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The effects of exercise and vibration therapy on bone density and physical function in females aged 55-80 with osteoporosis

Submission date
23/06/2011

Recruitment status
No longer recruiting

Registration date
11/07/2011

Overall study status
Completed

Last Edited
22/05/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoporosis is a condition that weakens bones, making them fragile and more likely to break. It is growing in prevalence and is proving costly for health care services. There are many aspects to treatment, one of which is exercise. The aim of this study is to compare two different forms of exercise to see which has a better effect on bone density, physical ability and quality of life, and also to compare the effect of these exercises to standard treatment (advice).

Who can participate?
Post-menopausal women between 55 and 80 years of age who have been diagnosed with low bone density, and have no significant mobility limitations or medical conditions that would preclude moderate exercise.

What does the study involve?
Participants will be requested to have an initial assessment including an interview, a bone density scan, a blood test for indicators of bone chemistry, and a series of balance and simple physical ability tests, as well as completion of three questionnaires including a standardised Quality of Life questionnaire which some people may find to include questions which are irrelevant to them or may be of a sensitive, personal nature. Once the initial testing is complete, participants will be randomly allocated to either the usual care group (i.e., to receive advice on bone health, diet and physical activity) or to one of the two exercise groups. The GP of each participant in the exercise groups will be notified and the doctor may decide to withdraw their patient from this study if, he/she feels it is in their best interest. One of the exercise groups will stand or lean on a vibrating plate while doing some of the exercises. Another group will complete the same exercise class and the same set of exercises on the vibration platform but the vibration will be switched off. All three groups will be reassessed using the same tests at the end of the exercise period and after 4 months.

What are the possible benefits and risks of participating?
For those in the standard care group there will be no added risks as all the assessments are routine clinical tests. There will be minimal risks with taking any blood sample such as fainting or

feeling light-headed, bruising or infection. Those who participate in the exercise programmes will be carefully screened prior to starting the programme by a Chartered Physiotherapist and will be monitored during the sessions where they will be exercising within levels deemed safe. All exercise activity will be carried out in University College Dublin and the personnel supervising will be professional therapists who have been trained on a life-saving course.

Where is the study run from?
University College Dublin (Ireland).

When is the study starting and how long is it expected to run for?
From December 2010 to December 2011.

Who is funding the study?
University College Dublin (Ireland).

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
The effects of exercise and whole body vibration on bone mineral density and physical function in postmenopausal ostoporotic and osteopenic females - a randomised controlled pilot trial

Study objectives
This randomised controlled pilot study proposes to investigate the effects of whole body vibration training and 'Osteofit', an integrated strength, fitness and falls risk bone health programme in postmenopausal osteoporotic or osteopenic women. The trial aims to discover the effects of the intervention in terms of biochemical bone turnover markers, Bone Mineral Density (BMD) of the lumbar vertebrae, femoral neck and wrist, as well as physical function and Quality of Life. One group will be assigned to receive a combination of exercise and vibration, another will partake in exercise alone and the control group will continue with standard care. The primary hypothesis to be tested is that the addition of the vibratory signal in the combined exercise and vibration group will result in a greater reduction in bone resorption and a greater increase in bone formation as determined by bone markers from blood serum samples, than the exercise alone or no intervention control group.

A secondary hypothesis is that wrist, femoral neck, lumbar spine BMD as measured by dual energy X-ray absorptiometry (DXA) scans will increase in both exercise groups compared to the control, with more apparent results in the combined exercise and vibration group. It is speculated that QOL determined by the Quality of Life questionnaire of the European Foundation for Osteoporosis (QUALEFFO) as well as physical function, measured by selected physical function tests, will render more effective results in the combined exercise and vibration group than exercise alone or control group in this specific population.

