Supporting information

Additional file 1. Confirmation by the Regional Committee for Medical and Health Research ethics in Mid-Norway of the submission of trial protocol. (see next page)

REK
REGIONAL COMMITTEES FOR MEDICAL AND HEALTH RESEARCH ETHICS

Region:	Executive officer:	Phone number:	Date:	Reference:
REC central	Karoline B. Berget	73597509	26.08.2024	465241

To whom it may concern,

CONFIRMATION OF ETHICAL APPROVAL OF RESEARCH PROJECT

Project title: Non-pharmacological treatment of sleep problems in primary care: A randomized controlled trial
Reference number: 465241
Institutions responsible for the research: Norwegian University of Science and Technology
Chief investigator: Maria Hrozanova

The above-mentioned project was evaluated by the Regional Committee for Medical and Health Research Ethics, Central Norway in its meeting on 27.04.2022, and the Committee granted its approval, stated in a letter of 13.05.2022. The project was approved with only a few minor comments on the informed consent document.

Minor amendments were approved dated 21.06.2022, 11.08.2022, 27.09.2022, 24.11.2022 and 05.03.2024 by authority of the Head of Secretariat of the Committee.

The Committee also confirms that the informed consent dated 13.07.2022 (Informasjonsskriv_Sov godt_3_tracked.pdf) and 23.11.2022 (Informasjonsskriv_Sov godt_kvalitativ.pdf) was approved 11.08.2022 and 24.11.2022. Last submitted protocol was 23.11.2022 (Forskningsprotokoll REK_5_tracked.pdf).

Sincerely,
Hilde Eikemo
Head of Secretariat

Karoline Bjørstad Berget
Senior executive officer
T: 73597509
REC Central Norway

Additional file 2. Intervention Description and Replication (TIDieR) checklist for *Sleep well*, group-delivered cognitive behavioural therapy for insomnia in Norwegian primary care

1	Name of intervention	Group-delivered cognitive behavioural therapy for insomnia (CBT-I)
2	Why	CBT-I is recommended as first-line therapy for insomnia. However, access to individual CBT-I is limited. In Norway, the Health Directorate has developed a group-delivered CBT-I sleep course *Sleep well*. The course has been implemented in the Norwegian primary care since 2018. The intervention is based on the main elements of CBT-I: psychoeducation, stimulus control, sleep restriction, cognitive restructuring, relaxation training, and sleep hygiene.
3	What: Materials	**Materials for course coordinators**: Course coordinators were provided all the up-to-date course materials to be used in the group-delivered CBT-I course, including a powerpoint presentation and participant booklet. **Materials for participants**: The course coordinators show a powerpoint presentation with the main learning outcomes throughout the course. Participants receive a printout of the presentation, and a booklet with a sleep diary, sleep hygiene tips and materials for the homework to be completed during the course. This includes the a single question about sleep quality on a Likert scale from 1 (very dissatisfied) to 10 (very satisfied), the Sleep Hygiene Index, space to choose three sleep-relayed habits to focus on during the group-delivered CBT-I course, the Dysfunctional Beliefs and Attitudes about Sleep questionnaire, and space to identify own dysfunctional beliefs and attitudes about sleep and how these be counteracted.
4	What: Procedures	**Session 1**: Consists of psychoeducation about sleep and insomnia, information about using the sleep diary, and practicing the Herbert Benson's relaxation response. In small groups, participants talk about their experiences with insomnia and course expectations. As homework, participants identify three sleep-related habits to target during treatment, fill out sleep diary and Sleep Hygiene Index. **Session 2**: Consists of sleep hygiene advice, overview of principles of stimulus control, and practicing progressive muscle relaxation. In small groups, participants talk about their experiences with filling out the sleep diary, the learning outcomes so far, and the sleep-related changes they have so far implemented. As homework, participants fill out sleep diary and questionnaire Negative Beliefs and Attitudes about Sleep, they apply sleep hygiene advice and calculate sleep efficiency. **Session 3**: Consists of information about the role of dysfunctional beliefs about sleep in insomnia and how to identify and change these, and principles of sleep restriction. In small groups, participants discuss the implemented changes and their effect so far. As homework, participants fill out sleep diary, make a plan for how to challenge own negative thoughts about sleep, and apply sleep restriction. **Session 4**: Consists of psychoeducation about management and maintenance of own sleep, and motivation for lasting change after the finalisation of the course. In small groups, participants talk about the implemented changes and their effect so far, the previously identified and applied alternatives to dysfunctional beliefs about sleep, and adapting the learning outcomes for maintenance of good sleep after the course.
5	Who provided	The course is provided by Healthy Life Centres practitioners, who are typically registered physiotherapists or nurses who received either in-person training of 10 hours, or digital training of 7 hours in how to deliver the group-delivered CBT-I course.
6	How provided	The intervention was provided in a group, classroom setting. The typical group sized varied from 5 to 15 participants, depending on the demand at the respective Healthy Life Centre.
7	Where	The course is provided at the municipal Healthy Life Centres. The centres provide health-promoting and preventive services for adults with a variety of health problems,

