

Does early identification and treatment of sleep problems bolster psychiatric therapeutic outcome?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON48467

Source

ToetsingOnline

Brief title

Early detection and treatment of sleep disorders

Condition

- Sleep disorders and disturbances

Synonym

sleep problems; slaap disorders

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Drenthe (Assen)

Source(s) of monetary or material Support: ZONmw subsidie, Espria

Intervention

Keyword: Early detection, Psychiatry, Sleep disorder treatment, Sleep disorders

Outcome measures

Primary outcome

The prevalence of sleep disorders will be assessed using descriptives. The effect of sleep disorder treatment will be compared between waiting-list control and immediate treatment groups. The main outcome parameters include, change in general psychiatric symptoms (OQ45 score), change in quality of life (MANSA scores), and change in specific psychiatric symptom scores (specific questionnaire for each psychiatric diagnostic group).

Secondary outcome

Secondary outcome parameters include difference in the primary outcome variable as a function of gender.

Study description

Background summary

Sleep is important for physical health, cognitive functioning and quality of life. The last decennia it has become clear that proper sleep is also crucial for mental health and the recovery of psychiatric disorders. In addition, sleep disorders are more prevalent in individuals with psychiatric disorders than in the general population. Prevalence of insomnia is, for instance, estimated at 30-80% in the psychiatric population. Unfortunately, in psychiatric care, sleep disorders are often poorly recognized and treatment often occurs late or not at all. Therefore, early detection and treatment of sleep disorders in psychiatric populations is of crucial importance for the improvement of care for these complex patients.

Study objective

The major aim of the proposed project is to investigate the clinical relevance

of early identification and adequate treatment of co-occurring sleep disorders in people suffering from mental disorders. The main questions underlying the present project proposal are: 1) What is the prevalence of the different sleep disorders in the GGZ Drenthe population? 2) Does screening for and early treatment of sleep disorders exert positive effects on the psychiatric outcome (symptom severity/treatment response/remission of mental diseases) and quality of life? 3) Does the impact of sleep treatment vary between the different mental disorders?

Study design

The prevalence of sleep disorders will be assessed in the GGZ Drenthe population by means of a screenings questionnaire (HSDQ). Using a randomized waiting-list control design, the effects of sleep disorder treatment on psychiatric well being will be assessed in those individuals who screened positive for a sleep disorder.

Intervention

Individuals screening positive for a sleep disorder will, either immediately or after a 6 month waiting period, receive extensive sleep disorder diagnosis, and subsequent sleep disorder treatment according to the standard of care for their specific sleep disorder, optimized for the psychiatric population,

Study burden and risks

The burden of this research project consists of filling out four questionnaires. Filling out the questionnaires takes about 20-25 minutes. For those patients that screen positive for a sleep disorder, there is an additional burden of participation in the diagnostic process and treatment of their sleep disorder and of filling out the questionnaires at two additional occasions (6 and 12 months). However, this burden is likely outweighed by the benefit of reduction of disordered sleep after treatment. Since only well established non-invasive treatments are employed the risks of treatment, and thereby this study, are negligible. Furthermore, the study potentially has large benefits for the participating patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 1) Referred to GGZ Drenthe for psychiatric treatment
- 2) 18 years or older
- 3) proficient in the Dutch language

Exclusion criteria

- 1) inability to adequately read or speak Dutch
- 2) deemed unfit by their practitioner to fill out the questionnaires

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2019
Enrollment:	472
Type:	Actual

Ethics review

Approved WMO	
Date:	09-08-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL69302.042.19