It is also hypothesised that both intervention groups i.e. exercise alone and the combined exercise/ vibration groups will result in more beneficial outcomes over the control group in the tested measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University College Dublin Human Research Ethics Committee - Sciences (HREC-LS) approved on 22nd February 2011, Research Ethics Reference Number (RERN): LS-11-09-McCarthy-Persson
2. St Vincent's Healthcare Ethics and Medical Research Committee approved on 19/10/2010

Study design
Single-centre single-blinded randomised controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Osteoporosis, Osteopenia

Interventions
1. One group will receive the Osteofit exercise programme alone
2. Another group will receive the Osteofit exercise programme in addition to whole body vibration therapy
3. The protocol for the Osteofit programme will be based on extensive literature reviews, best evidence available and clinical expertise which was designed by clinical specialists at the British Columbia (BC) Women's Hospital & Health Centre
4. Osteofit is a community-based exercise programme for those with osteoporosis
5. It aims to reduce falls risk and improve functional ability, thereby enhancing Quality of Life (QOL)
6. The programme targets posture, balance, gait, co-ordination and hip and trunk stabilisation
7. The focus on improving posture and balance differentiates this programme from other programmes for the elderly
8. The classes the participants of this trial will partake in are typical of those in the regular Osteofit classes
9. The workout will last approximately 40 minutes, consisting of strengthening and stretching exercises to combat medially rotated shoulders, protrusion of the mandible, extension of the cervical spine, thoracic kyphosis and loss of lumbar lordosis
10. Thera-band elastic bands and small free weights (1-2kg) will be used for resistance and strength training
11. Exercises to improve functional ability will also be used such as chair squats, balance exercise, tandem walking and getting up and down off the floor
12. Repetitions will be kept to between eight and sixteen in each set
13. Each subject will keep a diary to record attendance and any illness or injury
14. Participants in the exercise or exercise and vibration training will attend the sessions twice weekly throughout the duration of the intervention
15. All subjects randomised into the exercise and vibration group or the exercise alone group will perform the same exercises on the vibration platform (Power plate Pro 5, London UK)
16. These sessions will commence after the Osteofit class
17. Only those in the combined exercise and vibration group will receive the vibratory input from the plate, the other group will perform the same exercises on a plate which is powered off
18. Participants will train in accordance with a progressive exercise and vibration programme designed for use in a previous successful trial (Verschueren et al 2004)
19. The exercise that will be performed include squats (static, dynamic, unilateral), step up/down (forwards/side to side), single leg stance (supported), calf raises, lunges, weight bearing through hands, (increased load through arms, shifting weight right/left, press-ups.)
20. The training volume and intensity will be increased systematically over the 4 month training period by increasing the duration of the programme incrementally from 5 to 10 minutes, increasing the number of exercise repetitions, holds and sets, increasing the variety of exercises and increasing the load from bilateral to unilateral

21. The training intensity will be increased by shortening the rest periods and increasing the frequency of the vibration (30Hz40Hz) incrementally throughout the intervention
22. The progression of the training will be in accordance with the Overload Principle

Control Group
1. The control group will be advised to maintain their current level of physical activity and current daily routine and report any daily routine changes to the Investigators
2. They will receive advice on self-management of osteoporosis and osteopenia
3. They will be assessed at baseline and then again after the intervention has been completed

Intervention Type
Behavioural

Primary outcome measure
1. Blood serum tests for biochemical products of bone formation will be taken, by venipuncture in the phlebotomy department of an affiliating university hospital. Serum procollagen type 1 N-terminal peptide (P1NP) and Serum collagen type 1 cross-linked C-telopeptide (CTX) will be used as markers for bone formation and resorption, respectively. 1.2. Blood samples will be taken between 8am - 11am after a 12 hour fast
2. BMD will be tested by DXA (GE Lunar iDXA, Madison WI, USA)
2.1. Subjects will wear light clothing and remove all metal prior to scan
2.2. Scans will be taken at lumbar spine (L 1-4), non dominant hip (femoral neck and trochanter) and non dominant wrist (distal radius and ulna) of each participant
2.3. Standard positioning will be used with anterior posterior scans
2.4. The heights of the regions of interest (ROI) used in the DXA analysis will be adjusted to be anatomically comparable. All scan analyses, quality assurance and phantom spine calibration procedures will be performed daily prior to scanning sessions by the same technician, to ensure repeatability of the measures

