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The effects of sleep restriction therapy for insomnia on sleep-related melatonin levels: the ESPRIT study

Submission date
15/03/2019

Recruitment status
No longer recruiting

Registration date
15/03/2019

Overall study status
Completed

Last Edited
01/02/2021

Condition category
Nervous System Diseases

[X] 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. The treatment Studies in good sleepers have shown that a restricted time in bed, in combination with partial sleep deprivation, has effects beyond sleep and impacts the underlying circadian system. To date, no study has investigated how SRT affects the relationship between the circadian system and the sleep-wake cycle in insomnia. We therefore propose an exploratory within-subjects study design to determine the acute treatment effects of SRT on the relationship of the circadian system and the sleep-wake cycle (i.e. the timings of being awake and asleep).

Who can participate?
Persons aged 25 - 55 years who are suffering from insomnia and meet the other inclusion criteria can participate.

What does the study involve?
Participants will be prescribed a new bed and rise time that aims to consolidate sleep but also induces partial sleep deprivation during the acute treatment phase as time in bed is restricted. At the end of each week, bed and rise times will be modified based on sleep performance over the previous week. The study will last for 2 weeks.

What are the possible benefits and risks of participating?
All participants will receive sleep restriction therapy, a non-pharmacological treatment for insomnia recommended by the 'American Academy of Sleep Medicine' (AASM). Furthermore, all participants will be reimbursed £40 for each completed study phase (Baseline, Post-treatment). Thus, the payment for completing the study in full is £80. All participants who are interested in receiving a summary of the study findings will also be sent a copy of this at the end of the study via email. Furthermore, each participant will receive individual feedback about their melatonin levels at baseline. This includes explaining how the underlying circadian rhythms work and how the obtained measurements relate to them.

Where is the study run from?
Sleep and Circadian Neuroscience Institute, Sir William Dunn School of Pathology, Oxford.

When is the study starting and how long is it expected to run for?
April 2019 to December 2019

Who is funding the study?
Dr. Mortimer and Theresa Sackler Foundation

Who is the main contact?
Leonie Maurer, leonie.maurer@ndcn.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R60730

Study information

Scientific Title
Investigating the Effects of Sleep Restriction Therapy for Insomnia on Circadian Timing

Acronym

ESPRIT

Study objectives
To demonstrate a treatment effect of sleep restriction therapy on the alignment of the circadian system and the sleep homeostat.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/01/2019, Medical Sciences Interdivisional Research Ethics Committee (SSH IDREC Manager, Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD; 01865 (6)16578; ethics@socsci.ox.ac.uk), ref: R60730

Study design
Single centre non-randomised within-subjects interventional pilot study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Sleep restriction therapy (SRT) involves prescribing a restricted time in bed (TIB, 'sleep window') based on an individual's reported duration and pattern of sleep. The estimated total sleep time (TST) across the previous time span is averaged and initially used to set the sleep window. For example, a patient who reports to spend 9 hours in bed but only reports 6 of those sleeping would be assigned a 6 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 TIB. 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 over the previous week:
a) when the mean sleep efficiency (SE) is > 90% TIB is increased by 15 minutes.
b) When mean SE is < 85%, TIB is decreased to the mean TST of the previous 7 days.
c) If mean SE is 85-89%, then TIB is not altered.
In the present study SRT will be delivered and monitored over a 2-week period. Treatment will involve one main intervention session (45 minutes) to review baseline sleep diaries, discuss the rationale for SRT, and set a prescribed sleep window for the forthcoming week. Titration of the sleep window will be performed at the end of week 1 and 2. Instructions will be provided to the participant to support self-titration of the sleep window at home beyond the two week monitored phase. Adherence will be measured by continuous sleep diary and actigraphy.

Intervention Type
Behavioural

Primary outcome(s)
The Phase angle (in minutes) between dim light melatonin onset (DLMO) and average attempted sleep over the past 7 days, measured by sleep diary (Phase angle = attempted sleep

time – clock time of the DLMO) at baseline and post-treatment. DLMO will be measured by hourly collected saliva samples under standardised, dim light conditions at the sleep laboratory over an 8-9 hour period.

Key secondary outcome(s))
1. DLMO at baseline and post-treatment
2. Subjective and objective sleep consolidation at baseline and post-treatment indexed via the following sleep parameters: SE, SOL, and WASO
3. Repeated hourly assessment of subjective alertness (sleepiness question) and objectively-measured sustained attention (PVT) obtained at the laboratory sessions at baseline and post-treatment
4. Insomnia severity assessed by the ISI at baseline and post-treatment
5. Daytime impairments assessed by the ESS and the BC-CCI at baseline, after the first week of treatment and after the second week of treatment (post-treatment)
6. Daily changes in mood assessed by 6 mood items (3 negative, 3 positive) included in the evening part of the sleep diary and measured continuously over the whole study period (1 week baseline, 2 weeks treatment)
7. Daily changes in pre-sleep arousal (5 items of the pre-sleep arousal scale) and sleep effort as assessed by the morning part of the sleep diary and measured continuously over the whole study period (1 week baseline, 2 weeks treatment)

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study.
2. Male or Female, aged 25-55 years
3. Screen positive for persistent insomnia (chronicity >3 months) as indicated on the Sleep Condition Indicator and meet DSM-5 criteria for insomnia disorder
4. Sleep efficiency < 85%
5. Intermediate chronotype as indicated by the Morningness-Eveningness questionnaire (score between 31 and 69)
6. Participant is able to comply with study procedures
7. Body mass index between 18 and 30 kg/m2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Total final enrolment
18

Key exclusion criteria
1. Clinically significant anxiety or depressive symptoms (Anxiety (HADS) > 10)
2. Psychiatric diagnoses other than insomnia
3. Previous or current engagement with psychological treatment for insomnia (by healthcare professional or online)
4. Additional sleep disorder diagnosis or positive screen (e.g. Narcolepsy, circadian rhythm disorder)
5. Sleep-disruptive medical comorbidity or conditions contraindicated for SRT (e.g. epilepsy)
6. Current prescription of CNS or hormonal medication
7. Overnight, early morning, evening, or rotating shift work in the last 3 months
8. Pregnancy, lactation, perimenopausal or menopausal
9. Travelled across more than 2 time zones in the prior 3 months
10. Smoked more than 5 cigarettes/week in the previous 3 months
11. Consumed more than 300mg of caffeine per day on average
12. Extreme alcohol consumption (score >10 on the alcohol use disorders identification test = AUDIT)
13. Any comorbidities that are causing the sleep problems
14. History of drug abuse in the past 12 months

Date of first enrolment
01/04/2019

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sleep and Circadian Neuroscience Institute
Sir William Dunn School of Pathology
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Oxford
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OX1 3RE

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 current data sharing plans for this study are unknown and will be 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	13/12/2020	01/02/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes