Effectiveness of a Community-Based Multifactorial Intervention on Falls and Fall Risk Factors in Community-Living Older Adults: A Randomized, Controlled Trial

Anne Shumway-Cook,1 Ilene F. Silver,2 Mary LeMier,2 Sally York,3 Peter Cummings,4 and Thomas D. Koepsell4

1Department of Rehabilitation Medicine, University of Washington, Seattle.
3NorthWest Orthopaedic Institute, Tacoma.
4Department of Epidemiology and Harborview Injury Prevention and Research Center, University of Washington, Seattle.

Objective. The purpose of this study was to evaluate the effectiveness of a 12-month community-based intervention on falls and risk factors (balance, lower extremity strength, and mobility) in community-living older adults.

Methods. Four hundred fifty-three sedentary adults (65 years old or older) were randomized to either a multifaceted intervention (3 times a week group exercise, 6 hours of fall prevention education, comprehensive falls risk assessment results sent to primary health care provider) or control group (written materials on falls prevention). Primary outcome was fall incidence rates calculated from self-reported falls reported monthly for 12 months. Secondary outcomes were tests of leg strength, balance, and mobility prior to and following the 12-month intervention.

Results. Twelve-month follow-up was completed on 95% of participants. Intent-to-treat analysis found that the incidence rate of falls was 25% lower among those in the intervention group compared with control group (1.33 vs 1.77 falls/person-year, rate ratio 0.75, 95% confidence interval [CI], 0.52–1.09). This difference was not statistically significant. The risk ratio for any fall was 0.96 (95% CI, 0.82–1.13). Small but significant improvements were found on the Berg Balance Test (adjusted mean difference +1.5 points, 95% CI, 0.8–2.3), the Chair Stand Test (adjusted mean difference +1.2, 95% CI 0.6–1.9), and the Timed Up and Go Test (adjusted mean difference –0.7, 95% CI, –1.2 to –0.2).

Conclusions. A community-based multifaceted intervention was effective in improving balance, mobility, and leg strength, all known fall risk factors. Although the incidence of falls was lower, the confidence interval included the possibility of no intervention effect on falls.

Methods

The study was conducted by the Washington State Department of Health at two Washington State sites: Pierce County (Northwest Orthopaedic Institute, a nonprofit medical research and education organization) in western Washington, and Spokane County (Spokane Regional Health District) in eastern Washington. Enrollment activities were conducted from September 2003 through April 2004.

Study Participants

Volunteer participants were recruited through press releases and advertisements in newspapers, senior newsletters, a commercial advertising mailing service, and cable television programming. Approximately 70,000 adults older than 65 years live in Spokane County and in Pierce County, Washington, the two counties targeted for this trial. Eligibility screening occurred in two steps. An initial telephone interview screened based on the following criteria: age 65 years or older, community-dwelling, English-speaking, have a primary care physician seen within the previous 3 years, independent ambulators (could use a cane or walker), willingness to participate in group exercise.
classes for at least 6 months, access to transportation, minimal hearing and vision impairments, and no regular exercise in the previous 3 months. A follow-up in-person enrollment interview required potential participants to complete a 10-foot Timed Up and Go Test in < 30 seconds (7) and be able to pass the Pfeiffer Short Portable Mental Status Questionnaire with fewer than five errors (8) as eligibility screening tests. The study protocol was approved by the Human Research Review Section of the Washington State Department of Health.

Power calculations indicated that a total sample size of at least 476 was needed to achieve 80% power to detect a decrease in fall incidence of 29% or more, using alpha = .05 for a two-sided test and assuming 15% dropouts. These estimates were based on Monte Carlo simulations that assumed that falls would follow a Poisson distribution (9,10).

Participants were randomized to the control or intervention groups after completing the informed consent process and the health history questionnaire. Study enrollment staff was blinded to the randomization schedule, which was managed in a centralized location; randomization results were given to the designated study staff member after each participant completed the informed consent process and revealed to the participants after all enrollment data were collected.

A separate allocation sequence was generated for the two county recruitment sites using a computerized pseudorandom number generator to assign participants in equal numbers to intervention or control arms using permuted blocks randomly selected to be size 4 or 6. The allocation lists were prepared before any enrollments by an investigator who had no contact with study participants. Information about the blocking was not revealed to the screening staff. When an eligible individual passed the screening tests and signed the consent form, the designated study staff member telephoned the Olympia office, the individual was enrolled, and then the treatment arm was revealed to the screening staff and the participant.

**Intervention**

Intervention activities began in September 2003 and were completed in May 2005. Participants in the intervention group were given the opportunity to participate in group exercise classes (for 1 hour, 3 times a week for up to 12 months at the study exercise class community site of their choice) and in 6 hours of falls prevention group education classes. A summary of the intervention group participants’ fall risk assessment was mailed to their primary care physicians, with a copy of the Guideline for the Prevention of Falls in Older Persons (4). The exercise intervention used a community-based group exercise curriculum for seniors that had been previously shown to improve physical function (11,12); however, its effect on falls was unknown. Community organizations (three older adult residential facilities, two senior centers, two parks and recreation facilities, and one fitness facility) were recruited by the study sites to offer the exercise intervention and were provided with technical assistance, marketing support, exercise instructor training, equipment, and financial reimbursement necessary to offer exercise classes free of charge to the study participants. Each exercise class used a standardized format that included 30 minutes of moderate-intensity aerobic conditioning, 20 minutes of progressive strength training, and 10 minutes of flexibility and balance exercises, exercises known to impact fall risk (13,14). Strength training involved progressive resistive exercises, using adjustable 1- to 10-pound ankle and wrist weights. A sequence of progressively more difficult exercises to improve static and dynamic balance was also performed (15). Although exercises could be done seated, the importance of doing exercises in a standing position to improve balance was stressed. Intervention participants received telephone follow-up if their monthly exercise class attendance fell below 70% to determine reasons for low participation and to encourage resumption of exercise. Exercise instructors (certified fitness trainers) were evaluated twice during the study period to assure compliance with exercise protocols.

The intervention education component, presented by a nurse, included six 1-hour classes presented once a month in each group exercise class. The education component topics included falls risk and prevention, exercising after illness or injury, home safety, medication safety, footwear and use of gait devices, and strategies for exercise adherence. At enrollment, individuals in the control group were given two fall-prevention brochures developed by the Centers for Disease Control and Prevention: “What You Can Do to Prevent Falls,” and “Check for Safety: A Home Fall Prevention Checklist for Older Adults.”

**Data Collection**

Potential participants who passed the Timed Up and Go and Pfeiffer Short Portable Mental Status Questionnaire eligibility screening tests were accepted for enrollment. Enrolled study participants completed a health history questionnaire administered by a registered nurse that included their demographic data, health and exercise history, and health-related fall risk factors. Fall risk factors that were included in the Health History Questionnaire were selected from those most commonly used and recommended for fall screening and included: history of falls in the last 3 months, history of falls-related injuries in last 3 months, fear of falling or activity self-restriction due to fear of falls, comorbid conditions, polypharmacy (taking four or more medications and/or the use of medications known to increase fall risk [tranquilizers, antidepressants, antihypertensive, diuretics]), use of assistive device for walking, alcohol use of more than one drink daily, sensory impairment (vision, hearing, or touch), impaired balance and gait, lower extremity weakness, and reduced participation in physical activity (16,17). None of the participants received written results of their identified falls risk factors. Data on exercise class attendance in the intervention group were also collected in each class.

The main outcome measured was the incidence rate of falls based on self-reported data supplied on 12 monthly calendars. Falls were defined as unintentional descents to the ground or other supporting surface. A telephone call was made if a calendar was not received and (in the event of a fall) to determine if the fall was injurious and required medical attention. At enrollment and at the end of 1 year of
follow-up, a physical therapist, blind to group assignment, conducted tests of leg strength (Repeated Chair Stand test) (18), balance (Berg Balance Test) (19), and mobility (Timed Up and Go test) (20), which were viewed as important secondary outcomes because of their previously observed association with fall risk in community elders (20–23).

