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Whole body vibration for preventing and treating osteoporosis (Protocol)

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[Intervention Protocol]

Whole body vibration for preventing and treating osteoporosis

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To inform healthcare workers of:

1. whether whole body vibration is effective for the prevention and treatment of osteoporosis;

2. if effective, the efficacy and safety of reported protocols in the use of whole body vibration;

3. adverse effects associated with whole body vibration.

BACKGROUND

Description of the condition

Osteoporosis is a systemic skeletal disease characterised by low bone mass and microarchitectural deterioration of bone tissue. Osteoporosis results in increased bone fragility and susceptibility to fracture (Kanis 2008). Hip fractures linked to osteoporosis are a global health problem (Alvarez-Nebreda 2008; Dawson-Hughes 2001; Liu 2007; Lofthus 2001; Siqueira 2005). Worldwide, the incidence of hip fractures is predicted to be 6.3 million by 2050, 3.7 times the incidence recorded in 1990 (Cooper 1992). In 1997, the projected costs to global healthcare systems without adjustments for inflation were estimated to exceed $131 billion by 2050 (Johnell 1997). Hip fractures have a most significant impact on individuals because they result in hospitalisation, disability, and are linked to increased mortality. However, hip fractures are not necessarily directly attributable to mortality, because of other underlying conditions (Center 1999). The onset of osteoporosis occurs most widely in later stages of life. Nevertheless, young people with chronic conditions such as cerebral palsy, osteogenesis imperfecta, spina bifida, and celiac disease may also be susceptible to fractures associated with low bone mineral density (Dosa 2007; Huang 2006; Leet 2006; Ludvigsson 2007).

Several indicators for osteoporosis exist, but bone mineral density is currently considered the primary measure (Kanis 2008). Bone mineral density (BMD) is measured as the amount of bone mass per unit volume (volumetric density, g/cm^3) or per unit area (areal density, g/cm^2) (Kanis 2008). Several techniques have been reported within the literature to determine BMD including dual-energy X-ray absorptiometry (DXA), quantitative ultrasound (QUS), magnetic resonance imaging (MRI), quantitative computed tomography (QCT), and peripheral quantitative computed tomography (pQCT). While DXA is considered the current 'gold standard' for the clinical diagnosis of osteoporosis (Kanis 2008; O'Neill 2002), strengths and weaknesses of each method of analysis have been extensively discussed. For example, DXA images are two-dimensional and, as a result, may overestimate the true volumetric density in people with large bones (Kanis 2008).

Bone mineral density values are expressed in reference to healthy young caucasian women aged 20 to 29 years in standard deviation (SD) units and reported as a T-score (Table 1). That is, a T-score is a measurement expressed in SD units from the mean of young healthy person of the same gender. T-scores used in assessment of osteoporosis relate to how a person's bone mineral density, estimated by DEXA, compares with the value in the young healthy person. Where a database for specific populations does not exist, normative data from the US National Health and Nutrition Examination Survey (NHANES III) has been used. In Australia, the T-scores for fracture risk in women have been calculated from an Australian database. In men, a normative database does not exist and therefore the NHANES data are used.

Table 1: Categories and clinical criteria for men and postmenopausal women aged 50 years and older using DXA meaurements at the femoral neck (Kanis 2008).

Categories	Criteria
Normal bone	T-score ≥ -1 SD
Osteopenia	T-score between -1 and -2.5
Osteoporosis	T-score ≤ -2.5 SD

To date, the most published management strategies for preventing and treating osteoporosis and reducing the risk of osteoporotic-related hip fractures include antiresorptive (reducing breakdown of bone) therapies such as calcium and vitamin D supplementation (Homik 1998), hormone replacement therapy (Cranney 2003), bisphosphonates (Homik 1999; Ward 2007; Wells 2008a; Wells 2008b; Wells 2008c), selective estrogen-receptor modulators (Stevenson 2005), calcitonin (Cranney 2000), anabolic therapy (parathyroid hormone) (Vestergaard 2007), and hip protectors to reduce the force impact of falls (Parker 2000). Our understanding of the efficacy of several of these therapies for long-term use remains unclear (Hirano 2000; Sambrook 2006).

