A Randomized, Controlled Trial of Fall Prevention Programs and Quality of Life in Older Fallers

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OBJECTIVES: To compare the effects of three fall-prevention programs (education (ED), home safety assessment and modification (HSAM), and exercise training (ET)) on quality of life (QOL), functional balance and gait, activities of daily living (ADLs), fear of falling, and depression in adults aged 65 and older.

DESIGN: A 4-month randomized trial.

SETTING: Randomized, controlled trial.

PARTICIPANTS: One hundred fifty participants who had experienced a recent fall.

MEASUREMENTS: QOL was assessed according to the brief version of the World Health Organization Quality of Life instrument (WHOQOL-BREF), functional balance and gait according to functional reach and Tinetti balance and gait, ADLs according to the Older Americans Resources and Services questionnaire, fear of falling according to a visual analog scale, and depression level according to the Geriatric Depression Scale.

RESULTS: The score changes for the ET group were 2.1 points greater on the physical domain (95% confidence interval (CI) = −1.2–5.3), 3.8 points greater on the psychological domain (95% CI = 0.7–7.0), and for the WHOQOL-BREF, 3.4 points greater on the social domain (95% CI = 0.7–6.1) and 3.2 points greater on the environmental domain (95% CI = 0.6–5.7) than for the ED group. The score change for each domain of the WHOQOL-BREF for the HSAM group was greater than that for the ED group, although these results were not statistically significant. The ET group also had greater improvements in functional reach, Tinetti balance and gait, and fear of falling than the ED group.

CONCLUSION: The QOL outcome supports the superiority of ET over the other two interventions in older people who have recently fallen. This finding also parallels those gathered from the functional measures. **J Am Geriatr Soc 55:499–506, 2007.**

Key words: education; exercise; elderly people; fall; environment; quality of life

Preventing falls is an important consideration for older adults. Thirty percent to 50% of community-dwelling older adults fall at least once a year.[1–5] In people aged 65 and older, falls are the most common cause of injuries and hospital admissions,[6] accounting for 87% of all fractures, and are the second leading cause of spinal cord and brain injuries. Falls also lead to psychological trauma,[7–9] motor deficits, loss of autonomy,[1,4,5,10] and enormous economic costs.[11]

Clinicians typically underestimate patients' desires for information on their condition and on healthcare services.[12] In addition, enhancing patient participation in decision-making may result in better health outcomes and a better sense of well-being.[13,14] Health-related quality of life (QOL), a measure of health status filtered by perceptions and expectations of the individual,[15] have increasingly gained recognition as an important tool for evaluating effects of medical treatments and healthcare services.[16] The assessment of QOL in elderly people is particularly important, because it can predict healthcare utilization and mortality[17,18] and because improving QOL is considered to be the primary goal of medical treatment in this population.[19] Because QOL is a broad, multidimensional construct that includes at least such domains as physical, psychological, and social functioning[20] and because a fall prevention program often affects fall risks as well as many other aspects of health in older people, QOL measures can provide a comprehensive health profile resulting from such programs. Furthermore, QOL measures may also efficiently and objectively help enhance the selection of optimal interventions for older people. Nevertheless, little is known about potential benefits of fall prevention programs on the QOL of older people.

A randomized trial was conducted to compare the effects of education (ED), home safety assessment and

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DOI: 10.1111/j.1532-5415.2007.01146.x

0002-8614/07/$15.00

modification (HSAM), and exercise training (ET) on multiple QOL domains in older people. Secondary outcomes, such as functional balance and gait, activities of daily living (ADLs), fear of falling, and depression level, were also examined.

METHODS

Study Subjects

Shin-Sher Township, located in Taichung County in west-central Taiwan, is a rural agricultural area with 14.1% of people aged 65 and older in 2003, versus 9.2% in Taiwan as a whole.[21] Residents aged 65 and older and who had required medical attention due to sustaining a fall in the previous 4 weeks were eligible for the study. During an 18-month recruitment period, 207 individuals were identified from all of the 10 clinics and hospitals in or near Shin-Sher Township. On the first home visit, potentially eligible participants were invited to enroll in the study and, if they agreed, were asked to complete a baseline assessment before randomization. A total of 150 elderly subjects agreed to participate in the trial. Of nonparticipants, seven had sustained hip fractures and one had head injuries due to falling. These nonparticipants were older (78.5 vs 76.5) and in poorer health than the remaining 150 participants.

Following baseline assessments, participants were block randomized in groups of six to one of three intervention programs (ED, HSAM, or ET) for preventing falls and enhancing QOL. Fifty participants were assigned to each intervention program and made time available for the assigned intervention every 2 weeks. Follow-up assessments were also conducted for participants at 2 and 4 months after the intervention. Twenty-five subjects had incomplete follow-up assessments, primarily because of medical problems, relocation, restriction to bed, and death. The progression of the study participants through the trial is shown in Figure 1. The institutional review board of Taipei Medical University, Taipei, Taiwan, reviewed this research, and written consent was obtained from each participant.

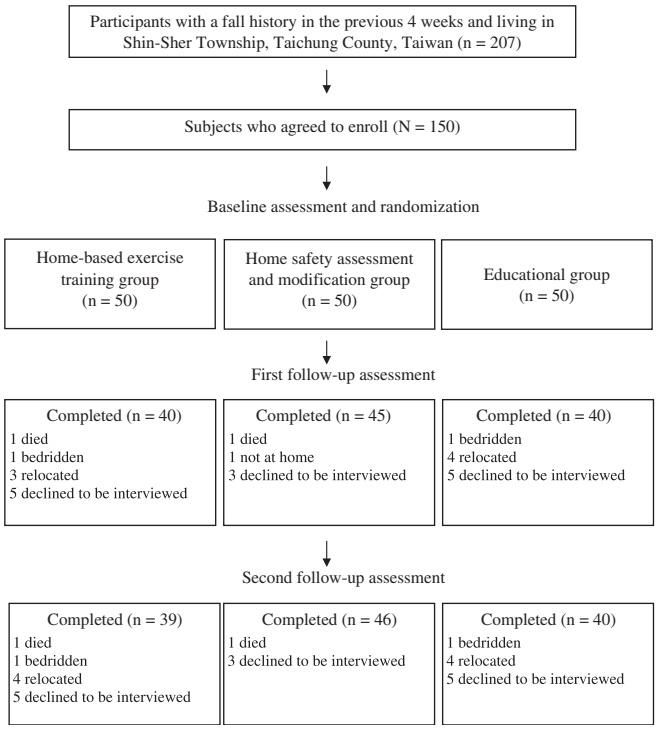

Figure 1. Flow diagram of study subjects.

Interventions

The interventions were conducted at each participant's residence once every 2 weeks during the 4-month intervention period. A physical therapist was responsible for the exercise training and two public health workers for the other two interventions.

Education

Subjects received one social visit of 30 to 40 minutes every 2 weeks over the study period to control for potential Hawthorne effects (i.e., the tendency for people to change their behavior due to being the target of special interest and attention in a study). Pamphlets provided information on fall prevention, including stretching and strengthening exercises for the lower extremities, use of walking aids, and home-environmental improvements, in an effort to encourage initiation and persistence in activities.

Home Safety Assessment and Modification

Home environmental hazards, which are thought to increase the risk of falling, and the absence of safety devices, which may prevent falls, were considered in the safety assessment. As summarized in Table 1, 28 items were developed based upon a review of the literature, consultations with experts, and investigations of existing fall prevention programs, with the primary intention of reducing falls among the participants. At each visit, 30 to 40 minutes was devoted to performing a safety assessment. A list of specifically recommended modifications of the identified home environmental hazards was provided to subjects or family members. Fourteen inexpensive modifications (Table 1) were developed for this study and completed within the first week in each participant's home.

Exercise Training

The intervention consisted of stretching, muscle strengthening, and balance training at increasing levels of difficulty. The training was individualized for each participant, supervised by a physical therapist, and reviewed every 2 weeks over the study period. Depending on each person's physical condition, each visit lasted 40 to 60 min, and consisted of approximately 10 minutes of warm-up, 30 minutes of exercise, and 10 minutes of cool-down. Stretching involved the major joints of the neck, shoulders, hips, knees, and ankles. A series of exercises was performed to increase the stability of the trunk muscles and to strengthen leg muscles, including the hip extensors and abductors, knee flexors and extensors, and ankle dosi- and plantarflexors. If a participant was capable, 1-kg ankle-cuff weights were applied to increase resistance. Balance training included rising from a sitting position to standing, standing on one leg, tandem walking, walking backwards and sideways, and turning

Table 1. Home Environmental Hazards Assessed in the Home Safety Assessment and Modification Group

Room or Area	Hazard
Overall	Poor lighting (too dim or with shadows or glare)*
	Slippery floor surface*
	Walkway with cords or other small objects one could trip over*
	Curled carpet edge*
Stairs	Hard-to-see step edge*
	No night light*
	No or inadequate handrail
	Stairs too steep, tread too narrow
	Steps in need of repair*
	High door sill
Living room/bed room	Low chair that is difficult to get out of
	Unstable chair or table*
	Unstable step stool*
	Shelves or cupboards too high or too low
	Low or high bed height
Bathroom/kitchen	Loose rug*
	Lack of grab rail
	Toilet seat too low
	No slip-resistant surface*
	Poorly placed light switches
	Light switches not visible in the dark*
	Hob on shower recess
Yard and entrance	Slippery, obstructed, or uneven pathway, ramp, or stairway
	Cracks in pavement, holes in lawn*
	Rocks, tools, and other tripping hazards*
Footwear	High-heeled shoes
	Soles and shoes too soft
	Slippery shoes

* Modified by this study.

360°. Safety was ensured by giving each participant adequate instruction on each exercise. Participants were instructed to practice these exercises at least three times a week.

Baseline Measures

Two assessors, blinded to group assignment, were responsible for the evaluation of baseline and two follow-up assessments. During baseline assessment performed at each participant's residence, information on birth date, sex, education, marital status, regular exercise, current smoking, alcohol use, comorbidity, cognitive status, fall history in the past year, number of body parts injured in the last fall, fracture status and injury severity of the last fall, ADLs, fear of falling, depression, and QOL was collected through direct interviews. Fall injuries were assessed using the Abbreviated Injury Scale (AIS).[22] AIS scores range from 0 to 5; 0 indicates no injury; 1, minor injury; 2, moderate injury; 3, severe, non-life-threatening injury; 4, severe, life-threatening injury; and 5, critical injury. If a fracture occurs, the AIS score is 2 or greater. Comorbidity was assessed using a list of 24 chronic conditions that are likely to affect older people. Cognitive status was assessed using the Mini-Mental State Examination (MMSE);[23,24] MMSE scores of 17 or less indicate severe cognitive impairment.[25]

Primary Outcome

The brief version of the World Health Organization's Quality of Life (WHOQOL-BREF) contains 26 items: two items from the overall quality-of-life and general health facet and one item from each of the remaining 24 health-related facets.[26] A facet is defined as a behavior (e.g., walking), a state of being (e.g., vitality), a capacity or potential (e.g., the ability to move around), or a subjective perception or experience (e.g., feeling pain).[27] The 24 facets or items are further categorized into four domains: physical capacity (7 items), psychological well-being (6 items), social relationships (3 items), and environment (8 items). The Taiwanese version of the WHOQOL-BREF was developed in compliance with WHO guidelines on procedures for translation as well as design and selection of appropriate items,[28] and excellent reliability and validity of this version in older people have been reported.[29] The Taiwan version includes 26 items translated from the standard WHOQOL-BREF and two additional items of local importance (i.e., being respected and food availability). The two local items were excluded from the analyses to facilitate potential future international comparisons. All items are rated on a 5-point Likert scale, and then domain scores are calculated by multiplying the mean of all facet scores included in each domain by a factor of 4, with a possible range of each raw domain score of 4 to 20. Each raw domain score is then standardized to a scale ranging from 0 to 100, with a higher score indicating a higher QOL.

Secondary Outcomes

More-objective functional measures such as ADLs, fear of falling, depression level, and functional balance and gait were also examined.

The Older Americans Resources and Services (OARS) ADL scale,[30] consisting of seven physical ADLs (self-feeding, self-dressing, grooming, walking, getting in and out of bed, bathing, and toileting) and seven instrumental ADLs (using a telephone, transporting oneself, shopping, preparing meals, doing housework, taking medication, and managing one's money), was used to assess independence, with a higher score indicating greater activity dependency. These items were graded as 0 points (inability), 1 point (needs some help), or 2 points (no help needed). Fear of falling was assessed using a 10-cm visual analog scale. Each end of the scale was marked with the labels "No fear" and "Extremely fearful." Participants were asked to place a mark on the line at a point representing the extent of their fear.[31] Depression was assessed using the 15-item Geriatric Depression Scale (GDS),[32,33] with a score greater than 10 indicating depression.[34]