Statistical Analysis
As falls within an individual may not be independent, we used a distribution-free Monte Carlo method for the analysis of fall incidence rates (24). The fall incidence rate was the number of falls divided by the total follow-up time. Using the known outcomes, participants were randomly reassigned to the trial arms (within their enrollment center and accounting for the permuted block design) to generate 20,000 rate ratio estimates; this sample of outcome permutations was used to estimate confidence intervals (CI) and a p value for the incidence rate ratio. The standard error of fall incidence rates was estimated from Poisson regression with a robust (sandwich) variance estimator (24), which produced CI values nearly identical to those from the Monte Carlo method. For the analysis of leg strength, balance, and mobility, all of which were continuous score outcomes, we estimated mean differences and CI values, adjusted for baseline scores, using a linear mixed model with study county as a random effect (25,26). Because final score results were missing for 5% of the participants, we multiply imputed the missing values and repeated the analyses using the multiply imputed data (27–30).

To examine the relationship between adherence and falls, we compared the fall incidence rate at three levels of adherence in the intervention group (> 75%, 75%–33%, ≤33% attendance). Because previous research has shown that people who are highly compliant tend to have better outcomes independent of the intervention (31), we used an instrumental variables analysis to compare fall incidence rates among participants in the intervention arm who attended at least 2/3 of their exercise classes to participants in the control arm who would have shown comparable compliance had they been assigned to the intervention arm (32,33). We calculated incidence rate ratios for the number of falls and the risk ratio for any fall, and used jackknife methods to estimate CI values (34). Analyses were done using Stata software (Stata Statistical Software, release 9.0; Stata Corporation, College Station, TX).

To examine the results of randomization, we compared baseline characteristics of the intervention and control participants using chi-square tests or the Fisher exact test, and we tested whether the probability of each treatment assignment was associated with the four main study outcomes within enrollment center, adjusted for actual treatment assignment (35,36).

RESULTS
We enrolled 453 of the 517 people (88%) who were screened and found eligible for the study (Figure 1). Of the individuals not meeting inclusion criteria (n = 142), most were excluded because they had participated in regular exercise more than twice a week during the 3 months prior to screening. Of 64 people who may have been eligible, 60 declined after the telephone screen, 4 after the in-person interview. Of the 453 individuals who enrolled in the study, 429 (95%) completed their full year of follow-up and returned for their exit interview and final testing.

The main analysis of all study outcomes was by intention to treat. For fall frequency, we report on all (n = 453) participants. For 11 participants who died or withdrew for health or personal reasons before completing 1 year of follow-up, we included their fall data up to the date of study withdrawal. We found almost no difference in mean follow-up time between intervention and control groups (.986 years vs .989 years; p = .67 for a t test of mean difference). For secondary outcomes related to balance, leg strength, and mobility, we report on the 429 participants for whom we had both baseline and final test scores. Final tests could not be done for 24 participants due to death (n = 5), illness or disability (n = 8), geographic relocation (n = 4), or other reasons (n = 7). There were no adverse effects associated with participation in the intervention.

Baseline Characteristics
At enrollment the mean age of study participants was 75.6 years (standard deviation [SD] 6.3, range 65–96 years). Most participants were female (77%) and white (96%). Table 1 compares risk factor profiles in the two groups. There were no significant differences between groups at baseline. The probability of treatment assignment was not statistically associated with any of the outcomes (p ≥ .12 for all outcomes).

Effect of the Intervention
The incidence rate of falls was 25% lower among participants in the intervention group than among those in the control group (1.33 vs 1.77 falls/person-year, rate ratio 0.75, 95% CI, 0.52–1.09) (Table 2). This comparison was influenced by a few people who had a large number of falls. The distribution of fall counts was quite similar between the groups except for the few participants with ≥10 falls. The risk of experiencing at least one fall during the follow-up year was only slightly lower in the intervention arm: risk ratio 0.96 (95% CI, 0.82–1.13). The incidence rate of falls with a medical visit was lower in the intervention group (0.18 falls/person-year) than in the controls (0.21 falls/person-year); rate ratio 0.72, 95% CI, 0.45–1.15; p = .16.

Participants in the intervention group had small but significantly greater improvements on all secondary outcome measures including balance, leg strength, and mobility (Table 3). After we adjusted for their baseline values, participants in the intervention group had a higher mean score on the Berg Balance Test (adjusted mean difference +1.5 points, 95% CI, 0.8–2.3), a higher count on the Chair Stand Test for leg strength (adjusted mean difference +1.2, 95% 0.6–1.9), and a shorter time on the Timed Up and Go Test for mobility (adjusted mean difference −0.7, 95% CI, −1.2 to −0.2). Using the multiply imputed data, the results for the Berg Balance and Chair Stand tests were unchanged, and the Timed Up and Go mean difference was −0.8, 95% CI, −1.3 to −0.2.
In an exit interview, fall risk factors were re-examined, and participants answered questions about changes they had made during the study. Participants in the intervention arm were more likely to have increased their exercise (65%) compared with controls (33%) (difference 31%, 95% CI, 22%–40%) and more likely to have discussed falls with their health care provider (19%) than were controls (11%) (difference 8%, 95% CI, 1%–15%). The two groups did not differ with respect to reviewing medications, making safety changes in the home, having a vision check, having other health problems checked, or making other changes related to management of fall risk factors.

Post hoc subgroup analyses were performed to test the hypothesis that the intervention would have a greater impact on specific subgroups based on age, gender, and fall history. As shown in Table 4, there were no statistically significant differences in the fall incidence rate ratio in the subgroups; however, the study was not powered for subgroup analyses.
Adherence

Participation in the exercise intervention, measured by the proportion of exercise classes attended, ranged from 9% to 97%, with a median of 86% (interquartile range 15%–75%). Participants in the intervention group who attended ≥75% of exercise classes (n = 56) had 41% fewer falls compared to those who attended ≤33% of exercise classes (n = 79) (0.82 vs 1.39 falls/person-year, incidence rate ratio 0.59, 95% CI, 0.37–0.95). Fall incidence rate in the group who attended <75% but >33% had the highest fall incidence rate at 1.60, with an incidence rate ratio of 1.16 (95% CI, 0.77–1.76) compared to the group with the lowest level of adherence.

Using the instrumental variable analysis, the incidence rate of falls was 53% lower among participants in the intervention arm who attended 2/3 of their exercise classes compared to a comparable group in the control arm (incidence rate ratio 0.47, 95% CI, 0.20–1.07). Similarly, the risk of any fall was lower among participants in the intervention arm (incidence rate ratio 0.89, 95% CI, 0.57–1.38).

Based on the monthly phone follow-up of low exercise class attendance, the most frequently self-reported reason for missing exercise classes was health related (38%), followed by leisure-time conflict (26%), personal or family care issues (11%), transportation (9%), class difficulty (7%), and other reasons (8%). The distribution of reasons for nonparticipation in exercise classes remained similar during the 16-month period in which they were offered.

Discussion

This study evaluated the feasibility and effectiveness of a community-based falls prevention program implemented through state and local public health partnerships. We found that a community based, multifactorial program produced small but significant improvements in fall risk factors (strength, balance, and mobility), but did not reduce the incidence rate of falls in sedentary, healthy, community-living older adults in a 12-month period. The overall reduction in falls of 25%, although not statistically significant, is similar to that reported in several meta-analyses of
randomized controlled trials that assessed a variety of exercise interventions, including endurance, flexibility, balance, and strength training (5,6,37).

