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Sleep in addiction care

Submission date	Recruitment status	[X] Prospectively registered
21/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/08/2008	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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.ggznml.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