Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2019;100:1-8

ORIGINAL RESEARCH

A Cost-Effectiveness Analysis of a Randomized Control Trial of a Tailored, Multifactorial Program to Prevent Falls Among the Community-Dwelling Elderly

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Abstract

Objective: To perform a cost-effectiveness analysis of a multifactorial, tailored intervention to reduce falls among a heterogeneous group of high-risk elderly people.

Design: Randomized control trial.

Settings: Communities.

Participants: Adults aged at least 65 years (N=354) seen at the emergency department (ED) for a fall or fall-related injury and discharged home.

Interventions: The intervention group received a tailored program of physical therapy focused on progressive training in strength, balance, and gait for a period of 3 months. They also received screening and referrals for low vision, polypharmacy, and environmental hazards. The Short Physical Performance Battery (SPPB) test was assessed at regular intervals to allocate participants into either a home-based or group center-based program. The control group received usual care prescribed by a physician and educational materials on falls prevention.

Main Outcome Measures: The incremental cost-effectiveness ratio (ICER) over the 9-month study period based on intervention costs and utility in terms of quality-adjusted life years (QALYs) calculated from EuroQol-5D scores.

Results: The ICER was 120,667 Singapore dollars (S$) per QALY gained (S$362/0.003 QALYs), above benchmark values (S$70,000). However, the intervention was more effective and cost-saving among those with SPPB scores of greater than 6 at baseline, higher cognitive function, better vision and no more than 1 fall in the preceding 6 months. The intervention was also cost-effective among those with 0-1 critical comorbidities (S$22,646/QALY).

Conclusion: The intervention was, overall, not cost-effective, compared to usual care. However, the program was cost-effective among healthier subgroups, and even potentially cost-saving among individuals with sufficient reserve to benefit.

Archives of Physical Medicine and Rehabilitation 2019;100:1-8

Falls are the second leading cause of accidental injury deaths worldwide[1] and the dominant cause of quality of life reduction due to injuries among older adults.[2] Nearly one-third of adults aged 65 years or older fall each year[3]; about half of fallers have recurrent falls in the next year,[4,5] and one-third of them sustain fall-related injuries, requiring medical treatment.[6] Falls are also significantly associated with poorer quality of life, higher levels of anxiety as well as increased stress on caregivers.[7,8] The economic burden of falls is substantial as direct medical costs due to

Supported by Ministry of Health Singapore under its Health Services Research Competitive Research Grant (grant no. HSRG/0020/2012).

Clinical Trial Registration No.: NCT01713543.

Disclosures: none.

0003-9993/18/$36 - see front matter © 2018 by the American Congress of Rehabilitation Medicine
https://doi.org/10.1016/j.apmr.2018.07.434

fall-related medical conditions among community-dwelling elderly people were estimated at 6 to 8 billion United States dollars (US$) per year in the United States.[9]

With populations aging worldwide, the burden of disease and economic impact of falls are expected to rise. In Singapore, one of the most rapidly aging societies in the world, falls accounted for 22% of injuries and 5.2% of the total disease and injury burden in 2010.[10] However, falls prevention research in Asia is limited.[11] Further, in part due to cost considerations, as well as heterogeneity of types of falls, falls victims, and treatment costs, there is a dearth in evidence of the cost-effectiveness of falls prevention.[12,13]

Based on existing programs and studies, the Steps to Avoid Falls in the Elderly (SAFE) program was designed as a model for a national falls prevention program, taking into account individually tailored physical therapy and screening for falls-related risk factors including low vision, polypharmacy, and environmental hazards. Findings indicated that while the intervention did not reduce the primary outcome, namely, any fall in 9 months, it was associated with fewer injurious falls. Also, effectiveness was concentrated in less severely ill individuals.[14]

In view of this, the primary objective of this study was to conduct a cost-effectiveness analysis of a randomized controlled trial (RCT) of a tailored falls prevention program for a heterogeneous group of high-risk community-dwelling elderly recruited at the emergency department (ED) of 2 tertiary hospitals.[14] A secondary objective of this study examines cost and effectiveness for salient subgroups reported in our previous publication.[14]

Methods

Study design

This economic evaluation was part of a 9-month multi-center, 2-arm, parallel group single-blinded RCT, the SAFE study. This study was approved by SingHealth Centralized Institutional Review Board and registered with the US Clinical Trials Registry, number NCT01713543. The design of the study, including the flow of participants, has been described in detail elsewhere.[14]

Study population

Participants were recruited at the ED of 2 large public tertiary hospitals, as fallers who present to the ED have been found to be at high risk of recurrent falls.[15] Participants were included if they were at least 65 years old, seen at the ED for a fall or fall-related injury, and subsequently discharged to their home in the community. If admitted to the hospital, the illness or disability was one from which patients were expected to recover basic activities of daily living or weight bearing in the lower extremity within the next month. Patients were excluded if they were cognitively impaired, measured by the Three Step Command,[16] or presented to the ED due to road traffic accidents or needing emergency inpatient surgery.

List of abbreviations:

ED	**emergency department**
ICER	**incremental cost-effectiveness ratio**
PT	**physiotherapist**
QALY	**quality-adjusted life year**
RCT	**randomized controlled trial**
S$	**Singapore dollars**
SAFE	**Steps to Avoid Falls in the Elderly**
SPPB	**Short Physical Performance Battery**
US$	**United States dollars**

Randomization and blinding

As reported elsewhere, following consent and baseline evaluation, the physiotherapist (PT) contacted the study coordinator to randomly assign participants to either the intervention or control group based on a computer-generated list created by the study statistician using the permuted-block randomization method, stratified by 2 recruitment sites and sex. All follow-up outcome assessments were conducted by trained nurses, not involved in the intervention and masked to the group assignment.

Intervention

The intervention is described in detail, elsewhere.[14] In brief, the intervention consisted of a multi-factorial program of risk screening and modification, and physical therapy aimed at improving deficiencies in gait, balance, or mobility. Participants were followed for 9 months after baseline. This follow-up period was divided into 2 phases: a 3-month active intervention phase during which intervention participants received physical exercise, and a 6-month maintenance phase.

The intervention protocol was documented in a manual in detail; training, retraining, and audits were conducted to ensure high fidelity to the protocol. The Short Physical Performance Battery (SPPB) was assessed at baseline to allocate intervention participants into appropriate exercise programs based on their level of functioning. Participants with an SPPB score less than 7 received an individualized home-based program three times a week for up to 12 sessions; remaining participants were assigned to a group therapy program held twice a week for up to 24 sessions. Both programs were supervised by a PT. At every fourth session, the SPPB score of participants in the individualized program were reassessed; if their SPPB was greater than 6, they were transitioned to the group setting program. Figure 1 illustrates this in more detail.

During the baseline assessment, PTs screened all participants for the following risk factors for falls: self-reported vision, polypharmacy (based on the number of prescribed medications), and environmental hazards (measured by the Centers for Disease Control and Prevention Home Checklist).[17] To correct for poor vision, intervention participants were advised to seek professional attention from ophthalmologists; to manage polypharmacy, intervention participants were referred to a transition care nurse to facilitate coordination of outpatient services for medication review and reconciliation. To modify environmental hazards, intervention participants and their caregivers received education and suitable recommendations.

Usual care

Currently, no standard approach to risk management for falls is available for fallers presenting to the ED and discharged home. Usual care for control participants included recommendations and prescriptions by their treating physicians.

Measurements

Monthly phone calls collected data on the frequency and nature of falls, verified by monthly falls calendars returned to the study coordinator.[18,19] At the end of each phase, participants were

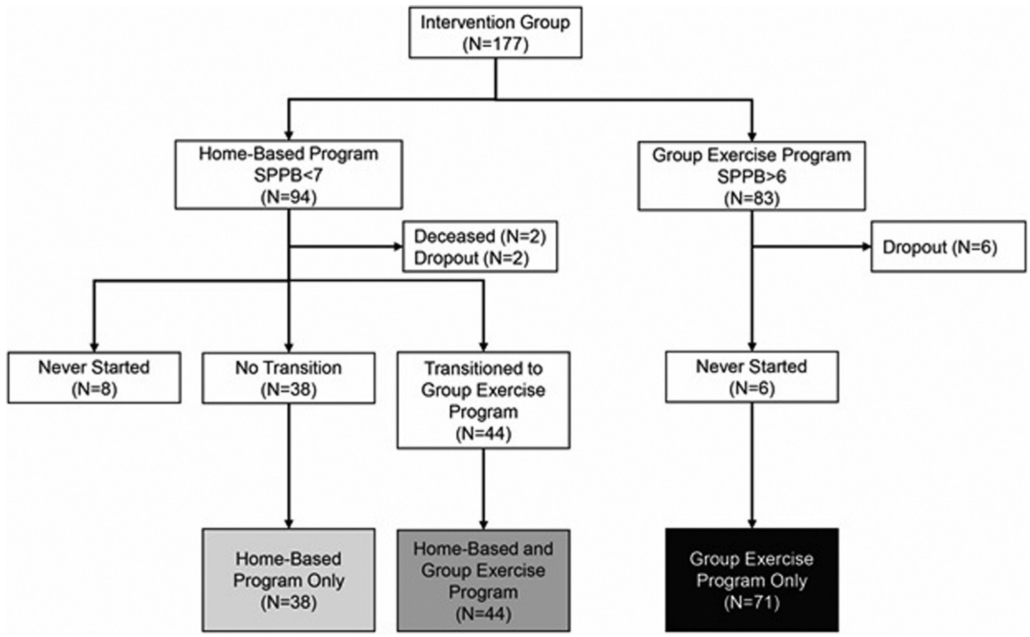

Fig 1 Flow diagram of participants assigned to the intervention.

reassessed on the same outcome measures (costs and health outcomes) as the baseline assessment.

Costs comprised program costs and other health care utilization costs, reported in Singapore dollars (S$) (approximately US$1 = S$1.33[20]) and measured from a health system's perspective. Program costs comprised the average cost of medical screening to assess the type of exercise program (individual or group-based) appropriate for the participant, and the cost of the program during the 3-month active intervention phase. The cost of screening for polypharmacy, vision, and environmental hazards were excluded from program costs as both control and intervention participants received them at baseline. Health care utilization costs comprised participants' gross service bills (excluding Goods and Services Tax) for each ED visit, specialist outpatient clinic visit, and hospital admission during the entire 9-month study period. Health care utilization costs were derived from participants' bills from the comprehensive set of inpatient and outpatient facilities affiliated with the 2 participating hospitals. As bills tend not to be inflated in the public system, charges were used as an approximation of true costs. Productivity costs,[21] were excluded as they are of limited relevance among the mostly retired elderly.

The primary health outcome measure was quality-adjusted life years (QALYs).[21] To calculate QALYs, we first converted responses to the 5-level EuroQol-5D instrument to a utility score. As recommended by Manca et al,[22] these utility scores were adjusted for baseline score differences and then averaged. QALYs for each group over the study period were calculated by taking the area under the curve constructed by linearly interpolating between observed scores. Figure 2 illustrates this approach. The sum of areas A and B constitutes total QALYs experienced over the 9-month follow-up period, on average, by individuals in a particular treatment group.

Statistical analysis

We compared baseline characteristics of the study participants by treatment group (see table 1) using chi-square tests for categorical variables and Student *t* tests for continuous variables. We repeated this for the participants who died or dropped out during the study period.

We calculated incremental cost from a health system perspective as the difference in total direct medical costs between intervention and control groups, taking into account program costs (see table 2). We calculated incremental effectiveness as the difference in QALYs accumulated by intervention and control groups.[22] When cost was negative (intervention was cost saving) and effectiveness was positive (intervention more effective), the intervention was deemed to be economically dominant. Where cost and effectiveness were both positive (ie, intervention was more costly and more effective), we calculated the incremental cost-effectiveness ratio (ICER) of the program as incremental cost divided by incremental effectiveness. If the result was less than a benchmark threshold of S$70,000, roughly one times the gross

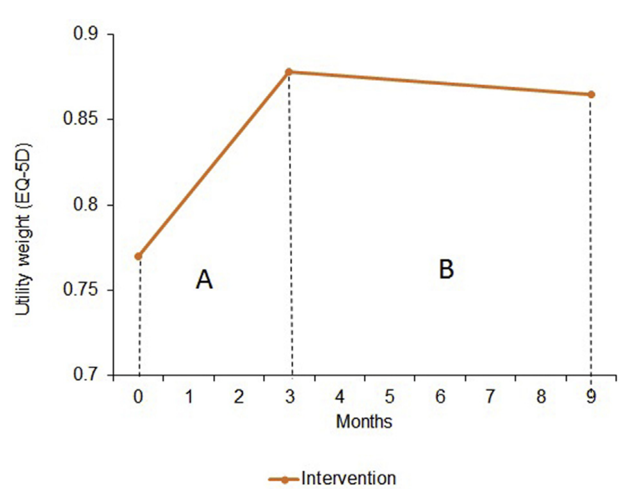

Fig 2 Illustration of QALYs gained using the area-under-the-curve (AUC) approach.

domestic product per capita,[21,23,24] the intervention was deemed cost-effective. Costs and QALYs were not discounted as the analysis is limited to the 9-month timeframe of the study.

Nonparametric bootstrapping (using random sampling with replacement) with 1000 replications was conducted to address uncertainty in estimates of incremental costs and effectiveness. Table 3 provides results from the analysis for all participants as a whole, and by preidentified subgroups.[14,a]

Results

Baseline characteristics

Recruitment of participants took place between December 1, 2012, and July 17, 2014, and the last 9-month assessment was completed on May 23, 2015. Both control and intervention groups had comparable sociodemographic and clinical characteristics,[11] as described in table 1. Of the 354 participants randomly assigned to either group (177 per arm), 323 (91%) completed the study (162 in the control and 161 in the intervention group), while the remaining 9% either dropped out or died during the study period. Participants who withdrew from the study were, on average, more likely to be men and have lower SPPB scores than those who completed the study. However, by the end of the study, both intervention and control groups remained comparable in terms of background characteristics. Nearly all (98%) of participants assigned to the home-based exercise program completed the prescribed number of sessions. Adherence levels among participants attending at least 1 group-based session (109/115) was 71%, similar to average rates reported for class-based exercises.[25]

Table 1 Baseline characteristics

	Randomized (n=323)		Lost to Follow-up (n=31)	
Characteristic	Control (n=162)	Intervention (n=161)	Control (n=15)	Intervention (n=16)
Age (y)	77.4±7.2 (65, 94)	78.2±6.9 (65, 99)	79.6±7.1 (66, 88)	79.3±4.2 (72, 86)
Men	24.7	21.1	26.7	62.5
Chinese	80.3	85.1	80.0	75.0
Highest education level				
No formal education	37.7	34.2	46.7	25.0
Primary	29.6	32.9	26.7	31.3
Secondary	21.6	19.3	26.7	25.0
Above secondary	11.1	13.7	0.0	18.8
Married	58.0	50.3	46.7	68.8
Working status				
Working full-time or part-time	5.6	5.0	0.0	0.0
Unemployed/retired/homemaker	94.4	95.0	100.0	100.0
Housing type				
HDB 1-3 rooms	28.4	31.1	33.3	26.7
HDB 4-5 rooms	58.0	49.7	40.0	33.3
Private housing	13.6	19.3	26.7	40.0
Availability of Primary Caregiver	85.1	87.0	86.7	87.5
Proportion of caregivers living with participant	72.8	68.9	66.7	68.8
Availiability of foreign domestic worker	25.2	30.8	46.7	37.5
Difference in systolic blood pressure between supine and standing position	11.8±10.4 (0, 60)	13.1±10.3 (0, 50)	10.0±10.4 (0, 50)	17.1±17.9 (3, 75)
Polypharmacy	54.3	54.7	60.0	62.5
Vision				
Good	45.7	40.4	40.0	43.8
Poor	54.3	59.6	60.0	56.3
Multiple comorbidities*	46.3	47.8	53.3	62.5
Total SPPB score	6.6±3.3 (1, 12)	6.2±3.6 (0, 12)	3.7±2.3 (1, 8)	5.9±3.5 (1, 12)
Total MoCA score	18.7±7.1 (3, 30)	18.5±6.9 (4, 30)	17.0±6.9 (6, 29)	18.6±7.7 (8, 30)
Total MFES	93.1±38.6 (2, 140)	87.9±40.3 (0, 140)	75.6±36.2 (0, 135)	79.1±42.9 (13, 140)
Fell more than once in the last 6 mo prior to baseline assessment	37.0	46.0	40.0	50.0
Quality of life (5-level EuroQol-5D)	0.79±0.21 (-0.009, 1)	0.76±0.25 (-0.06, 1)	0.76±0.23 (0.339, 1)	0.75±0.20 (0.389, 1)
Quality of life (EQ-VAS)	71.2±18.0 (10, 100)	68.3±20.2 (0, 100)	69.9±24.3 (25, 100)	62.9±16.4 (40, 90)

