Predicting the wide ranging effects of enhancing dopamine on cognition

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26989

Bron
Nationaal Trial Register

Verkorte titel
Dopamine & Cognition

Aandoening

Dopamine, Learning, Working memory, Motivation, Mental effort

Ondersteuning

Primaire sponsor: Radboud University Nijmegen
Donders Institute for Brain, Cognition and Behaviour - Centre for Cognitive Neuroimaging
Overige ondersteuning: NWO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Secundaire uitkomstmaten

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.

Toelichting onderzoek

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Donders Institue / Radboud University Nijmegen
Roshan Cools
Nijmegen
The Netherlands

Wetenschappelijk

Donders Institue / Radboud University Nijmegen
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2014
Aantal proefpersonen:	100

Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-06-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38150
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten