



Effective Health Care Program

Technical Brief
Number 10

Whole-Body Vibration Therapy for Osteoporosis



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Number 10

Whole-Body Vibration Therapy for Osteoporosis

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about healthcare. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments and Comparative Effectiveness Reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care. Technical Briefs are the most recent addition to this body of knowledge.

A Technical Brief provides an overview of key issues related to a clinical intervention or health care service—for example, current indications for the intervention, relevant patient population and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. Technical Briefs generally focus on interventions for which there are limited published data and too few completed protocol-driven studies to support definitive conclusions. The emphasis, therefore, is on providing an early objective description of the state of science, a potential framework for assessing the applications and implications of the new interventions, a summary of ongoing research, and information on future research needs.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly, while Technical Briefs will serve to inform new research development efforts.

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Whole-Body Vibration Therapy for Osteoporosis

Structured Abstract

Background. Osteoporosis is a skeletal system disease characterized by low bone density and deterioration of bone tissue. Current clinical guidelines recommend dietary and pharmacological interventions and weight-bearing exercise to treat osteoporosis and prevent bone fractures, but these interventions sometimes have low adherence and can cause adverse side effects. Whole-body vibration therapy has been proposed as an alternative or adjunctive intervention, but its role in preventing and treating osteoporosis, and the populations in which it has been studied, is unclear.

Purpose. To provide an overview of the key issues and evidence map related to the use of whole-body vibration therapy for the prevention and treatment of osteoporosis.

Methods. A review of the published and grey literature and interviews with Key Informants.

Findings. Very little scientific evidence evaluates the benefits and harms of whole-body vibration therapy for the prevention and treatment of osteoporosis; only 12 studies met the inclusion criteria for our review. A number of questions regarding the optimal population for treatment, optimal treatment protocol, key outcome measures, and whether whole-body vibration therapy is an adjunctive or distinctive therapy emerged from the published literature and key informant discussions. Reviewed studies offered little information on potential harms. However, safety concerns emerged from key informant discussions, including unknown long-term harms from the use of whole-body vibration therapy, and the potential inability of consumers to clearly distinguish low-intensity platforms intended for osteoporosis therapy from platforms intended for high intensity exercise. Claims about whole-body vibration therapy for the prevention and treatment of osteoporosis cannot be made without further research.

Contents

Background	1
Guiding Questions	3
Methods.....	4
Discussion With Key Informants.....	4
Grey Literature Search	4
Published Literature Search	4
Findings.....	6
Description of Existing Whole-Body Platform Technology	6
Existing Technology	6
Context in Which the Technology Is Used.....	8
Evidence Map	9
Current Evidence of the Technology	9
Summary and Implications	13
Important Issues Raised by the Technology	13
Next Steps	15
References.....	17

Tables

Table 1. Patient Populations in Vibration Studies	10
Table 2. Type of Vibration Platforms Used in Studies.....	10
Table 3. Characteristics of Vibration Intervention in Studies.....	11
Table 4. Outcomes in Vibration Studies	12

Appendixes

Appendix A. Definition of Terms	
Appendix B. Interview Guides for Key Informants	
Appendix C. Published Literature Search Strategy	
Appendix D. Example of Whole-Body Vibration Platform	
Appendix E. Evidence Tables	

Background

Osteoporosis is a skeletal system disease characterized by low bone density and deterioration of bone tissue.¹ The clinical ranges for osteoporosis, osteopenia, and normal bone density are presented in Appendix A. Osteoporosis affects 2 percent of men and 10 percent of women over the age of 50 in the United States.² In addition, 49 percent of older women and 30 percent of older men in the United States have low bone density or osteopenia.² Osteoporosis is a significant public health problem that leads to increased bone fragility and greater fracture risk, especially of the wrist, hip, and spine.¹ In an epidemiological study conducted in Switzerland, 50 percent of all fractures in women and 24 percent in men were considered osteoporotic.³ In the United States an estimated 1.5 million yearly osteoporotic fractures result in more than 500,000 hospitalizations, 800,000 emergency room visits, 2.6 million physician office visits, and 180,000 nursing home placements.¹ Hip fractures, in particular, are associated with an increased risk of death.¹ Fractures can also cause pain, height loss, and functional disability, as well as complications such as pressure sores and pneumonia.¹ By 2020, approximately half of all older Americans will be at risk for fractures from osteoporosis or osteopenia.¹

The U.S. Preventive Services Task Force recommends active screening for osteoporosis and early intervention to prevent bone fractures.^{4,5} Current clinical guidelines recommend dietary and pharmacological interventions to treat osteoporosis and prevent bone fractures.⁶⁻¹⁰ An increase of 1 standard deviation in bone mineral density in women would prevent 33 percent of hip fractures and 77 percent of vertebral fractures.¹¹ Despite proven effectiveness, these treatments may have low rates of long-term adherence. Pharmacological interventions can result in adverse outcomes, commonly minimal trauma atypical fractures, esophageal irritation, renal toxicity, and osteonecrosis of the jaw.^{5,12-17} Additionally, requirements of pharmacological interventions may be burdensome for patients. For instance, some may find it difficult to sit upright for 30 minutes after taking medications as is recommended for avoidance of esophageal irritation.⁵ Alternative therapies, including weight-bearing exercise, may also increase bone density^{18,19} and may be safer than medication, but risk of injury prevents some older persons from doing high intensity or weight-bearing exercise. The U.S. Preventive Services Task Force encourages research on new alternative osteoporosis prevention interventions that may have higher adherence rates and lower risks of side effects.^{5,20}

One possible alternative intervention is whole-body vibration therapy.²¹⁻²⁵ Whole-body vibration was originally proposed as a means to build bone density for astronauts in space,²⁶ and like other weight-bearing physical activities, it causes muscles and bones to work against gravity.² Recently, whole-body vibration has been considered a possible therapeutic intervention for increasing bone density in older persons and others at risk for osteoporosis.^{21,27-32} Literature on this topic already includes some discussion of vibration therapy to increase bone mass and decrease fracture risk,^{22-25,33-37} including recommendations from the International Society of Musculoskeletal and Neuronal Interactions.³⁸

How vibration therapy increases bone density is not well understood.^{33,39} One hypothesis suggests that vibration signals transmit and amplify into bone tissue, directly activating mechanosensors in bone cells.⁴⁰ Animal studies have demonstrated that vibration increases the anabolic (bone building) activity of bone tissue and increases bone density.^{26,41-43} Another hypothesis suggests that whole-body vibration, like other weight-bearing exercise,^{44,45} improves muscle strength and power by increasing neuromuscular activation.⁴⁶⁻⁵¹ Human studies on healthy volunteers examined adaptive muscle strength and performance after vibration therapy

and found its effects to be similar to those of short-term resistance exercise.^{44,45} Several studies have shown whole-body vibration therapy to improve muscle and bone circulation, increasing the supply of nutrients needed to build bones.^{22,52-56}

This technical brief describes the state of the science and summarizes the key issues related to the use of whole-body vibration therapy to improve bone density for the prevention and treatment of osteoporosis, including modalities, standards, relevant patient populations, outcomes measured, and implications for future research. This report's scope is confined to whole-body vibration platforms designed and marketed for prevention and treatment of osteoporosis; our review excludes exercise equipment with vibrating platforms intended for use in physical fitness or athletic regimens.

Guiding Questions

The questions below guided the data collection for this technical brief. Question 1 examines whole-body vibration in the context of other treatments for osteoporosis. Question 2 provides background on the use of whole-body vibration for osteoporosis in the United States. Results for Questions 1 and 2 are reported in the Findings section, “Description of Existing Whole-body Vibration Technology.” Question 3 examines the current evidence of vibration therapy for osteoporosis; we describe the populations included in studies, the detailed components of the platforms and treatment protocols, and the outcomes and harms measured. Results for this question are reported under Evidence Map in the Findings section. Issues of importance to different stakeholders and key areas for future research (question 4) are addressed in the “Summary and Implications” section.

1. Describe the existing technology.
 - a. What vibration modalities have been proposed or used in practice to treat osteoporosis?
 - b. What are the potential advantages and disadvantages of vibration therapy when compared to regular exercise and pharmacological treatments of osteoporosis in preventing osteoporotic fractures?
 - c. What are the potential safety issues and harms of vibration therapy when used to treat osteoporosis?
2. Describe the context in which the technology is used.
 - a. What kinds of training, certification, and staffing are required for vibration therapy?
 - b. How are treatment sessions in clinical settings billed?
 - c. What is the current U.S. Food and Drug Administration (FDA) approval status of vibration therapy for osteoporosis?
 - d. What modifications of vibration platforms are in development?
3. Describe the current evidence of the technology.
 - a. What are the inclusion and exclusion criteria of patients in therapeutic studies of vibration therapy for osteoporosis?
 - b. What modalities of vibration therapy for osteoporosis have been examined in therapeutic studies?
 - c. What was the length, intensity, and frequency of each vibration therapy session, and what was the total duration of the vibration therapy intervention?
 - d. What primary and secondary outcomes and harms were examined?
 - e. What comparators were used to examine benefits and harms?
 - f. What was the length of followup to examine benefits and harms?
 - g. What were the methodological approaches or study designs used (i.e., randomized controlled trial, cohort, case control, etc.)?
4. Identify the important issues raised by the technology.
 - a. What are the implications of reimbursement practices on accessibility?
 - b. What are the possible areas of confusion or potential harms from misuse in direct-to-consumer marketing and unsupervised consumer use?
 - c. What medical claims about effectiveness have been made, and how do they compare to what is available in the literature? What are the implications for third-party payers?
 - d. What are possible areas of future research?

