

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

Submission date 06/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 10/09/2009	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ 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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

France

31100

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

Caisse Nationale d'Assurance Maladie des Travailleurs Salaries (CNAMT) (France) - CNAMT-01044 03

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	01/02/2007		Yes	No