

# Assessing the Quality of a Non-randomized Pragmatic Trial for Primary Prevention of Falls among Older Adults

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**Abstract** Current approaches to falls prevention mostly rely on secondary and tertiary prevention and target individuals at high risk of falls. An alternative is primary prevention, in which all seniors are screened, referred as appropriate, and educated regarding falls risk. Little information is available on research designs that allow investigation of this approach in the setting of aging services delivery, where randomization may not be possible. *Healthy Steps for Older Adults*, a statewide program of the Pennsylvania (PA) Department of Aging, involves a combination of education about falls and screening for balance problems, with referral to personal physicians and home safety assessments. We developed a non-randomized statewide trial, Falls Free PA, to assess its effectiveness in reducing falls incidence over 12 months. We recruited 814 seniors who completed the program (503 first-time participants, 311 people repeating the program) and 1,020 who did not participate in the program, from the same sites. We assessed the quality of this non-randomized design by examining recruitment, follow-up across study groups, and comparability at baseline. Of older adults approached in senior centers, 90.5 % ( $n=2,219$ ) signed informed consent, and 1,834 (82.4 %) completed baseline assessments and were eligible for follow-up. Attrition in the three groups over 12 months was low and non-differential (<10 % for withdrawal and <2 % for other loss to follow-up).

Median follow-up, which involved standardized monthly assessment of falls, was 10 months in all study groups. At baseline, the groups did not differ in measures of health or falls risk factors. Comparable status at baseline, recruitment from common sites, and similar experience with retention suggest that the non-randomized design will be effective for assessment of this approach to primary prevention of falls.

**Keywords** Falls · Primary prevention · Aging services · Aging · Injuries

Falls prevention among older adults is a major public health challenge. Studies show that approximately one third of community-dwelling patients aged 65 years or older fall each year (Hammer 2010; Hausdorff et al. 2001). Among older adults, falls are the most common cause of non-fatal injuries as well as one of the top ten causes of death (National Center for Injury Prevention and Control 2012). While not every fall is injurious, falls in older adults may lead to decreased independence and social isolation due to fear of falling (Morley 2002). In 2005, costs associated with falls in the USA totaled about \$31.2 billion (including death, hospitalization, emergency department admissions, and loss of work days) (National Center for Injury Prevention and Control 2012; Stevens and Sogolow 2005). A challenge for public health is to reduce falls risk without encouraging reduced physical activity, which carries other risks.

Risk factors for falls have been the subject of much research. Rates for fall-related injuries are generally higher among women than men (Stevens and Sogolow 2005). Other well-known risk factors for falls include older age, white race (Stevens and Sogolow 2005), cognitive impairment (Whitney et al. 2012), medication (e.g., use of sedatives and hypnotics, antidepressants, and benzodiazepines) (Woolcott 2009), balance and gait problems (Tinetti and Kumar 2010), lower

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extremity weakness (Grabiner et al. 2008), Parkinson's disease (Hiorth et al. 2013), hypertension (Gangavati et al. 2011), stroke (Batchelor et al. 2012), arthritis (Levinger et al. 2011), vision and hearing impairment (Lopez et al. 2011), and environmental hazards (Chase et al. 2012).

Given the high prevalence of falls and their impact on older adults' quality of life, interventions to reduce the risk of falls are a high priority. Targets for falls prevention include assessment and modification of environmental hazards (Salkeld et al. 2008), group exercise programs for balance and lower extremity strength (Skelton et al. 2005), medication review (Pit et al. 2007), and educational programs to sensitize older adults to falls risk situations (Hill et al. 2011). Other approaches stress multifactorial interventions that combine assessment of individual risk factors with tailored interventions. These include counseling and guidance in fall prevention, home hazards assessment, group exercise, psychosocial support (Salminen et al. 2009), referral to community falls prevention services (Logan et al. 2010), or a combination depending on an individual's particular risk profile.

