ISRCTN10974094 https://doi.org/10.1186/ISRCTN10974094

Mechanisms of Sleep Restriction Therapy in Insomnia

Submission date
30/11/2018

Recruitment status
No longer recruiting

Registration date
01/02/2019

Overall study status
Completed

Last Edited
01/09/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Sleep restriction therapy (SRT) is an effective treatment for insomnia, but it is not known why or how this behavioural treatment works. The aim of this study is to compare SRT to a new intervention, named bedtime consistency therapy (BCT), which involves keeping a regular time in bed, to determine what the most effective treatment is (SRT or BCT) and investigate how the treatments may be working to change sleep and daytime functioning.

Who can participate?
People aged 25-55 from the Oxford area who are poor sleepers and who do not currently take medication for their sleep or mental health

What does the study involve?
Participants are randomly allocated to one of the two treatment groups (SRT or BCT). SRT involves prescribing a restricted time in bed ('sleep window') based on the individual's reported duration and pattern of sleep. In the BCT group, participants are instructed to maintain consistent bed and rise-times. Taking part involves a total of 14 weeks, during which participants have their sleep carefully assessed. This includes three overnight measurements at home, computer tasks, questionnaires, filling out a sleep diary and wearing an actiwatch.

What are the possible benefits and risks of participating?
Participants are reimbursed for each completed trial phase and receive free access to interventions aiming to improve sleep. There may be a benefit, therefore, of improved sleep when following the interventions. No risks are expected.

Where is the study run from?
Sleep and Circadian Neuroscience Institute (SCNi), Oxford (UK)

When is the study starting and how long is it expected to run for?
June 2017 to June 2018

Who is funding the study?
Dr Mortimer & Theresa Sackler Foundation

Who is the main contact?
Leonie Maurer

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
R51331

Study information

Scientific Title
Mechanisms of Sleep Restriction Therapy in Insomnia (MARTINI): a randomised, controlled evaluation comparing bedtime consistency therapy with sleep restriction therapy

Acronym
MARTINI

Study objectives
Primary clinical hypothesis:
1. To assess whether sleep restriction therapy (SRT) reduces self-reported insomnia severity relative to bedtime consistency therapy (BCT)

Secondary clinical hypotheses:
2. SRT reduces sleep-diary reported wake time after sleep onset (WASO) and sleep onset latency (SOL) during treatment phase relative to BCT
3. SRT improves sleep-related quality of life relative to BCT
4. SRT reduces self-reported symptoms of depression and anxiety relative to BCT
5. SRT reduces self-reported cognitive complaints relative to BCT

Primary mechanistic hypothesis:
1. SRT improves PSG-defined sleep continuity relative to BCT

Secondary mechanistic hypotheses:
2. SRT improves actigraphy-defined sleep continuity during treatment phase weeks relative to BCT

3. SRT potentiates homeostatic sleep drive relative to BCT
4. SRT increases subjective and objective measures of sleepiness during treatment phase relative to BCT
5. SRT decreases the objective-subjective discrepancy (SOL, WASO and total sleep time [TST]) relative to BCT
6. SRT reduces night-to-night sleep variability for diary-recorded SOL, WASO and TST relative to BCT
7. SRT increases inter-daily stability and reduces intra-daily variability in rest-activity (determined by actigraphy) relative to BCT
8. SRT reduces attention bias to sleep stimuli at the end of treatment relative to BCT
9. To compare self-reported adverse events between SRT and BCT groups
10. SRT reduces cognitive pre-sleep arousal and sleep-related thoughts relative to BCT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Sciences Inter-divisional Research Ethics Committee (IDREC), 14/06/2017, ref: R51331 /RE001

Primary study design
Interventional

Study design
Randomised controlled mechanistic evaluation

Study type(s)
Treatment

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

Interventions
Participants are randomly assigned to the treatment group, SRT, or a specific factors component control group, BCT (bedtime consistency therapy) (1:1) over a 14-week measurement period using a computerised randomisation procedure generated from 'sealedenvelope.com'. Randomisation and enrolment of the participants is performed by a member independent of the study team; the study team is therefore blind to future allocations. Randomisation is stratified by age (25-40:41-55) and gender (Male: Female). Treatment for both groups is delivered in a one hour session by the primary researcher at the Sleep and Circadian Neurosciences Institute (Oxford, Uk) according to a manualised protocol and personalised treatment slides (PowerPoint, 2013).

Test treatment:
Sleep restriction therapy involves prescribing a restricted time in bed ('sleep window') based on the individual's reported duration and pattern of sleep. The aim is to consolidate sleep and reduce awakenings and wakefulness during the night. Therefore, the estimated total sleep time across the previous two weeks is averaged and initially used to set the sleep window. For example, a participant who reports to spend nine hours in bed but only reports 6 of those sleeping would be assigned to a six hour sleep window. The time for rising is established first to fit the individual's wake schedule and then the time for retiring at night is set to equal the new

prescribed time in bed. A lower limit of 5 hours is set to avoid severe sleep loss. Changes to the sleep window are made according to the following criteria for the previous week: a) when the mean sleep efficiency (SE) is > 90% the TIB gets increased by 15 minutes. b) When the mean SE is < 85%, the TIB is decreased to the mean total sleep time (TST) of the previous five days. c) If the mean SE is in between 90% and 85%, then the TIB is not altered.

Specific factors component control:
Bedtime consistency therapy is the comparator of choice, because - similar to SRT - it involves sleep monitoring via daily diary, adherence to behavioural advice, and permits matching for therapist time and attention. However, unlike SRT, it does not aim to increase sleep efficiency or reduce time in bed. In this way BCT is a specific factors component control.
In the BCT group, participants are instructed to maintain consistent bed and rise-times. The sleep window is based on the average time in bed of the previous two baseline weeks and rising time is set to fit the individual's working day. Participants are introduced to a bed time consistency checklist, whereby they have to check if the previous reported daily bed and rise times were within 10 minutes of the new scheduled bed and rise times. Participants are informed that the bed time consistency will be reviewed on a weekly basis, at the overnight recordings and during the check-up phone calls.

Intervention Type
Behavioural

Primary outcome(s)
Self-reported insomnia severity is measured by the insomnia severity index (ISI) at baseline, post-treatment (4 weeks) and follow-up (12 weeks)

Key secondary outcome(s)
Secondary clinical outcomes:
2. Wake time after sleep onset (WASO) and sleep onset latency (SOL) are derived from continuous daily sleep diary (consensus sleep diary)
3. Quality of life is measured by the Glasgow sleep impact index (GSII) baseline, post-treatment (4 weeks) and follow-up (12 weeks)
4. Self-reported symptoms of depression and anxiety are measured by the hospital anxiety and depression scale (HADS) at baseline, post-treatment (4 weeks) and follow-up (12 weeks)
5. Self-reported cognitive complaints are measured with the British Columbia Cognitive Complaints Inventory (BC-CCI) at baseline, post-treatment (4 weeks) and follow-up (12 weeks)

Primary mechanistic outcome:
1. Objective sleep continuity will be obtained by polysomnography at baseline, during the acute treatment (1 week) and at the end of treatment (4 weeks)

Secondary mechanistic outcomes:
1. Objective sleep continuity (SOL and WASO) will be obtained by continuous actigraphy (2 weeks baseline and 4 weeks treatment)
2. Homeostatic sleep drive will be obtained by slow wave activity derived from polysomnography (PSG) at the end of week of treatment 1 and 4
3. Subjective sleepiness is measured by:
3.1. Daily self-reported sleep diary (2 weeks baseline, 4 weeks treatment)
3.2. The Epworth sleepiness scale (ESS) measured at baseline, weekly during treatment phase weeks 1-4 and at follow-up (12 weeks)
4. Objective sleepiness is measured by the psychomotor vigilance task (PVT) at baseline and at

the end of treatment week 1 and 4
5. Objective-subjective discrepancy of sleep estimates are derived from continuous sleep diary and actigraphy estimates over a 6-week period (2 weeks baseline, 4 weeks treatment) and polysomnography measurements at baseline and at the end of treatment week 1 and 4
6. Variability estimates of SOL, WASO and total sleep time (TST) extracted from continuous sleep diary and actigraphy over a 6-week period (2 weeks baseline, 4 weeks treatment)
7. Variability estimates of SOL, WASO and TST extracted from continuous sleep diary and actigraphy over a 6 week period (2 weeks baseline, 4 weeks treatment)
8. Attention bias to sleep stimuli is measured with the dot-probe task performed at baseline and at the end of treatment week 1 and 4
9. Self-reported adverse events are measured by the symptom checklist at the end of treatment week 1, 2, 3 and 4
10. Cognitive pre-sleep arousal and sleep-related thoughts are measured:
10.1. Continuously with 5 items of the pre-sleep arousal scale (PSAS) included in the sleep diary
10.2. Weekly and point-in time versions of the PSAS and the Glasgow Content of Thoughts Inventory (GCTI) are obtained at baseline and at the end of treatment week 4 and at follow-up (12 weeks)

Completion date
13/06/2018

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Adults aged 25-55 years
3. Screening positive for persistent insomnia (chronicity >3 months) as indicated on the Sleep Condition Indicator
4. Access to the internet with a tablet, laptop or desktop computer
5. Regular use of a personal mobile phone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
56

Key exclusion criteria
1. Psychiatric diagnoses other than insomnia
2. Anxiety (anxiety items of the HADS >10)
3. Depression (PHQ > 10)

4. Current substance misuse
5. Additional sleep disorders other than insomnia (e.g. narcolepsy, circadian rhythm disorder)
6. Sleep-disruptive medical comorbidity or conditions contraindicated for SRT (e.g. epilepsy)
7. Current prescription of medication or psychotherapy for sleep
8. Overnight shift work, evening, or rotating shift work
9. Pregnancy
10. Not living in the area of Oxford (participants' homes had to be accessible by the researcher for ambulatory PSG)

Date of first enrolment
01/08/2017

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
-
Oxford
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Dr. Mortimer and Theresa Sackler Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/11/2020	02/12/2020	Yes	No
Results article		31/08/2021	01/09/2021	Yes	No