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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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
10/09/2009

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

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
France
31100

Sponsor information

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

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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?
Results article	results	01/02/2007		Yes	No