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The Frail Older People-Activity and Nutrition study in Umeå

Submission date 17/06/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/07/2009	**Overall study status** Completed	
Last Edited 09/04/2014	**Condition category** Other	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
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 measure
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

Secondary outcome measures
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

Overall study start date
01/01/2002

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

Age group
Senior

Sex
Both

Target number of participants
191

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)

Sponsor details
Geriatric Medicine
Umeå
Sweden
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Sponsor type
University/education

Website
http://www.umu.se/english

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 Äldrecentrum 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

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	applicability results	01/04/2006		Yes	No
Results article	balance, gait ability, and lower-limb strength results	01/04/2006		Yes	No
Results article	fall results	01/02/2008		Yes	No
Results article	UTI results	01/02/2013		Yes	No
Results article	results	01/11/2013		Yes	No