Natural daylight to improve 24h metabolism and glucose control in type 2 diabetes individuals

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

Summary

ID

NL-OMON51072

Source
ToetsingOnline

Brief title
Natural office light and diabetes

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
adult-onset diabetes, type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: University of Maastricht
Source(s) of monetary or material Support: VELUX foundation

Intervention

Keyword: Circadian rhythm, Day-night rhythm, metabolism, Skeletal muscle

Outcome measures

Primary outcome

The primary endpoint is average 24h blood glucose assessed with a continuous glucose monitor.

Secondary outcome

Secondary study endpoints refer to postprandial metabolism upon a mixed-meal tolerance test and circadian transcriptome, lipidome and myokine secretion analyses in skeletal muscle tissue with culturing of human primary myotubes to assess circadian reporter characteristics.

Other exploratory parameters include:

• 24h blood profiles:

o metabolic compounds (glucose, triglycerides, free fatty acids)

o hormones (insulin)

o mass spectrometry-based lipidomics

• Sleep quality questionnaires: LSEQ and PSQI

• 24h indirect calorimetry: substrate metabolism and energy expenditure

• Actigraphy measures: activity count, sleeping times

• 24h blood pressure and heart rate (ambulatory)

• 24h saliva profiles:

o Melatonin and cortisol

• Core body temperature and skin temperatures

• mRNA and protein levels in blood PBMC*s of markers involved in the molecular

clock

• Body composition (BodPod)

Study description

Background summary

Obesity and type 2 diabetes mellitus (T2DM) are both strongly associated with a westernized lifestyle of low physical activity levels and high caloric intake. However, recently it has been recognized that also our 24-hour culture, characterized by working and eating late, reduced sleep (quantity and quality) and excessive light exposure in the evening and at night, should be considered as lifestyle factors that may negatively impact metabolic health. In this context, a factor that is often overlooked and underestimated is the lack of natural daylight since most people spend almost their entire work time in indoor office environments with limited access to natural daylight through windows. To date, only a limited number of studies have investigated the effects of light on human metabolism. Of those, most have investigated artificial light conditions exclusively. Given the fact that artificial light is very limited in its brightness levels and mostly contains a constant wavelength spectrum that is visible to the human eye but neither invisible ultra-violett (UV) nor infrared radiation that are present in sunlight, this leaves vast unprecedented territory to investigate the metabolic effects of natural daylight. Recent human studies that investigated the physiologicals consequences of changing the wavelength spectrum and intensity levels in artificial indoor lighting environments but also animal studies looking at the relevance of dosed UV light for metabolic health all suggest a positive impact of natural daylight on human metabolism. No study has yet determined the effect of an indoor environment that facilitates access to natural daylight through wide windows compared to a typical artificial light environment on metabolic outcomes in T2DM patients.

Study objective

The primary objective is to investigate the potential benefit of scheduled natural daylight exposure to improve glucose control in T2DM individuals and to unravel molecular mechanisms underlying effects of natural daylight on circadian clocks and (glucose) metabolism in human skeletal muscle from T2DM

patients.

Study design

The study will be carried out as a randomized cross-over trial in which each subject serves as its own control. Each participant will undergo two different light exposure sessions.

Intervention

Participants will stay at our research facilities and will be exposed to natural daylight or artificial light during daytime over 4.5 days. For both conditions, the evening and night will be spent under standardized dim and dark conditions.

Study burden and risks

Subjects will first visit the university once for screening purposes during which they will fill in 2 questionnaires and a blood draw will be taken in the fasted state. If subjects are eligible, they will visit the university 3 days before each study period to receive a wrist-worn sleep monitoring device (Actiwatch) and a food and sleep diary, which will be used to assess their sleep duration and meal patterns. In summary, the pre-study visits will require participants to stay 3 hours at the University. During the 3-day monitoring period at home, subjects will have to adhere to a pre-determined lifestyle with a regular sleep-wake cycle, which may limit them in their choice of daily activities. Subjects will then visit the university for two study periods. Each of the two study periods will require that subjects stay for 4.5 days on university premises (2 x 103h = 206 hours in total), which will be interrupted by at least 4 weeks time between two study periods. During daytime, subjects will stay inside in a room with either wide transparent windows under natural daylight or with shielded windows under artificial light. The evenings will be spent under controlled dim light (5 lux) and nights will be spent in complete darkness. On the 4th day, to obtain regular blood samples, an intravenous cannula will be placed into the antecubital vein that remains in place until the end of the study visit. A total of about 527 ml blood will be collected during each of the two study periods. In addition, a muscle biopsy will be performed in the morning of the last day. The blood sampling and muscle biopsy can occasionally cause a local hematoma or bruising. The risk of infection or prolonged bleeding is low due to state of the art techniques and sterility measures. We hypothesize that natural daylight has a positive influence on metabolic health of T2DM patients. However, since this is the first investigation looking into the effect of natural daylight in T2DM patients, it cannot be simply assumed that subjects will benefit in any way. Results of this study will potentially reveal the importance of natural daylight for metabolic outcomes and may hence provide a new non-pharmacological treatment strategy for

T2DM.

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

• Participants are able to provide signed and dates written consent prior to any study specific procedures
• Male + females (postmenopausal defined as at least 1 year post cessation of menses)
• T2D duration at least 1 year
• BMI: >= 25 kg/m²
• Age: 40-75
• Well-controlled diabetes with respect to glycemic control and on stable anti-diabetes medication regimes

• Habitual bedtime of 23:00 ± 2h
• Regular sleep duration (7-9 h/night)
• Stable dietary habits: no weight gain or loss > 5 kg in the last three months

Exclusion criteria

• Insulin treatment
• Uncontrolled hypertension
• Signs of active diabetes-related co-morbidities like active cardiovascular diseases, active diabetic foot, polyneuropathy or retinopathy
• Signs of active liver or kidney malfunction
• Use of SGLT2 inhibitors
• Using > 400mg caffeine daily (more than 4 coffee or energy drink)
• Extreme early bird or extreme night person (score <=30 or >=70 on MEQ-SA questionnaire)
• shift work or travel across more than one time zone in the 3 months before the study
• Heavily varying sleep-wake rhythm
• engagement in programmed exercise for more than 3h/week
• Any medication that will interfere with the study outcomes or hamper the safety of the participant
• Alcohol consumption of >2 servings per day for man and >1 serving per day for woman
• Subjects who do not want to be informed about unexpected medical findings during the screening /study, or do not wish that their physician is informed, 1 month prior to the screening visit
• Significant food allergies/intolerance (seriously hampering study meals)
• Participation in another biomedical study within 1 month before the first study visit
• Smoking in the past 6 months
A medical doctor will judge participation eligibility based on the medical history questionnaire, medication use and fasting blood parameters. If the medical doctor advises that a patient cannot participate, the patient will be excluded from enrollment.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-03-2022
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	03-12-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL77984.068.21

Study results

Date completed: 22-12-2022

Summary results
Trial ended prematurely