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Comparison of the direct effect of walking and resistant training

Submission date
15/04/2016

Recruitment status
No longer recruiting

Registration date
05/05/2016

Overall study status
Completed

Last Edited
23/02/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Low bone mass, also known as osteopenia, is a condition in which a person's bones are less dense than average. In some cases, it can lead to further bone loss and a condition called osteoporosis. Osteoporosis is a long term condition, which gets progressively worse, which makes bone weak, brittle and more likely to break. This deterioration can weaken the bones so much that person with low bone mass can suffer a fracture during everyday activities, such as lifting a bag of groceries. There is a great deal of evidence that weight-bearing and resistance exercises support the development of strong bones because the strain put on bones causes them to become more dense (osteogenic). The aim of this study is to compare the effects of a single session of resistance exercise or walking on the chemical indicators (biomarkers) of bone metabolism (breakdown) in people with low bone mass.

Who can participate?
Women with osteoporosis/osteopenia

What does the study involve?
Participants re randomly allocated to one of three groups. Those in the first group take part in a single session of resistance training, which lasts for around 46 minutes. This involves a series of exercises that use large muscle groups and major joints to strengthen muscles. Those in the second group take part in a single session involving moderate intensity brisk walking outdoors on even ground. Participants maintain their pace by keeping to a rhythm of 100 steps per minute for around 46 minutes. Those in the third group do not take part in any exercises. At the start of the study and then again within 5 minutes of completing the exercises, all participants have a sample of blood taken so that indicators of bone metabolism can be measured. Additionally, at the start of the study, participants have their bone mineral density measured using a type of x-ray.

What are the possible benefits and risks of participating?
Participants benefit from receiving information about their bone mineral density. There is a small risk of bruising or discomfort during and after blood tests.

Where is the study run from?
Zala County Hospital (Hungary)

When is the study starting and how long is it expected to run for?
November 2013 to November 2015

Who is funding the study?
University of Pécs (Hungary)

Who is the main contact?
Mrs Gabriella Császárné Gombos

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Study information

Scientific Title
Direct effects of physical training on markers of bone metabolism and serum sclerostin concentrations in older adults with low bone mass

Study objectives
The aim of this study is to examine the direct effects of a single session of resistance exercise or walking on biochemical markers of bone metabolism in participants with low bone mass.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Regional Committee of Science and Research Ethics, 24/11/2011, ref: 46/2011
2. Policy Administration Service of Public Health of Zala County, 09/03/2015, ref: ZAR/097/194-8/2015

Primary study design

Interventional

Study design
Three arm randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low bone mass

Interventions
The participants were randomly assigned to a resistance exercise group (RG; n = 50), walking group (WG; n = 50), or control group (CG; n = 50).

Resistance exercise group: Participants take part in a single resistance training exercise session. This involves 8 minutes of dynamic warm-up consisting of exercises requiring movements of large muscle groups and major joints that incorporated small impacts with the ground, approximately 30 minutes of exercises that include muscle-strengthening and core stabilization elements, and an 8 minute cool down consisting of walking and static and dynamic stretches was performed.

Walking group: Participants take part in a single session involving moderate intensity brisk walking to a rhythm (100 steps/min) provided by a metronome, continuously for 46 minutes outdoors on even ground.

Control group: Participants continue as normal and do not receive any interventions.

Intervention Type
Behavioural

Primary outcome(s)
1. Bone-specific alkaline phosphatase (BALP) concentration is measured using a photometric assay at baseline and immediately after the intervention
2. Carboxy-terminal cross-linked telopeptide of type I collagen (CTX) concentration is measured using an electrochemiluminescence immunoassay (ECLIA) at baseline and immediately after the intervention
3. Serum sclerostin concentration is measured using a qualitative sandwich enzyme-linked immunosorbent assay (ELISA) at baseline and immediately after the intervention

Several assistants performed sample collection simultaneously to ensure rapid collection within 0 –5 minutes after the exercise sessions.

Key secondary outcome(s)
Bone mineral density (BMD) is determined by dual energy X-ray absorptiometry (DEXA) using a LUNAR DPX densitometer at baseline.

Completion date
15/11/2015

Eligibility

Key inclusion criteria
1. Female
2. Aged between 35 and 65 years
3. New diagnosis of osteoporosis/osteopenia
4. Lack of endocrine or metabolic disease which would have an impact on bone mineral density or musculoskeletal system
5. Normal lifestyle and activity
6. Agreement to participate
7. Generally considered to be healthy

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Any condition influencing calcium and bone metabolism (except dietary calcium and Vitamin D supplementation),
2. Ongoing hormone replacement therapy
3. Any known endocrine/metabolic, renal, or hepatic disease (e.g., hypogonadism, hyperthyroidism, hyperparathyroidism, or increased glucocorticoid levels)
4. Any physical injury (orthopedic, rheumatologic) hindering the performance of physical activity
5. Osseous fracture of any origin during the previous 6 months
6. A diagnosis of cardiovascular disease or uncontrolled hypertension
7. Any non-antibiotic medication within the past year, including steroids of any type, thyroid hormones, diuretics, or anticoagulants
8. Any antibiotic use within the last 6 months

Date of first enrolment
01/11/2013

Date of final enrolment
15/03/2014

Locations

Countries of recruitment
Hungary

Study participating centre

Zala County Hospital (Zala Megyei Kórház)
Zalaegerszeg
Zrínyi Miklós u. 1
Zala
Hungary
8900

Sponsor information

Organisation
University of Pécs

ROR
https://ror.org/037b5pv06

Funder(s)

Funder type
University/education

Funder Name
University of Pécs

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/06/2016		Yes	No