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Research Methods, Protocols, Procedures

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Comparing the efficacy of technology-enabled treatments for insomnia: study protocol for a randomized controlled trial

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Abstract

Chronic insomnia is a prevalent sleep disorder where <1% of patients receive the recommended first-line treatment; Cognitive Behavioural Therapy for Insomnia. Digital technologies and self-managed therapies are scalable solutions to address this critical gap in patient care, but it is presently difficult to know which therapies are best. This study will test the comparative efficacy and cost-benefits of Intensive Sleep Retraining administered by the THIM sleep tracker, Sleep Healthy Using the Internet (SHUTi) treatment program, and their combination (THIM then SHUTi) versus a waitlist control group. This study is a 4 (treatment: +/− THIM and +/− SHUTi) × 3 (time: pretreatment, posttreatment, and 2-month follow-up) randomized controlled trial. Participants who meet the diagnostic criteria for Chronic Insomnia Disorder will be randomized to one of four groups. Sleep and daytime functioning symptoms will be assessed via self-report daily and weekly questionnaires, and objective sleep trackers during treatment and for 2 weeks at pre-treatment, post-treatment, and 2-month follow-up. The primary outcome is total wake time, with a reduction of ≥30 minutes considered a clinically meaningful difference. For the primary analysis, the interaction between the treatment group and time on total wake time will be analyzed using repeated measures analyses of variance (ANOVA). This project was approved by the Southern Adelaide Clinical Human Research Ethics Committee (2021/HRE00414) and registered in the Australian and New Zealand Clinical Trials Registry (ACTRN12622000778785). As the first study to investigate the comparative efficacy of two different technology-enabled treatments for insomnia, this study will help inform clinicians and public health policy regarding the use cases for public and private health-funded technology-enabled options for insomnia.

Key words: insomnia disorder; sleep onset insomnia; cognitive and behavioral therapy for insomnia; sleep initiation and maintenance disorders; wearables; actigraphy; digital health

Statement of Significance

Digital treatment options for insomnia are available and practical, yet deciding which treatments are best is currently difficult. This study will directly compare two digital options for insomnia, in terms of their efficacy for relieving insomnia symptoms and their cost-benefits. This large randomized controlled trial is recruiting people with chronic insomnia to receive either the THIM sleep tracker which delivers an overnight insomnia treatment, the 6-week Sleep Healthy Using the Internet (SHUTi) treatment program, their combination (THIM then SHUTi), or no treatment (control). Frequent collection of sleep and daytime functioning information will help determine which treatment approach is most efficacious. This trial will inform patients, clinicians, and other audiences about the most efficacious and cost-effective digital treatment options for insomnia.

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Background

An estimated 6–11% of the general population have chronic insomnia [1, 2], a sleep disorder that profoundly impairs daytime function and quality of life [3]. The critical problem in the management of this highly prevalent sleep disorder is that ≤1% of patients receive cognitive behavioral therapy for insomnia (CBT-I) [4], the treatment recommended by multiple health bodies as the first-line approach [5–8]. The overwhelming majority of patients (~95%) are instead prescribed medications. The major contributing factors toward patients not accessing CBT-I are: (a) the sheer volume of insomnia patients; (b) a lack of trained clinicians and resources for administering CBT-I; (c) patients being unable to engage in CBT-I, due to the inherent need for sleep loss that comes with behavioral therapeutic components (an intolerable side-effect for patients in some professions, e.g. surgeons, pilots); and (d) patients being unable to access in-person or telehealth CBT-I, typically due to commitments (work, family, etc.), the associated cost, and geographic location. Alternative viable treatment options are needed to address this gap between best practice guidelines for CBT-I and treatment accessibility.

Technology-enabled therapies provide a practical solution to this substantial treatment accessibility problem. Their ease of use, accessibility, affordability, and rapidly expanding capabilities mean that digital therapies have considerable potential for administering efficacious therapies for insomnia at-home in a self-guided or self-paced manner. This study protocol outlines the methodology for a randomized controlled trial designed to test two technology-enabled therapies for insomnia.

One therapy tested in this trial is THIM: a wearable sleep tracking ring [9]. THIM was designed to administer a behavioral therapy for insomnia called Intensive Sleep Retraining. This therapy is very brief and highly efficacious for treating difficulties initiating sleep, requiring just one treatment session, bypassing the 4–6 weeks of sleep loss and side effects inherent in other behavioral therapies (e.g. stimulus control therapy) [10, 11]. The Intensive Sleep Retraining procedure is as follows. Patients attempt to fall asleep at their typical bedtime and are woken up after 2–3 minutes of sleep, repeatedly for about 10 hours. Driven by rising homeostatic sleep drive and circadian rhythm pressures for sleepiness, patients fall asleep more rapidly with each subsequent sleep attempt. This is thought to extinguish the conditioned insomnia that patients typically experience when attempting to initiate sleep and retrain them to fall asleep more quickly [12]. In a randomized controlled trial, laboratory-based Intensive Sleep Retraining achieved a large decrease in sleep latency ($d = 0.61$) and a medium increase in total sleep time ($d = 0.53$), to levels comparable to 4 weeks of traditional behavioral therapy, but these effects emerged after just 24 hours [11]. The critical problem with Intensive Sleep Retraining was that it was restricted to the sleep laboratory; a costly resource with restricted availability. With THIM, individuals can self-administer Intensive Sleep Retraining at home [13, 14]. The main query remaining, which the current study will address, is whether THIM-administered Intensive Sleep Retraining is efficacious for treating insomnia.

The second therapy tested in this trial is Sleep Healthy Using the Internet (SHUTi): a brief form of CBT-I bundled into an online self-guided program. This six-session program comprises largely individually tailored stimulus control therapy, sleep restriction therapy, cognitive therapy, and sleep education. In two large ($N > 300$) randomized controlled trials, SHUTi significantly and substantially reduced sleep latency and wake after sleep onset in people with insomnia [15, 16], although adherence can be suboptimal [17]. Like THIM, SHUTi is readily accessible and consumes fewer resources than face-to-face CBT-I, making both therapies ideal for treating insomnia on a large scale for little cost. It therefore bears asking whether SHUTi or THIM is more efficacious to inform the implementation of remote therapy in clinical practice. Few studies have directly compared the efficacy of therapeutic techniques for treating insomnia, resulting in difficulties arising in clinician and patient decision-making regarding the choice of treatment [6]. The current study will be the first to directly compare technology-enabled insomnia therapies.

While CBT-I is itself a combination treatment of cognitive and behavioral techniques, evidence regarding the efficacy of the combination of other behavioral techniques is lacking [6]. There is reason to suspect that the combination of Intensive Sleep Retraining followed by digital CBT-I will be more efficacious than either treatment alone. In a previous randomized clinical trial, we administered Intensive Sleep Retraining followed by stimulus control therapy to great effect: the combination was more efficacious at reducing insomnia symptoms than either treatment alone [11]. We found that Intensive Sleep Retraining provided a substantial "kick-start" to treatment, such that reductions in sleep latency and wake after sleep onset emerged earlier (weeks 1–2 compared to weeks 3–4 for stimulus control) and were of a greater magnitude at posttreatment compared to either treatment alone. Because patients completed Intensive Sleep Retraining first, they commenced stimulus control therapy with less severe sleep onset difficulties than at pretreatment. Accordingly, patients recovered more quickly. A similar effect is expected through administering THIM followed by SHUTi. Thus, the combination of remote therapies may result in substantially greater treatment efficacy that, from a health economics perspective, may be a worthwhile trade-off for the additional cost.

When comparing treatment efficacy, it is imperative to assess the cost/benefit of each treatment approach to inform clinical decision-making and health policies. If THIM and/or SHUTi are found to be viable treatment options, evidence regarding their cost-effectiveness will be required to impact government policy toward their implementation in the health system. At present, no health economic analyses have been conducted on Intensive Sleep Retraining. Not only will the proposed study directly compare the efficacy of THIM, SHUTi, and their combination, but it will also examine the cost/resource utilization of these approaches. This is a necessary step toward a paradigm shift in the insomnia treatment model away from inexpensive but often ineffective medications toward more expensive in the short-term but potentially substantially more effective alternatives.

