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ORIGINAL ARTICLE

Establishing the compliance in elderly women for use of a low level mechanical stress device in a clinical osteoporosis study

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Abstract Non-pharmacologic approaches to prevent bone loss are well suited for elderly patients to avoid polypharmacy and medication side effects. One potential treatment is a vibrating platform that delivers low-level mechanical loading stimulating bone remodeling. However, compliance is a major concern with any daily treatment, and is unknown for an elderly group using this device. Thus we assessed compliance with standing 10 min/day on a vibrating platform device in elderly women, the target population for osteoporosis therapy. We also assessed satisfaction with daily use of the device. We conducted a randomized, placebo-controlled, double-blinded 6-month study for daily use of a 10-min vibrating platform treatment in elderly women who were residents of a Continuing Care Retirement community. Compliance for each subject was calculated as the number of days attended divided by the 182 days in the 6-month trial. The 24 elderly women (mean age 86, range 79–92 years) had 83% compliance (95% CI: 70.5, 94.5) for daily treatment over 6 months. Excluding three study drop-outs, the 21 women had 93% compliance (95% CI: 89.8, 95.6), with no difference in compliance between active and placebo treatment. Main reasons for missing treatment days over the 6 months were vacation (54% of missed days) and illness (29%). Three adverse events occurred; one (syncope) was possibly related to device use, whereas the other two were not related to device use. Among participants, 95% reported overall satisfaction with daily use of the vibrating platform, and 57% preferred the platform versus daily oral medications for prevention of bone loss. Elderly women showed high compliance, high satisfaction and few adverse experiences with a daily non-pharmacological treatment designed to inhibit bone loss. Larger randomized controlled trials should evaluate the long-term efficacy of vibrating platform devices for treatment of low bone mass and osteoporosis in elderly individuals.

Keywords Aging · Bone · Compliance · Elderly · Feasibility · Osteoporosis · Randomized controlled trial

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Introduction

Osteoporosis is a disease characterized by compromised bone strength and the progressive loss of bone, particularly in the weight-bearing skeleton, leading to fracture. Osteoporosis is among the most common health problems facing elders, affecting over 8 million women in the USA [1, 2, 3, 4]. Among women age 80 years and over, 70% have low bone density indicating osteoporosis [3, 4, 5]. Three treatment modalities currently dominate the clinical approach to osteoporosis. Treatment guidelines emphasize that for all individuals, increased dietary or supplemental calcium and vitamin D are now widely supported. In addition, weight-bearing physical activity is generally promoted for all individuals regardless of their degree of bone loss. Finally, for those individuals with the highest risk of fracture, pharmacological treatment that inhibits bone resorption or stimulates

formation is commonly prescribed, though compliance can be compromised by acute complications, the necessity for long-term treatment, and the risk of aberrant side effects [6, 7].

Elderly patients consume 30% of all prescription drugs in the USA [8] and commonly use multiple medications. The trend for increased medications with aging continues through age 80 years, increasing the risk for adverse reactions, drug interactions and lowering compliance [9]. Non-pharmacological treatments for low bone mass have generated much interest, especially in elderly populations [1, 10, 11, 12, 13]. Non-pharmacological approaches to prevent bone loss are particularly well suited for elderly patients to avoid polypharmacy and medication side effects [10, 14, 15]. One potential treatment is a vibrating platform that delivers a non-invasive, low-level mechanical loading [16]. In animal models, this intervention has been shown to inhibit disuse osteopenia and bone quality [17, 18, 19]. However, as with standard pharmacotherapy or any daily treatment intervention, compliance is a major concern [14, 20, 21, 22]. A prior study using the vibrating platform device in postmenopausal women showed low compliance, a major factor related to efficacy of the device [23].

Bone loss associated with aging results in part from a decrease in high frequency loading imposed on bone tissue by muscle contraction due to normal activity, yet older bone tissue retains its sensitivity to high frequency loads [24, 25]. The low-level vibrating platform (Optimass Model MSI-1000; Exogen, Inc.) is a prototype device that provides high frequency, low-magnitude acceleration intended to mimic the spectral content of muscle firing [26, 27]. Efficacy and safety of the loading from the vibrating platform device has been investigated in animal and clinical models [19, 30], and about 70% of a low-level, 30 Hz mechanical signal is delivered to the femur and spine in the standing human [28]. Safety of the device has also been demonstrated in a 6-month study of children with disabling conditions [29] and in a 1-year clinical trial of postmenopausal women [23] with no adverse effects reported.

