

# Sleep in addiction care

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<b>Registration date</b> 19/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/08/2008	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

3.000.014

## Study information

Scientific Title

Sleep in substance use disordered patients in addiction care

### **Study objectives**

Sleep will improve by a cognitive behavioural therapeutic intervention in patients admitted to an addiction care clinic that show problems in initiating and maintaining sleep in the subacute detoxification phase.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

To be submitted in July 2008 (as of 21/05/2008)

### **Study design**

Randomised, open clinical trial, in two addiction care centres.

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Insomnia in patients with substance use disorder

### **Interventions**

The study is a randomised controlled trial in a cohort of patients referred to addiction care (2 addiction clinics). The duration of the study for the participating patients is 15 weeks, plus a follow up at 2 months after completion of the intervention. In order to gather a large study population, the research takes 1.5 years.

Initially, 600 eligible patients will be enrolled in the study and will undergo various baseline assessments (T0; see primary and secondary outcome measures) and start standard treatment for their sleep problems. During the 4th week in treatment (T1), those who still continue with the treatment will be asked to undergo additional assessments (see primary and secondary outcome measures). In the 5th week of treatment, the patients who show problems in initiating or maintaining sleep at T1 are selected for the next stage of the study. The selected patients (90 patients) are randomly assigned to one of the two treatment groups.

The participants allocated to the intervention group receive sleep training, consisting of sleep hygiene, sleep education and cognitive behavioural therapy. Cognitive behavioural therapy will

be given in 6 sessions of 2 hours, as developed by I. Verbeek (1999; <http://www.ncbi.nlm.nih.gov/pubmed/10616231>).

The control group receives standard care (and no sleep training). This means a daily programme of cognitive therapy, group meetings, creative therapy, movement therapy, coffee breaks etc., the regular treatment for a normal addiction clinic.

The total duration of follow-up per individual is 2 months. On completion of this follow-up assessment, the participants in the control group will also receive the interventions if they wish.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Subjective sleep efficiency as measured by a sleep log. The sleep log will be recorded by the participants during the 6-week treatment period. The sleep log has several outcome measures: time in bed (TIB), total sleep time (TST), sleep onset latency (SOL), sleep efficiency (SE), wake after sleep onset (WASO) and number of awakenings (AWAK).
2. Sleep quality measured by the Pittsburgh Sleep Quality Index (PSQI) at timepoints T0, T1, T2, T3 and T4

Timepoints:

T0 = Day of clinical intake

T1 = 4th week of treatment

T2 = 6th week of treatment, before randomisation

T3 = At the end of sleep training

T4 = 2 months after the sleep training

## **Secondary outcome measures**

Vigilance during the day as measured by the Sustained Attention to Response Task (SART) at T1, T2, T3 and T4. SART will be carried out once a week during the period between T2 and T3.

Tertiary outcome measures:

1. Severity of dependency on drugs/ alcohol measured by the Composite International Diagnostic Interview - Substance Abuse Module (CIDI-SAM) at T0 and T4
2. Addiction measured using the addiction scales of the Addiction Severity Index (ASI) at T0 and T4
3. Presence of any psychiatric disorder assessed by the Mini International Neuropsychiatric Interview (MINI)
4. Presence of sleep disorders assessed by the SLEEP-50 at T0, T1, T2, T3 and T4
5. Symptom assessment by the Symptom Check List (SCL-90) at T0, T1, T2, T3 and T4
6. Quality of life assessed by the EQ-5D at T0, T1, T2, T3 and T4
7. Actigraphy at T1, T2, T3 and T4. The actigraph registers movements of the right arm in right handed subjects for 48 hours or more.
8. Go/No-Go response-inhibition task (T1)

Timepoints:

T0 = Day of clinical intake

T1 = 4th week of treatment  
T2 = 6th week of treatment, before randomisation  
T3 = At the end of sleep training  
T4 = 2 months after the sleep training

**Overall study start date**

01/09/2008

**Completion date**

01/09/2012

## **Eligibility**

**Key inclusion criteria**

1. Both males and females, age limit: 65
2. Patients who are admitted for at least 5 weeks to an addiction clinic
3. Those who are "clean" i.e. addicted patients that do not use drugs/alcohol anymore
4. Score of 5 or higher in the Pittsburgh Sleep Quality Index (PSQI)

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

90

**Key exclusion criteria**

1. Patients with sleep problems other than problems of initiating or maintaining sleep
2. Diagnosis of severe depression, attention deficit hyperactivity disorder (ADHD)
3. Patients who have a primary benzodiazepine addiction

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/09/2012

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Wanssumseweg 12**

Oostrum

Netherlands

5807 EA

## **Sponsor information**

### **Organisation**

Mental Health Group in North and Middle Limburg (GGZ Noord- en Midden-Limburg)  
(Netherlands)

### **Sponsor details**

Stationsweg 46

Venray

Netherlands

5803 AC

### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.ggznm.nl>

### **ROR**

<https://ror.org/00b3xjw51>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Mental Health Group in North and Middle Limburg (GGZ Noord- en Midden-Limburg)  
(Netherlands)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration