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# Health professional Administered Brief Insomnia Therapy (HABIT) trial

**Submission date**
30/04/2018

**Recruitment status**
No longer recruiting

**Registration date**
31/05/2018

**Overall study status**
Completed

**Last Edited**
27/08/2024

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Insomnia refers to persistent problems with falling asleep or staying asleep. Insomnia can have a significant effect on health and daily life. For example, it reduces the ability to concentrate, lowers mood and increases the risk of developing mental and physical illness. The best treatment for insomnia is a psychological therapy called cognitive-behavioural therapy (CBT), which involves supporting people with insomnia to improve their sleep behaviours and sleep-related thoughts. However, access to CBT in the UK is limited and there are not enough trained therapists to help the large number of poor sleepers (up to 10% of the adult population). The aim of this study is to test if a brief version of CBT called sleep restriction therapy (SRT), delivered by nurses working in GP practices, can help people with insomnia regain a normal sleep pattern.

Who can participate?
Patients aged 18 and over with insomnia

What does the study involve?
Participants are assigned, by chance, to one of two treatment groups. These groups will be either (1) sleep restriction therapy and sleep hygiene advice or (2) sleep hygiene advice only. Sleep restriction therapy involves meeting with a nurse for four weekly sessions. The nurse will support the patient to follow a new nightly sleep schedule over this four-week period. Sleep hygiene involves receiving a booklet with advice on how to improve sleep. Participants are asked to complete a number of questionnaires to measure their sleep, quality of life and daytime functioning before treatment, and also at 3, 6 and 12 months after treatment begins.

What are the possible benefits and risks of participating?
Participants may benefit from improved sleep and will also contribute to research which may help develop better treatments for people experiencing insomnia. There are no known serious side effects from taking part in this study, but any change in sleep patterns may be associated with a short-term increase in sleepiness. If participants feel sleepy during the study they are advised to avoid activities that require a high degree of vigilance, such as driving or operating heavy machinery. All participants are reimbursed after each completed visit. This takes the form of vouchers; £5 at baseline, £10 at 3 months, £15 at 6 months, and £10 at 12 months.

Participants (sleep restriction therapy and sleep hygiene group only) also receive a voucher for participation in interviews as part of the process evaluation (£10 voucher).

Where is the study run from?
University of Oxford (UK)

Who is funding the study?
The Health Technology Assessment (HTA) Programme – National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Nargis Begum and Barbara Robinson
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### Study website
https://www.phc.ox.ac.uk/research/participate/habitstudy

# Contact information

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Scientific

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## Additional identifiers

### EudraCT/CTIS number

### IRAS number
238138

### ClinicalTrials.gov number

### Secondary identifying numbers
37608; HTA 16/84/01, IRAS 238138

## Study information

### Scientific Title
A pragmatic, multicentre, randomised controlled trial comparing nurse-delivered sleep restriction therapy (SRT) for insomnia disorder to sleep hygiene (SH) in primary care

### Acronym
HABIT

### Study objectives

Systematic review evidence shows that a single component of cognitive-behavioural therapy (CBT) for insomnia, call sleep restriction therapy (SRT), is clinically efficacious. We aim to test whether nurse-delivered sleep restriction therapy (SRT) for insomnia disorder in UK primary care is both clinically and cost-effective.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Yorkshire and The Humber – Bradford Leeds REC, 14/05/2018, ref: 18/YH/0153

## Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Treatment

## Participant information sheet
See additional files

## Health condition(s) or problem(s) studied
Insomnia

## Interventions
Participants will be randomised (1:1) to one of the two intervention groups to receive either SRT+SH 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 yrs vs. > 65yrs), sex, baseline insomnia severity (ISI score <22 vs. 22-28) and depression symptom severity (PHQ-9 score <10 vs. 10-27) are balanced across the two groups.

## Intervention Type
Behavioural

## Primary outcome measure
Self-rated insomnia severity using the insomnia severity index (ISI) questionnaire collected at baseline, 3, 6 and 12 months post randomization. Primary outcome is at 6 months.

## Secondary outcome measures
Current secondary outcome measures as of 29/01/2021:

1. The effect of SRT+SH versus SH on health-related quality of life (HRQoL) measured using the SF-36 questionnaire (Mental component summary [MCS] score and Physical component summary [PCS] score) at baseline, 3, 6 and 12 months post-randomization
2. The effect of SRT+SH versus SH on subjective sleep. Subjective sleep recorded over 7 nights using the consensus sleep diary (CSD) (sleep-onset latency [SOL]; wake-time after sleep onset [WASO]; sleep efficiency [SE]; total sleep time [TST]; sleep quality [SQ]) at baseline, 6 and 12 months post-randomization
3. The effect of SRT+SH versus SH on object estimates of sleep. Actigraphy-recorded sleep over 7 nights (SOL; WASO; SE; TST) at baseline, 6 and 12 months post-randomization
4. The effect of SRT+SH versus SH on patient-generated quality of life. Self-rated quality of life using the Glasgow Sleep Impact Index [GSII Ranks 1,2,3] at baseline, 3, 6 and 12 months post-randomization
5. The effect of SRT+SH versus SH on depressive symptoms assessed by self-rated depressive symptoms severity measured using the Patient Health Questionnaire (PHQ-9) at baseline, 3, 6 and 12 months post-randomization.
6. The effect of SRT+SH versus SH on work productivity measured by the self-rated work productivity and activity impairment questionnaire (WPAI) at baseline, 3, 6 and 12 months post-randomization
7. The effect of SRT+SH versus SH on hypnotic medication use assessed by the use of prescribed hypnotics (quantified from 7-day diary) at baseline, 6 and 12 months post-randomization
8. The effect of SRT+SH versus SH on the use of other prescribed sleep-promoting medications measured by the use of other prescribed sleep-promoting medications (e.g., sedative antidepressants, antihistamines, antipsychotics, melatonin) quantified from 7 day diary, at baseline, 6 and 12 months post-randomization
9. The effect of SRT+SH versus SH on pre-sleep arousal and sleep effort measured by the pre-sleep arousal scale (PSAS) and Glasgow sleep effort scale (GSES) at baseline, 3, 6 and 12 months post-randomization
10. Incremental cost-effectiveness from both NHS and societal perspectives measured using trial records (time and number of nurse-led appointments), practice records (medications; baseline and 12 months only), Client Service Receipt Inventory (self-reported service use, medications), Insomnia Severity Index, WPAI, EQ-5D-3L (QALY) at baseline, 3, 6 and 12 months post-randomization
11. Intervention delivery, fidelity and acceptability assessed using semi-structured interviews with trial participants, nurses, GPs, and practice managers. The number of appointments attended/received by participants, fidelity appraisal of recorded consultations, and adherence to prescribed sleep window (from sleep diary), are collected throughout the trial
12. Adverse events between the groups assessed using a questionnaire at baseline, 3, 6, and 12 months

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Previous secondary outcome measures as of 24/08/2020:
1. The effect of SRT+SH versus SH on health-related quality of life (HRQoL) measured using the SF-36 questionnaire (Total Score, Mental component summary [MCS] score and Physical component summary [PCS] score) at baseline, 3, 6 and 12 months post-randomization
2. The effect of SRT+SH versus SH on subjective sleep. Subjective sleep recorded over 7 nights using the consensus sleep diary (CSD) (sleep-onset latency [SOL]; wake-time after sleep onset [WASO]; sleep efficiency [SE]; total sleep time [TST]; sleep quality [SQ]) at baseline, 6 and 12 months post-randomization
3. The effect of SRT+SH versus SH on object estimates of sleep. Actigraphy-recorded sleep over 7 nights (SOL; WASO; SE; TST) at baseline, 6 and 12 months post-randomization

