the person experiences insomnia symptoms during the night and sleepiness during the day or both. The symptoms must have been present for at least three months.

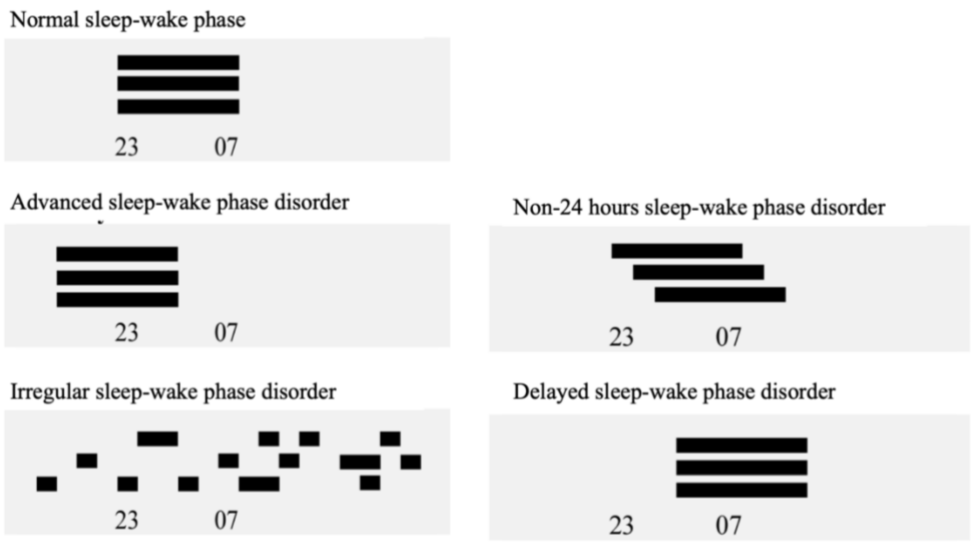

Figure 1, illustration from the Norwegian center of sleep medicine (SOVno)[26]. The three lines for each disorder represent three consecutive 24-hours. Black indicates sleep.

Treatments for sleep-wake rhythm disorders are referred to as chronotherapy. These strategies aim to restore proper alignment of sleep-wake cycles by way of proper timed

exposure to light such timed light exposure, blue-light blocking glasses, and chrono biotic medication such as the hormone melatonin[27]. In clinical practice these approaches are generally combined to provide the most effective treatment [28]. Light therapy and blue-light blocking glasses are used as tools to either advance or delay circadian rhythms via suppression or stimulation of signals to the suprachiasmatic nucleus through the retina in the eye. The glasses block the blue light spectrum as these light frequencies have been shown to be the most potent for signals in the circadian clock pathway in the brain[29]. Blue blocking glasses have been shown to advance the timing and increase the production of pineal melatonin[30-32]. The past decade, there has been increasing evidence that sleep-wake rhythm disorders are both common and have major adverse impacts on daily function[33]. Despite published guidelines on the use of chronotherapy for these disorders[26, 34], chronotherapeutic interventions are used to varying degrees in clinics, and when used the timing and combination of components vary. Moreover, there is to date no valid tool to evaluate the treatment effect of sleep-wake rhythm disorders. This leads to a gap in knowledge concerning the effectiveness of each chronotherapy intervention on its own and in combination from clinical settings.

Combined sleep disorders

There are also patients whose sleep-wake patterns align with both insomnia disorder and a parallel sleep-wake rhythm disorder. This is little described in sleep literature, although it is recognized that the symptomatology is somewhat overlapping and that it is important to distinct between the two disorders. Our clinical experience is that many of our sleep-wake rhythm disorder-patients have developed dysfunctional believes and behavioral patterns and that some of them over time develops a parallel insomnia disorder. On the other hand, it is well-established that a major subgroup in populations with insomnia disorder have either morningness or eveningness chronotype preference which is shown to have less effect of CBT-I[35]. The timely question is whether these patients have been correctly diagnosed. In any case, this shows that it is always important to consider both disorders. For the patients where we assess that they have both an insomnia disorder and a sleep-wake rhythm disorder, a combination of CBT-I and chronotherapy is be offered in the Sleep Clinic. The clinical prevalence of such combined sleep-wake disturbances is largely unknown in sleep literature and even less is known about how this patient group is treated and their outcome of treatment.

