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Effectiveness of group-delivered therapy for insomnia

Submission date
13/10/2022

Recruitment status
No longer recruiting

Registration date
17/11/2022

Overall study status
Ongoing

Last Edited
14/04/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Insomnia is the most common sleep disorder in the general population and in clinical practice. It has been linked with an increased risk of adverse health outcomes such as cardiovascular disease, type 2 diabetes, chronic multisite pain, depression and hypertension. However, treatment options for insomnia are limited. Currently, the most common way of treating insomnia is with pharmacotherapy. Pharmacotherapy has been shown to have low-to-moderate effects and is mainly recommended for short-term use, as symptoms often return after treatment. It is therefore recommended to use cognitive behavioral therapy for insomnia (CBT-I) as first-line treatment, due to its long-term effectiveness. However, CBT-I is not widely available due to the lack of trained therapists and long waiting lists in specialist sleep clinics. Since there are limited resources for high-quality individual CBT-I, a group-delivered course for individuals with insomnia symptoms was designed by the Norwegian Directorate of Health. The course is based on core CBT-I principles including sleep hygiene, stimulus control, sleep restriction, cognitive therapy, and relaxation training. An advantage of this course is that it can be delivered to up to 15 individuals at the same time, and may thus complement traditional treatments and relieve pressure on primary care. Although this therapy has already been implemented in several municipalities in Norway, its effectiveness has never been evaluated.

The study aims to test the effectiveness of group-delivered cognitive behavioral therapy for insomnia (CBT-I) in primary healthcare. We will compare participants who received the therapy (intervention group), and those who did not (i.e., waiting list control group). The primary aim is to examine the differential change in insomnia severity at 3 months post-randomization.
Secondary aims include:
1. Examine differential changes in health-related quality of life, fatigue, depression/anxiety, and sleep diary data at 3 months post-randomization, and 6 months post-randomization.
2. Examine whether potential treatment moderators (chronotype, reactivity to stress, recruitment location, duration of insomnia, length of insomnia treatment, lifestyle etc.) influence the effectiveness of the group-delivered CBT-I in primary care.
3. Collect national registry data at 1 and 2 years post-randomization to compare sick leave days, use of prescribed medication (psychotropic medications, sedatives) and healthcare resource utilization.
4. Explore mediating analyses to identify mechanisms of change in the primary and secondary

outcomes, focusing on psychological measures of beliefs about sleep and sleep-related self-efficacy.
5. Carry out a process evaluation to assess facilitators and barriers for treatment adherence and qualitative studies to explore participants' experience of group-delivered CBT-I.

Who can participate?
Adults (18 + years old) with symptoms of insomnia (Insomnia Severity Scale of 12 or higher)

What does the study involve?
The study involves either participating in the group-delivered therapy for insomnia (intervention group) or being on a waiting list for 6 months (control group). All participants fill out a questionnaire package and a 7-day sleep diary at 4 measurement time points (weeks 1 and 4, and months 3 and 6).

What are the possible benefits and risks of participating?
For the individual participant, participation in the study provides a good opportunity to survey and improve sleep quality. Overall, the intervention is currently being offered in many Norwegian municipalities, but its effectiveness has not yet been evaluated. Evaluating the effectiveness of the intervention will strengthen the treatment of insomnia in primary care. In addition, data from the project will be used to further develop the intervention in collaboration with the Directorate of Health and sleep experts in Norway.
By taking part in the study, the participants devote time and attention to questions about health and illness, which can cause unnecessary worries. Nevertheless, these are people who already have a sleep problem and wish to treat it, and we do not consider this a major risk. Moreover, certain participants may feel concerned that their sleep and health are being carefully surveyed during the duration of the study. It is specified that all data is anonymous and that no revealing or private data will be used. Participants who are randomized to the control group end up on a waiting list for the intervention and have to wait up to 6 months before they are offered to participate in a sleep course.

Where is the study run from?
Norwegian University of Science and Technology (Norway)

When is the study starting and how long is it expected to run for?
January 2022 to December 2025

Who is funding the study?
Norwegian Foundation for Health and Rehabilitation (ExtraStiftelsen, Stiftelsen Dam & Dam Foundation) (Norway)

Who is the main contact?
Maria Hrozanova (Principal Investigator) (Norway)
maria.hrozanova@ntnu.no

Study website
http://www.sovnbehandling.no

Contact information

Type(s)
Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2021/FOS374023

Study information

Scientific Title
Group-delivered cognitive behavioral therapy for insomnia in primary care: A pragmatic, multicenter randomized controlled trial

Study objectives
Participants in the intervention group, who receive 4 sessions of group-delivered cognitive behavioral therapy for insomnia will experience a greater reduction of insomnia symptoms and improved health-related quality of life than the wait-list control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/06/2022, Regional Ethics Committee in Mid-Norway (NTNU/REK midt, Det medisinske fakultet, Postboks 8905, 7491 Trondheim, Norway; +4773 59 75 11; rek-midt@mh.ntnu.no), ref: 46524

Study design
Multicenter interventional unblinded pragmatic randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
http://www.sovnbehandling.no

Health condition(s) or problem(s) studied
Insomnia

Interventions
Current interventions as of 13/12/2023:
Due to natural capacity limitations, some intervention group participants may have to wait to begin treatment. Waiting times over 2-3 months rarely occur. The last self-reported measurements are expected to be sent out by December 31st 2023. Thus, the data collection is expected to be finalized by January 15th 2024 at the latest.

All participants are self-referred to the study. Recruitment occurs primarily on social media (advertisements on Facebook) and through the Healthy Life Centres participating in this trial, and secondarily through information posters displayed in relevant places (e.g., GP or physiotherapy offices). Each adult interested in participating fills out a screening questionnaire, which can be found on the trial website www.sovnbehandling.no. Participants who fulfil the criteria for inclusion are sent a digital consent form with detailed information about trial participation. Those who return the signed consent form are randomized in the centre they participate. There are two trial arms:
Intervention group – participation in 4 sessions of group-delivered CBT-I. Group sizes vary from 5-15 depending on the capacity of the Healthy Life Centre. Employees deliver the intervention at the participating Healthy Life Centres (mostly physiotherapists). The intervention has been developed by the Norwegian Directorate of Health, in collaboration with the National competence centre for sleep disorders, the Public health institute and the Norwegian association for cognitive therapy. The intervention group is actively followed up for 6 months (self-reported questionnaires), and after that for 2 years (register data).
Control group – waiting list of 6 months. During the waiting period, participants fill out the same self-reported questionnaires as the intervention group. They are not offered any treatment during the 6-month waiting period. They are not prohibited from taking sleep medication at this time or seeking other forms of treatment (whether they received any treatment during their participation will be investigated at the 6-month assessment point). Control group participants are contacted once, upon randomization, by the Healthy Life Centre in their municipality, to offer them the possibility to participate in the intervention after the 6-month waiting period is finalized.

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Intervention Type
Behavioural

Primary outcome measure
Insomnia measured using the Insomnia Severity Index at baseline, 4 weeks, 3 months (primary measurement point), and 6 months

Secondary outcome measures
1. At baseline, 4 weeks, 3 months (primary measurement point), and 6 months, all participants fill out the following secondary outcome measures:
1.1. Fatigue measured using the Chalder Fatigue Scale
1.2. Subjective sleep patterns measured using a 7-day digital sleep diary
1.3. Health-related quality of life measured using EuroQol EQ5D-5L
1.4. Mental distress measured using the Hopkins Check List
1.5. Chronotype measured using Brief Horne-Østberg Morningness-Eveningness questionnaire
1.6. Patient beliefs and attitudes about sleep measured using Dysfunctional Beliefs and Attitudes about Sleep questionnaire
1.7. Sleep reactivity measured using Ford Insomnia Response to Stress Test

2. At baseline, intervention group participants fill out the following secondary outcome measures:
2.1. Motivation for treatment measured using Nijmegen Motivation List 2
2.2. Treatment expectancy measured using Credibility/Expectancy Questionnaire

3. At 3 months, intervention group participants fill out the following secondary outcome measures:
3.1. Utility of CBT-I measured using Treatment Components Adherence Scale

4. Participant demographic information measured using a questionnaire at baseline

5. At 12 months and 24 months the following outcomes will be measured:
5.1. Short - and medium-term impact of group-delivered CBT-I on rates of sick leave, and medication and health resource utilization measured by accessing national health registry data
5.2. Overview of health service utilization measured by obtaining data from the Norwegian Patient Registry
5.3. Overview of prescribed medication measured by obtaining data from the Norwegian Prescription Database
5.4. Information on sick leave measured by obtaining data from the National Insurance Administration

Overall study start date
01/01/2022

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Inclusion criteria based on self-report and national registries:
1. Adults older than 18 years of age
2. Self-referred to the study
3. Insomnia Severity Index score of 12 or higher

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Total final enrolment
309

Key exclusion criteria
Exclusion criteria based on self-report:
1. Bipolar disorder
2. Schizophrenia or other psychotic disorders
3. Personality disorders
4. Dementia and other neurodegenerative disorders
5. Heart surgery within the last 3 months
6. Untreated sleep apnea
7. Undergoing cancer treatment at the screening timepoint
8. Multiple sclerosis with an attack at screening timepoint
9. Adults without adequate skills in the Norwegian language to participate in the group-delivered course

Date of first enrolment
20/08/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
Norway

