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Effects of resistance training on muscle strength and physical activity in frail older people

Submission date
07/03/2018

Recruitment status
No longer recruiting

Registration date
23/03/2018

Overall study status
Completed

Last Edited
14/08/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims

Since 2010, the number of people in Norway aged over 67 years has increased by 13,000 per year. This is expected to continue until 2040. In addition, there is also expected a 50% increase of people over 90 years (1990 to 2020). Further, a third of older adults over 67 years of age have impaired functional ability and a similar proportion of 67-79 year olds receive home care. In 2012, 273 billion Norwegian kroner (NOK) were used on health related expenses; 28% of these expenses were used to pay for nursing services for approximately 163,000 older adults with home care needs including practical care (e.g. cleaning), medical care or a combination of these service needs. With increasing age, human skeletal muscles undergo both structural and functional changes, with a reduction in muscle volume and strength. Aging atrophy (sarcopenia) is associated with notable decreases in muscle strength, power and rate of force development. This can lead to a loss of function during daily living activities, reduced balance, increased risk of falls and fractures and reduced physical activity. Reduced physical function and physical activity can lead to increased risk of sudden death, isolation from social events, depression and the need for practical municipal home care. Generally, physical activity decreases the risk of sudden death and non-communicable diseases. Physical activity decreases with increasing age and only 6% of the elderly (80-85 years) adhered to the physical activity recommendations. However, objective measurements of daily physical activity among elderly with nurse- and care services are limited. Resistance training (RT) improves strength, power, rate of force development and muscle volume, which are associated with improved physical function (e.g. stair climbing, stair raise, walking), reduces risk of falls and improved balance. All of these variables are associated with self-reliance and independence of home care among older adults. We therefore plan to invite elderly with home care needs, living in their own residence, to participate in a randomized control trial (RCT) examining the effect of a 1-year resistance training program on physical function, daily physical activity, rate of falling, health-related quality of life and self-reliance with a 3-year follow-up. To determine the effects of a home-based resistance training program as a rehabilitation strategy, we will follow a population of frail elderly living at home with municipal home care over 1 year. The participants will be randomized to a RCT, where a) the effect of a home-based resistance training program on physical function, daily physical activity, number of falls and health-related quality of life will be examined, together with b) examination of the

effects improved physical function and the need of nurse- and care services in terms of their self-reliance and independence of further municipal care and c) develop, improve and implement a everyday rehabilitation program for individuals working with physical function among elderly.

Who can participate?
People aged 70 years or older who live in their own home and receive home-care services.

What does the study involve?
The participants will be divided into an intervention group and a control group. The intervention group will perform a resistance training program twice a week that contains 5-7 exercises and lasts approximately 30-40 minutes. The control group will continue their normal activities and will be encouraged to stay active and make active choices.

What are the possible benefits and risks of participating?
Due to population ageing, it is mandatory to recognize services and structures that would improve health and care services, and reduce/delay the need for institutionalized care. Knowledge about what facilitated every day rehabilitation programs and the improvement occupational public health, physical function and quality of life are some of many themes of great importance for individuals, municipalities and the general society. There are several novel aspects of the project. The present study is the first to investigate long-term effects on physical function, daily physical activity and self-reliance after implementing home-based RT-program among elderly receiving nurse- and care services. Previous studies have included other groups of elderly, and have often been limited to physical parameters over a short period. Our design will make it possible to assess the short- and long term effects of the home-based RT-program with respect to self-reliance, physical function, physical activity levels and cost-utility. Further, perform repeated measures of the daily physical activity may be used to examine whether they meet the recommendation to reduce the risk of cardiovascular diseases. Importantly, starting a resistance-training intervention with frail older adults, we will expect delayed onset of muscle soreness (DOMS). However, the DOMS effects are temporary and related to the first weeks of training. However, the effects of improving strength and possible physical function, are expected to surpass the DOMS effects in the long term.

Where is the study run from?
The project is run from the municipalities Sogndal, Luster and Leikanger in the county of Sogn og Fjordane in Norway. The project is a collaboration between the healthcare services in the municipalities and the Institute of Sport in Sogndal at Western Norway University. The project is sponsored by the Regional Research Council Vestlandet.

