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Digital insomnia therapy to assist your life as well as your sleep

Submission date
03/12/2015

Recruitment status
No longer recruiting

Registration date
04/12/2015

Overall study status
Completed

Last Edited
19/12/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
We want to find out if digital Cognitive Behavioural Therapy (dCBT) can improve health and well-being and whether any changes are the result of changes in sleep. In particular we are interested in the impact that sleep has on quality of life, psychological well-being, mood, energy, relationships, concentration, productivity and sleepiness. To find out whether better sleep improves people's health, quality of life and well-being, we are offering participants an online /mobile phone delivered course, proven (through previous research) to improve sleep. We want to see whether those people who receive this course immediately see any changes in their health, quality of life and well-being in comparison to those people who receive sleep hygiene education (i.e., habits and practices to promote better quality sleep).

Who can participate?
Men and women above 18 years of age with complaints of insomnia (difficulty getting to sleep or staying asleep).

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives dCBT straight away, delivered using the web and/or mobile phones. dCBT 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. The second group receives sleep hygiene education, which consists of advice on habits and routines that will help them to sleep better, provided via a website and a downloadable booklet. Both groups complete online surveys at weeks 0 (start of treatment), 4 (mid-treatment), 8 (after treatment), and 24 weeks (follow-up). At week 25 all participants allocated to sleep hygiene education are offered dCBT as well. Participants are invited to complete two more surveys at weeks 36 and 48. The online survey measures health and wellbeing, sleep, mood, fatigue, sleepiness, concentration, productivity and social functioning.

What are the possible benefits and risks of participating?
dCBT and sleep hygiene education are likely to be both interesting and helpful. They are not considered to involve significant risk to participants.

Where is the study run from?
The study will be coordinated at the University of Oxford, UK, but participants can be from anywhere around the world as the study will be completely online.

When is the study starting and how long is it expected to run for?
April 2015 to July 2017

Who is funding the study?
BigHealth Ltd (UK)

Who is the main contact?
Prof. Colin Espie or Dr Annemarie Luik
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Study website
www.sleepio.com/research/dials

Contact information

Type(s)
Scientific

Contact name
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Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of fully automated digital cognitive behavioural therapy for Insomnia versus sleep hygiene education: the impact of improved sleep on functional health and wellbeing

Acronym
DIALS

Study objectives
The primary hypotheses for the trial are that, compared to SHE:
1. The dCBT intervention will improve functional health status by the end of treatment (8 weeks)
2. The dCBT intervention will improve positive psychological wellbeing by the end of treatment (8 weeks)
3. The dCBT intervention will reduce patient-generated sleep-related quality of life impairment (8 weeks)
4. The effect of dCBT on outcomes (8 weeks) will be mediated by sleep status during the treatment phase (4 weeks)

The secondary hypotheses are that, compared to SHE:
1. The dCBT intervention will reduce symptoms of negative mood, fatigue and relationship /social dysfunction by the end of treatment (8 weeks)
2. The dCBT intervention will reduce problems with sleepiness, concentration and productivity by the end of treatment (8 weeks)
3. Improvements will be maintained at follow up (24, 36, 48 weeks)
4. The effect of dCBT on longer-term outcomes (24, 36, 48 weeks) will be mediated by sleep status during and upon completion of the treatment phase (4, 8 weeks)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Sciences Inter-divisional Research Ethics Committee, University of Oxford, 15/10/2015, ref: MS-IDREC-C2-2015-024

Study design
Parallel-group superiority randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
www.sleepio.com/research/dials

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

Interventions
All recruitment and study contact will be online, participants will be actively recruited in the UK, USA and Australia but participation is not limited to inhabitants of these countries.

Intervention: Digital Cognitive Behavioural Therapy for Insomnia + Treatment As Usual
Control: Sleep Hygiene Education + Treatment As Usual, after 24 weeks participants will receive access to the digital Cognitive Behavioural Therapy for Insomnia

Intervention Type
Behavioural

Primary outcome measure
1. Functional health and wellbeing: Global Health scale (PROMIS-10, Hays et al, 2009)
2. Psychological wellbeing: Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS, Tennant et al, 2007)
3. Sleep-related quality of life: Glasgow Sleep Impact Index (GSII, Kyle et al 2013)
All these measures will be taken at baseline, 4 weeks, 8 weeks, 24 weeks, 36 weeks and 48 weeks.

Secondary outcome measures
1. Mood: Patient Health Questionnaire (PHQ9, Kroenke, Spitzer & Williams, 2010) and Generalised Anxiety Disorder (GAD, Spitzer, Kroenke & Williams, 2006)
2. Energy: Flinders Fatigue Scale (FSS, Gradisar et al., 2007)
3. Relation satisfaction: Relation Assessment Scale (RAS, Hendrick et al., 1988)
4. Cognitive status: Cognitive Failures Questionnaire (CFQ, Broadbent, 1982)
5. Work performance and satisfaction: Work and Productivity and Activity Impairment Questionnaire (WPAI, Reilly et al., 1993) and 1 item about job satisfaction (Dolbier et al., 2005)
6. Sleepiness: Epworth Sleepiness Scale (ESS, Johns, 1991)
7. Life satisfaction (1 item, Cheung et al, 2014)
8. Sleep improvement: Sleep Condition Indicator (SCI, Espie et al, 2014)

All these measures will be taken at baseline, 4 weeks, 8 weeks, 24 weeks, 36 weeks and 48 weeks.

Overall study start date
01/04/2015

Completion date
01/07/2017

Eligibility

Key inclusion criteria
1. A positive screen for probable DSM-5 insomnia disorder
2. A test score of ≤16 on the Sleep Condition Indicator
3. Being aged 18 or older (no upper age limit)
4. Having reliable internet access at home or at work
5. Being able to read and understand English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Total final enrolment
1711

Key exclusion criteria
We will screen for comorbid conditions and medication use at baseline but exclude only those people whose health may be considered to be unstable such as significant current symptoms of:
1. An additional sleep disorder (e.g., excessively sleepy and possible obstructive sleep apnea)
2. Psychosis or mania
3. Serious physical health concerns necessitating surgery or with prognosis <6 months
4. Those undergoing a psychological treatment programme for insomnia with a health professional
5. Habitual night shift, evening, or rotating shift-workers.
We will not omit participants who take medication for sleep problems, or for any other physical or mental health problems providing they report their health to be stable.

Date of first enrolment
01/12/2015

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
Australia

England

United Kingdom

United States of America

Study participating centre
University of Oxford
United Kingdom
OX1 3RE

Study participating centre
BigHealth Ltd
United Kingdom
E1 6LT

Study participating centre
University of Sydney
Australia
NSW 2006

Study participating centre
Henry Ford Health Systems
United States of America
MI 48202

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Research Services
University Offices
Wellington Square
Oxford
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United Kingdom
OX2 2JD

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
BigHealth Ltd (UK)

Results and Publications

Publication and dissemination plan
Results of the study will be presented at national and international scientific meetings and will be published in leading peer-reviewed scientific journals.

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/05/2016		Yes	No
Results article	results	01/01/2019		Yes	No
Results article	results	01/08/2020	02/03/2020	Yes	No

Other publications	Secondary analysis of effects on QALYs	10/10/2022	11/10/2022	Yes	No
Other publications	Interaction between symptopms and impairment	08/12/2022	19/12/2022	Yes	No