Effectiveness of digital Cognitive-Behavioural Therapy for Insomnia in patients with musculoskeletal complaints and insomnia in primary care physiotherapy: a randomized controlled trial

Statistical Analysis Plan (SAP)

Version 1

Administrative information

Sponsor name	Norwegian University of Science and Technology (NTNU)
Sponsor address	Postboks 8905, MTFS, 7491, Trondheim, Norway
EudraCT number / REC no	Regional Committee for Medical and Health Research Ethics in Central Norway ref. 533381
Trial title	App-delivered cognitive-behavioural therapy for insomnia for patients in primary care with insomnia and musculoskeletal pain: a randomized clinical trial
Trial registration number	ISRCTN91221906

SAP and protocol version

SAP version and date	This SAP is version 1.0, dated 24.06.2025
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Roles and responsibilities

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Abbreviations

CBT-I	Cognitive behavioural therapy for insomnia
dCBT-I	Digital Cognitive behavioural therapy for insomnia
ISI	Insomnia severity index
IQR	interquartile range
NAV	Ny arbeids- og velferdsforvaltning
NTNU	Norwegian University of Science and Technology
OR	Odds ratio
RCT	Randomised controlled trial
RR	Risk ratio
SAP	Statistical analysis plan
SD	Standard deviation
WAS	Work ability Scale
WAI	Work ability index

Table of contents

1. Introduction

This statistical analysis plan (SAP) should be read in conjunction with the published study protocol named "Effectiveness of digital Cognitive Behavioural Therapy for Insomnia in patients with musculoskeletal complaints and insomnia in primary care physiotherapy: study protocol for a randomised controlled trial" published in BMJ Open (Skarpsno et al., 2024). The information presented in this document provides a description of the "Statistical analysis plan" section. The data will be available for the researchers after the last participant has responded to the questionnaire at 6 months follow-up, expected to be September 31st, 2025.

1.1. Purpose and scope of the statistical plan

This document provides the proposed analysis of the of the primary and secondary outcomes from the clinical trial named "Effectiveness of digital Cognitive-Behavioural Therapy for Insomnia in patients with musculoskeletal complaints and insomnia in primary care physiotherapy: a randomized controlled trial". Any deviations from the analyses outlined in this SAP will be described and justified in all papers from the project, including any additional analyses recommended by journal editors and referees. Modifications will be thoughtfully considered and aligned with the broad principles outlined here. The main purpose of this SAP is to describe the analyses. Any analyses in subsequent studies will follow the principles presented in this SAP but are not described in detail. Wherever feasible, data management and modeling decisions will be made before treatment allocation is revealed. The final analysis strategy will be available upon request when the papers are submitted.

1.2. Background and rationale

More than half of individuals seeking physiotherapy due to musculoskeletal complaints report insomnia symptoms (Pfeiffer, Triplett & Siengsukon, 2024). Those with both insomnia and chronic pain experience greater pain intensity (Alsaadi et la., 2014) lower pain tolerance (Woelk et al., 2020), and a lower probability of pain relief (Pakpour et al., 2018). The bidirectional association between sleep and pain (Santos et sl., 2023) indicates that sleep should be included in the treatment plan for individuals with musculoskeletal complaints and comorbid insomnia.

Cognitive Behavioural Therapy for Insomnia (CBT-I) is the recommended treatment for insomnia due to its long-term effectiveness (Riemann et al., 2017). However, lack of therapists and long waiting lists limit its availability (Grandner & Chakravorty, 2017). To address this issue, self-guided and digital versions of CBT-I (dCBT-I) have been developed (Hasan et al., 2022; Starke et al., 2024). These digital solutions have the potential to reach a broader patient population, and can easily be integrated and combined with existing treatment regimes.

1.3. Objectives

1.3.1. Primary objective

The primary objective of this randomised controlled trial is to evaluate the effectiveness of dCBT-I in addition to physiotherapy treatment in patients with chronic musculoskeletal complaints and insomnia, compared with physiotherapy treatment only. The primary outcome is insomnia severity at 3-month follow-up.

1.3.2. Secondary objectives

I. Evaluate the effectiveness of dCBT-I on physical function, pain intensity, health-related quality of life, mental distress, work ability, and self-reported use of sleep and pain medication at 6 weeks, 3 months follow-up (primary outcome) and 6 months follow-up.

