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

Submission date	Recruitment status	[ ] Prospectively registered
13/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2019	Mental and Behavioural Disorders	

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
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

Primary study design
Interventional

Study design
Multicenter randomized controlled study

Study type(s)
Quality of life

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(s)
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)

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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)

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

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