# Predicting the wide ranging effects of enhancing dopamine on cognition

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26989

**Source**
Nationaal Trial Register

**Brief title**
Dopamine & Cognition

**Health condition**

Dopamine, Learning, Working memory, Motivation, Mental effort

### Sponsors and support

**Primary sponsor:** Radboud University Nijmegen
Donders Institute for Brain, Cognition and Behaviour - Centre for Cognitive Neuroimaging
**Source(s) of monetary or material Support:** NWO

### Intervention

### Outcome measures

**Primary outcome**

Effects of methylphenidate on behavioural performance on a battery of computerized tasks:
1. Social Learning (contrast of personal versus social learning)
2. Working memory performance

3-4. Motivational influences on instrumental behaviour (Pavlovian-instrumental transfer and motivational Go/Nogo tasks)
5. Demand selection task task (Biases towards easy/difficult conditions)
6. Probabilistic reversal learning (reinforcement sensitivity and behavioural flexibility)

**Secondary outcome**

Baseline personality questionnaires:

- Spielberger Trait Anxiety Inventory (Spielberger, 2010);
- Multidimensional Scale of Perceived Social Support (Martinez et al., 2010); (http://www.yorku.ca/rokada/psyctest/socsupp.pdf)
- Dominance scale (Kalma et al., 1993);
- Barratt Simplified Measure of Social Status (Martinez et al., 2010 - http://socialclassoncampus.blogspot.co.uk/2012/06/barratt-simplified-measure-of-social. html);
- The Beck Depression Inventory (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961);
- Positive and negative affect scale (Watson et al., 1988) • The BIS/BAS (Behavioural Inhibition Scale/Behavioural Activation (BIS/BAS) Scale (Carver & White, 1994);
- The Barratt Impulsiveness Scale (Patton, Stanford, & Barratt, 1995);
- Need for Cognition Scale (Cacioppo, Pettz, and Kao, 1984)  B


Baseline assessment of executive function

- Listening span (Daneman and Carpenter, 1980);
- Digit Span (Wechsler 2008);
- Dutch Adult reading test (NLV - Schmand et al., 1991).

Methylphenidate-induced changes in mood and physiological measures

- Positive Affect Negative Affect (PANAS; Watson et al., 1988);
-  Mood rating scale (Bond & Lader, 1974);
-  Changes in blood pressure and heart rate;
-  Medical symptoms visual analogue rating scale.


# Study description

### Study design

2 separate testing days for placebo and drug conditions. Total testing time 4-5 hrs, 1 week - 2 months apart, starting time within 90 mins of same time of day.

### Intervention

Participants will twice complete a battery of computerized tests after administration of methylphenidate / placebo. On the day preceding testing, subjects will have to adhere to some simple restrictions with respect to medication, alcohol and drug intake.

## Contacts

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Roshan Cools
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## Eligibility criteria

### Inclusion criteria

1. Healthy volunteers;
2. Age 18 - 45 years;
3. Normal or corrected-to-normal vision;
4. Normal uncorrected hearing;
5. Willingness and ability to give written informed consent and willingness and ability to understand the nature and content, to participate and to comply with the study requirements.

### Exclusion criteria

1. History of / current
• psychiatric / neurological treatment
• neurological treatment
• endocrine treatment
• requent autonomic failure (e.g., vasovagal reflex syncope).
• clinically significant hepatic, cardiac, obstructive respiratory, renal, cerebrovascular, metabolic, ocular or pulmonary disease
• epilepsy in adulthood (inclusion when no insult after 18 years of age, no current medication for epilepsy and no insult in the last five years)

• drug dependence (opiate, LSD, (meth)amphetamine, cocaine, solvents, or barbiturate) or alcohol dependence
• Diabetes
2. Suicidality
3. Medication use:
• MAO inhibitor, anaesthetic, anti-depressant or anti psychotic drugs within the week prior to the start of the study.
• psychotropic medication, or of recreational drugs over a period of 24 hours prior to each test session, and use of alcohol within the last 24 hours before each measurement.
• Regular use of corticosteroids.
4. Uncontrolled hypertension, defined as diastolic blood pressure at rest > 95 mmHg or systolic blood pressure at rest > 180 mmHg
5. Irregular sleep/wake rhythm (e.g., regular nightshifts or cross timeline travel).
6 .Possible pregnancy or breastfeeding
7. Lactose intolerance (placebo pill is a lactose product)
8. One first degree or two or more second degree family members with a history of sudden death or ventricular arrhythmia
9. First degree family member with schizophrenia or bipolar disorder

# Study design

## Design

| Study type: | Interventional |
|---|---|
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| Recruitment status: | Recruitment stopped |
|---|---|
| Start date (anticipated): | 01-02-2014 |
| Enrollment: | 100 |
| Type: | Actual |

# Ethics review

Positive opinion
Date:                        19-06-2014
Application type:            First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 38150
Bron: ToetsingOnline
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
| --- | --- |
| NTR-new | NL4411 |
| NTR-old | NTR4653 |
| CCMO | NL47166.091.13 |
| OMON | NL-OMON26989 |

## Study results