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Effectiveness of an internet-delivered treatment for insomnia

Submission date	Recruitment status	[ ] Prospectively registered
12/06/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/06/2016	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/10/2019	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Insomnia is a widespread health problem. Main symptoms are inability to initiate and/or maintain sleep with several daytime consequences as extreme tiredness (fatigue), mood disturbances, poor concentration and memory problems. Around 5-15% of the population are affected by insomnia in the long term. Medications such as seditives are most often used as treatment for insomnia, however cognitive behavioral therapy (CBT) (a type of talking therapy aiming to change the way a person behaves) has been proven to be similarly effective. Additionally, CBT also seems to be more effective in the long term, while sleeping pills can lead to physical and mental addiction. CBT is usually provided face-to-face by a trained therapist, however in the last years, research has shown that CBT programs can be delivered online. Several studies showed similar effects for online treatment of Insomnia in comparison to face-to-face therapy. The aim of this study is to investigate the effectiveness of an internet-based CBT program for the treatment of insomnia in the German language.

Who can participate?
Adults with insomnia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are placed on a waiting list to receive the treatment for eight weeks. Those in the second group take part in the internet-delivered therapist-assisted cognitive behavioral therapy for Insomnia (eCBT-I). This involves completing four treatment modules made up of a range of lessons and exercises designed to change behaviour relating to sleep. The treatment is completed at each participant's own pace, within a period of 8-12 weeks. After treatment and after the waiting period respectively, sleep quality is measured in both groups by a sleep diary and specific questionnaires, in order to compare the effect of the online treatment with the effect of no treatment (or waiting for the treatment). After 6 months, participants repeat the questionnaires to look at the long term effects of the treatment on sleep.

What are the possible benefits and risks of participating?
The online treatment may improve participant's sleep quality and mental state. There are no notable risks involved with participating

Where is the study run from?
Clinic for Sleep Medicine Luzerne (Switzerland)

When is study starting and how long is it expected to run for?
December 2011 to December 2014

Who is funding the study?
Clinic for Sleep Medicine Luzerne (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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
Internet-delivered Therapist-assisted Cognitive Behavioral Therapy for Insomnia: A randomised controlled trial

Study objectives
The investigated Internet-delivered and therapist-assisted cognitive behavioral therapy is more effective in alleviating insomnia in comparison to a wait-list control condition.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Dienststelle Gesundheit Luzern (Department of Health, Lucerne), 14/05/2012, ref: 12030

Study design
Single-centre 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
Available in German - See additional files

Health condition(s) or problem(s) studied
Primary insomnia

Interventions
Recruited and eligible participants are randomly assigned to one of two groups using a computerised random number generator (www.random.org). Block randomisation with 10 subjects was used to optimize the equal distribution between the two groups. Results of the initial screening questionnaires (including primary and secondary measures) were used as baseline values for both study groups.

Intervention group: Participants are led through the treatment by an online therapist. The online treatment includes the common elements of manualised 'best practice' CBT-I (psychoeducation, relaxation training, bedtime restriction, stimulus control, identification and modification of dysfunctional thoughts, mindfulness exercises) and is divided into four treatment modules. As in common face-to-face CBT, the treatment consists of psychoeducative and therapeutic lessons and subsequent written homework assignments. Interaction between therapist and participant occurs remotely by text messages which are sent on the secured treatment website. All written material by the therapist and the participant is subsequently logged in a personal Web-based workbook by the computer system. Treatment duration depends on the subject’s speed, between eight and 12 weeks. Participants not completing the treatment within 12 weeks are asked to complete post-treatment questionnaires and can then continue with the treatment.

Wait-list control group: Participants receive treatment after a 8 week waiting period and subsequent completion of primary and secondary measure questionnaires. These measurements serve as post-treatment values.

During the treatment at the end of each module, insomnia severity is measured by the ISI. After the treatment, all participants complete questionnaires for the post-treatment measures (ISI,

DBAS, BDI-II, BSI, QoL). All participantss are asked to complete a follow-up measurement at 6 months (after post-treatment) including the post-treatment measures and seven days of sleep diary.

Intervention Type
Behavioural

Primary outcome measure
1. Insomnia Severity is measured by the Insomnia Severity Index (ISI) at baseline, post-treatment (8-12 weeks) and 6 months post-treatment
2. Sleep parameters (Total Sleep Time (TST), Wake after Sleep Onset (WASO), Sleep Onset Latency (SOL), Sleep Efficiency (SE)) are measured by an online sleep diary which the subjects are keeping on the treatment website daily throughout the 8-12 weeks. The means of the first seven entries serve as baseline measurement, means of seven entries before post-treatment (8-12 weeks) serve as post-treatment measure and seven entries at follow up after 6 month post-treatment as follow up measure.

Secondary outcome measures
1. Depression is measured using the Becks Depression Inventory (BDI questionnaire) at baseline, post-treatment (8-12 weeks) and 6 months post-treatment
2. Psychological Strain is measured using the Global Symptom Index of the Brief Symptom Inventory (BSI questionnaire) at baseline, post-treatment (8-12 weeks) and 6 months post-treatment
3. Quality of Life is measured using a single direct question to provide subjective estimate on a scale of 1-10 (Likert scale) at baseline, post-treatment (8-12 weeks) and 6 months post-treatment
4. Dysfunctional beliefs and attitudes about sleep is measured using the DBAS questionnaire at baseline, post-treatment (8-12 weeks) and 6 months post-treatment

Participants in the waiting list group receive treatment after 8 weeks waiting period and do not have to wait until the 6 month follow up period. Follow-up measurements are compared in a pooled fashion (no controlled comparison between groups).

Overall study start date
01/12/2011

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Meeting the criteria of a clinically relevant primary insomnia (according to ISI score and DSM-IV criteria).
2. Aged 18 years and over
3. Swiss residency

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

Total final enrolment
62

Key exclusion criteria
1. No regular internet access
2. No full ability to read and write German.
3. Presence of another sleep disorder (sleep related breathing disorders, sleep related movement disorders, parasomnias)
4. Presence of psychiatric disorders (mood disorders, anxiety disorders, somatoform disorders, psychotic disorders, substance-related disorders), or history of such disorders in the past
5. Presence of suicidal tendencies
6. Regular use of sleep medication
7. Shift-work
8. Current psychological treatment
9. Somatic conditions that are known to cause insomnia.
10. Pregnancy

Date of first enrolment
01/09/2012

Date of final enrolment
01/02/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
Clinic for Sleep Medicine Luzerne (Klinik für Schlafmedizin Luzern)
Lützelmattstrasse 3
Lucerne
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6006

Sponsor information

Organisation
Clinic for Sleep Medicine Luzern (Klinik für Schlafmedizin Luzern)

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Sponsor type
Hospital/treatment centre

Website
www.ksm.ch

ROR
https://ror.org/04g5zwy64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clinic for Sleep Medicine Luzern (Klinik für Schlafmedizin Luzern)

Results and Publications

Publication and dissemination plan
A manuscript of a pilot study (including a detailed description and functional evaluation of the treatment used in the actual study to be registered) is intended for publication before the results of this trial. As soon as the pilot study is published, the manuscript of this RCT will be submitted. At the moment, the manuscript of the pilot study is in preparation for re-submission. The submission for the RCT manuscript in a peer reviewed journal is estimated to take place around 01/10/2016.

Intention to publish date
01/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4	22/06/2016	22/06/2016	No	Yes
Basic results		26/09/2019	02/10/2019	No	No