The efficacy of these interventions has been assessed in a number of meta-analyses and systematic reviews (Gates et al. 2008; Sherrington et al. 2011; Chase et al. 2012), but recommendations for optimal falls prevention are still evolving (Moyer and US Preventive Task Force 2012; American Geriatrics Society 2010). An updated Cochrane Review reported that exercise and home safety programs reduce the rate of falls and risk of falling, but did not find benefit for interventions that increased knowledge about falls prevention without additional components (Gillespie et al. 2012).

An alternative to current approaches to falls prevention, which mostly rely on secondary and tertiary prevention, is primary or universal prevention. Primary prevention in the case of falls involves screening all older adults for balance and mobility problems, identifying potential risk factors for balance and mobility problems in people who may not have fallen, and developing appropriate referral mechanisms to address these falls risk factors. This approach differs from secondary prevention, which stresses outreach to people who are already aware of their falls risk status or who have a medical condition that increases their risk of falls. It differs as well from tertiary prevention, which seeks to reduce risk for falls among people who have already fallen and are usually identified in falls clinics or emergency departments.

The Pennsylvania (PA) Department of Aging has implemented a primary prevention approach to falls, *Healthy Steps for Older Adults*, a short-term, low-cost program in senior center settings that involves a combination of screening for balance problems and education about falls risk, along with referral to physicians and home safety assessments for older adults identified in the program as at risk for falls (Health Research for Action 2013; PA Department of Aging 2013). The half-day *Healthy Steps* program also offers a wide range

of falls-related education, covering exercise, physical hazards in the home, and medication usage.

In 2010–2013, we developed a research study, Falls Free PA, to assess the effectiveness of *Healthy Steps for Older Adults* in reducing falls incidence. This research can be considered a pragmatic effectiveness trial in that we compared participants in the program to a comparison group recruited from the same sites at the same time. We describe the design of this pragmatic trial, along with recruitment and follow-up, and compare characteristics of participants in the intervention with the comparison group. The trial did not allow randomization because the study was added to ongoing delivery of the program. However, comparable status at baseline, recruitment from common sites, standardized monthly assessment of falls in both groups, and similar experience with retention over follow-up would suggest that differences in falls incidence can be investigated well in this non-randomized design. To assess equivalence of the groups at baseline, we also examined retrospective reports of falls in the prior year in multivariate models.

## Methods

We assessed the effectiveness of Pennsylvania's *Healthy Steps for Older Adults* in reducing the incidence of falls by enrolling three groups of older adults. One group consisted of older adults completing *Healthy Steps* for the first time in 2010–2011. We enrolled about 12.5 % (503/4,040) of the total number of seniors in the state taking the program in the fiscal year. A second group consisted of an additional 311 seniors who completed *Healthy Steps* in 2010–2011 but had also taken the program in the prior 1–2 years. The two groups allow assessment of different “doses” of the program. Finally, we enrolled the comparison group ( $n=1,015$ ) from the same sites at the same time who did not take *Healthy Steps* but attended other programs, such as lunch or recreation programs. All groups completed an in-person telephone baseline interview after providing informed consent, and all were followed up to a year in monthly automated or in-person telephone interviews to track falls.

The University of Pittsburgh Institutional Review Board approved the research. All participants signed informed consent, which was obtained in person or mailed to the research team after participants discussed the study by telephone with research staff.

The project included a data-sharing agreement with the PA Department of Aging and involved PA Department of Aging staff as well as county Area Agency on Aging (AAA) health promotion coordinators (PrimeTime Health) at local sites. Stakeholders were engaged in the project from the start, both in the design phase and in follow-up through monthly conference calls. For example, the decision to include a group taking

the program for the second time came from local PrimeTime Health coordinators.

#### Inclusion/Exclusion Criteria

Adults aged 50 years and older attending PA Department of Aging programs in senior centers and venues offering *Healthy Steps* (for example, senior residential sites and churches) were eligible to participate. Exclusion criteria included inability to provide informed consent, language other than English or Spanish, residence in a skilled nursing facility, and inability to participate in telephone follow-up. Mobility limitation and prior history of falls was not a cause for exclusion, since *Healthy Steps* is offered to all seniors, including seniors who use assistive devices. We assessed cognitive status by telephone but did not exclude participants on this basis unless participants were unable to consent or participate in telephone assessments.

