

# Changing sleep timing to improve glucose metabolism

|                                        |                                                                |                                                                                                                         |
|----------------------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>17/10/2023   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>09/05/2024 | <b>Overall study status</b><br>Ongoing                         | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>07/11/2025       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data<br><input checked="" 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 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

### Contact name

Dr Femke Rutters

### ORCID ID

<https://orcid.org/0000-0002-1008-678X>

### Contact details

Meibergdreef 9

Amsterdam

Netherlands

1105AZ

+31 20 44 45860

f.rutters@amsterdamumc.nl

## Additional identifiers

### 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 Committee (Van der Boerhorststraat 7, Amsterdam, 1081BT, Netherlands; +31 (0)20-4445585; metc@amsterdamumc.nl), ref: 2023.0964

**Primary study design**

Interventional

**Study design**

Single center randomized controlled trial

**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? |
|-----------------------------------------------|-----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>              |           | 12/07/2024   | 16/07/2024 | Yes            | No              |
| <a href="#">Participant information sheet</a> | version 2 | 02/02/2024   | 22/03/2024 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version 3 | 21/02/2024   | 22/03/2024 | No             | No              |