

Effects of a physical exercise program on daily living activities in dementia

Submission date
13/04/2011

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/06/2011

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
29/01/2019

Condition category
Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

13DPD6_134852

Study information

Scientific Title

Effects of a physical exercise program on performance in activity of daily living (ADL) on acute hospitalized elderly patients with moderate to severe dementia: a multicenter, randomized, controlled trial

Study objectives

In addition to usual care, a physical exercise program of 20 group sessions is effective in maintaining or improving activity of daily living performance in acute hospitalized elderly with moderate to severe dementia, as opposed to a control group receiving only regular care and social activities of the same duration as the intervention group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cantonal Ethics Committee for Research on Humans (Etat de Vaud, Commission Cantonale d'éthique de la Recherche sur l'être Humain) approved on 27/01/2011, Ref: 250/08

Study design

Multicenter randomized controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Dementia

Interventions

1. Gradually increasing physical exercise program (20 group sessions of 30 minutes over 4 weeks) covering aerobic, strength, flexibility and balance training
2. Accompanied by music

Control group: social activities of the same form, frequency and duration as intervention group.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Independence in activities of daily living (ADL), measured with the Barthel index at baseline, 4 weeks and 6 weeks
2. The Functional Independence Measure (FIM)

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/06/2011

Completion date

30/11/2012

Eligibility

Key inclusion criteria

1. Informed consent
2. Patients over 65 years
3. Hospitalized in a acute psychiatric hospital
4. With dementia according to CIM-10 classification
5. With moderate or severe dementia according to CDR scores (clinical dementia rating of 2 or more)
6. Able to walk at least 6 meters, if necessary with assistance

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

240

Key exclusion criteria

1. Patient for whom a physical exercise program represents a risk
2. Life expectancy estimated less than 4 weeks
3. Hospital stay estimated to be less than 6 weeks
4. Musculoskeletal conditions which do not permit the application of the physical exercise program
5. Recent hemiplegia (< 4 weeks)
6. Somatic or psychiatric trouble requiring intensive care

Date of first enrolment

01/06/2011

Date of final enrolment

30/11/2012

Locations

Countries of recruitment

Switzerland

Study participating centre

University of Applied Sciences Western Switzerland

Carouge

Switzerland

1227

Sponsor information

Organisation

University of Applied Sciences Western Switzerland (Switzerland)

Sponsor details

Rue de la Jeunesse 1

Delémont

Switzerland

2800

-

info@hes-so.ch

Sponsor type

University/education

Website

<http://www.hes-so.ch>

ROR

<https://ror.org/01xkakk17>

Funder(s)

Funder type

Government

Funder Name

The Swiss National Science Foundation [National Suisse de la Recherche (FNS-SNF)] (Switzerland)
- Programme DoRe, Ref: 13DPD6_129863

Funder Name

Swiss Alzheimer Association [Association Alzheimer Suisse] (Switzerland)

Funder Name

University of Applied Sciences Western Switzerland (Switzerland)

Funder Name

University Hospital Vaudois [Centre Hospitalier Universitaire Vaudois] (Switzerland)

Funder Name

Fribourg Research Network of Mental Health [Réseau Fribourgeois de Santé Mentale]
(Switzerland)

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	01/02/2017	29/01/2019	Yes	No