

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

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		<input type="checkbox"/> Protocol
Registration date 08/01/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/05/2016	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 allocated 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

Primary study design

Interventional

Study design

Double-blind randomised placebo-controlled group trial

Study type(s)

Quality of life

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(s)

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 combination 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.

Key secondary outcome(s)

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. Reliability 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation

Kings College London (KCL) (UK)

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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