BMJ Open

# Primary care treatment of insomnia: study protocol for a pragmatic, multicentre, randomised controlled trial comparing nurse-delivered sleep restriction therapy to sleep hygiene (the HABIT trial)

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**To cite:** Kyle SD, Madigan C, Begum N, *et al*. Primary care treatment of insomnia: study protocol for a pragmatic, multicentre, randomised controlled trial comparing nurse-delivered sleep restriction therapy to sleep hygiene (the HABIT trial). *BMJ Open* 2020;**10**:e036248. doi:10.1136/bmjopen-2019-036248

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2019-036248).

Received 09 December 2019
Revised 29 January 2020
Accepted 03 February 2020



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## ABSTRACT

**Introduction** Insomnia is a prevalent sleep disorder that negatively affects quality of life. Multicomponent cognitive-behavioural therapy (CBT) is the recommended treatment but access remains limited, particularly in primary care. Sleep restriction therapy (SRT) is one of the principal active components of CBT and could be delivered by generalist staff in primary care. The aim of this randomised controlled trial is to establish whether nurse-delivered SRT for insomnia disorder is clinically and cost-effective compared with sleep hygiene advice.

**Methods and analysis** In the HABIT (Health-professional Administered Brief Insomnia Therapy) trial, 588 participants meeting criteria for insomnia disorder will be recruited from primary care in England and randomised (1:1) to either nurse-delivered SRT (plus sleep hygiene booklet) or sleep hygiene booklet on its own. SRT will be delivered over 4 weekly sessions; total therapy time is approximately 1 hour. Outcomes will be collected at baseline, 3, 6 and 12 months post-randomisation. The primary outcome is self-reported insomnia severity using the Insomnia Severity Index at 6 months. Secondary outcomes include health-related and sleep-related quality of life, depressive symptoms, use of prescribed sleep medication, diary and actigraphy-recorded sleep parameters, and work productivity. Analyses will be intention-to-treat. Moderation and mediation analyses will be conducted and a cost-utility analysis and process evaluation will be performed.

**Ethics and dissemination** Ethical approval was granted by the Yorkshire and the Humber - Bradford Leeds Research Ethics Committee (reference: 18/YH/0153). We will publish our primary findings in high-impact, peer-reviewed journals. There will be further outputs in relation to process evaluation and secondary analyses focussed on moderation and mediation. Trial results could make the case for the introduction of nurse-delivered sleep therapy in primary care, increasing access to evidence-based treatment for people with insomnia disorder.

**Trial registration number** ISRCTN42499563

## Strengths and limitations of this study

- This multicentre randomised controlled trial will recruit 588 participants and will be the largest trial of sleep restriction therapy (SRT) for insomnia.
- This study will test whether brief, nurse-delivered SRT in primary care is clinically and cost-effective.
- The control group will be provided with a sleep hygiene booklet while the SRT arm will receive both nurse-delivered SRT and a sleep hygiene booklet.
- The primary outcome is self-reported insomnia severity while secondary outcomes include actigraphy-defined sleep, use of sleep medication, quality of life and depressive symptoms.
- Owing to the nature of the intervention participants will not be blind to treatment allocation.

## INTRODUCTION

Insomnia disorder is characterised by persistent problems with sleep initiation and maintenance, significantly impairing quality of life.[1–3] Persistent insomnia affects approximately 10% of the adult population[4] and is a risk factor for several mental and physical health problems, particularly depression and cardiometabolic disease.[5 6] Insomnia is also an expensive condition, associated with substantial direct and indirect costs; chiefly reflecting increased healthcare utilisation, work-related absenteeism, reduced work productivity and elevated accident risk.[7–9]

Insomnia is treatable. The principal treatment options are hypnotic medication and cognitive behavioural therapy (CBT). The former is indicated for short-term use only, while the latter is the recommended first-line treatment and has been shown to

engender sustained improvement in self-reported sleep and insomnia severity.[10] Despite national and international clinical guidelines recommending CBT,[11–13] access is almost non-existent in routine care across many health systems. In the absence of available treatment, general practitioners (GPs) are limited to administering sleep hygiene guidelines, hypnotics and (off-label) sedative antidepressants;[14 15] yet none are evidence-based for persistent insomnia[12 16] and hypnotics have well-defined side-effects.[4] Barriers to wide-scale adoption of CBT in routine healthcare relate to limited training, expertise and funding. A major development in the insomnia field, therefore, has been the dismantling of multicomponent, multisession CBT into brief and focussed treatment packages[17] and the training of non-specialists to deliver such therapies.[18–20]

