

# Exercise Program in Nursing Home Residents with Alzheimer's disease (AD). A One-Year Randomized Controlled Trial.

<b>Submission date</b> 06/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/09/2009	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
01 044 03

# Study information

## Scientific Title

## Study objectives

That there is a benefit in activities of daily living (ADL) in patients with Alzheimers disease undergoing a regular exercise programme.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Institutional Review Boards of Toulouse

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

## Health condition(s) or problem(s) studied

Alzheimer's Disease

## Interventions

The intervention group received a regular exercise programme.

The control group received normal medical care but no regular exercise programme.

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

The primary efficacy outcome was decline from baseline in Katz Index ADL score compared with the control group at 12 months of follow-up.

## Secondary outcome measures

The secondary efficacy outcomes included measures of physical performance, nutritional status, behavioral disturbance and depression.

**Overall study start date**

01/02/2004

**Completion date**

01/02/2005

## Eligibility

**Key inclusion criteria**

1. To have met the National Institute of Neurological and Communicative Diseases and Stroke /Alzheimer Disease and Related Disorders Association criteria for probable or possible AD
2. To have lived in the nursing-home for at least 2 months
3. To be able to transfer from a chair and walk for at least 6 meters without human assistance
4. To have a Mini-Mental State Examination (MMSE) score <25

Enrolment lasted two weeks.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

150

**Key exclusion criteria**

1. Evidence of vascular dementia or Parkinson disease
2. Planned transfer from the nursing home or surgery in the year to come
3. A cardiac condition that might deteriorate during exercise, such as unstable angina or severe congestive heart disease
4. Diagnosis of a terminal illness with a life expectancy less than 6 months

**Date of first enrolment**

01/02/2004

**Date of final enrolment**

01/02/2005

## Locations

**Countries of recruitment**

France

**Study participating centre**  
170 Avenue de Casselardit  
Toulouse  
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## **Sponsor information**

### **Organisation**

Caisse Nationale d'Assurance Maladie des Travailleurs Salaries (CNAMT) (France)

### **Sponsor details**

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### **Sponsor type**

Government

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Caisse Nationale d'Assurance Maladie des Travailleurs Salaries (CNAMT) (France) - CNAMT-01  
044 03

## **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?
<a href="#">Results article</a>	results	01/02/2007		Yes	No