Black Tea and Attention

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Pilot:To investigate whether there is a significant difference in variability of performance on attention tests between the pilot and previous studies conducted by Unilever.Hoofdonderzoek: To show that black tea improves attention using attention...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34141

Source
ToetsingOnline

Brief title
Black Tea and Attention

Condition

- Other condition

Synonym
Attention, concentration

Health condition

alertheid, concentratie

Research involving
Human

Sponsors and support

Primary sponsor: Unilever
Source(s) of monetary or material Support: Unilever.

Intervention

Keyword: Attention, Black Tea

Outcome measures

Primary outcome

Pilot:

To investigate whether there is a significant difference in variability of

performance on attention tests between the pilot and previous studies conducted

by Unilever.

Hoofdonderzoek:

To show that black tea improves attention using attention tests.

Secondary outcome

Not applicable.

Study description

Background summary

Tea is the second most widely consumed beverage in the world only being surpassed by water. It has been historically associated with enhanced concentration, which refers to the psychological concept of attention.

Study objective

Pilot:
To investigate whether there is a significant difference in variability of performance on attention tests between the pilot and previous studies conducted by Unilever.

Hoofdonderzoek:
To show that black tea improves attention using attention tests.

Study design

Pilot:
16 Healthy males and females will participate. The study will consist of 1 screening and 1 visit.

Hoofdonderzoek:
40 Healthy males and females will participate. The study will consist of 1 screening and 4 visits.

Study burden and risks

The risks associated with this investigation are minimal. The burden on the volunteer will continue to work with the recording periods, and assessments preformed during the study. All volunteers are closely monitored and supervised by experienced doctors and studystaff.

Contacts

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Unilever

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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) Male and female participants in the age 18 - 50 at start of the study;
2) Weight range for males: 85 kg +/- 10 kg; Weight range for females: 65 kg +/- 10 kg;
3) BMI: 20.0 - 30.0 kg/m2;
4) Healthy
5) Alcohol consumption for females < 14 units/week and males < 21 units/week;
6) Informed consent signed;
7) Having a general practitioner (GP);
8) Capable of performing cognitive tests on a computer (performance > 50%;
9) Proficient in Dutch language (and able to understand written instructions);
10) Consumes caffeine (3 cups of either tea, cola or coffee per week minimum) maximum of 21 cups per week to avoid withdrawal effects.

Exclusion criteria

1) Being an employee of Unilever or the CRO;
2) Not usually having breakfast in the morning;
3) Currently on a medically prescribed or slimming diet;
4) Undergoing medical treatment that may interfere with the study outcome as assessed by the research physician;
5) Reported lactating (or lactating < 6 weeks ago), pregnant (or pregnant < 3 months ago) or wish to become pregnant during the study;
6) Use of systemic antibiotics in the period of 3 months prior to the study;
7) Intense exercise >10 h/w;
8) Reported weight loss/gain > 10% of body weight in the 6 month preceding pre-study examination;
9) Reported participation in another biomedical trial 3 months before the start or before last dosing;
10) The habit of smoking during the past 6 months or using nicotine containing products during the past month;
11) Reported participation in night shift work (1 week before screening and during the study);
12) Colour-blindness or self-reported dyslexia;
13) Participation in pilot study (only for main study).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2010
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO

Date:	27-06-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL33009.056.10