Timed exercise to acutely improve energy and substrate metabolism at night in men and women with prediabetes

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The primary study endpoint is the respiratory exchange ratio (RER) during the night. The secondary objectives are to examine how differentially timed exercise affects 1) 24h energy and substrate metabolism and 2) the immune response based on...

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

Summary

ID

NL-OMON49902

Source ToetsingOnline

Brief title TIM

Condition

• Glucose metabolism disorders (incl diabetes mellitus)

Synonym

glucose intolerance, insulin resistance

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

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Source(s) of monetary or material Support: NWO

Intervention

Keyword: Day-night rhythm, Exercise, Immune system, Substrate oxidation

Outcome measures

Primary outcome

Substrate utilization and energy expenditure

Secondary outcome

Parameters regarding the immune systeem

Study description

Background summary

In recent years, several key metabolic processes have proven to be rhythmic over the course of a day. Furthermore, this rhythmicity in metabolism has been shown to be disturbed in adults with obesity and related metabolic disturbances, such as insulin resistance and type 2 diabetes (T2D). Accordingly, we previously observed a clear 24h rhythmicity in energy and substrate metabolism in healthy, lean men but a complete lack of such rhythmicity in insulin-resistant men, at risk for developing T2D. Most strikingly, fat oxidation increased profoundly during the night in healthy men whereas individuals with pre-diabetes did not readily switch to the fat oxidative state during the night.

Appropriate timing of lifestyle interventions may facilitate healthy rhythmicity in metabolism and optimize the effectiveness of such interventions in improving metabolic health. In this context, exercise is well-known to improve (skeletal muscle) energy metabolism and is an established intervention to improve muscle insulin sensitivity and to counter the development of T2D. In addition, exercise may also have beneficial effects on the immune response that is known to impact on insulin sensitivity and overall metabolic health. Here, we hypothesize that exercise performed at different times of the day exerts a differential effect on 24h metabolism in people at risk for developing T2D.

Study objective

The primary study endpoint is the respiratory exchange ratio (RER) during the night. The secondary objectives are to examine how differentially timed

exercise affects 1) 24h energy and substrate metabolism and 2) the immune response based on circulating immune cell phenotypes and 3) continuously measured blood glucose levels over the 7 days following the exercise bout.

Study design

Randomized cross-over design

Intervention

Exercising in the morning or late afternoon

Study burden and risks

Low risk

Contacts

Public Universiteit Maastricht

Universiteitssingel 60 Maastricht 6229 ER NL **Scientific** Universiteit Maastricht

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Males and post-menopausal females at risk for type 2 diabetes

Exclusion criteria

Any underlying disease or conditions interfering or hampering study activities

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	16-03-2022
Enrollment:	60
Туре:	Actual

Ethics review

Approved WMO	
Date:	07-01-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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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 ClinicalTrials.gov CCMO

ID NCT05073068 NL78628.068.21