#### Recruitment

In a partnership with the PA Department of Aging, the research team contacted local Area Agencies on Aging (AAA), which deliver aging services in PA counties. County AAA PrimeTime Health coordinators publicized the study, which included explaining the study to local site staff, sharing schedules for *Healthy Steps* programs with the research team, and helping research staff identify people who had completed *Healthy Steps* (which was subsequently verified with state program data) and maintain contact with participants over the course of follow-up.

The research team identified *Healthy Steps* participants either by contacting them at sites on the day of the program, or by calling them shortly after they had completed the program. Research staff recruited non-participants through presentations at the same sites. Sixty sites in 19 counties participated, so the research team traveled the length of the state for recruitment.

Special efforts were made to recruit minority seniors. The research team targeted senior centers with largely African-American attendance in Pittsburgh, Philadelphia, and other urban centers. The study also sought to enroll Latino seniors in areas with high concentrations of Spanish speakers, including Philadelphia and Lancaster county.

#### Pragmatic Trial Rather than Randomization

Falls Free PA participants were not randomly assigned to study conditions for the following reasons: (i) the interval between the time the *Healthy Steps* program was announced and offered was in most cases very short, which prevented identification of participants who could be randomly assigned before the program was offered; (ii) many participants were

walk-ins who signed up for the program that day; (iii) sites offering the program were compensated by the PA Department of Aging and required to conduct health promotion efforts, and thus, many did not want to deny participants access to *Healthy Steps*. More generally, the Falls Free PA study was added to ongoing delivery of *Healthy Steps* with an attempt to avoid disruption of the program or add burden to local sites.

#### Intervention

Pennsylvania's Department of Aging has offered *Healthy Steps* on a statewide basis through its senior centers since 2007. The program was developed under the auspices of Health Research for Action at the University of California–Berkeley. Information about the program is available through the PA Department of Aging (2013). Each year, between 4,000 and 7,000 adults aged 50 years or older complete the program, and to date, approximately 32,000 people have participated. Overall, 40 of 67 PA counties have hosted *Healthy Steps*, which is funded through federal and state sources. Older adults may complete the program as part of their normal attendance at senior center events or specifically because of an interest in falls prevention.

*Healthy Steps* includes the following elements: physical performance assessments of balance and mobility conducted by staff or trained volunteers (Timed Get Up and Go, One-Legged Stand, 60-sec Chair Stand); referrals for physician care and home safety for participants scoring below age- and gender-based norms on performance assessments; and a 2-h falls prevention class involving recognition of home hazards and falls risk situations as well as demonstration of exercises designed to improve balance and mobility. Two of the performance tests, the Timed Up and Go and Chair Stand, are validated assessment tools included in the Centers for Disease Control and Prevention (CDC) Stopping Elderly Accidents, Deaths, and Injuries (STEADI) falls assessment tool kit (Stevens and Phelan 2013). Program data were entered in a standard web-based system and made available to the research team through a data-sharing agreement.

The PrimeTime Health office of the PA Department of Aging assures program fidelity by training staff at sites, monitoring data entry, conducting brief follow-up interviews with a random 10 % sample of participants after programs, and hosting monthly conference calls with county Area Agencies on Aging.

#### Identifying Falls: Automated Monthly Telephone Assessments

The primary outcome in this pragmatic trial was falls incidence over 12 months of follow-up, which we measured in two ways: (i) number of months in which participants reported

a fall (fall months) per 100 person-months of follow-up and (ii) number of fall months per 100 person-months of follow-up adjusted for how active participants were each month. The latter measure adjusted the denominator for follow-up time according to self-reports of activity. We also examined the number of people who reported falls in each group using the same denominators.

Falls and weekly activity were elicited in a monthly telephone call using an interactive voice response (IVR) system (Wijlhuizen et al. 2006). We tracked all falls, not just injurious falls. Participants who signed consent were registered in a web-based system that generated monthly telephone calls. Participants were scheduled for a call each month, every 30 days, beginning 30 days after their baseline interview. As the scheduled date approached, the automated system generated two calls each day (one morning, one evening) for up to 8 days around the scheduled day until the person answered and the monthly interview was completed. If a respondent did not complete the follow-up interview in the 8-day window, the follow-up was considered missing and a call was attempted in the next month.

The automated call elicited falls, weekly activity, hospitalization, and emergency department use in the past 30 days. A final question asked if participants would like to receive a telephone call from the research team. Respondents answered questions by pushing buttons on the telephone. For falls, respondents were asked, “Think about the last 30 days. Did you fall in the last 30 days, that is, end up on the floor or ground because you were unable to stop yourself? Press 1 for yes, 2 for no.” When participants reported a fall, the system generated an email message to the research team, who followed up with an in-person telephone interview to collect information about the fall.

About half of respondents completed all assessments by automated telephone contact, 20 % completed all follow-up with in-person calls, and the remainder was reached with a combination of the two. Participants could opt out of the automated IVR system at any point over follow-up. In-person telephone calls were reserved for people with hearing impairment, Spanish speakers, and people lacking touchtone telephones. The automated call, consisting of six questions, took a mean of 2 min to complete. To assess the reliability of IVR-reported falls, we compared falls reports from a subset of people ( $n=65$ ) who completed an IVR assessment and an in-person telephone assessment in the same month. In 62 (95.3 %) of the respondents, reports of falls were concordant across the in-person and automated calls.

#### Assessments

In addition to self-reported falls and activity over monthly follow-up, we collected measures at baseline, 6, and 12 months to assess comparability of the *Healthy Steps* and comparison

groups. Given the geographic dispersion of the sample across 19 PA counties, all measures were obtained by telephone. The following assessments were obtained in personal (not automated) telephone calls:

*Sociodemographics* Respondents reported birth date, race-ethnicity, gender, education, address, marital status, living arrangement, and adequacy of monthly income.

*Self-Reported Medical Conditions* Respondents were asked if a physician had ever diagnosed any of the following medical conditions: stroke, diabetes, high blood pressure, heart attack, macular degeneration, arthritis, osteoporosis, glaucoma, depression, chronic obstructive pulmonary disease, congestive heart failure, neuropathy, Parkinson’s disease, cognitive impairment, fractures, or cancer.

*Quality of Life* Respondents completed the EQ-5D to assess the domains of mobility, self-care, daily activities, frequency of pain, and symptoms of anxiety or depression, as well as ratings of global health (0–100 visual analog scale) (Kind et al. 1998; Shaw et al. 2005). Each of the five domains has three levels: no problems, some problems, extreme problems.

*Falls History and Self-Rated Balance, Mobility, and Use of Assistive Devices* Respondents rated their mobility and balance on 5-point Likert scales, as well as whether they used assistive devices. They reported if they had fallen in the past 30 days and past 12 months, and if so, whether they sustained injury or received medical care for the fall.

*Prescription Medications* Respondents were asked to gather all prescription medications before the call and reported names of medications and daily regimens of use. We calculated the total number of prescription medications each respondent reported.

*Memory Performance* Participants completed the Memory Impairment Screen-Telephone (MIS-T). In the MIS-T, respondents are tested to see if they can repeat four words along with a semantic category cue. They are then asked to remember the four words after 3–4 min of distraction (Buschke et al. 1999; Lipton et al. 2003). If they remembered the word without the semantic cue, they received 2 points. If they required the semantic cue, they earned 1 point. Scores ranged from 0 to 8. A score of 4 or less indicated possible dementia.

*Falls Self-Efficacy* Respondents completed the Falls Efficacy Scale, a 10-item measure of self-perceived risk of falls during different daily activities (Tinetti et al. 1990). The measure involves 10-point ratings of confidence in the ability to perform tasks without falling. We summed scores to develop a composite measure of confidence in performing tasks without falling.

**Daily Activities** Respondents completed the Community Healthy Activities Model Program for Seniors (CHAMPS) physical activity measure (Stewart et al. 2001). The questionnaire assesses weekly frequency and duration of 40 different activities typically undertaken by older adults. These range from highly prevalent activities, such as taking a walk, to participation in sports (tennis) or recreational activities (dancing). We summed the number of tasks performed in the prior week to develop a measure of total physical activity.

**Sample Size and Statistical Power**

Our sample of approximately 1,800 allowed 80 % power to detect incidence rate ratios of 0.876, 0.873, and 0.869, assuming retention rates of 90, 85, and 80 %, respectively. These correspond to reductions of 13–14 % in falls incidence, which we considered reasonable for this low-intensity, population-based program.

**Analyses of Differences between Healthy Steps and Comparison Groups**

Descriptive statistics were calculated for the *Healthy Steps* and comparison groups. Differences between groups at baseline were assessed by tests of means (*t*-tests and one way analysis of variance) and proportions ( $\chi^2$ ). A key measure of comparability was whether the two groups at baseline were equally likely to report falls in the year and month prior to the baseline interview. We developed logistic regression models to assess

whether the groups differed in prior falls experience after adjusting for other covariates related to falls risk.

**Results**

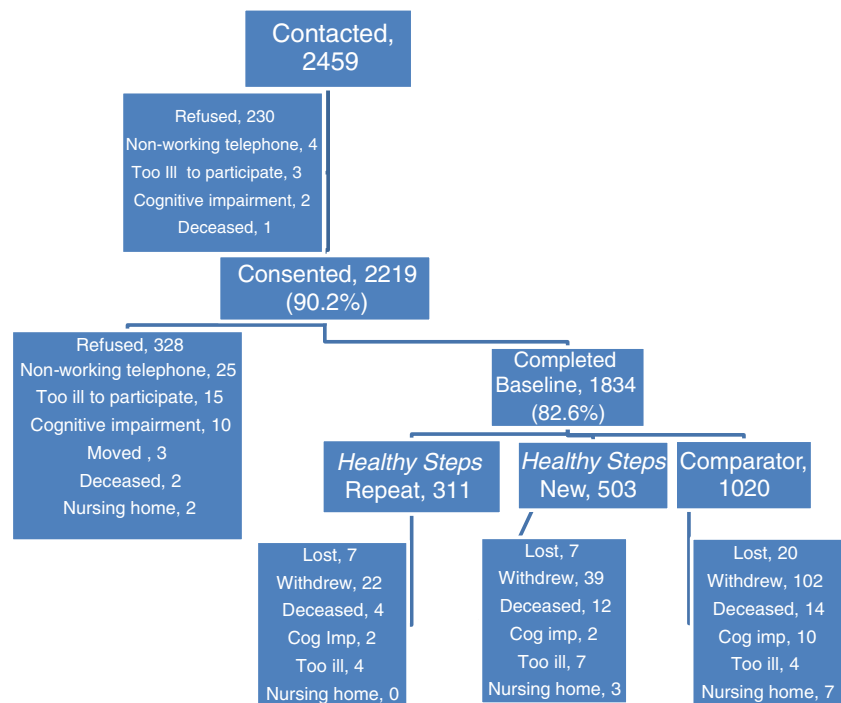
**Falls Free PA Sample Relative to State Healthy Steps Program Participation**

Falls Free PA enrolled participants in 19 counties. As mentioned earlier, the three study groups included 503 taking *Healthy Steps* for the first time, 311 taking the program the second time, and 1,020 in the comparison group. The *Healthy Steps* groups in Falls Free PA matched the geographic distribution of program participants in the state as a whole.

**Recruitment and Study Retention**

Figure 1 details study recruitment and retention. A total of 2,459 older adults were identified at senior centers offering *Healthy Steps* and agreed to give contact information to the research team. These people were mailed a consent form, given an opportunity to call the research team to discuss the Falls Free PA study, and asked to sign and return the consent form by mail. Ten percent (*n*=240) did not mail the signed informed consent form back to the research team. We determined that 10 were ineligible and considered the remaining 230 refusals. We have no further information about this refusal group because they did not sign consent and our protocol did not allow data collection before consent was obtained. Of the

**Fig. 1** Study flow chart



2,219 who signed consent, 1,834 (82.4 %) were successfully contacted and completed the baseline. Participants who did not complete the baseline ( $n=385$ ) included 328 refusals. Others were ineligible because of impairment, moves, or non-community residence (Fig. 1). In total, 74.6 % of people contacted (1,834/2,459) completed the baseline assessment and were eligible for follow-up. Ninety-seven percent (1,772/1,834) of participants completing the baseline provided one or more monthly follow-up assessments.

Attrition in the three groups was low and non-differential. As shown in Fig. 1, the proportion withdrawing from the study during follow-up was 8 % in the group who took *Healthy Steps* for the first time, 7 % in the group repeating *Healthy Steps*, and 10 % among those who had never taken *Healthy Steps*. Similar proportions were seen for loss to follow-up, death, nursing home admission, or inability to participate because of cognitive problems or illness (all <2 %).

Follow-up in the three groups was also similar. Median follow-up in the three study groups was 10 months, as indicated by completed monthly telephone assessments. In addition to monthly contact, 88.3 % ( $n=1,620$ ) completed more detailed in-person telephone interviews at 6 months and 86.2 % ( $n=1,581$ ) at 12 months.

#### Features of the Sample

The sociodemographic characteristics of the three study groups are presented in Table 1. Overall, the majority was women (79.1 %) and white (87.6 %), with a mean age of 75.6 (s.d., 8.5) years. This distribution is similar to *Healthy Steps* 2010–2011 participation in the state as a whole, which included 75.7 % women, 87.2 % white, and mean age of 76.1 (s.d., 9.2). While nearly half of the Falls Free PA sample reported some education after high school, less than 20 % reported they had completed college. Approximately half reported they lived alone, and most reported income adequate to meet needs.

Among the three Falls Free PA study groups, participants repeating *Healthy Steps* were significantly older, more likely to be white, and less likely to be currently married. First-time

*Healthy Steps* participants differed from the comparison group only in the greater proportion of women (81.3 vs. 75.6 %). The three groups were similar in other sociodemographic features, including race-ethnicity, proportion living alone, education, and income.

#### Medical Status of Participants in Falls Free PA

As shown in Table 2, the three Falls Free PA groups did not significantly differ in physician-diagnosed medical conditions, EQ-5D quality of life measures (including global ratings of health), use of prescription medications, or cognitive performance (and proportion with possible dementia).

#### Falls Risk Factors in Falls Free PA

The three Falls Free PA groups did not significantly differ in risk factors for falls, including self-reports of fair–poor balance or mobility, falls in the past 12 months or past 30 days, use of an assistive device for walking, falls self-efficacy, or weekly physical activity, as shown in Table 3.

To check the comparability of the three groups across sociodemographic, medical, and falls risk factors, we modeled self-reports of falls over the past year using logistic regression models. This approach allows a look at the full set of correlates relative to Falls Free PA study group membership. As shown in Table 4, falls in the past year were significantly associated with reports of fair or poor self-rated balance (odds ratio [OR] 2.86, 95 % confidence interval [CI]: 2.21, 3.71), greater number of prescription medications (OR 1.04, 95 % CI: 1.02, 1.08), and lower falls self-efficacy (OR 0.98, 95 % CI: 0.96, 0.99). In the multivariable models, study group membership was not significantly associated with reports of falls in the prior year, again suggesting comparability.

#### Discussion

The current study had two main objectives: first, to assess the quality of study recruitment and retention in Falls Free PA, a

**Table 1** Sociodemographic characteristics of participants

	<i>Healthy Steps</i> , repeat ( $n=311$ )	<i>Healthy Steps</i> , new ( $n=503$ )	Comparison ( $n=1,020$ )
Age, mean (s.d.) <sup>***</sup>	77.7 (7.7)	75.2 (8.7)	75.2 (8.6)
Female, % <sup>***</sup>	87.5	81.3	75.6
Married, % <sup>***</sup>	25.4	35.7	36.9
African-American, % <sup>***</sup>	11.6	10.8	6.2
Latino, %	3.2	4.4	2.1
Live alone, %	63.7	49.3	51.8
College graduate, %	13.5	16.7	15.5
Income reported adequate to meet needs, %	83.5	79.7	82.1

<sup>\*\*\*</sup>  $p < .001$  by oneway ANOVA or  $\chi^2$

**Table 2** Falls Free PA: medical status

	<i>Healthy Steps</i> , repeat ( <i>n</i> =311)	<i>Healthy Steps</i> , new ( <i>n</i> =503)	Comparison ( <i>n</i> =1,020)
Physician-diagnosed conditions, current or history, %			
Stroke	11.9	7.6	10.2
Diabetes	26.5	23.6	24.4
Hypertension	70.6	65.0	67.7
Myocardial infarction	6.5	9.0	10.0
Macular degeneration	10.0	8.0	10.1
Arthritis	67.7	69.8	65.8
Osteoporosis	23.2	25.6	23.7
Glaucoma	12.6	9.6	10.0
Depression or anxiety	19.4	25.8	23.1
Chronic obstructive pulmonary disease	14.5	14.8	12.6
Congestive heart failure	6.8	4.0	6.2
Peripheral neuropathy	18.1	19.4	16.5
Parkinson’s disease	0.0	0.4	0.8
Memory or cognitive impairment	2.6	4.4	4.3
Cancer	18.3	22.2	20.3
EQ-5D quality of life			
Problems with mobility, %	39.4	35.0	39.0
Problems with self-care, %	6.1	5.2	6.2
Problems with usual activities, %	27.1	27.2	28.8
Moderate or severe pain, %	59.4	60.7	61.4
Problems with anxiety or depression, %	29.4	29.5	29.3
Self-Rated Health, 0–100, mean (s.d.)	80.3 (17.2)	79.8 (15.8)	78.9 (16.0)
Prescriptions			
Any prescription, %	90.2	88.9	90.3
Number, mean (s.d.)	3.9 (3.2)	3.6 (3.0)	3.7 (3.1)
Cognitive performance			
Memory score, mean (s.d.)	6.3 (1.6)	6.3 (1.7)	6.4 (1.5)
Possible dementia, %	8.8	11.6	9.1

All group comparisons N.S.

research study designed to assess the effectiveness of Pennsylvania’s *Healthy Steps for Older Adults* in reducing falls; and second, to assess comparability of the three Falls Free PA study groups. The key question was

whether a non-randomized design could approximate random assignment, as judged by baseline comparability on a series of preselected factors likely to be significant for falls risk.

**Table 3** Falls Free PA: falls risk factors

	<i>Healthy Steps</i> , repeat ( <i>n</i> =311)	<i>Healthy Steps</i> , new ( <i>n</i> =503)	Comparison ( <i>n</i> =1,020)
Self-rated balance, fair–poor, %	26.7	27.8	25.7
Self-rated mobility, fair–poor, %	16.4	18.7	20.5
Use assistive device for walking, %	24.8	20.9	24.6
Fall in past 12 months, %	32.2	30.6	29.3
Fall in past 30 days, %	7.4	7.0	6.9
Injury from fall, %	52.2	54.3	51.4
Falls Efficacy Scale, confidence in 10 daily tasks, 0–100, mean (s.d.)	95.7 (6.9)	95.4 (7.7)	95.5 (8.8)
CHAMPS weekly physical activities, 0–40, mean (s.d.)	10.5 (3.0)	10.4 (3.3)	10.1 (3.5)

All group comparisons N.S.

**Table 4** Falls Free PA group status relative to reported falls in prior year

Correlate	OR (95 % CI)
Gender	
Male	1.0
Female	0.99 (0.74, 1.31)
Education	0.99 (0.95,1.03)
Age	0.98 (.097–1.01)
Marital status	
Not currently married	1.0
Married	0.91 (0.71, 1.18)
Race-ethnicity	
White	1.0
African-American	1.19 (0.80, 1.77)
Latino	0.78 (0.38, 1.61)
Number Rx medications	1.04 (1.02, 1.08)*
Self-rated balance	
Excellent–very good–good	1.0
Fair–poor	2.86 (2.21, 3.71)***
Memory performance	0.94 (0.87, 1.01)
Falls efficacy (confidence in tasks)	0.98 (0.96, 0.99)**
CHAMPS physical activity (number activities)	1.02 (0.98, 1.05)
Falls Free PA Status	
Comparison	1.0
New <i>Healthy Steps</i>	1.11 (0.86, 1.43)
Repeated <i>Healthy Steps</i>	1.12 (0.82, 1.53)

\*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p < .001$

Model  $\chi^2 = 127.7$ , 14 df,  $p < .001$

Study recruitment and retention were excellent. Over 90 % of seniors attending PA Department of Aging *Healthy Steps* sites consented to participate in the research, and 82.6 % of these completed baseline interviews. We did not offer payment, so this level of participation is impressive. The sample closely resembled the distribution of participants in the state as a whole, both in sociodemographic characteristics and location. Attrition in the three study groups did not differ, with 7–10 % withdrawing in each group and no differences by group in the proportions unable to continue to participate because of death or illness. The median follow-up in the three study groups was equivalent at 10 months.

Overall, the three Falls Free PA groups were quite similar. Differences between participants completing *Healthy Steps* and the comparison group mostly involved participants repeating the program for the second time. These people were older, on average, than the comparison group (by 2 years), more likely to be women, and less likely to be currently married. The group of people taking *Healthy Steps* for the first time differed from the comparison group only in the proportion who were women. Thus, the non-random design introduced some bias in sociodemographic features, which was

most pronounced for the group taking *Healthy Steps* for the second time. The comparison group and people taking *Healthy Steps* for the first time differed only in the proportion of women (81.3 vs. 75.6 %), a key covariate in any case.

By contrast, the groups did not differ significantly in any self-reported measure of health, whether disease condition, health-related quality of life, number of prescription medications, or memory performance. Nor did the groups differ in falls risk factors, including perception of fair–poor balance or mobility, use of an assistive device, falls history, falls self-efficacy, or weekly physical activity. A multivariate model adjusting for sociodemographic, health, and falls risk factors showed that Falls Free PA group status was not significantly associated with past 12-month history of falls, again suggesting comparability.

This research in primary prevention of falls in older people complements similar efforts directed toward primary care physicians and aging services providers. One prevention effort targeted these providers for falls prevention education and reached 60 % of primary care physicians and over 90 % of home care agencies and rehabilitation centers. This effort was associated with 9 % reduction in falls incidence in areas served by these providers (Tinetti et al. 2008).

Results from this research should be interpreted in light of limitations in study design. As we have stressed, assignment to *Healthy Steps* groups and the comparison group was not random. Yet, analyses show that the groups were quite similar at baseline. Also, high compliance with the automated monthly falls assessment and non-differential attrition suggests that bias based on non-random assignment will be small for the falls outcome. Finally, because participants were drawn from across the state, we were limited to telephone contact.

We conclude that Falls Free PA was able to recruit a representative sample of older adults in Pennsylvania completing *Healthy Steps* and a comparable control group for prospective analyses. Baseline features of the sample, such as the 29–32 % reporting a fall in the past year and mean of nearly four prescription drugs, suggest that findings from this study of falls incidence will be generalizable to the population of older adults who use senior services. Future research will examine the effect of *Healthy Steps* on falls incidence, injurious falls, and physical activity. Evidence for the effectiveness of the program in reducing falls incidence would be very valuable because *Healthy Steps* is a short-term, low-cost, population-wide program that uses existing aging services infrastructure.

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