Insomnia treatment and glycemic outcomes in type 2 diabetes

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We hypothesize that improving sleep will improve glycaemic control in people with T2DM and insomnia.

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

Summary

ID

NL-OMON23530

Source
Nationaal Trial Register

Brief title
Diaslaap

Condition

- Sleep disorders and disturbances

Health condition

T2DM and insomnia.

Research involving
Human

Sponsors and support

Primary sponsor: VU Medical Center
Source(s) of monetary or material Support: Dutch Diabetes Research Foundation

Intervention

- Psychosocial intervention

Explanation

Outcome measures

Primary outcome

Primary study parameters/endpoints: at baseline, 3 months and 6 months, we will determine glycaemic control, measured by levels of HbA1c.

Secondary outcome

At baseline, 3 months and 6 months fasting glucose and diabetes medication use as well as sleep, measured by validated questionnaires, sleep diaries, accelerometers and sleep medication prescriptions. Additionally, at baseline, 3 months and 6 months cardiovascular risk factors, including BMI, waist circumference, lipid levels, cholesterol levels, dietary intake, physical activity, mood and quality of life are measured. These parameters are determined using anthropometrical measurements, blood pressure measurements, lipid levels by measuring triglycerides and cholesterol, while dietary intake is measured using a food frequency questionnaire, physical activity by wearing an accelerometers, while mood and quality of life are measured by validated questionnaires.

Study description

Background summary

We established the following objectives: 1) investigate if improving sleep by internet-based cognitive behavioural therapy (CBT) can improve insomnia and glycaemic control in people with T2DM; 2) assess whether CBT also improves BMI, waist circumference, lipids, blood pressure, dietary intake, physical activity, mood and quality of life. We will therefore perform a randomized controlled trial to assess the effect of CBT (i-sleep) versus care as usual on insomnia and glycaemic control in 80 people with T2DM and insomnia. Randomization will take place at the individual level on a 1:1 ratio, using random sequence block randomisation (blocks of 2 or 4 or 6). Participants will receive the outcome of randomization by email. Due to the nature and design of the study, blinding of the researchers and participants is not possible. This multi-disciplinary and innovative project will provide information on the pathophysiology of sleep and T2DM progression as well as provide a ready-to-use, targeted intervention. Because would it not be great if we can improve glycaemic status in people with T2DM by improving sleep, rather than prescribing pills?

Study objective

We hypothesize that improving sleep will improve glycaemic control in people with T2DM and insomnia.

Study design

Baseline, 3 months and 6 months

Intervention

The I-Sleep intervention is a 5 week online CBT i-sleep program to be completed by the participant at home and consisting of psycho-education, sleep hygiene, sleep restriction, stimulus control, cognitive restructuring and relapse prevention. A research nurse will offer guidance and feedback to increase motivation and adherence. The control condition is care-as usual. The control group will gain access to the intervention six months after inclusion.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

We recruit people with T2DM and self-reported insomnia.

Exclusion criteria

We will exclude participants who self-report the following psychiatric problems depression, schizophrenia, psychosis or suicidality; as well as those on medication affecting sleep (i.e. anti-psychotics, anxiolytic), pregnant, working night shifts or reporting excessive alcohol use (>21 alcoholic consumptions per week). People who answer yes to the questions did you receive psychological treatment in the last six months for insomnia will also be excluded. Those suffering from additional sleep disorders will not be excluded, but their diagnosis will be accounted for in the analysis.

Study design

Design

Study phase:	N/A
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):	04-04-2019
Enrollment:	57
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
Use of the data can be requested by the Hoorn study group.

Ethics review

Approved WMO Date:	12-02-2019
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam)
	Kamer G4-214
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	1100 DD Amsterdam
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Study registrations

Followed up by the following (possibly more current) registration

ID: 48417
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7665
CCMO	NL68074.029.18
OMON	NL-OMON48417

Study results

Summary results
Yes