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The effects of cognitive training and modafinil on cognition and functioning in healthy subjects

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Registration date 08/01/2013	**Overall study status** Completed	
Last Edited 17/05/2016	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RAA09-002

Study information

Scientific Title
The effects of cognitive training and modafinil on cognition and functioning in healthy subjects: a double-blind, randomised placebo-controlled group trial

Acronym
CogMod

Study objectives
Procedure:
It is of considerable academic and clinical interest to investigate whether and to what extent cognitive functioning can be ameliorated as this may have broad advantages for clinical populations. The strategies to improve cognition include pharmacological (based on modulation of brain chemistry), and non-pharmacological approaches (based on training interventions to improve cognitive abilities) and research has shown that both approaches can modestly improve cognition. We propose to combine the two approaches of both pharmacology and cognitive intervention to study the extent of their combined effect in improving cognition. Participants will be randomly allocatead to receive either modafinil (the pharmacological cognition-enhancing agent) or an inactive compound and will undergo cognitive training sessions, during which they will complete attention, memory and learning tasks. Level of cognitive performance will be measured before and after the intervention so that change can be measured.

It is hypothesised that combination of modafinil with cognitive training will enhance the learning capacity of the research participants compared to placebo and cognitive training. We expect that cognitive enhancement will generalize into increased performance on standard (not part of cognitive training) neuropsychological tests. We also expect that the improved performance of participants receiving the combination of modafinil with cognitive training on neuropsychological assessments will be retained after the discontinuation of the training and medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Moorfields and Whittington Research Ethics Committee, 30/04/2010, ref: 10/H0721/25

Study design
Double-blind randomised placebo-controlled group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cognitive functioning

Interventions
1. Intervention: cognitive training and modafinil
2. Control: cognitive training and placebo

The study is a randomised controlled trial. Participants will be randomised to receive a cognitive enhancer (modafinil) or placebo. Study participants will receive 200 mg of modafinil once/day for 12 days. The first day of modafinil/placebo treatment, we will assess the effects of a single dose of modafinil on the participants' neuropsychological performance. From day 2 to day 11, all participants will undergo cognitive training exercises after having received the daily dose of modafinil/placebo. On day 12 we will assess the effects of modafinil/placebo+ cognitive training combination on neuropsychological performance.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Modafinil

Primary outcome measure
The effect of the combination of modafinil and cognitive training on learning capacity of the research participants, i.e. the percentage of correct responses and mean response time on the cognitive training tasks as a function of cognitive training, and the effect of the cobmination of modafinil and training on the cognitive outcome measures (MATRICS Consensus Cognitive Battery [MCCB] and CogState).

Outcomes will be measured every day during the combined intervention period (Day 2 to Day 11) and also once during the 2nd week of the follow-up period.

Secondary outcome measures
1. Change in the composite scores of the neuropsychological batteries (CogState and MCCB) scores following a single dose of modafinil - this measures the difference in scores between the second and third assessments (pre-training)
2. Reliabillity of CogState and MACCB batteries in the face of repeating testing - performance will be examined across the 5 assessments; 3 pre-training assessments, and 2 post-training

Overall study start date
18/07/2010

Completion date

01/04/2011

Eligibility

Key inclusion criteria
1. Participants will have no personal history of schizophrenia or other psychotic disorder
2. Participants will have no family history to second degree relative, of schizophrenia or other psychotic disorder
3. Age between 18 and 45 years
4. Males and females
5. Raw score of 6 or greater on the Wechsler Test of Adult Reading (WTAR)
6. A negative result in a pregnancy test performed prior to the trial
7. Use of effective contraceptive methods for the duration of the trial
8. Subjects must read and write English at a level sufficient to understand and complete study-related procedures
9. Women of child-bearing potential, who are sexually active, will be considered as potential participants if they are using acceptable methods of contraception, which include barrier method with spermicide, intrauterine device (IUD), steroidal contraceptive (oral, transdermal, implanted, and injected). Women on combined and progestogen-only contraceptives and on contraceptive patches and vaginal rings will be required to use additional contraceptive precautions for the duration of the trial and 4 weeks after stopping taking modafinil for the study purposes because modafinil may reduce the effectiveness of both combined and progestogen-only contraceptives.
10. Written and witnessed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) diagnosis of alcohol or drug dependence in the 3 months preceding the screening visit
2. No current treatment with psychostimulants, modafinil, cyclosporine, phenytoin, oestrogens, anticoagulants or barbiturates
3. Pregnant or breast-feeding women
4. History of a neurological disorder or a systemic illness with known neurological complications
5. Head injury
6. Uncontrolled hypertension, arrhythmia, left ventricular hypertrophy
7. Any known drug allergies, including sensitivity to modafinil, and the development a drug-associated rash in the past

8. Unwillingness or inability to follow or comply with the procedures outlined in the protocol
9. Participation in other ongoing medicinal trial or within the last four months

Date of first enrolment
18/07/2010

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
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Sponsor type
University/education

Website
http://www.iop.kcl.ac.uk/departments/?locator=26

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council - Strategic Appointments Scheme

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No