

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

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In people experiencing insomnia together with different levels and types of emotional distress and mental health complaints; ICBT including keeping a sleep diary as compared to only keeping a sleep diary is effective in improving insomnia, as...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON21458

### Bron

NTR

### Verkorte titel

Better nights, better days?

### Aandoening

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

## Ondersteuning

**Primaire sponsor:** Stichting Vrije Universiteit Medisch Centrum, Afdeling Psychiatrie

**Overige ondersteuning:** Hersenstichting; Health-Holland; Zon-Mw

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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).

## Toelichting onderzoek

### Achtergrond van het onderzoek

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 fundamentals 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).

## **Doel van het onderzoek**

In people experiencing insomnia together with different levels and types of emotional distress and mental health complaints; ICBT 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.

## **Onderzoeksopzet**

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

## **Onderzoeksproduct en/of interventie**

ICBT 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

## **Contactpersonen**

### **Publiek**

Amsterdam UMC, locatie VUmc  
Shanna van Trigt

020-7884511

## Wetenschappelijk

Amsterdam UMC, locatie VUmc  
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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years or older,
- Insomnia Severity Index score  $\geq 10$ ,
- 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 ( $\geq 8$ ), Social Anxiety Disorder ( $\geq 12$ ), Panic disorder ( $\geq 9$ ) or Generalized Anxiety Disorder ( $\geq 11$ ), or according to the Ultrashort BPD Checklist (BPDC) indicated by a score  $\geq 14$ .

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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  $\geq 12$  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.

## Onderzoeksopzet

## Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

## Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	576
Type:	Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies	
Datum:	07-10-2021
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52321  
Bron: ToetsingOnline  
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

## Resultaten