NOTE. Percentage is reported for categorical variables. Mean ± SD with a range indicated in parentheses is reported for continuous variables.
Abbreviations: EQ-VAS, EuroQol-Visual Analog Scale; HDB, Housing and Development Board (it is responsible for public housing in Singapore); MFES, Modified Falls Efficacy Scale; MoCA, Montreal Cognitive Assessment.
* Two or more of emphysema, cardiac failure, circulation problem in arms and legs, stroke, Parkinson disease, cancer, and MoCA<26.

Costs and effectiveness (utility)

Mean differences in intervention costs and health care utilization costs for control and intervention groups are summarized in table 2. The total cost per patient over the 9-month study period was S$3718 for intervention participants and S$3356 for control participants (S$362 more for the intervention).

The average intervention cost (inclusive of medical screening and the 3-month exercise program) was S$965 per participant (n=148). Individuals using exclusively the home-based exercise program had the highest intervention costs (S$1316), while those who used exclusively the group-based program had the lowest intervention costs (S$792) and those who started with the home-based program and transited to group-based program had intermediate costs (S$1253). Compared to the control group, average health care utilization costs in the intervention group was lower (S$2754 and S$3356, respectively). These savings were attributable to fewer ED and specialist outpatient clinic visits, and hospitalizations.

In terms of effectiveness, intervention participants experienced a gain of 0.003 QALYs over their control group counterparts over the 9-month study period (see table 3 and fig 2).

Cost-effectiveness analyses

The cost-effectiveness of the program overall based on the ICER was S$120,667/QALY gained (S$362/0.003 QALYs) (see table 3). The threshold of S$70,000 per QALY implies that the intervention was, overall, not cost-effective compared to usual care. This was supported by the bootstrapped analysis in which only 25% of sample pairs were situated in the southeast quadrant of the cost-effectiveness plane, indicating the intervention was economically dominant (ie, better outcomes at lower cost), while 39% of pairs were situated in the northeast quadrant of the plane indicating the intervention was dominated (ie, higher effectiveness at higher cost).

Based on the effect modifiers of the intervention that were identified in our previous study,[14] we examined cost and effectiveness for salient subgroups (see table 3). The intervention was cost-effective among participants with 1 or fewer critical comorbidities, with an ICER of S$22, 646 per QALY gained (see fig 3). The intervention was also dominant among those whose baseline SPPB was greater than 6, those with a Montreal Cognitive Assessment score of at least 26, less frequent fallers (defined as those who had less than 2 falls in the preceding 6m) and those with good or excellent self-reported vision. However, a substantial degree of variability was observed in the bootstrapped analyses.