The lack of a statistically significant effect on falls could result from failing to target persons who would benefit most, an insufficiently potent intervention, or insufficient adherence to the intervention. The intervention targeted sedentary but otherwise healthy older adults, with 75% of the sample reporting no history of falls in the previous 3 months, 50% considered low risk based on initial Berg Balance Scores (≥50 of 56) (22), and only 15% with Timed Up and Go scores of >14 seconds, the suggested cut point for increased falls risk in community-living older adults (21,38). The program might have had a greater impact on fall rates if we had targeted older adults with increased risk as defined by significant lower extremity strength and balance impairments (15), older adults with a history of falls (4), women 80 years old or older (39), or adults 70 years old or older with one or more fall risk factors (40). Our post hoc analyses of subgroups did not find statistically significant variations in the intervention effect; however, our study was not powered for an analysis of subgroups. Finally, another possible explanation for the lack of effect on falls is that the participants who attended exercise class were in general more active than controls, and thus their exposure to fall opportunities was greater. Because we did not collect data on participation in physical activity (other than exercise adherence in the intervention group), we were unable to examine whether increased exposure to fall opportunities varied between participants in the intervention group compared to those in the control group.

Although the study included a comprehensive assessment of fall risk factors performed by a registered nurse, the management component was limited to mailing a summary of fall risks and recommended guidelines for management of these risks to each participant’s primary care physician. The study did not include a process for monitoring fall risk reduction recommendations. A number of studies in which strategies to reduce specific risk factors were implemented and monitored have been successful in reducing falls (41,42). A recent study suggested that an effective multifactorial risk management program requires educating both the health care provider and the patient regarding the management of fall risk factors (43). In our study providing participants with education regarding fall risk management and sending a summary of each participant’s fall risk factors and recommended management guidelines to their primary care provider did not result in a significant change to many of those fall risk factors. A more formal structure for managing fall risk factors by participants and educating their health care practitioners might have improved the effectiveness of this program.

The effectiveness of exercise programs for older adults hinges on being able to keep people engaged in exercise. Participants who attended exercise class on average 2.3 times per week had significantly fewer falls and better performance on balance and mobility measures compared to those whose attendance was less than one time per week, consistent with other studies reporting improved physical function in older adults who exercise a minimum of two times a week (14,44,45). We cannot rule out the possibility that people who comply tend to have better outcomes than people who do not comply, as the CI in our instrumental variables included the possibility of no intervention effect on falls. Therefore, further research is needed to elucidate the level of participation required to impact falls among community-dwelling older adults.

The most frequently reported reason given for a temporary lapse in exercise class attendance was health-related, consistent with other reports citing health status as a major factor in determining adherence to exercise in older adults (46–48). Older adults reported difficulty in resuming exercise following a change in health, and often did not discuss returning to exercise with their health care providers, thus an educational module on strategies for resuming exercise following health-related lapses was created.

The study found that it was feasible to implement a community-based falls prevention program using existing

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**Table 3. Effect of Intervention on Secondary Study Outcomes**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention (N = 212)</th>
<th>Control (N = 217)</th>
<th>Mean (SD)</th>
<th>Mean (SD)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berg Balance Test (range 0–56, higher is better)</td>
<td>50.3 (5.6)</td>
<td>50.2 (6.0)</td>
<td>51.1 (6.2)</td>
<td>49.4 (7.4)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Adjusted mean difference†</td>
<td>1.5 (95% CI, 0.8–2.3)</td>
<td>&lt;.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chair stand (count, higher is better)</td>
<td>8.6 (3.3)</td>
<td>8.5 (3.7)</td>
<td>10.8 (5.2)</td>
<td>9.5 (4.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Adjusted mean difference</td>
<td>1.2 (95% CI, 0.6–1.9)</td>
<td>&lt;.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timed Up and Go (s, shorter is better)</td>
<td>10.5 (2.8)</td>
<td>10.8 (3.3)</td>
<td>9.1 (3.5)</td>
<td>10.1 (4.4)</td>
<td>.005</td>
</tr>
<tr>
<td>Adjusted mean difference</td>
<td>−0.7 (95% CI, −1.2 to −0.2)</td>
<td>.005</td>
<td></td>
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</tr>
</tbody>
</table>

**Notes:** †Adjusted mean differences are the final intervention score minus the final control score, adjusted for each participant’s baseline score.

