

# The Frail Older People-Activity and Nutrition study in Umeå

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
17/06/2009	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
09/07/2009	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
09/04/2014	Other	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Yngve Gustafson

### Contact details

Geriatric Medicine  
Umeå University  
Umeå  
Sweden  
SE-901 87

## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

The Frail Older People-Activity and Nutrition study in Umeå: a cluster-randomised controlled trial

### Acronym

FOPANU

## **Study objectives**

1. A high-intensity functional exercise program will improve balance, gait ability, and lower-limb strength in the short- and long-term
2. An intake of protein-enriched energy supplement immediately after the exercises will increase the effect of the training
3. The high-intensity functional exercise program will reduce dependence in mobility and personal care and increase activity and will have a positive effect on depressive symptoms and psychological wellbeing, in the short- and long-term, and will increase safety and reduce falls
4. The exercise program is applicable and is perceived as positive by the participants

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Committee of the Medical Faculty of Umeå University approved on the 13th November 2001 (ref: 391/01)

## **Study design**

Cluster-randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Residential care facilities

## **Interventions**

### **Exercise intervention:**

The exercise intervention was based on the High-Intensity Functional Exercise Program (the HIFE Program). The program included functional exercises consisting of everyday tasks challenging leg strength, postural stability, and gait ability. The physiotherapist selected exercises for each participant according to their functional deficits. All exercises were performed in weight-bearing positions, e.g., squats, turning trunk and head while standing, and walking over obstacles. The participants were encouraged by the physiotherapists to exercise with a high intensity and to increase load and difficulty progressively, considering changes in function and health status. Strength exercises were intended to be performed at 8 - 12 repetition maximum. Balance exercises were intended to challenge the participant's postural stability fully. In co-operation with a staff member, at the end of the exercise period, physical tasks were introduced with the purpose of maintaining physical function.

### **Control activity:**

The control activity program included activities while sitting, e.g., watching films, reading, singing, and conversation. The program was based on themes, e.g., the old country shop, famous persons, and games from the past, and was expected to be interesting and stimulating for older persons including those with severe cognitive impairment.

### **Nutrition intervention and placebo:**

The nutrition intervention consisted of a protein-enriched energy supplement. The supplement

was a milk-based 200 ml drink that contained 7.4 g protein, 15.7 g carbohydrate, and 408 kJ per 100 g. The placebo drink (200 ml) contained 0.2 g protein, 10.8 g carbohydrate, and 191 kJ per 100 g. Both drinks were served in the same type of non-transparent package and had similar flavours.

**Procedure:**

The exercise intervention and the control activity started in March 2002, and was performed in groups of three to nine participants supervised by two physiotherapists (exercise) or one occupational therapist (control). The sessions lasted approximately 45 minutes and were held five times every two weeks for three months (13 weeks), in total on 29 occasions. The nutrition drinks were offered within five minutes after each session.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. Balance ability by Berg balance scale, at 3 (end of intervention period) and 6 months
2. Gait ability by 2.4 metre timed test, self-paced and maximum speed, at 3 and 6 months
3. Lower-limb-strength by 1 Repetition Maximum in a leg-press machine, at 3 and 6 months

**Key secondary outcome(s)**

1. Attendance, adverse events and, for the exercise group, intensity achieved, by a structured report developed for this study and completed by the supervisors after each session
2. Participants perception of participating and their perception of changes due to the activity, by a questionnaire developed for this study and for the exercise group also by an interview
3. Staff's perception of participants' changes in function by questionnaire developed for this study, at 3 months
4. Dependence in mobility and personal care by the Barthel ADL Index, at 3 and 6 months
5. Activity by the Life Space Diameter and by questions developed for this study, at 3 and 6 months
6. Falls followed-up in six months from the end of intervention period and perceived balance ability and risk of falling by questions developed for this study, at 3 and 6 months
7. Depressive symptoms and psychological wellbeing by Geriatric Depression Scale (GDS-15) and Philadelphia Geriatric Centre Morale Scale, respectively, at 3 and 6 months
8. Mobility by the Chair-stand test and the Timed up and Go, at 3 and 6 months
9. Muscle mass by bioelectric impedance and by anthropometry, at 3 and 6 months
10. Nutritional status by Mini Nutritional Assessment, body weight, and BMI, at 3 and 6 months
11. Mortality, diseases, and hospital admission, by reviewing participants' hospital records and death certificates in 2 years from the end of the intervention
12. Effect among people with dementia or with depression (compared to those without), respectively, on the primary outcome measures, ADL, and falls
13. Explanatory sub-group analyses of the effect on the primary outcomes, ADL, falls and attendance and motivation during exercise sessions. Independent variables: Barthel ADL Index, Mini-Mental State Examination, Life Space Diameter, BMI, Mini Nutritional Assessment, Berg Balance Scale, body composition by bioelectric impedance and by anthropometry, depression, dementia, previous stroke, drugs, age, sex, self-perceived health, perceived balance ability and risk of falling, perceived possibility of exercise effect and attitude towards the exercise

**Completion date**

01/07/2004

## Eligibility

**Key inclusion criteria**

1. Age 65 or over, either sex
2. Dependent on assistance from a person in one or more personal activities of daily living according to the Katz Index
3. Able to stand up from a chair with armrests with help from no more than one person
4. A Mini-Mental State Examination score of 10 or more
5. An approval from the resident's physician

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

01/07/2004

## Locations

**Countries of recruitment**

Sweden

**Study participating centre**

Geriatric Medicine

Umeå

Sweden

SE-901 87

## Sponsor information

**Organisation**

Umeå University (Sweden)

**ROR**

<https://ror.org/05kb8h459>

**Funder(s)****Funder type**

Research council

**Funder Name**

The Swedish Research Council (Sweden) (ref: K2002-27VP-14165-02B, K2002-27VX-14172-02B, K2005-27VX-15357-01A)

**Funder Name**

The Vårdal Foundation (Sweden)

**Funder Name**

The Swedish Council for Working Life and Social Research (Sweden)

**Funder Name**

The Dementia Fund (Sweden)

**Funder Name**

The County Council of Västerbotten (Sweden)

**Funder Name**

The Umeå University Foundation for Medical Research (Sweden)

**Funder Name**

The Magnus Bergvalls Foundation (Sweden)

**Funder Name**

The Äldrecenterum Västerbotten (Sweden)

**Funder Name**

The Gun and Bertil Stohne Foundation (Sweden)

**Funder Name**

Erik and Anne-Marie Detlof's Foundation (Sweden)

**Funder Name**

The Loo and Hans Ostermans Foundation (Sweden)

**Funder Name**

The Borgerskapet in Umeå Research Foundation (Sweden)

**Funder Name**

The Ragnhild and Einar Lundström's Memorial Foundation (Sweden)

**Funder Name**

Norrmejerier (Sweden)

## 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>	applicability results	01/04/2006		Yes	No
<a href="#">Results article</a>	balance, gait ability, and lower-limb strength results	01/04		Yes	No

<a href="#"><u>Results article</u></a>	fall results	/2006 01/02 /2008	Yes	No
<a href="#"><u>Results article</u></a>	UTI results	01/02 /2013	Yes	No
<a href="#"><u>Results article</u></a>	results	01/11 /2013	Yes	No
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11 /2025	No	Yes