II. Examine the difference in the proportion of participants in the intervention and the control group that achieves a clinically relevant (i.e., 8-point Insomnia Severity Index [ISI] decrease) improvement in insomnia severity at 6 weeks, 3 months follow-up (primary outcome) and 6 months follow-up.

1.3.3. Additional objectives

If the data material allows it, we will in additional publications examine the following objectives:

I. Assess the long-term effects of dCBT-I on primary and secondary outcomes at 12-months follow up.

II. Compare sick leave days, use of prescribed medication (eg, psychotropics, sedatives) and healthcare resource utilization, using national registry data at 12-months post-treatment between the intervention and the control group.

2. Study design

2.1. Type of design

The study is a two-arm multicentre randomised controlled trial (RCT).

2.2. Randomization and treatment assignment

Participants will be block randomized in a 1:1 ratio to either the intervention group (usual treatments provided by a physiotherapist + dCBT-I) or the control group (usual treatments provided by a physiotherapist). Randomization will be performed by a researcher using a secure digital platform for multicentre clinical studies, eForsk. In eForsk, a third-party user from the Section for Research at St Olav's hospital will set up the randomization procedure, blinded to the project group. Jonas G. Hofmo will conduct the allocation.

2.3. Intervention

2.3.1. Usual treatments provided by a physiotherapist

Participants in the control group will receive usual treatments provided by the physiotherapist. This includes any diagnostic procedure, treatment or referral the physiotherapist finds relevant based on the medical history, clinical findings and pragmatic, daily clinical practices to address musculoskeletal complaints. Participants are allowed to seek care and treatment elsewhere as they find relevant. After the completion of the long-term follow-up at 12 months, participants in the control group will be offered to use the app given to the intervention group.

2.3.2. dCBT-I in addition to usual treatment provided by physiotherapists

Participants randomised to dCBT-I in addition to usual treatment provided by a physiotherapist will receive the sleep intervention delivered via a smartphone app. The trial will use a Norwegian dCBT-I programme named *Assistert Selvhjelp* (In English: 'Assisted Self-Help', website: https:// assistertselvhjelp.no/). The app consists of six interactive self-managing modules based on the principles from face-to- face CBT-I including sleep hygiene, stimulus control, sleep restriction, cognitive therapy, and relaxation training. Sleep restriction is covered in module 3, while both stimulus control and sleep hygiene are included in module 4. The modules also consist of tasks such as write sleep diary, practice sleep restriction and change lifestyle behaviour, learning material like quizzes and materials explaining and educating the patients about important aspects about sleep. These activities facilitate self-management and emphasize an active role in reducing insomnia symptoms. Patients will be recommended to use the app during the first six weeks after starting the physiotherapy treatment but are allowed to use the app in their own pace and during the whole project period. They will receive weekly notifications in the app.

2.4. Determination of sample size

Previous studies show that the intervention effect in ISI from baseline to after intervention was 2.8-4.7 points in the intervention group compared to the control group (Vedaa et al., 2020; Wiklund et al., 2022). We therefore estimated that a sample size of 144 (72 in each group) was necessary to detect a 3-point difference with 90% power and a 2-sided alpha level of .05. Previous RCTs of dCBT-I report sample attrition rates between 12% and 50%(Christensen et al., 2016; Vedaa et al., 2020). To allow for a 30% dropout rate a 3-months follow-up, we aim to include 188 participants (94 participants in each arm) to answer our primary aim.

2.5. Framework

The study is designed as a multicentre RCT to evaluate the effectiveness of dCBT-I in addition to usual treatments provided by a physiotherapist, compared with usual treatments alone, on insomnia severity among patients with chronic musculoskeletal complaints and insomnia in primary care physiotherapy in Norway.

2.6. Statistical interim analyses

Interim analyses are not planned for the trial, because major adverse events of the treatment are not expected.

2.7. Stopping guidance

If the intended sample size is not reached during the intended recruitment period (ending 31 March 2025), the inclusion of participants will stop at 140 participants (70 participants in each arm), which will ensure adequate statistical power to detect a 3-point difference with 80% power, anticipating a 30% dropout rate during the follow-up.

