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The Stroll Safe Randomized Controlled Trial: Program Effects on Falls Self-Efficacy

Tracy Chippendale PhD, OTR/L [a,*], Lijing Wei BS [b], Alex Dahlen PhD [b]

[a] Department of Occupational Therapy, Steinhardt School of Culture, Education, and Human Development, New York University, New York, NY, USA
[b] Biostatistical Collaboration and Consultation Core, Department of Biostatistics, School of Global Public Health, New York University, New York, NY, USA

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A B S T R A C T

Objective: Outdoor falls can negatively impact the health and functional abilities of community-dwelling older adults. Although there are existing evidence-based programs for falls prevention, none specifically target outdoor falls. To fill this gap in research and practice, the Stroll Safe program was developed. Prior studies have examined outcomes for Stroll Safe related to knowledge of outdoor fall risks and safe strategy use. The purpose of this study was to examine outcomes related to outdoor falls self-efficacy.
Design: In this cluster randomized controlled trial, we examined the effects of the Stroll Safe program on outdoor falls self-efficacy as per scores on the Outdoor Falls Self-Efficacy Questionnaire (OFSQ).
Setting and Participants: The study was conducted in 8 naturally occurring retirement communities. Participants (N = 93) were community-dwelling older adults with a history of outdoor falls and/or who were fearful of falling outside.
Methods: Linear mixed-effects models were used for the analyses.
Results: The intervention group had a significantly higher OFSQ score post-intervention ($P < .001$), which persisted at the 6-week follow-up ($P < .001$). Four of the 5 items in the OFSQ showed the same behavior.
Conclusions and Implications: Results reveal that the Stroll Safe program is effective in increasing outdoor falls self-efficacy building on previously established program benefits.

Outdoor falls can negatively impact the health and well-being of community-dwelling older adults. Existing falls prevention programs include multifactorial programs, such as Stepping On and Matter of Balance, and exercise-based programs such as the Otago and Stay Active and Independent for Life programs.[1-3] However, despite differences in risk factors for indoor and outdoor falls,[4-7] existing falls prevention programs focus primarily on indoor risk factors. To fill the gap in outdoor falls prevention, the Stroll Safe program was developed, piloted, and subsequently studied using a phase 2 efficacy trial. Previously studied outcomes for Stroll Safe include knowledge of outdoor fall risks and safe community mobility strategy use as per the Outdoor Falls Questionnaire, and concern about falls while performing everyday activities according to the Falls Efficacy Scale-International (FES-I).[8–11]

Self-efficacy can be defined as a person's belief that they can be successful while carrying out a specific task.[12] In the current study, outdoor falls self-efficacy includes belief in one's ability to safely perform activities outside of the home, address outdoor environmental hazards, reduce risk of injury, and get up safely after outdoor falls.[13,14] Prior studies have demonstrated that falls self-efficacy is an important protective factor against future fall events.[15] Further, the feasibility study for the Stroll Safe program revealed that some of the most helpful aspects of the program, such as improved self-efficacy for minimizing risk of injury, and navigating public transportation safely,[8] were not being captured by existing outcome measures. Therefore, the 5-item Outdoor Falls Self-Efficacy Questionnaire (OFSQ) was developed. The purpose of this study was to examine the effects of the Stroll Safe program on outdoor falls self-efficacy as per findings from the phase 2 multisite clinical trial.

Methods

Design

A cluster randomized controlled trial design was used given the strong risk of contamination within sites uncovered during the

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* Address correspondence to Tracy Chippendale, PhD, OTR/L, Department of Occupational Therapy, Steinhardt School of Culture, Education, and Human Development, New York University, 82 Washington Square East, 6th floor, New York, NY 10003, USA.
E-mail address: tlc223@nyu.edu (T. Chippendale).

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feasibility study.[8] Eight community sites were randomized to the treatment (4 sites) or wait list control group (4 sites) using random numbers generated by Excel. Participants were recruited following random assignment of community sites to the treatment or wait list control group.

Participants

Participants were actively recruited through scheduled information sessions and by making announcements after regularly scheduled programs at 8 naturally occurring retirement community (NORC) program sites in New York City. Information sessions and announcements after regularly scheduled programs were attended by approximately 12 to 35 older adults, depending on the site. At each site, between 8 and 14 participants enrolled in the study. Inclusion criteria were English speaking, aged 60 years or older, able to ambulate outdoors independently with or without a walking aid, obtain a score of >2 on the Mini-Cog,[16] and must answer "yes" to 1 or more of the following questions: (1) Have you fallen outdoors and hurt yourself in the past year? (2) Have you fallen outdoors 2 or more times in the past year? (3) Have you had 2 or more stumbles or trips outdoors in the past month? (4) Are you afraid that you might fall outdoors? Participants who were acutely ill or who did not meet the inclusion criteria were excluded.

Procedures

The institutional review board at the principal investigator's home institution approved the study. This phase 2 trial was also registered with ClincialTrials.gov. Four program sites participated in the study in 2019 (2 treatment and 2 wait list control). Similarly, 4 sites participated in 2021-2022. Given that the study did not pivot to an online delivery format, the project was on hold in 2020 due to COVID restrictions. Recruitment was conducted each year of the study (ie, in 2019 and again in 2021). During information sessions and announcements at the community sites, potential participants were told that if their community site was assigned to participate in the program first, they would participate in the Stroll Safe program shortly after enrolling in the study. If their site was assigned to participate in the program the second time it was offered, people were informed that they would receive written information first about outdoor falls before participating in the Stroll Safe program in a few months' time. Following informed consent, participants completed the background questionnaire and pre-tests orally using standardized instructions. The treatment group then participated in the Stroll Safe program and the wait list control group participants were sent written information with tips for outdoor falls prevention. Post-tests were administered after the treatment group completed the 7-week program and then again 6 weeks post intervention. Following post-test data collection, participants in the wait list control group were then invited to participate in the Stroll Safe program. Details about the research methods and study procedures have been reported previously.[9,17] Before conducting statistical analyses for the current study on outcomes related to outdoor falls self-efficacy, an analysis plan was registered with Open Science Framework.

Intervention

Stroll Safe is a manualized occupational therapist-led, group-based 7-week outdoor falls prevention program that addresses behavioral change through knowledge sharing, group discussion and problem solving, self-advocacy for environmental change, action planning, community mobility practice/coaching, and a participant-led walkability audit using the Stakeholders' Walkability/Wheelability Audit in Neighborhood tool.[9,18] The program was informed by existing research on outdoor fall risks and the Ecological and Health Belief Models.[19–24] Topics covered include the built environment, the social environment, neighborhood conditions, and intrapersonal factors associated with outdoor fall risk. Details about the program content of Stroll Safe have been described elsewhere.[9,17]

Measures

The 5-item OFSQ examines falls self-efficacy related to outdoor/out-of-home activities as well as fall recovery techniques and strategies to reduce risk of fall-related injury. The OFSQ was informed by an existing outcome measure, the Falls Prevention and Management Questionnaire, designed for a fall prevention program targeting adults with multiple sclerosis.[13] The OFSQ asks participants to rate their know-how on a 5-point Likert scale ranging from "Strongly disagree" to "Strongly agree" for getting up safely after a fall, falling safely/reducing risk of an injury, using public transit safely, and identifying hotspots for outdoor falls in general, as well as windy and icy locations specifically. The score for individual questions on the measure range from 1 to 5, therefore the total score ranges from 5 to 25. Strong test-retest reliability of the OFSQ has been established ($r = 0.96$, $P < .001$) (Tracy Chippendale, PhD, April 4th, 2024). The Minimal Clinically Important Difference for the scale has not yet been established.

Analysis

A priori power analysis was conducted for the primary outcome measure for the phase 2 trial, safe strategy use, as measured by the Outdoor Falls Questionnaire (OFQ) strategy use subscale. A G*Power analysis revealed that for an analysis of covariance with 2 covariates, using a medium to large effect size (0.33), and power set to 0.80, a total of 75 participants were needed. To account for possible attrition, the recruitment goal was N = 90.

In the current study, demographic and background information were examined using descriptive statistics. To determine any differences between the treatment and wait list control groups at baseline, independent samples *t*-tests were used for continuous variables and χ^2 or Fisher's exact tests were used for categorical variables. Any initial differences between groups were included as covariates in the analyses. Differences in total scores between the 2 groups at baseline, post-intervention, and at 6-week follow-up were examined using linear mixed-effects models, with random intercepts at the patient- and site-levels, to account for repeat measurements and any potential clustering. Our primary outcome was the total score, and we considered each individual question on the 5-item OFSQ measure as secondary outcomes in their own models. Last, we conducted sensitivity analyses to ensure results of outcome testing were robust. To evaluate our approach to the covariates, we ran 2 additional models: one that included all covariates and one with the covariates removed; to evaluate our implicit assumption of missingness at random, we ran an additional complete case analysis (although missing data rates were small). All the analyses used .05 as the significance level.

Results

Participant background information is presented in Supplementary Table 1 and the CONSORT diagram is shown in Supplementary Figure 1. Use of mobility aid ("Yes" or "No"), education ("Less than college" or "College degree"), and physical activity participation ("Three or less times/week" or "Four or more times/week") were collapsed into 2 categories. Significant differences between the treatment and wait list control group were noted at baseline for age and number of activities of daily living/instrumental

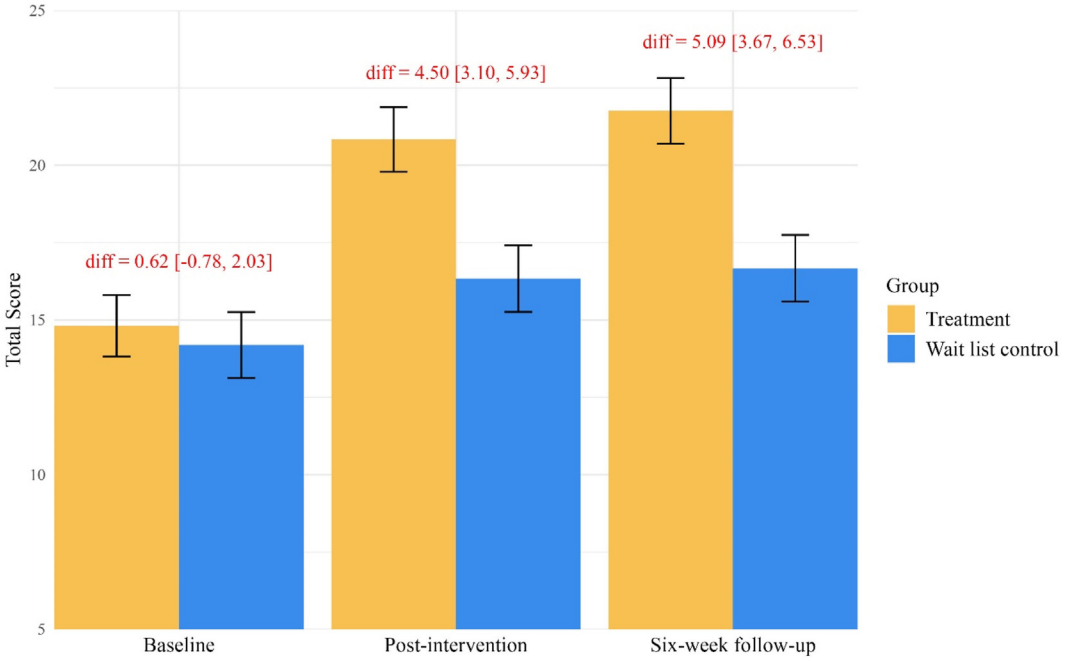

Fig. 1. The total score for treatment and wait list control groups at each time point. The numbers in red represent the estimated differences in scores between the treatment and wait list control groups at each time point, along with their 95% CIs. The total score for the OFSQ ranges from 5 to 25 and the y-axis shows the entire range.

activities of daily living that require assistance (both with $P < .05$), therefore these variables were included as covariates in the primary analyses.

Results from the linear mixed-effect model reveal that the difference in the OFSQ total score between the treatment and wait list control groups was significant at both post-intervention and 6-week follow-up (95% CI at post-test, 3.10–5.93; 95% CI at 6-week follow-up, 3.67–6.53) (see Figure 1 and Table 1). Specifically, on a scale that ranges from 5 to 25, we found a mean difference of 4.5 between the groups at post-test. The difference was not statistically significant at baseline (95% CI, −0.78 to 2.03) (see Figure 1, Table 1, and Supplementary Table 2 for full model results). The sensitivity analyses produced similar results, highlighting the robustness of these findings (see Supplementary Table 3).

The first 4 components of the OFSQ showed a similar pattern, with significant differences appearing at post-intervention and persisting at the 6-week follow-up; the differences in scores for the final question ("I know where the windy and icy locations are near my home") were not to our threshold of statistical significance (see Table 1).

Discussion

The purpose of this study was to examine the effects of the Stroll Safe program on outdoor falls self-efficacy. Results reveal significant differences between the treatment and wait list control groups on the OFSQ total score and for 4 of the 5 individual items on the measure post-program and at 6-week follow-up.

Different fall-related psychological constructs have been highlighted previously in the literature and include balance confidence, fear or concern about falls, and falls self-efficacy.[14] Previous study findings on the Stroll Safe program revealed that the program did not result in significant improvements on the Falls Efficacy Scale-International (FES-I),[9] which despite this instrument's name, measures concern about falls rather than falls self-efficacy.[14] The OFSQ on the other hand specifically addresses falls self-efficacy or know-how related to one's ability to identify outdoor environmental hazards, minimize risk for injury, safely perform activities outside the home, and recover after a fall. Further, although the FES-I focuses on the related construct of concern about falls, most of the questions address

Table 1
Difference in Measures Between Treatment and Wait List Control Groups at Post-intervention and 6-Week Follow-up

Measure	Difference at Post-intervention			Difference at 6-Week Follow-up		
	Estimate	95% CI	*P* value	Estimate	95% CI	*P* value
Total score	4.50	3.10–5.93	<.001	5.09	3.67–6.53	<.001
I know how to safely get up after a fall.	1.07	0.59–1.55	<.001	1.25	0.77–1.74	<.001
I know how to "fall safely"/protect myself in case of a fall.	1.33	0.82–1.83	<.001	1.36	0.85–1.87	<.001
I know how to safely use the bus and subway.	0.64	0.31–0.97	<.001	0.72	0.38–1.05	<.001
I know common locations or "hot spots" for outdoor falls.	1.01	0.47–1.54	<.001	1.34	0.80–1.89	<.001
I know where the windy and icy locations are near my home.	0.46	−0.01 to 0.90	.07	0.43	−0.02 to 0.88	.09

The total score for the OFSQ ranges from 5 to 25 and each question has a range of 1 to 5.

the performance of indoor rather than outdoor activities,[11] the latter being the focus of the Stroll Safe program.

Significant findings may be attributed in part to the fact that the Health Belief Model was used to inform the Stroll Safe program. This model specifically targets the promotion of self-efficacy in addition to addressing perceived susceptibility, severity, and the benefits of taking action to address health-related concerns.[22] To address self-efficacy, the Stroll Safe program uses a multipronged approach including knowledge sharing, a participant directed walkability audit that provides the opportunity to practice identifying environmental hazards, and practice and coaching in the use of safe community mobility strategies.

Limitations of the study include the short-term follow-up period of 6 weeks and the fact that the trained research assistants who assisted with data collection for the OFSQ and other outcome measures were not blinded to group assignment. Although test-retest reliability has been established for the OFSQ, further psychometric testing of this measure is warranted. Also, the Minimal Clinically Important Difference for the scale should be established. However, despite limitations, this study adds to the growing body of knowledge on the benefits of the Stroll Safe program.

Conclusions and Implications

In conclusion, the Stroll Safe program was shown to be effective in improving outdoor falls self-efficacy among community-dwelling older adults. This study adds to previously established Stroll Safe program benefits, which have included improved knowledge of outdoor fall risks and an increase in safe community mobility strategy use.[9]

Disclosure

The authors declare no conflicts of interest.

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Supplementary Data

Supplementary data related to this article can be found online at https://doi.org/10.1016/j.jamda.2024.105478.

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