4. The effect of SRT+SH versus SH on patient-generated quality of life. Self-rated quality of life using the Glasgow Sleep Impact Index [GSII Ranks 1,2,3] at baseline, 3, 6 and 12 months post-randomization
5. Tthe effect of SRT+SH versus SH on depressive symptoms assessed by self-rated depressive symptoms severity measured using the Patient Health Questionnaire (PHQ-9) at baseline, 3, 6 and 12 months post-randomization.
6. The effect of SRT+SH versus SH on work productivity measured by the self-rated work productivity and activity impairment questionnaire (WPAI) at baseline, 3, 6 and 12 months post-randomization
7. The effect of SRT+SH versus SH on hypnotic medication use assessed by the use of prescribed hypnotics (quantified from 7-day diary) at baseline, 6 and 12 months post-randomization
8. The effect of SRT+SH versus SH on the use of other prescribed sleep-promoting medications measured by the use of other prescribed sleep-promoting medications (e.g., sedative antidepressants, antihistamines, antipsychotics, melatonin) quantified from 7 day diary, at baseline, 6 and 12 months post-randomization
9. The effect of SRT+SH versus SH on pre-sleep arousal and sleep effort measured by the pre-sleep arousal scale (PSAS) and Glasgow sleep effort scale (GSES) at baseline, 3, 6 and 12 months post-randomization
10. Incremental cost-effectiveness from both NHS and societal perspectives measured using trial records (time and number of nurse-led appointments), practice records (medications; baseline and 12 months only), Client Service Receipt Inventory (self-reported service use, medications), Insomnia Severity Index, WPAI, EQ-5D-3L (QALY) at baseline, 3, 6 and 12 months post-randomization
11. Intervention delivery, fidelity and acceptability assessed using semi-structured interviews with trial participants, nurses, GPs, and practice managers. The number of appointments attended/received by participants, fidelity appraisal of recorded consultations, and adherence to prescribed sleep window (from sleep diary), are collected throughout the trial
12. Adverse events between the groups assessed using a questionnaire at baseline, 3, 6, and 12 months

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Previous secondary outcome measures as of 19/02/2020:
1. The effect of SRT+SH versus SH on insomnia severity using self-rated health-related quality of life (HRQoL) measured using the SF-36 questionnaire (Total Score, Mental component summary [MCS] score and Physical component summary [PCS] score) at baseline, 3, 6 and 12 months post-randomization
2. The effect of SRT+SH versus SH on subjective sleep. Subjective sleep recorded over 7 nights using the consensus sleep diary (CSD) (sleep-onset latency [SOL]; wake-time after sleep onset [WASO]; sleep efficiency [SE]; total sleep time [TST]; sleep quality [SQ]) at baseline, 6 and 12 months post-randomization
3. The effect of SRT+SH versus SH on object estimates of sleep. Actigraphy-recorded sleep over 7 nights (SOL; WASO; SE; TST) at baseline, 6 and 12 months post-randomization
4. The effect of SRT+SH versus SH on patient-generated quality of life. Self-rated quality of life using the Glasgow Sleep Impact Index [GSII Ranks 1,2,3] at baseline, 3, 6 and 12 months post-randomization
5. Tthe effect of SRT+SH versus SH on depressive symptoms assessed by self-rated depressive symptoms severity measured using the Patient Health Questionnaire (PHQ-9) at baseline, 3, 6 and 12 months post-randomization.
6. The effect of SRT+SH versus SH on work productivity measured by the self-rated work productivity and activity impairment questionnaire (WPAI) at baseline, 3, 6 and 12 months post-randomization

7. The effect of SRT+SH versus SH on hypnotic medication use assessed by the use of prescribed hypnotics (quantified from 7-day diary) at baseline, 6 and 12 months post-randomization
8. The effect of SRT+SH versus SH on the use of other prescribed sleep-promoting medications measured by the use of other prescribed sleep-promoting medications (e.g., sedative antidepressants, antihistamines, antipsychotics, melatonin) quantified from 7 day diary, at baseline, 6 and 12 months post-randomization
9. The effect of SRT+SH versus SH on pre-sleep arousal and sleep effort measured by the Pre-sleep arousal scale (PSAS) and Glasgow sleep effort scale (GSES) at baseline, 6 and 12 months post-randomization
10. Incremental cost-effectiveness from both NHS and societal perspectives measured using trial records (time and number of nurse-led appointments), practice records (medications; baseline and 12 months only), Client Service Receipt Inventory (self-reported service use, medications), Insomnia Severity Index, WPAI, EQ-5D-3L (QALY) at baseline, 3, 6 and 12 months post-randomization
11. Intervention delivery, fidelity and acceptability assessed using semi-structured interviews with trial participants, nurses, GPs, and practice managers. The number of appointments attended/received by participants, fidelity appraisal of recorded consultations, and adherence to prescribed sleep window (from sleep diary), are collected throughout the trial
12. Adverse events between the groups assessed using a questionnaire at baseline, 3, 6, and 12 months

Previous secondary outcome measures:
1. To compare the effect of SRT+SH versus SH on insomnia severity using self-rated health-related quality of life (HRQoL) measured using the SF-36 questionnaire (Total Score, Mental component summary [MCS] score and Physical component summary [PCS] score) at baseline, 3, 6 and 12 months post-randomisation.
2. Subjective sleep recorded over 7 nights using the consensus sleep diary (CSD)
(sleep-onset latency [SOL]; wake-time after sleep onset [WASO]; sleep efficiency [SE]; total sleep time [TST]; sleep quality [SQ]) at baseline, 6 and 12 months post-randomisation.
3. Actigraphy-recorded sleep over 7 nights (SOL; WASO; SE; TST) at baseline, 6 and 12 months post-randomisation.
4. Self-rated quality of life using the Glasgow Sleep Impact Index [GSII Ranks 1,2,3] at baseline, 3, 6 and 12 months post-randomisation.
5. Self-rated depressive symptoms severity using the Patient Health Questionnaire (PHQ-9) at baseline, 3, 6 and 12 months post-randomisation.
6. Self-rated work productivity and activity impairment questionnaire (WPAI) at baseline, 3, 6 and 12 months post-randomisation.
7. Use of prescribed hypnotics (quantified from 7-day diary) at baseline, 6 and 12 months post-randomisation.
8. Use of other prescribed sleep-promoting medications (e.g., sedative antidepressants, anti-histamines, antipsychotics, melatonin) quantified from 7 day diary, at baseline, 6 and 12 months post-randomisation.
9. Incremental cost-effectiveness from both NHS and societal perspectives measured using trial records (time and number of nurse-led appointments), practice records (medications; baseline and 12 months only), Client Service Receipt Inventory (self-reported service use, medications), Insomnia Severity Index, WPAI, EQ-5D-3L (QALY) at baseline, 3, 6 and 12 months post-randomisation.
10. Intervention delivery, fidelity and acceptability assessed using semi-structured interviews with 1) trial participants; 2) nurses 3) GPs and 4) practice managers; number of appointments attended/received by participants; fidelity appraisal of recorded consultations; and adherence to

prescribed sleep window (from sleep diary), throughout the trial.
11. Adverse events between the groups assessed using questionnaire at baseline, 3, 6, and 12 months.

### Overall study start date
01/10/2017

### Completion date
06/04/2021

## Eligibility

### Key inclusion criteria
Current participant inclusion criteria as of 19/02/2020:
1. Participant is willing and able to give informed consent for participation in the study
2. Screen positive for insomnia symptoms on the Sleep Condition Indicator (SCI) questionnaire AND meet criteria for insomnia disorder according to DSM-5 (American Psychiatric Association) on structured checklist review
3. Sleep efficiency < 85% over the past month
4. Age ≥18 years
5. 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
6. Registered at a GP practice taking part in the trial

Previous participant inclusion criteria:
1. Participant is willing and able to give informed consent for participation in the study
2. Screen positive for insomnia symptoms on the Sleep Condition Indicator (SCI) questionnaire AND meet criteria for insomnia disorder according to DSM-5 (American Psychiatric Association) on structured checklist review
3. Sleep efficiency < 85% over the past month
4. Age ≥18 years
5. 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

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
A minimum of 628 participants will be recruited from three centres in the UK. Participants will be randomised to one of two groups. In addition, we plan to recruit 15 practice nurses and 15 GPs or practice managers for semi-structured qualitative interviews as part of our process evaluation.

