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Effectiveness of Cognitive Behavioral Therapy for sleeplessness in adolescents

Submission date
12/10/2012

Recruitment status
No longer recruiting

Registration date
14/11/2012

Overall study status
Completed

Last Edited
21/10/2019

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
Many adolescents suffer from trouble with sleeping because of social, hormonal and behavioral changes. Treatment for this age group however has not been researched conclusively while young people tend not to seek help with their sleep problems. For adults cognitive behavioral therapy for insomnia (CBT-i) has been proven effective to treat insomnia (sleeplessness) with long-lasting results. We investigate the effectiveness of CBT-I in adolescents and aim to implement CBT-i in an online and group setting for better accessibility.

Who can participate?
Adolescents between 13 and 19 years of age with insomnia.

What does the study involve?
For the study, three groups of adolescents are recruited of each about 50 participants. One group will receive cognitive behavioral therapy via internet sessions, the second group will get group therapy at a community health care center, and the third group will be put on a wait-list. All groups will be measured at the start of the study, directly after the treatment of 6 weeks, two months after the treatment, just before both treatment groups get one final treatment booster session, again after six months and finally after 12 months to see if the treatment is effective in the long term.

What are the possible benefits and risks of participating?
Possible benefits for participants are improvements of sleep by sleeping deeper and longer, and improvements of daily functioning that may have been impacted negatively by long-term sleep problems, like school performance and social functioning. There is no risk in participating in the study and/or having CBT-i in group or internet settings.

Where is the study run from?
The study is set up and run by the University of Amsterdam, the Netherlands in collaboration with several treatment centers in the Netherlands.

When is the study starting and how long is it expected to run for?
The study started in 2010 and will run until 2014.

Who is funding the study?
The study is funded by ZonMW, The Netherlands Organisation for Health Research and Development.

Who is the main contact?
Ed de Bruin
eddebruin@uva.nl

Contact information

Type(s)
Scientific

Contact name
Mr Ed de Bruin

Contact details
Universiteit van Amsterdam
Nieuwe Prinsengracht 130
Amsterdam
Netherlands
1018 VZ
+31 (0)20 525 1327
eddebruin@uva.nl

Additional identifiers

Protocol serial number
NL3182701810

Study information

Scientific Title
Sleep problems of adolescents and efficacy of treatment: a study on effective and easily accessible treatment for sleep problems of adolescents

Study objectives
Cognitive behavioral therapy for insomnia (CBT-i) has been proven to be effective for treatment of insomnia in adults. We hypothesize CBT-i is also effective for the treatment of insomnia in adolescents and test two treatment modalities in groups and via internet therapy, which we hypothesize to be equally effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the Academic Medical Center, Amsterdam (AMC), 18/05/2010, ref: NL3182701810

Study design
Randomised wait list controlled parallel-group multi-site trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment for primary insomnia in adolescents

Interventions
Cognitive Behavioral Therapy for insomnia in group sessions and internet sessions and a wait-list group.

Intervention Type
Behavioural

Primary outcome(s)
1. Sleep efficiency
2. Sleep onset latency
3. Wake after sleep onset
4. Total sleep time
5. Insomnia severity
6. Chronic sleep reduction

Key secondary outcome(s))
1. Behavioral measures from the Youth Self Report with several scales for both internalising problem behavior (anxiety, depression etc) and externalising behavior (aggressiveness etc)
2. Dysfunctional beliefs and attitudes.

Completion date
01/01/2014

Eligibility

Key inclusion criteria
1. Age between 13-19
2. No other psychiatric disorders at present or under treatment for this
3. Difficulty initiating or maintaining sleep, or not feeling rested after the night
4. More than 3 days a week sleep problems, for more than 1 month
5. Problems in daily life (academic, social functioning etc) due to the sleep problems
6. Sleep problems not due to other sleep disturbances (like apnea or circadian rhythm sleep disorder), nor due to drugs or medication, nor due to a physical disorder
7. Living within traveling distance to one of the treatment centers and willing to take part in group therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
19 years

Sex
All

Total final enrolment
116

Key exclusion criteria
Other psychiatric disorders, drug use, treatment for a psychiatric disorder, physical conditions that interfere with good sleep

Date of first enrolment
01/10/2010

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Universiteit van Amsterdam
Amsterdam
Netherlands
1018 VZ

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development [ZonMw] (Netherlands)

ROR

https://ror.org/01yaj9a77

Funder(s)

Funder type
Government

Funder Name
Netherlands Organisation for Health Research and Development

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

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	01/04/2015		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	01/08/2016		Yes	No
Results article	results	01/05/2018	21/10/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes