Effect of caffeine on attention and alertness as evaluated in an at home setting

Published: 11-07-2013
Last updated: 22-04-2024

The current study is aimed to evaluate the procedure of performing a non invasive intervention study by subjects themselves performing the tests at home.

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

Summary

ID

NL-OMON38931

Source
ToetsingOnline

Brief title
Caffeine effect on attention and alertness

Condition

- Other condition

Synonym
alertness, cognition

Health condition

aandacht en alertheid

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: ca 100kEURO

Intervention

Keyword: caffein cognition at home

Outcome measures

Primary outcome

Effects on alertness and attention will be established by three computerized tests provided by Quantified Mind. The tests will be performed by the subjects at t=0 (baseline, prior to coffee consumption) and t=1h in one go. Each test will be performed during 5 minutes. During the training session the participants will be instructed to get acquainted with the task.

Secondary outcome

Adverse events

Study description

Background summary

There is increasing interest in the general public in measuring health parameters at home, instead of in a medical setting. Many tests for measuring health parameters are commonly available in drug stores as well as online. When structured, this trend may also be used for performing a randomized intervention trial. TNO started a project to design a randomized double blind study, in which parameters will be measured in the at-home setting instead of in a clinical setting

Study objective

The current study is aimed to evaluate the procedure of performing a non invasive intervention study by subjects themselves performing the tests at

home.

Study design

The study is designed as a randomized placebo-controlled double blind crossover study.

Intervention

Subjects have to consume a cup of coffee after an overnight fast. Coffee will be prepared from a powder coffee containing either regular coffee or decaf coffee.

Study burden and risks

We do not foresee any risk. The coffee products are commercially available and therefore prepared according to food laws. The recruited subjects are habitual coffee drinkers, and the studied dose is a normal portion of caffeine.

Contacts

Public
TNO

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NL
Scientific
TNO

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy as assessed by the:
- health and lifestyle questionnaire
2. Adult age (>18y)
3. Able to perform computerized tests
4. Voluntary participation
5. Having given written informed consent
6. Willing to comply with the study procedures
7. Moderate caffeine users
8. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data
9. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned

Exclusion criteria

1. Having a history of medical or surgical events that may significantly affect the study outcome, including psychiatric disorders
2. Physical, mental or practical limitations in using computerized systems
3. Use of concomitant medication including medication known for its effects on mood and/or attention (anti-depressives, sleep medication, etc)
4. Alcohol consumption > 28 units/week for males and > 21 units (drinks)/week for females
5. TNO personnel location Zeist or Soesterberg, their partner and their first and second-generation relatives
6. Not having a general practitioner
7. Not willing to accept information-transfer concerning participation in the study, or information regarding his/her health. For example, findings at health and lifestyle questionnaire interview, and eventual adverse events communicated to and from their general practitioner

Study design

Design

Study type:	Interventional
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):	01-11-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-10-2013
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	NL45382.028.13