Sleep restriction therapy (SRT) has emerged as one of the primary active ingredients within multicomponent CBT. The therapy involves restricting and standardising a patient's time in bed with the aim of increasing homeostatic sleep pressure, over-riding cognitive and physiological arousal and strengthening circadian regulation of sleep.[21] Tailored prescription of bed and rise times over several weeks leads to improved sleep consolidation and reduction in insomnia severity. Its short length and simplicity renders SRT ideally suited for delivery by generalist staff in primary care.

A systematic review of trials comparing single-component SRT to waitlist control or sleep hygiene advice found medium-to-large effects on sleep continuity measures.[22] Moreover, recent trials suggest SRT may be as effective as multicomponent CBT.[23 24] One primary care trial compared brief SRT (delivered by one GP) with sleep hygiene advice.[25] The participants were highly selected so that they were free from comorbidity or medication use. SRT significantly reduced insomnia severity at 6 months (Cohen's d=0.54). While this was an important first study, a pragmatic trial in primary care testing a scalable model of treatment delivery is clearly required.

We have developed a brief SRT protocol based on (1) our extensive research using multicomponent CBT[18–20] and (2) systematic examination of the patient experience of SRT.[26] We aim to test whether brief SRT (alongside sleep hygiene advice) is both clinically and cost-effective, relative to sleep hygiene advice on its own. We have chosen practice nurses instead of GPs based on previous successful trial experience with this professional group[18–20] and with cost-effectiveness and scalability in mind. Practice nurses are increasingly involved in chronic disease management (where sleep disturbance is a common comorbidity) and the delivery of brief behavioural interventions in primary care.[27] While previous studies in UK primary care show multicomponent CBT to be effective when delivered by nurses,[18 19] counsellors[28] or through self-help CBT booklets,[29] there has been no large-scale evaluation of the clinical and cost-effectiveness of a brief and scalable behavioural intervention.

### Study objectives

The primary objective of the HABIT (Health-professional Administered Brief Insomnia Therapy) trial is to establish whether nurse-delivered SRT(+sleep hygiene (SH)) for insomnia disorder in primary care improves insomnia more than SH alone. We hypothesise that participants allocated to SRT(+SH) will demonstrate lower insomnia severity at 6 months post-randomisation compared with those allocated to SH alone.

Our secondary hypotheses are as follows:

1. Compared with SH, participants allocated to SRT(+SH) will report improvements in health-related quality of life, sleep-related quality of life, depressive symptoms, work productivity, pre-sleep arousal and sleep effort (at 3, 6 and 12 months).
2. Compared with SH, participants allocated to SRT(+SH) will demonstrate improvements in sleep parameters (diary and actigraphy-recorded) and report a reduction in use of sleep-promoting medication (6 and 12 months).
3. The effect of SRT(+SH) on insomnia severity will be mediated via reduction in sleep effort and pre-sleep arousal, consistent with theoretical models.[21]

Other objectives:

4. To establish whether nurse-delivered SRT(+SH) for insomnia disorder in primary care is cost-effective compared with SH, from National Health Service (NHS) and societal perspectives.
5. To undertake a process evaluation to understand intervention delivery, fidelity and acceptability.
6. To test whether insomnia phenotype moderates clinical benefit obtained from SRT(+SH). One prominent model posits that participants with objective short sleep duration are less likely to experience improvement in insomnia relative to those with normal sleep duration.[5] We will examine whether actigraphy-defined sleep duration (<6 hours vs ≥6 hours) at baseline moderates the effect of SRT on clinical outcomes (at 6 months)
7. To test whether SRT adherence mediates degree of clinical change (Insomnia Severity Index (ISI)) from baseline to 3 months, and from baseline to 6 months.

## METHODS AND ANALYSIS

### Trial design

This is a pragmatic, multicentre, individually randomised, parallel group, superiority trial to test whether nurse-delivered SRT(+SH), compared with SH alone, reduces insomnia severity. Both groups will receive treatment as usual without restriction. Participants will be recruited from general practices across three regions in the UK (Thames Valley, Greater Manchester and Lincolnshire). Assessments will take place at baseline, 3, 6 and 12 months post-randomisation (see figure 1 for trial flow). The trial is prospectively registered with the ISRCTN. There is a Trial Steering Committee and Data Monitoring and Ethics Committee, both comprised of majority independent members.

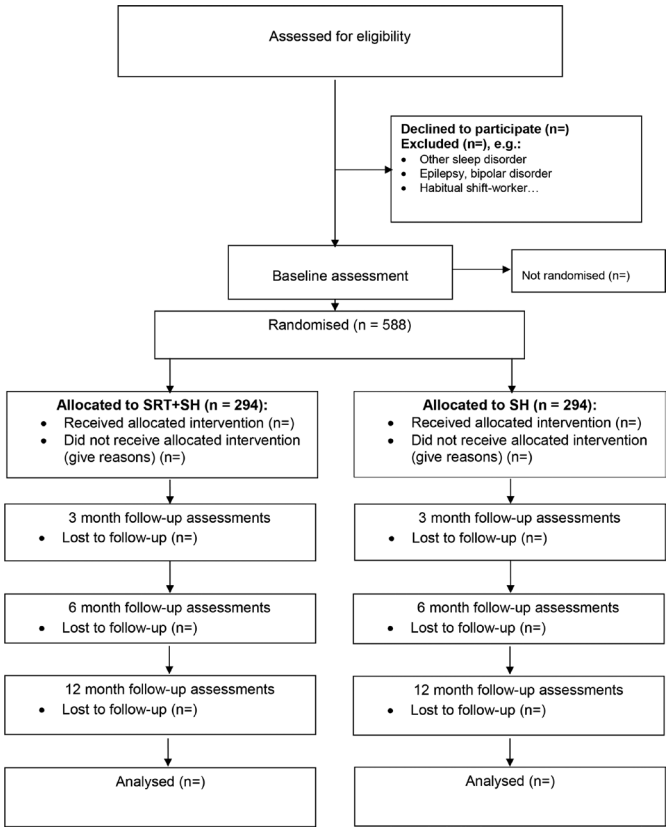


**Figure 1** Trial flow. SH,sleep hygiene; SRT, sleep restriction therapy.

## Participants and recruitment

We aim to recruit participants aged 18 years and above in primary care practices who meet criteria for insomnia disorder. Since insomnia is not commonly coded within practice records we will search records for broad sleep-related terms, sleep-related medications and associated conditions to identify those most likely to be eligible, while applying exclusionary diagnoses. We will send invitations to identified individuals. We will also identify potential participants through (a) direct face-to-face GP referral (participants will be provided with an information sheet and contact details for the research team), (b) placing posters in practices (containing study contact details) and (c) posting study adverts on the Internet (eg, practice websites, Facebook).

Participants will be screened for eligibility over the phone by the research team, or through self-completion of an online questionnaire. The inclusion criteria are as follows: (a) participant is willing and able to give informed consent for participation, (b) screen positive for insomnia symptoms on the Sleep Condition Indicator[30] and meet DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) criteria for insomnia disorder, (c) self-reported sleep efficiency <85% over the past month, (d) age ≥18 years and (e) able to attend appointments during baseline and 4-week intervention (both face-to-face at the practice and over the phone) and adhere to study procedures.

Exclusions will be limited principally to conditions which may be contraindicated for SRT, or render SRT inappropriate or ineffective: (a) pregnant/pregnancy planning in the next 6 months; (b) additional sleep disorder diagnosis (eg, restless legs syndrome, obstructive sleep apnoea, narcolepsy) or 'positive' screen on screening questionnaire;[31] (c) dementia or mild cognitive impairment; (d) diagnosis of epilepsy, schizophrenia or bipolar disorder; (e) current suicidal ideation with intent[32] or attempted suicide within past 2 months; (f) currently receiving cancer treatment or planned major surgery during treatment phase; (g) night, evening, early morning or rotating shift-work; (h) currently receiving psychological treatment for insomnia from a health professional or taking part in an online treatment programme for insomnia and (i) life expectancy of <2 years. On completion of screening, eligible participants will be invited to a baseline appointment with a member of the research team where they will give written informed consent (see *appendices*), complete baseline questionnaires (see *assessments* section) and be provided with a sleep diary and actigraph watch for the following week. Participants will return the completed diary and actigraph watch to the research team via postal mail.

## Interventions

### Sleep hygiene

Usual care for persistent insomnia typically involves sleep hygiene advice, repeat hypnotic prescription and use of sedative antidepressants or antihistamines.[14 15] For those aged 55+ years, melatonin may also be prescribed for insomnia, consistent with English guidelines from the National Institute for Health and Care Excellence (NICE; [13]). Evidence shows that access to and awareness of CBT for insomnia in primary care is very limited.[14]

Since NICE recommends that individuals with persistent insomnia should receive sleep hygiene advice, it is likely that some participants will have been exposed to such information in the past. Therefore, to avoid bias, all participants in both arms will be provided with the same standardised sleep hygiene information. We will provide a booklet comprising standard behavioural guidance about lifestyle and environmental factors associated with sleep and sleeplessness.[33] Participants randomised to the SH arm will be sent their booklet via email or post.

Consistent with the requirements of a pragmatic trial, there will be no restrictions on usual care for both groups. In this way, the trial represents a comparison of SRT(+SH) (+treatment as usual (TAU)) versus SH(+TAU), permitting clear judgement to be made regarding the relative clinical utility of SRT in routine clinical practice.

### Sleep restriction therapy

Participants in the intervention arm will be offered nurse-delivered insomnia therapy in the form of SRT, a manualised behavioural intervention. See online supplementary table 1 for a detailed description of the intervention according to the template for intervention description

and replication (TIDieR) checklist.[34] We will initially aim to train practice nurses to deliver SRT but in order to overcome scheduling issues that may arise, or limitations on practice capacity, we will also train research nurses from clinical research networks to support delivery. Nurses will receive a 4 hour training session on insomnia and the delivery of SRT as well as access to supporting resources (eg, recorded video clips and a list of frequently asked questions and answers in relation to treatment delivery). Trained nurses will deliver manualised SRT over four brief, weekly sessions (total contact time=approximately 1 hour 5 mins). In session 1 the nurse will work through slides with the participant to introduce the rationale for SRT alongside a review of sleep diaries, selection of bed and rise times, management of daytime sleepiness (including implications for driving) and discussion of barriers/facilitators to implementation. Participants will also be provided with a booklet to read in their own time, which includes information on theory underlying SRT and a list of sleep hygiene guidelines (identical to those provided to the control arm). Participants will be provided with diaries and sleep efficiency calculation grids to support implementation of SRT instructions and permit weekly review of progress. Sessions 2, 3 and 4 will be brief sessions (10 to 15 min) to review progress, troubleshoot any difficulties and advise on adaptation of the sleep schedule.[35] Sessions 1 and 3 will be in-person at the practice while sessions 2 and 4 will be over the phone.

## Randomisation and blinding

Following completion of baseline assessments participants will be randomised (1:1) to SRT (+SH) or SH using a fully validated web-based randomisation programme (Sortition), with a non-deterministic minimisation algorithm to balance region (Thames Valley, Lincolnshire, Greater Manchester), use of prescribed sleep promoting medication (yes/no), age (18 to 65 years vs >65 years), sex, baseline ISI[36] score (<22 vs 22 to 28) and depression symptom severity (Patient Health Questionnaire-9 (PHQ-9)[37] score <10 vs 10 to 27) across the two groups. Members of the research team will inform participants of their allocation.

This is an open-label study and therefore both participants and nurses will be aware of allocation. The participant information sheet will inform participants that the study compares two different sleep intervention programmes but will not reveal the study hypothesis. Treatment providers (nurses) will not be involved in the collection of trial outcomes. Outcomes (questionnaires, diaries and actigraphy) are self-completed, remotely, by participants. It will be impractical to blind the research team however actigraph data will be scored by a sleep researcher blind to group allocation and the trial statisticians will remain blind to group allocation.