The primary study aim is to investigate the comparative efficacy of technology-enabled therapies (THIM, SHUTi, the combination versus control) for treating insomnia. Secondary study aims to include:

- Compare the cost-effectiveness of each treatment approach;
- Assess treatment efficacy of novel therapies on other critical outcomes of interest (e.g. self-reported sleep continuity, objective sleep continuity, insomnia severity symptoms reported via questionnaires, and night-to-night variability);
- Investigate which insomnia phenotypes respond best to each therapy as well as other potential baseline predictors of treatment response; and
- Explore the trajectory of changes in insomnia and other symptoms over the time course of treatment.

The project outcomes will support clinicians to make informed decisions about the digital therapies to provide optimal, patient-centered, cost-effective care for insomnia. The study will also inform public health policy by building the case for public and private health-funded technology-enabled treatment options for insomnia.

Methods and Analysis

This study protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist, see the checklist in Supplementary Material S1.

Study design

This study is a 4 (treatment: +/– THIM and +/– SHUTi) × 3 (time: pretreatment, posttreatment, and 2-month follow-up) randomized controlled trial where the combined condition is sequential (THIM first then SHUTi) and the nontreatment group is a waitlist control. Patients who meet the International Classification of Sleep Disorders (ICSD)—third edition [18] diagnostic criteria for Chronic Insomnia Disorder and have sleep onset difficulties (with/without sleep maintenance or early morning awakening difficulties) will be randomly allocated via block randomization to one of the four groups. Only those with sleep onset difficulties are eligible for inclusion given that Intensive Sleep Retraining is designed to treat this form of insomnia; however eligible individuals may present with a combination of sleep initiation and other sleep difficulties (i.e. sleep maintenance, early morning awakening). Participants in the waitlist group will be re-randomized to an active treatment group after completing the control group protocol.

Participants

A total of 200 individuals will be recruited, with an expected completion of 160 participants in this 2.5-year study ($N = 40$ completers per group). Recruitment will include multiple strategies that have been effective in previous clinical trials. Participants will largely be recruited via the Adelaide Institute for Sleep Health research volunteer registry. Additional participants will be recruited via our Australian research participant database as well as via print (newspapers, flyers), media (radio, television), and online advertisements (e.g. university website, Facebook, and Twitter). This study will recruit participants from across Australia, increasing the sample pool and enabling the inclusion of rural and remote communities often under-represented in clinical trials.

Inclusion criteria: to be eligible for this study, participants will meet the diagnostic criteria for Chronic Insomnia Disorder according to the ICSD-3 [18] diagnostic criteria, operationalized as the following:

- Respond "moderate," "severe," or "very severe" to "Please rate the current severity of your insomnia problem(s): difficulty falling asleep" (item 1 on the Insomnia Severity Index [19]). Participants must then indicate that this problem is present for >3 nights per week for ≥3 months.
- Report impaired daytime function on the Fatigue Severity Scale [20], Daytime Feelings and Functioning Scale [21], or the Functional Outcomes of Sleep Questionnaire [22].
- Report a habitual bedtime between 09:30 pm and 11:30 pm and a habitual wake time between 6:00 am and 8:00 am on items 1 and 3 of the Pittsburgh Sleep Quality Index, to avoid comorbidity with circadian rhythm sleep-wake disorders [23].

Additional inclusion criteria include:

- Aged 18 to 74 years.
- Fluent in English, as is a requirement to self-administer the therapies.
- Reliable access to an internet-enabled smartphone or personal computer.
- Agree not to commence any other new sleep treatments during their participation in the trial.

Exclusion criteria:

- Currently undertaking night shift work.
- Other known sleep disorder diagnoses (e.g. obstructive sleep apnea, restless legs syndrome), or scores on self-report questionnaires indicating the presence of potentially undiagnosed disorders on the Sleep Disorders Symptom Check List [24].
- Self-reported uncontrolled health conditions via a general health screener for further screening via phone call, including the following: heart disease, cancer, diabetes, hypertension, asthma, chronic obstructive pulmonary disease, tinnitus, chronic pain, psychiatric conditions (depression, anxiety, bipolar, and post-traumatic stress disorder), and any neurological disorder.
- Self-reported recent (past 4 weeks) hypnotic medication or drug use.