**Table 4. Incidence Rate Ratios for Falls in the Intervention Arm Compared With the Control Arm, by Study Subgroups**

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>N</th>
<th>Incidence Rate Ratio</th>
<th>95% CI</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>348</td>
<td>0.78</td>
<td>0.50–1.22</td>
<td>.79</td>
</tr>
<tr>
<td>Male</td>
<td>105</td>
<td>0.70</td>
<td>0.38–1.29</td>
<td></td>
</tr>
<tr>
<td>Fall in past 3 mo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>124</td>
<td>0.61</td>
<td>0.34–1.10</td>
<td>.20</td>
</tr>
<tr>
<td>No</td>
<td>329</td>
<td>0.95</td>
<td>0.68–1.33</td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 65</td>
<td>223</td>
<td>0.82</td>
<td>0.50–1.34</td>
<td>.65</td>
</tr>
<tr>
<td>≥76</td>
<td>230</td>
<td>0.69</td>
<td>0.41–1.18</td>
<td></td>
</tr>
<tr>
<td>Timed Up and Go, s</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 12</td>
<td>309</td>
<td>0.70</td>
<td>0.43–1.14</td>
<td>.54</td>
</tr>
<tr>
<td>≥12</td>
<td>144</td>
<td>0.87</td>
<td>0.52–1.46</td>
<td></td>
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</tbody>
</table>

**Notes:** *p values are for a test of no difference in the subgroup rate ratios. CI = confidence interval.
resources such as senior centers, parks and recreation programs, and assisted and independent living facilities that have the capacity to offer group exercise programs to seniors. Critical to the successful implementation of this community-based program were the development of public–private and state–local partnerships and linkages between senior service, health care, and public health organizations. The strengths of the study were the completeness of data, with few study dropouts, high compliance with fall calendars, and the return of nearly all participants for a final testing. Thus, results may generalize to similar community-dwelling older adults, excepting those with major health conditions or functional impairments. The study participants provided a high amount of feedback on the interventions during phone follow-up for reported falls and in the exit interviews. This feedback was invaluable in identifying barriers to adopting fall prevention interventions as reported by community-dwelling older adults. Barriers identified by older adults included difficulty in discussing falls and fall prevention strategies with their health care provider, a lack of awareness regarding their own risk factors and strategies to reduce their own risk, a lack of information about, and access to, community resources for falls prevention, and a lack of support by health care providers in helping older adults initiate and maintain an appropriate exercise program.

**Conclusion**

A community-based multifactorial intervention including exercise, individualized fall risk assessment, and education on falls prevention was successful in improving modifiable fall risk factors including strength, balance, and mobility, but did not significantly affect the incidence rate of falls. Additional research is needed to understand and respond to reasons for low participation in exercise classes, the effects of formally involving community-dwelling older adults in identifying and addressing their individual risk factors, identifying an exercise threshold that reduces falls in older adults with varying levels of risk, and the role of health care professionals in promoting falls prevention and exercise adherence in older adults.

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**Author Contributions:** Anne Shumway-Cook, study concept and design, interpretation of data, preparation of manuscript; Ilene Silver, study concept and design, interpretation of data, preparation of manuscript; Mary LeMier, study concept and design, subject acquisition, data collection, analysis and interpretation of data, preparation of manuscript; Thomas Koepsell, data analysis and interpretation of data, preparation of manuscript.

**Correspondence**

Address correspondence to Anne Shumway-Cook, PhD, Department of Rehabilitation Medicine, Box 356490, University of Washington, Seattle, WA 98195. E-mail: ashumway@u.washington.edu

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