Study participating centre
Alstahaug Healthy Life Centre
Åsgata 13
Sandnessjøen
Norway
8800

Study participating centre
Arendal Healthy Life Centre
Østensbuveien 55
Arendal
Norway
4848

Study participating centre
Asker Healthy Life Centre
Nordre Bondi gård, Fredtunveien 25
Asker
Norway
1386

Study participating centre
Bodø Healthy Life Centre
Speiderveien 4
Bodø
Norway
8008

Study participating centre
Fredrikstad Healthy Life Centre
Jens Wilhelms gate 1
Kråkerøy
Norway
1671

Study participating centre
Færder Healthy Life Centre
Øreveien 13
Nøtterøy
Norway
3120

Study participating centre
Gausdal Øyer and Lillehammer Healthy Life Centre
Jørstadmovegen 690
Fåberg
Norway
2625

Study participating centre
Jæren Healthy Life Centre
Ole Nielsensvei 20
Ålgård
Norway
4330

Study participating centre
Hamar Healthy Life Centre
Ankerskogvegen 7
Hamar
Norway
2319

Study participating centre
Hole Healthy Life Centre
Furuhallveien 17B
Helgelandsmoen Næringspark
Røyse
Norway
3530

Study participating centre
Holmestrand Healthy Life Centre
Revåveien 18
Sande

Norway
3070

Study participating centre
Inderøy Healthy Life Centre
Vennalivegen 7
Inderøy
Norway
7670

Study participating centre
Kristiansand Healthy Life Centre
Kjøita Park 17 og 19
Kristiansand
Norway
4630

Study participating centre
Lindesnes Healthy Life Centre
Lars O. Røllandsgate 7
Mandal
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4514

Study participating centre
Midt-Telemark Healthy Life Centre
Gullbring Kulturanlegg
Gullbringvegen 34
Bø
Norway
3800

Study participating centre
Modum Healthy Life Centre
Furumoveien 70
Geithus
Norway
3360

Study participating centre
Moss Healthy Life Centre
Larkollveien 7
Dilling
Norway
1570

Study participating centre
Notodden Healthy Life Centre
Skolegata 11
Notodden
Norway
3674

Study participating centre
Oslo - Nordre Aker Healthy Life Centre
Maridalsveien 292
Oslo
Norway
0872

Study participating centre
Ringebu Healthy Life Centre
Freskus, Tromsnesvegen 34
Fåvang
Norway
2634

Study participating centre
Ringerike Healthy Life Centre
Storgata 13
Hønefoss
Norway
3510

Study participating centre
Skien Healthy Life Centre
Kongensgate 31
Skien
Norway
3717

Study participating centre
Steinkjer Healthy Life Centre
Inn-Trøndelag helse- og beredskapshus, 5.et., Seilmakergata 10
Steinkjer
Norway
7725

Study participating centre
Tromsø Healthy Life Centre
Seminarbakken 1
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9008

Study participating centre
Trondheim Healthy Life Centre
Helse- og arenabygget Granåsen
Smistadveien 13
Trondheim
Norway
7026

Study participating centre
Verdal Healthy Life Centre
Ringveg Nord 1
Verdal
Norway
7650

Sponsor information

Organisation
Norwegian University of Science and Technology

Sponsor details
Høgskoleringen 1
Trondheim
Norway
7034

+47 73 59 50 00
ism-post@mh.ntnu.no

Sponsor type
University/education

Website
http://www.ntnu.edu

ROR
https://ror.org/05xg72x27

Funder(s)

Funder type
Charity

Funder Name
EkstraStiftelsen Helse og Rehabilitering (Stiftelsen Dam)

Alternative Name(s)
Norwegian Foundation for Health and Rehabilitation, EkstraStiftelsen Helse og Rehabilitering, ExtraStiftelsen, Stiftelsen Dam & Dam Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Norway

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal.
2. Participation in national and international scientific conferences
3. Results will be disseminated in Norwegian knowledge bases and at meetings/seminars organized by user organizations such as Mental Health.
4. Share a summary of the project with relevant user organizations, health blogs and websites.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made publicly available due to participant confidentiality and considerations relating to data security. Participant-level data can be made accessible to specific users by contacting the project leader. The users must then be registered with the regional Medical Ethical Committee, in Norway. The need for restrictions may change over time, allowing the data to be made accessible at a later point.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			24/10/2022	No	Yes
Protocol article	protocol	02/03/2023	03/03/2023	Yes	No
Statistical Analysis Plan	version 1	25/01/2024	19/02/2024	No	No
Statistical Analysis Plan	version 2	06/03/2024	08/03/2024	No	No
Statistical Analysis Plan	version 3	10/04/2024	15/04/2024	No	No
Results article		02/04/2025	14/04/2025	Yes	No