Extreme phenotype social jetlag study

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The objective of this study is to investigate which pathways explain the association between social jetlag, insulin sensitivity and glucose metabolism in people with prediabetes with and without social jetlag.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON56332

Source
ToetsingOnline

Brief title
Extreme phenotype social jetlag study

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: Diabetes Fonds

Intervention

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

Outcome measures

Primary outcome

The first main outcome is glycaemic control, measured with fasting blood glucose levels, HbA1c levels, and 2h glucose levels after an oral glucose tolerance test, comparing those with and without social jetlag.

Secondary outcome

Additionally, to assess which factors mediate this association, we will assess physical activity, (para)sympathetic nervous systemactivity from ECGs and electrochemical skin conductance tests, the Dim Light Melatonin Onset (DLMO) in saliva samples, HPA-axisactivation from cortisol awakening reaction in saliva samples and visceral fat distribution.Physical activity and sleep times and phases will be measured using an activity tracker and a sleep measuring headband. Dietaryintake will be assessed from the central Hoorn Study visit (or the RISC of HOM study visit).

Study description

Background summary

Social jetlag is defined as the discrepancy between work schedules, social obligations and biological needs. The effects of social jetlag on our metabolism and health have been studied during the past years in the general population, and social jetlag has been associated specifically with adverse glycaemic measures, and parameters of metabolic syndrome and Type 2 Diabetes (T2D) in the general population. The pathways that explain these associations are still under debate.

Study objective

The objective of this study is to investigate which pathways explain the

association between social jetlag, insulin sensitivity and glucose metabolism in people with prediabetes with and without social jetlag.

Study design

A small observational study conducted in people with prediabetes from the Hoorn Study Cohort.

Study burden and risks

Participants will perform some of the measurements themselves from home, and will come to the research centre twice, where they will undergo several assessments. They will undergo non-invasive ECGs(twice), skin conductance tests (twice), saliva collection (9 times), and will fill out 5 questionnaires. More invasive measurementsthat will be performed are a blood draw, which will be done two times from a cannula to perform an OGTT and measure HbA1c.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

40 participants with prediabetes (FPG 6.1-7.0mmol/l) who have provided consent to be informed about future research will be identified in the New Hoorn Study Cohort in the measurement of 2021-2023. 20 of them having more than 1 hour of social jetlag and 20 of them having less than 1 hour of social jetlag.

Exclusion criteria

Excessive alcohol use (>14 alcoholic consumptions per week)
Having crossed more than 1 time zone in the month prior to participation
Working shifts more than once per month
Unable to give written informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-02-2023
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-04-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2023
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

No registrations found.

In other registers

Register	ID
CCMO	NL80321.029.22