The effect of acute caffeine consumption on performance and brain activity following a *real-life* workday

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON35704

Source
ToetsingOnline

Brief title
The effect of caffeine on brain activity

Condition

- Cognitive and attention disorders and disturbances

Synonym
burnout, life-long learning

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Caffeine, Fatigue, Functional neuroimaging, Learning

Outcome measures

Primary outcome

The main outcome measures are subjective fatigue and vitality ratings, neuropsychological performance (mean reaction time and accuracy) and the fMRI blood oxygen level dependent (BOLD) response during working memory and verbal learning tasks.

Secondary outcome

Secondary outcome measures are the concentration of caffeine in saliva throughout the test sessions and blood glucose levels at the beginning of the test session.

Study description

Background summary

The stimulant effects of caffeine result in its common consumption by individuals in an attempt to combat the detrimental effects of fatigue on performance. However, inconsistent findings regarding the effects of caffeine on cognitive performance mean that the actions of caffeine on cognition are unclear. Further, very few studies have examined brain activity underlying caffeine induced behavioural effects. The present study will use functional magnetic resonance imaging (fMRI) to investigate the effects of acute caffeine consumption in the *real life* context of habitual caffeine use on the brain activity of individuals fatigued by a *real life* workday. Findings will shed light on the mechanisms whereby caffeine affects behaviour and alleviates fatigue.
The study also has a much broader research aim to investigate the use of fMRI as a more sensitive tool for the detection of the effects of nutritional interventions. Functional MRI has already been demonstrated to be a more sensitive method for the detection of subtle cognitive impairment following mild traumatic brain injury, multiple sclerosis, human immunodeficiency virus

and chronic fatigue syndrome. The use of fMRI provided validation of cognitive complaints in these groups where assessment using neuropsychological tasks could not. Similarly, it is hoped that fMRI will be able to provide validation of the subjective fatigue alleviating effects of nutritional interventions by demonstrating cognitive task related changes in brain activation.

Study objective

This study aims to determine the effects of acute coffee consumption compared to consumption of decaffeinated coffee on subjective fatigue and vitality ratings, neuropsychological performance and brain activity during working memory and learning tasks. Acute effects will be investigated following a *real life* workday during which caffeine was consumed according to the participant*s habitual regime.

Study design

The study employs a within-subject design and is a placebo controlled intervention study.

Intervention

All participants will be tested twice: once after acute caffeinated coffee administration (100 mg caffeine, equivalent to 1 cup of coffee) and once after acute decaffeinated coffee administration (placebo).

Study burden and risks

Before inclusion in the study, participants will complete a medical questionnaire and a questionnaire that checks for MRI contraindications and factors affecting caffeine pharmacokinetics. When included, the participants will visit the laboratory three times: for a training session (1 hour) and two test sessions (2 hours each). During each test session participants will complete questionnaires at three different time points, will perform neuropsychological tasks outside the MRI scanner (30 min) and two cognitive tasks (1 hour) inside scanner. The risks related to this study are negligible.

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

Male, aged 40-60, right handed, moderate caffeine consumers.

Exclusion criteria

Psychological or physical health conditions and MRI contraindications.

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:	Recruitment stopped
Start date (anticipated):	27-10-2009
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	23-03-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-06-2010
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

ID: 20613
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL26036.068.08
Other	to be advised
OMON	NL-OMON20613