Performance tests of functional reach and balance and gait were also conducted. In the functional reach test,[35] each participant was positioned next to the wall with one arm raised 90° with the fingers extended, and a yardstick was mounted on the wall at shoulder height. The distance in

centimeters that a subject was able to reach forward from an initial upright posture to the maximal anterior leaning posture without moving or lifting the feet were measured using visual observation of the position of the third finger tip against the mounted yardstick. The distances of two trials were averaged as the score of functional reach, with a greater distance indicating better dynamic postural control. The Tinetti balance test is one part of the Performance-Oriented Assessment of Mobility Problems[36] and consists of 13 maneuvers such as sitting balance, sit to stand, immediate standing balance (first 3–5 seconds), standing balance, balance with eyes closed, turning 360°, nudging the sternum, turning the neck, unilateral stance, extending the back, taking on object down from above, picking an object up, and sitting down. Each maneuver was graded as 2 points (normal), 1 point (adaptive), or 0 points (abnormal). Tinetti balance test scores range from 0 to 26, with a higher score indicating better overall balance. The Tinetti gait test is the other part of the Performance-Oriented Assessment of Mobility Problems and consists of the nine components of initiation of gait, step height and length, step symmetry and continuity, path deviation, trunk stability, walking stance, and turning while walking. Each component is graded as 1 point (normal) or 0 points (abnormal). Tinetti gait scores range from 0 to 9, with a higher score indicating better functional mobility.

Follow-up Measures

Two follow-up visits were performed at 2 and 4 months after the intervention, at which times the WHOQOL-BREF, functional reach, Tinetti balance and gait, OARS ADLs, fear of falling, and the level of depression were reassessed.

Falls Outcomes

When a fall occurred, participants were asked to report their falls by telephone or postcard; they were also contacted by telephone every 2 weeks to ascertain the occurrence of falling. Because this study focused on the QOL outcome, only brief fall-related information is reported here.

Statistical Analysis

Baseline characteristics in the ED, HSAM, and ET groups were compared using the analysis of variance test for continuous variables, the Pearson chi-square test for categorical variables, and the Mantel-Haenszel chi-square test for ordinal variables. When unbalanced characteristics were detected, these potential confounders were included in the subsequent multivariable analysis. A further comparison was made between the three groups to ascertain whether there was any difference between them in adherence to the two follow-up assessments. The logistic regression model was accordingly applied to identify factors associated with incomplete follow-up that would subsequently need to be controlled for to possibly eliminate a response bias when comparing the effects of the three intervention programs on each outcome of interest.

Crude score changes on the WHOQOL-BREF domains, as well as on secondary outcomes such as functional reach, Tinetti balance and gait, ADLs, fear of falling, and level of depression, from baseline to the first or second follow-up assessment for the three intervention groups were compared using the paired *t* test. Because these primary and secondary outcomes were repeated continuous measures, the linear mixed-effect model for each outcome was applied to estimate how it changed before and after an intervention and how the change depended on other variables.[37] By specifying the use of random intercepts, the linear mixed-effect model can take into account the heterogeneity arising from the repeated measures of each outcome within a single subject. In the model, unbalanced baseline characteristics between the three intervention groups and variables identified for the incomplete follow-up were also accounted for. The regression coefficient of an intervention interacting with time can be interpreted as changes in each outcome over the intervention period.

The effect size was used to determine the clinical significance of score changes in the four domains of the WHOQOL-BREF between the three intervention groups. The effect size was calculated as the difference in the mean change in scores for that domain over the intervention period divided by the standard deviation of score differences.[38] According to Cohen's recommendation, a clinically meaningful effect size of 0.2 to 0.5 is considered to be small, 0.5 to 0.8 to be moderate, and 0.8 or higher to be large.[39]

SAS version 8.0 (SAS Institute, Inc., Cary, NC) was used for all statistical analyses.

RESULTS

Of 150 participants, the mean age was 76.8, 49% were men, 37% had no formal education, 66% lived with a spouse, 58% exercised regularly, 17% smoked cigarettes, 9% consumed alcohol regularly, 63% had two or more chronic conditions, 30% were cognitively impaired, and 13% had experienced at least one fall in the previous year. In the more-recent fall, 39% of subjects had injured two or more body parts, 28% had fractures, and 29% had an AIS score of 2 or higher.

