Long-term effects of green tea on gut flora, fat absorption, body composition and resting energy expenditure

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To investigate the long-term effects of green tea on gut flora, fat absorption, resting energy expenditure and body composition.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON37757

Source
ToetsingOnline

Brief title
Long-term effects of green tea

Condition

- Appetite and general nutritional disorders

Synonym
obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fat absorption, green tea, gut flora, resting energy expenditure

Outcome measures

Primary outcome

The primary endpoint of this study is the possible change in gut flora and fat absorption.

Secondary outcome

Secondary study parameters/endpoints are resting energy expenditure and body composition.

Study description

Background summary

Green tea may have positive effects for weight control and on body composition via several approaches such as a positive effect on the gut flora, a decrease in fat absorption from the intestines and an increase in resting energy expenditure.

Study objective

To investigate the long-term effects of green tea on gut flora, fat absorption, resting energy expenditure and body composition.

Study design

The study will be conducted in a randomized, placebo-controlled, double-blind parallel design with four groups consisting of control groups and green tea groups with normal weight subjects and obese subjects. At three time points (baseline, 6 weeks and 12 weeks) faeces are collected for analyzing the gut flora composition and fat content. Furthermore, measurements of resting energy expenditure and body composition will be conducted. Activity will be measured during three weeks (baseline, week 6 and week 12).

Intervention

Subjects will receive either green tea or placebo in capsule form after their baseline measurement, which they have to consume three times daily for a period of twelve weeks.

Study burden and risks

The study does not include any major risk for the subjects. The collection of faeces will be harmless. Anthropometric and body composition measurements will not be invasive for the subjects. Deuterium dilution has been shown to be a safe method for determining total body water and thereby body composition. Furthermore, the air in the hood is continuously regulated.
Administering green tea will not form any health risk. Green tea is a natural product, which is safe in the given dose.

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

A total of 100 subjects (50 males and 50 females) with a BMI between 18.5-25 kg/m2 and *30 kg/m2 and aged between 18-50 years will be included in the study. All subjects will be healthy, weight stable, dietary unrestraint, not using a more than moderate amount of alcohol (>10 consumptions/wk) or more than 100 mg caffeine per day, not drinking tea, not using probiotics, being weight stable (weight change < 3kg during the last 6 months), dietary unrestraint and not using antibiotics during the last 6 months. The Dutch translation of the Three Factor Eating Questionnaire (TFEQ) will be used to determine eating behaviour (10). Non-restrained eaters (<9 times factor 1), these are persons who are not consciously occupied with food and who are not caloric restricted, will be selected. Subjects will be free of medication except for oral contraceptives use in women.

Exclusion criteria

Subjects will be excluded if they are not healthy, smoking, using a more than moderate amount of alcohol or more than 100 mg caffeine per day, drinking tea, using probiotics, not being weight stable, dietary restraint, using medication or supplements except for oral contraceptives in women, using antibiotics or if they do not meet the criteria for BMI and age. Pregnant and lactating women, and subjects with allergies for the used food items will also be excluded from participation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	04-07-2012
Application type:	First submission
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
ClinicalTrials.gov	NCT01556321
CCMO	NL38773.068.11