Treatment conditions

THIM.

The THIM group will self-select a night convenient for them to undergo Intensive Sleep Retraining, i.e. a night with minimal activities the following day to mitigate the daytime effects of sleep restriction. To undergo THIM, they will connect the device to their internet-enabled smartphone and follow the THIM app instructions to set up the device. If the individual does not have a suitable smartphone, they will be sent a phone to use for the purpose of administering this treatment. They will be instructed to then lie down in bed and attempt to fall asleep at their habitual bedtime (calculated from pretreatment sleep diaries) while wearing THIM on the index finger of their dominant hand. THIM will emit subtle vibratory stimuli approximately every 30 seconds to which they must respond by tapping their finger against their thumb. When the user fails to respond to the stimulus, typically shortly after entering light sleep [13], THIM will infer that they have fallen asleep and subsequently wake the participant by emitting a high-intensity vibration until they tap their finger twice to acknowledge that they woke up. They will remain awake for a 2-minute break before THIM instructs them to attempt to fall asleep again on the next trial. This process will continue overnight for 10 hours.

After Intensive Sleep Retraining ends in the morning, participants will be instructed to remain awake until at least 1 hour before their habitual bedtime on the following night. After the anticipated long recovery sleep, they will be advised to maintain a consistent sleep phase (between 10:00 pm and 8:00 am) and sleep opportunity (maximum 9 hours) in the weeks following treatment.

SHUTi.

The SHUTi group will receive a subscription to the established six-module, self-guided program and be encouraged to complete

one module per week, as recommended [25]. The content of the six modules are as follows: (a) overview of insomnia and setting treatment goals; (b) sleep restriction therapy and sleep habits; (c) stimulus control therapy; (d) sleep education; (e) cognitive therapy; and (f) relapse prevention. Daily sleep diaries in the SHUTi program will inform the administration of sleep restriction therapy.

THIM followed by SHUTi.

The combined treatment group will undergo THIM as described above prior to the administration of sleep restriction therapy (week 2) in the SHUTi program, before subsequently completing the full SHUTi program.

Waitlist control.

The waitlist control group will be advised to undertake no sleep treatments during their participation. They will complete the outcome measures at "pre-treatment," for 6 weeks "during treatment," and at "post-treatment." If they wish to continue participation in the trial, they will subsequently be re-randomized to one of the three active treatment groups and asked to commence as soon as possible.

Study materials

Aside from the sleep tracker data, all data will be collected via REDCap data capture software [26, 27] hosted at Flinders University. Personalized URLs to all questionnaires are sent via text message or email, whichever participants prefer, and at their nominated time of the day for the morning sleep diaries and nightly sleepiness and fatigue scales. Up to two reminders will be issued using email or text messages if participants miss assessments. All data will be re-identifiable by study researchers during the conduct of the trial and then nonidentifiable after the trial.

Sleep diaries.

The 20-item Sleep Diary assesses participants' self-reported night-time sleep (timing, continuity, and quality), napping behavior, and daily activities which may impact sleep including alcohol and caffeine intake and medication use. Participants are asked to respond with the clock time of events (e.g. "What time did you get into bed?"), duration of an event (e.g. "In total, how long did you sleep for?"), or ratings on a scale (e.g. "How would you rate the quality of your sleep?" from "very poor" to "very good"). Self-report sleep diaries are the best measure of insomnia because it directly bears on disease diagnosis, severity, and recovery [28]. Range checks will be undertaken on data values to ensure data quality.

Sleep trackers.

Participants are asked to use three sleep trackers in this study. A Fitbit Charge 4 device monitors sleep and activity 24/7. This device incorporates signals from triaxial accelerometry and photoplethysmography to primarily assess movement, heart rate, and oxygen saturation for the purpose of sleep continuity and staging estimation. Validation testing against polysomnography showed that this model is moderately accurate for assessing sleep stages (*sensitivity* = 75–85%) and total sleep time (*M difference* = 5.67 minutes) [29]. The Withings Sleep Analyzer also monitors sleep as well as breathing. This under-mattress sensor uses ballistography to measure pressure changes in the internal air bladder to estimate movement, heart rate, and breathing rate. From our in-laboratory testing, we have shown that this device has comparable accuracy to other consumer and research-grade sleep trackers [30]. Finally, the Somfit device obtains detailed physiological information each night for sleep staging purposes. The forehead-worn device uses an adhesive patch with three clip electrodes and a spring-loaded photoplethysmography sensor to derive electroencephalography and other physiological signals needed to infer sleep staging. The device is licensed as a Class IIa medical device for sleep assessments by the Therapeutic Goods Administration in Australia [31].

Nightly sleepiness and fatigue scales.

One hour before bedtime, participants will be asked to complete the Karolinska Sleepiness Scale each night: a single item to assess momentary levels of sleepiness [32]. Participants will also be asked to complete a single item to assess momentary levels of fatigue, on a scale from 1 = "extremely energetic" to 10 = "extremely fatigued." These scales were administered to examine changes in these daytime symptoms over the course of treatment.

Weekly questionnaires.

Each week, participants will complete the following questionnaires to assess sleep and daytime function symptoms associated with insomnia: Insomnia Severity Index [19], Epworth Sleepiness Scale [33], Fatigue Severity Scale [20], and the Sleep Need Questionnaire [34].

Timepoint questionnaires.

At each timepoint (pre-treatment, treatment, post-treatment, and follow-up), the following questionnaires are added to the weekly questionnaire: Pittsburgh Sleep Quality Index [23], Daytime Feelings and Functioning Scale [21], Dysfunctional Beliefs and Attitudes about Sleep [35], Functional Outcomes of Sleep Questionnaire—10 items [22], Reduced Morningness-Eveningness Questionnaire [36], Sleep Disorders Symptom Checklist-25 [24], Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance and Sleep-Related Impairments questionnaires [22, 37], Profile of Mood States-short form [38], Patient Health Questionnaire—9 items [39], Beck's Anxiety Inventory [40], 12-item Short Form Survey [41], and the EQ5D_5L [42]. This battery of questionnaires will enable the comprehensive assessment of sleep, daytime function, and other related symptoms and consequences of insomnia [43], and test for any changes over time.

Study procedure

Figure 1 presents an overview of the study procedure and Supplementary Material S2 details the timing of study assessments. Potential participants who are eligible for the study after screening will be asked to attend a virtual consultation with a study researcher (via private rooms in Microsoft Teams or via phone call, whichever participants prefer). In this meeting, participants will be asked to provide written informed consent via electronic signature on a PDF consent form. If consent cannot be obtained via electronic signature (i.e. due to technical difficulties), then participants will be asked to sign the consent form and return it to study researchers (in person or via post).

If participants consent to the study, they will be randomly allocated in blocks of 4, 8, or 12 to one of the four groups using the randomization module in REDCap. Treatment allocation will be concealed until after consent but neither the researcher nor the participant will be blinded once randomized. Parcels