No significant differences in the distributions of any of baseline characteristics but alcohol use ($P = .04$) were detected between the ET, HSAM, and ED groups. At the two follow-up assessments, no significant differences in the baseline characteristics for subjects who dropped out of the study were found between the three groups. In the results of the logistic regression model for the incomplete follow-up, subjects who were widowed, divorced, or single (odds ratio (OR) = 2.2 and 95% confidence interval (CI) = 1.2–3.7) and with more body parts injured in the last fall (OR = 1.41 and 95% CI = 1.1–2.0) were less likely to have completed the two follow-up assessments than those who were married and those who had fewer body parts injured.

Primary and secondary outcomes in the ED, HSAM, and ET groups at the baseline and first and second follow-up visits are shown in Table 2. For the ED group, scores on the physical domain of the WHOQOL-BREF and the ADL increased significantly at the two follow-up assessments, whereas scores on the social domain of the WHOQOL-BREF declined at the first follow-up. For the ET group, scores on the four domains of the WHOQOL-BREF and those on all secondary outcomes except depression level improved significantly at the first or second follow-up. For the HSAM group, scores on the physical and environmental

Table 2. Outcome Variables at the Baseline and Two Follow-up Assessments in the Exercise Training (ET), Home Safety Assessment and Modification (HSAM), and Educational (ED) Groups

Outcome	ET			HSAM			ED		
	Baseline	First Follow-Up	Second Follow-Up	Baseline	First Follow-Up	Second Follow-Up	Baseline	First Follow-Up	Second Follow-Up
	Mean ± Standard Deviation								
Brief version of the World Health Organization Quality of Life instrument									
Physical domain score	51.0 ± 17.9	59.0 ± 12.5†	62.8 ± 9.9†	52.6 ± 15.1	60.9 ± 9.5†	60.9 ± 14.5†	48.9 ± 17.3	52.6 ± 13.8*	55.5 ± 15.3*
Psychological domain score	55.2 ± 13.6	62.9 ± 13.2†	64.4 ± 12.6†	58.1 ± 13.2	59.3 ± 13.5	61.5 ± 13.1	55.7 ± 16.0	53.8 ± 17.0	56.3 ± 17.6
Social domain score	69.9 ± 11.4	71.9 ± 10.0	75.4 ± 9.4*	70.9 ± 11.9	71.9 ± 11.2	73.6 ± 10.2	68.8 ± 10.6	63.8 ± 14.8*	66.3 ± 13.3
Environmental domain score	64.1 ± 12.5	70.2 ± 9.4†	74.9 ± 6.8†	65.8 ± 10.5	69.0 ± 10.7	70.2 ± 9.6*	62.5 ± 9.8	62.1 ± 14.4	65.1 ± 14.3
Functional reach score	14.4 ± 8.8	17.3 ± 7.2†	18.4 ± 7.6†	15.1 ± 8.1	15.0 ± 7.5	15.8 ± 7.5	13.6 ± 9.3	13.4 ± 7.4	15.2 ± 7.5
Tinetti balance score	18.5 ± 6.9	21.2 ± 6.7†	21.1 ± 6.7†	18.7 ± 6.2	20.4 ± 5.8*	20.9 ± 5.8†	18.4 ± 5.5	18.5 ± 6.1	18.5 ± 5.1
Tinetti gait score	6.3 ± 2.6	7.5 ± 2.5†	7.6 ± 2.7†	6.7 ± 2.3	7.5 ± 2.0†	7.7 ± 2.1†	6.2 ± 2.1	6.7 ± 2.1	6.6 ± 1.9
Activity of daily living score	20.0 ± 7.9	22.5 ± 5.3*	22.5 ± 5.9*	21.5 ± 5.3	22.7 ± 4.9†	23.2 ± 4.1†	20.7 ± 7.1	23.0 ± 5.7†	22.7 ± 6.2*
Fear of falling score	7.0 ± 3.5	6.4 ± 3.5*	5.6 ± 3.6*	6.8 ± 3.8	7.8 ± 3.5*	7.0 ± 3.6	7.4 ± 3.3	8.0 ± 2.8	7.5 ± 2.1
Level of depression score	9.7 ± 3.4	9.4 ± 2.7	9.4 ± 2.6	8.9 ± 3.0	8.1 ± 2.9	8.3 ± 2.5	9.2 ± 3.2	9.7 ± 2.8	10.0 ± 2.8

$P <$ *.05 and † .01, according to the paired t test, for the mean difference between scores at the baseline and those at the first or second follow-up.

domain of the WHOQOL-BREF and functional reach, Tinetti balance and gait, and ADLs increased significantly at the first or second follow-up, and those on the fear of falling increased significantly at the first follow-up.

