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A high-intensity functional exercise program for older people with dementia and living in residential care facilities (The Umeå Dementia and Exercise Study The UMDEX Study)

Submission date
27/10/2011

Recruitment status
No longer recruiting

Registration date
14/11/2011

Overall study status
Completed

Last Edited
20/02/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Dementia describes a set of symptoms that may include memory loss and difficulties with thinking, problem-solving or language. Dementia disorders are very common, especially among older people, and due to population ageing there will be more and more cases in the future. The aim of this study is to evaluate the effects of physical exercise in older people with dementia.

Who can participate?
Older people with a diagnosed dementia disorder in residential care facilities (institutional housing) in Umeå, Sweden.

What does the study involve?
Participants are randomly allocated to one of two groups: the exercise group or the control group.
The exercise group attend the High-Intensity Functional Exercise (HIFE) Program. The control group attends a program that includes activities while sitting. The exercise and the control activity are held five times each 14 days for 4 months, in total 40 sessions for each participant. After each session the supervisors register attendance, adverse events, and for the exercise group, the intensity achieved, in a structured report for each participant.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Residential care facilities in Umeå, Sweden.

When is the study starting and how long is it expected to run for?
August 2011 to February 2013.

Who is funding the study?
The Swedish Research Council (Sweden)
The Swedish Dementia Foundation (Sweden)
The King Gustav V and Queen Victoria Foundation of Freemasons (Sweden)
The Umeå University, Faculty of Medicine (Sweden)
The County Council of Västerbotten (Sweden)
The Bothnia Atlantica Program (European Union)
The Umeå University Foundation for Medical Research (Sweden)
The Ragnhild and Einar Lundström's Memorial Foundation (Sweden)
Erik and Anne-Marie Detlof´s Foundation (Sweden)

Who is the main contact?
Dr Erik Rosendahl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A high-intensity functional exercise program for older people with dementia and living in residential care facilities: a randomized controlled trial (The Umeå Dementia and Exercise Study The UMDEX Study)

Acronym
UMDEX

Study objectives
1. A high-intensity functional exercise program will reduce dependence in personal activities of daily living (ADL).
2. The high-intensity functional exercise program will reduce falls, especially among people able to independently rise up from a chair, and improve physical (balance, mobility) and cognitive functions.
3. The exercise program will have a positive effect on depressive symptoms, psychological wellbeing, and behaviour and psychological symptoms of dementia (BPSD).
4. The exercise program is applicable, perceived as positive by the participants, and will not have a negative impact on mortality, diseases, or hospital admissions.
5. High levels of parathyroid hormone (PTH) and low levels of vitamin D will decrease the effect of the exercise program on ADL, falls, and physical and cognitive functions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Umeå, 09/08/2011, ref: 2011-205-31-M

Study design
Cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

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 disorders

Interventions
Exercise intervention: The exercise intervention is based on the High-Intensity Functional Exercise Program (the HIFE Program). The program includes functional exercises consisting of everyday tasks challenging leg strength, postural stability, and gait ability. The physiotherapists select exercises for each participant according to their functional deficits. All exercises are performed in weight-bearing positions, eg squats, turning trunk and head while standing, and walking over obstacles. The participants are 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 are intended to be performed at 812 repetition maximum. Balance exercises are intended to challenge the participants postural stability fully.

Control activity: The control activity program includes activities while sitting. The program is based on themes, e.g. birds, famous persons, and seasons, and is expected to be interesting and stimulating for older persons with dementia.

Procedure: The exercise intervention and the control activity starts in October 2011, and are performed in groups of three to eight participants supervised by two Physiotherapists (exercise) and one Occupational Therapist or Occupational Therapy Assistant (control). The sessions last approximately 45 minutes and are held five times every two weeks for four months (16.5 weeks), a total of 40 sessions. After each session the supervisors will register attendance, adverse events, and for the exercise group, the intensity achieved, in a structured report.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Dependence in personal activities of daily living (ADL) using the Functional Independence Measurement (FIM) and the Barthel ADL Index, at 4 (end of intervention period) and 7 months (follow-up 3 months after the intervention period), respectively.

