ISRCTN19682964 https://doi.org/10.1186/ISRCTN19682964

Digital sleep treatment for metabolic health in people who are at high risk of type 2 diabetes and have insomnia

Submission date
31/01/2022

Recruitment status
No longer recruiting

Registration date
02/02/2022

Overall study status
Completed

Last Edited
09/04/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Frequent problems with falling asleep or staying asleep (insomnia) have been linked to the development of type 2 diabetes. Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high. We would like to test whether improving sleep, through an effective behavioural treatment called cognitive behavioural therapy, can help improve metabolic health in people who are at risk of type 2 diabetes. This is best tested in a randomised controlled trial (a large study with lots of participants undergoing different procedures to compare which is best) but before we test this idea in a large group, we will be conducting this small feasibility study (SleepTMH) to see how the study might work. The SleepTMH study will allow us to gather data to inform the design of a future randomised controlled trial.

Who can participate?
We are inviting 20 people who regularly struggle to fall asleep or stay asleep during the night and who may have a risk of developing diabetes in the future. This is determined by your recent blood glucose tests conducted by your GP or previous conversations you may have had with your GP. You may not necessarily develop diabetes but your records suggest you might be at risk in the future and you may be eligible for the study.

What does the study involve?
Participants will be identified at up to ten participating primary care sites in Oxfordshire. All potential participants will be asked to complete an eligibility assessment. Eligible participants will be invited to attend a Baseline appointment (Visit 1) at the Oxford Centre for Diabetes Endocrinology and Metabolism (OCDEM) Clinical Research Unit (CRU) at the Churchill Hospital where informed consent will be taken and baseline assessments completed.

Participants will also be fitted with a continuous glucose monitor (CGM) and asked to wear it and an actigraph watch for 7 days. This is the first of at least four face-to-face contacts with participants. After 7 days (Week 1, Visit 2) the CGM and actigraph watch will be removed and the participant will be asked to begin using the Sleepio® digital CBT sleep intervention for the next

10 weeks. Participants will be invited back to the OCDEM CRU during week 11 (Visit 3) where post-intervention assessments will be carried out. Participants will again be fitted with a CGM and an actigraph watch and asked to wear these for the next 7 days. 7 days later (week 12, Visit 4) the CGM and actigraph will be removed, marking the end of study participation. Post- study, participants will be invited to a voluntary telephone call with a member of the research team to give feedback on the study. This is in addition to the formal study procedures and there will be no requirement on the participant to complete this additional task. Study Participation will last for approximately 12 weeks from the time consent is provided with an additional four weeks post participation to complete the optional trial feedback interview (a maximum duration of approximately 16 weeks).

What are the possible benefits and risks of participating?
The Sleepio programme has been found to improve sleep quality in the majority of users. There is therefore a good possibility that your sleep quality will improve as a result of completing the programme. If your sleep does improve we think this could also be beneficial to metabolic health, however this is what we hope to find out by conducting research and so we cannot guarantee you will see any such benefits. We hope that this work will inform the design of future research studies and may help other patients in the future.
You will receive a £25 Amazon voucher after returning the CGM and actigraph watch during visit 2 and visit 4. As such if you complete the study in full you will receive a total of £50 of Amazon vouchers over the course of the study

As part of the study you will be asked to provide some blood samples and wear a continuous glucose monitor (CGM). All blood samples will be taken by a qualified member of the research team to minimise the possibility of bruising. Some people can find the experience of blood being drawn as uncomfortable or they may feel lightheaded or faint. Equally, some people may find the experience of having a CGM fitted uncomfortable. The CGM may itch or become uncomfortable as you wear it. The Sleepio programme involves making changes to your sleep pattern that may cause a short-term increase in sleepiness. If you do feel sleepy during the study we advise that you avoid activities that require a high degree of vigilance, such as driving or operating heavy machinery. If you become concerned about your mental or physical health at any time during the study we recommend that you speak with your GP/doctor. You are free to stop the sleep improvement programme at any point. You will be asked questions about your mental health and how you are feeling. If you find this too distressing, you can take a break from answering questions. You can also decline to answer certain questions. You will have to attend two approximately hour/ hour and a half long clinic visits with two further (much shorter) visits to retrieve the study equipment and SleepTMH Sleep Diary.

Where is the study run from?
This study is organised by researchers based at the Departments of Clinical Neurosciences, and Primary Care Health Sciences at the University of Oxford (UK) alongside the Oxford Centre for Diabetes, Endocrinology and Metabolism, where the study procedures will take place.