		including insomnia. 26 Healthy Life Centres participated in the trial, from the following Norwegian municipalities: Alstahaug, Arendal, Asker, Bodø, Fredrikstad, Færder, Gausdal / Øyer / Lillehammer, Gjesdal / Klepp / Time / Hå, Hamar, Hole, Holmestrand, Inderøy, Kristiansand, Lindesnes, Midt-Telemark, Modum, Moss, Notodden, Oslo - bydel Nordre Aker, Ringebu / Sør-Fron, Ringerike, Skien, Steinkjer, Tromsø, Trondheim, Verdal.
8	When and how much	The intervention was delivered over four in-person sessions. Each session lasted for 2 hours.
9	Tailoring	The only personalised part of the intervention was sleep restriction, which was advised for participants with sleep efficiency < 85% (based on 7-day averages of time in bed and time asleep from sleep diaries). The goal of sleep restriction is to restrict time in bed to the time that is spent asleep. Each participant found their typical time asleep, and then chose their ”sleep window” based on the rise time and bedtime fitting to their usual schedule. If sleep efficiency reached ≥ 85% in the chosen sleep window, participants were instructed their time in bed by 15 minutes.
10	Modifications	The intervention was modified prior to the start of the trial to increase focus on sleep restriction, by introducing the calculation of sleep efficiency already during session 2. All participating centres were informed about this change and were instructed to deliver the updated version of the course. No further changes were implemented during the course of the trial.
11	How well: Planned	Fidelity assessments were not planned. Data collection about intervention adherence was planned and carried out, see below.
12	How well: Actual	Intervention adherence was assessed by recording the attendance of each intervention participant on each session. Of the participants that did not drop out during the four-weeks of the intervention (n=168), the following amount participated in the different sessions: Session 1 = 95.0%, Session 2 = 90.5%, Session 3 = 83.3%, Session 4 = 77.4%.

Additional file 3. CONSORT checklist.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3
Methods3			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			4

Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4, 5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	4
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8,9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	

Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17
Other information			
Registration	23	Registration number and name of trial registry	3-4
Protocol	24	Where the full trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	If full submission

Citation: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. 2010;8:18.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

Additional file 4. Minimal clinically relevant change in insomnia severity

Of the participants receiving group-delivered CBT-I, 51% (n = 92 out of 181 participants) reported a minimal clinically relevant change in insomnia severity (i.e., ≥6 points on ISI), compared to 21% (n = 27 out of 127 participants) on the waiting list, corresponding to an OR of 3.9 (95% CI: 2.2 to 6.8, p<0.001). The estimated odds of obtaining a clinically relevant change in insomnia severity were also higher for participants receiving group-delivered CBT-I than the waiting list at 1-month follow up (OR 3.1, 95% CI: 1.8 to 5.3, p<0.001) and 6-month follow-up (OR=7.7, 95% CI: 3.4 to 17.7, p<0.001), but there was little evidence that the ORs were different at the different follow-up time points.

Additional file 5. Per-protocol analyses of the group-delivered CBT-I treatment for the primary and secondary outcomes of insomnia severity.

