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Defining the impact of improved sleep on cognitive function

Submission date
11/10/2016

Recruitment status
No longer recruiting

Registration date
17/10/2016

Overall study status
Completed

Last Edited
01/06/2020

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 is a type of sleep disorder which involves an inability to initiate and/or maintain sleep with several daytime consequences, such as extreme tiredness (fatigue), mood disturbances, poor concentration and memory problems. This study is looking at a digital Cognitive Behavioural Therapy (a type of therapy that changes behaviour) for insomnia called Sleepio, in order to find out if it can improve cognition (mental processing) and whether any changes are the result of changes in sleep. To find out whether better sleep improves people's cognition, participants will be offered an online/mobile phone-delivered course, proven (through previous research) to improve sleep. The aim of this study is to see whether those people who receive this course immediately see any changes in their cognition (specifically their concentration and memory) in comparison to those people who do not receive this treatment and are placed on a wait-list to receive the treatment after a period of 24 weeks.

Who can participate?
Men and women aged 25 and over who complain of insomnia and difficulties with concentration or memory.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in the first group receive the CBT course immediately, delivered using the web and/or mobile phones. The CBT course consists of 6 weekly, tailored sessions with a virtual animated therapist, and access to a range of digital tools (such as an online sleep diary and audio help) and an online community of people who are also working through the programme. Those in the second group are placed on a waiting list and so do not receive any treatment. Both groups complete online surveys and computerised tasks at weeks 0 (start of treatment), 10 (after treatment) and 24 weeks (follow-up). At week 25 all participants allocated to the wait-list control group are offered the CBT course as well. The online surveys measure self-reported cognitive impairment, insomnia severity, fatigue, sleepiness, mood, chronotype (behaviour related to biological clock), sleep medication usage and usage of other sleep treatments. The computerised tasks measure cognitive performance by assessing simple attention, episodic memory (memory of events in the order they happen), working memory (ability to hold on to and mentally manipulate information over short periods of time), visual attention and complex processing speed.

What are the possible benefits and risks of participating?
CBT is likely to be both interesting and helpful to participants. Compensation will also be provided via Amazon vouchers. A voucher code will be emailed upon completion of each assessment point. The amounts will be £5 for the 0-week assessment, £10 for the 10-week assessment and £15 for the 24-week assessment. There are no notable risks associated with participating in this study.

Where is the study run from?
The study is run by the University of Oxford and takes place on the internet (UK)

When is the study starting and how long is it expected to run for?
May 2016 to January 2018

Who is funding the study?
National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (UK)

Who is the main contact?
1. Ms Madeleine Hurry (public)
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2. Dr Claire Sexton (scientific)
3. Dr Simon Kyle (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Defining the Impact of improved Sleep on COgnitive function: a randomised-controlled trial of digital Cognitive Behavioural Therapy for insomnia versus wait-list control

Acronym
DISCO

Study objectives
Primary hypothesis:
1. Digital CBT-I will reduce self-reported cognitive impairment at the end of treatment (10 weeks) relative to WLC

Secondary hypotheses:
1. Digital CBT-I will reduce self-reported cognitive impairment at follow-up (24 weeks) relative to

WLC
2. The digital CBT intervention will result in improvements in simple attention, visual attention, episodic memory, working memory, and complex processing speed, relative to WLC (10 and 24 weeks)
3. Digital CBT-I will reduce insomnia severity and improve sleep efficiency relative to WLC (10 and 24 weeks)
4. Changes in insomnia (severity and sleep efficiency) at week 10 will mediate change in self-reported cognitive impairment and task performance at week 24
5. Digital CBT-I will lead to improvements in fatigue, sleepiness, self-reported cognitive failures, depression and anxiety relative to WLC (week 10 and 24)
6. Advancing age will be positively associated with treatment-related improvements in self-reported cognitive impairment and objective cognitive performance

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Sciences Inter-divisional Research Ethics Committee (IDREC), 28/07/2016, ref: R46116/RE001

Study design
Single-centre parallel group superiority interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Participants are randomised to one of two study groups in a 1:1 ratio using an in-built randomisation feature in the survey software.