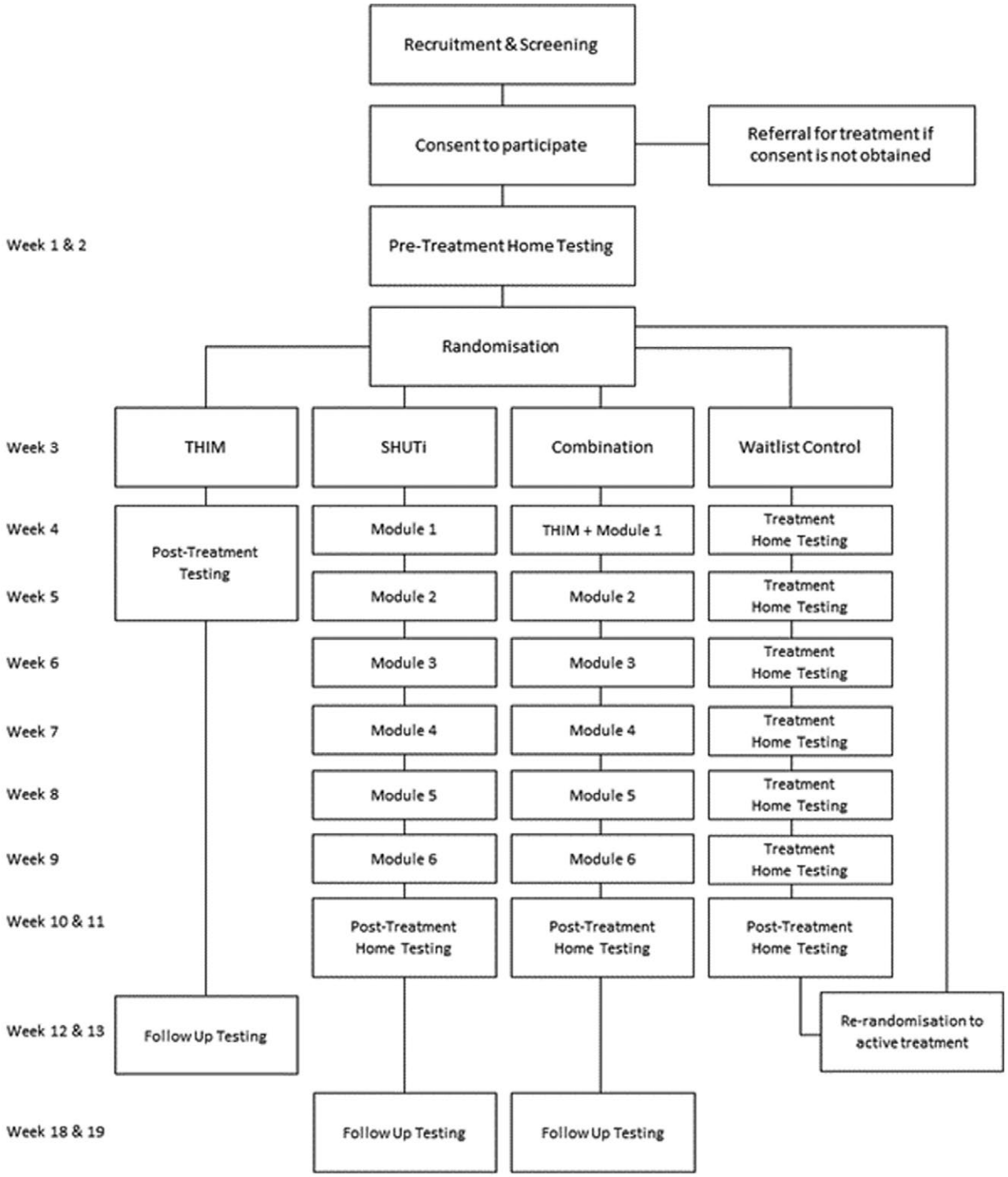

Figure 1. Study protocol flowchart.

will subsequently be sent via registered post to the participant's postal address with the study equipment needed for their participation.

Pre-treatment home testing.

Following consent and prior to treatment initiation, participants will be asked to complete home testing for 2 weeks. This testing involves the morning Sleep Diaries, nightly sleepiness and fatigue scales, using sleep tracker devices, a weekly questionnaire battery, and a timepoint questionnaire battery at the end of the 2 weeks.

Treatment.

During treatment, all participants will be asked to continue measuring their sleep and daytime functioning via the home testing procedures outlined above, as well as complete their allocated treatment.

The duration of participation in the treatment assessment phase is dependent upon which of the four groups they are assigned to: one day for the THIM treatment, up to 43 days for the combination treatment group.

Post-treatment home testing.

Like at pre-treatment, participants will be asked to complete home testing after treatment for 2 weeks. After completing the post-treatment testing, participants in the waitlist control group who agree to continue will be re-randomized to one of the three active treatment arms in blocks of 3, 6, or 9, and re-start their participation from the treatment phase.

Follow-up home testing.