	Intention-to-treat analysis*		Per-protocol analysis (compliers only)*	
Insomnia Severity Index				
	Mean difference (95% CI)	p-value	Mean difference (95% CI)	p-value
1 month	-2.4 (-3.4 to -1.4)	<0.001	-2.4 (-3.4 to -1.3)	<0.001
3 months	-2.9 (-3.9 to -1.9)	<0.001	-3.2 (-4.2 to -2.1)	<0.001
6 months	-1.8 (-2.9 to -0.8)	<0.001	-2.0 (-3.0 to -0.9)	<0.001
Clinically relevant improvement in insomnia severity (reduction of ≥8 points on ISI)				
	Conditional OR (95% CI)	p-value	Conditional OR (95% CI)	p-value
1 month	18.4 (3.5 to 96.5)	0.001	16.6 (3.1 to 88.6)	0.001
3 months	11.0 (3.0 to 40.4)	<0.001	11.9 (3.2 to 44.4)	<0.001
6 months	6.6 (1.9 to 23.3)	0.003	6.5 (1.8 to 23.0)	0.001
***** Mean difference in change from baseline for Insomnia Severity Index is estimated by Linear Mixed Models not assuming equal baseline means for both analyses, since the randomization assumption is violated in the per protocol analyses.				

Additional file 6. Sensitivity analyses of the primary and secondary outcomes for the equal baseline assumption, due to delay between randomization and baseline assessment.

	With constrained baseline means		**Without constrained baseline means**	
	Intervention vs Control	p-value	Intervention vs Control	p-value
Insomnia Severity Index				
1 month	-2.8 (-3.7 to -2.0)	<0.001	-2.4 (-3.4 to -1.4)	<0.001
3 months	-3.4 (-4.3 to -2.5)	<0.001	-2.9 (-3.9 to -1.9)	<0.001
6 months	-2.3 (-3.2 to -1.4)	<0.001	-1.8 (-2.9 to -0.8)	<0.001
Fatigue (Chalder Fatigue Scale)				
1 month	-3.0 (-4.0 to -2.0)	<0.001	-2.7 (-3.9 to -1.6)	<0.001
3 months	-2.4 (-3.4 to -1.3)	<0.001	-2.1 (-3.3 to -0.9)	0.001
6 months	-1.7 (-2.8 to -0.7)	0.002	-1.4 (-2.6 to -0.2)	0.018
Mental distress (Hopkins Symptom Check List)				
1 month	-0.16 (-0.27 to -0.05)	0.004	-0.03 (-0.05 to 0.00)	0.019
3 months	-0.15 (-0.26 to -0.04)	0.010	-0.03 (-0.05 to 0.00)	0.040
6 months	-0.16 (-0.27 to -0.04)	0.007	-0.03 (-0.05 to 0.00)	0.028

Sleep diary measures				
Daytime functioning (1-5)				
1 month	0.14 (0.02 to 0.26)	0.023	0.17 (0.04 to 0.31)	0.014
3 months	0.28 (0.16 to 0.41)	<0.001	0.31 (0.18 to 0.45)	<0.001
6 months	0.27 (0.15 to 0.40)	<0.001	0.30 (0.17 to 0.44)	<0.001
Sleep quality (1-5)				
1 month	0.14 (0.01 to 0.27)	0.029	0.12 (-0.03 to 0.27)	0.114
3 months	0.31 (0.18 to 0.44)	<0.001	0.28 (0.13 to 0.43)	<0.001
6 months	0.28 (0.15 to 0.41)	<0.001	0.25 (0.10 to 0.41)	0.001
Sleep onset latency (min) *				
1 month	-0.04 (-0.33 to 0.24)	0.758	-0.35 (-0.71 to 0.00)	0.053
3 months	-0.16 (-0.45 to 0.12)	0.268	-0.48 (-0.84 to -0.12)	0.009
6 months	-0.10 (-0.38 to 0.19)	0.512	-0.38 (-0.75 to -0.02)	0.037
Daytime napping **				
1 month	0.38 (0.17 to 0.83)	0.016	0.36 (0.14 to 0.91)	0.031
3 months	0.64 (0.28 to 1.42)	0.271	0.60 (0.23 to 1.55)	0.295
6 months	0.84 (0.38 to 1.87)	0.667	0.80 (0.31 to 2.04)	0.634
Use of medication **				
1 month	0.30 (0.10 to 0.85)	0.024	0.20 (0.06 to 0.66)	0.008
3 months	0.12 (0.04 to 0.36)	<0.001	0.08 (0.02 to 0.27)	<0.001
6 months	0.57 (0.20 to 1.67)	0.308	0.39 (0.12 to 1.27)	0.118

Note. Results are shown for variables not analysed by non-parametric methods. Results are estimated differences in mean change from baseline between intervention and control. # shows results of non-parametric test. * Mean differences on log-scale. ** Conditional ratio of odds ratios.