

The Influence of Vibration on Bone Mineral Density in Women Who Have Weak Bones After Menopause

This study is ongoing, but not recruiting participants.

Sponsors and Collaborators:	University Health Network, Toronto The Physicians
Information provided by:	University Health Network, Toronto
ClinicalTrials.gov Identifier:	NCT00420940

Purpose

This study will examine whether whole-body vibration slows down bone loss in healthy postmenopausal women with osteopenia. Whole-body vibration is a promising novel therapy that involves standing on a platform which produces extremely small and fast up-and-down movements. Some but not all research studies have found that whole-body vibration slowed down bone loss in postmenopausal women. One of the reasons why different studies found different results may be because they used various speeds of vibration. This study looks at how different speeds of whole-body vibration influence bone mineral density differently in postmenopausal women who have osteopenia. Two hundred postmenopausal women will take part in this 12-month study. Women will be randomly assigned into three groups (67 women per group) and these groups will be compared. Group 1 will receive very fast whole-body vibration, Group 2 will receive fast whole-body vibration, and Group 3 will not receive whole-body vibration. We will look at various bone mineral density and bone quality measurements, obtained with three different types of technologies, at the beginning of the study and at 12 months of follow-up. The hypothesis of this study is that the in comparison to Group 3 (no vibration), Groups 1 and 2 will experience reduced bone loss over 12 months, and that the greatest reduction in bone loss will be experienced by Group 1. The results of this study will help us determine whether whole-body vibration at different speeds

produces variable effects on bone, hence explaining the inconsistency of the results obtained in previous studies.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Bone Density Osteopenia Osteoporosis Post-Menopause	Device: Juvent 1000 Dynamic Motion Therapy Platform	Phase III

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

[U.S. FDA Resources](#)

Study Type: Interventional
Study Design: Prevention, Randomized, Open Label, Active Control, Parallel Assignment, Efficacy Study

Official Title: The Effect of Daily Whole-Body Vibration on Tibial Trabecular Bone Mineral Density in Osteopenic Postmenopausal Women

Further study details as provided by University Health Network, Toronto:

Primary Outcome Measures:

- Trabecul volumetric bone mineral density (BMD) of the lower tibia (using peripheral quantitative computed tomography; pQCT)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]

Secondary Outcome Measures:

- Total BMD of the lower tibia (using pQCT)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]
- Cortical BMD and cortical thickness of the lower tibia (using pQCT)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]

- Trabecular thickness, separation, and number of the lower tibia (using pQCT)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]
- Total BMD of the distal radius (using pQCT)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]
- Cortical BMD and cortical thickness of the distal radius (using pQCT)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]
- Trabecular BMD and thickness, separation, and number of the distal radius (using pQCT)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]
- BMD at the total hip (using dual x-ray absorptiometry; DXA) [Time Frame: Baseline and 12 months]
[Designated as safety issue: No]
- BMD at the femoral neck (using DXA)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]
- BMD lumbar spine (using DXA)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]
- BMD at the calcaneus (using quantitative ultrasound; QUS) [Time Frame: Baseline and 12 months] [Designated as safety issue: No]
- Speed of sound and broadband ultrasound attenuation at the calcaneus (QUS)
[Time Frame: Baseline and 12 months]
[Designated as safety issue: No]

Estimated Enrollment: 200
 Study Start Date: November 2006
 Estimated Study Completion Date: October 2009
 Estimated Primary Completion Date: October 2009 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
1: Experimental	Device: Juvent 1000 Dynamic Motion Therapy

90 Hz whole-body vibration	Platform whole-body vibration at a magnitude of ~0.3g (acceleration due to the gravity) at a frequency of 30 Hz or 90 Hz
2: Experimental 30 Hz whole-body vibration	Device: Juvent 1000 Dynamic Motion Therapy Platform whole-body vibration at a magnitude of ~0.3g (acceleration due to the gravity) at a frequency of 30 Hz or 90 Hz
3: No Intervention control group (receiving no vibration)	

Detailed Description:

BACKGROUND:

Recent animal studies have shown that whole-body vibration increases bone mineral density. The effect of whole-body vibration on bone has been examined in only six small human studies with inconsistent results. Two of these studies have shown whole-body vibration reduces bone loss after menopause. Studies that used higher speed whole-body vibration may have produced greater reductions in bone loss.

OBJECTIVE AND HYPOTHESIS:

The objective of this study is to examine the effects of two whole-body vibration speeds trabecular BMD in the lower leg in osteopenic postmenopausal women. Two hundred postmenopausal women will take part in this 12-month study. Women will be randomly assigned into three groups (67 women per group) and these groups will be compared. Group 1 will receive very fast (90 Hz) whole-body vibration, Group 2 will receive fast (30 Hz) whole-body vibration, and Group 3 will not receive whole-body vibration. The hypothesis of this study is that the in comparison to Group 3 (no vibration), Groups 1 (very fast vibration, 90 Hz) and 2 (fast vibration, 30 Hz) will experience reduced bone loss over 12 months, and that the

greatest reduction in bone loss will be experienced by Group 1.

METHODOLOGY:

Women with any clinical conditions that affect bone and those receiving drugs that affect bone will be excluded. The whole-body vibration therapy will involve standing barefoot and upright on a vibration platform daily for 20 minutes. Data will be collected at baseline, and at 12 months of follow-up. Our primary analysis will evaluate whether there are differences in changes in trabecular BMD in the lower leg (as measured by peripheral quantitative computed tomography; pQCT) between Groups 1, 2, and 3. Our secondary analyses will examine whether there are differences in changes in the following bone characteristics between Groups 1, 2, and 3:

1. trabecular bone quality in the lower leg (as measured by pQCT)
2. cortical bone BMD and quality in the lower leg (as measured by pQCT)
3. trabecular and cortical bone BMD and quality in the wrist (as measured by pQCT)
4. BMD at the hip and spine (as measured by dual x-ray absorptiometry, DXA)
5. BMD and quality at the heel (as measured by quantitative ultrasound).

SIGNIFICANCE:

Based on current scientific understanding of bone remodeling, vibration devices have the potential to play a significant part in maintaining bone health in postmenopausal women. The results of this study will help us determine whether low-magnitude, high-frequency WBV at different vibration rates produces variable effects on bone, hence explaining the inconsistency of the results obtained previously. This study will also lay the ground work for future large-scale randomized controlled trials that are needed to investigate the long-term effects of WBV on preventing postmenopausal bone loss. If effective, WBV can be another non-pharmaceutical strategy to decrease bone loss in postmenopausal women. This

in turn will decrease the number of osteoporotic fractures and their associated morbidity and mortality.

► Eligibility

Genders Eligible for Study: Female
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- osteopenic
- postmenopausal

Exclusion Criteria:

- use of HRT in the past 12 months
- use of raloxifene or parathyroid hormone in the past 6 months
- use of bisphosphonates or fluoride in the past 3 months or ever taken for more than 3 months
- current use of calcitonin
- use of other medications that may indirectly affect bone metabolism
- presence of metabolic bone disease or diseases that indirectly affect bone metabolism
- occurrence of fragility fracture over 40 years of age
- presence of unhealed non-fragility fracture (i.e., occurring less than 6 months ago)
- having body mass ≤ 28 kg and ≥ 90 kg
- having knee or hip joint replacements and spine implants
- having poor balance (assessed by Timed-Up-and-Go)
- presence of other medical risks for the study
- inability to stand erect daily for 20 minutes
- planned vacation or other activities that would prevent one from using the platform for ≥ 1 month

▶ **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier:
NCT00420940

Locations

Canada, Ontario

University Health Network
Toronto, Ontario, Canada, M5G 2C4

Sponsors and Collaborators

University Health Network, Toronto

The Physicians

Investigators

Principal Investigator: Angela M Cheung, M.D., Ph.D. University Health Network, I

▶ **More Information**

[Click here for more information about the bone vibration study](#) 

Responsible Party:	University Health Network/University of Toronto (PI - Dr. Angela M. Cheung)
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Keywords provided by University Health Network, Toronto:

vibration
mechanical loading
bone mineral density
women's health
osteoporosis

Study placed in the following topic categories:

Musculoskeletal Diseases	Bone Diseases, Metabolic
Asthenia	Bone Diseases

Osteoporosis

Menopause

ClinicalTrials.gov processed this record on December 11, 2008

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