Effects of exercise on knee cartilage and bone

Submission date 22/04/2008	Recruitment status No longer recruiting
Registration date 24/07/2008	Overall study status Completed
Last Edited 29/04/2025	Condition category Musculoskeletal Diseases

[] Prospectively registered

[] Protocol

- [] Statistical analysis plan
- [X] Results
- [] Individual participant data

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 123140

Study information

Scientific Title

Controversial effects of exercise on articulate cartilage and bone

Acronym

LuRu

Study objectives

Osteoarthritis (OA) and osteoporosis (OP) are two common diseases, closely associated with aging, morbidity and disability. The predicted aging of population will accentuate the burden of OA and OP on health care systems. Without population level intervention, the increasing trend is likely to continue thus creating a true public health problem for our societies. Consequently, there is an obvious social need for efficient and cost-effective prevention of bone loss and reduce the impact of arthritis and chronic joint symptoms. Importantly, these actions should be feasible at the population level and that the intervention would not require special resources or expertise from the health care professionals.

Hypothesis:

Physical exercise regimens similar to that used in this trial will decrease the degenerative process of the joint and age related bone loss. Additionally, the exercise regimen improves functional ability and quality of life of the subjects. Further knowledge on the potential relationship of the effects of exercise on osteoarthritis (OA) and osteoporosis (OP) is crucial, because regardless of the causality of OA-OP interaction, it may prevent disability and pain or bone fractures with people suffering from OA or OP.

Ethics approval required

Old ethics approval format

Ethics approval(s) Ethics Committee of the Central Finland Health Care District, 23/01/2008, ref: Dnro 1E/2008

Study design Randomised, controlled, single-centre trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

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 (OA) and osteoporosis (OP)

Interventions

The participants will be randomly allocated to the two arms in equal numbers (i.e. 40 each).

Exercise training group:

Supervised aerobic and step-aerobic programme. A qualified trainer will provide supervised training sessions, three times a week for 12 months. Each session lasts 60 minutes. Each workout will include 15 minutes warming-up, 20 minutes multidirectional acceleration, stops, deceleration and turns with music, 15 min calisthenics (body strengthening) and 10 minutes period for cooling-down. The training will be an aerobic programme that has been shown to be osteogenic and that includes accelerating and decelerating forwards and sideways, walking with stops and turns with a music.

Control group:

The control group will pay a social visit to the University once every two months and will otherwise be asked to maintain their pre-study level of physical activity. These visits will be designed to standardise exercise habits and to maintain the control group's interest in the study.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

The following will be assessed at baseline and 12 months:

Cartilage measurements

Structural changes of the tibiofemoral cartilage will be revealed by magnetic resonance imaging (MRI) at 1.5T magnetic field strength. The combination of two techniques, T2 relaxation time, indexing the collagen component of cartilage, and dGEMRIC, reflective of glycosaminoglycan concentration, and volumetric MRI assessment of cartilage thickness will be used to provide a comprehensive assessment of the cartilage status. T2 mapping and structural analysis of bone will provide MRI parameters sensitive to the properties of bone according our previous studies.

Bone measurements

Peripheral quantitative computed tomography (pQCT) (XCT 2000, Stratec Medizintechnik GmbH) will be performed to measure tibial shaft and distal tibia geometry, bone mass distribution and bone strength.

Dual energy X-ray absorptiometry (DXA) will be performed to assess bone mineral content (BMC) (in grams) and areal bone mineral density (aBMD) (in g/cm^2) at the proximal femur, distal femur and proximal tibia.

In addition, a structural analysis of the narrowest section of the femoral neck will be carried out using a customised bone strength analysis software. Based on our previous study, the quality of subchondral bone will be evaluated with MRI using the T2 relaxation time measurements.

Secondary outcome measures

The following will be assessed at baseline, 6 and 12 months:

1. Knee pain will be evaluated by a 100 mm visual analogue scale (VAS) with 0 mm and 100 mm indicating no pain and the worst possible pain, respectively. Pain will be measured before, during and after every training session.

2. Physical function and clinically-important symptoms will be evaluated by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Knee Injury and Osteoarthritis Outcome Score (KOOS). Physical function and symptoms will be correlated with structural changes of cartilage assessed with MRI. This will brings up clinically important information in terms of cartilage alterations association with clinical findings.

3. X-ray (weight-bearing anteroposterior and mediolateral radiographs) will be taken for both knees. The radiographs will be evaluated by two physicians without knowledge in which study arm the subject belongs to, using the criteria for the classification of osteoarthritis of the knee (blinded assessment).

4. Quality of life will be evaluated by the RAND 36-Item Health Survey questionnaire.

5. Muscle strength (leg extension and flexion) will be measured using the David-200 and 210 dynamometers.

6. Dynamic balance and agility will be evaluated with a timed figure-of-eight running test.

7. Physical activity monitoring: Physical activity will be monitored using an accelerometer-based body movement monitor (Newtest Ltd), analysing the activity data at different acceleration levels to evaluate the intensity of exercise according to our procedures.

Overall study start date

17/03/2008

Completion date

30/11/2009

Eligibility

Key inclusion criteria

1. Voluntary, 52-65 years old postmenopausal women

2. Regular intensive exercise (such as strength or aerobic, impact type of training) no more than two times a week

3. No history of any illness for which exercise is contraindicated or that would limit their participation in the exercise programme

4. Subjects with mild to moderate knee pain during the last 12 months

5. Willingness, and voluntarily signed informed consent to undergo testing and intervention procedures with all of its aspects

6. Weight-bearing knee x-rays show grade 1-2 OA according to Kellgren-Lawrence grade I or II

Participant type(s) Patient

Age group Not Specified

Sex Female

Target number of participants 80

Key exclusion criteria

- 1. Body-mass index over 34
- 2. Knee instability or trauma
- 3. Inflammatory joint disease
- 4. Intra-articular steroid injections in the preceding 12 months in the knee
- 5. Osteoporosis and medications

Date of first enrolment

17/03/2008

Date of final enrolment 30/11/2009

Locations

Countries of recruitment Finland

Study participating centre Department of Health Sciences Jyväskylä Finland 40014

Sponsor information

Organisation University of Jyväskylä (Finland)

Sponsor details

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Funder(s)

Funder type Government

Funder Name Academy of Finland (Finland) (ref: 123140)

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

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location Finland

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?
<u>Results article</u>	results	01/01/2014		Yes	No
<u>Results article</u>	Secondary analysis	11/04/2025	29/04/2025	Yes	No