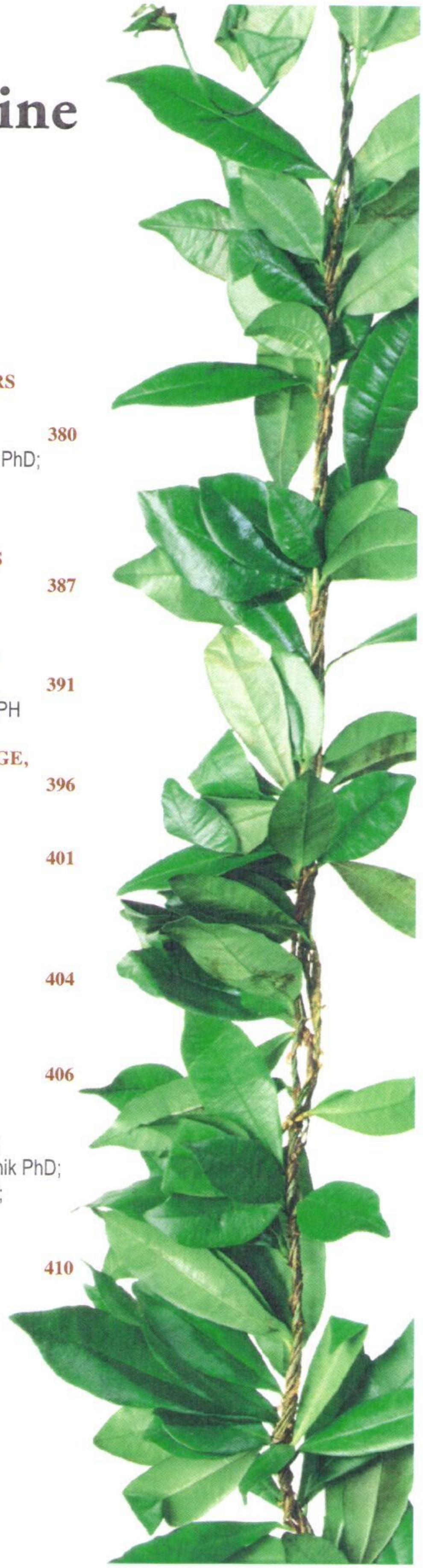
Hawai‘i Journal of Medicine & Public Health

A Journal of Asia Pacific Medicine & Public Health

November 2013, Volume 72, No. 11, ISSN 2165-8218



Hawai'i Journal of Medicine & Public Health

A Journal of Asia Pacific Medicine & Public Health

ISSN 2165-8218 (Print), ISSN 2165-8242 (Online)

The Journal's aim is to provide new scientific information in a scholarly manner, with a focus on the unique, multicultural, and environmental aspects of the Hawaiian Islands and Pacific Rim region.

Published by University Clinical, Education & Research Associates (UCERA)

Hawai'i Journal of Medicine & Public Health
677 Ala Moana Blvd., Suite 1016B
Honolulu, Hawai'i 96813
http://www.hjmph.org
Email: info@hjmph.org

The Hawai'i Journal of Medicine & Public Health was formerly two separate journals: The Hawai'i Medical Journal and the Hawai'i Journal of Public Health. The Hawai'i Medical Journal was founded in 1941 by the Hawai'i Medical Association (HMA), which was incorporated in 1856 under the Hawaiian monarchy. In 2009 the journal was transferred by HMA to University Clinical, Education & Research Associates (UCERA). The Hawai'i Journal of Public Health was a collaborative effort between the Hawai'i State Department of Health and the Office of Public Health Studies at the John A. Burns School of Medicine established in 2008.

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An Exercise Program to Prevent Falls in Institutionalized Elderly with Cognitive Deficits: A Crossover Pilot Study

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Abstract

Falls are the leading cause of injury among older adults in the United States, with the institutionalized elderly at elevated risk for injury and death. Physical weakness and mental frailty, prevalent in institutionalized elderly, are major risk factors for falls. The purpose of this study was to evaluate a program that addresses both the physical and mental aspects of exercise to reduce falls in institutionalized elderly. Twenty-seven volunteer subjects residing in an assisted living facility participated in the 24 week randomized crossover study. After demographic, fall history, and mental status examinations, subjects were randomly assigned first to ten weeks of either an exercise class or a control group, followed by a four week "washout period" of no activity, then cross assigned to ten weeks as either a control group or exercise class, respectively. Falls as well as mental status changes were monitored during the study. After adjusting for differences in baseline risk between the control and treatment groups, and for potential residual effects of the treatment during the crossover phase, a statistically significant ($P = .025$) reduction in falls was found during treatment compared to the control periods. No change in mental status was seen. This small, pilot study shows that exercise programs, which emphasize mental strengthening as well as physical fitness, have the potential to reduce falls among mentally impaired, institutionalized seniors.

Introduction

Falls amongst the elderly represent a major public health concern in Hawai'i, with falls contributing to excess morbidity and mortality in the geriatric community.[1] As of 2012, falls were the leading cause of death from unintentional injuries in Hawai'i and 79% of the deceased were seniors over the age of 65. Additionally, 68% of all hospitalizations from falls occurred in elderly residents.[2] In the United States as a whole, one out of three adults aged 65 and over experience a fall annually, with falls being the leading cause of injury-related deaths among older adults.[3,4] As the population of the United States ages, falls are projected to become an increasing burden on the health care system. From 1980 to 2008, the population of individuals in the United States over 75 years of age nearly doubled, with this age cohort currently composing 6% of the population.[1]

Due to the changes in strength, gait, vision, and mental clarity that accompany the natural process of aging, the elderly tend to suffer serious medical consequences such as brain injuries, hip fractures and lacerations when they do fall.[5] In 2007, the United States reported 400,000 hospitalizations for falls. The elderly whose falls result in hip fractures have a 20% to 30% mortality rate within a year of the fall incident.[6,7] In addition to the physical damage that falling causes, the experience of suffering a fall has negative effects on the mental health of older adults. The majority of the elderly who fall develop an intense fear of falling, causing anxiety and self-imposed mobility restrictions amongst both community dwelling and independently living seniors.[8] This inhibition of mobility as a result of fear decreases physical fitness and activity levels in the elderly, in turn increasing the risk that an individual will experience another fall.[9]

Seniors who reside in assisted living institutions, on average, tend to be in worse health than their counterparts living in the community, making them especially prone to health problems associated with (leading to and resulting from) falls. Over 25% of residents in assisted living suffer from 4-10 chronic health conditions including dementia, osteoporosis, arthritis, cancer, and heart disease.[10] Older adults in institutions also tend to have lower levels of mental clarity as compared to their home dwelling counterparts, often exacerbated by extensive medication use.[11] The combination of these factors puts seniors in assisted living facilities at high risk of falls due to their functional limitations and overall elevated levels of frailty. Almost 10% of those who fall in institutions sustain a serious injury and 25% to 75% of them do not recover their pre-fall level of mobility or ambulatory function in daily life.[12] Injuries sustained from falling are a common reason for the need to transfer older adults from assisted living to skilled nursing facilities, leading to an increase in cost and a decrease in independence and autonomy for the individual.[13]

While modifications to the built environment such as ramps and grab bars have been shown to reduce falls in the independently living elderly, residents of assisted living continue to fall despite extensive physical modifications for safety within elder care facilities.[14] Almost 30% of falls in these facilities can be attributed to hazards that are not directly related to the built environment, including spills on the floor, sedative medication use, and an inability of the seniors to be safely motile while simultaneously performing a mental task.[14] Previous research has shown that exercise programs can mitigate these fall risks in seniors by improving balance and cognitive functioning.[11,13,15] In this paper, we present findings from a randomized controlled study in which we examine the effects of the exercise program *Move With Balance*® (MWB) on reducing the incidence of falls. We did not examine the effect on the severity/consequences of falls, once they occurred.

Methods

The study was conducted at a 98-unit assisted living community located in Kahului, Maui, Hawai'i. An integrative physical and mental exercise program served as the study intervention. The study program (MWB) consisted of a set of 60 activities combining strength and balance training with cognitive and spatial awareness tasks. The latter can involve any type of sensory input, mental processing, and expression. The two specific exercises from MWB exemplify these principles: Participants were paired off facing each other, one showing the other an "arrow chart"; a sequence of arrows in 4 random directions. The first round of exercises asked the responder to thrust out their arms and call out the direction of the indicated arrow. When this was mastered, the next round had the responder say and do the opposite of what the arrow showed. In the final round, the participant was to say the opposite direction but move their arms in the same direction as the arrow. Roles were subsequently switched. Another exercise had the participants slowly march in place touching opposite hands to knees. After a rhythm was established this basic cross crawl pattern was repeated with eyes closed, eyes open while walking around, eyes moving left and right, and finally while counting out loud backwards from 100 by 3. In 2012, the program was selected by the American Society on Aging and the MetLife Foundation as the winner of the MindAlert Award in the category for programs designed to enhance mental fitness in older adults.[16]

A randomized crossover study design was used to examine the effects of the intervention. The study subjects, who gave either personal or guardian informed consent, were randomly assigned to begin the study in either the treatment (Group A) or control (Group B) groups. Treatment consisted of weekly exercise sessions for 10 weeks, each an hour-long MWB class. During their period as controls participants were monitored for falls but did not participate in exercise classes. No placebo was offered. Following the initial ten weeks, all participants were placed in a 4 week "washout period" in which no intervention was given. After the washout period, the two groups crossed-over, with Group A continuing in the study for 10 weeks as controls and Group B serving as the intervention group. For this study the term exercise arm will refer to the combined exercise periods of both groups A and B and control arm as the combined control periods of both groups A and B.

The study ran for 24 weeks. Baseline demographic data was collected on subjects at the start of the study and falls were monitored throughout. A fall incident was defined as an event in which at least three points of the body made contact with the ground. Prior to the study, the staff at the assisted living facility had routinely kept records of all falls experienced by residents of the institution. The study team chose the number of recorded falls during the previous 18 months as the key marker for the subjects' baseline risk of falling. Because not all of the study participants had resided at the facility for that time period, the average of the number of falls for those living in the facility for the previous 18 months was chosen as a representative sample of the entire group of study subjects. The crossover design of the study was intended to balance the baseline risk factors for falling between treatment and control arms.

Three stages of data analysis were planned for the results. The first stage was to compare fall incidence densities during the treatment sessions with falls during the control sessions. Both randomization and the crossover design would minimize confounding variables between the intervention and control arms. The second stage was to examine if the 4 week washout period was an adequate length of time to remove the residual effects (if any) of the treatment from Group A. If this refinement were needed only the controls from Group B would be used, as they had no previous exposure to the exercise program which could "contaminate" their use as controls. This refinement would remove the power of the crossover design to match the study and control arms with respect to confounding factors, such as baseline risk of falls. If an adjustment for baseline risk of falls between arms was needed a third stage analysis would be done. No other (stratified, modeling, etc) analysis was planned to assess intervention efficacy.

Previous research has shown a correlation between poor mental state and falls amongst the elderly, validating mental clarity as a possible marker for fall risk.[17] In order to account for changes in mental state as a result of the intervention, mental status testing was administered to the study subjects before and after participation. The facility at which the research was conducted uses its own mental status examination consisting of a series of verbally administered questions over the course of a 3-minute interview. These questions test the subjects' orientation to time, remembering/recalling 3 objects, and counting backwards from 20. Scores on this examination range from 0 to 9 with 9 being the maximum possible score of mental clarity. Tests were administered by the staff of the assisted living facility before and after each 10 week session.

The statistical tests used were exact binomials and t-tests of means for descriptive data. The first analysis and two refinements use an incidence density approach, equivalent to a 2 X 1 Chi-square comparison of the observed to expected number of falls in each study arm.[18] The third stage analysis would also incorporate a theoretical model based on baseline fall rates analogous to a Chi-square goodness of fit approach. It is in the calculation of the expected number of falls that one can adjust for unequal group size as well as an unequal baseline risk of falls. The unit of analysis used is a man-session. The analysis does not pair data but uses aggregate data. For example, if 7 subjects were randomized to treatment then to controls (Group A) while 6 other subjects were first assigned as controls then crossed over to treatment (Group B) there are 13 man-sessions in the treatment arm and 13 man-sessions in the control arm. The expected number of falls are calculated from the null hypothesis that exercise had no effect; ie, that the baseline fall rates continue for the duration of each 10 week arm. These arms are the combination of Groups A and B but may not be identical if some subjects dropped out of one arm but not the other.

If a third stage analysis were needed to adjust for differences in the baseline fall risk between study arms the method to calculate the expected number of falls under the null hypothesis (no exercise effect) is as follows:

Exercise Arm: Number in arm = $N_{exercise}$; baseline fall risk = $B_{exercise}$; rate of falls per 10 week duration = $R_{exercise}$

Control Arm: Number in arm = $N_{control}$; baseline fall risk = $B_{control}$; rate of falls per 10 week duration = $R_{control}$

Total Number of observed falls is equal to the total number of expected falls = T_{falls}

The two unknowns are $R_{exercise}$ and $R_{control}$.

The two equations used to solve for these values are:

$$B_{exercise}/B_{control} = R_{exercise}/R_{control}$$

$$N_{exercise} \times R_{exercise} + N_{control} \times R_{control} = T_{falls}$$

After solving the values of $R_{exercise}$ and $R_{control}$ one multiplies by the number in each arm to get the expected number of falls under the null hypothesis.

The State of Hawai'i Department of Health Institutional Review Board gave approval for the use of human subjects.

Results

Twenty-seven subjects volunteered to participate in the crossover study, of whom all were current residents of assisted living. If subjects did not keep more than 70% of their treatment sessions they were dropped from the study. By random assignment 12 subjects were assigned to Group A and 15 to Group B (of which 6 dropped out during their intervention period.) Of these 6 who dropped out from Group B, 3 did so after the first week, 2 after the second and 1 after the third. Of the 6 who dropped out there was a total of 11 falls registered during the 18 months prior to the start of the study (baseline). No subject dropped out during assignment as a control (initially or after crossing over). This resulted in a total of 27 man-sessions in the control arm and 21 man-sessions in the treatment arm.

Eighty-five percent of the subjects were women with an average age of 88 years (standard deviation [SD] 5.2) and average time in facility of 35 months (SD 23.8). During the 18 months prior to the start of the study those who were in the facility (n=21) reported an average of 2.3 (SD 3) falls per individual. For those who were institutionalized for the entire 18 month period prior to the start of the study, Group A had a fall rate for these 18 months of 33 falls/11 subjects=ave.3 and Group B had an average of 16 falls /11subjects=ave. 1.5.

Using baseline fall data, the expected number of falls during the study period for the study arms was 9 for intervention and 11 for control. The first stage of analysis using data from both groups A and B shows the intervention (n=21) and control arms (n=27) experiencing an observed number of falls of 7 and 13, respectively (Table 1). Chi-square value for this analysis is 0.80, corresponding to a *P*-value of 0.35. Baseline fall rates between intervention and control arms did not differ significantly, even after adjusting for dropouts in the exercise groups.

The 15 subjects in Group B (started with assignment to control arm) experienced a total of 10 falls during their control weeks. For the 12 controls from Group A, however, there were only 3 falls during the control period. This lower rate of falls during Group A's control session suggests that there might have been a residual effect of the exercise session carrying over and tainting results in the control period. Furthermore, this argument is strengthened if one considers that baseline fall rates were higher for Group A (3 per subject per 18 months) than for Group B (1.5 per subject per 18 months). After removing the potentially contaminated controls of Group A, the intervention arm (n=21) had an observed fall number of 7 while the control arm (n=15) experienced 10 falls. These values correspond to new expected total falls of 9 for the intervention group and 7 for the control group (Table 2). Chi-square value for this first refinement is 2.20, corresponding to a *P*-value of .15.

The third data analysis adjusts for the higher risk of falls at baseline present in the treatment arm compared to the control arm as a result of removing controls contaminated by primary participation in the intervention group. This relative risk at baseline is 2.6 : 1.8 = 1.4, causing it to be a potential confounding factor. The calculation of adjusted expected values is described in the methods section with results shown in Table 3. The Chi-square value for the comparison between observed and expected number of falls is 4.9, corresponding to a *P*-value of .025 showing a statistically significant reduction in the number of falls for subjects participating in the program.

The average mental status score for all subjects at the beginning of the study was 4.6 with a 95% confidence interval (CI) (3.4-5.8). For those (n=21) who participated in MWB sessions the average change in mental status scores was -0.17 with a 95% CI (-1.2- 0.93). Excluding contaminated controls and controls who lacked before and after mental status testing, the change was 0.83 with a 95% CI (0.0-1.7) for those in the control group (n=12.) These results do not show a significant change. The six dropouts had a mean mental status score of 3.7, near the lower limit of the confidence interval of the mean scores of the entire group.

Table 1. Table of expected vs observed number of falls for the intervention vs control groups using aggregate data from both Groups A and B. Corresponding *P*-value is .35.

	Intervention (n*=21)	Control (n=27)
Observed Total Falls	7	13
Expected Total Falls	9	11
Baseline Falls	39 falls/15 persons=2.6 ave.	49 falls/20 persons=2.45 ave.

*N = number of man sessions

Table 2. Table of expected vs observed number of falls for the intervention arm and uncontaminated controls. Corresponding *P*-value is .15 for this first refinement of the data.

	Intervention (n=21)	Control (n=15)
Observed Total Falls	7	10
Expected Total Falls	9	7
Baseline Falls	39 falls/15 persons = 2.6 ave.	16 falls/9 persons = 1.8 ave.

Table 3. Table of expected vs observed number of falls for the intervention arm and uncontaminated controls following a second refinement of the data. *P*-value corresponding to this table is .025.

	Intervention (n=21)	Control (n=15)
Observed Total Falls	7	10
Expected Total Falls	11.3	5.7
Baseline Falls	39 falls/15 persons = 2.6 ave.	16 falls/9 persons = 1.8 ave.

Discussion

The risk of falling is a clear burden on the elderly that can lead to physical and psychological complications, as well as the need to transfer previously independent seniors to expensive skilled-nursing facilities. This pilot study has shown that participation in physical and mental exercise classes may offer some risk reduction potential for ambulatory seniors. The data indicates that seniors experienced a statistically significant ($P < .05$) decrease in fall incidence as a result of treatment after accounting for contamination of controls and adjusting for different baseline risk of falls between the treatment and control study arms. Besides the promise of efficacy during the intervention itself, our study shows the possibility that the residual effects of exercise may be significant as well. While this effect ruined the cross over study design, the authors were happy to see it, as it could represent a valuable aspect of this public health intervention – especially when programs are short of resources and cannot provide ongoing MWB classes for everyone. Future studies, which try to confirm our results, should focus on this equally important aspect of residual effect. Until it can be clearly shown how long this effect lasts a cross over design to control for confounders should not be attempted. .

While this study has shown some promise for demonstrating the effects of an effective treatment program for fall prevention, a longer study period with a larger sample size is necessary to achieve more certain results. The original study design and protocol were also based on the assumption that 4 weeks was a reasonable period of time for residual effects of the exercise classes to subside. Previous research, however, has shown persistent effects of exercise programs on reducing fall incidence in the elderly.[19] The mental status examination given to subjects may not have been sensitive enough to pick up potential benefits of the exercise program. Alternatively there may have been a subtle effect on mental status change but only detectable following a much longer period of intervention. For now the reduction in falls is the best outcome marker to follow.

One remaining source of confounding that needs further discussion are the dropouts of Group B, who left after they starting the exercise arm. These 6 dropped out during the first 3 weeks of MWB sessions after completing the control arm. Could it be that these six were especially vulnerable to falls? That had they continued in the exercise arm their higher rate of falls would have lowered the significance of our findings regarding exercise efficacy? If one examines their baseline fall risk there were a total of 11 falls during the 18 months prior to the start of the study, a rate that is lower than the average baseline of 2.6 falls per person in the included treatment group subjects. This difference in risk suggests that had they not dropped out from the exercise arm the intervention might have shown an even greater effect on reducing falls.

Further research on the effects of physical fitness programs on elderly falls is necessary given the negative consequences on quality of life that the elderly suffer as a result of falling. In terms of prevention, exercise programs have the ability to enhance physical balance, reaction time, and visual-spatial awareness; a lack of which predisposes individuals to experience a fall.[20,21] Of course the effects of exercise in this group may not be so direct. It may be that exercise simply affords participants a good night's sleep that leads to reduced falls the following day. Reducing the incidence of falls amongst our nation's elderly will only become increasingly relevant as the population ages and the physical, mental, and financial toll of elderly falls rises.

Disclosures/Conflict of Interest

Necessary funding for this study was provided from a grant awarded by the Home Instead Senior Care Foundation, Omaha, NE.

Karen Peterson is the founder of *Move With Balance*® and has published a book *Move With Balance®: Healthy Aging Activities for Brain and Body*, which outlines the method of the program for further duplication. (2013, ISBN-13 978-0-9859938-0-1).

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References

1. Siracuse J, Odell D, Gondek S, et al. Health care and socioecomomic impact of falls in the elderly. *Am J Surg.* 2012;203:335-338.
2. Hawaii State Department of Health. Hawaii Injury Prevention Plan 2012-2017. Available: http://hawaii.gov/health/healthy-lifestyles/injury-prevention/PDF/HIPP%20Final%20Aug%202012.pdf. Accessed May 18, 2013.
3. Hausdorff JM, Rios DA, Edelberg HK. Gait Variability and Fall Risk in Community-Living Older Adults: A 1-Year Prospective Study. *Arch Phys Med Rehabil.* 2001;82:1050-1056.
4. National Center for Injry Prevention and Control, Centers for Disease Control and Prevention. Web-based injury statisitcs query and reporting system. Available at: http://www.cdc.gov/injury/wisqars/index.html. Accessed July 8, 2012.
5. Tinetti M, Doucette J, Claus E, et al. Risk factors for serious injury during falls by older persons in the community. *J Am Geriatr Soc.* 1995;43:1214-1221.
6. National Center for Injry Prevention and Control, Centers for Disease Control and Prevention. Web-based injury statisitcs query and reporting system. Available at: http://www.cdc.gov/injury/wisqars/index.html. Accessed July 8, 2012.
7. Rubenstein LZ, Josephon KR. Falls and Their Prevention in Eldelry People: What Does the Evidence Show? *Med Clin N Am.* 2006;90:807-824.
8. Pawlson LF, Goodwin M, Keith K. Wheelchair use by ambulatory nursing home residents. *J AM Geriatr Soc.* 1986;34:860-864.
9. Vellas BJ, Wayne SJ, Romero LJ, et al. Fear of falling and restriction of mobility in elderly fallers. *Age Ageing.* 1997;26:189-193.
10. Centers for Disease Control and Prevention. Residents Living in Residential Care Facilies: United States, 2010. Available: http://www.cdc.gov/nchs/data/databriefs/db91.htm. Accessed July 22, 2012.
11. Meyers AH, Young Y, Langlois JA. Prevention of falls in the elderly. *Bone.* 1996;18 Suppl:87S-101S.
12. Rubenstein LZ, Josephon KR. Falls and Their Prevention in Eldelry People: What Does the Evidence Show? *Med Clin N Am.* 2006;90:807-824.
13. Centers for Disease Control and Prevention. Falls in Nursing Homes. Available: http://www.cdc.gov/HomeandRecreationalSafety/Falls/nursing.html. Accessed July 22, 2012.
14. Federal Emergency Management Agency. Leading Community Risk Reduction. Available: http://www.usfa.fema.gov/pdf/efop/efo42424.pdf. Accessed July 24, 2012.
15. Carter ND, Khan KM, McKay HA, et al. Community-based excerise program reduces risk factors for fals in 65- to 75-year-old women with oseoporosis: a randomized controlled trial. *Can Med Assoc J.* 2002;167:997-1004.
16. American Society on Aging. Recognizing Innovations in Mental Fitness Programming for Older Adults. Available: http://www.asaging.org/mindalert-award. Accessed September 10, 2012.
17. McMichael KA, Vander Bilt J, Lavery L, et al. Simple Balance and Mobility Tests Can Assess Falls Risk When Cognition is Impaired. *Geriatr Nurs.* 1996;143:1129-1136.
18. Kleinbaum DG, Kupper LL, Morgenstern H. *Epidemiologic Research Principles and Quantitative Methods.* 1982:284-290.

19. Bird ML, Hill KD, Fell JW. A Randomized Controlled Study Investigating Static and Dynamic Balance in Older Adults After Training With Pilates. *Arch Phys Med Rehabil.* 2012;93:43-49.
20. King EC, Mckay SM, Cheng KC, et al. The use of peripheral vision to guide perturbation-evoked reach-to-grasp balance-recovery reactions. *Exp Brain Res.* 2010;207:105-118.
21. Van Imp A, Coxon JP, Goble DJ, et al. Ipsilateral coordination at preferred rate: effects of age, body side and task complexity. *Neuroimage.* 2009;47:1854-1862.