Two months after treatment (6 weeks after completing the post-treatment home testing), participants will be asked to complete home testing again for 2 weeks, as per above. Participants will be asked to return all study equipment using a reply-paid postage sticker provided. Upon receipt of the parcel, participants will be reimbursed for their participation in the study.

Strategy to minimize attrition.

While the lack of participant contact is a strength of the current study since it provides greater external validity to the study design, will minimize investigator bias on study outcomes, and reduces personnel/resource consumption, it may have the undesirable consequence of higher attrition. As a strategy to encourage completion of the study outcome measures, all participants will be eligible for a monthly study lottery. Participants will receive one entry into the lottery for every survey completed during the past month. One entry will be selected at random per month and the winner sent a $500 gift card. This strategy has been successful in our previous studies to increase the completion rate of study measures [44].

Study outcomes

Primary outcome.

Total wake time will be the primary outcome measure and will be derived from Sleep Diaries. Total wake time was chosen as the primary outcome because it reflects changes in the primary complaint of prolonged wake and has also been selected in previous randomized controlled trials of insomnia treatments [45, 46]. Alternatives include sleep latency, which would have neglected potential gains on wake after sleep onset and vice versa; sleep efficiency, which does not reflect the magnitude of total wake time and can be misleading as it is influenced by sleep duration; or total sleep time, which is inappropriate considering that the primary sleep complaint is prolonged wake, not short sleep. Total wake time will be calculated by summing sleep latency (response to "how long did it take you to fall asleep?"), wake after sleep onset (response to "how long did these awakenings last for?"), and early morning awakening (difference between time of final awakening and time to get out of bed) per night and averaging across the study assessment period.

A reduction of ≥30 minutes in total wake time between pre- and post-treatment will be considered a clinically meaningful difference. Thirty minutes was chosen as it is a common quantitative threshold for a significant duration for sleep latency and wake after sleep onset. Accordingly, a mean reduction ≥30 minutes in total wake time between any group will also be considered a meaningful difference between remote therapies.

Additional outcomes.

Additional measures will be administered to further explore treatment response, listed below.

- Sleep continuity (sleep latency, total sleep time, sleep efficiency, etc.), quality, efficiency, timing, and regularity variables, calculated from daily Sleep Diaries and sleep trackers (Fitbit, Withings Sleep Analyzer, Somfit device).
- Scores on the Insomnia Severity Index [19], Pittsburgh Sleep Quality Index [23], Morningness-Eveningness Questionnaire [47], and Sleep Disorders Symptom Checklist-25 [24].
- Sleepiness, assessed using the Karolinska Sleepiness Scale [32] (before bedtime) and weekly using the Epworth Sleepiness Scale [32, 33].
- Fatigue, assessed using a 9-point Likert scale (before bedtime) and weekly using the Fatigue Severity Scale [20].
- Daytime function, assessed using the Functional Outcomes of Sleep Questionnaire [22], the Patient-Reported Outcomes Measurement Information System Sleep Disturbance and Sleep-Related Impairments questionnaires [37], and the Profile of Mood States-short form [38].
- Mental health was assessed using the Patient Health Questionnaire [39] and the Beck's Anxiety Inventory [40].
- Health-related quality of life, assessed using the 12-item Short Form Survey [41].
- Quality of life, assessed using the EQ5D_5L [42].

Statistical analyses

Supplementary Material S3 provides the detailed Statistical Analysis Plan for this trial. To summarize, the primary analysis upon which sample size is calculated is a repeated measure analysis of variance (ANOVA) assessing the mean change on Sleep Diary-derived total wake time between groups (4 groups) and over time (3 timepoints). A sample size of 40 per group ($N = 160$ total) is required to achieve 90% statistical power with α 5% to detect a clinically meaningful difference of 30 minutes or more in mean total wake time. Adjustment for baseline total wake time will ensure the primary analysis will have power exceeding 90%. We expect that attrition will be less than the typical 25% found in digital therapy trials, but we have conservatively planned for the randomization of $N = 200$ patients ($N = 50$ per group). If more than 10% of the data is missing, we will conduct linear mixed models to permit the inclusion of participants with partial records (e.g. those who complete most but not all surveys).

