Clinical and cost-effectiveness of nurse-delivered sleep restriction therapy for insomnia in primary care (HABIT): a pragmatic, superiority, open-label, randomised controlled trial

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Summary

Background Insomnia is prevalent and distressing but access to the first-line treatment, cognitive behavioural therapy (CBT), is extremely limited. We aimed to assess the clinical and cost-effectiveness of sleep restriction therapy, a key component of CBT, which has the potential to be widely implemented.

Methods We did a pragmatic, superiority, open-label, randomised controlled trial of sleep restriction therapy versus sleep hygiene. Adults with insomnia disorder were recruited from 35 general practices across England and randomly assigned (1:1) using a web-based randomisation programme to either four sessions of nurse-delivered sleep restriction therapy plus a sleep hygiene booklet or a sleep hygiene booklet only. There was no restriction on usual care for either group. Outcomes were assessed at 3 months, 6 months, and 12 months. The primary endpoint was self-reported insomnia severity at 6 months measured with the insomnia severity index (ISI). The primary analysis included participants according to their allocated group and who contributed at least one outcome measurement. Cost-effectiveness was evaluated from the UK National Health Service and personal social services perspective and expressed in terms of incremental cost per quality-adjusted life year (QALY) gained. The trial was prospectively registered (ISRCTN42499563).

Findings Between Aug 29, 2018, and March 23, 2020 we randomly assigned 642 participants to sleep restriction therapy (n=321) or sleep hygiene (n=321). Mean age was 55·4 years (range 19–88), with 489 (76·2%) participants being female and 153 (23·8%) being male. 580 (90·3%) participants provided data for at least one outcome measurement. At 6 months, mean ISI score was 10·9 (SD 5·5) for sleep restriction therapy and 13·9 (5·2) for sleep hygiene (adjusted mean difference –3·05, 95% CI –3·83 to –2·28; p<0·0001; Cohen's *d* –0·74), indicating that participants in the sleep restriction therapy group reported lower insomnia severity than the sleep hygiene group. The incremental cost per QALY gained was £2076, giving a 95·3% probability that treatment was cost-effective at a cost-effectiveness threshold of £20 000. Eight participants in each group had serious adverse events, none of which were judged to be related to intervention.

Interpretation Brief nurse-delivered sleep restriction therapy in primary care reduces insomnia symptoms, is likely to be cost-effective, and has the potential to be widely implemented as a first-line treatment for insomnia disorder.

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See Comment page 940

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Introduction

Insomnia disorder affects 10% of the adult population. Evidence shows that insomnia reduces quality of life and increases risk for psychiatric disorders, type 2 diabetes, cardiovascular disease, and suicide.[1] Insomnia commonly presents alongside a range of chronic conditions, is persistent if left untreated, and is associated with substantial direct and indirect costs.[2,3]

International guidelines suggest that the first line of treatment should be multicomponent cognitive behavioural therapy (CBT), but access is extremely limited worldwide because of inadequate resources and expertise. A study in Switzerland[4] found that just 1% of patients with insomnia received CBT. Instead, patients are provided with sleep hygiene advice, and prescribed hypnotic medication or off-label sedative antidepressants.[5] None of these approaches are evidence based for the long-term management of insomnia, and hypnotic medications are associated with a range of side-effects.[6] New models of care are needed to increase access to guideline intervention, especially in general practice where people with insomnia seek treatment.

Research in context

Evidence before this study

Multicomponent cognitive-behavioural therapy (CBT) is the recommended first-line treatment for insomnia, but access to this type of CBT is almost non-existent. One principal component of CBT is a behavioural treatment called sleep restriction therapy, which could potentially be delivered as a brief single-component intervention by generalists in primary care. We published a systematic review and meta-analysis of the sleep restriction therapy literature in 2021. We searched EMBASE, PsycINFO, CINAHL, AMED, and PubMed databases, and hand searched relevant sleep journals for peer-reviewed research articles published in English between Jan 1, 1987 (the year the first sleep-restriction therapy study was published) and July 6, 2020. We included the following search terms: "insomnia" or "chronic insomnia" or "sleeplessness" or "sleep disorder*" or "sleep initiation" or "sleep maintenance" or "poor sleep" or "sleep problem" or "sleep disturbance" and "sleep restriction", "time in bed restriction", "bedtime restriction", "sleep compression", "behavio?ral treatment", "behavio?ral intervention", "behav*therap*" or "behav* modification". We found eight studies with a combined sample size of 533. Only one study was done in a primary care setting. This study showed potential treatment effects of a brief adapted sleep restriction intervention versus sleep hygiene at 6 months, but the sample was small (n=97), comprised of participants with primary insomnia who were not taking hypnotic medication (and therefore not reflective of patients in clinical practice), and the sleep restriction treatment was delivered by a single study general practitioner.

Added value of this study

We did a definitive test of whether brief sleep restriction therapy delivered in primary care is clinically effective and cost-effective. The trial shows that nurses without previous clinical experience of sleep disorders or sleep intervention can be successfully trained to deliver sleep restriction therapy in a brief and manualised manner, and with high levels of fidelity. Results indicate superiority of nurse-delivered sleep restriction therapy over sleep hygiene in reducing insomnia symptoms at all timepoints. A cost-utility analysis suggested that the intervention is likely to be cost–effective at established cost-effectiveness thresholds. Significant treatment effects were also observed for depressive symptoms, mental health-related quality of life, sleep-related quality of life, and work productivity.

Implications of all the available evidence

Brief nurse-delivered sleep restriction therapy in primary care is clinically effective for insomnia disorder, safe, and likely to be cost-effective. Sleep restriction therapy could become part of a stepped-care approach to insomnia treatment, helping to facilitate the implementation of international guidelines and increase access to evidence-based interventions.

Treatment access could be addressed by simplifying CBT. One central element of CBT is sleep restriction therapy,[7] which involves systematically restricting and regularising time in bed to consolidate and stabilise sleep. It counters behaviours that perpetuate insomnia, specifically time-in-bed extension, variability in sleep–wake timing, and daytime napping.[8] The brief and protocolised nature of sleep restriction therapy, combined with evidence of efficacy as a single component intervention,[9] suggests sleep restriction might be a scalable intervention for deployment in clinical practice.[10] Although previous work shows that sleep restriction can be delivered as part of multicomponent treatment in primary care,[11,12] there is uncertainty around whether it can be delivered by generalists as a single component intervention, whether it leads to long-term improvement in insomnia, and whether it is cost-effective. We did a pragmatic trial in primary care to test whether brief nurse-delivered sleep restriction therapy (alongside sleep hygiene advice) is both clinically effective and cost-effective.

Methods

Study design and participants

The health-professional-administered brief insomnia therapy (HABIT) trial was a pragmatic, superiority, open-label, randomised controlled trial of sleep restriction therapy versus sleep hygiene. Participants meeting The Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 criteria for insomnia disorder were recruited from 35 general practices in the UK National Health Service, across three regions of England (Greater Manchester, Lincolnshire, and Thames Valley). Assessments took place at baseline, 3 months, 6 months, and 12 months after randomisation.

Clinical guidelines recommend that patients should be provided with sleep hygiene advice as part of the management pathway, although there is no evidence that sleep hygiene is effective as a monotherapy. General practitioners (GPs) commonly provide advice on sleep hygiene, but there is little standardisation of such information, either in terms of delivery format or content. Assuming that some participants would have been exposed to such information in the past, and to avoid potential bias, participants in both groups were provided with the same sleep hygiene information. Consistent with the requirements of a pragmatic trial, there were no restrictions on usual care for both groups. In this way, the trial was a comparison of sleep restriction therapy plus sleep hygiene plus treatment as usual versus sleep hygiene plus treatment as usual.

The trial was prospectively registered (ISRCTN42499563) and the trial protocol is published.[13] Changes to the protocol are detailed in the appendix (p 3). The trial received both Health Research Authority

See Online for appendix

approval (IRAS 238138) and ethical approval (Yorkshire and the Humber, Bradford Leeds Research Ethics Committee, 18/YH/0153).

The principal method of recruitment was through practice record search and mailout, and through GP referral. Participants were screened for eligibility over the phone, or through self-completion of an online questionnaire. The inclusion criteria were as follows: participant was willing and able to give informed consent for participation; screened positive for insomnia symptoms on the Sleep Condition Indicator[14] and met DSM-5 criteria[15] for insomnia disorder; had a self-reported sleep efficiency of less than 85% over the past month;[16] was aged 18 years or older; and was 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 were primarily limited to conditions which might be contraindicated for sleep restriction therapy, or render it inappropriate or ineffective: pregnancy or pregnancy planning in the next 6 months; additional sleep disorder diagnosis (eg, restless legs syndrome, obstructive sleep apnoea, or narcolepsy) or positive screen for potential sleep disorder on questionnaire assessment;[17] dementia or mild cognitive impairment; epilepsy, schizophrenia, or bipolar disorder; current suicidal ideation with intent or attempted suicide within past 2 months; currently receiving cancer treatment or planned major surgery during treatment phase; night, evening, early morning, or rotating shift work; currently receiving psychological treatment for insomnia from a health professional or taking part in an online treatment programme for insomnia; life expectancy of less than 2 years; and another person in the household participating in the trial.

Randomisation and masking

Participants were randomly assigned (1:1) to sleep restriction therapy or sleep hygiene using a validated web-based randomisation programme (Sortition) with a non-deterministic minimisation algorithm to ensure recruitment site, use of prescribed sleep promoting medication (yes or no), age (18–65 years or >65 years), sex (female or male), baseline insomnia severity (Insomnia Severity Index[18] score <22 or 22–28), and depression symptom severity (Patient Health Questionnaire 9[19] score <10 or 10–27) were balanced. Appropriate study members at each site had access to the web-based randomisation software to complete randomisation and inform participants of their allocation.

This was an open-label study and therefore both participants and nurses were aware of allocation. The participant information sheet informed participants that the study compared two different sleep intervention programmes to balance expectation of benefit. Treatment providers (nurses) were not involved in the collection of trial outcomes. It was impractical to mask the research team to therapy allocation, but they were not involved in assessing outcomes, which were self-completed. Statisticians were masked to allocation when doing the analysis.

Procedures

After screening, eligible participants were invited to a baseline research appointment where they provided written informed consent, completed baseline questionnaires, and were provided with a sleep diary and actigraphy watch for the following week. Participants subsequently returned the completed diary and actigraphy watch via post and were randomly assigned to treatment groups.

Sleep hygiene was provided to all participants through a booklet comprising standard behavioural guidance in relation to lifestyle and environmental factors associated with sleep and sleeplessness.[20] Participants randomly assigned to the sleep hygiene group were sent their booklet via email or post.

Participants in the intervention group were offered nurse-delivered sleep restriction therapy, a manualised behavioural intervention (a detailed description is shown in the TIDieR[21] checklist, appendix p 83). Primary care nurses received a 4 h training session on sleep, insomnia, and the delivery of sleep restriction therapy. Treatment was delivered over four consecutive weeks, involving one brief session per week (two in-person sessions and two sessions over the phone). Session 1 introduced the rationale for sleep restriction therapy alongside a review of sleep diaries, helped participants to select bed and rise times, advised on management of daytime sleepiness (including implications for driving), and discussed barriers to and facilitators of implementation. Participants were provided with a booklet to read in their own time, which included information on sleep restriction therapy and a list of sleep hygiene guidelines (identical to those provided to the control group). Participants were asked to complete daily diaries and sleep-efficiency calculation grids to support implementation of instructions on sleep restriction therapy and permit weekly review of progress. Session 2, session 3, and session 4 involved reviewing progress, discussion of difficulties with implementation, and titration of the sleep schedule according to a sleep efficiency algorithm.

All in-person sleep-restriction therapy sessions were audio recorded and fidelity was assessed by a clinical psychologist for a subsample of recordings using a bespoke rating scale (range 0–26 for treatment session 1 and 0–16 for session 3, converted to a percentage score).

We assessed whether participants in the control group obtained sleep restriction therapy from the trained nurse in their practice (contamination) using a variant of the Client Service Receipt Inventory.[22] Positive responses were clarified through a structured phone interview.

Outcomes

Outcomes were measured at baseline, 3 months, 6 months, and 12 months after randomisation. Participants were compensated with vouchers at each assessment point. The primary outcome was self-reported insomnia severity assessed by the ISI[18] at 6 months. The ISI is a seven item self-reported measure assessing both night-time and day-time symptoms of insomnia, with scores ranging from 0 to 28; higher scores indicate more severe symptoms. The internal consistency of the measure is high (α >0·90) in both clinical and community samples. To further contextualise treatment effects, we descriptively report the percentage of participants in each group who exhibited a clinically significant treatment response (reduction of ≥8 points on the ISI). Secondary outcomes were health-related quality of life (36-Item Short-Form Health Survey [SF-36][23] physical and mental health component scores), sleep related quality of life (Glasgow Sleep Impact Index [GSII]),[24] depressive symptoms (PHQ-9),[19] work productivity (Work Productivity and Activity Impairment questionnaire [WPAI]),[25] sleep effort (Glasgow Sleep Effort Scale [GSES]),[26] and presleep arousal (Pre-Sleep Arousal Scale [PSAS])[27] at 3 months, 6 months, and 12 months. Sleep medication use, self-reported sleep (Consensus Sleep Diary),[28] and actigraphy-defined sleep (MotionWatch 8; CamNtech, Cambridge, UK) were measured over a 7 day period at 6 months and 12 months. Self-reported sleep parameters were derived from sleep diaries. An experienced scorer, masked to treatment allocation, used event markers and sleep diaries to define the analysis window for actigraphy, and sleep variables were calculated by the inbuilt algorithm of the MotionWare software (version 1.2.47). The following sleep parameters were derived from sleep diaries and actigraphy recordings: sleep onset latency; wake time after sleep onset; sleep efficiency; total sleep time; and sleep quality (diary only).

Use of hypnotics and sleep-promoting medication was quantified from diaries at 6 months and 12 months, from which we calculated the proportion of nights of use per participant and the proportion of participants that used medication at least once in the 7 day reporting period.

Intervention records captured resources to train nurses in sleep restriction therapy and for nurses to deliver sleep restriction therapy sessions (appendix p 37). CSRI[22] captured health service use for insomnia provided by the NHS at each timepoint, and any out-of-pocket spending. Health-related quality of life was captured by the EuroQol Questionnaire (EQ-5D-3L),[29] EQ-5D-3L plus sleep bolt on,[30] and SF-36 (from which the SF-6D was derived)[31] at each timepoint, and was used to calculate quality-adjusted life years (QALYs). WPAI[25] was used to capture productivity loss (reduced productivity at work and absenteeism caused by insomnia; appendix p 39).

Adverse events of interest were incidences of falls, accidents (road-traffic accidents and work-related injuries), near-miss driving incidents, and falling asleep while driving, collected using a bespoke questionnaire at baseline, 3 months, 6 months, and 12 months after randomisation.

We also collected data on serious adverse events from randomisation until the 6-month follow-up point (or at withdrawal), through reporting from general practices, participants, and responses on the CSRI.

Statistical analysis

It was estimated that 235 participants would be required in each group to detect a group difference of 1·35 points (SD 4·5; effect size 0·3) on the ISI with a power of 90% at a 5% level of significance (two-sided t test). Accounting for 20% attrition, we aimed to recruit 588 participants (294 per group). During the trial, attrition was initially higher than expected, and therefore we made a protocol amendment to increase the sample size. Attrition was estimated to be around 25% and therefore our revised target sample size was 628 participants (314 per group).

A statistical analysis plan was prepared and finalised before data collection was complete (appendix p 40). The primary analysis population included all eligible randomly assigned participants who had at least one outcome measurement. Participants who withdrew from the trial were included in the analysis until the point they withdrew. Participants were analysed according to their allocated treatment group irrespective of what treatment they actually received.

For the primary outcome, a three-level linear mixed-effect model was fitted to the ISI score assessed at 3 months, 6 months, and 12 months. Practice and participant were included as random effects. The model specified an unstructured variance–covariance structure for the random effects. Fixed effects were randomised group, minimisation factors (baseline ISI score, site, age, prescribed sleep medication, sex, and baseline PHQ-9 score), time, and a time by randomised group interaction term to allow estimation of the treatment effect at each timepoint. The estimated difference between groups at 6 months was extracted from the model by means of a linear contrast statement.

Continuous secondary outcomes were analysed using the same method. Secondary outcomes that were binary were analysed using generalised linear mixed-effect models with appropriate link function. Mann-Whitney tests were used for secondary outcomes that violated model assumptions. Serious adverse events were analysed on the basis of the number of participants who actually received the intervention and Fisher's exact test was used to compare sleep restriction therapy and sleep hygiene. For continuous outcomes, standardised effect sizes (Cohen's *d*) were calculated as the adjusted treatment effect divided by the pooled standard deviation for the entire sample at baseline.

Prespecified sensitivity analyses examined the robustness of primary outcome results to different assumptions regarding missing data. This process

involved adjusting for baseline covariates found to be predictive of missingness, using a pattern mixture model to examine the robustness of the missing-at-random assumption, and an analysis that assumed plausible group-specific differences between participants who had outcomes and those that did not.[32] Multiple imputation of the primary outcome analysis was also done as a post-hoc sensitivity analysis. Sleep might have been affected by the lockdown and COVID-19 pandemic so we did a sensitivity analysis on the primary outcome to examine differences in treatment effect before the pandemic (before March 23, 2020) compared with during the pandemic (inclusive of and after March 23, 2020, the date of the national lockdown in the UK).

A complier-average causal effect (CACE) analysis of the primary outcome was carried out to determine the impact of compliance with the allocated intervention on the treatment effect. Compliance was defined as attending at least one treatment session. CACE models were estimated using an instrumental variable approach in which the outcome was total ISI score at 6 months adjusted for baseline ISI. Models were fitted adjusting for baseline characteristics that appeared to be associated with compliance. Sensitivity analyses were done adjusting the definition of compliance to attending at least two, three, or four sessions, and multiple imputation was done on the primary CACE analysis as a sensitivity analysis to assess the effect of missing data.

We did a prespecified subgroup analysis of the primary outcome by baseline actigraphy-defined sleep duration (<6 h *vs* ≥6 h), prescribed sleep medication use (yes or no), depression severity (PHQ-9 <10 *vs* ≥10), age (18–65 *vs* >65), level of deprivation (index of multiple deprivation, national quartiles 1 and 2 *vs* 3 and 4), and chronotype (intermediate *vs* morning *vs* evening chronotype assessed with the Morningness Eveningness Questionnaire, reduced version).[33] We added a three-way interaction term between randomised group, assessment timepoint, and a subgroup indicator variable to allow the treatment effect to be estimated at each timepoint and in each level of the subgroups.

In mediation analyses, using the Baron and Kenny[34] approach adapted for linear mixed-effect models, we assessed whether sleep effort (GSES) and presleep arousal (PSAS) measured at 3 months mediated the 6 month ISI outcome. All models included baseline assessments of the mediator and ISI as covariates.

A within-trial economic evaluation was done to estimate the incremental cost-effectiveness of sleep restriction therapy over sleep hygiene. Analyses were prespecified in a health economic analysis plan (appendix p 73). We did a cost–utility analysis from the NICE-recommended NHS and personal social services (PSS) perspective[35] and expressed in terms of incremental cost per QALY gained. Staff inputs associated with the training for and delivery of sleep restriction therapy were prospectively measured and valued using national reference values (appendix p 85). Resource-use questionnaires completed at each follow-up timepoint provided a profile of broader resource use, which was valued using data from national cost compendia (the Personal and Social Services Research Unit,[36] NHS reference costs,[37] and the NHS Prescription Cost Analysis Database).[38] Costs were valued at 2018–19 prices and expressed in pounds sterling. QALYs