The one previous randomized, double blind, placebo-controlled clinical trial to examine the potential of low-level mechanical stimulation (0.2 g at 30 Hz) to inhibit bone loss in postmenopausal women [23] showed a positive effect on bone density. However, the effect was only seen in analyses restricted to women who were at least 60% compliant with device use. Only 37% were at least 80% compliant with the 20 min per day regimen. Increased compliance was associated with increased effectiveness of the loading treatment. Based on these findings, a shorter daily treatment at forces of 0.3 g was devised and found to yield similar osteogenic results with a single 10-min treatment [31]. Yet, the compliance results raised concerns over the ability of elderly women to adhere to a daily treatment regime requiring standing. Various factors affect compliance, including severity of co-morbid disease, age, and occurrence of side effects. Although this one clinical trial of the vibrating platform examined women 3–8 years past menopause, it is unclear if compliance would be greater or even less in an elderly population, the group at highest risk of osteoporosis, for whom such a non-pharmacological approach may be most appropriate.

The purpose of the current study was to establish the 6-month compliance of standing 10 min/day on a vibrating platform device in elderly women, half of whom were treated with a placebo device. A secondary objective was to assess the satisfaction with use of the vibrating platform device in the target population for osteoporosis treatment; elderly women ages 70 years and older. Compliance and satisfaction with a non-pharmacological approach to osteoporosis treatment, such as this one, have not been described.

Materials and methods

As compliance was the major limiting factor in previous work and in grant reviews, we decided to conduct a compliance study focusing on a senior housing center since the limited number of available devices could be accessed by a group, and also because other studies are increasingly using these housing centers as recruitment sites. Therefore, we planned to recruit elderly women with an anticipated practical number to enroll between 20 and 24 women, as both funds and space limited allowable enrollment.

Subjects

Women at least 70 years of age with a body mass index (BMI) less than 30 kg/m^2 were recruited from a continuing care retirement community (CCRC) in Massachusetts by an informational seminar held on-site and a direct mail announcement. Informed consent was obtained from subjects who agreed to participate in the study. Women who met the following inclusion criteria were accepted into the study: ambulatory (including use of assistive devices), able to stand 10 min, able to follow the device protocol, likely to survive the 6-month study period and not traveling during the treatment period for more than 2 weeks. Exclusion criteria included the following conditions: hip or knee replacement, neuromuscular diseases (e.g. Parkinson's, stroke), recent change in thyroid medications, hyperparathyroidism; current participation in a weight loss program or in another clinical trial.

Using concealed assignment, enrolled subjects were randomized to either the active or placebo treatment in a blinded randomization scheme. Elderly women were targeted for this study for several reasons: 1) this age group continues to lose bone; 2) most of these women are relatively sedentary; 3) these women are likely to exhibit some degree of frailty; and 4) these ages would likely be the target population for a larger scale osteo-

porosis treatment trial. The Institutional Review Board for Human Research at the Hebrew Rehabilitation Center for Aged approved the study and all participants provided written consent.

Intervention device

The investigational device used in this study was the Exogen Optimass Model MSI-1000 Mechanical Stress Device, a prototype developed to examine the ability of low-level physical signals to modulate bone mass in humans. This vibrating platform device provided 10 min of low intensity, high frequency (30 Hz, with limits of 27–33 Hz) mechanical acceleration (0.3 *g*, with limits of 0.27–0.33 *g*) to the upright lower appendicular and axial skeleton through the plantar surface of the feet. This level of vibration is well below the 4.24 *g* peak-peak acceleration exposure limit set by The International Organization for Standardization in 1985 (International Organization for Standardization, standard ISO-2631, 1985). FDA officials in1994 deemed the Optimass vibrating platform device to be a non-significant risk device and that clinical trial protocols need only to be submitted to the appropriate Institutional Review Boards. The device was used by subjects for a single 10-min period each day for 6 months. Exogen, Inc. supplied the active and placebo vibrating platform therapy devices for this study.

