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Effects of aquatic training on knee cartilage

Submission date
21/08/2012

Recruitment status
No longer recruiting

Registration date
19/09/2012

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is a condition where the protective surface that allows your joints to move smoothly (the cartilage) is lost, causing the joints to become painful and stiff. People with osteoarthritis suffer from pain, reduced mobility and lower quality of life, which leads to high social and medical costs to society. There is no known cure for osteoarthritis, but there is new evidence that exercise can positively affect the quality of cartilage and therefore could prevent progression to severe osteoarthritis. This has not been studied in aquatic exercise (exercises performed in water). The aim of this study is to assess the effect of aquatic exercise for postmenopausal women with the early signs of knee osteoarthritis.

Who can participate?
Postmenopausal women aged 60-68 with mild osteoarthritis

What does the study involve?
Participants are randomly allocated into two groups. The participants in the intervention group undergo an aquatic exercise training program. The aquatic training lasts one hour and takes place three times a week with the training period lasting for 16 weeks. The participants in the control group are asked to continue their normal daily activities and are also offered a one-hour stretching session twice during the four-month study period. All participants are tested before and after the four-month study period. Measurements include an MRI scan, bone mineral density scan, physical performance testing, and self-reported quality of life and impairment as a result of osteoarthritis. Participants are tested again one year later.

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

Where is the study run from?
Department of Health Sciences at the University of Jyväskylä (Finland)

When is study starting and how long is it expected to run for?
January 2012 to June 2014

Who is funding the study?
Academy of Finland and the Social Insurance Institution of Finland (KELA)

Who is the main contact?
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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
Therapeutic effects of aquatic resistance training on knee cartilage in postmenopausal women: a randomized controlled quantitative MRI study

Study objectives
1. Aquatic resistance training will decrease the degenerative process of the joint.
2. The exercise regimen improves functional ability and quality of life of the subjects.
3. The possible benefits can be maintained at least partly by spontaneous physical activity after Aquatic rehabilitation intervention.

Osteoarthritis (OA), the most common degenerative joint disease, primarily affects the articular cartilage and subchondral bone of a synovial joint and results in joint failure. In knee joint OA the destruction of the joint causes pain and limits the range of motion, which leads with disuse to decreased muscle strength and muscle mass and increased mobility limitation. Finally, pain and disability causes the loss of working capacity and later independence in aging people, which

leads to extensive social and medical costs to the society. Currently, there is no known cure for OA; however, disease-related factors, such as impaired muscle function and reduced fitness, are potentially amenable to therapeutic exercise. Whether therapeutic exercise is beneficial or detrimental to articular structures of weight-bearing joints is unclear.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Central Finland Health Care District, 17/12/2011, ref: 19U/2011

Study design
Randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Osteoarthritis

Interventions
The study will be a 4-month, randomized controlled study (RCT) in postmenopausal women with mild OA who will be randomly assigned into two groups:
1. An aquatic exercise group
2. A control group

Aquatic training classes will be held at the Telkänpesä care centre in Jyväskylä in a therapy pool with water temperature of 32 degrees and depth of 1.3-1.5m. Training sessions will be conducted three times a week in small classes containing 5-7 persons. All the classes will be supervised by an experienced physiotherapist.

Each session will be started with a 12-min warm-up including exercises to enhance neuromuscular activity (balance and plyometric exercises) as well as lower leg muscle strengthening and stretching. This will be followed by 30-40 min of resistance training and then a 5-min cooling down period. The progression of the exercise program will be ensured by using resistance boots of different sizes and by varying the amount and duration of sets. Intensity of

training will be monitor using polar heart rate monitors, BORG and lactate tests will be performed before and immediately afterwards to obtain quantitative measures of training intensity.

The control group will be participate to the stretching exercise class (i.e. sham exercise) once every other month and asked to maintain their pre-study level of physical activity.

Both groups will keep a physical activity diary.

Intervention Type
Behavioural

Primary outcome measure
Cartilage measurements
Structural changes of the tibiofemoral and patella cartilage will be revealed by Magnetic Resonance Imaging (MRI) at 1.5T magnetic field strength. The combination of two techniques will be used, T2 relaxation time, indexing the collagen component of cartilage, and dGEMRIC, reflective of glycosaminoglycan concentration, volumetric MRI assessment of cartilage thickness and morphology. Also, the quality of subchondral bone will be evaluated. In our laboratory, the reproducibility of bulk dGEMRIC is good (CVrms 4.2 4.8%)

Body composition:
Dual energy X-ray absorptiometry (DXA) will be performed to assess body composition. The body fat, lean body mass as well as femoral neck and lumbar spine areal bone mineral density (BMD, g/cm2) and bone mineral content (BMC, g) will be analyzed.

Secondary outcome measures
1. Knee pain will be evaluated by a 100 mm visual analog scale (VAS)
2. Physical function and clinically-important symptoms will be evaluated by Knee Injury and Osteoarthritis
3. Knee Injury and Osteoarthritis Outcome Score (KOOS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
4. X-ray (weight-bearing anteroposterior and mediolateral radiographs) will be taken from both knees for the classification of osteoarthritis of the knee
5. Quality of life will be evaluated by the RAND 36-Item Health Survey questionnaire
6. Muscle strength (leg extension and flexion) will be measured using an adjustable dynamometer chair (Good Strength; Metitur, Jyväskylä, Finland)
7. Muscle power will be measured with a Nottingham powerrig
8. Dynamic balance and agility will be evaluated with a timed figure of 8 running test

Overall study start date
04/01/2012

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Voluntary women 60-68 years of age, regular intensive exercise (such as strength training) no more than two times a week

2. No history of any illness for which exercise is contraindicated or that would limit their participation in the Aquatic exercise program
3. Subjects with mild to moderate knee pain during the last 12 months
4. Willingness and voluntarily signed informed consent to undergo testing and intervention procedures with all of its aspects
5. Weight-bearing knee x-rays show Kellgren-Lawrence grade 1-2 OA according to Altman et al. (1986)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
The target total recruitment of participants is 80 that randomly assigned into two groups (40 and 40)

Key exclusion criteria
1. Body-mass index over 34
2. Knee instability or trauma that would jeopardize the training
3. Inflammatory joint disease
4. Intra-articular steroid injections in the preceding 3 months in the knee

Date of first enrolment
04/01/2012

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
Finland

Study participating centre
Department of Health Sciences
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Government

Funder Name
Academy of Finland (Finland) ref: 253198

Alternative Name(s)
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Funder Name
The Social Insurance Institution of Finland (Finland) ref: 34/26/2011

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?
Protocol article	protocol	07/03/2013		Yes	No
Results article	results	01/10/2016	21/01/2019	Yes	No
Results article	results of the effects of high-intensity resistance aquatic training on body composition and walking speed in women with mild knee osteoarthritis,	01/08/2017	21/01/2019	Yes	No
Results article	results of the relationship between physical activity and cartilage quality in women with knee osteoarthritis,	01/07/2017	21/01/2019	Yes	No