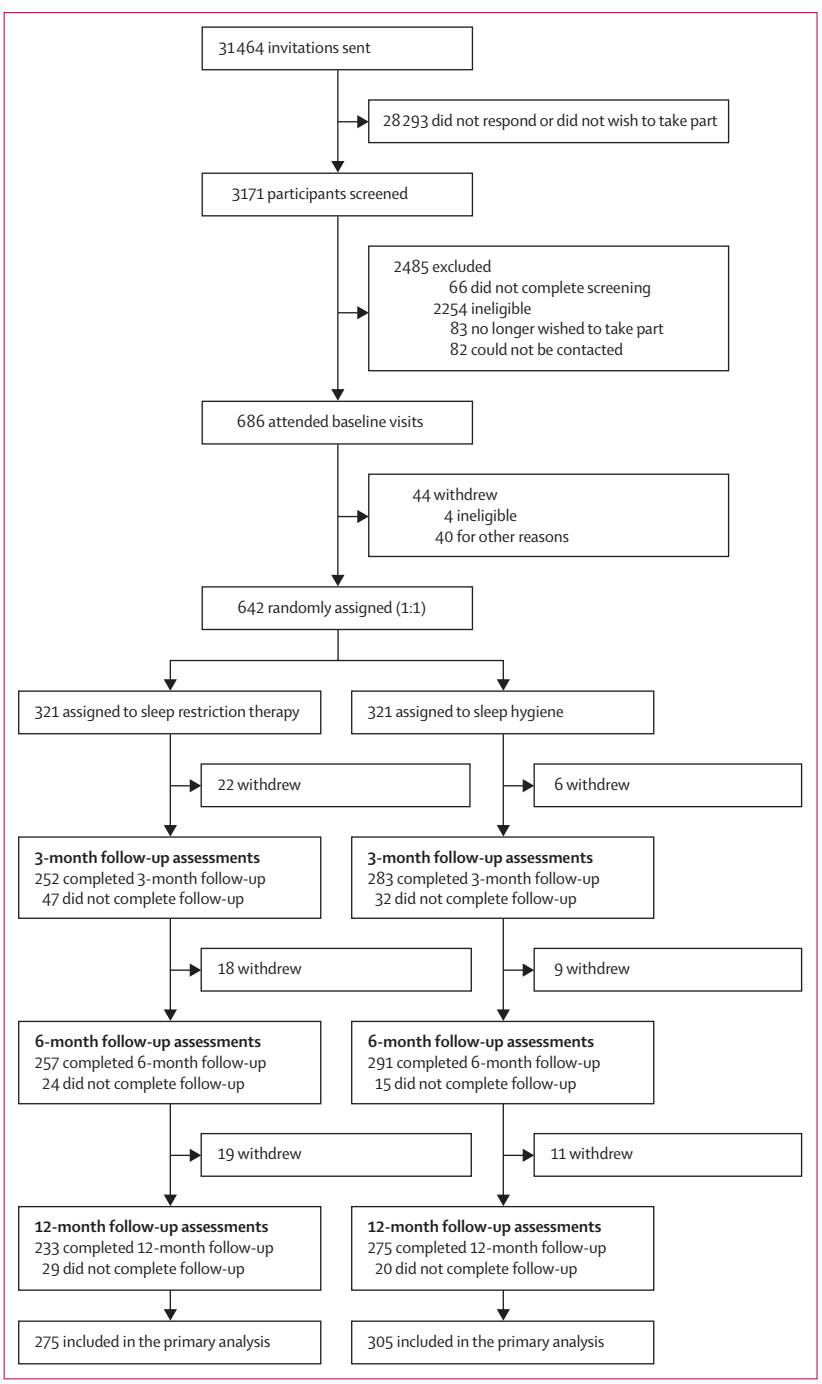

Figure 1: **Trial profile**

	SRT (n=321)	Sleep hygiene (n=321)	Overall (n=642)
Region			
Thames Valley	156 (48·6%)	156 (48·6%)	312 (48·6%)
Greater Manchester	109 (34·0%)	111 (34·6%)	220 (34·3%)
Lincolnshire	56 (17·4%)	54 (16·8%)	110 (17·1%)
Age	55·7 (15·3)	55·2 (16·5)	55·4 (15·9)
Sex			
Female	245 (76·3%)	244 (76·0%)	489 (76·2%)
Male	76 (23·7%)	77 (24·0%)	153 (23·8%)
Ethnicity			
White	312 (97·2%)	312 (97·2%)	624 (97·2%)
Asian or Asian British	3 (0·9%)	6 (1·9%)	9 (1·4%)
Black, African, Caribbean, or Black British	1 (0·3%)	1 (0·3%)	2 (0·3%)
Mixed or multiple ethnic groups	2 (0·6%)	1 (0·3%)	3 (0·5%)
Other ethnic group	2 (0·6%)	1 (0·3%)	3 (0·5%)
Prefer not to say	1 (0·3%)	0 (0)	1 (0·2%)
Education level			
None	16 (5·0%)	22 (6·9%)	38 (5·9%)
GCSE or equivalent	82 (25·5%)	70 (21·8%)	152 (23·7%)
A-levels or equivalent	50 (15·6%)	76 (23·7%)	126 (19·6%)
University undergraduate	80 (24·9%)	65 (20·2%)	145 (22·6%)
University postgraduate	90 (28·0%)	85 (26·5%)	175 (27·3%)
Choose not to say	3 (0·9%)	3 (0·9%)	6 (0·9%)
Marital status			
Single	48 (15·0%)	54 (16·8%)	102 (15·9%)
Married or in a domestic partnership	220 (68·5%)	195 (60·7%)	415 (64·6%)
Divorced	21 (6·5%)	37 (11·5%)	58 (9·0%)
Widowed	24 (7·5%)	22 (6·9%)	46 (7·2%)
Separated	7 (2·2%)	10 (3·1%)	17 (2·6%)
Prefer not to say	1 (0·3%)	3 (0·9%)	4 (0·6%)
Index of multiple deprivation score (quintiles)			
1 (most deprived)	10 (3·1%)	8 (2·5%)	18 (2·8%)
2	30 (9·3%)	36 (11·2%)	66 (10·3%)
3	52 (16·2%)	35 (10·9%)	87 (13·6%)
4	82 (25·5%)	93 (29·0%)	175 (27·3%)
5 (least deprived)	144 (44·9%)	146 (45·5%)	290 (45·2%)
Missing	3 (0·9%)	3 (0·9%)	6 (0·9%)
BMI	26·7 (5·5)	26·3 (5·3)	26·5 (5·4)
Missing	18 (5·6%)	35 (10·9%)	53 (8·3%)
Duration of insomnia (years)	10·0 (4·8–20·0)	10·0 (4·2–20·0)	10·0 (4·5–20·0)
Consulted for insomnia	249 (77·6%)	237 (73·8%)	486 (75·7%)
Patient currently taking prescribed sleep medication	83 (25·9%)	80 (24·9%)	163 (25·4%)
Number of medical conditions			
None	38 (11·8%)	34 (10·6%)	72 (11·2%)
One	60 (18·7%)	52 (16·2%)	112 (17·4%)
Two	73 (22·7%)	60 (18·7%)	133 (20·7%)
Three or more	150 (46·7%)	175 (54·5%)	325 (50·6%)
Insomnia severity			
ISI score	17·7 (4·0)	17·4 (4·2)	17·5 (4·1)
Depressive symptoms			
PHQ9 score	10·4 (5·3)	10·1 (5·3)	10·2 (5·3)
PHQ9 score ≥10	159 (49·5%)	157 (48·9%)	316 (49·2%)

(Table 1 continues on next page)

were calculated using the area under the baseline-adjusted utility curve of EQ-5D-3L utility scores across the baseline, 3 month, 6 month, and 12 month intervals, using the trapezoid rule[39] (base case analysis). The time horizon for cost and QALY estimation was 12 months, and therefore no discounting was applied.

Parametric *t* tests (bootstrapped 95% CIs, 1000 resamples) compared mean costs, EQ-5D-3L values, and QALYs by treatment group at each assessment point. Chained equations and predictive mean matching (with *k* nearest neighbour=8) were applied for full conditional multiple imputation regressing on baseline covariates (ISI score, site, age, prescribed sleep medication, sex, baseline PHQ-9 score, EQ-5D-3L utility score, and NHS costs). Imputation was done for the key cost categories and utility values for all timepoints in the two trial groups. A total of 50 imputed samples were generated for the base case analysis, which were subsequently combined using Rubin's rule.[40]

Bivariate regression using seemingly unrelated regression was used to estimate incremental NHS and PSS costs and incremental QALYs between sleep restriction therapy and sleep hygiene, controlling for baseline covariates (ISI score, site, age, prescribed sleep medication, sex, and baseline PHQ-9 score, and either baseline EQ-5D-3L utility scores, for incremental QALYs, or baseline NHS and PSS costs, for incremental costs). The mean estimate of the incremental cost-effectiveness ratio (ICER) was calculated by dividing incremental costs by incremental QALYs.

Non-parametric bootstrapping was used to quantify uncertainty surrounding the mean ICER estimate by resampling 1000 times from incremental costs and incremental QALYs obtained from the seemingly unrelated regression. The outputs were displayed graphically on a cost-effectiveness plane. Net monetary benefits were estimated from the incremental costs and incremental QALYs at alternative cost-effectiveness thresholds of £15 000, £20 000, and £30 000 per QALY gained to reflect the overall resource gain or loss associated with sleep restriction therapy. By calculating net monetary benefits for each of these 1000 simulated ICER values at alternative levels of the cost-effectiveness threshold, the probability of cost-effectiveness of sleep restriction therapy (defined as the proportion of positive net monetary benefits at a given threshold level) was calculated and plotted as a cost-effectiveness acceptability curve.

We did the following sensitivity analyses: adopting a societal perspective, incorporating out-of-pocket health-care costs and productivity loss because of insomnia; complete case analysis without data imputation; and adjusting the nurse training cost for sleep restriction therapy. Secondary analyses were done using QALYs derived from either EQ-5D-3L+sleep 'bolt-on' or SF-6D utility values.

All analyses were conducted using Stata (version 16.1). All tests and reported p-values were two-sided.

Role of the funding source
The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

We recruited participants from 35 practices across England between Aug 29, 2018, and March 23, 2020. Of 3171 participants that were screened for inclusion, 642 were randomly assigned (321 to intervention and 321 to control; figure 1). The main reasons for exclusion were not meeting insomnia criteria, shift work, and suspected sleep disorder other than insomnia (appendix p 86).

Baseline characteristics were similar between the two groups (table 1). Mean age was 55·4 years (range 19–88), with 489 (76·2%) participants being female and 153 (23·8%) being male, 624 (97·2%) from a White ethnic background, and 320 (49·8%) had a university degree. Mean baseline ISI score was 17·5 (SD 4·1) and within the clinical range, median duration of insomnia was 10 years (IQR 4·5–20·0), 486 (76%) participants had previously consulted their doctor for insomnia, and 163 (25%) reported current use of prescribed sleep medication (table 1).

458 (71%) participants had two or more comorbid conditions (table 1), 265 (41%) experienced mental health problems (appendix p 87), and 316 (49%) scored above the threshold for depression on the PHQ9 (score ≥10; table 1).

Sleep restriction therapy sessions were provided by 40 nurses (31 practice nurses and nine research nurses). 266 (92·2%) participants attended at least one treatment session, 250 (77·9%) attended at least two sessions, 219 (68·2%) attended at least three sessions, and 207 (64·5%) attended all four sessions. Mean total therapy duration for those completing all four sessions was 85·5 min (SD 24·6). The most common reasons for withdrawing from treatment were finding implementation of sleep restriction therapy challenging, not finding sleep restriction therapy useful, and personal circumstances (appendix p 88). Fidelity ratings were high for sampled audio recordings (session 1, n=53, median percentage score 100%, IQR 96–100; and session 3, n=26, median percentage score 87·5%, 75–100). No participant in the sleep hygiene group met the criteria for contamination at 3 months or 6 months.

580 (90·3%) participants (305 [95·0%] in the sleep hygiene group and 275 [85·7%] in the sleep restriction therapy group) provided data at a minimum of one follow-up timepoint and were analysed to assess the primary outcome (figure 1; reasons for withdrawal from the trial are shown in the appendix p 89). 6 months after randomisation, 548 (85·3%) participants provided data on the primary outcome (ISI), with a significantly higher number who completed the outcome in the sleep hygiene group (291 [90·6%]) versus the sleep restriction therapy group (257 [80·1%]; p<0·0001; appendix p 90).

The estimated adjusted mean difference on the ISI at 6 months was −3·05 (95% CI −3·83 to −2·28; p<0·0001; Cohen's *d* −0·74), indicating that participants in the sleep restriction therapy group reported lower insomnia severity (table 2). Treatment effects were also evident at 3 months and 12 months. Group differences were reflected in the number of participants showing a treatment response (ISI reduction ≥8 points). At 6 months, 108 (42·0%) of 257 participants in the sleep restriction therapy group met the criteria for a clinically significant treatment response, whereas 49 (16·8%) of 291 in the sleep hygiene group met the criteria.

Sensitivity analysis of the impact of missing data, including differential attrition, showed that the treatment effect was similar when adjusting for baseline predictors

	SRT (n=321)	Sleep hygiene (n=321)	Overall (n=642)
(Continued from previous page)			
Health-related quality of life			
SF36 PCS	46·9 (10·9)	47·3 (10·2)	47·1 (10·5)
SF36 MCS	39·8 (12·0)	39·3 (11·9)	39·6 (11·9)
Sleep-related quality of life			
GSII rank 1	17·9 (17·4)	20·7 (18·1)	19·3 (17·8)
GSII rank 2	27·5 (17·7)	31·0 (20·7)	29·2 (19·3)
GSII rank 3	40·4 (22·0)	40·4 (21·5)	40·4 (21·7)
Work productivity			
WPAI absenteeism*	5·9 (16·9)	7·5 (21·6)	6·6 (19·2)
WPAI presenteeism*	44·2 (22·1)	43·3 (22·5)	43·8 (22·2)
WPAI work productivity loss*	45·9 (22·9)	44·8 (23·2)	45·4 (23·0)
WPAI activity impairment	53·2 (23·5)	51·8 (23·4)	52·5 (23·5)
Sleep diary			
SOL (minutes)	45·0 (36·8)	47·4 (39·5)	46·2 (38·2)
WASO (minutes)	104·1 (62·9)	104·7 (60·6)	104·4 (61·7)
Sleep efficiency (%)	65·3% (13·1)	64·5% (13·6)	64·9% (13·4)
TST (minutes)	351·1 (73·7)	346·7 (75·6)	348·9 (74·6)
Sleep quality	2·6 (0·6)	2·5 (0·6)	2·5 (0·6)
Actigraphy			
SOL (minutes)	12·5 (15·0)	12·1 (12·7)	12·3 (13·9)
WASO (minutes)	73·8 (35·1)	72·5 (28·7)	73·1 (32·0)
Sleep efficiency (%)	80·7% (7·3)	80·8% (6·5)	80·8% (6·9)
TST (minutes)	436·4 (60·0)	437·4 (52·5)	436·9 (56·3)
Sleep effort			
GSES	8·0 (2·9)	7·8 (3·0)	7·9 (2·9)
Pre-sleep arousal			
PSAS cognitive	25·4 (6·7)	25·1 (6·5)	25·3 (6·6)
PSAS somatic	14·3 (6·4)	14·4 (6·2)	14·3 (6·3)

Data are presented as n (%), median (IQR), or mean (SD). For GSII, ranks 1–3 reflect the three most important patient-generated life domains affected by poor sleep. GSES=Glasgow Sleep Effort Scale. GSII=Glasgow Sleep Impact Index. ISI=Insomnia Severity Index. PHQ-9=Patient Health Questionnaire. PSAS=Pre-Sleep Arousal Scale. SRT=sleep restriction therapy. SOL=sleep-onset latency. SF-36 PCS=Short-Form Health Survey, Physical Component Summary. SF-36 MCS=Short-Form Health Survey, Mental Component Summary. TST=total sleep time. WASO=wake-time after sleep onset. WPAI=Work Productivity and Activity Impairment questionnaire. *Completed by people in employment.

Table 1: **Participant baseline characteristics**

	SRT		Sleep hygiene		Adjusted treatment difference (95% CI)*	P value†	Cohen's d‡
	Mean (SD)	Number	Mean (SD)	Number			
Primary analysis							
Insomnia Severity Index§							
3 months	10·9 (5·47)	252	14·8 (5·11)	283	−3·88 (−4·66 to −3·10)	<0·0001	−0·95
6 months¶	10·9 (5·51)	257	13·9 (5·23)	291	−3·05 (−3·83 to −2·28)	<0·0001	−0·74
12 months	10·4 (5·89)	233	13·5 (5·52)	275	−2·96 (−3·75 to −2·16)	<0·0001	−0·72
Secondary outcomes							
SF-36 PCS§							
3 months	48·4 (10·78)	244	46·1 (10·80)	285	1·87 (0·76 to 2·98)	0·0001	0·18
6 months	48·1 (10·90)	233	47·2 (10·28)	280	0·77 (−0·35 to 1·89)	0·18	0·07
12 months	48·6 (10·26)	224	47·4 (10·47)	265	0·94 (−0·20 to 2·09)	0·11	0·09
SF-36 MCS§							
3 months	44·6 (11·27)	244	41·2 (11·79)	285	2·80 (1·37 to 4·23)	<0·0001	0·24
6 months	44·7 (11·88)	233	42·2 (11·79)	280	1·97 (0·52 to 3·43)	0·0078	0·17
12 months	44·7 (11·29)	224	42·3 (11·29)	265	2·01 (0·53 to 3·49)	0·0077	0·17
GSII rank 1§							
3 months	48·2 (28·39)	246	35·4 (21·63)	282	12·82 (8·71 to 16·93)	<0·0001	0·72
6 months	50·6 (28·00)	235	37·7 (23·42)	278	12·80 (8·63 to 16·96)	<0·0001	0·72
12 months	52·1 (29·42)	224	40·3 (24·79)	266	11·77 (7·54 to 16·00)	<0·0001	0·66
GSII rank 2§							
3 months	51·5 (26·78)	246	38·6 (22·23)	283	12·78 (8·79 to 16·77)	<0·0001	0·66
6 months	53·2 (27·74)	234	40·7 (23·66)	279	12·45 (8·40 to 16·49)	<0·0001	0·65
12 months	54·9 (28·63)	224	41·5 (24·55)	266	13·72 (9·60 to 17·84)	<0·0001	0·71
GSII rank 3§							
3 months	51·6 (27·01)	246	41·1 (23·14)	283	10·06 (6·02 to 14·10)	<0·0001	0·46
6 months	54·2 (27·11)	232	43·0 (23·90)	279	10·93 (6·82 to 15·03)	<0·0001	0·50
12 months	57·1 (28·97)	224	45·1 (24·11)	266	11·70 (7·53 to 15·87)	<0·0001	0·54
PHQ-9§							
3 months	7·2 (5·72)	244	9·1 (5·62)	284	−1·86 (−2·56 to −1·16)	<0·0001	−0·35
6 months	7·2 (5·77)	234	8·8 (5·75)	278	−1·60 (−2·31 to −0·90)	<0·0001	−0·30
12 months	7·0 (5·82)	224	8·6 (5·51)	264	−1·61 (−2·32 to −0·89)	<0·0001	−0·30
Percent absenteeism‖							
3 months	..	111	..	117	..	0·095	..
Score of 0	97 (87%)	..	94 (80%)	..	..	..	..
Median (IQR)**	5·6 (4·1–7·1)	..	21·1 (8·1–33·3)	..	..	..	..
6 months	..	101	..	113	..	0·014	..
Score of 0	94 (93%)	..	92 (81%)	..	..	..	..
Median (IQR)**	16·7 (5–100)	..	15·4 (6·7–20·4)	..	..	..	..
12 months	..	100	..	111	..	0·0049	..
Score of 0	95 (95%)	..	91 (82%)	..	..	..	..
Median (IQR)**	20·0 (18·9–100·0)	..	17·4 (10·5–45·0)	..	..	..	..
Percent presenteeism§							
3 months	29·6 (23·66)	111	41·4 (21·91)	113	−10·56 (−16·25 to −4·87)	0·0003	−0·48
6 months	24·6 (22·01)	99	34·5 (23·38)	111	−10·69 (−16·56 to −4·81)	0·0004	−0·48
12 months	22·4 (22·62)	98	33·8 (24·37)	107	−11·76 (−17·73 to −5·79)	0·0001	−0·53
Work productivity loss§							
3 months	30·6 (24·71)	111	42·7 (22·93)	113	−10·90 (−16·80 to −5·01)	0·0003	−0·47
6 months	25·0 (22·39)	99	35·9 (24·71)	111	−11·96 (−18·04 to −5·87)	0·0001	−0·52
12 months	22·7 (22·98)	98	35·1 (25·34)	107	−12·96 (−19·14 to −6·77)	<0·0001	−0·56

(Table 2 continues on next page)

	SRT		Sleep hygiene		Adjusted treatment difference (95% CI)*	p value†	Cohen's d‡
	Mean (SD)	Number	Mean (SD)	Number			
(Continued from previous page)							
Activity impairment§							
3 months	33·5 (25·07)	247	46·7 (23·37)	285	−13·23 (−16·79 to −9·68)	<0·0001	−0·56
6 months	31·0 (25·05)	234	42·9 (24·03)	280	−11·99 (−15·60 to −8·38)	<0·0001	−0·51
12 months	31·0 (26·44)	222	40·1 (24·42)	267	−9·11 (−12·80 to −5·43)	<0·0001	−0·39

GSII=Glasgow Sleep Impact Index. SF-36=Short-Form Health Survey. SRT=sleep-restriction therapy. *SRT versus sleep hygiene. †p=0·05. ‡Cohen's d defined as the adjusted treatment effect divided by the sample SD at baseline. §Linear mixed-effects model with an unstructured variance-covariance structure for the random effects, modelled against randomised group, with outcome score at baseline, minimisation factors (baseline ISI score, site, age, use of prescribed sleep promoting medication, sex, and baseline PHQ-9 score), assessment timepoint, and an interaction between randomised group and assessment timepoint as fixed effects, GP practice as a random effect, and a random intercept for each participant. ¶Primary outcome. ||Mann-Whitney U test. **Median (IQR) based on non-zero.

Table 2: **Adjusted treatment effects for primary and secondary outcomes**

of missing outcome data, following multiple imputation of missing outcome data, when assuming plausible differences between participants who had outcome data and those who did not, and following pattern mixture modelling (figure 2; appendix pp 95–98). There was no evidence that treatment effects differed before versus during the pandemic (appendix p 99). CACE analyses adjusting for baseline predictors of compliance showed that attending more treatment sessions was associated with a greater treatment effect (appendix pp 100–102).

At 6 months, the sleep restriction therapy group reported better mental health-related quality of life (SF-36 MCS), better sleep-related quality of life (GSII), lower depressive symptoms (PHQ-9), and lower activity impairment (WPAI) than the sleep hygiene group (table 2). Group effects on these measures were observed at all follow-up timepoints. For employed participants, those in the sleep restriction therapy group reported less absenteeism (6 months and 12 months), less presenteeism (3 months, 6 months, and 12 months), and less work productivity loss (WPAI; 3 months, 6 months, and 12 months). Physical health-related quality of life (SF36 PCS) was higher for the sleep restriction therapy group at 3 months, but there was no evidence of group difference at 6 months or 12 months.

Data completion for sleep diaries and actigraphy at 6 months and 12 months was low (≤41%), primarily because diaries and actigraphs were not sent out during the COVID-19 pandemic. All sleep diary metrics were improved versus the control group at 6 months (appendix p 103), and these effects were largely maintained at 12 months (except for sleep-onset latency). At 6 months, actigraphy-defined sleep efficiency and wake time after sleep onset were improved, whereas total sleep time was reduced in the sleep restriction therapy group compared with the sleep hygiene group. The only group difference at 12 months was a small reduction in total sleep time for sleep restriction therapy versus control. There was no evidence of group differences for use of prescribed sleep medication at 6 months or 12 months (appendix p 103).

Our proposed mediators of interest, sleep effort and presleep arousal, were reduced at all timepoints in the sleep restriction therapy group versus control (appendix p 104). In mediation analyses, we found that reduction in sleep effort and presleep cognitive and somatic arousal at 3 months significantly mediated the treatment effect (14·5–35·5% of the total effect) on the ISI at 6 months (appendix p 103).

In exploratory analyses of the primary outcome at 6 months, we found no significant subgroup differences for baseline measures of actigraphy-defined sleep duration, chronotype, depression severity, age, sleep medication use, or level of deprivation (appendix p 105).

There was no evidence of differences in the occurrence of predefined adverse events at any timepoint (appendix p 106). Eight participants in each group had serious adverse events; none were judged to be related to the intervention (appendix p 106).

The mean cost of delivering sleep restriction therapy was £52·60 per participant. The mean training cost per participant for sleep restriction therapy was £31·70 (appendix p 107). Patterning of missing health economic data is detailed in appendix pp 108–110, and appendix p 111 summarises mean health resource utilisation by category and group. For participants with complete service-use data over 12 months, mean insomnia-related NHS and PSS costs and EQ-5D-3L utilities and QALYs were similar between groups (appendix p 113).

The base case analysis, using multiple imputed data, covariate adjustment, and done from an NHS and PSS perspective, generated incremental costs of £43·59 (95% CI −18·41 to 105·59) and incremental QALYs of 0·021 (95% CI 0·0002 to 0·042) associated with sleep restriction therapy relative to sleep hygiene (appendix pp 116–117). These findings resulted in a mean ICER of £2075·71 per QALY gained. The probability that sleep restriction therapy is cost-effective at the NICE cost-effectiveness threshold of £20 000 per QALY was 95·3%, with a mean net monetary benefit of £377·84 (appendix pp 116–117). The cost-effectiveness plane displays graphically the uncertainty

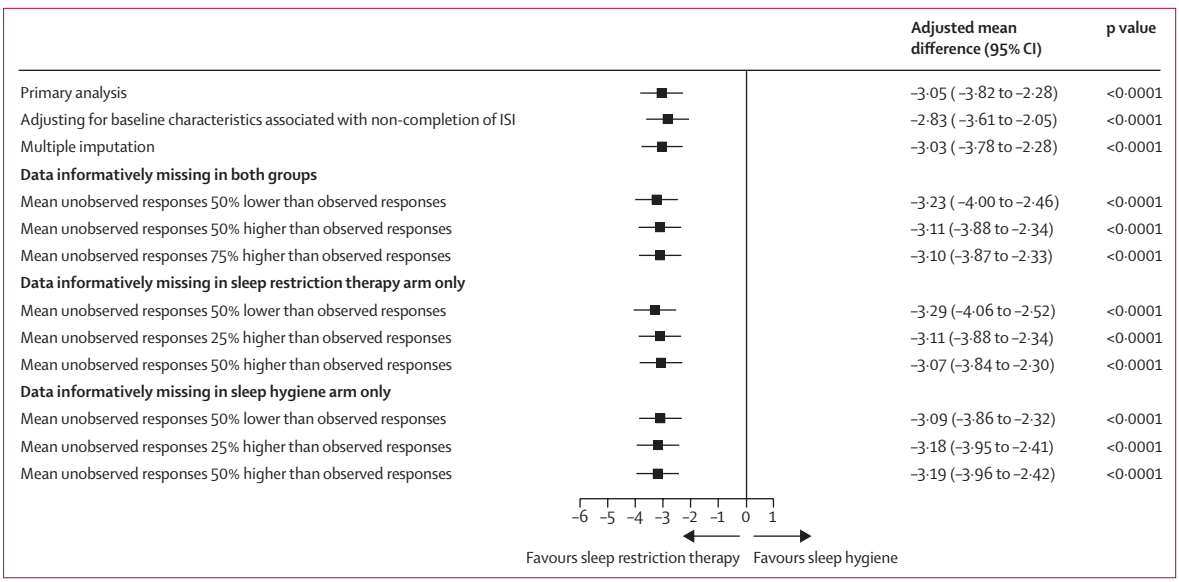

Figure 2: **Sensitivity analyses for the primary outcome (ISI)**
Treatment effects are displayed first for the primary analysis, second after adjusting for baseline variables associated with missing data, third for multiple imputation of missing data, and fourth assuming plausible group-specific differences between participants who had outcome data and those who did not (appendix pp 91–98).

