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Evaluation of internet cognitive behavioural therapy for insomnia disorder

Submission date
18/01/2011

Recruitment status
No longer recruiting

Registration date
18/05/2011

Overall study status
Completed

Last Edited
17/12/2012

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims:
This study was carried our to investigate if online cognitive behaviour therapy (CBT) given via the internet would be effective in the treatment of persistent insomnia. Insomnia is a very common problem, so providing treatment in this way could potentially reach many people who have problems sleeping. CBT is a non-drug treatment where people are helped to overcome the problem of the racing mind, and to establish a new healthy sleep pattern.

Who can participate?
Adults with persistent sleep problems, identified from their participation in the online Great British Sleep Survey.

What does the study involve?
People were randomly allocated to receive CBT, the standard treatment, or to a group that had to wait to receive treatment. In all groups information on sleep, mood and daytime functions (like energy and concentration) were gathered regularly so that we could evaluate the outcomes across the 6 weeks. They were then followed up 8 weeks later to see if benefits lasted. The online CBT was delivered by a virtual sleep expert (a cartoon character).

What are the possible benefits and risks of participating?
Benefits of participating included improvement in daytime wellbeing and in quality of sleep. There were no known risks associated with participating in the trial.

Where is the study run from?
The study was run online and there was no contact with participants except by email and through the web-based programme.

When is study starting and how long is it expected to run for?
The study ran from February to June 2011.

Who is funding the study?
Sleepio Ltd, London, UK

Who is the main contact?
Professor Colin Espie
colin@sleepio.com

Study website
https://www.sleepio.com/research/

Contact information

Type(s)
Scientific

Contact name
Prof Colin Espie

Contact details
University of Glasgow Sleep Centre
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FM06509

Study information

Scientific Title
The comparative efficacy of online cognitive behavioural therapy (CBT) versus online imagery relief therapy (IRT) as treatments for insomnia disorder: a randomised placebo controlled trial

Acronym
Sleepio

Study objectives
Online cognitive behavioural therapy (CBT) for adults with insomnia disorder will be associated with increased sleep efficiency at post treatment relative to a to a credible placebo intervention and a waiting list control condition

Ethics approval required

Old ethics approval format

Ethics approval(s)
University of Glasgow Faculty of Medicine Research Ethics Committee approved on the 20th August 2010

Study design
Placebo controlled randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
This is a pragmatic, randomised controlled trial comprising three treatment arms:
1. Online cognitive behavioural therapy (CBT)
2. Online IRT (placebo)
3. Waiting list comprising usual care (treatment as usual [TAU])
2. Major assessments will be at baseline, post-treatment, and follow-up 6 weeks and 12 weeks later
3. All data will be analysed on an intention to treat basis
4. Participants randomised to the IRT placebo or TAU care arm will be offered CBT upon completion of the study.
5. CBT: is a 6 session treatment course guided by an animated personal therapist. It is both engaging and interactive and uses email, SMS technologies, and other motivational tools to prompt and support the user to progressively and systematically implement behavioural and cognitive strategies
6. The rationale given is that thoughts and behaviour influence engagement with sleep, sleep pattern and sleep quality, and subsequent daytime functioning
7. The programme provides effective strategies to deal with sleeplessness, to reduce dysfunctional sleep behaviour, attitudes and beliefs, and to help restore normal sleep patterns
8. The content of the therapy is based entirely upon proven methods, such as sleep hygiene education, relaxation, imagery, stimulus control, sleep restriction, cognitive restructuring and other cognitive techniques
9. Social networking methods will also be used to afford support to people undertaking the CBT programme

10. IRT: is also is a 6 session treatment, designed to mimic the structure and ethos of CBT but without any known therapeutic ingredient or advice on dealing with sleeplessness.
11. Thus non-specific factors such as credibility, expectation, regular sessions and support will be controlled
12. The rationale and instructions are based on a quasi-desensitisation model
13. The participant constructs a list of chronologically ordered typical evening/bedtime activities and a list of 6 mental images
14. These are then paired with the hierarchy items in a pseudo-deconditioning paradigm 15. They are told that by using early evening regular practice they will become desensitised to their insomnia
16. The IRT placebo has been validated and found credible in numerous RCTs of face to face individual and group CBT for insomnia over the past 25 years
17. TAU: is essentially a wait list control condition, where people complete all measures at the required times, and are entirely free to continue with whatever their usual care for insomnia is
18. Indeed, this much is true for all 3 conditions. So for example; GPs are free to prescribe/or not, unaffected by participation in the study

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Sleep efficiency: this is the percentage of the time spend in bed that the person is asleep
2. Sleep Condition Indicator (SCI), a valid and reliable patient-reported outcome measure which is brief (8-item; range 0 - 32), valid (based on DSM-V) and reliable (a = 0.83). The SCI profiles daytime consequences of poor sleep and classifies clinical sleep status. Total
3. Derived sleep status category (very good, good, average, poor, very poor)
4. Measured at baseline, post-treatment evaluation and the 14 and 20 week follow-up evaluations

Secondary outcome measures
1. Standard daily sleep diary data (e.g. sleep onset latency, wakeful time after sleep-onset)
2. Depression Anxiety and Stress Scales (DASS)
3. Sleep Disturbance Questionnaire (SDQ)
4. Content of Thoughts Inventory (CTI)
5. Sleep Effort Scale (SES)
6. Descriptive information on demographics and general physical and mental health, including alcohol use and lifestyle
7. CBT user experience and satisfaction
8. Adherence with treatment advice
9. Measured at baseline, post-treatment evaluation and the 14 and 20 week follow-up evaluations

Overall study start date
01/03/2011

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Healthy participants from the community at large (18+ years, either sex)
2. Completed the on-line Great British Sleep Survey (www.sleepio.com)
3. Meet proposed Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) criteria for insomnia disorder: complaint of poor sleep (difficulty initiating and/or maintaining sleep, early morning wakening, or non-restorative sleep), with daytime consequences for greater than or equal to 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
156 (52 per condition)

Key exclusion criteria
1. Possible significant mental (e.g. depression) or physical health problems (e.g. cardiovascular disease)
2. Disorders of sleep other than insomnia (e.g. sleep apnoea)
3. Dementia
4. Heavy alcohol use, excluded conservatively
5. Using online screening tools

Date of first enrolment
01/03/2011

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre

University of Glasgow Sleep Centre
Glasgow
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G51 4TF

Sponsor information

Organisation
University of Glasgow (UK)

Sponsor details
College of Medicine
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Sponsor type
University/education

Website
http://www.gla.ac.uk/

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Industry

Funder Name
Sleepio Ltd (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2012		Yes	No