## Assessments

The primary outcome is insomnia severity assessed by the ISI,[36] and will be measured at baseline, 3, 6 and 12 months post-randomisation. Secondary outcomes will similarly be measured at all four timepoints and they are health-related quality of life (ShortForm 36 Questionnaire (SF-36); [38]), sleep-related quality of life (Glasgow Sleep Impact Index (GSII; [3])), depressive symptoms (PHQ-9; [37]), work productivity and activity impairment (Work Productivity and Activity Impairment questionnaire (WPAI); [39]), sleep effort (Glasgow Sleep Effort Scale (GSES); [40]) and arousal (Pre-Sleep Arousal Scale (PSAS); [41]). Questionnaires will be completed online or on paper, depending on participant preference. Self-reported sleep and use of sleep medication will be captured over 7 days using the consensus sleep diary[42] collected at baseline, 6 and 12 months. The consensus sleep diary will also be completed by the SRT group during the 4-week intervention phase. Actigraphy-defined sleep (CamNtech Ltd., MotionWatch 8) will be measured at baseline, 6 and 12 months. A modified version of the Client Service Receipt Inventory (CSRI; [43]) and the EuroQol Questionnaire (EQ-5D-3L; [44]) will be administered at baseline, 3, 6 and 12 months to inform the cost-effectiveness evaluation. Participants will receive vouchers for completion of outcomes at each assessment point (vouchers = £5 at baseline, £10 at 3 months, £15 at 6 months and £10 at 12 months). A summary of outcomes in relation to study objectives can be found in table 1.

## Process evaluation

Consistent with Medical Research Council guidance for trials of complex interventions we will conduct a process evaluation.[45] The aim of the process evaluation is to explore nurse-delivered SRT in the primary care setting by examining implementation, mechanisms of impact and contextual factors that facilitate or impede intervention delivery. This will complement the outcomes evaluation, helping to understand the trial results through exploring:

i. Nurse perceptions of SRT, including training and support.
ii. Fidelity of intervention delivery by nurses.
iii. Whether participants in the control group also receive SRT (ie, contamination).
iv. The participant experience of SRT, including reflections on implementing the sleep schedule and perceptions of benefit, as well as any unexpected consequences.
v. Whether level of adherence mediates degree of clinical improvement.
vi. Views of primary care staff in relation to the implementation of SRT beyond the context of the trial.

In order to capture experiences and perceptions of SRT semi-structured interviews will be conducted by the research team with a sample of practice nurses (n=15), trial participants (n=15) and practice managers or GPs (n=15) across the three study sites. Interview participants will be invited from five practices from each of the three trial recruitment centres. The practices will be selected to reflect a range of practice types (eg, based on practice size, or membership of a consortium) and, for each

Table 1 Objectives and outcome measures

| Objectives | Outcome measures | Timepoint(s) of evaluation of this outcome measure |
|---|---|---|
| Primary objective:<br>To compare the effect of SRT+SH vs SH on insomnia severity | Self-rated insomnia severity using the ISI questionnaire | Baseline, 3, 6 and 12 months post-randomisation. *Primary outcome is at 6 months*. |
| Secondary objectives:<br>To compare the effect of SRT+SH vs SH on HRQoL | Self-rated HRQoL using the SF-36 questionnaire (total score, MCS, PCS) | Baseline, 3, 6 and 12 months post-randomisation. |
| To compare the effect of SRT+SH vs SH on subjective sleep | Subjective sleep recorded over 7 nights using the CSD (SOL; WASO; SE; TST; SQ) | Baseline, 6 and 12 months post-randomisation. |
| To compare the effect of SRT+SH vs SH on objective estimates of sleep | Actigraphy-defined sleep over 7 nights (SOL; WASO; SE; TST) | Baseline, 6 and 12 months post-randomisation. |
| To compare the effect of SRT+SH vs SH on (1) patient-generated quality of life, (2) depressive symptoms, (3) work productivity, (4) hypnotic medication use, (5) use of other prescribed sleep-promoting medications and (6) pre-sleep arousal and sleep effort | 1. Self-rated quality of life using the GSII (ranks 1, 2, 3)<br>2. Self-rated depressive symptoms severity using the PHQ-9<br>3. Self-rated WPAI questionnaire<br>4. Use of prescribed hypnotics (quantified from 7 day diary)<br>5. Use of other prescribed sleep-promoting medications (quantified from 7 day diary)<br>6. Self-rated arousal and sleep effort using the PSAS and GSES | Baseline, 3, 6 and 12 months post-randomisation.<br>Medication use will be quantified from diaries at baseline, 6 and 12 months post-randomisation. |
| To compare the incremental cost-effectiveness of SRT+SH over SH, from both NHS and societal perspectives | Trial records (time and number of nurse-led appointments), practice records* (medications), CSRI, ISI, WPAI, EQ-5D-3L | Baseline, 3, 6 and 12 months post-randomisation.<br>*Baseline and 12 months only |
| To undertake a process evaluation to explain trial results and understand intervention delivery, fidelity and acceptability. | Semi-structured interviews with (1) trial participants, (2) nurses, (3) GPs or practice managers. | Throughout the trial. |
| *Moderator analysis:*<br>Test whether objective short sleep duration at baseline (<6 hours vs ≥6 hours) moderates the effect of SRT on clinical outcomes (at 6 months) | Actigraphy, ISI, GSII, SF-36 | Baseline and 6 months. |
| *Mediator analysis:*<br>Test whether group difference on the ISI (6 months) is mediated by change in PSAS and GSES assessed at month 3<br>Test whether SRT adherence mediates degree of clinical change on the ISI | ISI, PSAS, GSES<br>Sleep diary during intervention phase, ISI | Baseline, 3 and 6 months. |
| To compare the number of specified adverse events between the groups | Questionnaire | Baseline, 3, 6 and 12 months. |

