

Changing sleep timing to improve glucose metabolism

Submission date 17/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/05/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/07/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Social jetlag is a chronic disruption of sleep timing that is characterized by different sleep timing during workdays and free days. It has been associated with higher risk of obesity and diabetes. In this intervention study we will investigate whether a combination of bright light therapy in the morning, bright light reduction in the evening, and sleep timing instructions for 3 weeks compared to regular sleep habits can reduce social jetlag and if this results in changes in glucose levels, metabolism, sleep, mood, and quality of life in people with (pre)diabetes after 3 and 12 weeks follow-up.

Who can participate?

60 people with pre-diabetes and diabetes with >1 hour social jetlag from the Hoorn Study and Diabetes Care System cohorts can participate.

What does the study involve?

The study involves measurements at the study center (height and weight, fat percentage, ECG and SUDO scan, questionnaires, blood pressure, blood draw), collecting saliva samples at home and performing at-home sleep measurements using a headband.

The intervention consists of wearing light dimming goggles at night, using a bright light lamp in the morning and adhering to sleep instructions for 3 weeks. To assess adherence to the study protocol, participants in the intervention group will be asked to wear an accelerometer and light sensor and fill in a sleep diary for one week during the intervention. After that, all measurements from the baseline are repeated after 3 and 12 weeks.

What are the possible benefits and risks of participating?

Study participants need to invest time in the study and they need to adhere to the minimally invasive intervention protocol daily. Furthermore, a total amount of 26ml of blood will be drawn. Participants have no direct benefit from this study. By participating in the study, new data on the health of the participant can be detected. If important health information is discovered, a participants general practitioner will be informed. We expect that people who follow the intervention protocol will be able to reduce their social jetlag and consistently improve their glycemic control.

Where is the study run from?

Amsterdam UMC at the study location in Hoorn (Netherlands)

When is the study starting and how long is it expected to run for?

July 2023 to October 2024

Who is funding the study?

Dutch Diabetes Foundation Diabetes Fonds Fellowship, Grant/Award Number: 2019.82.002

Who is the main contact?

Dr Femke Rutters, f.rutters@amsterdamumc.nl

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Grant/Award Number: 2019.82.002

Study information

Scientific Title

A randomized controlled trial to assess change in glucose metabolism by changing sleep timing in people with (pre)diabetes

Study objectives

A combination of bright light therapy in the morning, bright light reduction in the evening and sleep advance instructions for 3 weeks reduces social jetlag and results in changes in glycemic and metabolic control, sleep, mood and quality of life in people with (pre)diabetes after 3 and 12 weeks follow-up.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 14/03/2024, Amsterdam UMC Medical Research Ethics Committee (Van der Boechorststraat 7, Amsterdam, 1081BT, Netherlands; +31 (0)20-4445585; metc@amsterdamumc.nl), ref: 2023.0964

Study design

Single center randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Prevention

Participant information sheet

See outputs table

Health condition(s) or problem(s) studied

Prevention of diabetes for people with social jetlag

Interventions

The intervention consists of 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 3 weeks. The control group adheres to their regular sleep habits and conditions.

Randomization will be performed by a statistician from the data management department, who is not involved in the study by using a randomization list. Blocked randomization will be used to ensure good balance of participant characteristics in each group. Randomization will be stratified on sex, two strata of age and two strata of social jetlag to prevent misbalance. Allocation will be determined by using a computerized random number generation process. Due to the nature of the intervention, blinding is not possible. However, since the primary outcomes are glycemic parameters, we do not expect large placebo effects on these outcomes.

Intervention Type

Behavioural

Primary outcome measure

Glycemic control measured as HbA1c levels comparing the intervention and control group in an intention to treat analysis at baseline after 12 weeks.

Secondary outcome measures

All outcomes will be measured over the duration of 3 weeks and 12 weeks:

1. Other glycemic measures: fasting blood glucose and insulin levels, medication use and frequency of hypoglycemic sensation;
2. Metabolic outcomes, including BMI, waist, blood pressure, fat percentage, (para)sympathetic nervous system activity from ECGs and electrochemical skin conductance tests,
3. Sleep measured as sleep times, sleep quality and sleep phases using a sleep measuring Headband (only after 3 weeks);
4. Mood including depression, fatigue and anxiety measured using questionnaires
5. Quality of life measured using the EQ5D questionnaire.
6. Additionally, to assess other factors that might play a role (possible mediators), we will assess the Dim Light Melatonin Onset (DLMO) in saliva samples (in a subgroup), feeling of satiety and satiation is assessed using a 10-cm VAS scale and physical activity using an accelerometer.

Overall study start date

09/07/2023

Completion date

01/10/2024

Eligibility

Key inclusion criteria

1. Social jetlag (>1h) (calculated as difference between midpoint of sleep during week days and free weekend days)
2. (Pre) diabetes: HbA1c >39 mmol/mol (5.7%), fasting plasma glucose >5.6 mmol/l, or 2-hour OGTT >7.8mmol/l (according to the American Diabetes Association) including the use of any glucose-lowering medication
3. Informed consent to be contacted for future research
4. Willing to comply with the study procedures

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

79 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Excessive alcohol use (>21 alcoholic consumptions per week);
2. Having crossed more than 1 time zone in the month prior to participation;
3. Working shifts more than once per month;
4. Unable to provide written informed consent;
5. Visually impaired;

Date of first enrolment

01/04/2024

Date of final enrolment

09/07/2024

Locations

Countries of recruitment

Netherlands

Study participating centre

Amsterdam UMC

Maelsonstraat 7

Hoorn

Netherlands

1624NP

Sponsor information

Organisation

Amsterdam UMC Location VUmc

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.vumc.nl/>

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Charity

Funder Name

Diabetes Fonds

Alternative Name(s)

Dutch Diabetes Research Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/06/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the Hoorn Steering Committee (hoornstudy@amsterdamumc.nl).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	02/02/2024	22/03/2024	No	Yes

Protocol file	version 3	21/02/2024	22/03/2024	No	No
Protocol article		12/07/2024	16/07/2024	Yes	No