Methods

We integrated information from key informants and the literature review to address the guiding questions. In particular, responses to questions 1, 2, and 4 relied on information from key informants and published information about vibration technology, the applications of the technology, and the FDA approval process. Responses to question 3 were based on peer-reviewed published studies that examined bone outcomes after whole-body vibration therapy for osteoporosis.

Discussion With Key Informants

We identified relevant key informants for this technical brief with the goals of efficient data collection and balanced viewpoints. We included osteoporosis experts, whole-body vibration experts, practicing clinicians who use whole-body vibration, consumer advocates, and potential consumers. We also included several representatives from different whole-body vibration platform manufacturers to get diverse perspectives from device producers. We located key informants from frequently listed and cited authors of relevant literature, Internet searches for possible candidates of relevant viewpoints, and nominations by other key informants. In cases where we were not able to identify a specific individual to represent a specific organization, we invited the organization to nominate an individual. In some cases, key informants with a viewpoint or expertise critical to this report had a conflict of interest, so we interviewed them separately from other key informants to avoid undue influence.

We conducted semi-structured interviews with key informants via telephone or in person during December 2010. Interview guides for each group of key informants were developed in advance. The guides are presented in Appendix B.

Grey Literature Search

We conducted a grey literature search of Federal Government Web sites (e.g., www.medicare.gov) for current coverage and/or payment policies, the FDA Web site for approval reviews, and presentations of unpublished studies at scientific meetings. We also searched the Internet with different engines (e.g., Google Scholar, Scirus, LexisNexis) to obtain information on availability and other issues and controversies regarding vibration platforms. We surveyed enrolling and ongoing clinical trials through the ClinicalTrials.gov Web site. We also searched the CSA Physical Education Index, the Web of Science[®], and Medscape[®] databases to find studies that were presented in scientific meetings.

Published Literature Search

For Question 3 we searched for relevant articles on the use of whole-body vibration for the prevention and treatment of osteoporosis and for patients with low bone density. We searched several databases: MEDLINE[®] via OVID and via PubMed[®], the Cochrane Library, AMED, CINAHL, the CSA Physical Education Index, the Web of Science, PEDro, and Academic Search[™] Premier. Exact search strategies were developed in consultation with the EPC librarian and guided by the Scientific Resource Center. We developed an a priori search strategy based on relevant medical subject headings (MeSH) terms, text words, and a weighted word-frequency algorithm to identify related articles. The search strategy is shown in Appendix C.

We screened the abstracts against the following exclusion criteria:

1. Animal studies.
2. Studies examining healthy adults and children without low bone mineral density or risk for osteoporosis.
3. Studies examining patients with other primary conditions such as cerebral palsy, Parkinson's disease, multiple sclerosis, cystic fibrosis, and spinal cord injuries because it is unknown whether these populations may have safety concerns that are different than for other individuals at risk for or with osteoporosis.
4. Studies on whole-body vibration as an exercise modality with no clinical bone measures reported.
5. Market evaluations of whole-body vibration platforms.

We included studies published in English of any sample size, any design (randomized controlled trials (RCTs), controlled clinical trials, uncontrolled observational trials, and case reports and series) and studies that report any clinical bone outcome (e.g., bone density, bone mineral content, bone fractures). We retrieved and reviewed full articles on eligible studies to determine final inclusion.

Findings

Description of Existing Whole-Body Platform Technology

Existing Technology

Whole-body vibration is the mechanical repetitive movement, or oscillatory motion, around an equilibrium point.³⁸ It is delivered through the use of a vibrating platform on which static poses are held or dynamic exercises can be performed, depending on the type and force of the machine. Whole-body vibration exercise is a forced oscillation that transfers energy from a vibration platform to a human body.³³ The vibrations generated by motors underneath the platform are transmitted to the person on the machine. Available vibration exercise platforms produce sinusoidal shaped oscillations described by their frequency, amplitude, and phase angle.³³

The International Society of Musculoskeletal and Neuronal Interactions (ISMNI) developed consensus criteria to describe sinusoidal vibrations, the type of vibration currently used in whole-body vibration platforms. Vibration frequency is defined as the repetition rate of the oscillation cycle, and the frequency of oscillations per second is reported in hertz (Hz). The amplitude, which is the maximal displacement from the equilibrium position, is reported in millimeters (mm). Displacement in mm from the lowest to highest point of the vibrating platform position is the peak-to-peak displacement. Peak acceleration, defined as the maximal rate of change in velocity during an oscillation cycle, is a function of the frequency and of peak-to-peak displacement (meters/second*second). Peak acceleration is often expressed as multiples of Earth's gravity (9.80665 meters/second*second) denoted by the symbol (g).³⁸ While acceleration can be calculated from reported frequency and displacement, the ISMNI recommends reporting acceleration directly for consistency. Vibration acceleration distinguishes the acceptable dose of therapeutic whole-body vibration, as compared to the hazardous dose of vibration defined by the International Organization for Standardization (ISO). Even though available whole-body vibration platforms are meant to produce sinusoidal shaped oscillations, it is important to note that actual oscillations produced by the platforms may diverge from a pure sinusoidal shape, and the vibrations transmitted to human subjects may depend not only on the vibration parameters but also on the position of the individual on the platform and on the rigidity of the platform plates.³⁸ Characteristics of whole-body vibration modalities are an essential part of patent applications. Patent claims for various platforms include direction, amplitude, frequency, and vibration acceleration (patents 20100049105; 20090269728; 20090076421; 20080009776; 20070290632; 20070225622; 20070219052; 20050251068).

Whole-body platforms can be further categorized by acceleration levels and by the way in which they apply vibration. Platforms that provide acceleration of less than 1g are considered low intensity while those that provide acceleration of greater than 1g are considered high intensity. Platforms where the left and right feet move up and down simultaneously are described as operating in a synchronous way. Platforms that use a reciprocating vertical displacement on the left and right side of a fulcrum are described as operating in a side-alternating way.³⁸ Platforms that oscillate in three planes are described as tri-planar or elliptical.⁵⁷ The ISMNI recommends that both the whole-body platform type and intensity be reported.

There are two different theories regarding the optimal settings for a vibration session. One theory proposes using amplitude and frequency settings that do not change during a single

vibration session. The other theory proposes using a low amplitude setting along with various frequencies during the vibration session to engage different muscle frequencies.⁵⁸ It is unclear which theory is best for specific individuals and outcomes.

The FDA has not approved whole-body vibration platforms for medical purposes; therefore, no FDA standards regulate their manufacture, and designs vary widely. An example of a whole-body vibration platform is shown in Appendix D. Some low-intensity platforms are small rectangular devices raised several inches off the ground, resembling a bathroom scale in size and shape, while some high-intensity platforms are larger and resemble typical exercise machines. Some platforms have safety features, such as a handrail for balance.

Low-intensity vibration platforms are currently marketed for home use for about \$1,600. Some of these platforms automatically calibrate the treatment to each user's weight and body mass index. Suggested treatment sessions involve standing on the platform for 10 minutes per day. Manufacturers advise that home use requires no supervision. Newer models are very low height and offer an optional wheelchair mount (e.g., www.livtherapy.com/products/index.html). Technological developments currently underway will allow individuals with mobility problems to use vibration platforms in a seated or supine position (e.g., <http://vibetechglobal.com/prototype.aspx>).

High-intensity vibration platforms produce a gravitational force greater than 1g regardless of frequency. High-intensity whole-body platforms marketed as exercise equipment are used in clinical physical therapy or rehabilitation settings, exercise facilities, and in the home. Currently, no organization provides accreditation or training for vibration therapy use in professional settings. Some exercise facilities provide proprietary training to personal trainers (e.g., Powerplate, www.powerplate.com) for proper use in exercise programs, but this training is not specific to osteoporosis prevention or treatment.