When is the study starting and how long is it expected to run for?
August 2019 to March 2024

Who is funding the study?
NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?
Associate Professor Simon Kyle, simon.kyle@ndcn.ox.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Simon Kyle

ORCID ID
https://orcid.org/0000-0002-9581-5311

Contact details
Sir Jules Thorn Sleep and Circadian Neuroscience Institute (SCNi)
Nuffield Department of Clinical Neurosciences
New Biochemistry Building
University of Oxford
South Parks Road
Oxford
United Kingdom
OX1 3QU
+44 1865618675
simon.kyle@ndcn.ox.ac.uk

Type(s)
Public

Contact name
Dr Rachel Sharman

Contact details
Sir Jules Thorn Sleep and Circadian Neuroscience Institute (SCNi)
Nuffield Department of Clinical Neurosciences
New Biochemistry Building
University of Oxford
South Parks Road
Oxford
United Kingdom
OX1 3QU
+44 1865618675
rachel.sharman@ndcn.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
266313

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
IRAS 266313, CPMS 44649

Study information

Scientific Title
Sleep improvement for metabolic health: feasibility trial of a digital sleep treatment in people who are at high risk of type 2 diabetes and have insomnia

Acronym
SleepTMH

Study objectives
This is a feasibility study to determine feasibility of recruiting participants with a high risk of type 2 diabetes who have insomnia from primary care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/03/2020, East of England - Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 2071048227; Essex.REC@hra.nhs.uk), ref: 20/EE/0046

Study design
Single-arm feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
People who are at high risk of type 2 diabetes and have insomnia

Interventions
Participants will also be fitted with a continuous glucose monitor (CGM) and asked to wear it and an actigraph watch for 7 days. This is the first of at least four face-to-face contacts with participants. After 7 days (Week 1, Visit 2) the CGM and actigraph watch will be removed and the participant will be asked to begin using the Sleepio® digital CBT sleep intervention for the next 10 weeks. Participants will be invited back to the OCDEM CRU during week 11 (Visit 3) where post-intervention assessments will be carried out. Participants will again be fitted with a CGM and an actigraph watch and asked to wear these for the next 7 days. 7 days later (week 12, Visit 4) the CGM and actigraph will be removed, marking the end of study participation. Post- study, participants will be invited to a voluntary telephone call with a member of the research team to give feedback on the study. This is in addition to the formal study procedures and there will be no requirement on the participant to complete this additional task. Study Participation will last

for approximately 12 weeks from the time consent is provided with an additional four weeks post participation to complete the optional trial feedback interview (a maximum duration of approximately 16 weeks).

Intervention Type
Behavioural

Primary outcome(s)
Ability to recruit participants from primary care measured by site activity reports and recruitment rate during the planned study period (12 months).

Key secondary outcome(s))
1. Engagement with digital sleep treatment: Proportion of participants who complete ≥ 4 out of 6 Sleepio® intervention sessions by week 12.
2.1. Insomnia measured with the Insomnia severity index (ISI) at baseline and week 12
2.2. Health status measured with the EuroQoL (EQ-5D) at baseline and week 12
2.3. Depressive symptoms measured with the Center for Epidemiologic Studies Depression Scale (CES-D) at baseline and week 12
2.4. Self-reported sleep measured with the consensus sleep diary (CSD) at baseline and week 12.
2.5. Working memory performance measured with the visual short term memory task (VSTM) at baseline and week 12.
2.6. Rest-activity rhythms measured with actigraphy at baseline and week 12.
2.7. Glucose metabolism recorded by the G6 continuous glucose monitor for 7 days at baseline and week 12
2.8. Fasting blood test (for HbA1c, FBC, C+E/lipids, glucose and biomarker) measured at baseline and week 12.
3. Participant acceptability of the trial ascertained via semi structured interview (performed within 4 weeks of conclusion of 12 week intervention phase).

Completion date
08/03/2024

Eligibility

Key inclusion criteria
1. HbA1c 6-6.4% within the past 12 months and/or a diagnosis of pre-diabetes
2. Insomnia disorder
3. Reliable access to the internet
4. Capable of attending visits at the OCDEM Clinical Research Unit (CRU) at Oxford
5. Capable of complying with the study procedures and intervention
6. Able to understand study instructions in English
7. Age ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Diagnosis of diabetes/prescribed diabetes medication
2. Prescribed sleep medication
3. Diagnosed or probable obstructive sleep apnea (OSA), narcolepsy, restless legs syndrome /periodic limb movement disorder, circadian sleep-wake rhythm disorder, parasomnia;
4. Psychosis (schizophrenia or bipolar disorder)
5. Shift worker
6. Dementia or mild cognitive impairment
7. Suicidal ideation with intent
8. Epilepsy
9. Pregnant/planning pregnancy
10. Previously accessed or used the Sleepio® programme or is a current user
11. Currently receiving psychological therapy for insomnia or enrolled in another sleep intervention trial
12. Allergy to hypoallergenic adhesive plasters

Date of first enrolment
28/02/2022

Date of final enrolment
15/11/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
Sir Jules Thorn Sleep and Circadian Neuroscience Institute (SCNi)
Nuffield Department of Clinical Neurosciences
New Biochemistry Building
University of Oxford
South Parks Road

Oxford
United Kingdom
OX1 3QU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes