

"VIBES"--Low Magnitude Mechanical Stimulation to Improve Bone Mineral Density

This study is currently recruiting participants.

Verified by National Institute on Aging (NIA), September 2007

Sponsored by:	National Institute on Aging (NIA)
Information provided by:	National Institute on Aging (NIA)
ClinicalTrials.gov Identifier:	NCT00396994

Purpose

The purpose of this study is to determine if daily low magnitude, high frequency whole body vibration can improve bone density in seniors.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Low Bone Density	Device: Low magnitude high frequency whole body vibration	Phase II

[MedlinePlus](#) related topics: [Minerals](#)

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Study Type: Interventional

Study Design: Prevention, Randomized, Double-Blind, Placebo Control, Parallel Assignment, Safety/Efficacy Study

Official Title: Low Magnitude Mechanical Stimulation (LMMS) to Improve Bone Mineral Density (BMD)

Further study details as provided by National Institute on Aging (NIA):

Primary Outcome Measures:

- Changes in volumetric trabecular BMD of the spine and hip by quantitative computed tomography
- (CT scan)

Secondary Outcome Measures:

- Changes in biochemical markers of bone formation (Procollagen type 1 N-terminal peptide and Bone Specific Alkaline Phosphatase) and resorption (C-terminal Telopeptide of type I collagen)

Estimated Enrollment: 200
Study Start Date: February 2007
Estimated Study Completion Date: March 2010

Detailed Description:

The treatment options for osteoporosis, a major health complication in the aged population, are limited to pharmacologic interventions, the majority of which are antiresorptive. Preliminary data demonstrate that high frequency, low magnitude mechanical stimulation (LMMS) can preserve bone mineral density (BMD) against systemic pressures to resorb (e.g., disuse, aging), and can stimulate new bone formation.

To confirm and extend these observations, this study is a two-year, double-blind, randomized, placebo-controlled clinical trial of LMMS in 200 elderly women and men (65 years of age and older). A clinical center located in Boston, MA will recruit participants from six independent living facilities in close geographic proximity serving a population of 2,082 residents. Following a two-week trial run-in period with an inactive vibrating platform, participants meeting the inclusion/exclusion criteria will be randomized to either brief daily exposure to LMMS on a vibrating platform or a placebo platform over a two year period. All participants will receive 500 mg of elemental calcium and 400 IU of vitamin D per day.

This study will provide new and important information about the role of low magnitude high frequency mechanical stimulation on the skeleton.

▶ Eligibility

Ages Eligible for Study: 65 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Men and women 65 years and over of all ethnic groups
- Relatively normal weight (BMI 27 or less)
- Absence of terminal cancer or other illness necessitating hospice level services
- Capable of following the protocol and of understanding and providing informed consent; scoring over 23 on the Folstein Mini-mental Status Examination

Exclusion Criteria:

- Immobilization of the axial or lower appendicular skeleton within the last year
- Nonambulatory (ambulation with an assistive device will be permitted)
- Malignancy other than cured thyroid cancer or skin cancer
- Hip replacement or internal fixation, total knee replacement, or lower limb fracture within the past year, or bilateral hip replacement
- Medications: glucocorticoids, suppressive doses of thyroid hormone as determined by screening TSH, anticonvulsant drugs (phenytoin, phenobarbital, carbamazepine), estrogen/testosterone replacement, selective estrogen receptor modulators (SERMs), PTH, or bisphosphonates more than 1 month in past year, calcitonin therapy within the preceding month, fluoride therapy at any time

- Paget's disease of bone, rheumatoid arthritis or other connective tissue disorders requiring systemic treatment with disease modifying drugs, or a history of Cushing's syndrome

▶ **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier:
NCT00396994

Locations

United States, Massachusetts

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Contact: Judith P. Stone, MSW 617-363-8638 <mailto:jstone%40mail.hrca.har>

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Sponsors and Collaborators

National Institute on Aging (NIA)

Investigators

Principal Investigator: Douglas P. Kiel, MD, MPH Institute for Aging Research,

Principal Investigator: Marian T. Hannan, DSc, MPH Institute for Aging Research,

▶ **More Information**

Publications:

[Ward K, Alsop C, Caulton J, Rubin C, Adams J, Mughal Z. Low magnitude mechanical loading is osteogenic in children with disabling conditions. J Bone Miner Res. 2004 Mar;19\(3\):360-9. Epub 2004 Jan 27.](#)

[Rubin C, Recker R, Cullen D, Ryaby J, McCabe J, McLeod K. Prevention of postmenopausal bone loss by a low-magnitude, high-frequency mechanical stimuli: a clinical trial assessing compliance, efficacy, and safety. J Bone Miner Res. 2004 Mar;19\(3\):343-51. Epub 2003 Dec 22.](#)

[Gilsanz V, Wren TA, Sanchez M, Dorey F, Judex S, Rubin C. Low-level, high-frequency mechanical signals enhance musculoskeletal development of young](#)

[women with low BMD. J Bone Miner Res. 2006 Sep;21\(9\):1464-74.](#)

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Health Authority: United States: Federal Government

Keywords provided by National Institute on Aging (NIA):

biomechanics
osteogenesis
osteoporosis
bone regeneration

Study placed in the following topic categories:

Osteoporosis

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