

The effect of sweet orange and pomegranate extract supplementation on exercise capacity: a randomized controlled parallel intervention study in healthy overweight individuals

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The aim of the present study is to investigate the effect of 12-week long daily administration of a sweet orange and pomegranate extract on exercise capacity in healthy adults (40 - 65 y).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52281

Source

ToetsingOnline

Brief title

ActiFul 2

Condition

- Other condition

Synonym

performance, physical fitness

Health condition

physical fitness

Research involving

Human

Sponsors and support

Primary sponsor: Faculty of health, medicine and life sciences

Source(s) of monetary or material Support: Ministerie van OC&W, Bedrijf: BioActor BV, BioActor B.V.

Intervention

Keyword: Exercise capacity, Orange, Polyphenols, Pomegranate

Outcome measures

Primary outcome

Change in aerobic capacity (VO₂max), assessed with an Eklom-Bak submaximal cycling test.

Secondary outcome

- Daily physical activity as determined by accelerometer
- Dietary intake as measured by a 3-day food record
- Muscle strength as measured by Handgrip strength
- Muscle cell proliferation and differentiation and mitochondrial biogenesis assessed in skeletal muscle biopsies
- Quality of Life as measured by the WHO-QOL-100 questionnaire
- General health as measured by SF-36 questionnaire
- Vitality as measured by the Dutch Vitality Questionnaire (Vita-16)
- Cardiometabolic health biomarkers, cortisol, C-reactive protein determined with ELISA
- Antioxidative capacity measured with a Trolox equivalent antioxidant capacity (TEAC) assay

Study description

Background summary

Polyphenols have been studied for their protective effect against the development of ROS-related diseases like cancers, cardiovascular diseases, diabetes, osteoporosis, and neurodegenerative diseases. The combined supplementation of pomegranate and sweet orange polyphenols could be an effective strategy to improve exercise performance, due to their antioxidant character and ability to stimulate NO production, to stimulate mitochondrial biogenesis and to accelerate muscle repair and decreasing muscle tissue damage. The study aims to assess the effect of a combined supplementation of pomegranate and sweet orange extract on exercise capacity, physical activity, muscle strength and quality of life in healthy adults.

Study objective

The aim of the present study is to investigate the effect of 12-week long daily administration of a sweet orange and pomegranate extract on exercise capacity in healthy adults (40 - 65 y).

Study design

Randomized, double-blind, placebo-controlled parallel trial

Intervention

12-week supplementation with 650 mg sweet orange and pomgranate extract (2 capsules per day) compared to placebo (760 mg maltodextrin).

Study burden and risks

In a period of 14 weeks, participants will attend five test days, resulting in a time investment of approximately 6.5 hours in total. Furthermore, participants have the possibility to take part in the sub-study, in which two more study days will be performed with a time investment of 45 minutes each. During the study, participants will perform a sub-maximal cycling test which might lead to tiredness and muscle soreness. Blood samples will be taken, which might lead to minor discomfort and could cause small and transitory hematoma/bruises to appear. Participants will be asked to wear an accelerometer twice for a period of 7 days and to fill in a 3-day food record on three occasions. The muscle biopsy could cause local hematoma and after the biopsy, some participants may report muscle muscle stiffness or pain for a couple of

days.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Healthy male/female (based on medical history provided during a general health questionnaire)
- Age between 40 - 65 yrs
- Overweight (BMI ≥ 25 to ≤ 29.9 kg/m²)
- Inactive subjects (< 600 MET minutes of structured aerobic exercise per week as assessed by the Physical Activity Questionnaire (IPAQ))

Exclusion criteria

- Allergy to test product/control or citrus fruits and pomegranate
- Medical conditions that might interfere with endpoints or compromise participant safety during testing (e.g. Cardiovascular diseases, cancer, Parkinson*s disease, Gastrointestinal diseases or abdominal surgery) to be decided by the principal investigator
- Use of medication that might interfere with endpoints (i.e.: β -blockers, antioxidant, antidepressants.)
- High fasting blood glucose (FBG ≥ 126 mg/dL)
- Recent skeletal muscle injury in less than one month before the start of the study
- Use of antibiotics within 3 months prior Visit 2
- Use of probiotics or supplements containing vitamins, minerals or antioxidants four weeks prior to Visit 2
- Regular smoking (including use of e-cigarettes)
- Inability to correctly perform the PA test during screening/familiarization
- Abuse of alcohol (alcohol consumption >20 units/week) and/or drugs
- Plans to change diet or medication for the duration of the study
- Treatment with an investigational drug (phase 1-3) 180 days before the start of the study
- Inability to understand study information and/or communicate with staff

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2021
Enrollment:	52

Type: Actual

Ethics review

Approved WMO

Date: 25-08-2021

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 04-04-2022

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

CCMO

ID

NL77699.068.21