Better nights, better days? The role of sleep in (dis)stress, anxiety and emotion regulation

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This study aims to transdiagnostically evaluate effectiveness of guided Internet CBT for insomnia (ICBTI) to improve sleep, reduce emotional distress and improve responsiveness to regular treatment through sleep improvement, and to foster...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52321

Source
ToetsingOnline

Brief title
Better nights, better days?

Condition

- Other condition
- Psychiatric and behavioural symptoms NEC

Synonym
insomnia, sleep problems

Health condition

insomnie

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Buitenamstel (Amsterdam)
Source(s) of monetary or material Support: ZonMW;Hersenstichting;HealthHolland

Intervention

Keyword: cognitive behavioural therapy, Insomnia, psychiatric disorders, sleep

Outcome measures

Primary outcome

The primary outcome of the RCT is the insomnia severity. Insomnia Severity is measured with the Insomnia Severity Index (ISI). For the study with subjects with borderline personality disorder, the amount of BPD symptoms is the primary outcome measure, this is measured with the Borderline Personality Disorder Severity Index (BPDSI).

Secondary outcome

Secondary outcomes address three domains: sleep, mental health, and daytime functioning and well-being. They include I) other indicators of sleep and overnight alleviation of distress assessed from a sleep diary kept online for a week and from headband EEG assessed at home for four nights within that week (unless participant decides not to take part in the EEG assessments); II) the severity of mental health complaints characterizing different diagnostic dimensions, as well as well-being and daytime functioning including health behaviors and use of care, all assessed by online surveys at T0, T1 (2 months) and T2 (8 months). For the study with subjects with borderline personality disorder an additional clinical interview is done at T0, T1 (2 months) and T2 (8 months). Qualitative assessment of experiences with the intervention in a

sub-sample of participants (process evaluation interviews)

Study description

Background summary

Emotional distress and mental health complaints are among the most common and burdensome problems for individuals and society. One in five people experience the problems so severely at least once in their life that a psychiatric diagnosis is warranted. The persistence of these diagnoses is evident from the 12-month prevalence of near one in five people. Especially frequent (17.3%) are diagnoses characterized by inadequate regulation of emotional distress, including anxiety disorders, post-traumatic stress disorder and borderline personality disorder. Regular treatment does not suit everyone well, and after recovery, relapse often occurs. Therefore, it is urgent to prevent first-onset of psychiatric disease, and improve treatment efficacy. Attention to insomnia offers the best chance to do so. Insomnia is a primary risk factor for most mental disorders. Insomnia is also the transdiagnostically most commonly shared complaint across mental disorders. Unfortunately, regular treatment does not explicitly address insomnia. This situation is disquieting because good sleep is essential for regulating emotions and learning new cognitions and behaviours - the core fundaments of regular cognitive behavioural therapy (CBT) for mental disorders.

Study objective

This study aims to transdiagnostically evaluate effectiveness of guided Internet CBT for insomnia (ICBTI) to improve sleep, reduce emotional distress and improve responsiveness to regular treatment through sleep improvement, and to foster implementation of ICBTI through a process evaluation.

Study design

This study is a transdiagnostic randomized controlled trial with stratified randomisation at the participant level. As a pragmatic (or practical) clinical trial (PCT), the study is performed in a way that allows for immediate upscaled implementation in real-world practice, in case the intervention proves effective. The study additionally entails a mixed-method process evaluation.

Intervention

ICBTI is a guided, internet-based cognitive behavioural therapy program for insomnia, and consists of five online sessions:
1. Psycho-education

2. Sleep restriction
3. Rumination and relaxation techniques
4. Cognitive restructuring
5. Relapse prevention

Study burden and risks

The sole burden of participating in this trial will be adhering to the program, i.e. completing assignments and assessments. There are no known serious risks associated with the investigational treatment, although participants may temporarily experience side effects of the treatment due to sleep restriction, e.g. fatigue, daytime sleepiness, loss of motivation/energy and headaches. It is hypothesized that participants randomized to the active condition will experience some improvement of their sleep and if so, a more favourable progress of their mental health symptoms. Participants motivated to participate but uncomfortable with EEG-assessments will not be excluded. The additional process evaluation interview is only conducted on a sub-sample of all participants and is optional, so participants will only commence in the interview if they are willing to.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

18 years or older
Insomnia Severity Index score >=10
Self-considered capability of completing online questionnaires and diaries in Dutch.
Clinically relevant mental health complaints according to the Rapid Measurement Toolkit 20-item (RMT-20) questionnaire cut-offs in at least one of its dimensions of PTSD (>=8), Social Anxiety Disorder (>=12), Panic disorder (>=9) or Generalized Anxiety Disorder (>=11), or according to the Ultrashort BPD Checklist (BPD-C) indicated by a score >=14. Patients recruited through GGZ are required to be diagnosed with an anxiety disorder according to the MINI or BPD diagnosis (or other personality disorder with at least 4 BPD traits of which at least one of the following traits: *affective instability*, *impulsivity*, *parasuicidal behavior*, *anger attacks*, according to the SCID-5-P.

Exclusion criteria

The main exclusion criteria are based on the probable inability to comply with ICBTI instructions and the assessments, as we expect to occur in people currently diagnosed with bipolar disorder, psychotic disorder, and alcohol or substance dependency. Potential participants that underwent CBT-I treatment in the last 3 months will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2021
Enrollment:	576
Type:	Actual

Ethics review

Approved WMO Date:	04-10-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-03-2024
Application type:	Amendment
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

ID: 21458
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76232.029.21
OMON	NL-OMON21458