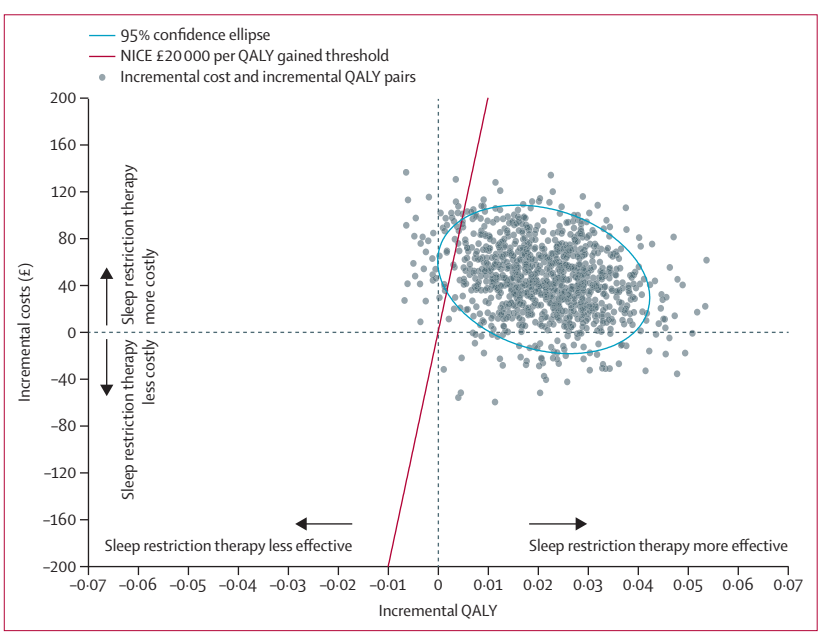

Figure 3: **Cost-effectiveness plane representing bootstrapped mean differences in costs and QALYs for sleep restriction therapy compared with sleep hygiene**
QALY=quality-adjusted life year.

surrounding the mean ICER estimate (figure 3), whereas the cost-effectiveness acceptability curve summarises the effects of uncertainty surrounding the value of the cost-effectiveness threshold (appendix p 118). All sensitivity analyses and secondary analyses confirmed the robustness of the result that sleep restriction therapy is likely to be cost effective at a cost-effectiveness threshold of £20 000 per QALY (appendix pp 116–123).

Discussion

A low-intensity sleep intervention delivered by generalist nurses in primary care improved outcomes relative to usual care in people with insomnia disorder. We found medium-to-large and sustained treatment effects for reduction in insomnia severity. There was strong evidence of commensurate improvements in depressive symptoms and mental health-related quality of life, but less evidence of an effect on physical health-related quality of life. Work-related productivity and general activity impairment, self-reported sleep, and sleep-related quality of life were also improved at all timepoints. Improvements in actigraphy-defined sleep were apparent at 6 months but not at 12 months, and there was no evidence of an effect on hypnotic or sleep-promoting medication use. The incremental cost per QALY gained was £2076, giving a 95·3% probability that sleep restriction therapy is cost-effective at a cost-effectiveness threshold of £20 000 per QALY gained. There was no evidence of subgroup differences in treatment effect or that sleep restriction therapy increased adverse events, and the treatment effect was mediated, in part, by plausible mechanisms (reduction in sleep effort and presleep arousal).

The main strength of our study was the comprehensive assessment of the benefits and potential harms of an abbreviated and simplified form of CBT for insomnia delivered in routine primary care. To our knowledge, HABIT is the largest pragmatic clinical trial of psychological therapy for insomnia to date. Our findings create a new pathway for the treatment of insomnia disorder, an area where current practice is deficient and guideline-recommended treatment is rare.[4,5] There were,

however, limitations to our study. Although retention was good at 6 months (85%), and exceeded other primary care-based evaluations,[12] participants in the treatment group were less likely to complete the primary outcome, which has the potential to introduce bias in the treatment estimate if participants who do not have data had worse outcomes. We attribute this difference to greater demands placed on participants in the intervention group relative to sleep hygiene, and because some participants did not derive benefit from sleep restriction (although a high proportion of participants [56/62] who withdrew from the intervention continued to provide outcome data). Importantly, multiple sensitivity analyses confirmed the robustness of the conclusion for the primary outcome, even under conservative assumptions (models assuming high score differences between participants with a missing and non-missing ISI outcome). The pandemic affected collection of data for sleep diary parameters, medication use, and actigraphy-defined sleep; these analyses should be interpreted with caution. Our sample reflects the clinical reality of insomnia insofar as most participants were female, had insomnia for a long time, and had a range of comorbid conditions. Nonetheless, our results might not be generalisable to the entire UK insomnia population because participants tended to be well educated (50% had a university degree), were more likely to be from a White ethnic background (97%), and lived in areas with low levels of deprivation. There was no evidence that the treatment effect differed by socioeconomic circumstances, but these analyses did not have the power to detect such moderation. Treatment engagement was generally good, and higher than or consistent with other pragmatic trials in primary care,[11,41] but 35 (11%) participants withdrew because they did not derive benefit or found the intervention too difficult to implement. Although effective, sleep restriction therapy is known to be a challenging treatment.[42] Future studies should test strategies designed to improve treatment engagement and adherence. We excluded people with comorbidities that could potentially be aggravated by restricted time in bed. Our results, therefore, cannot be generalised to these populations, who might require an adapted version of sleep restriction therapy.

To our knowledge, this is the first large-scale trial of sleep restriction therapy for insomnia disorder. Previous trials were mainly done in research settings and recruited small samples of patients who were free from comorbidities and who were not taking medications, and with short-term follow-up periods.[9] Direct comparisons, therefore, are difficult; however, magnitude of treatment effects on the ISI exceed clinical significance thresholds used to appraise insomnia treatments.[43] Effect sizes were greater than those observed in trials assessing diverse forms of CBT delivered in primary care or community settings[12] and trials assessing the long-term effects of CBT.[44] Whether brief sleep restriction therapy delivered by non-specialists is non-inferior to multicomponent CBT could be tested in future work. For important secondary outcomes of health-related quality of life and daytime functioning, effect sizes tended to be in the small-to-medium range, consistent with a meta-analysis of CBT for insomnia.[45] We did not specifically recruit a sample of people with depression, or target depression during treatment, but effect sizes for depressive symptoms were similar to a meta-analysis of the effect of CBT for depression in primary care (individual, group, and guided self-help formats).[46]

Our results have implications for practice. We have shown that a nurse-delivered programme that makes moderate demands on nursing time can be effective in routine primary care. Nurse-delivered treatment could feature as part of a stepped-care management approach to insomnia and complement initiatives to increase access to digital therapies. Future implementation-focused research is needed to investigate facilitators and barriers to adopting sleep restriction therapy (including practice nurse capacity), and the assessment and referral pathway. The brief training and delivery model might also be suitable for other non-specialists in primary care, and could potentially be incorporated into the Improving Access to Psychological Therapies programme in England, given the high level of comorbidity between mental health problems and insomnia.

In conclusion, brief primary care nurse-delivered sleep restriction therapy is effective in treating insomnia disorder and improving other aspects of mental health and functioning. It is likely to be cost-effective and provides a practicable approach for clinicians wanting to follow guidelines for patients with insomnia disorder.

Contributors

SDK was Chief Investigator, developed the original idea for the study and funding application with coinvestigators, oversaw the delivery of the trial, led the intervention design, training, and delivery, and led the writing of the manuscript. PB, PA, L-MY, ANS, CAE, and EO were coinvestigators on the funding application, designed the study, and contributed to the writing of the manuscript. L-MY led the statistical analysis and supervised trial statisticians ET, VH, and SM. YY led and did the health economic evaluation under the supervision of SP, and both YY and SP contributed to the writing of the manuscript. NB was the trial manager, contributed to data collection, and commented on the manuscript. LFM contributed to data collection, led the actigraphy analysis, and commented on the manuscript. BR, CG, JP, SA, and VL contributed to data collection and commented on the manuscript. All authors provided feedback on the manuscript, approved the final manuscript for submission, and are accountable for the accuracy and integrity of the manuscript. All authors had full access rights to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

CAE declares being cofounder of and shareholder in Big Health, outside the submitted work. LFM declares consultancy fees from Mementor DE, outside the submitted work. SDK declares non-financial support from Big Health in the form of no cost access to the digital sleep improvement programme, Sleepio, for use in clinical research, outside the submitted work. All other authors declare no competing interests.