Whole-body vibration therapy may offer advantages to individuals who cannot continue or do not want to continue or initiate pharmacological treatment to increase bone density. While bisphosphonates are a first line treatment for osteoporosis, associated adverse effects lead to treatment discontinuation in 10-15 percent of patients.⁵⁹ Common adverse effects from bisphosphonates include minimal trauma atypical fractures, esophageal irritation, renal toxicity, acute-phase reactions, gastrointestinal toxicity, and osteonecrosis of the jaw.^{5,12,14-17} The percentage of patients persisting with bisphosphonate therapy for 1 year or more ranged from 17.9 percent to 78.0 percent.⁶⁰ Therefore, a large percentage of patients receive no pharmacological treatments to prevent fractures. Whole-body vibration may offer an alternative for individuals unable to perform high-impact exercise, and the ease of use may result in better overall compliance. Disadvantages of whole-body vibration therapy include unknown long-term safety and out-of-pocket costs to the consumer.

Vibration exposure, therapeutic and occupational, presents safety concerns. Vibration has been recognized as an occupational hazard associated with low back pain,^{61,62} musculoskeletal problems,⁶³ cardiovascular disorders,⁶⁴ neurovestibular disorders⁶⁵ and Raynaud's syndrome.⁶⁶ ISO has defined vibration limits for comfort, performance proficiency, and safety based on the known occupational hazards, and ISO 2631-1 defined high intensity vibrations (those that produce more than 1g force) as hazardous regardless of frequency (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=51514). Safety concerns for vibration as a therapeutic intervention include the possibility of an individual losing contact with the vibration platform and becoming air-bound when acceleration exceeds 1 g; the resulting impact as the feet return to the platform may be harmful for individuals with

fragile bones.³³ Vibration may also be harmful to the soft tissue organs of the head and chest. Further, since vibration transmissibility to the head and trunk can be altered by knee flexion and posture, an individual's shifting of position on the platform may complicate accurate measurement of vibration in different body parts.³³ Additionally, different body parts have their own resonant frequencies, and vibration platform-induced acceleration at frequencies greater than 20 Hz may match a resonant frequency for a particular body part. This would cause the acceleration experienced in that body part to be greater than those set on the platform, and this amplification may be harmful for individuals with fragile bones.⁶⁷ Nomograms have been developed to estimate the safe length of time, frequency, and acceleration for using different whole-body vibration platforms for exercise based on the ISO standards and known occupational hazards of vibration.⁶⁸

Key informants indicated that harms from whole-body vibration therapy may include plantar fasciitis, itchy legs, blurred vision, tinny hearing (tinnitus), white-finger disease (a secondary form of Raynaud's syndrome), orthostatic hypertension, and aggravation of soft-tissue and joint injuries. Dislocation of an intraocular lens after cataract surgery may also be a concern, particularly since the population using whole-body vibration for osteoporosis prevention and treatment is at greater risk for cataract.⁶⁹ Since various parts of the human body can resonate at different frequencies, and these frequency resonances can be highly individual, unintended injuries could occur without better understanding of the optimal vibration dosage and transmission to different parts of the body. Other concerns expressed by key informants included loss of balance and falls during platform use and lack of clear distinction between platforms intended for powered exercise and those intended for osteoporosis therapy.

Context in Which the Technology Is Used

Whole-body vibration platforms are used in the home, in clinical physical therapy or rehabilitation settings, and in exercise facilities. Whole-body vibration platforms have not been approved by the FDA for treatment purposes, so unlike therapeutic devices, they have been marketed without vigorous standard testing in clinical trials II-III. Manufacturers of high-intensity whole-body vibration platforms market the devices as powered exercise equipment. These high-intensity whole-body vibration platforms may be used for medical purposes, such as muscle or joint rehabilitation, but they are exempt from the FDA premarket notification procedures [48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]. Manufacturers marketing low-intensity whole-body vibration platforms for treatment of osteoporosis or improvement of bone mineral density (BMD) specify through disclaimers on their Web sites that their device is considered investigational and that they do not make medical claims for osteoporosis (e.g., www.juvent.com, www.marodyne.com/technology). However, many Web sites of manufacturers and distributors of whole-body vibration platforms do provide summaries of, or links to, scientific research papers for potential consumers to review.

The manufacturer suggested billing codes (CPT codes) for therapy procedures include codes 97110, 97112 and 97530. The Medicare Outpatient Therapy Billing defines such codes as therapy services "delivered under an outpatient physical therapy plan of care." Overall, Medicare payments for outpatient physical therapy increased between 2003 and 2008 by 70 percent, from \$631,532,770 to \$1,070,996,026, respectively. Since CMS did not specify billing codes for whole-body vibration therapy, we could not determine true utilization of this therapy among Medicare beneficiaries. We found no published articles about utilization of whole-body vibration

therapy across other health insurance plans, and we were unsuccessful in locating a health plan key informant who could provide relevant information. Other key informants expressed no awareness of any third-party payers covering costs for whole-body vibration therapy, so individuals pay out-of-pocket for clinical sessions or for platforms for their homes. Manufacturers do not provide information about total sales of whole-body vibration platforms; therefore, we could not determine utilization outside of health care settings.

Evidence Map

Current Evidence of the Technology

The literature search yielded a total of 344 studies, with 245 abstracts and full-text articles screened for final inclusion. Only 12 studies met the criteria for the correct patient population, intervention, and outcome measures.^{21,27,30-32,47,52,57,70-73} Studies that were excluded due to patient population (n = 133) included those that examined athletes, healthy and active children and young adults, patients with cerebral palsy, Parkinson's disease, multiple sclerosis, cystic fibrosis, spinal cord injuries, or those who have suffered a stroke, are bed-ridden, are experiencing pain, or have occupational injuries. We excluded studies (n = 37) that did not evaluate whole-body vibration, such as those that evaluated airway vibration for asthmatics or periodontal vibratory devices. A number of studies (n = 21) that examined whole-body vibration for the patient population of interest but did not assess any bone outcomes were also excluded. Evidence tables for the included studies are shown in Appendix E. Other reviews and background studies on whole-body vibration were retained (n = 42), but data was not abstracted.

Patient Populations

The patient populations included in studies of whole-body vibration therapy for the prevention and treatment of osteoporosis can be classified into three groups: individuals diagnosed with osteoporosis, individuals with low BMD, and individuals at risk for low BMD or osteoporosis. The breakdown of the studies into these three groups is shown in Table 1.

Two studies focused on postmenopausal women diagnosed with osteoporosis.^{31,70} Participants in both studies were not previously taking any medications that could affect bone. Women were excluded from these studies if they had any number of conditions such as high blood pressure, heart disease, thrombosis, herniated discs, vertigo, or osteoarthritis.

Three studies focused on children and adolescents with low BMD. One study included male and female children with osteogenesis imperfecta, a disease characterized by brittle bones.⁷¹ One study included female children with endocrine disorders that had low BMD and were not taking any medication that could affect their bones.⁷² The third study included white female adolescents with low BMD who had previously sustained a fracture. Participants in this study had no underlying diseases or chronic illnesses, were not taking any medications, and had completed puberty.⁴⁷

The remaining seven studies evaluated individuals at risk for low BMD or osteoporosis. All but one study of this group evaluated post-menopausal women.^{21,27,30,32,52,57} The other study included one older male participant.⁷³ Five of the seven studies reported that participants were not taking any medications that could affect bone,^{21,27,30,32,57} while two of the seven did not report whether participants were using any medications that could affect their bones.^{52,73} Individuals were excluded if they had a number of conditions, such as heart problems, thrombosis, musculoskeletal problems, disorders affecting bone or muscle, orthopedic or arthritic problems,

or eye disorders, if they did not have adequate nutrition, or if they were physically unable to complete the vibration protocol.

Table 1. Patient populations in vibration studies

Focus Population	Number of Studies	Study Design	Number Testing Vibration Therapy Only
Osteoporotic individuals	2	1 RCT, 1 CT	1
Individuals with low bone mineral density	3	1 CT, 2 CS	3
Individuals at risk for low bone mineral density or osteoporosis	7	5 RCT, 1 CT, 1 CS	5

RCT = randomized controlled trial, CT = controlled trial, CS = case-series

Vibration Modalities

Studies on vibration therapy for osteoporosis have used synchronous, side-alternating, and tri-planar whole-body vibration platforms. The distribution of studies using these types of platforms is listed in Table 2. All studies using side-alternating platforms have been completed outside of the United States.^{21,31,52,71} The tri-planar platform has been used in only one study thus far.⁵⁷ Two studies listed the platform manufacturer but did not explicitly state the type of whole-body vibration platform.^{32,73} Studies have examined use of vibration platforms both in the clinic setting, where study participants attended supervised sessions at a research or therapeutic location, and in the home setting, where participants used the platform on their own schedule.