2.8. Timing of final analysis

The primary and secondary outcomes will be assessed at 6 weeks, and at 3, 6, and 12 months follow up. Because of the funding period, data from the 6-week, 3-month, and 6-month assessments will be analysed, and published together. Data from 12-month follow up will be handled separately.

2.8.1. Timing of outcome assessments

The trial has five measurement points (Table 1): Baseline measurements prior to the randomization and the start of the intervention, and follow-up at 6 weeks, and 3-, 6-, and 12 months after start of intervention. Primary outcome is ISI at 3 months follow up.

Table 1: Assessed variables with respective questionnaires and schedule of assessment.

Name of variable	Measurement points				
	Baseline	**6-weeks**	**3-months (Primary endpoint)**	**6-months**	**12-months**
Demographics					
Sex, age, education, economy, work schedules, shift work, living status and number of children under and/or over six years old living at home	X				
Lifestyle and health-related parameters					
Leisure time physical activity	X		X		
Alcohol consumption and use of drugs	X				
Height and body weight	X				
Self-reported and prescribed sleep and pain medications	X	X	X	X	X
Health literacy	X				
Work ability assessed by the Work Ability Index (de Zwart et al., 2002; El Fassi et al., 2013)	X		X		X
Sleep and circadian rhythms					
Insomnia severity assessed using the Insomnia severity index (Morin et al., 2011)	X	X	X	X	X
Sleep diary (intervention only). Collected by app	X	X			
Beliefs and attitudes about sleep assessed using the Pain-Related Beliefs and Attitudes about Sleep (Afolalu et al., 2016)	X				
Stress-induced sleep reactivity assessed using Ford Insomnia Response to Stress (Drake et al., 2004)	X				
Chronotype assessed using the reduced Horne-Ostberg-Morningness-Eveningness Questionnaire (Chelminski et al., 2000)	X				
Duration of sleep problems	X				
Previous treatment of insomnia	X				
Other sleep therapy/sleep advice during the project period	X	X	X	X	X
Sleep self-efficacy	X	X	X		
Sleep-talking, sleepwalking, possible restless legs/sleep apnea	X				
Pain					
Pain duration	X				
Pain intensity last week assessed using the Örebro Musculoskeletal Pain Screening Questionnaire short form (Linton et al., 2011)	X	X	X	X	X
Patients' expectations about the treatment	X				
Fear avoidance assessed using the Örebro Musculoskeletal Pain Screening Questionnaire short form	X				
Pain sites assessed using the Standardised Nordic questionnaires (Kuorinka et al., 1987)	X				
Musculoskeletal health assessed using the Musculoskeletal health questionnaire (Hill et al., 2016)	X	X	X	X	X
Pain self-efficacy assessed using the Pain Self-Efficacy Questionnaire-2 items (Nicholas et al., 2015)	X				
Other physical and mental health problems					
Somatic and mental conditions	X				
Health-related quality of life assessed using the EuroQol EQ5D-5L (Solberg et al., 2015)	X	X	X	X	X
Mental distress assessed using the Hopkins Symptom Check List -5 item version (Strand et al., 2003; Derogatis et al., 1974)	X	X	X	X	X
Fatigue assessed using the fatigue Severity Scale (Lerdal et al., 2005)	X	X	X		

Work productivity and activity impairment assessed using the Work Productivity and Activity Impairment questionnaire (Reilly et al., 1993)	X	-	X		X
Sick leave. Register based data	X	X	X	X	X
Health service utilisation. Register based data	X	X	X	X	X
Physiotherapy treatment					
Patients' beliefs about the treatment	X				
Treatment approaches		X	X		
Sleep focus during treatment		X	X	X	X
Subjective experience of changes in pain and sleep		X	X	X	X
App (only for intervention group)					
Patients' beliefs about the digital sleep therapy	X				
Digital literacy skills (use of app)	X				
Adherence to treatment components		X	X	X	X
eHealth Usability Benchmarking Instrument assessed using the eHealth UsaBility Bechmarking Instrument (Broekhui & van Velsen et al., 2022)		X			
Negative effects of the sleep therapy		X			

3. Statistical principles

3.1. Confidence intervals and p-values

Estimates will be presented as mean differences or odds ratios with 95% confidence intervals. All p-values will be two-sided, and the significance level will be set to 0.05. No formal adjustment for multiple testing for secondary endpoints is made, but the issue of multiple testing will be kept in mind when interpreting results.

3.2. Adherence

Sleep restriction and stimulus control are considered the most effective components in CBT-I (Furukawa, 2024). In the app, sleep restriction is covered in module 3, while stimulus control is included in module 4. Therefore, good adherence will be defined as completing at least the first four modules of dCBT-I. This will be defined based on the data on module unlocks.

3.3. Analysis

3.3.1. Intention-to-treat analysis

Effectiveness analyses of primary and secondary outcomes will be performed according to the intention-to-treat principle, i.e., we will include all participants that were included and randomized.

3.3.2. Per-protocol analysis

The per protocol analysis will include adherent participants in the intervention group (defined as above in "3.2 Adherence").

3.4. Blinding in statistical analyses and interpretation of results

Upon completion of data collection, patient data will be exported from the eForsk database. The project statistician will supervise the statistical analyses og both primary and secondary outcomes. The results will be presented graphically, excluding group labels, group size, and confidence intervals to the rest of the project group. The syntax for the main analyses will be prepared in advance and made available upon request.

4. Presentation of study population

4.1. Screening data, eligibility, recruitment, and follow-up

Once the data collection is finalized, a CONSORT flow diagram will be created to show the number of participants that were screened, excluded (incl. reasons for exclusion), randomized and included, how many dropped out, how many participated in the different measurement timepoints and finally, how many finalized the data collection. See the CONSORT flow diagram in Figure 1.

4.2. Withdrawal/Follow-up

All participants will be able to withdraw from the study at any time. The number of withdrawals in each group will be presented in the flow chart (Figure 1), including the reason for withdrawal if possible. Note that due to ethical considerations, participants are not obliged to explain their reason for withdrawing. Unless participants who drop out from the study explicitly request the removal of their data, the collected data will be used. If participants do not answer the questionnaire, they will be registered as 'lost to follow-up'. Lost to follow-up will be presented in a figure or in text.

4.3. Baseline patient characteristics

Descriptive statistics will be presented separately for the intervention and control group. Descriptive statistics will include age, sex, education level, employment status, physical and psychological health, medication and substance/alcohol use, sleep- and pain-related variables, and earlier treatment. Baseline values for primary and secondary outcomes (see 5.1 & 5.2) will be reported. Continuous data will be summarized as mean (SD) or median (interquartiles), depending on the distribution. Categorical data will be presented as numbers with percentages (%).