## Total final enrolment
642

## Key exclusion criteria
Current participant exclusion criteria as of 19/02/2020:
1. Pregnant/pregnancy planning in the next 6 months
2. Additional sleep disorder diagnosis (e.g., restless legs syndrome, obstructive sleep apnoea, narcolepsy) OR screen “positive” on screening
3. Dementia/ Mild Cognitive Impairment (MCI)
4. Epilepsy
5. Psychosis (schizophrenia, bipolar disorder)
6. Current suicidal ideation with intent OR attempted suicide within past 2 months
7. Currently receiving cancer treatment OR planned major surgery during treatment phase
8. Night, evening, early morning or rotating shift-work
9. Currently receiving psychological treatment for insomnia from a health professional
10. Life expectancy of <2 years
11. Another person in the same household participates in this trial

Previous exclusion criteria as of 17/09/2019:
1. Pregnant/pregnancy planning in the next 6 months
2. Additional sleep disorder diagnosis (e.g., restless legs syndrome, obstructive sleep apnoea, narcolepsy) OR screen “positive” on screening
3. Dementia/ Mild Cognitive Impairment (MCI)
4. Epilepsy
5. Psychosis (schizophrenia, bipolar disorder)
6. Current suicidal ideation with intent OR attempted suicide within past 2 months
7. Currently receiving cancer treatment OR planned major surgery during treatment phase
8. Night, evening, early morning or rotating shift-work
9. Currently receiving psychological treatment for insomnia from a health professional
10. Life expectancy of < 2 years

Previous exclusion criteria as of 21/08/2018:
1. Pregnant/pregnancy planning in the next 6 months
2. Additional sleep disorder diagnosis (e.g., restless legs syndrome, obstructive sleep apnoea, narcolepsy) OR screen “positive” on screening
3. Dementia
4. Epilepsy
5. Psychosis (schizophrenia, bipolar disorder)
6. Current suicidal ideation with intent OR attempted suicide within past 2 months
7. Currently receiving cancer treatment OR planned major surgery during treatment phase
8. Night, evening, early morning or rotating shift-work
9. Currently receiving psychological treatment for insomnia from a health professional or taking part in an online treatment programme for insomnia.
10. Life expectancy of <2 years

Previous exclusion criteria:
1. Pregnant/pregnancy planning in the next 6 months
2. Additional sleep disorder diagnosis (e.g., restless legs syndrome, obstructive sleep apnoea, narcolepsy) OR screen “positive” on screening
3. Dementia
4. Epilepsy

5. Psychosis (schizophrenia, bipolar disorder)
6. Current suicidal ideation with intent OR attempted suicide within past 2 months
7. Currently receiving cancer treatment OR planned major surgery during treatment phase
8. Night, evening, early morning or rotating shift-work
9. Trans-meridian travel planned during the baseline assessments or for > 3 nights during treatment phase
10. Currently receiving psychological treatment for insomnia from a health professional
11. Life expectancy of < 2 years

### Date of first enrolment
01/08/2018

### Date of final enrolment
31/03/2020

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of Oxford**
Primary Care Clinical Trials Unit
Radcliffe Primary Care Building
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Woodstock Road
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### Study participating centre
**University of Manchester**
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### Study participating centre
**University of Lincoln**
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**Sponsor type**
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**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**

National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
The trialists will publish their primary findings (on clinical and cost -effectiveness of SRT) in high-impact, peer reviewed journals. They will make their primary findings open access so they can be accessed by the widest number of people possible, including policy-makers and members of the public. They will publish additional important journal outputs in relation to process evaluation and secondary, exploratory moderator analyses. They will send trial participants a summary of study outcomes and present their findings at national (e.g. British Sleep Society, Society for Academic Primary Care), international (e.g. Sleep, North American Primary Care Research Group) and practitioner (e.g. RCGP) conferences.

### Intention to publish date
01/05/2023

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Simon Kyle (simon.kyle@ndcn.ox.ac.uk). Other data sharing details will become available when the study has all the required approvals in place.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version v2.0 | 11/07/2018 | 21/08/2018 | No | Yes |
| Participant information sheet | version v3.0 | 29/07/2019 | 17/09/2019 | No | Yes |
| Participant information sheet | version V4.0 | 20/12/2019 | 18/02/2020 | No | Yes |
| Protocol file | version V5.0 | 20/12/2019 | 18/02/2020 | No | No |
| Protocol article | protocol | 04/03/2020 | 15/02/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 10/08/2023 | 14/08/2023 | Yes | No |
| Results article | | 01/08/2024 | 27/08/2024 | Yes | No |