

# Primary care diagnostics or diagnostics in a memory clinic in older persons with memory complaints - A long-term cost-effectiveness trial with non-inferiority design

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What is the comparative efficacy and safety between dementia diagnostics in primary care and dementia diagnostics in a memory clinic for older persons with memory complaints?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Dementia and amnestic conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON53325

### Source

ToetsingOnline

### Brief title

PRIMED: PRImary care vs. MEmory clinic Dementia Diagnostics

### Condition

- Dementia and amnestic conditions

### Synonym

dementia, memory problems

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum

**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** dementia diagnostics, non-inferiority, primary care, randomised controlled trial

## Outcome measures

### Primary outcome

Daily functioning using the Amsterdam iADL questionnaire (A-iADL-Q-SV)

Outcomes are measured at baseline and at 6, 18 and (24-)30 months

### Secondary outcome

Quality of life

- Behavior and mood
- Caregiver burden and perseverance time
- Acute admissions, time to institutionalization, time to mortality
- Healthcare costs
- Accuracy of the initial diagnosis
- Anxiety or dissatisfaction after diagnostic trajectory

Outcomes are measured at baseline and at 6, 18 and 30 months

## Study description

### Background summary

In The Netherlands, dementia is more often diagnosed in a memory clinic than in

primary care. In a memory clinic, the diagnosis is often made earlier, but the extensive diagnostic work-up in a memory clinic is often experienced as burdensome by patients and caregivers. Therefore, it is questionable whether referral to a memory clinic is in the interest of patients, particularly in the absence of a disease-modifying treatment. Moreover, memory clinic diagnostics are more expensive.

**HYPOTHESIS:** In absence of disease-modifying treatment for dementia, a diagnostic trajectory in primary care is not inferior to memory clinic diagnostics with respect to long-term outcomes relevant to patients and caregivers and generates less healthcare costs

### **Study objective**

What is the comparative efficacy and safety between dementia diagnostics in primary care and dementia diagnostics in a memory clinic for older persons with memory complaints?

### **Study design**

Single-center randomized controlled diagnostic trial with a non-inferiority design (RCT).

Two diagnostic trajectories, both in line with current guidelines for dementia diagnostics, are compared.

18-11-2024: Addition of a prospective cohort alongside the randomized design. In the cohort, we include participants who do not wish to be randomized, using the same outcome measures as in the RCT.

### **Intervention**

Although this is a randomised diagnostic study, we labelled the two diagnostic trajectories as intervention and control, in line with the ZonMW comparative effectiveness funding scheme that funded the project

Intervention: dementia diagnostics in primary care

Control: dementia diagnostics in a memory clinic

### **Study burden and risks**

The burden for participants consists of filling out questionnaires together with a researcher. At baseline this will take 60 minutes. At three follow-up visits over a period of (24-)30 months, it will take 30-45 minutes during each visit. The total burden is 150-195 minutes.

Because we compare two diagnostic trajectories which both fall within

prevailing Dutch guidelines, there is no additional burden and there are no risks to participating in this research.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Elderly (65 years and older)

### Inclusion criteria

- adults 70 years and over
- memory complaints

### Exclusion criteria

- focal signs on neurological examination
- expected uncommon cause of dementia

- strong preference of GP or patient for location of diagnostics (either in primary care or in memory clinic)
- advanced dementia

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	24-07-2023
Enrollment:	182
Type:	Actual

## Ethics review

Approved WMO	
Date:	30-05-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	02-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	09-12-2024
Application type:	Amendment

## 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

<b>Register</b>	<b>ID</b>
ISRCTN	ISRCTN18043557
CCMO	NL83486.091.22