Treatment group: Participants recieve digital Cognitive Behavioural Therapy (dCBT) delivered via the Sleepio programme. This comprises of six weekly 30 minute sessions delivered by an animated virtual therapist, plus self-monitoring and report of sleep parameters and mood. In addition to this, participants continue to receive their usual treatment.

Control group: Participants are placed on a waiting list and receive only their usual treatment for 24 weeks. At 25 weeks, participants in this group are given the opportunity to receive the dCBT course.

At 10 and 24 weeks, participants in both groups complete a range of online surveys to assess self-reported cognitive impairment, insomnia severity, fatigue, sleepiness, mood, chronotype, sleep medication usage and usage of other sleep treatments, as well as computerised tasks to measure cognitive performance by assessing simple attention, episodic memory, working memory, visual attention and complex processing speed.

Intervention Type
Behavioural

Primary outcome measure
Self-reported cognitive impairment is measured using the British Columbia Cognitive Complaints Inventory (BC-CCI) at baseline, post-treatment (10 weeks) and follow-up (24 weeks)

Secondary outcome measures
1. Objective cognitive performance is measured using an online battery of tasks developed by UK Biobank Cognitive Psychology Sub-Group for Cognitive Assessments, including measures of simple attention, episodic memory, working memory, visual attention and complex processing speed at baseline, 10 and 24 weeks
2. Insomnia severity is measued using the Insomnia Severity Index (ISI) and four items from Pittsburgh Sleep Quality Index (PSQI) at baseline, 10 and 24 weeks
3. Fatigue is measured using the Multidimensional Fatigue Inventory (MFI) at baseline, 10 and 24 weeks
4. Sleepiness is measured using the Epworth Sleepiness Scale (ESS) at baseline, 10 and 24 weeks
5. Cognitive failures is measured using the Cognitive Failures Questionnaire (CFQ) at baseline, 10 and 24 weeks
6. Emotional distress (depression and anxiety) will be measured using the Patient Health Questionnaire 9 (PHQ-9) and two items from the Generalised Anxiety Disorder 7 questionnaire (GAD-7) at baseline, 10 and 24 weeks
7. Information on the use of sleep medication will be collected by asking how many nights the participant has used prescribed or non-prescribed medication to aid sleep over the past two weeks at baseline, 10 and 24 weeks

In addition:
8. Additional sleep treatment usage is assessed through asking participants during treatment and follow-up phase
9. Profiling of self-reported chronotype is done using one item from the Morningness-Eveningness Questionnaire (MEQ) at baseline

Overall study start date
01/05/2016

Completion date
28/01/2018

Eligibility

Key inclusion criteria

1. Positive screen for probable DSM-5 insomnia disorder using items from the Sleep Condition Indicator (SCI)
2. Endorsement of difficulties with concentration or memory
3. Being aged 25 and above
4. Reliable internet access at home or work
5. Being able to read and understand English
6. Currently living in the UK

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
404

Total final enrolment
410

Key exclusion criteria
1. Additional sleep disorder (e.g. possible obstructive sleep apnoea, restless legs syndrome)
2. Diagnosis of mild cognitive impairment or dementia
3. Psychosis or mania
4. Serious physical health concerns necessitating surgery or with prognosis of <6 months
5. Those undergoing a psychological treatment programme for insomnia with a health professional
6. Habitual night, evening, or rotating shift-workers
7. Those taking prescribed sleeping pills on study entry
8. Those with suicidal ideation

Participants will not be omitted for any other physical or mental health problems providing they report their health to be stable.

Date of first enrolment
18/10/2016

Date of final enrolment
21/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
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Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
National Institute for Health Research (NIHR) Oxford Biomedical Research Centre

Results and Publications

Publication and dissemination plan
Planned publication of the results of this study, irrespective of magnitude or direction of effect, in peer-reviewed journals. Findings will also be presented at national and international scientific meetings. The results will be made available online wherever possible, if permitted by journal policies.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The current 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?
Protocol article	protocol	17/06/2017		Yes	No
Results article	results	14/09/2020	01/06/2020	Yes	No