The vibrating platform device provides an efficient means for inducing a small and controlled amount of mechanical strain to the human skeleton [27]. The vibrating system consists of a rectangular shaped aluminum plate on which an individual stands for treatment (see Fig. 1) with a handlebar for the subject to hold when stepping on or off the plate and during treatment. Two active and two placebo devices were set up for daily use at a central location in the CCRC. The placebo platform was similar to the active vibrating platform in appearance. Both devices had a 500 Hz. tone audible to the patient during each treatment session to maintain double-blinding, while the active devices also had a barely discernable vertical displacement action. Participants stood on the platform in their stocking feet and used only their assigned specific platform device. The intervention continued for 6 months after enrollment into the study.

Study design

This was a randomized, placebo-controlled, double-blinded 6-month clinical trial for daily use of a 10-min vibrating platform treatment in elderly women. This design was used as we wanted to see if compliance differed for active versus placebo vibrating platform treatment and as we wanted to use the exact protocol planned for a larger study to identify any issues with compliance or operations. The two active and two placebo devices were assigned a color code for ease of participant assignment and subjects were randomized across these four vibrating platform devices. Both subjects and study personnel remained blinded as to which device was an active or placebo unit. All information regarding the randomization scheme was kept confidential and secure. Subjects used the device for a single 10-min treatment per day. When daily therapy sessions were missed, each subject was instructed that she should not make up the missed sessions. At baseline, 1-, 3-, and 5-month milestones, participants received incentive gifts regardless of their compliance level (socks, T-shirts, tote bags and coffee mugs).

Fig. 1 Vibrating platform typical stance and use for 10-min protocol (from Rubin et al. [23])

Compliance

All subjects were evaluated for compliance. To enhance early familiarity with the devices, the field staff supervised all sessions during the first 2 weeks for each participant. During this time, any missed sessions were followed up within 24 h to identify early problems with scheduling or other issues. Field staff was present for the subsequent 2 months but did not provide individual monitoring of sessions. After subjects completed the 3-month evaluations, field staff was available only by voice mail for problems or equipment issues. Each day during the 6-month follow-up, participants recorded

treatment start and end time using a daily sign-in sheet. The sign-in sheets were reviewed by the field staff on a weekly basis. If a participant missed a single session, no contact was made regarding compliance. However, if two or more sessions had been missed by any participant during a week, the field staff contacted the subject by phone to determine the reason for the missed sessions. Compliance for each subject was calculated as the number of total days the individual attended a treatment session divided by the 182 days in the 6-month trial.

Assessments

At the baseline visit, weight and height were measured and questionnaires administered. Weight was measured to the nearest tenth of a pound using a portable digital, calibrated scale. Height was measured using a stadiometer to the nearest 0.25 inch. Body mass index (BMI) was calculated as the weight in kilograms divided by the square of the height in meters (kg/m^2). Physical activity was assessed using a validated, interviewer-administered questionnaire of self-reported activity over the past seven days (Physical Activity Scale for the Elderly–PASE) [32]. The PASE produces a physical activity score using validated items that are appropriate for older respondents. Questions on current medication use were limited to bone active agents. Estrogen use was classified as current or no use at the time of the examination. The interview also assessed typical calcium intake, current use of calcium supplement, vitamin D supplement and multivitamin use. Information was obtained on disease history, fracture and fall history, alcohol and smoking history. Concomitant medications were permitted in participants of this study. Study subjects had a 1-month, 3-month and 6-month follow-up visit after start of treatment. Satisfaction with daily use of the device (very dissatisfied, dissatisfied, no opinion, satisfied, very satisfied) was queried via self-administered questionnaire at each of the follow-up study visits.

Adverse events were recorded as reported to study staff as well as directly queried at scheduled assessments. Adverse device events were defined as those that occurred during the treatment period that had an effect on health or safety. One investigator (D.P.K.) evaluated each adverse experience and assigned causality (possibly, probably, or definitely related to the device). No a priori evidence exists to suggest that mechanical stress therapy at acceleration levels of <0.3 g and 30 Hz may cause any adverse effects.

Statistical analysis

The primary goal of the study was to estimate compliance with standing ten minutes per day on a vibrating platform device, aiming to achieve at least 80% compliance regardless of treatment group. The primary outcome of compliance for each subject was calculated as the number of total sessions attended divided by the total number of days in the 6-month treatment period (intent-to-treat analysis). An intent-to-treat analysis that excluded the three subjects who dropped out of the study (completers per-protocol analysis) was also performed. Compliance was also measured in several other ways. ''When present'' compliance was calculated as the total number of sessions attended divided by the total number of days when the participant was neither ill, on vacation, or unavailable for other ''excused'' reasons. We also examined the proportion of subjects with ≥80% compliance. Ninety-five percent confidence intervals were calculated for all measures of compliance. Continuous measures of compliance were compared between active and placebo groups using the Wilcoxon rank-sum test, and categorical variables were compared using the Fisher's exact test. In addition to compliance, we considered general satisfaction (collapsing the five-item Likert scale into dissatisfied, no opinion, satisfied) with daily use of the vibrating platform device queried at the 6-month end of study visit.

Results

Our target enrollment number of 24 elderly women was met in the initial 6 weeks of this clinical trial. Approximately 65 men and women attended the information seminar, of which 53 elderly women volunteered for study screening. Twenty-one women were found to be ineligible (primarily due to knee or hip replacement, plans for a vacation longer than 2 weeks during the study period, or medical history) and four were no longer interested after their baseline assessment. Of the remaining 28, the first 24 elderly women from the CCRC who had ability to ambulate and were cognitively intact were enrolled in this trial. Half were randomized to active vibrating platform device, while the other 50% were randomized to placebo device. The mean age of participants was 86 years and ranged from 79 to 92 years of age. Table 1 shows the characteristics of study participants by treatment assignment. The only baseline measures that differed by treatment allocation were weight and BMI. Women in the active treatment group weighed less than the women in the placebo group. During the first 2 weeks of treatment, when field staff was present, no early problems were identified with scheduling or machine use.

As seen in Table 2, the primary intent-to-treat analysis showed that the mean compliance rate of the 24 total subjects (including the three subjects who dropped out) was 82.5% (95%CI: 70.5, 94.5) with a range of 7–100%. Of the 24 women enrolled in the clinical trial, 21 completed the study with a mean compliance of 92.7% (95% CI: 89.8, 95.6) with daily treatment over the 6 months of study. Figure 2 shows the relatively stable compliance rates across the 6 months of study for the intent-to-treat and for the per-protocol completers analyses (intent-to-treat without the drop-outs). Both

Table 1 Baseline characteristics of study participants by treatment allocation to active device or placebo device group

Characteristics	Active device ($n=12$)	Placebo device ($n=12$)
Mean ± SE (range)		
Age (years)	85.7 ± 1.1 (79.8–92.1)	86.4 ± 1.2 (80.5–91.8)
Weight (lb)	120.5 ± 4.4* (92.5–141.0)	139.5 ± 6.2 (110.0–184.5)
Body mass index (kg/m^2)	23.3 ± 0.9** (16.9–27.5)	26.4 ± 0.5 (24.6–30.7)
Height (inches)	60.4 ± 0.6 (58.0–65.0)	60.8 ± 1.0 (55.0–66.5)
Calcium intake (mg/day)	927.0 ± 161.4 (307–2247)	947.8 ± 136.5 (182–1750)
Physical activity score	65.7 ± 9.6 (24.8–140.1)	53.4 ± 7.9 (6.4–88.6)
Number (percent)		
Current use of estrogen replacement	3 (25.0%)	1 (8.3%)
Any current osteoporosis treatment	5 (41.7%)	4 (33.3%)
Any falls in past year	4 (33.3%)	4 (33.3%)
Any broken bone since age 20	9 (75.0%)	7 (58.3%)

*$P=0.021$
**$P=0.009$

analyses indicate a high rate of compliance throughout the study. Figure 3 shows the compliance rates across the study for the active and placebo device groups (intent-to-treat). Compliance between women receiving active versus placebo treatment did not differ ($P=0.71$) over the 6-month trial. There were three study drop-outs: two reported ''no further interest'' in the study after 1 month, while the third woman dropped out due to lingering respiratory illness. None of the drop-outs was due to treatment effects of the vibrating platform. When drop-outs were excluded, the active and placebo daily compliance rates had similar high levels over the study, ending at over 90% for both active and placebo device groups.

Compliance was also measured using ''when present'' compliance and the percent of subjects with ≥80% compliance (for both intent-to-treat measures). The mean ''when present'' compliance figures, representing those with ''excused'' absences, were all above 95% and ranged from a low of 86% to 100% (Table 2). Overall, 83% of subjects had ≥80% compliance (95% CI: 68.3, 98.3). If compliance was examined without the three subjects who dropped out (per-protocol completers), 95% (95% CI: 86.1, 100) of study subjects achieved compliance of at least 80% (91% of those assigned to active platforms and 100% of those participants assigned to placebo platform devices, no statistically significant difference, $P=0.49$). When examined over the course of the six-month study, compliance rates remained very high with little evidence of a continued decline over time (see Fig. 2 and 3), regardless of study group assignment or analysis.

All but one study participant had at least one missed daily session (Table 3). The main reasons for missing treatment days over the 6 months were vacation (54% of missed days) and illness (29%). A total of three adverse events occurred over the 6-month intervention, one event (syncope) was possibly related to platform use, whereas the other two (short-term respiratory illnesses) were not related to device use.

Among participants, 95% reported overall satisfaction (76% satisfied, 19% very satisfied) with daily use of the vibrating platform, over the 6-month study; the remaining 5% had no opinion regarding satisfaction with the device. These satisfaction figures remained stable from the 1-month and 3-month visits to the final 6-month follow-up study visit. When queried about treatment options, over half of the women (57%) preferred the platform (33% strongly preferred, 24% preferred) to daily oral medications for prevention of bone

Table 2 Study compliance measures by treatment group for intent-to-treat, per-protocol completers, and ''when present'' analyses

	Total	Active device	Placebo device
A. Intention to treat			
No.	24	12	12
Compliance rate (mean ± SE)	82.5 ± 5.8	84.7 ± 7.3	80.2 ± 9.2
95% confidence interval	(70.5, 94.5)	(68.6, 100)	(60.0, 100)
Range	7–100	7–99	10–100
≥80% compliance	83.3%	83.3%	83.3%
95% confidence interval	(68.3, 98.3)	(62.2, 100)	(62.2, 100)
B. Completers per protocol (intent-to-treat excluding drop-outs)			
No.	21	11	10
Compliance rate (mean ± SE)	92.7 ± 1.4	91.8 ± 2.2	93.7 ± 1.7
95% confidence interval	(89.8, 95.6)	(87.0, 96.6)	(90.0, 97.4)
Range	73–100	73–99	82–100
≥80% compliance	95.2%	90.9%	100%
95% confidence interval	(86.1, 100)	(74.0, 100)	(99.4, 100)
C. ''When present'' (excludes excused absences, e.g. planned vacations)			
No.	21	11	10
Compliance rate (mean ± SE)	96.5 ± 0.7	97.2 ± 0.6	95.8 ± 1.4
95% confidence interval	(95.1, 98.0)	(95.9, 98.5)	(92.7, 98.9)
Range	86–100	94–100	86–100