Discussion

In our previous study, we demonstrated that for a very heterogeneous population of elders with falls seeking care in the ED a tailored, intensive intervention was not uniformly effective in reducing any fall.[14] While injurious falls were reduced among intervention subjects compared to controls leading to lower health utilization costs, the savings in heathcare utilization costs was less than the cost of the intervention. More severely ill individuals tended to benefit less and because they often received more expensive home-based services, they had higher intervention costs.

Anticipating population heterogenity, we planned specific subgroup analyses; these provided a strong indication that effectiveness of the falls prevention program was substantialy modulated by premorbid factors such as poor SPPB, cognitive impairment, and multiple major comorbidities. In this study we

Table 2 Intervention cost and health care utilization cost (S$) by treatment group

Cost	Control n	Intervention n	*P* Value	ΔCost
Intervention cost				
Physician-conducted medical screening	NA	84.9 158	NA	NA
Home-based exercise program	NA	1316.0 38	NA	NA
Group-based exercise program	NA	792.0 71	NA	NA
Home-based and group-based exercise program	NA	1160.8 44	NA	
Total intervention cost	NA	964.6±471.7 177	NA	964.6
Health care utilization cost				
Emergency department	248.3±455.3 177	247.3±845.7 177	.989	NT
Hospitalization	2911.8±9118.3 177	2323.6±7778.1 177	.514	NT
Specialist outpatient clinics	196.3±456.1 177	183.0±446.2 177	.781	NT
Total health care utilization cost	3356.4±9558.6 177	2753.9±8505.8 177	.531	-602.6
Total cost from health system's perspective	3356.4±9558.6 177	3718.5±8469.0 177	.706	362.0

NOTE. Mean ± SD is presented.
Abbreviations: NA, not applicable; NT, not tested.

Table 3 Incremental costs and QALYs gained

Characteristic	Incremental Costs (S$)	QALYs Gained	ICER	Note	Distribution on CE-Plane			
					NE %	NW (Inferior) %	SW %	SE (Dominant) %
Overall	362.0	0.003	120, 667	Intervention more costly and more effective	39.30	26.50	9.70	24.50
Critical comorbidities								
0-1	543.5	0.024	22, 646	Intervention more costly and more effective	53.20	23.20	2.60	21.00
≥2	321.6	-0.005	NA	Usual care dominant	7.50	53.50	31.40	7.60
SPPB								
>6	-784.0	0.006	NA	Intervention dominant	14.50	5.10	21.60	58.80
≤6	1262.0	0.004	315, 500	Intervention more costly and more effective	25.30	52.90	13.20	8.60
MoCA								
≥26	-1428.4	0.005	NA	Intervention dominant	7.40	18.40	53.60	20.60
<26	888.1	-0.0001	NA	Usual care dominant	17.40	61.90	15.10	5.60
No. of falls in the last 6 mo								
≤1	-609.3	0.008	NA	Intervention dominant	20.30	10.50	19.20	50.00
≥2	1546.9	0.005	309, 380	Intervention more costly and more effective	16.00	69.00	9.70	5.30
Self-reported vision								
Good or excellent	-474.8	0.006	NA	Intervention dominant	14.80	19.90	34.70	30.60
Fair or poor	919.5	0.0007	1,313,557	Intervention more costly and more effective	18.60	53.50	17.00	10.90

Abbreviations: CE-Plane, Cost-Effectiveness Plane; NA, not applicable; NE, Northeast; NW, Northwest; SE, Southeast; SW, Southwest.

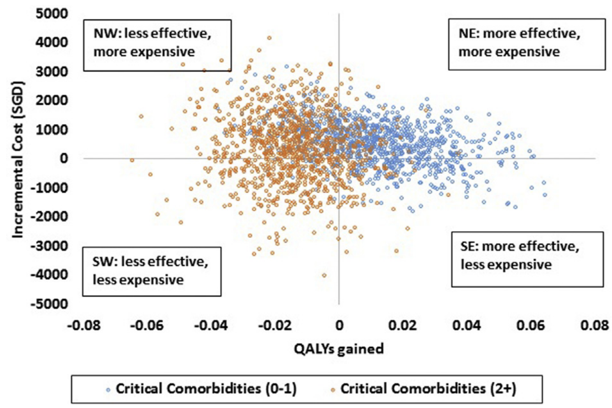

Fig 3 Bootstrapped scatterplot of the incremental cost effectiveness ratio by number of critical comorbidities.

