

Health professional Administered Brief Insomnia Therapy (HABIT) trial

Submission date 30/04/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 31/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/08/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Type(s)
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

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. 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

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 objective 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, 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, antihistamines, 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
Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG

Study participating centre

University of Manchester

Division of Population Health
Health Services Research and Primary Care
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Study participating centre

University of Lincoln

School of Health and Social Care
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Sponsor information

Organisation

University of Oxford

Sponsor details

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Sponsor type

University/education

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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