When is the study starting and how long is it expected to run for?
The study started in September 2016 and will continue to June 2019.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of resistance training on muscle properties, physical function and physical activity among frail older people: a randomized controlled trial.

Acronym
ISRAE

Study objectives
Resistance training benefits frail older adults by improving muscle strength, peak rate of force development (RFD), physical function and physical activity

Ethics approval required
Old ethics approval format

Ethics approval(s)
REK sør-øst B, 15/03/2016, 2016/ 51

Study design
Randomised parallel-group controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Frailty in people aged over 70 years

Interventions
This research project will be conducted in three municipalities in the Sogn og Fjordane county. The three municipalities have approximately 16,000 residents and have representative municipal nurse and care services comparable to other small- and medium sized municipalities. All participants receive nurse and care services but live in their own home.

Before starting the trial, we conducted a pilot study examining the ability to conduct a resistance training program with the elderly. The pilot study recruited elderly from one municipality who undertook the program twice a week for 10 weeks. The study design was stratified by six and volunteers were randomised into a control and intervention group.

A two-armed parallel group cluster randomised controlled trial was conducted. Participants were elderly people living in three municipalities in Sogn and Fjordane County (Sogndal, Leikanger and Luster). Clusters were based on geographical location, based on the residency of the participants. 12 clusters were identified and cluster size ranged from 5 to 16 participants. The study will be reported according to the CONSORT statement extension to cluster randomized trials.

Intervention group: The intervention was applied on participant level. Project co-workers organised and implemented 30–45 minutes of group-based resistance training (RT) twice a week for 10 months. The sessions were held at the nurse and care centres. The training consisted of exercises aiming to strengthen and increase muscle mass of the large muscle groups often used in daily living. To ensure progression, the training load and volume were increased by introducing new exercises and increasing series and resistance. All repetitions were tobe performed with high intentional velocity during the concentric phase, and slow and controlled in the eccentric phase (work ratio 1:3). The participants trained to muscular fatigue during each series. Additionally, participants were encouraged to continue their daily activity.

Control group: The control group was encouraged to stay active and continue their daily activities. Every 6th week the participants received a motivational conversation about physical activity and training by phone or a visit. In addition, they received a physical education booklet from the Ministry of Health and Care Services and guidelines to stay active.

Intervention Type
Behavioural

Primary outcome measure

Pilot study (10 weeks)
In the pilot study, the primary outcome was feasibility of performing the resistance training program with frail people.

Main trial (3 years): Outcomes were assessed every 6 months
The primary outcome was the ability to live self-reliantly and independently in their own home.

Secondary outcome measures
Pilot study: The following measurements were taken at baseline and after the 10 weeks of intervention.
1. Physical function assessed using time up and go, preferred and maximum walk speed, chair-raise and stair-climb)
2. Muscle strength assessed by maximal isometric contraction and rate of force development in leg and arm)
3. Daily physical activity measured by ActiGraph GT1M over a 5-day period.

Main trial: Endpoints were assessed every 6 months
1. Physical function (time up and go, preferred and maximum walk speed, chair-raise and stair-climb)
2. Muscle strength (maximal isometric contraction and rate of force development in leg and arm)
3. Daily physical activity measured by ActiGraph GT1M over a 14-day period
4. Quality of life using EQ-5D-5L questionnaire
5. Fear of falling using Short FES I questionnaire

Overall study start date
01/08/2016

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Aged >70 years
2. Living at home
3. Receiving home care due to functional and/or medical disabilities

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants
120

Total final enrolment

Key exclusion criteria
1. Serious mental disorders and/or diagnoses/conditions that prevent testing or training

Date of first enrolment
01/09/2016

Date of final enrolment
30/10/2016

Locations

Countries of recruitment
Norway

Study participating centre
Sogn og Fjordane
Sogndal, Leikanger and Luster
Norway
N-6856

Sponsor information

Organisation
Regional Research Council Vestlandet

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Sponsor type
Research council

Website
https://www.forskningsradet.no/servlet/web/prognett-vestlandet/Framsida/1253953763244

ROR
https://ror.org/00epmv149

Funder(s)

Funder type
Research council

Funder Name
Regional Research Council Vestlandet

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

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	03/06/2018		Yes	No
Results article	results	07/08/2020	14/08/2020	Yes	No