followed up these results with an economic analysis which indicates that these subgroups for which intervention was effective, achieved benefit at lower cost (falls prevention program is economically dominant), or at least were reasonably cost-effective (with an ICER well below a benchmark value for willingness to pay for improved QALYs).[23,24]

This study contributes to the current literature of falls prevention programs as prevention programs targeting single or multifactorial risk factors have been found to be effective at reducing falls and fall-related injuries.[26,27] However, findings on the cost-effectiveness have been mixed, and dependent on the degree of adaptation of particular measures to given environments, patients, and disease patterns.[28-30] The contribution of this study is that it demonstrates that falls prevention programs can make economic sense, particularly for healthier subgroups. This evidence will be valuable to policymakers considering implementing falls prevention programs, broadly.

Study limitations

A limitation of the current study is that the power was diminished by an unexpectedly lower incidence of recurrent falls in the study population, about two-thirds of the expected rate based on previous studies, as reported elsewhere.[14,31] Secondly, the lack of baseline or follow-up data of the control subjects regarding home environment, vision, or polypharmacy hindered our ability to control for such factors. Thirdly, the duration of the follow-up was only 9 months and benefits as well as cost impacts are likely to continue to accumulate beyond the study period. A fourth limitation is that we took a health system perspective, excluding direct nonmedical costs such as caregiver time. To the extent that nonmeasured costs correlate with measured costs (eg, fewer injurious falls would mean less caregiver time to assist the person falling), not measuring these costs would bias the analysis against the intervention.[32] Further, we accounted for health care costs in inpatient and outpatient facilities, which does not include costs in the private sector or in other regional hospitals. However, approximately 80% of inpatient services are provided in public hospitals[33] and most individuals seeking care use services associated with their regional hospital.[34] Costs not accounted for in this analysis should be minor, and, on average, affect intervention and control participants similarly. Another limitation is the possibility of volunteer bias as informed consent occurred before randomization. As a general matter with RCTs, volunteer bias can affect the generalizability of study results.[35] The alternative approach would be a nonrandomized study; however, such studies introduce biases of their own.[36] Moreover, limited data on nonparticipants found that their age and sex were similar to that of participants. Last, a substantial degree of variability was observed in the bootstrapped analyses. This is due in part to the relatively small health benefit observed as well as the limited power due to an unexpectedly low falls rate for control subjects compared to Western populations.[14,32,37] Future research could include sample sizes informed by baseline falls rates locally.

Conclusion

For a heterogeneous population of elders seen in the ED for a fall, the multifactorial falls prevention program was, overall, not cost-effective compared to usual care. However, the program was more effective and less costly among those with higher cognitive function, higher SPPB scores and less frequent falls; the intervention was also cost-effective among those with fewer than 2 critical comorbidities. These results suggest there is a sweet spot—where an intensive, tailored falls prevention program for individuals who have sufficient reserve to benefit is cost-effective, or even cost saving. More precise delineation of this sweet spot should be the subject of future research. In the meantime, we believe that implementation efforts should focus on strategies to roll out high-fidelity versions of SAFE or similar programs to benefit the community.

Supplier

a. Stata, version 14; StataCorp LP.

Keywords

Cost analysis; Falls; Randomized controlled trial; Rehabilitation

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Acknowledgments

We thank all the staff at Emergency Department and Physical Therapy Department at Singapore General Hospital, Changi General Hospital, Alexandra Hospital, and St. Andrew's Community Hospital. We thank Karen Koh, BHlthSci, from Life Skills for facilitating the intervention. We also thank all our collaborators from the Agency for Integrated Care ACTION team, Health Promotion Board, and Wake Forest School of Medicine. We appreciate all the Advisory Committee members for their contributions to the successful completion of the study.

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