A randomized control trial to assess if changing sleep timing can improve glucose metabolism in people with (pre)diabetes

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To investigate whether a reduction in social jetlag for 3 weeks can improve glycemic and metabolic control, sleep, mood and quality of life in people with (pre)diabetes.

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

Summary

ID

NL-OMON56641

Source
ToetsingOnline

Brief title
Social jetlag trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 2 diabetes; non-insulin-dependent diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Diabetesfonds

Intervention

Keyword: Circadian rhythm, Glucose metabolism, Insulin sensitivity, Sleep timing

Outcome measures

Primary outcome

The primary outcome is , glycemic control, measured as HbA1c after 12 weeks, comparing the intervention and control group in an intention to treat analysis.

Secondary outcome

1)social jetlag, measured using questionnaires and objective measurements after 4 and 12 weeks 2) Glycemic control measured as fasting glucose, HOMA-IR insulin resistance and hypoglycemic sensations and diabetes medication; 2h glucose tolerance 3) metabolic outcomes, including weight, BMI, waist, fat percentage, blood pressure, ; 4) mood including depression, fatigue and anxiety; 5) quality of life.

Additionally, we will assess factors that might play a role (possible mediators and confounders): Dim Light Melatonin Onset (DLMO) in a subgroup, physical activity, age, sex, ethnicity, education status, stress level, diet, alcohol consumption, smoking, work status and other medication, nervous system activity and cardiovascular health, sleep measured as sleep timing, sleep quality, sleep duration and phases.

Study description

Background summary

Social jetlag is a chronic disruption of sleep timing that is characterized by different sleep timing during workdays and free days. Social jetlag has been associated with adverse glucose metabolism, insulin sensitivity and parameters of metabolic syndrome and Type 2 Diabetes (T2D).

Study objective

To investigate whether a reduction in social jetlag for 3 weeks can improve glycemic and metabolic control, sleep, mood and quality of life in people with (pre)diabetes.

Study design

A randomized controlled trial.

Intervention

Bright light therapy (5000 lux) emitted by Vitamine-L (Lumie, UK) or dim light (10 lux) for 30 minutes each morning, following sleep advance instructions, and wearing bright light dimming goggles every evening for a period of 3weeks. The control group adheres to their regular sleep habits and conditions.

Study burden and risks

For the baseline visit, people will be asked to come to the research center twice for a visit of 1 and one of 1,5-2,5 hours subsequently. In between the visits they will be asked to perform some measurements themselves from home (in total this takes 2 hours) and to wear an accelerometer and sleep measuring headband for 7 days. During the second visit, we will draw a small amount of blood (8ml total (+ 22ml for the combination group)). At the baseline visit, 30 participants will be allocated to the intervention group and will be asked to follow a minimally invasive study protocol to reduce their social jetlag. The control group retains their regular sleeping habits. After a 3-week intervention period, participants receive another accelerometer and sleep measuring headband to wear for 7 days and are invited back to the research center for the same visit as the second baseline visit of 1,5 hours approximately. This is repeated once more after 8 weeks.

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

60 people with pre-diabetes and diabetes with >1 hour social jetlag from earlier cohorts who have provided consent to be informed about future research will be included.

Exclusion criteria

- Excessive alcohol use (>14 alcoholic consumptions per week);
- Having crossed more than 1 time zone in the month prior to participation;
- Having any other form of diabetes not considered type 2 diabetes (e.g. steroid-induced diabetes, diabetes type 3c, MODY, LADA).
- Working shifts more than once per month;
- Unable to provide written informed consent
- Visually impaired

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2024
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	14-03-2024
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
Other	ISRTCN nog niet bekend
CCMO	NL85663.018.23