In the Sleep Clinic, we assess and treat the above-stated sleep-wake disturbances. We do not, however, have data on the use of each treatment component and the corresponding outcome of treatment, especially for those with sleep-wake rhythm disorders. Firstly, by collecting data on treatment as usual in the Sleep Clinic we can be able to improve the treatment outcomes by finding for instance patterns or timing of treatment components that are typically effective or not effective, making it possible to simplify the treatment and avoid unnecessary exertions for the patients. Another prospect with a collection of data in the Sleep Clinic is to identify moderators of treatment outcomes before treatment to identify subgroups that are most likely to attain positive outcomes. Moreover, we may identify subgroups that tend to have less favorable outcomes that may need tailored treatment regimes. Secondly, with data from the Sleep Clinic, we will be able to compare the treatment outcomes with other international studies and consider whether our treatment effects are in alliance with other published results. Additionally, it is a major gap in sleep literature of how to measure treatment outcome of chronotherapy, something that we can approach with data in the sleep Clinic. Thirdly, while the overall treatment approach tends to be well described in publications from sleep clinics, the timing and the duration of treatment components for sleep disorders are generally less documented, especially for sleep-wake rhythm disorders. Therefore, describing the practice and outcomes of treatment for sleep-wake rhythm disorders, will be a novel contribution to the sleep literature.

Accordingly, the primary aims of the Sleep Clinic Outcome and Practice Study (SUP-study) are to improve sleep treatments (CBT-I and chronotherapy for sleep-wake rhythm disorders) by describing the practice and outcomes - more specifically:

1) the use, timing, and duration of specific sleep treatment components in a clinical setting
    a) CBT-I for insomnia disorder
    b) Chronotherapy for sleep-wake rhythm disorders
2) clinical outcomes after sleep treatment
    a) CBT-I for insomnia disorder
    b) Chronotherapy for sleep-wake rhythm disorders, testing a method of operationalizing effects of chronotherapy.

c) And a combination of CBT-I and chronotherapy for patients with both disorders

The secondary aims are

1) exploring the effectiveness of sleep treatment outcomes in different modes of treatment delivery:
   a) Group versus individual delivery of sleep treatment.
   b) Telemedicine versus face-to-face delivery of sleep treatment

Methods

Trial design and participants

Patients will be recruited from the Sleep Clinic at St. Olavs Hospital. Patients are referred from regional general practitioners and other outpatient mental health care clinics. All patients referred to the Sleep Clinic will be asked to participate by an informational consent sent by mail before the first consultation with a clinician. In the first consultation, patients will be assessed through a standardized clinical sleep interview. The clinicians will carry out a diagnostic assessment and consider eligibility to participate in the study.

Inclusion criteria

1. Referred to the Sleep Clinic at St. Olavs Hospital for an assessment of a sleep-wake disruption.
2. Age >= 18 years.
3. Willing and able to provide written informed consent.
4. Meeting the diagnostic criteria for at least one of the following disorders:
    a. F51.0 Insomnia disorder
    b. G47.2 Sleep-wake rhythm disorders, considered being either:
        i. Delayed sleep-wake phase disorder
        ii. Advanced sleep-wake phase disorder
        iii. Non-24-hour sleep-wake disorder
        iv. Irregular sleep-wake disorder
5. Desire non-pharmacological sleep treatment

Exclusion criteria

Individuals working night shifts or that otherwise have external conditions that result in inadequate sleep opportunity, such as caring for an infant or does not have permanent housing etc. Patients being blind or psychotic or having epilepsy or having an ongoing substance abuse will also be excluded.

If the participant is considered eligible and has a signed consent, she/he will be included in the study.

Interventions

In the Sleep Clinic, either psychiatrists or clinical psychologists deliver the treatments. All patients considered being eligible will receive treatment as usual in the Sleep Clinic, one out of the two sleep-wake disorder treatments described underneath, or a combination of these. However, regardless which of the treatments they receive, there are common features in the treatment approach for all patients;

a) All patients will be assessed as usual with a standardized assessment interview developed at the Sleep Clinic. Diagnoses is assessed, and in the case of difficult assessments, the clinician can discuss the patient in the clinicians weekly Sleep Clinic meetings.
b) Step 1 in the treatment for all patients is psychoeducation about sleep, circadian rhythms and a description of the treatment adapted to their disorder. Everyone is sent a workbook that supports the content of the lesson.
c) Step 2 in the treatment regardless of disorder is to stabilize the sleep-wake rhythm, hence aiming for relatively fixed rise times and bed times.
d) In the last consultation the clinician and the patient summarize the treatment approaches used and the effect and benefits of these for the patients. It is also made strategies as preventive measures and a plan for what the patient can do if the sleep disorder relapses.

After psychoeducation and stabilizing the sleep-wake rhythms, the specific treatment components is dependent of the sleep disorder:

1) Cognitive Behavioral Therapy for Insomnia (CBT-I)

CBT-I[18] has several components and consists of the following interventions including psychoeducation about sleep: sleep hygiene, sleep restriction therapy, stimulus control, and challenging beliefs and perceptions of sleep. Special emphasis is placed on providing a rationale for behavior change as a primary means of improving sleep[36] as well as addressing dysfunctional beliefs the patients may hold about sleep. During treatment, tapering sleep medication is not necessary. However, if the patients are motivated to do so, this is discussed and a plan for tapering is provided. Treatment duration is typically between 4 to 8 consultations over 1 to 4 months depending on the patients' needs and progress during treatment.

2) Chronotherapy for sleep-wake rhythm disorders

Chronotherapy [27] aims to restore the proper circadian pattern of the sleep-wake cycle[27] through adequate sleep hygiene, timed light and dark exposure, and the use of melatonin, which affects the output phase of the circadian rhythm. The effect of chronotherapy depends on the timing of interventions in relation to the individual's current internal circadian rhythms. The effect of light exposure follows a phase-response curve where circadian phase advancement is strongest in the biological morning, whereas light in the biological evening/night may lead to a phase delay. Light therapy is provided by 30 min light exposure using 10 000 lux light boxes. Clinical practice guidelines also recognize melatonin administrated in the evening as a treatment option for DSWPD[37]. In the Sleep Clinic melatonin 3 milligram (mg) is prescribed in tablet forms (not depot), usually 12 hours before the planned rise time. Additionally, blue-light-blocking glasses are used to block light exposure at night, which has been found to advance circadian rhythms in patients with DSWPD[30]. In the Sleep Clinic, patients are advised to wear their blue-blocking glasses 12 hours before rise time. Which chronotherapeutic interventions that are used, is considered individually by the clinicians in the Sleep Clinic, but often all three treatment components are used at the same time. Duration of chronotherapy given in the Sleep Clinic vary from 4 to 8 consultations over 1 to 4 months depending on the patients' needs and progress during treatment.

Data management

Primary and secondary outcomes of the study will be registered by the clinicians in eFORSK which is an electronic data collection solution. eFORSK was developed by HEMIT and is operated by Norsk Helsenett. A risk and vulnerability analyses has been carried out and the solution has been approved for use in national studies based in Helse Midt-Norge. A data processing agreement has been created and all processing of data will be in accordance with the requirements of the current regulations. Data extending primary outcomes will be retrieved from assessments in electronic hospital records. This data will be de-identified and the files will be stored on secure data servers.

