

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

<b>Submission date</b> 13/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/01/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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**  
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

### **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. 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

**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?
<a href="#">Results article</a>	results	01/02/2017	29/01/2019	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes