

Sleep problems of adolescents and efficacy of treatment. A study on effective and easily accessible treatment of sleep problems of adolescents.

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There are three main questions:1. How effective is internet treatment of insomnia in adolescents compared with group treatment of insomnia and control groups?2. Are the principles of cognitive behavioral therapy of insomnia in adolescents correct?3...

Ethical review	Approved WMO
Status	Pending
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON34758

Source

ToetsingOnline

Brief title

Sleep problems of adolescents and efficacy of treatment.

Condition

- Sleep disorders and disturbances

Synonym

insomnia, sleeplessness

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: adolescents, cognitive behavioral therapy, Insomnia, internet therapy

Outcome measures

Primary outcome

Outcome measures: statistically significant improvement between baseline and follow-up measurements on different scales from questionnaires that measure social and behavioral problems, significant improvements in sleep variables, sleep duration, sleep efficiency and sleep quality, and significant improvement of costs associated with and affected by sleep (school, grades, illness, doctor visits, etc.).

Secondary outcome

Not applicable

Study description

Background summary

From the literature it is known that many adolescents have sleep problems. Estimations are that 15-50% have problems falling asleep or waking up after sleep onset and 4-5% suffer from insomnia as diagnosed according to the DSM-IV. Cognitive behavioral therapy has been proven effective in the treatment of insomnia in adults. This treatment consists of a combination of four parts: sleep hygiene, stimulus control, sleep restriction and relaxation. Based on effect studies these techniques are recommended by the American Academy of Sleep Medicine as effective therapy for insomnia and where sleep hygiene was seen as a promising. From studies it is known that efficacy of cognitive behavioral therapy in the short term is comparable to medication and on the long term it is comparable or even better than medication. However, almost no effect studies for this treatment with adolescents have been published. In a research with 55 adolescents results from a cognitive behavioral therapy showed a significant improvement of sleep. There was also a significant decrease of

worrying and improvement of mental health. However, so far no effect studies have been conducted for adolescents with insomnia in the Netherlands. Also cost effectiveness of this treatment for insomnia in adolescents has not been researched. Based on this information, for this research it is hypothesized that adolescents with insomnia after treatment with cognitive behavioral therapy in group sessions and through the internet, compared to no treatment, will improve in sleep, will show a decrease in social and behavioral problems, will show higher cost effectiveness, and these effects will be comparable between group therapy and internet therapy.

Study objective

There are three main questions:

1. How effective is internet treatment of insomnia in adolescents compared with group treatment of insomnia and control groups?
2. Are the principles of cognitive behavioral therapy of insomnia in adolescents correct?
3. How cost-effective is internet treatment of insomnia in adolescents compared with group treatment of insomnia and control groups?

Purpose of the study is to develop an internet treatment for insomnia, to determine and compare effectiveness of internet therapy and group therapy, and then to incorporate these treatments into the database of effective youth interventions of the NJI. After the study, these treatments will be made available for use in the practice of treatment.

Study design

The study is designed in a randomized controlled trial with an open structure with parallel groups that get internet cognitive behavioral therapy and group cognitive behavioral therapy, and two waiting list groups. The first waiting list group records sleep using a sleep diary as is done in the treatment groups. As this registration is known to affect sleep there is another waiting list group that keeps a minimal record of sleep in a sleep diary for the synchronization of the actometers.

Intervention

For 6 weeks the two treatment groups have cognitive behavioral therapy for insomnia in 6 counseling sessions and two months after a follow-up a booster session. In the internet condition this therapy consists of digital internet counseling through a website. In group therapy the treatment consists of face to face group sessions. Each session is approximately one and a half hours.

The therapy consists of:

Sleep Hygiene in which all factors that negatively affect sleep are optimized. These include setting a regular bedtime, limiting excessive light before sleep, limiting noise, limiting coffee and other stimulating drinks, limiting daytime

naps and two hours prior to sleep restricting activities to quiet and relaxing activities (eg no exercise or sports during the evening).

Stimulus control: the client leaves the bed and sleeping environment for a short while when awake for longer than 20 minutes, so sleep will be dissociated from the bed and sleeping environment.

Sleep Restriction: the client gets bedtimes from the therapist that come as close as possible to an optimal sleep efficiency. This means a reduction of the bed time to a value close to the time they actually sleep. This creates a slightly elevated sleep pressure by which the client falls asleep easier, and the fragmentation of sleep that is characteristic of insomnia decreases.

Stress reduction through relaxation: the client gets some relaxation exercises that reduce stress and tension that are associated with sleep.

Study burden and risks

The burden consists of completing the questionnaires at each measurement time. In the treatment groups this consists of 5 measurements and in the control groups of 3 measurements because after the 3rd time the controls get the opportunity to follow one of the therapies. Completion of these questionnaire takes approximately 45 minutes each time. In addition, participants keep a daily sleep diary prior to the intake and over the course of one weeks each measurement time, and during all weeks of treatment. In total there are 70 days to complete a diary. It takes 2 minutes each time to fill out the diary. All questionnaires and sleep diaries are filled out via the Internet. Participants will also make a recording of sleep through the use of actometers. An actometer is a small instrument which is similar to a wristwatch that is worn during the time in bed and keeps record of movements. This record is a reliable measure of sleep parameters. Also, prior to treatment, an intake will be conducted with all participants of approximately 45 minutes duration, for an anamnesis and further information on the research. Furthermore, participants in the treatment conditions will get a counseling session each week for 6 weeks and a booster session two months after, each of approximately one and a half hour.

This study is bound to the group of adolescents aged 13 to 19 years with insomnia since the treatment of adolescents may have specific characteristics that differ from adults and that could influence effectiveness. There are no expected negative side effects of treatment. It is important to determine the effectiveness of treatment compared with a control group. Therefore, for three months after the intake the participants in the control groups are given no treatment. After that period the importance of the measurements is smaller and the participants from the control groups can follow one of the two treatments according to their own choice.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Sleep disturbances (insomnia) according to the diagnostic criteria from the Diagnostic and Statistical Manual (DSM-IV), age between 13 and 19.

Exclusion criteria

No diagnosed or apparent other psychological or psychiatric disturbances, no use of sleep medication or other medication that influences sleep (for instance medication for mood-disorders), no excessive drug or alcohol use.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2010
Enrollment:	352
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

CCMO

ID

NL31827.018.10