Nurse-delivered sleep restriction therapy to improve insomnia disorder in primary care: the HABIT RCT

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Scientific summary

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Scientific summary

Background

Insomnia disorder affects approximately 10% of the adult population. It reduces quality of life, increases risk of poor physical and mental health, and is associated with substantial direct and indirect costs. The first-line treatment is multicomponent cognitive–behavioural therapy (CBT) delivered by a trained clinician, but access remains extremely limited, particularly in primary care where insomnia is typically managed. Instead, patients are provided with self-help sleep hygiene (SH) advice, or prescribed hypnotic or sedative antidepressant medication.

Sleep restriction therapy (SRT) is one of the principal active components of CBT. It involves implementation of a prescribed and restricted sleep schedule, which is reviewed and adjusted each week by a therapist in order to optimise sleep efficiency (the proportion of time spent in bed asleep). Time in bed is initially restricted to match reported total sleep time (with 5 hours set as the minimum sleep opportunity). The structured and prescriptive nature of SRT means it could potentially be delivered as a brief intervention by generalists in primary care. Meta-analysis of post-treatment data shows that single-component SRT is effective for insomnia, but trials to date have mainly been performed in specialist research settings, recruiting small samples of insomnia patients without comorbidity. While both SRT and CBT for insomnia have been evaluated in the primary care context, there has been no large-scale test to assess clinical and cost-effectiveness of a brief and scalable behavioural treatment for insomnia delivered within routine clinical practice.

Objective(s)

The primary objective of the Health-professional Administered Brief Insomnia Therapy trial was to establish whether nurse-delivered SRT in primary care improves insomnia relative to SH. Secondary objectives were to establish whether nurse-delivered SRT is cost-effective compared with SH, from a NHS and Personal Social Services (PSS) perspective, and from a societal perspective, and to explore both moderators and mediators of treatment effects. We also undertook a process evaluation to understand intervention delivery, fidelity and acceptability.

Design

Pragmatic, multicentre, individually randomised, parallel-group, superiority trial with embedded process evaluation. Participants were randomised (1 : 1) to SRT or SH using a validated web-based randomisation programme (Sortition), with a non-deterministic minimisation algorithm to ensure site, use of prescribed sleep promoting medication (yes/no), age (18–65 vs. > 65 years), sex, baseline

insomnia severity [Insomnia Severity Index (ISI) score < 22 vs. 22–28] and depression symptom severity [Patient Health Questionnaire-9 (PHQ-9) score < 10 vs. 10–27] were balanced across the two groups. The trial was prospectively registered with the ISRCTN (ISRCTN42499563).

Setting

National Health Service (NHS) general practice in three regions of England (Thames Valley, Lincolnshire and Greater Manchester). Potentially eligible participants were initially identified by searching practice records and invited to complete an eligibility questionnaire.

Participants

Eligible participants were adults who met diagnostic criteria for insomnia disorder. Exclusions were principally limited to conditions which contraindicate SRT, or render SRT inappropriate or ineffective: (1) pregnant/pregnancy planning in the next 6 months; (2) additional sleep disorder diagnosis or 'positive' for those disorders on a screening questionnaire; (3) dementia or mild cognitive impairment; (4) diagnosis of epilepsy, schizophrenia or bipolar disorder; (5) current suicidal ideation with intent or attempted suicide within past 2 months; (6) currently receiving cancer treatment or planned major surgery during treatment phase; (7) night, evening, early morning or rotating shift-work; (8) currently receiving psychological treatment for insomnia from a health professional or taking part in an online treatment programme for insomnia and (9) life expectancy of < 2 years. For the qualitative substudy, we sought to recruit 15 participants from the SRT intervention arm, 15 nurses, and 15 practice managers or general practitioners (GPs).

Intervention

Participants in the intervention arm were offered nurse-delivered SRT. Practice nurses and research nurses from the clinical research network were trained to deliver SRT. Nurses received a 4-hour training session on sleep, insomnia, and the delivery of SRT as well as access to supporting resources. Trained nurses delivered manualised SRT over four brief weekly sessions. In session 1, nurse therapists introduced the rationale for SRT alongside a review of sleep diaries, selection of bed and rise times, management of daytime sleepiness, and discussion of barriers/facilitators to implementation. Participants were provided with a booklet to read in their own time, which included information on theory underlying SRT and a list of SH guidelines (identical to those provided to the control arm). Participants were 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 comprised brief sessions (10–15 minutes) to review progress, troubleshoot difficulties, and advise on adapting the sleep schedule. Sessions 1 and 3 took place in-person at the practice while sessions 2 and 4 were conducted over the phone. In-person treatment sessions were audio-recorded (if consent was given) and a subsample were appraised for fidelity by a clinician independent of the research team.

Control

Participants randomised to the control arm were sent a SH booklet via e-mail or post mail. The booklet provided advice on how lifestyle factors, bedroom factors and sleep routine can influence sleep quality, and recommended changes that may improve sleep. Consistent with the requirements of a pragmatic trial, there were no restrictions on usual care for both groups.

Outcomes

Key outcomes were assessed at baseline and 3, 6 and 12 months post randomisation. The primary outcome was self-reported insomnia severity using the ISI at 6 months. Secondary outcomes included:

- health-related quality of life [Short Form questionnaire-36 items (SF-36)]
- sleep-related quality of life [Glasgow Sleep Impact Index (GSII)]
- depressive symptoms (PHQ-9)
- use of prescribed sleep medication (diary)
- sleep diary parameters and actigraphy-recorded sleep
- work productivity and activity impairment (WPAI)
- pre-sleep arousal scale (PSAS)
- sleep effort [Glasgow Sleep Effort Scale (GSES)].

We measured pre-defined adverse events (AEs) at all time points (falls, driving accidents, near-miss driving events, sleepiness while driving and work-related accidents) and the occurrence of serious adverse events (SAEs) between baseline and 6 months. Cost-effectiveness was evaluated using the incremental cost per quality-adjusted life-year (QALY). Utility was measured using the EuroQol-5 Dimensions, three-level version at baseline and 3, 6 and 12 months, while healthcare and PSS resource use was captured with a modified version of the Client Service Receipt Inventory and valued using national tariffs, including the Personal Social Services Research Unit Costs of Health and Social Care compendium and NHS Reference Costs. We estimated whether the intervention was cost-effective at the established National Institute for Health and Care Excellence (NICE) threshold of £20,000 per QALY. For the process evaluation we performed semistructured interviews with participants from the SRT arm, nurse therapists, practice managers and GPs to explore implementation, mechanisms of impact and contextual factors surrounding nurse-delivered SRT. Participant qualitative data were also integrated with quantitative sleep diary data recorded during the 4-week intervention period.

Analysis

The primary analysis population included all participants according to their allocated group and who had at least one outcome measurement. We fitted a three-level linear mixed-effect model to the ISI score assessed at 3, 6 and 12 months with practice and participant included as random effects and randomised group and minimisation factors (baseline ISI score, site, age, use of prescribed sleep medication, sex and baseline PHQ-9 score) fitted as fixed effects. We tested whether self-reported PSAS and GSES measured at 3 months mediated treatment effects on the ISI at 6 months. We also investigated the effect of compliance (SRT session attendance) on the treatment effect and performed exploratory moderation analyses of baseline demographic and clinical variables. For cost-effectiveness, the incremental cost-effectiveness ratio was constructed as the ratio of the differences between mean costs and mean effects (QALYs) between the SRT and SH groups. Net monetary benefit from treatment was reported at a range of cost-effectiveness thresholds. Framework analysis was used for qualitative data.

Results

Between 29 August 2018 and 23 March 2020, 642 participants were recruited and randomised to SRT (n = 321) or SH (n = 321). Ninety-two per cent of participants in the SRT arm attended at least one treatment session, while 65% attended all four sessions. Eighty-five per cent of participants contributed primary outcome data at 6 months. The estimated adjusted mean difference on the ISI was −3.05 [95% confidence interval (CI) −3.83 to −2.28; $p < 0.001$, Cohen's d = −0.74], indicating that participants in the

SRT arm reported lower insomnia severity compared to the control group. Large treatment effects were also found at 3 months (−3.88, 95% CI −4.66 to −3.10; $p < 0.001$, $d = -0.95$) and 12 months (−2.96, 95% CI −3.75 to −2.16; $p < 0.001$, $d = -0.72$). Findings were consistent across a range of pre-specified sensitivity analyses.

For secondary outcomes, SRT demonstrated evidence of improvement in mental health-related quality of life (SF-36 mental component summary), depressive symptoms (PHQ-9), absenteeism, presenteeism, WPAI, and patient-generated quality of life (GSII) over SH at 3, 6 and 12 months. Effect sizes (Cohen's *d*) were in the small-to-medium range. Outcome completion was low (32–41% of participants) for sleep diary parameters, sleep medication use, and actigraphy chiefly because the trial team were not able to send such measures during the COVID-19 pandemic. At 6 months, the SRT group reported shorter sleep latency and wake-time after sleep onset, as well as higher sleep efficiency, total sleep time, and sleep quality. These effects were largely maintained at 12 months (except for sleep latency). Actigraphy-defined wake-time after sleep onset and total sleep time were both decreased at 6 months, while sleep efficiency was increased. We found no between-group difference in use of prescribed sleep medication.

Our pre-specified mediators, pre-sleep cognitive and somatic arousal (PSAS) and GSES, were reduced in the SRT group relative to SH at 3 months post randomisation. Mediation analyses showed statistically significant indirect effects for sleep effort (35.6% mediated), cognitive arousal (34.6% mediated) and somatic arousal (14.5% mediated) at 3 months on the ISI at 6 months. Pre-specified moderation analyses did not find evidence for the impact of objective short sleep duration, age, chronotype, depression severity, sleep medication use, or level of deprivation on insomnia severity (ISI) at 6 months. Eight participants in each group had SAEs but none were judged as related to the intervention. Pre-defined minor AEs did not differ between the groups.

The mean cost of SRT (including training and delivering) was £84.3 per participant. In the primary economic analysis, both mean incremental NHS and PSS costs (£43.59, 95% CI −18.41 to 105.59) and mean incremental QALYs (0.021, 95% CI 0.0002 to 0.042) were marginally higher in the intervention arm, giving an incremental cost per QALY of £2075.71. There was a 95.3% probability that the intervention was cost-effective at a cost-effectiveness threshold of £20,000 per QALY, translating into a mean net monetary benefit of £377.84.

Fidelity ratings for the audio recordings of nurse-delivered sessions were high (median coverage was 100% for session 1 and 87.5% for session 3). The process evaluation found that SRT can be successfully delivered by nurses in general practice, with high fidelity, and that it was generally well received by patients. Recommendations were made to further support patient engagement with SRT, and to facilitate implementation within primary care.

Conclusions

Brief nurse-delivered SRT in primary care is clinically effective for insomnia disorder, safe and likely to be cost-effective. SRT could become part of a stepped care approach to insomnia treatment, helping to facilitate the implementation of NICE guidelines and increase access to evidence-based intervention. Future work should develop a training and delivery pathway to support primary care integration and assess generalisability across diverse primary care patients with insomnia.

Trial registration

This trial is registered as ISRCTN42499563.

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