CSD, Consensus Sleep Diary; CSRI, client service receipt inventory; EQ-5D-3L, EuroQol 5 Dimensions 3 Levels Questionnaire; GPs, general practitioners; GSES, Glasgow Sleep Effort Scale; GSII, Glasgow Sleep Impact Index; HRQoL, health-related quality of life; ISI, Insomnia Severity Index; MCS, mental component summary score; NHS, National Health Service; PCS, physical component summary score; PHQ-9, patient health questionnaire; PSAS, Pre-Sleep Arousal Scale; SE, sleep efficiency; SF-36, Short Form 36 Questionnaire; SH, sleep hygiene; SOL, sleep-onset latency; SQ, sleep quality; SRT, sleep restriction therapy; TST, total sleep time; WASO, wake time after sleep onset; WPAI, work productivity and activity impairment questionnaire.

selected practice, one nurse, one trial participant and one GP or practice manager will be interviewed. These will be in-depth semi-structured telephone, *Skype,* or face-to-face interviews lasting 30 to 60 min using separate interview schedules for each group. Consent process and interviews will be digitally audio recorded and transcribed verbatim. Professionals will be asked about their working role in relation to delivering the SRT intervention. Participant interviews will take place after the intervention phase.

Participants will receive a £10 voucher for interview participation.

To enable fidelity assessment, all in-person SRT sessions will be recorded (if participants consent). A sample of these sessions will be rated by a trained member of the research team using a bespoke rating scale. We will monitor potential for control group contamination (ie, SH participants accessing SRT via the trained practice nurse) through questionnaire[43] completion at 3 and 6 months follow-up. SRT engagement will be measured with respect to number of treatment sessions attended, while adherence to therapeutic instructions (prescribed bed and rise times) will be quantified from sleep diaries recorded during the 4-week intervention phase.

## Sample size

To detect a difference on the ISI of 1.35 points (SD=4.50) between the group means of SRT+SH and SH, with a power of 90% at 5% level of significance (two-sided), 235 participants would be required in each treatment group. This equates to a standardised effect size of 0.3. The SD was based on the results from the primary care evaluation of SRT conducted by Falloon and colleagues.[25] Accounting for 20% attrition the total number of participants required to be recruited is 588 (294 per group). Should attrition be higher, at 25% or 30%, the total number of participants required would be 628 (314 per group) or 672 (336 per group), respectively.

Most CBT evaluations show large effects on the ISI[46] but these studies have small samples, are tightly controlled and recruit participants from the community, who are generally free from comorbidity or medication. Given that our study is a pragmatic trial, across multiple NHS sites, with a varied group of insomnia patients (representing clinical reality), we would anticipate a lower effect size for the ISI. Falloon and colleagues[25] recruited a highly selected group of patients and delivered treatment via one research GP, observing an effect size of 0.54 at 6 months on the ISI. Thus, powering the study for a moderate standardised effect size of 0.3 is conservative and appropriate given our design features. The sample size will also allow us to detect an average difference of 2.7 points (SD=9.0[47]) on the SF-36 (health-related quality of life), our important secondary outcome, at 90% power and 5% level of significance.