Withdrawal criteria

An individual can decline to participate at any stage of the study

Time frame

The primary measure of the effect of chronotherapy will be based on a score of 12 (summing 3 questions that are scored from 0 to 4). In a Norwegian study [38] the researchers found an effect size, Cohen's d = 0.75, on the Bergen Insomnia Scale (BIS) after two weeks of treatment for delayed sleep phase syndrome with light therapy and melatonin. BIS is conceptually similar to ISI, and we assume a similar effect size. However, ISI measures the patient's assessment of the severity of their sleep difficulties over the past two weeks and how much it has hindered them in carrying out daily activities, which we believe aligns more closely with the treatment goals than BIS. Research at St. Olav's Hospital has also shown that ISI is the questionnaire that best predicts a diagnosis of sleep disorders [39]. Participants in Saxvig et al.'s study had contacted the researchers themselves, were younger, and had a higher daily functioning level compared to patients referred to St. Olav's Hospital, Division of Mental Health Care, the Sleep Clinic. We therefore expect a somewhat lower effect in our population.

We estimate that we will find an effect size of Cohen's d = 0.6. Furthermore, we want an 80% probability of detecting this difference. For this, approximately 45 patients who complete the measurements are needed. In other research and clinical settings, we see that about 50% of patients do not respond to questionnaires or drop out of treatment. We therefore assume about 50% dropout. Given these premises, we need to include 90 patients in the study to have approximately 45 patients at the outcome measurement.

We estimate that 200 patients will be included in the SUP-study annually. Of these, about 60 patients will be circadian rhythm patients and 140 would be pateints with insomnia disorders. We expect that about 50% will consent to participate in the study and that there will be about 50% dropout during the treatment period. These estimates mean that we will be able to collect data on 15 circadian rhythm patients annually, and to reach the number of 90 included patients, we will need to include patients over 6 years. If the project starts on 01.01.2025, we plan to include patients until the end of 2030 (31.12.2030). We estimate that data will be collected from 35 patients with

insomnia disorder each year, resulting in a total of 210 patients insomnia disorder over the 6-year data collection period.

Assessments

See Table 1 for information about when in the study the various assessments are collected.

Background assessments

Patients will provide data on demographics; age, sex, socioeconomic status (marital status, children in household, educational level, and employment status), somatic diseases, mental illness, medication use and previous sleep medication used, lifestyle (use of alcohol and substances, use of caffeine, physical activity, number of days during a week where they have commitments outside the home).

Sleep information

a) The consensus sleep diary (CSD)

The CSD[40] estimates sleep and wakefulness (from the previous night). The diary was specifically developed for, and is widely used in insomnia research.[41]. The patients are sent the sleep diaries to log their sleep patterns every day for 14 consecutive days before their first consultation. The sleep diaries are used in the diagnostic assessment. The following sleep metrics are extracted from the CSD: bedtime (BT) in hh:mm, sleep onset latency (SOL) in minutes, wake after sleep onset (WASO) in minutes, and rise time (RT) in hh:mm. Time in bed (TIB) and total sleep time (TST) (in minutes) estimates were calculated from the other variables.

b) Sleep-wake phase diary

In clinical practice, St. Olavs Hospital have developed a sleep-wake phase diary that provides a visual estimate of sleep and wakefulness across weeks, focusing more on the sleep-wake cycle whilst sleep onset and offset times are somewhat less detailed compared with the CSD. This sleep-wake estimation is especially beneficial for patients where sleep-wake rhythm is a focus during treatment as the rhythm is easily assessed both by the patient and the clinician. The following sleep metrics are extracted from the

sleep-wake phase diary: BT in hh:mm, SOL in minutes, WASO in minutes, and RT in hh:mm. TIB and TST (in minutes) estimates were calculated from the other variables.

c) Revised Morningness Eveningness Questionnaire (rMEQ)

The revised Morningness Eveningness Questionnaire[42] is a reduced version of the Horne-Östberg Morningness-Eveningness Questionnaire containing five items. The score ranges from 4 to 25, with higher scores indicating greater preference for morningness. Individuals are classified as either evening type (those scoring from 4 to 11), intermediate type (those scoring between 12 to 17), or morning type (those scoring between 18 and 25).