Data sharing

De-identified participant data will be available in anonymised form from the corresponding author (SDK) on reasonable request (including a study outline), subject to review.

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References

1 Riemann D, Benz F, Dressle RJ, et al. Insomnia disorder: state of the science and challenges for the future. *J Sleep Res* 2022; **31:** e13604.
2 Morin CM, Benca R. Chronic insomnia. *Lancet* 2012; **379:** 1129–41.
3 Daley M, Morin CM, LeBlanc M, Grégoire JP, Savard J. The economic burden of insomnia: direct and indirect costs for individuals with insomnia syndrome, insomnia symptoms, and good sleepers. *Sleep* 2009; **32:** 55–64.
4 Maire M, Linder S, Dvořák C, et al. Prevalence and management of chronic insomnia in Swiss primary care: cross-sectional data from the "Sentinella" practice-based research network. *J Sleep Res* 2020; **29:** e13121.
5 Everitt H, McDermott L, Leydon G, Yules H, Baldwin D, Little P. GPs' management strategies for patients with insomnia: a survey and qualitative interview study. *Br J Gen Pract* 2014; **64:** e112–19.
6 Riemann D, Baglioni C, Bassetti C, et al. European guideline for the diagnosis and treatment of insomnia. *J Sleep Res* 2017; **26:** 675–700.
7 Spielman AJ, Saskin P, Thorpy MJ. Treatment of chronic insomnia by restriction of time in bed. *Sleep* 1987; **10:** 45–56.
8 Maurer LF, Espie CA, Kyle SD. How does sleep restriction therapy for insomnia work? A systematic review of mechanistic evidence and the introduction of the Triple-R model. *Sleep Med Rev* 2018; **42:** 127–38.
9 Maurer LF, Schneider J, Miller CB, Espie CA, Kyle SD. The clinical effects of sleep restriction therapy for insomnia: a meta-analysis of randomised controlled trials. *Sleep Med Rev* 2021; **58:** 101493.
10 Falloon K, Elley CR, Fernando A, 3rd, Lee AC, Arroll B. Simplified sleep restriction for insomnia in general practice: a randomised controlled trial. *Br J Gen Pract* 2015; **65:** e508–15.
11 Espie CA, MacMahon KM, Kelly HL, et al. Randomized clinical effectiveness trial of nurse-administered small-group cognitive behavior therapy for persistent insomnia in general practice. *Sleep* 2007; **30:** 574–84.
12 Cheung JMY, Jarrin DC, Ballot O, Bharwani AA, Morin CM. A systematic review of cognitive behavioral therapy for insomnia implemented in primary care and community settings. *Sleep Med Rev* 2019; **44:** 23–36.
13 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.
14 Espie CA, Kyle SD, Hames P, Gardani M, Fleming L, Cape J. The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder. *BMJ Open* 2014; **4:** e004183.
15 American Psychiatric Association. Diagnostic and statistical manual of nental disorders (DSM-5). Virginia: American Psychiatric Publishing, 2013.
16 Buysse DJ, Reynolds CF, 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989; **28:** 193–213.
17 Wilson SJ, Nutt DJ, Alford C, et al. British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders. *J Psychopharmacol* 2010; **24:** 1577–601.
18 Morin CM, Belleville G, Bélanger L, Ivers H. The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep* 2011; **34:** 601–08.
19 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. *J Gen Int Med* 2001; **16:** 606–13.
20 Espie CA, Emsley R, Kyle SD, et al. Effect of digital cognitive behavioral therapy for insomnia on health, psychological well-being, and sleep-related quality of life: a randomized clinical trial. *JAMA Psychiatry* 2019; **76:** 21–30.
21 Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014; **348:** g1687.
22 Beecham J, Knapp M. Costing psychiatric interventions. Measuring mental health needs. London: Gaskell and Royal College of Psychiatrists, 1992: 163–83.
23 Ware Jr JE. SF-36 health survey. The use of psychological testing for treatment planning and outcomes assessment, 2nd ed. Mahwah: Lawrence Erlbaum Associates Publishers; 1999: 1227–46.
24 Kyle SD, Crawford MR, Morgan K, Spiegelhalder K, Clark AA, Espie CA. The Glasgow Sleep Impact Index (GSII): a novel patient-centred measure for assessing sleep-related quality of life impairment in insomnia disorder. *Sleep Med* 2013; **14:** 493–501.
25 Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics* 1993; **4:** 353–65.
26 Broomfield NM, Espie CA. Towards a valid, reliable measure of sleep effort. *J Sleep Res* 2005; **14:** 401–07.
27 Nicassio PM, Mendlowitz DR, Fussell JJ, Petras L. The phenomenology of the pre-sleep state: the development of the pre-sleep arousal scale. *Behav Res Ther* 1985; **23:** 263–71.
28 Carney CE, Buysse DJ, Ancoli-Israel S, et al. The consensus sleep diary: standardizing prospective sleep self-monitoring. *Sleep* 2012; **35:** 287–302.
29 Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001; **33:** 337–43.
30 Yang Y, Brazier J, Tsuchiya A. Effect of adding a sleep dimension to the EQ-5D descriptive system: a "bolt-on" experiment. *Med Decis Making* 2014; **34:** 42–53.
31 Brazier J, Roberts J, Deverill M. The estimation of a preference-based measure of health from the SF-36. *J Health Econ* 2002; **21:** 271–92.
32 White IR, Horton NJ, Carpenter J, Pocock SJ. Strategy for intention to treat analysis in randomised trials with missing outcome data. *BMJ* 2011; **342:** d40.
33 Adan A, Almirall H. Horne & Östberg morningness-eveningness questionnaire: a reduced scale. *Pers Indiv Diff* 1991; **12:** 241–53.
34 Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. *J Pers Soc Psychol* 1986; **51:** 1173–82.
35 National Institute for Health and Care Excellence. Guide to the methods of technology appraisal. London: National Institute for Health and Care Excellence, 2013.
36 Curtis L, Burns, A. Unit costs of health and social care 2019, personal social services research unit. Canterbury: University of Kent, 2019.
37 NHS. NHS prescription cost analysis database. 2019. https://www.nhsbsa.nhs.uk/statistical-collections/prescription-cost-analysis-england/prescription-cost-analysis-england-2019 (accessed Dec 15, 2022).
38 NHS. NHS England 2018/19 national cost collection data publication. https://www.england.nhs.uk/publication/2018-19-national-cost-collection-data-publication/ (accessed March 8, 2022).
39 Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. Methods for the economic evaluation of health care programmes, 3rd edn. Oxford: Oxford University Press, 2005.
40 White IR, Royston P, Wood AM. Multiple imputation using chained equations: issues and guidance for practice. *Stat Med* 2011; **30:** 377–99.

41 Van der Zweerde T, Lancee J, Slottje P, Bosmans JE, Van Someren EJW, van Straten A. Nurse-guided internet-delivered cognitive behavioral therapy for insomnia in general practice: results from a pragmatic randomized clinical trial. *Psychother Psychosom* 2020; **89:** 174–84.

42 Kyle SD, Morgan K, Spiegelhalder K, Espie CA. No pain, no gain: an exploratory within-subjects mixed-methods evaluation of the patient experience of sleep restriction therapy (SRT) for insomnia. *Sleep Med* 2011; **12:** 735–47.

43 Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med* 2021; **17:** 263–98.

44 van der Zweerde T, Bisdounis L, Kyle SD, Lancee J, van Straten A. Cognitive behavioral therapy for insomnia: a meta-analysis of long-term effects in controlled studies. *Sleep Med Rev* 2019; **48:** 101208.

45 Benz F, Knoop T, Ballesio A, et al. The efficacy of cognitive and behavior therapies for insomnia on daytime symptoms: a systematic review and network meta-analysis. *Clin Psychol Rev* 2020; **80:** 101873.

46 Santoft F, Axelsson E, Öst LG, Hedman-Lagerlöf M, Fust J, Hedman-Lagerlöf E. Cognitive behaviour therapy for depression in primary care: systematic review and meta-analysis. *Psychol Med* 2019; **49:** 1266–74.