For the interviews we aim to recruit 15 participants, consistent with our previous experience of Framework analysis[48] and guidelines recommending that a minimum of 12 interviews are needed to achieve data saturation.[49]

## Adverse events

The likelihood of serious adverse events (SAEs) occurring due to treatment is low since neither CBT/SRT nor sleep hygiene advice have been reported to cause them. We define SAEs as any untoward medical occurrence that either: (a) results in death, (b) is life-threatening, (c) requires inpatient hospitalisation or prolongation of existing hospitalisation, (d) results in persistent or significant disability/incapacity or (d) consists of a congenital anomaly or birth defect. Nurse therapists and participants will be prompted to self-report SAEs. Along with self-reporting of SAEs, we will also use responses on the CSRI[43]—which includes questions on hospitalisations—to follow-up participants who report being hospitalised. We will record planned hospital admissions at baseline and, when they occur, these will not be counted as SAEs. SAEs will be assessed for severity, seriousness and relatedness to study procedures by a medically qualified member of the team. SAEs will be reported after date of randomisation until either the date of trial withdrawal or 6-month follow-up completion, whichever is earlier.

Because implementation of SRT may be associated with increased sleepiness we will also record falls, accidents (including road-traffic accidents and work-related injuries) and near-miss driving incidents alongside outcomes at baseline, 3, 6 and 12 months post-randomisation and report these by randomised group.

## Analysis plan

### Statistical analysis

The primary statistical analysis will be carried out on the basis of intention-to-treat (ITT). We will endeavour to obtain full follow-up data on every participant to allow full ITT analysis, but we will inevitably experience the problem of missing data due to withdrawal, loss to follow-up or non-response to some questionnaire items. The results from the trial will be prepared as comparative summary statistics with 95% CIs. All the tests will be performed at a 5% two-sided significance level. The study results will be reported in accordance with the Consolidated Standards of Reporting Trials guidelines.[50] A full detailed statistical analysis plan will be prepared and finalised before data collection is complete.

A three-level mixed effect linear model based on an unstructured covariance matrix will be fitted to the primary outcome data (ISI at 6 months), utilising 3, 6 and 12 month timepoints. Practice and participant will be included as random effects. Fixed effects will include randomised group, baseline ISI score, stratification variables, time and a time by randomised group interaction term to allow estimation of treatment effect at each timepoint.

Missing data will be reported (alongside reasons for missingness where available) and the missing data pattern will be explored, though the mixed effects model implicitly accounts for data missing at random. Standard residual diagnostics will be assessed for the appropriateness of the model and if assumptions are violated we will consider alternative non-parametric approaches for the main analysis. Continuous secondary outcomes will be analysed using the same method. Secondary outcomes that are binary (eg, zero hypnotic use over 7 days) or count variables (eg, number of nights hypnotic-free over 7 nights) will be analysed using generalised linear mixed effect models with appropriate link function. We will undertake

prespecified subgroup analysis of the primary outcome by actigraphy-defined sleep duration at baseline (<6 hours vs ≥6 hours). Mediation analyses will be conducted using the approach of Baron and Kenny[51] but will follow the adaptation in Freeman *et al*[52] which makes use of linear mixed effects models. This will allow us to determine the extent to which the 3-month arousal outcomes (PSAS, GSES) mediate the 6-month ISI outcome. All models will include the baseline assessments of the mediator and ISI as covariates. A complier-average causal effect (CACE) analysis of the primary outcome will be carried out to determine the impact of the treatment effect when accounting for non-compliance of the allocated intervention (ie, SRT session attendance). CACE is a measure of the causal effect of an intervention for participants who received it as intended by the original group allocation. We will also explore the effect of level of adherence to prescribed bed and rise times (captured by sleep diaries) on the primary outcome in those who received SRT.

### Economic analysis

A within-trial economic evaluation alongside the RCT will estimate the incremental cost-effectiveness of SRT+SH over SH, from both NHS and societal perspectives. In our economic analyses we will adopt the UK NHS and personal social services perspective, consistent with NICE guidelines.[53] Additional analyses will examine costs from a societal perspective, quantifying productivity losses in relation to absenteeism and presenteeism.

From trial records we will quantify participants' attendance at SRT sessions and hence nurse time and also assess the resources used in training. We will collect data on healthcare usage through GP records (medication use) and a self-reported version of CSRI.[43] The Personal Social Services Research Unit Costs of Health and Social Care[54] and NHS Reference Costs[55] will be used to apply national average unit costs to service utilisation and construct a cost profile per participant. Productivity will be quantified from the WPAI questionnaire[39], and costed using the human capital approach.

Analysis of the ISI (assessed at baseline, 3, 6 and 12 months) will indicate the incremental cost per unit change in self-reported insomnia severity. As recommended by NICE, cost-utility analysis will examine incremental quality-adjusted life-years (QALYs). This will be achieved through collecting data on health status using the EQ-5D-3L[44] at baseline, 3, 6 and 12 months, and calculating the area under the curve. An incremental cost-effectiveness ratio will be calculated using costs-per-QALY with a 12-month time horizon. We will add a sleep dimension[56] to the standard EQ-5D-3L allowing us to examine, in exploratory analysis, the relationship between sleep bolt-on responses and other measures of insomnia severity, to identify whether the sleep question correlates with other measures of sleep satisfaction and self-reported health. Probabilistic and deterministic sensitivity analysis will be conducted to characterise the uncertainty around the cost-effectiveness estimates.

### Qualitative analysis

We will use a Framework approach[57] for qualitative data analysis supported by QSR NVivo (V.11), with the framework based on the main areas of implementation, mechanisms of impact and contextual factors together with the more detailed issues that arise from these. Analysis will occur as the interviews are transcribed and this analysis will allow schedules and data collection to be further developed. We will analyse qualitative process data prior to knowing trial outcomes to avoid biassed interpretation.

## Patient and public involvement

Four people from the Healthier Ageing Public and Patient Involvement group, University of Lincoln, read and provided detailed comments on the original grant proposal, helping to shape key methodological choices (eg, measurement selection). Two individuals will contribute during the trial by reviewing participant information sheets, consent form, therapy workbooks and questionnaire measures. They will advise on recruitment procedures and methods to engage prospective participants/retain enrolled participants. Finally they will support the dissemination of trial results through review of the final report to the funder, lay summary (which we will send to trial participants on completion of analysis) and media releases by the University of Oxford.

## Ethics and dissemination

The trial has received both Health Research Authority approval (IRAS: 238138) and ethical approval (Yorkshire and the Humber - Bradford Leeds Research Ethics Committee, reference: 18/YH/0153). We will publish our findings in high-impact, peer-reviewed journals. We will send trial participants a summary of study outcomes.

## Trial status

The trial commenced recruitment in August 2018 and will continue recruiting until approximately March 2020, with final outcome data expected around April 2021.

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**Contributors** SDK is the Chief Investigator, conceived the project, had overall responsibility for the trial design and treatment design and drafted the trial protocol. CM contributed to the trial protocol and drafted the manuscript. PA, CAE, PB, AS, LMY, LA, EO, SA contributed to trial design. SDK, CAE and AS contributed to treatment design. LMY is responsible for statistical analysis. LA is responsible for economic analysis. AS/SA are responsible for the process evaluation analysis. NB is the Trial Manager and helped draft the manuscript. Centre leads are SDK/PA (Oxford), PB (Greater Manchester) and AS (Lincoln). All authors inputted to the trial protocol and commented on the manuscript.

**Funding** The trial is funded by the National Institute for Health Research Health Technology Assessment Programme. HTA Project: 16/84/01. SDK and CE are supported by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC) based at Oxford University Hospitals NHS Trust and the University of Oxford. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

**Competing interests** Colin Espie is co-founder of and shareholder in Big Health Ltd, a company which specialises in the digital delivery of cognitive behavioural therapy for sleep improvement (the Sleepio programme). This study is in no way connected to Big Health Ltd or Sleepio. SDK declares non-financial support from Big Health Ltd in relation to no-cost access to Sleepio for use in clinical trial research. All other authors declare no competing interests.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.



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