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Changing sleep timing to improve glucose metabolism

Submission date
17/10/2023

Recruitment status
No longer recruiting

Registration date
09/05/2024

Overall study status
Ongoing

Last Edited
07/11/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 December 2026

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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 Committe (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

Study type(s)
Prevention

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

Key secondary outcome(s))
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.

Completion date
01/12/2026

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
79 years

Sex
All

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

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

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?
Protocol article		12/07/2024	16/07/2024	Yes	No
Participant information sheet	version 2	02/02/2024	22/03/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3	21/02/2024	22/03/2024	No	No