For the primary aim, the interaction between the treatment group and time on total wake time will be analyzed using repeated measures ANOVAs. All primary analyses will be conducted on an "intention-to-treat" basis. All analyses will be unadjusted in the first instance and then adjusted for baseline values and participant demographics. Adjustments for multiple comparisons will also be made where appropriate. No interim analyses will be conducted. Participant preference will not be accounted for in the analyses.

Health economic analyses

Unit changes in the ISI and quality adjusted life years (QALYs) gained over 6 months will be the primary and secondary economic outcomes, respectively. To calculate QALYs for all groups, patient-level measures of utility derived from the EQ5D-5L will be integrated with survival curves using the quality-adjusted

survival analysis method. Incremental costs will be estimated from patient data on Medical Benefits Schedule, Pharmaceutical Benefits Schedule, and diagnosis-related group utilization. Bootstrapped mean costs and effectiveness for the THIM, SHUTi, and combined THIM-SHUTi treatment groups will be compared with those of the waitlist control group, and incremental cost-effectiveness ratios presented with confidence intervals. The analysis includes cost-effectiveness, acceptability, net benefit, and expected net loss curves to inform the optimal strategy at any threshold for different subgroups.

Discussion

There is a clear need for randomized controlled trials testing the comparative efficacy of technology-enabled therapies for insomnia, to help inform clinicians about the best approaches to consider for managing insomnia in clients presenting predominantly with sleep onset complaints. Further analysis of the cost-versus-benefits of each therapy will also critically inform public health policy regarding the case for public and private health-funded options, increasing the reach of effective and scalable insomnia treatments. These steps are necessary to meet the current demand-supply problem which is a common problem in Australia and globally.

A major strength of this study is the use of in-home objective sleep measures in combination with an array of daily and weekly self-report measures. Such a comprehensive measurement approach will help elucidate subjective and objective treatment effects on a nightly level, during treatment, and over time. This study will be one of the most comprehensive subjective and objective assessments of insomnia treatment response to date. The study measurement and outcome approach were designed to also help test for potential baseline predictors of treatment response and toward more personalized and targeted insomnia treatment approaches, which will guide the future need and design of technology-enabled treatment strategies needed to help further improve sleep and daytime function in patients with insomnia.

Supplementary material

Supplementary material is available at *SLEEP Advances* online.

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Author contributions

Hannah Scott (Conceptualization [lead], Data curation [lead], Funding acquisition [lead], Investigation [lead], Methodology [lead], Project administration [lead], Supervision [lead], Writing—original draft [lead], Writing—review & editing [lead]), Madelaine Green (Data curation [equal], Methodology [equal], Project administration [equal], Writing—original draft [supporting], Writing—review & editing [supporting]), Kerri Jones (Methodology [supporting], Project administration [supporting], Writing—original draft [supporting], Writing—review & editing [supporting]), Kelly A. Loffler (Conceptualization [equal], Funding acquisition [equal], Methodology [equal], Project administration [equal], Software [lead], Writing—original draft [supporting], Writing—review & editing [supporting]), Nicole Lovato (Conceptualization [supporting], Methodology [supporting], Writing—review & editing [supporting]), Barbara Toson (Methodology [equal], Writing—original draft [equal], Writing—review & editing [supporting]), Darah-Bree Bensen-Boakes (Methodology [supporting], Writing—review & editing [supporting]), Michael Perlis (Conceptualization [supporting], Funding acquisition [supporting], Methodology [supporting], Writing—review & editing [supporting]), Sean P.A. Drummond (Conceptualization [supporting], Funding acquisition [supporting], Methodology [supporting], Writing—review & editing [supporting]), and Leon Lack (Conceptualization [supporting], Funding acquisition [supporting], Methodology [supporting], Writing—review & editing [supporting])

Ethics approval and consent to participate

This project was reviewed and approved by the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC), project number: 2021/HRE00414. Participants will provide informed consent in two stages: consent is sought electronically prior to completing the initial screening questionnaires and written consent to the full study is sought after confirming study eligibility at the first interview.

Consent for publication

Not applicable.

Data Availability

Not applicable.

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