Description of the intervention

Systematic meta-analysis has shown aerobic exercise, resistance training, and walking to be effective non-pharmacological interventions to attenuate bone loss (Bonaiuti 2002). Paradoxically the act of exercise, such as walking, exposes individuals with fragile bones to the risk of fracture from a fall (Rubin 2004). Whole body vibration exercise may offer a safer alternative for reducing bone loss in people who are highly susceptible to hip fracture.

Whole body vibration exercise consists of standing statically or performing dynamic movements on an oscillating platform. Various forms of oscillation have been discussed or appear within the literature including tilting or vertical, or a combination of vertical and tilting, perturbations (for example Abercromby 2007; Lorenzen (2009); Russo 2003; Verschueren 2004). The potential benefits cited by researchers include improved muscular strength (Delecluse 2003; Roelants 2004), flexibility (Cochrane 2005; van den Tillaar 2006), and postural control in older adults (Bogaerts 2007) and people with neuromuscular diseases such as multiple sclerosis (Schuhfried 2005), reduced back pain (Rittweger 2002) and, specific to this review, whole body vibration may provide an osteogenic stimulus (Ward 2004) or prevent bone loss (Rubin 2004) in individuals susceptible to osteoporosis.

The intensity of whole body vibration exercise can be manipulated by the frequency of oscillations (or up-and-down movements) per second, measured in Hertz (Hz); or the amplitude (size of the movement of the vibration platform) defined as the displacement of the platform from a horizontal position, measured in mm). The product of the frequency and amplitude of vibration is acceleration,

which has been reported in metres per second per second ($m.s^{-2}$) or in g-forces relative to the earth's gravitational force (g). Variation of exercises, such as dynamic and static squatting, can also be used to maniplulate muscle activation during whole body vibration exercise (Abercromby 2007).

How the intervention might work

Mechanisms explaining human responses to whole body vibration exercise are currently unclear. Several explanations have been proposed including, but not limited to, (1) the tonic vibration reflex, as mechanical vibration may induce reflexive action in opposing groups of muscles (agonist and antagonist) (Cardinale 2003; Russo 2003; Torvinen 2002); (2) bone loading and change in the shape of bone that may increase the flow of fluid and pressure within bone (intramedullary) (Ward 2004); and (3) stochastic resonance, the 'noise' generated by vibration that enhances the bone cell sensation of motion (mechanoreception) (Tanaka 2003).

Why it is important to do this review

Various combinations of frequency and amplitude of vibrations, as well as static and dynamic exercise, have been used by researchers. Inconsistent prescriptions of whole body vibration make it difficult for clinicians to determine the safest and most effective whole` body vibration exercise program. Furthermore, it is unclear whether whole body vibration is effective for the treatment of osteoporosis. The high accelerations used by some researchers have been suggested by others to be dangerous for musculoskeletal health (Rubin 2003). The most effective exercise session duration and number of sessions per week are unclear.

OBJECTIVES

To inform healthcare workers of:

1. whether whole body vibration is effective for the prevention and treatment of osteoporosis;

2. if effective, the efficacy and safety of reported protocols in the use of whole body vibration;

3. adverse effects associated with whole body vibration.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised and quasi-randomised (that is trials that allocated participants in ways that are not truly random, for example by date of birth or hospital record number) controlled trials using whole body vibration exercise for the prevention or treatment of osteoporosis will be considered for this review. Comparisons will be made with placebo and control groups with or without an intervention. Where all participants are accounted for, trials not reporting an intention-to-treat analysis will be included.

Types of participants

People (male and female) deemed to be at risk of, or who have, osteoporosis using DXA derived definitions for osteopenia and osteoporosis. More specifically: (1) normal = T-score ≥ -1 SD; (2) osteopenia (low bone mass) = T-score < -1, and > -1 but not more than -2.5 SD; (3) osteoporosis = T-score ≤ -2.5 SD (Kanis 2008). In this review, 'at risk' will be inclusive of any person with the clinical definition of osteopenia or osteoporosis. We will limit inclusion criteria to primary osteoporosis (not secondary to disease).

Types of interventions

All randomised controlled trials (RCTs) involving whole body vibration compared with other intervention, placebo, or control conditions will be included. The comparisons will not include whole body vibration studies combined with other interventions such as exercise and pharmaceutical therapy unless the effect of vibration alone can be determined (for example exercise alone compared with vibration combined with exercise).

Types of outcome measures

The primary outcomes of interest will be bone mineral density, incidence of fractures and falls, and adverse events. Secondary outcomes will include blood and urine borne markers of bone metabolism (bone formation markers, for example serum bone-specific alkaline phosphatase, amino-terminal propeptide of type 1 procollagen; and bone resorption markers, for example urine or serum telopeptides of collagen crosslinks), quality of life, and compliance relative to time spent. Not all studies will report these secondary outcomes.

Primary outcomes

Bone mineral density

Assessment of bone mineral density (BMD), at baseline and six months or longer post-intervention, measured by various methods including single and dual X-ray absorptiometry (DXA), quantitative computed tomography (QCT), and quantitative ultrasound (QUS). Units for bone density are reported in $g.cm^2$, area in mm^2, and bone strength in mm^3.

If the data includes both areal and volumetric BMD, standardised mean differences (SMDs) will be used. The difference in percentage of bone lost relative to time (that is expressed as proportion of the duration of the intervention) between experimental and control groups will be used as the measure of the intervention effect for pooling the data.

Incidence of fractures and falls

Reports of falls occurring during interventions will be extracted as counts. Retrospective (for example recall of falls in the past month) and prospective reports of incidence of fractures and falls will be analysed. More specifically, studies citing falls will be included if the severity of the fall resulted in injury, medical attention, or fracture.

Adverse events

Reports of adverse events associated with whole body vibration trials.

Secondary outcomes

Serum and urine biochemical markers of bone turnover

Secondary outcomes will include bone formation markers such as serum bone-specific alkaline phosphatase, amino-terminal propeptide of type 1 procollagen; and bone resorption markers such as urine or serum telopeptides of collagen crosslinks. Secondary outcomes of blood and urinary-borne measures may be reported for times shorter than six months.

Quality of life

Where validated measures have been used, such as the SF-36, the outcome of quality of life will be included.

Compliance

The outcome of compliance will be denoted by studies recording absences from supervised sessions, use of self-reported log books or alternative electronic memory devices.

Search methods for identification of studies

To identify whole body vibration trials with outcomes of interest, a search of the literature will be conducted (from 1966 to time of search). The search strategy is listed in the Appendix 1. No language restrictions will be imposed on either the search or the included trials.

Electronic searches

Electronic searches will be performed using the following databases: Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*), MEDLINE, and CINAHL via EBSCOhost and EMBASE.

Searching other resources

Other sources of information will be obtained from manual searches of bibliographies, unpublished dissertations, and consultation with experts in the field. Experts in the field will be sent a comprehensive list of relevant articles along with the inclusion criteria and will be asked if they are aware of other pertinent research that has not been included. They will also be asked if they are aware of any ongoing trials. These trials will be listed and tracked for future updates. In addition, manufacturers' reports will be accessed where further specifications of devices are required. Manufacturers' websites will also be sourced for potential studies.

Data collection and analysis

Selection of studies

Two authors (CL, GN) will independently identify studies to be assessed by reviewing the titles, abstracts, and keywords of all records obtained from the search. Full articles will be sourced for further assessment when the initial information appears to align with the review criteria. Trials not fulfilling the outlined selection criteria will be excluded. If review authors (CL, GN) disagree on a study for elimination, discussion will also take place with a third independent author (DG or MC). Furthermore, a measure of inter-rater agreement using Cohen's kappa statistic will be performed (Peat 2005). Documentation of agreement will be entered into a separate form entitled 'Consensus on articles with initial disagreement'.

Data extraction and management

Two authors (CL, GN) will independently extract the data on the study population, intervention, and outcomes onto a pro forma piloted on three studies. Authors of trials with incomplete reporting of data will be contacted. The pro forma will include the following.

1) Generic publication information such as the type of publication, title, authors, and year of publication.

2) Research design such as randomised controlled study, blinding of outcome assessors, allocation concealment, and sources of bias (selection, performance, attrition, and detection).

3) Descriptive characteristics of participants such as age, sex, baseline measures, diagnoses; inclusion and exclusion criteria and, if applicable, randomisation outcomes such as numbers allocated to each group at baseline, withdrawals, intention-to-treat numbers, and losses to follow up.

4) Intervention characteristics such as whole body vibration duration, intensity (amplitude and frequency), method of vibration, protocol (e.g. continuous or intermittent), comparator methods, and post-intervention follow up.

5) Outcomes: primary and secondary outcomes of a continuous, ordinal, or dichotomous nature.

6) Results: baseline and post-intervention means and SDs from the intervention and comparator groups will be recorded for continuous data. When the required data for analysis are not presented data will be derived, if possible.

Unsuccessful direct contact with study authors may result in a conservative, best estimate approach. More specifically, pre and post-intervention means and SDs will be inferred from graphs, if only graphs are available.

Disagreements in data extraction will be resolved via discussion and further scrutiny of the original data.

Assessment of risk of bias in included studies

For assessment of risk of bias in the selected studies we will use the Cochrane Collaboration's tool for assessing risk of bias (Higgins 2008). A template for appraising the risk of bias will include the following key criteria: random sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; incomplete outcome data; selective outcome reporting; and other sources of bias. Bias will be judged as 'Yes' (high risk of bias), 'No' (low risk of bias), or 'Unclear risk of bias'.

Measures of treatment effect

To assess intervention efficacy, we will present the means, SDs and 95% confidence intervals (CI) for continuous outcomes; and relative risk (RR) and 95% CI for dichotomous outcomes.

For continuous data, results will be presented as mean differences, if possible. However, where different scales are used to measure the same outcome or concept, standardized mean differences (SMD) will be used.

Unit of analysis issues

Cluster RCTs not accounting for 'clustering' may be identified. We will incorporate an approximate analysis of the trial as per methods outlined in the Cochrane Handbook, (Higgins 2009), incorporating an estimate of the intra-cluster correlation coefficient (ICC), or using external estimates obtained from similar studies if necessary.

Count data of adverse events (for example fractures, falls) will be extracted and reported both as total number of events and events per number of participants. New events (incidents) will be counted.

Ongoing and pre-existing events (prevalence) will not be included in our data extraction and analyses.

Dealing with missing data

Where data cannot be directly extracted, the trial authors will be contacted, or data will be converted or imputed. If we impute data, we will note so in the table 'Characteristics of included studies'. Also, we will investigate the possible impact of missing data on the findings of the review in sensitivity analyses.

Assessment of heterogeneity

The Chi^2 test will be used to establish heterogeneity (P = 0.1) and the I^2 statistic will be used to quantify inconsistency across the results (I^2 = [Q df / Q] x 100%; where Q is the Chi^2 statistic and df is the degrees of freedom). An I^2 > 50% will be considered to represent substantial heterogeneity. Where heterogeneity is found, data will be checked for incorrect extraction or entry into RevMan5. Subsequently, a random-effects model meta-analysis will be performed.

Assessment of reporting biases

In the event of a relatively large number of studies meeting the inclusion criteria, funnel plots (produced in RevMan5) will be used to review publication bias. Treatment effects will be plotted against standard error. Two review authors will visually inspect the funnel plot for asymmetry. Where disagreement exists, a third review author will be consulted.

