

Early detection and treatment of sleep disorders in psychiatric patients

No registrations found.

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

Summary

ID

NL-OMON26242

Source

Nationaal Trial Register

Brief title

STaP (Sleep Treatment and Psychiatry)

Health condition

Psychiatric disorders:

- Depressive disorder,
- Bipolar disorder,
- Anxiety disorder,
- Post traumatic stress disorder (PTSD),
- Attention Deficit (Hyperactivity) Disorder (AD(H)D)
- Autism spectrum disorder (ASD)
- Schizophrenia spectrum disorder (SSD),
- Personality disorder

Groups of sleep disorders:

- Chronic insomnia,
- Parasomnia (e.g. frequent nightmares),
- Circadian rhythm sleep-wake disorders (e.g. delayed sleep phase syndrome (DSPS)),
- Hypersomnia,
- Sleep-related movement disorders (e.g. Restless Legs Syndrome (RLS),
- Sleep-related breathing disorders (e.g. Obstructive Sleep Apnoea Syndrome (OSAS))

Sponsors and support

Primary sponsor: GGZ Drenthe

Source(s) of monetary or material Support: ZonMW / Espria

Intervention

Outcome measures

Primary outcome

1. The prevalence of different sleep disorders (HSDQ) in the study population,
2. The effect of early sleep interventions on general psychiatric symptoms (OQ45), specific psychopathology (QIDS, STAI-state, ASRM, PCL-5, ASRS-v1.1, AQ, or PHAMOUS-basis psychosesvragen), and on quality of life (I-ROC, MANSA).

Secondary outcome

1. Effects of the sleep interventions on objective outcome parameters, such as length of stay and number of hospitalizations.
2. Gender differences in the prevalence of specific sleep disorders and in the effects of the sleep intervention in the more prevalent psychiatric disorders: depression and PTSD.

Study description

Background summary

Background: Sleep is important for physical health, cognitive functioning and quality of life. Additionally, it has become clear that proper sleep is also crucial for mental health and recovery of psychiatric disorders. Therefore, early detection and adequate treatment of sleep disorders in psychiatric populations may be very relevant to improve the care of these patients. Unfortunately in psychiatric care sleep disorders are often overlooked and thus, treated late or not at all. In order to increase knowledge and improve care of patients with comorbid mental and sleep disorders in the proposed wait-list control study we will investigate the clinical relevance of early identification and treatment of sleep disorders in psychiatric patients. The two aims of the proposed project are 1) to determine the prevalence of sleep disorders in a psychiatric patient population, and 2) to investigate the contribution of early identification and adequate treatment of sleep disorders in people suffering from mental disorders.

Study design: The prevalence of sleep disorders will be assessed in the GGZ Drenthe population by means of a screening questionnaire (HSDQ). Those patients scoring above the cut-off criteria for at least one of the HSDQ subscales will be invited for diagnosis and

treatment of their sleep disorder. The effect of sleep disorder treatment in addition to psychiatric treatment as usual (TAU) will be assessed on general and specific mental well-being and quality of life, using a randomized wait-list control design. To ensure a good fit with this complex psychiatric patient population adjustments will be made to standard sleep interventions.

Study population: Patients (≥ 18 yrs) newly referred to GGZ Drenthe during the 3-year inclusion period who are capable of filling out questionnaires in the Dutch language are invited to participate in this study. Those patients screening positive for a sleep disorder will be invited to participate in the intervention part of the study.

Study objective

Generally, we expect to observe a higher prevalence of sleep disorders in the psychiatric patient population than has previously been reported for the general population.

Concerning the psychiatry-tailored sleep interventions, we expect that effective treatment of sleep disorders will improve mental well-being and quality of life in a large group of our patients. Specifically we hypothesize that:

- o The effect of sleep intervention(s) added to TAU on psychiatric symptoms will exceed those of TAU alone.
- o Added sleep intervention(s) will improve quality of life relative to TAU.
- o Early treatment of sleep disorders, within 6 months, will improve psychiatric symptoms and quality of life to a larger extent than sleep disorder treatment initiated after 6 months.

Study design

- T0= Baseline
- T1= 6 months
- T2= 12 months

Intervention

Sleep disorder treatment

Contacts

Public

Rijksuniversiteit Groningen / GGZ Drenthe
MARIKE LANCEL

0625006430

Scientific

Rijksuniversiteit Groningen / GGZ Drenthe

Marieke Lancel

0625006430

Eligibility criteria

Inclusion criteria

- Referred newly to GGZ Drenthe for psychiatric treatment
- Registered as a patient at GGZ Drenthe
- Written informed consent
- 18 years or older
- Proficient in the Dutch language

Exclusion criteria

- Inability to adequately read or speak Dutch
- Deemed unfit to fill out the questionnaires by their practitioner

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2019
Enrollment:	472
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 19-02-2020

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8389
Other	METc UMCG : 60-63600-98-641

Study results