Table 2. Type of vibration platforms used in studies

Type of Vibration Platform	Number of Studies	Country of Studies	Site of Vibration Sessions
Synchronous	5	3 United States, 1 Germany, 1 China	3 Clinic, 2 Home
Side-alternating	4	1 Spain, 1 Germany, 1 Italy, 1 Japan	3 Clinic, 1 Home
Tri-planar	1	1 United States	1 Clinic
Not reported	2	1 United States, 1 Belgium	2 Clinic

Vibration Intervention

The characteristics of the whole-body vibration interventions used in the 12 included studies are presented in Table 3. The vibration intervention varied considerably across the 12 studies. Terminology was also inconsistent for both the platform characteristics and study protocols. No separate calculations were made to determine platform settings; we present here only those explicitly reported in the studies.

The frequency of the vibration platforms ranged from 12-40 Hz across 11 of the studies, while one study did not report the frequency.⁷³ Five of the studies had frequency settings that changed, either during an individual vibration session or during the intervention study period.^{27,32,52,57,71}

The amplitude ranged from 0.7-5 mm across the seven studies that reported it;^{21,27,31,32,57,70,71} four studies reported only acceleration and not amplitude,^{30,47,52,72} and one study reported neither amplitude nor acceleration.⁷³ The amplitude setting changed during the intervention period in one study.³² The seven studies that reported amplitude explained it with various terms, including “amplitude,” “vertical amplitude,” “peak to peak,” and “upwards and downwards.”

The acceleration of the platforms ranged from 0.1-10 g across the six studies that reported it.^{30,32,47,52,57,72} Five studies reported no acceleration but only amplitude,^{21,27,31,70,71} while one study reported neither acceleration nor amplitude.⁷³ The six studies that reported acceleration

described it with various terms, including “acceleration,” “acceleration magnitude,” “vertical acceleration,” “peak acceleration,” and “peak to peak.”

Each vibration session ranged from 15 seconds to 30 minutes. Three studies had session lengths that changed during the intervention period,^{32,52,57} and three studies had multiple sessions per day.^{30,71,73} Six studies included rest periods during the vibration session,^{21,27,32,52,57,71} and one study included rest periods between the multiple sessions per day.³⁰

The vibration session frequency ranged from 1 to 7 days per week. The duration of the vibration intervention ranged from 8-72 weeks, as did the length of followup for analyzing outcomes.

Of the six studies that reported acceleration, three had levels below 1g,^{30,47,72} and three had levels above 1g.^{32,52,57} The three studies with acceleration levels below 1g used synchronous whole-body vibration platforms with a 30 Hz setting; sessions were more frequent for these studies compared to those reporting acceleration below 1g (3 or 7 days compared to 2 or 3 days) and the session lengths tended to be longer (10, 20, or 30 minutes compared to 15 seconds to 30 minute total session with warm up and cool down).

Four studies had participants perform dynamic exercises or extend their lower extremities while on the vibration platform.^{27,32,57,71} A number of studies instructed participants to flex their knees while standing on the platform^{21,31,52,71} and several studies had participants flex their knees while performing exercises on the platform.^{27,32,57} Only three studies reported the type of footwear that participants used while on the platform,^{21,32,57} and five studies stated, or visually showed, that there was a support device available on the platform.^{30,70-73}

Three studies evaluated whole-body vibration in addition to another intervention (whole-body vibration plus exercise or resistance training and whole-body vibration plus bisphosphonate use).^{27,31,57} Three studies provided Vitamin D and/or calcium supplementation to study participants,^{27,47,52} while another two studies advised participants on their calcium intake.^{31,57}

Table 3. Characteristics of vibration intervention in studies

Vibration Frequency	Vibration Amplitude	Vibration Acceleration	Vibration Session Length	Vibration Session Frequency	Duration of Vibration Intervention	Length of Followup
12-40 Hz	0.7-5 mm	0.1-10 g	15 s-30 min	1-7 days per week	8-72 weeks	8-72 weeks

Outcomes

The distribution of outcomes assessed in the 12 whole-body vibration studies is listed in Table 4. Eleven of the 12 studies measured BMD.^{21,27,30-32,47,52,57,70,72,73} Out of these 11 studies, eight used only a dual-energy x-ray absorptiometry (DXA) to obtain a measure of BMD.^{21,27,30-32,57,70,73} Two of the 11 studies used only computed tomography (CT) to measure BMD,^{52,72} while one study used both DXA and CT to measure BMD.⁴⁷ The location of the BMD measurements included the femoral neck, lumbar spine (L1-L4), total body, total hip, trochanter, and forearm. Only one study reported bone mineral content along with the BMD.⁴⁷

Only two studies included fractures as an outcome measure.^{31,71} The one study that did not measure BMD counted fractures,⁷¹ and the other study assessed fracture through x-rays at the end of the vibration intervention period.³¹

No studies used a validated measure of quality of life. Only two studies reported minor harms from the vibration intervention.^{52,71} It was not clear that harms were systematically collected in all studies; most studies relied on self-report for harms.

Eleven of the 12 studies also evaluated other outcomes.^{21,27,30-32,47,52,57,70-72} The outcomes included bone turnover markers, falls, balance, mobility, back pain, postural control, bone area, muscle force, muscle strength, muscle power, muscle mass, muscle area, fat mass, compliance with study protocol, and efficacy of device use.

Table 4. Outcomes in vibration studies

Bone Mineral Density (N Studies/RCTs)	Bone Mineral Content (N Studies/RCTs)	Fracture (N Studies/RCTs)	Quality of Life (N Studies/RCTs)	Reported Harms (N Studies/RCTs)	Other Outcomes (N Studies/RCTs)
11/6	1/0	2/1	0/0	2/1	11/6

Comparators

The three case-series studies did not have a comparison group by design.⁷¹⁻⁷³ The comparison groups for the RCTs and controlled trials included control groups that did not complete any program, a walking program control group, a resistance training or exercise control group and control group that did not complete any program, a bisphosphonate control group, and a placebo device control group.

Study Designs

Study designs included RCTs, controlled trials, and case-series. Half of the studies were RCTs,^{21,27,30-32,52} one-quarter were controlled trials,^{47,57,70} and one-quarter were case-series.⁷¹⁻⁷³ Breakdown by study population is shown in Table 1. Specific efficacy claims have not been made for whole-body vibration platforms since the devices are still investigational and the FDA has not yet approved them for medical use. Published research explores whether whole-body vibration improves bone density for individuals with osteoporosis, low BMD, or are at risk for low BMD. Harms have been minimally reported and it is not clear whether harms information was systematically collected in many studies.

Summary and Implications

Important Issues Raised by the Technology

Little scientific evidence evaluates the benefits and harms of whole-body vibration therapy for the prevention and treatment of osteoporosis. Key informants unanimously urged caution in making claims about whole-body vibration for osteoporosis because of the lack of evidence about the optimal target population, optimal treatment protocol, and long-term effects. Other issues of concern emerged in the published literature and in key informant discussions.

It is not clear which population groups might benefit from whole-body vibration, or whether certain groups may be more susceptible to harms. Published studies focused on individuals with osteoporosis, individuals with low BMD, and individuals at risk for osteoporosis or low BMD. Since only a few studies assess each of these groups, the literature lacks clear guidance about the optimal target population. Additionally, there is no clear evidence for individuals with different risks for osteoporosis or severity of the disease. Key informants differed in opinion about the optimal population group for whole-body vibration therapy. Most published studies excluded individuals with health issues, such as heart problems or musculoskeletal problems, so the potential harms for individuals with certain health conditions remain unclear. Key informants mentioned that the effects of whole-body vibration are unknown for some individuals, and they listed contraindications such as joint replacement. Treatment protocols varied widely among the published studies, reflecting uncertainty regarding the platform type, platform settings, and session length and frequency that may be necessary to demonstrate measureable benefits for the prevention and treatment of osteoporosis. Studies also varied in other aspects of the treatment protocol, such as whether participants flexed their knees while on the platform, performed dynamic exercises while on the platform, or were required to wear specific footwear while standing on the platform and whether platform settings changed during vibration sessions or intervention period, so the impact of these aspects on treatment benefits is unclear. Characteristics of the intervention protocol were not reported consistently across studies.

Uncertainty persists about whether whole-body vibration therapy can be a distinctive therapy for the prevention and treatment of osteoporosis, or whether it should be used as an adjunctive therapy. A few studies evaluated whole-body vibration as an adjunctive therapy; two studies examined whole-body vibration along with an exercise program,^{27,57} and one study examined whole-body vibration along with drug therapy.³¹ A few studies required participants to have adequate nutritional intake in order to be included,^{21,27} and some studies either provided Vitamin D and/or calcium or advised participants about appropriate levels of these nutrients.^{27,31,47,52,57} This raises an important question as to whether whole-body vibration therapy can be considered as a distinct treatment or whether it should be used in addition to other osteoporosis therapies. Several key informants indicated that whole-body vibration therapy should not replace but instead be used in addition to other osteoporosis therapies.

The length of followup was relatively short in the scientific studies reviewed for this report, and little is known about whether any benefits from whole-body vibration therapy will persist over time, or about potential long-term side effects or harms. Studies used many different outcome measures to evaluate the benefits of whole-body vibration therapy. Most studies measured BMD as the bone outcome of interest,^{21,27,30-32,47,52,57,70,72,73} but some studies also measured other bone outcomes such as bone mineral content, fractures, and bone turnover markers.^{30-32,47,57,71,72} Studies also evaluated other outcomes such as balance, falls, mobility,

postural control, and muscle strength.^{21,27,31,32,47,52,57,71,72} Several key informants indicated that fractures are the ideal outcome of interest, in addition to other bone outcomes. Many of them also suggested that additional outcomes, such as muscle strength and balance, may be valuable to measure because they could be particularly important for preventing fractures and falls. However, key informants pointed out that assessing rare outcomes such as fractures requires a large number of participants and long followup period. They also indicated that most bone outcomes occur slowly, so, observing significant changes may require long followup periods. The type of measurement technique chosen for studies may also influence whether significant changes in bone outcomes are observed. For instance, peripheral quantitative computed tomography (pQCT) measures volumetric BMD, whereas DXA measures areal BMD. pQCT may be more accurate and offer more diagnostic information than DXA.⁷⁴ Therefore, consideration of measurement technique is important when evaluating bone outcomes.

Compliance and access to whole-body vibration therapy must also be considered when analyzing the potential benefits for the prevention and treatment of osteoporosis. Whole-body vibration platforms are available in therapeutic or clinical settings and can also be purchased by consumers for home use. Studies that installed whole-body vibration platforms in the participants' home required them to use the platforms 7 days per week,^{30,47,71} while studies that had participants use the platform at a research or clinical facility required them to attend sessions 1-5 days per week.^{21,27,31,32,52,57,70,72,73} Both the site and the frequency of sessions may affect long-term compliance. Studies that measured compliance found a wide range, raising questions about long-term adherence for various treatment protocols. Additionally, the site and frequency of sessions may affect access to this therapy. Currently, third-party payers do not cover whole-body vibration devices, so consumers must pay out-of-pocket to purchase a platform for their home or to use a platform in a clinical setting. The out-of-pocket costs may affect whether, where, and how often a consumer uses a whole-body vibration platform.

A number of safety issues for consumers, including safety features available on the devices and the use of direct-to-consumer advertising, must also be considered. Individuals using whole-body vibration therapy may be at risk of falls whether from balance problems or disorientation during platform use. They may also experience other side effects while using the platform, such as decreased blood pressure. It is not clear that all whole-body vibration platforms used for osteoporosis have safety features, such as handrails, to address these issues. Nor do we know the potential long-term harms from using whole-body vibration therapy. Direct-to-consumer marketing for whole-body vibration platforms raises specific concerns, as well. Some key informants suggested that consumers may not be able to clearly distinguish low-intensity platforms intended for osteoporosis therapy from platforms intended for high intensity exercise.

Next Steps

Whole-body vibration therapy for the prevention and treatment of osteoporosis is still investigational with little known about benefits and harms. Further research is needed to fully understand what role this therapy should have. Since bone outcomes take a long time to show clinical changes and fractures are rare events, randomized controlled trials would require longer followup periods. The length of followup required will vary depending on the outcomes of interest and measurement techniques used to assess outcomes, but studies should followup for a minimum of one year and for up to several years for rare outcomes. Multiple outcomes would need evaluation, including measures of bone and muscle, fractures, balance, and quality of life, because these outcomes may be closely related to osteoporosis. A thorough understanding of measurement issues for bone outcomes (e.g., pQCT versus DXA) would be useful. Harms should be systematically collected and reported along with the outcomes of interest. Studies need to focus on the population groups that could benefit from whole-body vibration (e.g., individuals with osteoporosis, individuals with low BMD, or individuals at risk for osteoporosis or low BMD), and individuals at risk for harms, such as those with certain health conditions. In future studies with a large number of participants, studies should focus on benefits and harms for individuals with different risks for osteoporosis and severity of the disease. Studies should also focus on the optimal treatment protocol to achieve benefits for the prevention and treatment of osteoporosis, including the platform type, platform settings (frequency, amplitude, acceleration), session length, and session frequency. Additionally, studies should focus on whether it is optimal for the platform settings to change during a session or during the intervention. Further research could also address the issues of whole-body vibration as an adjunctive versus a distinctive therapy, and treatment compliance for the populations of interest.

Studies need to consistently report all aspects of the treatment protocol. Additional aspects of the study and treatment protocol should be specified, including whether participants had adequate nutritional intake, completed therapy sessions at home or in a supervised clinical/research setting, flexed their knees while on the platform, performed dynamic exercises during the vibration session, wore specific footwear while on the platform, and whether the platforms had safety features or automatically calibrated settings to an individual's weight. Studies might also assess the actual vibration intensity transmitted to the study participants.

We use the PICO framework to present research recommendations that would provide information important to clinicians, consumers, and policymakers.

- **Study type.** RCTs with long followup period. Because the followup period may vary depending on the outcomes of interest and measurement technique, a minimum of one year is needed.
- **Populations.** Individuals that could benefit from whole-body vibration therapy (individuals with osteoporosis or low BMD or individuals at risk for osteoporosis or low BMD), which includes individuals who cannot or do not want to follow drug or exercise regimens, and individuals that could experience harms from whole-body vibration therapy. Subgroups with differing risks for osteoporotic fracture, severity of osteoporosis, and contraindications to other preventative treatments.
- **Intervention protocol.** Platform type, platform settings (frequency, amplitude, acceleration), session lengths, session frequency, changes in platform settings, adjunctive versus distinctive therapy.

- **Comparator.** Pharmacological treatments or exercise and diet programs, including direct comparisons as distinctive treatments and comparisons as adjunctive treatments. Noninferiority studies with pharmacological treatment for patients who cannot tolerate such treatment or prefer nonpharmacological treatment options.
- **Outcomes.** Bone outcomes such as BMD and fractures, muscle outcomes such as muscle strength, balance, quality of life, and systematic reporting of harms.
- **Additional considerations.** Compliance, nutritional intake, location of therapy, posture/knee flexion, whether dynamic exercises are performed, safety features, the actual transmission of vibration from the platform to different parts of the body and skeletal region.

Several ongoing or completed clinical trials are examining whole-body vibration therapy for osteoporosis (NCT00420940; NCT00396994; NCT00667667). These studies will add to the literature and may offer more insight into the use of this therapy.

In addition to more research, clear information should be made available to consumers about the correct whole-body vibration devices for the prevention and treatment of osteoporosis. Since certain levels of vibration are harmful, particularly for the population using these platforms for osteoporosis rather than for high intensity exercise, consumers need access to educational material about different whole-body vibration platforms available to them in clinical settings, rehabilitation facilities, exercise facilities, and for home use. Consumers also need information about the correct settings, session length, and session frequency to achieve benefits. Finally, potential consumers need to know about the benefits and harms of all treatments available to them.

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Appendix A. Definition of Terms

Bone mineral density:

The amount of mineral (calcium phosphate) per square centimeter of bone. Bone mineral density values are calculated by using reference values for healthy young white women who are 20 to 29 years of age and are expressed in standard deviation (SD) units and reported as a T-score.⁷⁵

Normal bone density: T-score ≥ 1 SD below young adult reference mean

Osteopenia: T-score between 1 and 2.5 below young adult reference mean

Osteoporosis: T-score ≤ 2.5 SD below young adult reference mean

Whole-body vibration therapy:

Whole-body vibration is the mechanical repetitive movement, or oscillatory motion, around an equilibrium point. Whole-body vibration therapy is a forced oscillation, where vibrations generated by motors underneath a vibration platform are transmitted to the person on the machine. Whole-body vibration platforms currently available produce sinusoidal shaped oscillations.

Whole-body vibration frequency:

Repetition rate of the cycles of oscillation. The frequency of oscillations per second is denoted in hertz (Hz).

Whole-body vibration amplitude:

Maximal displacement from equilibrium position. The amplitude is denoted in millimeters (mm).

Whole-body vibration peak-to-peak displacement:

Displacement from the lowest to the highest point of the vibrating platform position. The peak-to-peak displacement is denoted in mm.

Whole-body vibration acceleration:

Maximal rate of change in velocity during an oscillation cycle. It is a function of the frequency and peak-to-peak displacement (meters/second*second), and it is often expressed as multiples of Earth's gravity (9.80665 meters/second*second) denoted by the symbol (g).

Appendix B. Interview Guides for Key Informants

Questions for osteoporosis experts, whole-body vibration experts, and manufacturers.

- a. What are the criteria used to determine appropriate patient populations for whole-body vibration therapy?
- b. What are the potential advantages and disadvantages of vibration therapy when compared to regular exercise and pharmacological treatments of osteoporosis in preventing osteoporotic fractures?
- c. What modifications of vibration platforms are available in the U.S.? What modifications of vibration platforms are in development?
- d. What is the current FDA-approval status of vibration therapy for adults with osteoporosis?
- e. What kinds of training, certification, and staffing are required for vibration therapy?
- f. What type of research is needed most? What research designs are most likely to answer the important research questions?
- g. What outcomes are appropriate measures of the efficacy and effectiveness of vibration therapy?
- h. When should patient outcomes be measured (length of followup)?

Questions for clinicians, patients, and patient advocates.

- a. What has been your experience with whole-body vibration therapy?
- b. What information do clinicians and patients need to know to make informed decisions about whole-body vibration (effectiveness, safety, FDA approval, doctor recommendation, other)?
- c. What information do clinicians and patients need to know when to use alternative therapeutic options for osteoporosis?
- d. What is the measurement of successful treatment for osteopenia and osteoporosis?

Questions for third-party payers.

- a. What information about whole-body vibration is most needed by payers?
- b. What criteria (clinical effectiveness, safety, FDA approval, market value, others) are the most critical when making payment coverage decisions for whole-body vibration?
- c. What kinds of research would be most useful to make evidence-based coverage decisions?
- d. What outcomes do payers take into consideration for coverage decisions?

Appendix C. Published Literature Search Strategy

Preliminary literature search. We searched the MEDLINE, Cochrane Library, CINAHL, CSA Physical Education Index Web of Science, PEDro, and Academic Search Premier databases using the key words “whole body vibration,” “vibration,” and “osteoporosis.”

Software: Ovid Technologies, Inc. Email Service

Search for: 18 not 19

Results: 120

Database: Ovid MEDLINE(R) <1950 to August Week 4 2010>

Search Strategy:

1 exp Vibration/tu [Therapeutic Use] (511)
2 whole body.mp. (39402)
3 1 and 2 (71)
4 exp Muscle Strength/ (10075)
5 exp "Recovery of Function"/ (19156)
6 4 or 5 (28640)
7 1 and 6 (27)
8 3 or 7 (85)
9 wbv.mp. (309)
10 1 and 9 (36)
11 8 or 10 (85)
12 exp Muscle, Skeletal/ (165830)
13 1 and 12 (65)
14 11 or 13 (114)
15 exp Physical Therapy Modalities/ (99436)
16 1 and 15 (206)
17 14 or 16 (278)
18 limit 17 to (English language and humans and yr="2000 -Current") (127)
19 limit 18 to (case reports or editorial) (7)
20 18 not 19 (120)
21 exp Osteoporosis/rh, th [Rehabilitation, Therapy] (2609)
22 1 and 21 (14)

PubMed search strings	#
Search "Vibration/therapeutic use"[MAJR] Limits: Humans, Randomized Controlled Trial, English	68
Search "Vibration/therapeutic use"[MAJR] Limits: Humans, Journal Article, English	1287
Search "Vibration"[Mesh] Limits: Humans, Journal Article, English	6541
Search vibration AND osteoporosis Limits: Humans, Journal Article, English	71
Search vibration AND osteoporosis	119
Cochrane Library: Whole body vibration for preventing and treating osteoporosis (Protocol)	
CINAHL: 212 references	

Appendix D. Example of Whole-Body Vibration Platform



Source: Journal of Bone and Mineral Research, 2004. Used with permission.³⁰

Rubin C, Recker R, Cullen D, et al. Prevention of postmenopausal bone loss by a low-magnitude, high-frequency mechanical stimuli: a clinical trial assessing compliance, efficacy, and safety. Journal of Bone & Mineral Research 2004 Mar; 19(3):343-51 (Figure 1A).

Appendix E. Evidence Tables

Evidence Table 1. Patient populations

Author, Year Country, Study Design	Inclusion Criteria	Exclusion Criteria	Presence of Men	Presence of Minorities	Comorbidities	Prior Treatments for Osteoporosis
Gusi, 2006 ²¹ Spain RCT	Women; At least 5 years from last menstruation; adequate nutritional status according to World Health Organization (determined by questionnaire); Non-smoker; Consumption of no more than 4 alcoholic beverages per week; The ability to follow the protocol; Free from disease or medication known to affect bone metabolism or muscle strength	Acute hernia; Thrombosis; Any pharmacologic intervention for osteopenia within the previous 6 months; Any history of severe musculoskeletal problems; Engaged in high-impact activity at least twice a week (any weight-bearing activity or exercise more intense than brisk walking)	No	Not reported	Not reported	Individuals excluded who had any pharmacologic intervention for osteopenia within previous 6 months; Individuals excluded who engaged in high-impact exercise more than 2 times per week; Unknown diet/calcium intake
Ruan, 2008 ⁷⁰ China CT	Women with osteoporosis; Postmenopausal women without typical menopausal symptoms; No older than 80 years old; Women willing to participate as volunteers	Women with blood pressure higher than 160/110 mmHg on medication; Women with systolic blood pressure less than 90 mmHg; Women with heart disease or cerebrovascular disease; Women with epileptics; Women with thrombosis or a history of thrombosis within the past 6 months; Women with body implants or heart stents; Women with lumbar disc herniation or spondylolisthesis, spinal nerve canal stenosis or oppression; Women in poor health and with symptoms of imbalance or vertigo; Women on treatment with drugs for osteoporosis or other agents affecting bone metabolism; Women unrecovered from surgical operations; Women un-recovered from joint injuries, fractures, or muscle strain	No	Not reported	Not reported	Women excluded who were taking drugs for osteoporosis or other agents affecting bone metabolism; Unknown physical activity levels apart from intervention; Unknown diet/calcium intake

Evidence Table 1. Patient populations (continued)

Author, Year Country, Study Design	Inclusion Criteria	Exclusion Criteria	Presence of Men	Presence of Minorities	Comorbidities	Prior Treatments for Osteoporosis
Semler, 2008 ⁷¹ Germany Case series	Motor-impaired children with osteogenesis imperfecta	NA	Yes	Not reported	Not reported	Yes - bisphosphonates; Unknown diet/calcium intake
Bemben, 2010 ⁵⁷ US CT	Healthy women volunteers, 55-75 years of age; Subjects who were at least 5 years postmenopausal; Subjects who were not taking hormone replacement therapy (HRT); Previous HRT users had not taken HRT for at least 1 year; Subjects who had not participated in a weight training program for at least 1 year prior to the study; Subjects who were medically stable, ambulatory, and capable of undergoing physical strength testing and training; Subjects who were of a mental capacity to give written informed consent and comply with the protocols	Women with diagnosed osteoporosis or a BMD site with a T-score less than -2.5; Women with physical disabilities preventing them from being strength tested and trained, including orthopedic or arthritic problems; Women with heart problems such as congestive heart failure and arrhythmias, chronic high blood pressure, or those on Beta Blockers; Current smokers or past smokers within the previous 15 years; Women with current diagnosis or a history of renal disease, chronic digestive or eating disorders, rheumatoid arthritis, or uncontrolled thyroid disease; Women taking medications that affect bone density, such as steroid hormones, calcitonin, or corticosteroids; Women taking medications for osteoporosis treatment, including bisphosphonates, selective estrogen receptor modulators, or parathyroid hormone	No	Not reported	Not reported	Women with osteoporosis were excluded; Women excluded who were taking medications that affect bone density or medications for osteoporosis treatment (bisphosphonates, selective estrogen receptor modulators, or parathyroid hormone); Baseline calcium and physical activity recorded

Evidence Table 1. Patient populations (continued)

Author, Year Country, Study Design	Inclusion Criteria	Exclusion Criteria	Presence of Men	Presence of Minorities	Comorbidities	Prior Treatments for Osteoporosis
Verschueren, 2004 ³² Belgium RCT	Women 60-70 years of age; Noninstitutionalized; Free from diseases or medications known to affect bone metabolism or muscle strength	Women with total body BMD t- score of less than -2.5	No	Not reported	Not reported	Women with osteoporosis excluded; women excluded who were taking medications that affect bone metabolism; Unknown prior exercise; Unknown diet/calcium intake
von Stengel, 2010 ²⁷ Germany RCT	Postmenopausal women aged 65 years and older living independently in the community in Germany were contacted by mail (mailing lists were obtained from the Siemens Health Insurance Company database)	Diseases or medication affecting bone metabolism; Diseases or medication affecting neuromuscular performance and falls; Implants of the lower extremity or of the spine; Eye diseases affecting the retina; Low physical capacity (<50 W)	No	Not reported	Not reported	Individuals excluded who were taking medication affecting bone metabolism; Baseline calcium, vitamin D, and physical activity recorded
Rubin, 2004 ³⁰ US RCT	Normal nutritional status (as determined by questionnaire); Stable weight maintenance (i.e., no elective weight loss or diet); Estimated daily calcium intake of ≥ 500 mg/day; Capability of following the protocol for daily use of the device as well as understanding and providing informed consent; Body mass greater than 45 kg and less than 84 kg (due to design constraints of the oscillating device)	Any pharmacologic intervention for osteopenia within the previous 6 months; Any use of steroids; Current smoking status; Consumption of excessive alcohol (>2 drinks/day), evidence of osteomalacia; Paget's disease; Osteogenesis imperfecta; Gastrointestinal disease; History of malignancy; Prolonged immobilization of the axial or appendicular skeleton within the last 3 years	No	Not reported	Not reported	Individuals excluded who had any pharmacologic intervention for osteopenia within previous 6 months; Unknown prior exercise; Minimum calcium intake required for participation