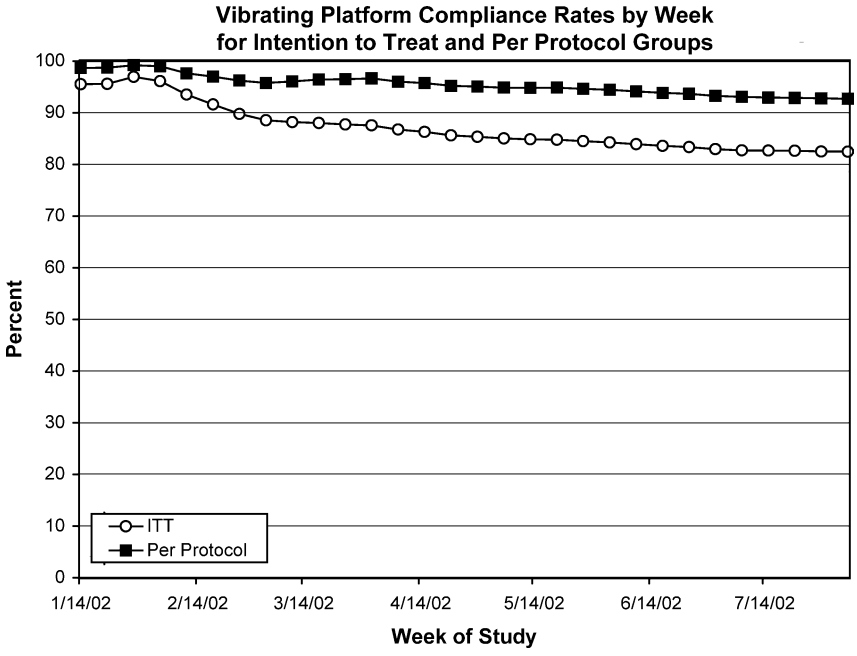

Fig. 2 Vibrating platform compliance rates by week for intention to treat and per protocol groups

loss (19% had no preference and 24% preferred oral medications).

Discussion

This study suggests that the compliance with standing 10 min/day on a vibrating platform device is high among elderly women recruited from a life care community. The purpose of this trial was to establish compliance using clinical trials methods and procedures that could be followed in future protocols. The mean compliance in the intent-to-treat analysis was 82.5% among all subjects (84.7% in the active group and 80.2% in the placebo group). While one study participant had 100% compliance over the 6-month study (i.e. daily attendance of all sessions across the 6 months), 95% of the study completers were 80% or better in compliance. The main reasons for missing treatment days over the 6 months were reasonable for a community dwelling elderly population, namely over half were vacation days, while nearly 30% were due to acute illness.

Elders in the US take an average of 5.7 drugs per day and as the number of medications taken by elders in-

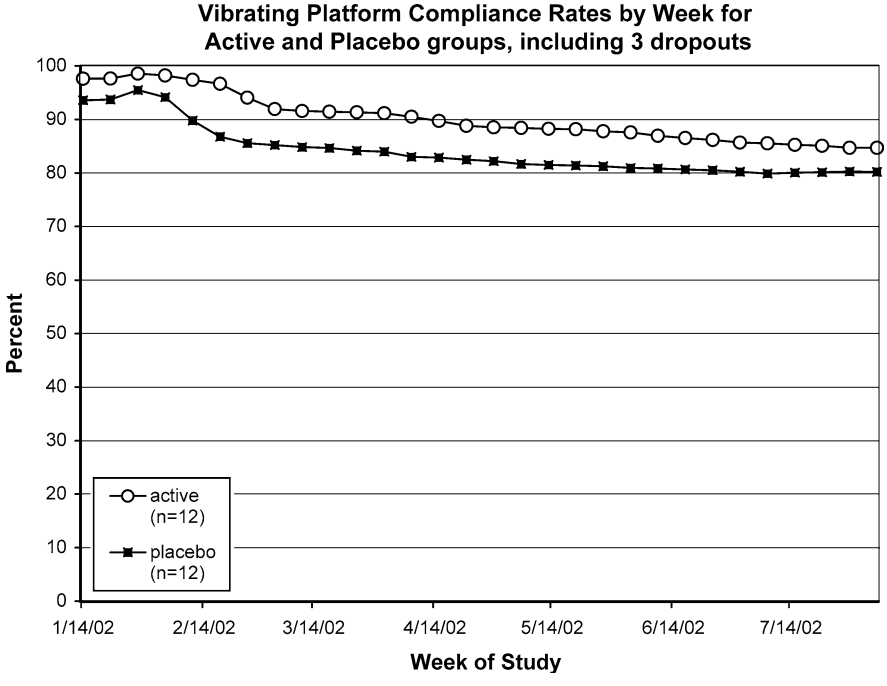

Fig. 3 Vibrating platform compliance rates by week for active and placebo device groups, intention to treat

Table 3 Distribution of missed daily sessions and reasons for missed sessions by treatment group (excluding drop-outs)

	Total ($n=21$)	Active device ($n=11$)	Placebo device ($n=10$)
Percent subjects ever missed one session in any week	85.7	90.9	80.0
Percent subjects ever missed more than one session in any week	76.2	90.9	60.0
Reasons for missed sessions[a]			
No. missed sessions	185 missed sessions across 21 subjects	114 missed sessions across 11 subjects	71 missed sessions across 10 subjects
Vacation	53.5%	39.5%	76.1%
Illness	29.2%	36.8%	16.9%
Forgot	8.1%	11.4%	2.8%
Scheduling problems	7.6%	12.3%	0
Spouse died	1.6%	0	4.2%
Total	100.0%	100.0%	100.0%

