Effect of fasting and exercise on physical performance and muscular oxidative metabolism

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

Summary

ID

NL-OMON38613

Source
ToetsingOnline

Brief title
Effect of fasting and exercise

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
insulin resistance syndrome, metabolic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: European Nutriceutical Services BV

Intervention

Keyword: Exercise, Fasting, Oxidative metabolism, Physical performance

Outcome measures

Primary outcome

The main outcome of the current study is the change in body composition and in physical performance in the intervention group as compared to the control group.

Secondary outcome

The secondary outcomes of the current study are differences between the experimental group and the control group in the following parameters: 1) a change in health indicators; 2) a change in the outcome of several questionnaires; 3) a change in histology; and 4) a change in several markers of mitochondrial biosynthesis and fat oxidation.

Study description

Background summary

Recently, a program which combines fasting with exercise, has been developed. This program is called Sport Fasting (www.sportvasten.nl) and consists of ten days in which nutrient availability is slowly reduced (three days), maintained low (three days), and increased again (four days). In addition to this diet program, participants need to train 30 minutes each day and receive additional amino acids, omega 3 and 6 fatty acids, minerals, and anti-oxidants. This program claims a shift towards fat oxidation and an increased mitochondrial density in the muscles, which are associated with long-term weight loss, an improved health status, and an enhanced endurance capacity. Qualitative, non-controlled results suggest positive effects of the Sport Fasting program on body mass, and physical performance, in addition to a list of other health benefits.
The experienced success of Sport Fasting is based on the hypothesis that fasting in combination with exercise is more effective in establishing weight

loss and increasing endurance performance than fasting alone. This hypothesis is based on the assumption that the combination of fasting and an exercise program may enhance fat oxidation and oxidative capacity within the active skeletal muscles. As yet, effects of fasting in combination with an exercise program on these parameters and the underlying mechanisms are unknown. In addition, not all subjects who completed the program do benefit from this program. In order to improve this program, it is important to obtain insight in the effects and mechanisms of a period of fasting in combination with an exercise program. Furthermore it is important to explore whether fasting in combination with exercise is more effective than fasting alone in establishing weight loss, as well as improving endurance capacity, by increasing mitochondrial density and fat oxidation within the skeletal muscles.

Study objective

The main objective is to explore the effects of a 10-day fasting and exercise program on body composition and physical performance (peak power, endurance capacity, efficiency and resting VO2¬) of overweight, fit men and compare these effects with those of fasting alone. The secondary objective is to investigate the effects of a 10-day fasting and exercise program on the determinants of physical performance at the molecular level and relate these to changes in physical performance parameters (the exercise tests). For this purpose subjects will be subjected to exercise tests and muscle biopsies. The muscle biopsies will be analysed with respect to histological characteristics related to oxidative and anaerobic metabolism (mitochondrial density, myoglobin concentration, muscle fiber typing, muscle fiber size and capillary density, GAPDH) in the vastus lateralis muscle of overweight, fit men in comparison with fasting alone.

Study design

A randomized controlled (pilot) study using a longitudinal study design to determine the effects of the proposed intervention.

Intervention

One group will be subjected to a 10-day fasting protocol, which implies 3 days of reducing food intake, 3 days of drinking fruit juices and 4 days of building up food intake again (control group). The other group will be subjected to the exact same fasting protocol, but with an addition of 30 minutes exercise each day (intervention group).

Study burden and risks

The burden for the participants consists mainly of the number of hours that the participants need to invest in the research project (measurements, meetings

etc.). The total number of hours that the participants need to present at the Vrije Universiteit or at Medico Vision, is estimated to be about 25 hours. In addition, the participants need to perform 30 minutes of intense exercise each day during the 10 day program. However, 30 minutes exercise is part of the program, so participants who take part in the Sport Fasting protocol but not in the research also need to invest this amount of time. The burden of the muscle biopsies is minor. The procedure does not take very long and the discomfort afterwards is minimal. The risks of the additional measurements are negligible. In contrast, the participants might benefit from taking part in this research project. The possibility that they will lose weight and enhance their endurance capacity is high. Furthermore, the program will be offered for free to participants taking part in this research project and after the research participants can take part in another free (complete) Sport Fasting program. Besides that, this project will most likely increase our knowledge regarding the effects and mechanisms of the program and will create the possibility to optimize the program for further use.

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

* Men, age 18-45 year
* BMI 25-30 kg/m2
* Blood pressure > 70/110
* Healthy: based on the outcome of the anamnesis form
* Free of medication
* Be able to cycle at least half an hour at 150 W
* Be able to take enough time and rest to complete the 10-day program

Exclusion criteria

* Smokers
* Alcohol or drug abuse
* Eating disorders (or history of eating disorders)
* Sensitive to stress and psychological problems
* Participated in a Sport Fasting program within 6 months before the start of the current study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-05-2013
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO Date:	07-06-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL43423.029.13