Evidence Table 1. Patient populations (continued)

Author, Year Country, Study Design	Inclusion Criteria	Exclusion Criteria	Presence of Men	Presence of Minorities	Comorbidities	Prior Treatments for Osteoporosis
Russo, 2003 ⁵² Italy RCT	Women belonging to a hospital volunteers association; Women at least 1 year postmenopausal; Women not affected by conditions that contraindicated the vibration training; Women on hormone replacement therapy were considered eligible	Women with metabolic bone disorders	No	Not reported	Not reported	Not reported; Minimum calcium and vitamin D intake required for participation
Iwamoto, 2005 ³¹ Japan RCT	Post-menopausal women, aged 55-88, with osteoporosis (in Japan this means patients whose BMD t-score was <70 or 70-80% with a history of osteoporotic fractures) who were patients at the hospital in Japan; Chronic back pain that did not require bed-rest treatment; No subjects had a history of HRT or had ever taken medication that affects bone metabolism prior to this study; No subjects had taken medication such as nonsteroid anti-inflammatory drugs to relieve chronic back pain; All were instructed to take 800 mg of calcium daily in food	Patients with osteoarthritis of the knee; Patients with moderate to severe spondylosis or degenerative disc disease of the thoracic and lumbar spine; Patients with musculo-skeletal diseases other than osteoporosis that cause back pain; Patients who had undergone arthroplasty of the knee or hip joint	No	Not reported	Not reported	No medications affecting bone metabolism prior to this study; all participants had low physical activity; Unknown diet/calcium intake

Evidence Table 1. Patient populations (continued)

Author, Year Country, Study Design	Inclusion Criteria	Exclusion Criteria	Presence of Men	Presence of Minorities	Comorbidities	Prior Treatments for Osteoporosis
Gilsanz, 2006 ⁴⁷ US CT	Healthy white females 15-20 years old who had previously sustained at least one fracture; Females who had completed puberty (Tanner stage V of sexual development); Out of the 150 candidates who matched these criteria, the 50 females with the lowest CT values for vertebral cancellous BMD (~1 SD below mean peak BMD values) were invited to participate in the intervention phase	Females who had a diagnosis of any underlying disease or chronic illness; Females who had been ill for >2 weeks during the previous 6 months; Females who had been admitted to the hospital at any time during the previous 3 years; Females who were taking any medications including oral contraceptives; Females who were pregnant, had ever been pregnant, or with an absence of menses for >4 consecutive months or two cycle lengths after establishing regular cycles; Females in whom the epiphyses of the phalanges and the metacarpals had not fused completely	No	No	No	No medications; Baseline physical activity and calcium intake recorded
Pitukcheewanont, 2006 ⁷² US Case series	Female children diagnosed with endocrine disorders of various etiologies and low bone density; Only children at Tanner stage I or II for sexual development were allowed to participate	Any medication known to affect bone density	No	Not reported	Not reported	No medications; Unknown exercise; Unknown diet/calcium intake
Ezenwa, 2008 ⁷³ US Case series	At least 65-years old; Able to go from sitting to standing without assistance; Walk up and down 3 steps; Ambulate 50 feet with or without a cane and without exhibiting shortness of breath or chest pain	Any medical condition that might affect BMD (e.g., bone cancer, end-stage renal disease, long-term steroid use, etc.); Other neurological conditions affecting balance and strength (e.g., history of stroke, Parkinson's disease, vertigo)	Yes	Not reported	Not reported	Not reported

Evidence Table 2. Vibration modalities

Author, Year Country	Setting	Living Arrangement of Participants	WBV Platform Type	Manufacturer
Gusi, 2006 ²¹ Spain	Clinic (Assumed)	Community	Side-alternating	Galileo 2000, Novotec, Germany
Ruan, 2008 ⁷⁰ China	Clinic	Community (campus of Beijing Institute of Technology)	Synchronous	ZD-10, Beijing Maidakang Medical Equipment Company, China
Semler, 2008 ⁷¹ Germany	Home	Community	Side-alternating	Cologne Standing and Walking Trainer System Galileo (modified til-table combined with the Galileo whole body vibration system)
Bemben, 2010 ⁵⁷ US	Clinic	Community	Triplanar	Power-Plate North America, Inc., Northbrook, Illinois
Verschueren, 2004 ³² Belgium	Clinic	Community	Not reported	PowerPlate, Amsterdam, The Netherlands
von Stengel, 2010 ²⁷ Germany	Clinic & Home	Community	Synchronous	Vibrafit, Solms, Germany
Rubin, 2004 ³⁰ US	Home	Community	Synchronous	Model LA18-18; BEI San Marcos, California
Russo, 2003 ⁵² Italy	Clinic	Community	Side-alternating	Galileo 2000
Iwamoto, 2005 ³¹ Japan	Clinic	Community	Side-alternating	Galileo, Novotec, Pforzheim, Germany
Gilsanz, 2006 ⁴⁷ US	Home	Community	Synchronous	Not reported explicitly
Pitukcheewanont, 2006 ⁷² US	Clinic	Community	Synchronous	BEI model LA18-18; San Marcos, California
Ezenwa, 2008 ⁷³ US	Clinic	Community	Not reported	Developed for study

Evidence Table 3. Vibration interventions I

Author, Year	WVB Intervention Frequency	WBV Intervention Amplitude	WBV Intervention Acceleration	WBV Intervention Session Length	WBV Intervention Session Rest Periods	Changes in Platform Settings During Session	Changes in Platform Settings During Intervention Period	Flex Knees While on Platform	Extend Lower Extremities
Gusi, 2006 ²¹	12.6 Hz	3 mm (vertical amplitude)	Not reported	First 2 weeks 3 minutes, Last 6 weeks 6 minutes	Yes - 1 minute vibration, 1 minute rest	No	No	Yes	No
Ruan, 2008 ⁷⁰	30 Hz	5 mm (amplitude)	Not reported	10 minutes	No	No	No	No	No
Semler, 2008 ⁷¹	15-25 Hz	1-2 mm (amplitude)	Not reported	9 minutes., 2 times per day	Yes - 3 minutes vibration, 3 minutes rest	Yes - changes in frequency	Yes - changes in frequency and tilting-angle	Yes	Yes - bend and straighten knees while on platform
Bemben, 2010 ⁵⁷	30-40 Hz	2-4 mm (peak to peak)	2.16-2.8 g (acceleration magnitude)	15-60 second sessions with 1-3 sets	Yes - 15 second rest between sets	No	Yes - changes in frequency, acceleration, session length, and sets	Yes - during certain exercises	Yes - during certain exercises
Verschueren, 2004 ³²	35-40 Hz	1.7-2.5 mm (amplitude)	2.28-5.09 g (peak acceleration)	30 minutes which included warming up and cooling down	Yes	No	Yes - changes in duration of session, number of series of one exercise, number of different exercises, amplitude, frequency,	Yes - during certain exercises	Yes

Evidence Table 3. Vibration interventions I (continued)

Author, Year	WVB Intervention Frequency	WBV Intervention Amplitude	WBV Intervention Acceleration	WBV Intervention Session Length	WBV Intervention Session Rest Periods	Changes in Platform Settings During Session	Changes in Platform Settings During Intervention Period	Flex Knees While on Platform	Extend Lower Extremities
von Stengel, 2010 ²⁷	25-35 Hz	1.7 mm (amplitude)	Not reported	6 minutes	Yes - 1 minute break with stretching between exercises	No	Yes - changes in frequency, exercise intensity	Yes - during certain exercises	Yes - during certain exercises
Rubin, 2004 ³⁰	30 Hz	Not reported	0.2 g (peak to peak)	10 minutes, 2 times per day	Yes - at least 10 hours. between 2 daily sessions	No	No	No	No
Russo, 2003 ⁵²	12-28 Hz	Not reported	0.1-10 g (acceleration)	First 1 month 3 minutes, Last 5 months 6 minutes.	Yes - 1 or 2 minutes vibration (3 sets), 1 minute rest between	No	Yes - change in frequency, session length	Yes	No
Iwamoto, 2005 ³¹	20 Hz	0.7-4.2 mm (upwards and downwards)	Not reported	4 minutes	No	No	No	Yes	No
Gilsanz, 2006 ⁴⁷	30 Hz	Not reported	0.3 g (peak to peak)	10 minutes	No	No	No	Not reported	No
Pitukcheewanont, 2006 ⁷²	30 Hz	Not reported	0.3 g (vertical acceleration)	30 minutes	No	No	No	Not reported	No
Ezenwa, 2008 ⁷³	Not reported	Not reported	Not reported	15 minutes, 2 times per session	Not reported	Yes – changes in frequency	No	Not reported	Not reported

Evidence Table 4. Vibration interventions II

Author, Year	Type of Footwear Worn on Platform	Support Device	Intervention Frequency	Intervention Duration (week)	Combination of Treatments	Concomitant Treatments for Osteoporosis	Calcium Supplementation	Length of Followup (week)
Gusi, 2006 ²¹	Barefoot	Not reported	3 days per week, at least 1 day of rest in between sessions	32	No - but WBV program included warm-up with 5 minutes bicycling and 5 minutes stretching	No medications at start	No	32
Ruan, 2008 ⁷⁰	Not reported	Yes	5 times per week	24	No	No bone medications at start	No	24
Semler, 2008 ⁷¹	Not reported	Yes - patients strapped to tilt-table	7 days per week	24	No	Yes - medications and physiotherapy continued	No	24
Bemben, 2010 ⁵⁷	Shoes while standing; also sat on platform	Not reported	3 days per week	32	Yes - WBV (which included dynamic movements) and resistance training	No bone medications at start	No but instructed to increase calcium intake if less than 1500 mg/day	32
Verschueren, 2004 ³²	Shoes	Not reported	3 days per week, at least 1 day of rest in between sessions	24	No - but WBV program included exercise on platform, warm-up, cool-down	No bone medications at start	No	24
von Stengel, 2010 ²⁷	Not reported	Unknown	2 clinical, 2 home	72	Yes - WBV and training	No bone medications at start	Yes - to participants that needed it - 1500 mg calcium and 400 IE vitamin D	72

Evidence Table 4. Vibration interventions II (continued)

Author, Year	Type of Footwear Worn on Platform	Support Device	Intervention Frequency	Intervention Duration (week)	Combination of Treatments	Concomitant Treatments for Osteoporosis	Calcium Supplementation	Length of Followup (week)
Rubin, 2004 ³⁰	Unknown	Yes	7 days per week	48	No	No bone medications at start	No	48
Russo, 2003 ⁵²	Not reported	Not reported	2 days per week	24	No	Not reported if medications taken	Yes - all participants received calcium and Vitamin D	24
Iwamoto, 2005 ³¹	Not reported	Not reported	1 day per week	48	Yes - WBV and alendronate (5 mg daily)	Yes - medication	No but instructed to get 800 mg in food daily	48
Gilsanz, 2006 ⁴⁷	Not reported	Not reported	7 days per week	48	No	No medications at start	Yes - all participants took 500 mg tablet daily	48
Pitukcheewanont, 2006 ⁷²	Not reported	Yes	3 days per week	8	No	No bone medications at start	No	8
Ezenwa, 2008 ⁷³	Not reported	Yes	3 times per week	20	No	Not reported if medications taken	No	20

Evidence Table 5. Vibration outcomes I

Author, Year	Measured Compliance	Comparators	N for Comparator (ITT)	N for Comparator (Completed)	Bone Mineral Density	Measure of Bone Mineral Density	Harms
Gusi, 2006 ²¹	Yes – reported rate	Walking program training group	18	14	Yes	Dual-energy x-ray absorptiometry (DXA)	None reported
Ruan, 2008 ⁷⁰	Not reported	Control group (no program)	50	43	Yes	Dual-energy bone densitometers	None reported
Semler, 2008 ⁷¹	Reported there was high compliance but did not report specific rate (may have been self-report)	NA	NA	NA	No	NA	Yes – some patients reported itching after vibration session; one patient reported localized pain at the end of an intramedullary rod which had been dislocated prior to the vibration intervention; one patient dropped out of the study after dislocation of a telescopic rod (which had happened before in this patient)
Bemben, 2010 ⁵⁷	Yes – reported rate	Resistance training group and control group (no program)	Unknown	22 Resistance TG; 12 Control	Yes	DXA	None reported
Verschueren, 2004 ³²	Not reported	Resistance training group and control group (no program)	22; 23	22; 23	Yes	DXA	None reported

Evidence Table 5. Vibration outcomes I (continued)

Author, Year	Measured Compliance	Comparators	N for Comparator (ITT)	N for Comparator (Completed)	Bone Mineral Density	Measure of Bone Mineral Density	Harms
von Stengel, 2010 ²⁷	Yes – reported rate	Exercise training group and wellness program control group	50; 51	47; 48	Yes	DXA	None reported
Rubin, 2004 ³⁰	Yes – reported rate and assessed outcomes by compliance	Placebo device control group	37	28	Yes	DXA	None reported
Russo, 2003 ⁵²	Yes – reported rate	Control group (no program)	17	14	Yes	Peripheral quantitative computed tomography device (pQCT)	Yes - transient lower leg itching and erythema in 6 of 17 patients; moderate knee pain in 2 overweight participants with preexisting knee osteoarthritis
Iwamoto, 2005 ³¹	Not reported	Alendronate-only (bisphosphonate) control group	25	25	Yes	DXA	None reported
Gilsanz, 2006 ⁴⁷	Yes – reported rate and assessed outcomes by compliance	Control group (no program)	25	24	Yes	Computed tomography (CT); DXA	None reported
Pitukcheewanont, 2006 ⁷²	Yes – reported all participants completed study	NA	NA	NA	Yes	CT	None reported
Ezenwa, 2008 ⁷³	Not reported	NA	NA	NA	Yes	DXA	None reported

Evidence Table 6. Vibration outcomes II

Author, Year	Site of Bone Mineral Density Measure	Bone Mineral Content	Bone Mineral Content Measure	Fracture	Measure of Fracture	Quality of Life	Quality of Life Measure	Other Outcomes
Gusi, 2006 ²¹	Right proximal femur (femoral neck, trochanter and Ward's triangle); lumbar spine	No	NA	No	NA	No	NA	Balance; BMI
Ruan, 2008 ⁷⁰	Lumbar spine L2-L4; femoral neck	No	NA	No	NA	No	NA	Chronic back pain
Semler, 2008 ⁷¹	NA	No	NA	Yes	Count	No	NA	Mobility (Brief Assessment of Motor Function); Tilting-angle to calculate ground reaction force and measure improvement in muscle force
Bemben, 2010 ⁵⁷	Total body; AP lumbar spine L1-L4; Dual proximal femur (femoral neck, trochanter, total hip); 33% radius of forearm	No	NA	No	NA	No	NA	Bone turnover markers from blood samples (C-terminal telopeptide of Type 1 collagen (CTX) for bone resorption and bone alkaline phosphatase (Bone ALP) for bone formation); Muscle Strength
Verschueren, 2004 ³²	Total hip; Total body; lumbar spine	No	NA	No	NA	No	NA	Bone turnover markers from blood samples (serum osteocalcin for bone formation and C-telopeptide level (CTX) for bone resorption); Muscle strength (isometric, dynamic); Fat mass and muscle mass; Postural control
von Stengel, 2010 ²⁷	Lumbar spine L1-L4; proximal femur	No	NA	No	NA	No	NA	Falls
Rubin, 2004 ³⁰	Proximal right and left femora: neck, trochanter; lumbar spine, distal one-third of nondominant radius	No	NA	No	NA	No	NA	Compliance; Efficacy of device use; Bone formation and resorption through serum and urine samples
Russo, 2003 ⁵²	Tibia: trabecular and cortical	No	NA	No	NA	No	NA	Muscle power
Iwamoto, 2005 ³¹	Lumbar spine L1-L4 antero-posterior view	No	NA	Yes	X-ray	No	NA	Back pain; Urinary NTX, serum ALP, serum calcium, serum phosphorous); Falls
Gilsanz, 2006 ⁴⁷	Lumbar spine L1-L3; Total body	Yes	DXA	No	NA	No	NA	Muscle area

Evidence Table 6. Vibration outcomes II (continued)

Author, Year	Site of Bone Mineral Density Measure	Bone Mineral Content	Bone Mineral Content Measure	Fracture	Measure of Fracture	Quality of Life	Quality of Life Measure	Other Outcomes
Pitukcheewanont, 2006 ⁷²	L1-L3 of lower axial spine (cancellous BD); Femurs (cortical BD)	No	NA	No	NA	No	NA	Fat mass; Femoral muscle mass; Bone area; Bone-specific alkaline phosphatase (BALP)
Ezenwa, 2008 ⁷³	Lumbar spine L1-L4; Total hip; Femoral neck; Trochanter; Forearm	No	NA	No	NA	No	NA	NA