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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21458

Source
NTR

Brief title
Better nights, better days?

Health condition

Insomnia disorder in combination with (symptoms of) anxiety (GAD, SAD, PD, PTSD) or borderline personality disorder.

Sponsors and support

Primary sponsor: Stichting Vrije Universiteit Medisch Centrum, Afdeling Psychiatrie
Source(s) of monetary or material Support: Hersenstichting; Health-Holland; Zon-Mw

Intervention

Outcome measures

Primary outcome

Primary outcome of the RCT is insomnia severity, as measured with the Insomnia Severity Index (ISI). For the study with subject with borderline personality disorder (BPD), 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 participants decide 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 behaviours and use of care, all assessed by online survey or clinical interview at T0, T1 (2 months) and T2 (8 months). For the study with subjects with BPD, insomnia severity, as measured with the ISI is an additional secondary outcome.

Study description

Background summary

Rationale: Emotional distress and mental health complaints are among the most common and burdensome problems for individuals and society. One in three people experience the problems so severely that a psychiatric diagnosis is warranted at least once in their life (Steel et al., 2014). 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 (Wittchen et al., 2011). 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 (Cuijpers et al., 2012). 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.
Objective: This multicenter study aims to transdiagnostically evaluate effectiveness of guided Internet CBT for insomnia (ICBTI) to reduce emotional distress and improve responsiveness to regular treatment through sleep improvement. Study design: This multicenter 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.
Study population: A unique feature of our study is that it evaluates intervention effectiveness across all levels of mental health care, i.e. (1) in people with pre-clinical complaints; (2) in people referred to generalistic basic mental healthcare; (3) in people referred to specialized

mental healthcare. Based on recent findings on the role of sleep in overnight emotion regulation, the study transdiagnostically focuses on complaints and diagnoses marked by insufficient overnight dissolving of emotional distress, i.e. anxiety-, stress- and borderline personality-related problems.
Intervention: I-Sleep is a supervisor-guided ICBTI with a demonstrated large favourable effect on insomnia in several populations. However, these effects have not been established in samples with primary anxiety-, stress- and borderline personality-related problems. I-Sleep consists of 5 online sessions: 1) psycho-education on sleep, sleep disorders and sleep hygiene, 2) sleep restriction and stimulus control training, 3) rumination and relaxation techniques, 4) cognitive restructuring, 5) relapse prevention. Keeping a sleep diary is a major component of i-Sleep. The control condition consists of keeping a sleep diary only. Among the participants will be people that are on a waitlist for the onset of regular treatment for mental health complaints. This allows us to evaluate whether targeting sleep before entering a regular disorder-specific treatment facilitates effectiveness of the latter as compared to effectiveness of regular treatment in those assigned to the control condition.
Main study outcomes/endpoints: The primary outcome measure is insomnia severity. 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; II) the severity of mental health complaints characterizing different diagnostic dimensions, as well as well-being and daytime functioning including health behaviours and use of care, all assessed by online survey or clinical interview at T0, T1 (2 months) and T2 (8 months).

Study objective

In people experiencing insomnia together with different levels and types of emotional distress and mental health complaints; ICBTI including keeping a sleep diary as compared to only keeping a sleep diary is effective in improving insomnia, as indicated by reducing subjective (questionnaire) insomnia symptoms.

Study design

T0, T1 (at 2 months), T2 (at 8 months)

Intervention

ICBTI is a guided, internet-based cognitive behavioral 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

Contacts

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Eligibility criteria

Inclusion criteria

● 18 years or older,
● Insomnia Severity Index score ≥10,
● Self-considered capability of completing online questionnaires and diaries in Dutch.
● For patients recruited through SGGZ at GGZ Ingeest: meeting the criteria for an anxiety disorder according to the M.I.N.I. International Neuropsychiatric Interview or the criteria for borderline personality disorder according to the SCID-5-P structured clinical interview for DSM-5 personality disorders (section BPD).
● 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 (BPDC) indicated by a score ≥14.

Exclusion criteria

The main exclusion criteria are based on the probable inability to comply with i-Sleep instructions and the assessments, as we expect to occur in people currently diagnosed with bipolar disorder or psychotic disorder (single question), or misusing alcohol or drugs (scores of ≥ 12 on the AUDIT (Saunders et al., 1993) and DUDIT (Kraanen, 2008) questionnaires). We aim to include both males and females. Additionally, people that have undergone CBT treatment for insomnia in the past three months will be excluded.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2020
Enrollment:	576
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52321
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9776
CCMO	NL76232.029.21
OMON	NL-OMON52321

Study results