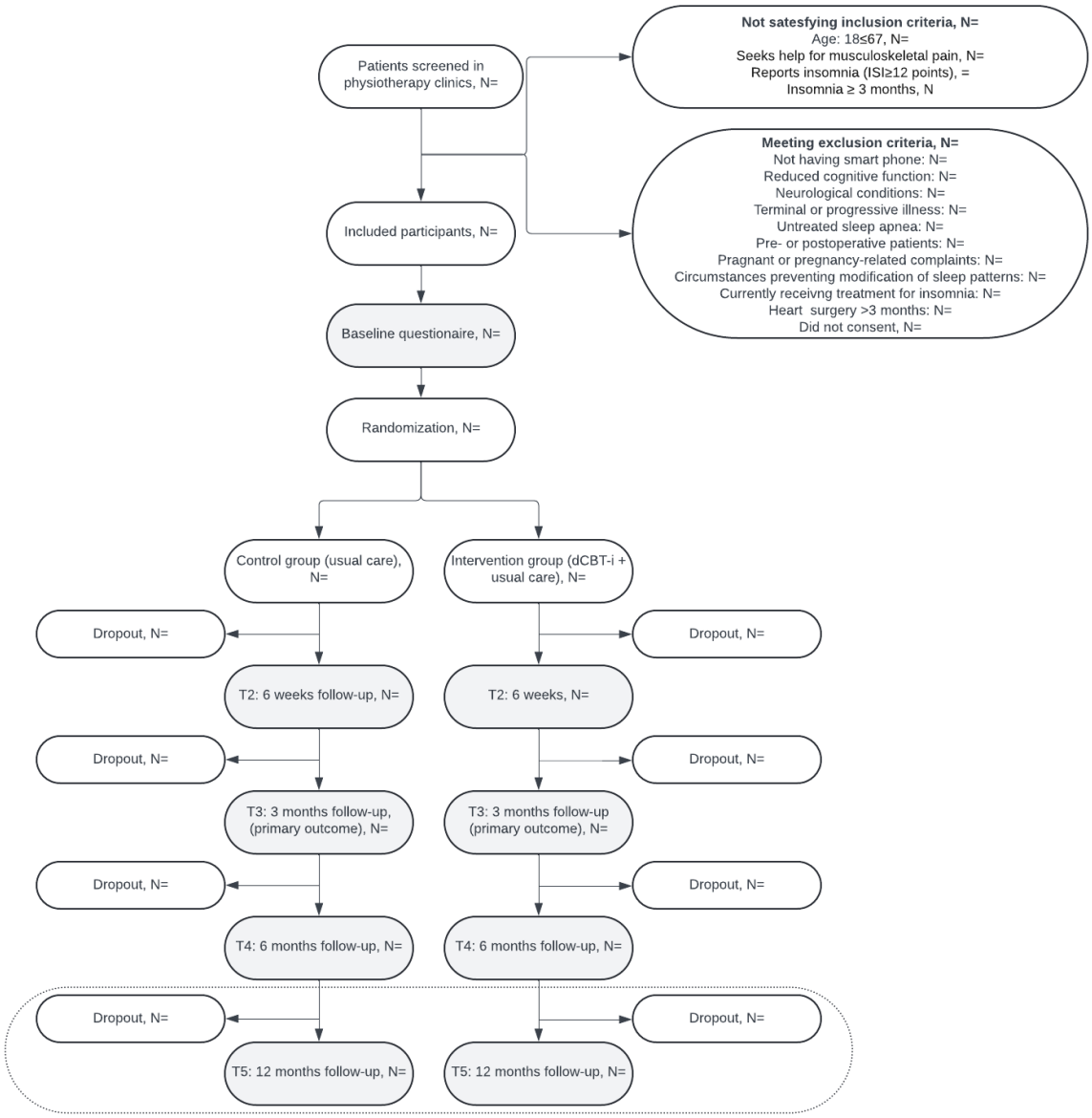

Figure 1: CONSORT flow diagram showing screening, allocation, and follow-up data.

5. Analysis

5.1. Primary outcome

5.1.1. Definition of primary outcome measures

The primary outcome measure is the participants' insomnia severity at 3 months follow up, assessed using the ISI (Morin et al., 2011). The ISI consists of 7 items, each scored on a 5-point scale. The composite score ranges from 0 to 28, with higher values indicating greater insomnia severity. For the primary analyses, ISI will be included as a continuous variable.

5.1.2. Analysis of primary outcome

In the primary analysis we will use linear mixed model analysis to estimate mean difference in ISI between the two groups at 3 and 6 months of follow-up, with 3 months as the primary endpoint for the outcome measurement. The model will include participant ID as a random effect. Time, group, and time-group interaction, will be used as fixed effects. Group means will be constrained to be equal at baseline due to the randomization (Coffman, Edelman & Woolson, 2016). Following evidence-based recommendations (Kahan & Morris, 2012; Kahan et. al., 2014), we will adjust for potentially important predictors of the outcome including age (years), sex (male vs female) and mean pain intensity level (0-10 scale). Unadjusted analysis will also be performed. The model assumptions for mixed models will be checked.

5.2. Secondary outcomes

1. Proportion of participants that achieves an 8-point improvement in ISI
2. Pain intensity measured using a numerical rating scale from 0 to 10.
3. Health-related quality of life measured by the EuroQol 5-Dimension (EQ-5D).
4. Mental distress using the Hopkin symptoms checklist-5.
5. Work ability using the Work Ability Index (WAI).
6. Self-reported use of sleep and pain medication

5.2.1. Analysis of secondary outcomes

For continuous secondary outcomes assessed at multiple follow-up timepoints, similar linear mixed effects models (LMMs) as for the primary outcome measure (ISI) will be used. For binary secondary outcomes we will use a mixed logistic regression model to estimate the odds ratio (OR).

5.3. Missing data

We will use the linear mixed model analyses, which provides unbiased effect estimates under the assumption that the outcome data is missing at random. In a sensitivity analysis, missing values will be imputed using a multivariate normal approach with 20 imputed data sets.

5.4. Statistical software

All analyses will be performed using StataMP 18 (StataCorp. 2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC).

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