# Can Methylphenidate (Ritalin) improve memory and attention in mild cognitive impairment? An EEG study

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We aim to examine, in the impaired older population, whether a treatment using methylphenidate, a DA re-uptake inhibitor that enhances DA, improves attention and memory.

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

## Summary

### ID

NL-OMON41157

**Source**
ToetsingOnline

**Brief title**
Ritalin and memory in MCI

### Condition

- Other condition
- Cognitive and attention disorders and disturbances

**Synonym**
memory impairment; MCI

**Health condition**

geheugenklachten

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Attention, MCI, Memory, Ritalin

## Outcome measures

### Primary outcome

The main endpoints are the total number of words recalled at immediate recall in a verbal learning test (VLT); the number of words recalled in VLT at a delay of 30 minutes; accuracy and reaction time of the recognition test of VLT; the amplitude of the N400 and P600 ERP components during encoding and recognition of words of the VLT.

### Secondary outcome

Secondary endpoints are performance on the visual and auditory N-back test, a sustained attention to response tak (SART) and a motor task; amplitude of ERP components during the visual and auditory N-back test, as well as the SART.

# Study description

### Background summary

Traditionally, memory impairments in the elderly population are treated using cholinesterase inhibitors, although impairments remain after treatment. Dopamine (DA) is also involved in cognition and is especially of interest in healthy ageing because of the role in processing speed and cognitive control. To what extent dopamine treatment improves memory and attention in older impaired individuals is unknown. However, such an effect is conceivable because of the close relationship between memory and attention in aging and since improved processing speed and cognitive control may lead to improved memory.

### Study objective

We aim to examine, in the impaired older population, whether a treatment using methylphenidate, a DA re-uptake inhibitor that enhances DA, improves attention and memory.

### Study design

The study will be conducted according to a cross-sectional, double-blind, placebo-controlled, 2-way cross-over design.

### Intervention

Participants will be treated once with 20 mg methylphenidate (MPH) and once with placebo. All medications will be administered orally with a capsule. The treatment order will be established by counterbalancing.

### Study burden and risks

The time investment for the participants will be around 570 min (9.5 hours), which is comprised of 1) medical screening (60 min), 2) training session of cognitive tasks (90 min), and 3) two test sessions of around 210 min. The day before each test day, the participants are not allowed to drink any alcohol.

## Contacts

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## Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• The participant has been diagnosed with Mild Cognitive Impairment, either of the amnestic or the non-amnestic type.
• In the opinion of the investigator, the participant is capable of understanding and complying with protocol requirements.
• The participant signs and dates a written informed consent form.
• The volunteer is male or female.
• The participant is aged 60 to 80 years, inclusive, at the time of informed consent.
• The participant has a body mass index of 18.5-30, inclusive, at medical screening.
• The volunteer is healthy, i.e. absence of all exclusion criteria and has normal static binocular acuity (corrected or uncorrected) as well as normal hearing (using a whisper test during medical screening).

## Exclusion criteria

• The subject has 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 subject has uncontrolled hypertension.
• The volunteer has hyperthyroidism.
• The participant has known hypersensitivity to any component of the formulation of MPH or related compounds.
• The participant has glaucoma.
• 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 abstrain 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.

# Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 22-06-2015 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

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| Product type: | Medicine |
| Brand name: | Ritalin |
| Generic name: | Methylphenidate |
| Registration: | Yes - NL outside intended use |

# Ethics review

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| Approved WMO Date: | 21-08-2014 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 03-11-2014 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |

# 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 |
|---|---|
| EudraCT | EUCTR2014-003117-28-NL |
| CCMO | NL50315.096.14 |