[a]Figures are percent of total number of sessions missed across participants, excluding drop-outs. When included, "dropped out" accounts for 54.7% of 370 missed sessions

creases, compliance decreases [9, 33, 34]. Several studies have reported that compliance rates for all drug therapies range between 40% and 50% [35, 36, 37]. In fact, the major reasons for non-compliance in elderly patients are polypharmacy, side effects, and an absence of perceived benefit [8, 14, 22, 33, 37, 38, 39]. Non-compliance is also a key issue for non-pharmacological treatments. Inouye et al. showed a range of 10–85% compliance for five protocols in a large clinical trial of non-pharmacologic treatments to prevent delirium, and an overall compliance of 57% [15]. Thus, as with medications and even without a polypharmacy component, compliance in non-pharmacological interventions must be maximized for effectiveness of treatment. Delmas notes that compliance is particularly poor in patients treated for osteoporosis [10]. Further, osteoporosis medications often require stringent administration protocols that also have a negative effect upon compliance. Many osteoporotic patients cannot, or will not, take the currently available medications for osteoporosis, prompting a search for more tolerable agents [40, 41]. Indeed, a recent review of 34 clinical trials using osteoporosis medications report that over half had over 20% of patients discontinue treatment due to adverse events [42]. The high level of discontinuation and strict regimen of osteoporosis medications coupled with polypharmacy make a non-pharmacological approach to treat bone loss in elderly patients very appealing.

The findings of this study have several ramifications in design of clinical trial studies of osteoporosis. First, compliance in elderly patients is a key factor and needs much more attention in the design and conduct of clinical trials. Pauler et al. highlight this point, stating that monitoring of compliance not only provides insight into analyses of a primary endpoint, but also addresses the question of whether the prescribed regime can be feasibly applied to the general public [43]. Second, non-pharmaceutical approaches to osteoporosis are of keen interest to elderly women, the major group of patients with osteoporosis. As many older adults receive medications that may cause more harm than good, having options beyond oral medications may lead to better patient compliance [8, 44]. Finally, issues such as polypharmacy, safety, satisfaction, convenience and cost in the selection of treatments are all critically important factors in the treatment of osteoporotic patients.

An overwhelming majority of the study participants (95%) in our study reported general satisfaction with daily use of the vibrating platform over the 6 months. One of the major concerns with the daily use of the vibrating platform was that individuals might lose interest over time. This concern was not borne out in our study, as most participants maintained attendance and also indicated continuing overall satisfaction with the use of the device (same levels of satisfaction at 1 month and 3 month visits). Further, when queried about treatment options, over half of the women preferred using the vibrating platform to adding a daily oral medication for prevention of bone loss while only 24% would have preferred to take pills.

This study is not generalizable to elderly individuals who do not live in a congregate housing setting, and is limited to women. Nevertheless, it is important to note that this type of senior housing is growing exponentially throughout the United States. CCRCs, as only one type of senior housing, are expected to house over 18% of adults ages 75 and older by the year 2020, and are rapidly becoming sites of study for health-related issues in elders [45, 46] Women typically live longer than men, such that women make up a larger percentage of these congregate housing facilities, and also have a higher prevalence of osteoporosis.

In conclusion, elderly women living in a life care retirement community showed high compliance and satisfaction and a low incidence of adverse events with a daily non-pharmacologic treatment designed to inhibit bone loss. This non-pharmacological treatment may be an important alternative to drug therapy for osteoporosis to avoid polypharmacy, but compliance must be a key focus and this trial shows that high compliance can be achieved. These compliance findings underscore the importance of integrating compliance into study design and highlighting that importance to study participants in the early stages of a clinical trial. These compliance trial results set the stage for larger randomized controlled trials to evaluate the long-term efficacy of the

vibrating platform device for treatment of low bone mass and osteoporosis in elderly men as well as women.

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Dr. Clinton Rubin has served as a consultant for Smith & Nephew Orthopaedics, and is one of the inventors of the mechanical stress system technology.

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