The relation between cognitive performance and decision making: modulation with modafinil

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49250

Source
ToetsingOnline

Brief title
Cognition and decision making

Condition

- Other condition

Synonym
not applicable

Health condition

geen aandoening

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognition Enhancement, Decision Making, Modafinil

Outcome measures

Primary outcome

The main study parameters are behavioral data from economic decision-making paradigms. In particular, elicited parameters describing preferences over risk, time, and losses.

Secondary outcome

Social preferences, trust, and reciprocity are secondary parameters, as well as cognitive performance on our control tasks.

Study description

Background summary

Cognition is a broad concept and entails many brain functions. This includes attention or memory but also more complex decision making. Recently, a relation between a good performance in neuropsychological tasks (measuring attention and memory) and complex decision making processes (for example gambling tasks in which probabilities of outcomes differ, economic decisions) has attracted a lot of interest. It is generally assumed that better cognition is associated with better decision making, although the exact causal link has not been shown yet. In this study, we would like to investigate the relation between these two cognitive dimensions. In order to modulate cognitive performance, and to test whether this is associated with better decision making, we will use modafinil treatment. While modafinil is widely known to improve cognitive performance, it is yet unknown how it affects decision making. Thus, this allows investigating the relation between cognition and decision making.

Study objective

The main objective is to test whether an improved cognitive performance, achieved by administering modafinil, is associated with improved economic decision making, in particular regarding preferences over time, risk and losses, as well as social preferences and trust.

Study design

The experiment will be randomized, double-blind and placebo-controlled. All effects are measured between subjects.

Intervention

Given the between-subjects design, subjects will either receive placebo or 200 mg modafinil. The medication will be administered orally. The participants will be asked to perform various tests related to cognitive performance and decision making.

Study burden and risks

The time investment for the participants will be around 270 min, which is comprised of 1) filling in medical questionnaire, 30 min and 2) one test session of around 210 min. The day before their test day, the participants are not allowed to drink any alcohol. On the test day, participants are not allowed to smoke or drink caffeinated drinks. Furthermore, they are asked to refrain from using drugs throughout the study. The treatments are a single dose of either modafinil 200 mg or placebo.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• In the opinion of the investigator, the participant is capable of understanding and complying with protocol requirements.
• The participant is male or female.
• The participant has a body mass index of 18.5-30 kg/m2, inclusive, as stated in the medical screening form.
• The participant is aged 18 to 40 years, inclusive, at the time of informed consent.
• The volunteer is healthy, i.e., the absence of all exclusion criteria and had normal or corrected to normal static binocular acuity with or without correction.
• The participant signs and dates a written informed consent form before the start of the experiment.

Exclusion criteria

• The subject has an uncontrolled, clinically significant neurologic, cardiovascular, pulmonary, hepatic, renal, metabolic, gastrointestinal, or endocrine disease or other abnormality which may impact the ability of the subject to participate or potentially confound the study results.
• The volunteer has uncontrolled existing major psychiatric symptoms.
• The participant has known hypersensitivity to any component of the formulation or Modafinil or related compounds.
• The subject has a history of drug abuse (defined as any illicit drug use) or a history of alcohol abuse within 1 year prior to the first visit or is unwilling to agree to abstain from alcohol from 24 hours prior to each test day and/or drugs throughout the study.
• The participant has any sensory or motor deficits which could reasonably be expected to affect test performance.

• Other exclusion criteria are smoking, excessive drinking (>20 glasses of alcohol-containing beverages a week), use of medication.
• For females, exclusion criteria are taking the birth control pill and being pregnant.

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:	Recruiting
Start date (anticipated):	16-05-2019
Enrollment:	142
Type:	Actual

Ethics review

Approved WMO Date:	06-02-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-03-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	18-03-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL66481.068.18