Pillow or Pills? The role of sleep in the glycaemic progression of T2DM

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON48417

Source
ToetsingOnline

Brief title
Diasleep: Sleep and T2DM progression

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Sleep disorders and disturbances

Synonym
insomnia; inability to sleep

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Diabetes fonds

Intervention

Keyword: glycaemic control, Insomnia, sleep, Type 2 Diabetes

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 cardiovascular risk factors, including fasting glucose and diabetes medication use as well as sleep, measured by validated questionnaires, sleep dairies, accelerometers and sleep medication prescription. In addition, BMI, waist circumference, lipid levels, cholesterol levels, dietary intake, physical activity, mood and quality of life measured. These parameters are determined using anthropometrical measurements, blood pressure measurements, lipid levels by measuring triglycerides and cholesterol, while dietary intake will be 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

A novel lifestyle factor associated with type 2 diabetes mellitus (T2DM) are sleep disturbances. Our recent meta-analysis shows that sleep problems, especially insomnia are 3 times more prevalent in people with T2DM, compared to the general population, with 20-40% of all people with T2DM suffering from sleep problems. In addition, our recent meta-analysis showed that insomnia is associated with faster diabetes progression. The question that remains is can

we improve glycaemic control in people with T2DM by treating their insomnia? Previously, a small pilot study on cognitive behavioural therapy in 9 women with T2DM with insomnia showed that although not significantly by treatment of insomnia, HbA1c levels reduced on average 0.26 ± 0.28% from pre-test to the three-week follow-up.

Study objective

We hypothesize that improving sleep will improve glycaemic control in people with T2DM and insomnia. To test this hypothesis, 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.

Study design

We will perform a randomized controlled trial to assess the effect of CBT (i-sleep) versus care as usual on insomnia and glycaemic control in 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.

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.

Study burden and risks

The main burden of participating in this trial will be adhering to the online CBT program, i.e. completing homework assignments and questionnaires, and wearing an accelerometer. Patients may experience side effects of the treatment during the first 1-2 weeks due to instructed sleep restriction, e.g. fatigue, daytime sleepiness, and/or loss of motivation/energy. In addition, participants will be asked to visit the research centre three times, during which anthropometric measures, blood pressure, questionnaires, blood collection and wearing an accelerometer for a week. In relation to the possibility of damage, the severity of potential harm and the vulnerability of the participants, it is

concluded that the conduct of the research involves a negligible risk to human participants and is therefore justified.

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

• Able to speak, write and understand Dutch;
• Voluntary participation;
• >= 18 years of age;
• Access to a computer and the internet;
• Provided written informed consent;
• Willing to comply with the study procedures ;
• Meeting criteria of diagnosis insomnia (DSM-5) as assessed by the online baseline screening

- Difficulty initiating or maintaining sleep for at least 3 nights per week,
- for at least 3 months,
- causing clinically significant distress or impairment in daily functioning.
Daytime consequences will be assessed using 5 items introduced by Espie et al. (2012)

Exclusion criteria

• Working night shifts;
• Meeting criteria of the diagnosis of sleep apnoea;
• Using medication affecting sleep (i.e. anti-psychotics, anxiolytic);
• Having received psychological treatment for insomnia in the last six months;
• Pregnancy or breast feeding during the trial;
• Current depression, schizophrenia, psychosis or suicidal ideation;
• Alcohol consumption > 21 units/week;
• Not willing to give up blood donation during the study;
• Any significant medical reason for exclusion as determined by the investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2019
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23530
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68074.029.18
OMON	NL-OMON23530