Timing exercise training as strategy to improve nocturnal glucose levels and substrate metabolism in men and woman with pre-diabetes

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

Summary

ID

NL-OMON53883

Source
ToetsingOnline

Brief title
Timed Training Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
glucose intolerance, insulin resistance

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: NWO

Intervention

Keyword: day-night rhythm, Exercise, insulin sensitivity, substrate oxidation

Outcome measures

Primary outcome

The primary study endpoint is the nocturnal glucose levels measured by a continuous glucose monitor (CGM).

Secondary outcome

The secondary outcomes are 24h energy and substrate metabolism. Exploratory outcomes are body composition, intrahepatic lipid content, hepatic insulin sensitivity, hepatic glycogen levels, maximal aerobic capacity, skeletal muscle oxidative capacity, visceral and subcutaneous adipose tissue volume, sleeping metabolic rate, blood glucose levels (continuously measured over 7days), feet sensitivity, immune responses and patient perceived experiences with timed exercise.

Study description

Background summary

Various metabolic processes, including resting metabolic rate, insulin sensitivity and insulin secretion, follow a recurring 24-hour cycle. These rhythms are shown to be disturbed in in pre-diabetes volunteers compared to young healthy volunteers. In a retrospective analysis of an exercise training program performed either in the morning or afternoon, we found that the afternoon training group improved their peripheral insulin sensitivity and fasting plasma glucose levels to a greater extent than the morning group. However, underlying mechanisms are unclear.

Study objective

The main objective of this study is to determine whether prolonged exercise training in the afternoon (15:00-17:00 PM) differs from exercise training in the morning (07:00-09:00 AM) in improving nocturnal glucose levels in individuals with pre-diabetes, and to investigate its underlying mechanisms.

Study design

The present study is a randomized double arm longitudinal intervention study in a pre and post design.

Intervention

Participants will perform a 12-weeks supervised high intensity interval training (HIIT) program with three ~30 min exercise sessions per week. Participants will be randomly assigned to the morning or afternoon training time. To assess the outcomes, participants will come to the university for a 35,5h measurement period both before and after the 12-week training program.

Study burden and risks

Before starting the exercise training, participants will visit the University 3 times for a screening and two pre-intervention visits including a 35,5h stay at the research unit. During the exercise intervention period, subjects will visit the University 3 times per week for 12 consecutive weeks to receive supervised exercise training. After 12 weeks of exercise training, participants will again stay at the research unit for 35,5h and measurements will be repeated. The main burden of this study is the large time investment for the exercise training period (12 weeks, 3 times/week). Moreover, the pre- and post-training test days comprise several non-invasive and invasive measurements. The used techniques are safe, but the muscle biopsies can cause some discomfort and may result in a local bruise or hematoma. Likewise, blood sampling can cause a local hematoma. The risk of infection and/or prolonged bleeding is very low due to state-of-the-art techniques and sterility measures. In total, we will draw approximately 271 ml blood during the entire study period. Measurements performed during the time course of the study can potentially lead to unexpected medical findings. Participants and their GP will be informed about such a finding. If a participant does not want to be informed about incidental findings, participation in this study is not possible.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6200 MD
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6200 MD
NL

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 dated written informed consent prior to any study specific procedures
• Aged 40-75 years
• Body mass index (BMI) >=25 kg/m2
• Male, or postmenopausal (at least 1 year post cessation of menses) female
• Have suitable veins for cannulation or repeated venepuncture
• Pre-diabetes based on one or a combination of the following criteria:
o Impaired Glucose Tolerance (IGT): plasma glucose values >= 7.8 mmol/l and <= 11.1 mmol/l 120 minutes after glucose drink consumption during OGTT in screening
o Impaired Fasting Glucose (IFG): Fasting plasma glucose >= 6.1 mmol/l and <= 6.9 mmol/l
o Insulin Resistance: glucose clearance rate <= 360 mL/kg/min, as determined during the OGTT using OGIS120
o HbA1c of 5.7-6.4%

Exclusion criteria

• Type 2 diabetes
• Patients with active congestive heart failure and and/or severe renal and or liver insufficiency
• Uncontrolled hypertension
• Any contra-indication for MRI scanning
• Alcohol consumption of >3 servings per day for man and >2 serving per day for woman
• Smoking
• Unstable body weight (weight gain or loss > 5kg in the last 3 months)
• Previous enrolment in a clinical study with an investigational product during the last 3 months or as judged by the Investigator which would possibly hamper our study results
• Medication use known to hamper subject*s safety during the study procedures
• Subjects who do not want to be informed about unexpected medical findings
• Men: Hb <8.0 mmol/L, Women: Hb <7.0 mmol/l
• Heavily varying sleep-wake rhythm (i.e. night shift work and travels across time zones).
• Significant food allergies/intolerance (seriously hampering study meals)
• Blood donation during or within 2 months prior to the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-12-2023
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	12-06-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-12-2024
Application type:	Amendment
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
Other	n.n.b.
CCMO	NL83421.068.22