Data synthesis

For clinically homogeneous studies, we will pool outcomes in a meta-analysis using the random-effects model as a default, as the random-effects model is identical to the fixed-effect model if there is no statistical heterogeneity (if I^2 = 0%). If included studies do not permit the calculation of the SDs (and the information is not available from the researchers), then a descriptive approach to synthesis will be used. This descriptive approach may also apply if an insufficient number of trials (< 2) or high heterogeneity (I^2 > 50%) remain following selection processes.

Subgroup analysis and investigation of heterogeneity

Where a sufficient quantity of studies exists (that is at least 10) a meta-regression analysis will be performed. Heterogeneity may exist due to differences in protocols of whole body vibration prescription. Therefore, the subgroup analyses will focus on frequency and amplitude of vibration. Where amplitude is the same across trials, frequencies will be compared. Conversely, where frequency is constant among trials, amplitudes will be compared. Subgroupings may also be possible relative to foot placement, International Organisation for Standardisation (ISO) and National Institute for Occupational Safety and Health (NIOSH) guidelines, and modes of vibration (vertical, horizontal tilting, and multidirectional). A further subgroup analysis will compare studies reporting osteoporosis variables as primary and secondary outcomes. Also subgrouping may be possible using sex, menopausal status, compliance, intensity of intervention in terms of session duration and frequency, pre-existing physical activity levels, and vitamin D status.

Sensitivity analysis

Where evidence exists of between study heterogeneity, the heterogeneity will be explored by repeating analyses with the following refinements:

1) trial sample size - where outliers may only be excluded at post hoc analysis;

2) trial quality as listed in the risk of bias section, e.g. we will test the robustness of the results by examining the effect of adequate allocation concealment on the effect size;

3) excluding studies with industry sponsorship or financial backing;

4) excluding studies that use quantitative ultrasound to measure BMD.

Summary of findings tables

The main results of the review will be presented in summary of findings tables, which provide key information concerning the quality of evidence, the magnitude of effect of the interventions examined, and the sum of available data on the main outcomes; as recommended by The Cochrane Collaboration (Schünemann 2008a). Outcomes to be included in the summary of findings tables are: changes in bone mineral density over time, blood and urine markers of bone metabolism, incidence of fractures, incidence of falls, standardised measures of quality of life, compliance with the intervention, and any other adverse events reported. In addition to the absolute and relative magnitude of effect provided in the summary of findings table, the number needed to treat (NNT) will be calculated from the control group event rate (unless the population event rate is known) and the relative risk using the Visual Rx NNT calculator (Cates 2004).

For continuous outcomes, the NNT will be calculated using the Wells calculator software available at the CMSG editorial office. The minimal clinically important difference (MCID) for each outcome will be determined for input into the calculator. The summary of findings table includes an overall grading of the evidence related to each of the main outcomes using the GRADE approach (Schünemann 2008b).

Justifications given by researchers for selected intensities will be included in the table.

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APPENDICES

Appendix 1. MEDLINE search strategy

1. exp Osteoporosis/
2. osteop$.tw.
3. bone density/
4. bone densit$.tw.
5. exp "Bone and Bones"/
6. bone loss$.tw.
7. or/1-6
8. Vibration/
9. vibrat$.tw.
10. 8 or 9
11. 7 and 10
12. randomized controlled trial.pt.
13. controlled clinical trial.pt.
14. randomized.ab.
15. placebo.ab.
16. drug therapy.fs.
17. randomly.ab.
18. trial.ab.
19. groups.ab.
20. or/12-19
21. (animals not (humans and animals)).sh.
22. 20 not 21
23. 11 and 22

WHAT'S NEW

Date	Event	Description
25 September 2009	Amended	CMSG ID A039-P

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DECLARATIONS OF INTEREST

None known

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