Secondary outcome measures
1. The Five Times Sit to Stand Test (FTSTS) will be used to determine functional lower limb strength
1.1. The subjects will stand up and sit down 5 times as quickly as possible and their time will be measured using a digital stop watch
1.2. They will be asked to repeat this three times with the average of the three scores being recorded
1.3. The height of the chair will be standardised to 43cm from seat to floor, with no arm rests
1.4. Subjects will be instructed not to use hands for support on their legs or chair
1.5. All participants will undergo one set of 5 sit to stands as a familiarisation trial prior to the test
2. Dynamic balance will be measured barefoot using the Star Excursion Balance Test (SEBT)
2.1. The anterior, posteromedial, and posterolateral directions of the SEBT will be used
2.2. Three consecutive trials in each direction will be performed and the average value obtained in each direction taken as the score
2.3. Participants will be required to reach as far as possible along the directional component of the SEBT (i.e. anterior, posteromedial, or posterolateral direction) and make a light touch with the foot
2.4. All participants will be instructed to perform three familiarisation trials in each direction prior to the test commencing
3. Maximal isometric strength of leg extensors will be measured using a myometer (M.I.E. Medical Research, Yorkshire, UK.)

3.1. Subjects will sit with their knees and ankles at an angle of 90° of flexion while pressing maximally against the myometer
3.2. The isometric strength of the non dominant leg will be recorded for three maximal efforts and the average of the three readings will be used as a test score
4. Grip Strength will be measured using a standard grip strength dynamometer (M.I.E. Medical Research, Yorkshire, UK.)
4.1. The average of three readings from the non dominant hand will be used as a test measure
4.2. The physical tests will be preceeded by one familiarisation trial (one in each direction for the balance test) before testing begins
5. The Batak-pro system will be used to test reaction, hand eye co-ordination and stamina (Quotronics Limited, Surrey, U.K.)
5.1. BATAK Pro is a piece of equipment specifically designed to test reaction, hand eye co-ordination and stamina
5.2. Subjects will tap the lighting target on receiving a visual stimulus from one of the twelve visually bright light emitting diode (LED) cluster targets which are under the control of a dedicated computer
5.3. The targets will be lit up in a random manner
5.4. Hits will be timed and scored on a central Liquid Crystal Display (LCD) and verbal instructions will be issued to the participating subject from the device
5.5. Reaction tests will be conducted twice and the average score recorded
6. The 10 Metre Walk Test (10MWT) will be used to assess short-duration walking speed 25. The volunteer will walk a course of ten metres (marked on a level floor), with two metres for acceleration and two metres for deceleration
6.1. Timing will begin as the volunteer passes the first two acceleration metres and will stop when the ten metres of the course are completed
6.2. The volunteer will be instructed to walk the course at her normal pace five times and asked to repeat the same course five times at maximal speed
6.3. In order to familiarise participants with the requirements of this test, the first two ten metre courses completed at each speed will not be recorded
6.4. The final three courses of ten metres at each speed will be used to obtain the average speed walked under each condition
7. The QUALEFFO questionnaire will be used to determine QOL in the domains of pain, physical function and mental health. This has good repeatability, adequate internal consistency in the specific osteoporotic population

Overall study start date
10/12/2010

Completion date
10/12/2011

Eligibility

Key inclusion criteria
1. Women between 55 and 80 years of age
2. Diagnosis by DXA scan with osteopenia or osteoporosis

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Functional disability/pathology preventing participation in the intervention
2. Cognitive impairment questioning the ability to give informed consent/follow trial protocol
3. Lack of spoken and/or written English impairing ability to give informed consent/follow trial protocol
4. Medical conditions/contraindications to a moderate functional exercise programme according to the American College of Sports Medicine
5. Mobility limitations hampering travel for assessments as well as the exercise programme
6. Those already engaged in high impact activity at least twice a week (any weight bearing exercise or activity more intense than brisk walking

Date of first enrolment
10/12/2010

Date of final enrolment
10/12/2011

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
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004

Sponsor information

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University/education

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Funder(s)

Funder type
University/education

Funder Name
University College Dublin - School of Physiotherapy (Ireland) (Seed Fund)

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