ISRCTN86442281 https://doi.org/10.1186/ISRCTN86442281

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

Submission date	Recruitment status
13/04/2011	No longer recruiting
Registration date	**Overall study status**
22/06/2011	Completed
Last Edited	**Condition category**
29/01/2019	Mental and Behavioural Disorders

[ ] 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
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. Hopitalized 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
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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