Secondary outcome measures
1. Balance using Berg Balance Scale (BBS), at 4 and 7 months, respectively.
2. Mobility using self-paced timed walk (forward and backward, with and without ordinary walking aid if any) and the Chair-stand test, at 4 and 7 months, respectively
3. Cognitive functions using the Alzheimers Disease Assessment Scale-Cognitive Subscale (ADAS-Cog), verbal fluency, and Mini-Mental State Examination (MMSE), at 4 and 7 months, respectively.
4. Incidence of falls reported prospectively by staff and analysed at 6 and 12 months, respectively, from the end of intervention period.
5. Behaviour and psychological symptoms of dementia (BPSD) using the Neuropsychiatric Inventory (NPI) and delirium using the Organic Brain Syndrome (OBS) scale, at 4 and 7 months, respectively.
6. Attendance, adverse events and, for the exercise group, intensity achieved, using a structured report completed by the supervisors after each session.
7. Participants experiences of participating in the exercise, by an interview
8. Depressive symptoms using Geriatric Depression Scale (GDS-15) and Montgomery Åsberg Depression Rating Scale (MADRS), at 4 and 7 months, respectively.
9. Psychological wellbeing using Philadelphia Geriatric Centre Morale Scale (PGCMS) and experienced loneliness, at 4 and 7 months, respectively.
10. Mortality, diseases, and hospital admission, by reviewing participants hospital records and death certificates for 12 months from the end of the intervention
11. Analyses of the levels of parathyroid hormone (PTH) and levels of vitamin D of the effect on ADL, falls, and physical and cognitive functions.
12. Explanatory analyses of the effect on ADL. Independent variables: FIM, Barthel ADL Index, MMSE, Mini Nutritional Assessment, BBS, depression, type of dementia disorder, drugs, age, sex, self-perceived health.
13. Sub-group analyses of the effect on falls among people able to independently rise up from a chair.

Overall study start date
29/08/2011

Completion date
02/02/2013

Eligibility

Key inclusion criteria
1. Diagnosed dementia disorder and living in residential care facilities
2. Age 65 or over
3. Dependent on assistance from a person in one or more personal activities of daily living according to the Katz Index
4. Able to stand up from a chair with armrests with help from no more than one person
5. A Mini-Mental State Examination (MMSE) score of 10 or more
6. An approval from the residents physician
7. Able to hear sufficiently well to participate in the assessments
8. Able to understand Swedish language sufficiently well to participate in the assessments

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
183

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
29/08/2011

Date of final enrolment
02/02/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Umeå University
Umeå

Sweden
SE-901 87

Sponsor information

Organisation
Umeå University (Sweden)

Sponsor details
Department of Community Medicine and Rehabilitation
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Sponsor type
University/education

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

ROR
https://ror.org/05kb8h459

Funder(s)

Funder type
Government

Funder Name
The Swedish Research Council (Sweden) (K2009-69P-21298-01-4, K2009-69X-21299-01-1)

Funder Name
The Swedish Dementia Foundation (Sweden)

Funder Name
The King Gustav V and Queen Victoria Foundation of Freemasons (Sweden)

Funder Name

Umeå Universitet

Alternative Name(s)
Umeå University, Ubmeje universitiähta, Universitas Umensis

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name
The Bothnia Atlantica Program

Funder Name
The County Council of Västerbotten (Sweden)

Funder Name
The Umeå University Foundation for Medical Research (Sweden)

Funder Name
The Ragnhild and Einar Lundströms Memorial Foundation (Sweden)

Funder Name
Erik and Anne-Marie Detlof's Foundation (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	results	01/01/2016		Yes	No
Results article	results	01/08/2016		Yes	No
Results article	results	01/03/2017		Yes	No
Results article	results	01/03/2017		Yes	No
Results article	results	14/11/2018		Yes	No
Results article	results	01/07/2019		Yes	No
Results article	1 results	01/10/2019		Yes	No