Beneficial effects of vegetable consumption and a diet intervention on health in lean and obese men.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33178

Source
ToetsingOnline

Brief title
Vegetable consumption in relation to health.

Condition

- Other condition

Synonym
inflammation, oxidative stress, recovery, resilience

Health condition

niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Volksgezondheid, Welzijn en Sport (VWS)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Challenge test, Health, Recovery/resilience, Vegetables

Outcome measures

Primary outcome

Main study parameters/endpoints: A *challenge test* will be used as a physical stress test to examine whether subjects show more or less resilience to the test. The reaction and recovery of the human system to the exercise test may be used as indicators of health status on different biological analyses (transcriptomics; metabolomics; rules based medicine pm). Different analyses to measure oxidative stress will be performed. Also standard health biomarkers will be determined to examine the intervention effects.

Secondary outcome

Additional blood variables.

Effect of body weight loss on these parameters.

Study description

Background summary

Consumption of vegetables is generally considered to be associated with several positive effects on health. Vegetables are a heterogeneous group of our diet which is rich in bio-actives. The vegetables contain a range of vitamins, minerals, dietary fibres and phytochemicals like potassium, flavonoids, carotenoids, and vitamin C. The recommended intake of vegetables by the Dutch Health Council is 200 grams daily (Health Council, 2006).
Health in this project is defined as the possibility of a subject to change and

adapt easily in response to a certain challenge. Healthy subjects show resilience in different physiological processes related to oxidative stress, metabolic stress, neurological stress and inflammatory stress. The reaction/response to a challenge might be changed when subjects have consumed more or less vegetables and have an improved health status. The response might also differentiate between subjects differing in BMI (healthy weight versus overweight/obese). Supplementation of vegetables will be provided in two conditions: a low and a high daily intake (50 versus 200 grams daily). An intervention known to have positive effects on health is weight loss. This will be studied in relation to health (the reaction to the challenge test) as well. A beneficial effect is present when 5% improvement of health markers is shown with vegetable supplementation, similar as is known from weight loss studies.

Study objective

The primary objective of the present study is to set-up a methodology to investigate health based on the resilience to challenge. A secondary objective is the effectiveness of the challenge concept with a food intervention. The vegetable supplementation study is a first example to test the challenge concept. Therefore, vegetable consumption according to the recommendations of the Dutch Health Council of 200 grams of vegetables daily will be studied with an exercise challenge test, to investigate the beneficial *health* effects.

Study design

The study is designed as a randomized, cross-over and parallel, open study.

Intervention

Intervention: each intervention lasts four weeks:
* High Vegetable treatment: consumption of 200 grams of vegetables daily;
* Low Vegetable treatment: consumption of 50 grams of vegetables daily;
* An energy restricted diet intervention with the habitual vegetable consumption.

Study burden and risks

Healthy lean and obese subjects will participate in a vegetable intervention study to examine the difference in physiological responses due to body weight differences. Lean and obese subjects might represent a range in disease state, with the obese being representatives for disease in whom less flexibility to challenges are expected. In the study subjects undergo three treatments, lasting four weeks each, therefore they are in study for 12 weeks. After three weeks abdominal subcutaneous fat samples will be collected. At the end of each treatment period subjects will visit TNO for a test day. Blood samples will be drawn and a maximal exercise stress test will be performed in combination with

a sugar test to determine the intestinal permeability. Urine will be collected for 24 hours after the exercise test and a blood sample will be drawn 24 hours after exercise as well. No risk or real burden is of concern in this study.

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

1. Healthy as assessed by the
- health and lifestyle questionnaire, (P8374 F02; in Dutch)
- physical examination
- results of the pre-study laboratory tests
2. Males aged * 18 and * 45 years at Day 01 of the study
3. Body Mass Index (BMI): for the lean : >= 20 and <= 25 kg/m2; obese >= 30 and <= 35 kg/m2

4. Normal Dutch eating habits as assessed by P8374 F02
5. Used to consume vegetables daily and liking vegetables (P8374 F02 and F06)
6. Physically able to perform a maximal cycling exercise test
7. Voluntary participation
8. Having given written informed consent
9. Willing to comply with the study procedures
10. Appropriate veins for blood sampling according to TNO
11. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years
12. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

Exclusion criteria

1. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study
2. Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study, including no blood sampling and/or oral, intravenous, or inhalatory administration of substances
3. Having a history of medical or surgical events that may significantly affect the study outcome, including cardiovascular disease or hypertension and/or (food) allergy
4. Using prescribed medication or taking pain killers on a regular basis (judged by the medical investigator) ;
5. Smoking
6. Exercise regularly and exceed the Dutch Standard of Healthy Physical Activity of 2.5 hours/week
7. Alcohol consumption > 28 units/week
8. Reported unexplained weight loss or gain of > 2 kg in the month prior to the pre-study screening
9. Reported slimming or medically prescribed diet
10. Recent blood donation (<1 month prior to the start of the study)
11. Not willing to give up blood donation during the study
12. Personnel of TNO Quality of Life, their partner and their first and second degree relatives
13. Not having a general practitioner
14. Not willing to accept information-transfer concerning participation in the study, or information regarding his health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2009
Enrollment:	32
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	09-07-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-09-2009
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL28861.028.09