Primary outcomes

a) Timing and duration of treatment components

The prescription, self-reported compliance, timing and duration of specific sleep treatment components will be logged by the clinician during treatment.

i. Psychoeducation
ii. Sleep restriction
iii. Stimulus control
iv. Cognitive restructuring / Experiments
v. Sleep hygiene
vi. Relaxation exercises
vii. Tapering sleep medication
viii. Melatonin
ix. Blue-light blocking glasses
x. Light therapy
xi. Stabilizing sleep-wake rhythm
xii. Sleep-phase advancement or delay

b) Treatment effects:

i. Insomnia Severity Index with additional question (ISI*)

The Insomnia Severity Index (ISI)[43] is recommended as a standard measure for insomnia symptoms in the assessment of sleep problems and outcome in RCTs.[41] It comprises 7 items rating the severity of sleep-wake problems, impairment in daytime

functioning, and concerns about sleep problems. Each item is rated on a 0 to 4 scale indicating its severity over the preceding 14 days and a higher total score indicates greater insomnia severity. An ISI score of ≥15 points is a recommended cut-off for clinical insomnia. Individuals who demonstrate an overall reduction in the ISI score >=8 points are considered to show clinical response, whilst individuals with a total ISI score <= 7 are considered to show remission [8].

For patients with sleep-wake rhythm disorder, there is no validated questionnaire to rate the severity of their sleep-wake disruption. As we want to measure how satisfied the patients are with their present sleep-wake rhythm and how much it affects their daily function, we will extract these questions from the ISI.
"How satisfied/dissatisfied are you with your current sleep pattern?" and
"To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) currently?". Both questions are answered on a scale from 0 to 4. In addition, we will include a question that we consider relevant for those with delayed sleep-wake phase disorder: "On a score from 0 to 4, how difficult is it to rise in the morning?". We will then combine these three questions to a sleep-wake rhythm severity index raging from 0 to 12, where higher score indicates a higher severity.

ii. Clinical impression scale

We will have a brief rating scale where the clinician's impression is weighted. This will be similar to the well-used and validated Clinical Global Impression scale[44], which was developed for clinical trials to provide a brief, stand-alone assessment of the clinician's view of the patient's global functioning prior to and after initiating a study medication. In our clinical impression scale, the clinician is asked to rate the treatment compliance, treatment response and daily function. Each question is rated from 0 to 10 with a higher number indicating a more improved outcome. By this, the study can compare the clinician impression with the patients self-reported (ISI*) effects of the treatment. Thus, it will strengthen our aim to test a method of operationalizing effects of chronotherapy.

At baseline after first consultation:

1. Based on your overall clinical experience with this patient group: How much benefit will the patient get from the treatment?
2. Based on your overall clinical experience with this patient group: To what extent does the patient now have a circadian rhythm (if mainly insomnia: sleep-wake rhythm) that enables him/her to manage his/her daily tasks?
3. Based on your overall clinical experience with this patient group: To what extent do you think the patient will comply with the treatment?
4. How many years of clinical experience do you have with this patient group?

Post treatment:

1. Based on your overall clinical experience with this patient group: How useful has the treatment been for the patient?
2. Based on your overall clinical experience with this patient group: To what extent does the patient now have a circadian rhythm (if mainly insomnia: sleep-wake rhythm) that enables him/her to manage his/her daily tasks?
3. Based on your overall clinical experience with this patient group: To what extent has the patient complied with the treatment plan?

Secondary outcomes

Information about how the consultations are provided is logged

a) individual or group therapy
b) face-to-face therapy or telemedicine.

Table 1: Timing of when various assessments are collected in the study.

		Baseline	**Under ongoing treatment**	**Post treatment**
Background assessments		X		
Sleep diaries		X (2 weeks)	X	
rMEQ		X		
Timing and duration of treatment components			X	
Clinical outcomes of treatment	ISI*	X		X
	Clinical impression	X		X
Information about how the consultations are provided		X	X	

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