As shown in Table 3, after adjustment for alcohol use (to account for baseline differences), marital status, and the number of body parts injured in the last fall (for follow-up differences), no significant differences in the baseline scores for the four domains of the WHOQOL-BREF were detected between the ED, HSAM, and ET groups. Over the intervention period, scores on the physical domain for the ED group increased significantly (by 3.9 (95% CI = 1.6–6.2) points); no significant changes in scores of the other three domains were detected. The score changes over the intervention period for the ET group were 2.1 (95% CI = –1.2–5.3) points greater on the physical domain, 3.8 (95% CI = 0.7–7.0) points greater on the psychological domain, 3.4 (95% CI = 0.7–6.1) points greater on the social domain, and 3.2 (95% CI = 0.6–5.7) points greater on the environmental domain than for the ED group, with the latter three results being statistically significant. The score changes over the intervention period for the HSAM group were 1.0 (95% CI = –2.1–4.2) point greater on the physical domain, 1.4 (95% CI = –1.7–4.5) points greater on the psychological domain, 2.4 (95% CI = – 0.2–5.1) points greater on the social domain, and 0.4 (95% CI = – 2.0–2.9) points greater on the environmental domain than for the ED group, although these results were not statistically significant.

As shown in Table 4, after adjustment for alcohol use, marital status, and number of body parts injured in the most-recent fall, no significant differences were detected between the ED, HSAM, and ET groups in functional reach, Tinetti balance and gait, ADLs, fear of falling, or depression at baseline. For the ED group, ADL scores and depression level increased significantly (by 0.9 (95% CI = 0.2–1.7) and 0.5 (95% CI = 0.1–1.0) points, respectively) over the intervention period, and no significant changes in other outcomes were detected. The ET group increased significantly more than the ED group (by 1.5 (95% CI = 0.3–2.6) centimeters in functional reach distance, 1.3 (95% CI = 0.2–2.4) points more on the Tinetti balance score, and 0.4 (95% CI = 0.1–0.8) points more on the Tinetti gait score). Additionally, the fear of falling score for the ET group declined significantly (by 0.8 (95% CI = –1.5 to – 0.1) points). The GDS score for the HSAM group declined significantly more than for the ED group by 0.9 (95% CI = – 1.5 to – 0.2) points); no significant differences in score changes on the other outcomes were detected between the two groups.

After adjustment for baseline differences and variables for incomplete follow-up, the effect sizes of score changes on the physical, psychological, social, and environmental domains of the WHOQOL-BREF were 0.70, 0.79, 0.41, and 0.94 for the ET group; 0.69, 0.27, 0.20, and 0.35 for the HSAM group; and 0.38, 0.04, – 0.28, and 0.22 for the ED group, respectively.

Over a 6-month period, the fall incidence rate per 1,000 person years was 2.4 in the ED group, 1.1 in the HSAM group, and 1.6 in the ET group; differences in the rate of falling between the three groups were not statistically significant.

Table 3. Results of the Mixed Model Analysis for Each Domain of the World Health Organization Quality of Life Instrument

Characteristic	Physical	Psychological	Social	Environmental
	Relative Difference (95% Confidence Interval)			
Intercept	44.4 (38.1–50.7)	51.0 (44.9–57.2)	65.3 (60.5–70.1)	61.9 (57.2–66.7)
Group				
Education	0.0	0.0	0.0	0.0
ET	3.6 (– 1.8–9.0)	0.1 (– 5.2–5.3)	1.5 (– 2.7–5.8)	2.6 (– 1.5–6.7)
HSAM	2.0 (– 3.6–7.6)	–0.1 (– 5.5–5.4)	2.5 (– 1.8–6.8)	3.3 (– 1.0–7.5)
Time	3.9 (1.6–6.2)	0.7 (– 1.5–3.0)	– 1.2 (– 3.1–0.7)	1.8 (– 0.1–3.5)
Group × time				
ET × time	2.1 (– 1.2–5.3)	3.8 (0.7–7.0)	3.4 (0.7–6.1)	3.2 (0.8–5.7)
HSAM × time	1.0 (– 2.1–4.2)	1.4 (– 1.7–4.5)	2.4 (– 0.2–5.1)	0.4 (– 2.0–2.9)

Note: Adjusted for alcohol consumption, marital status, and number of body parts injured in the last fall.
ET = exercise training; HSAM = home safety assessment and modification.

DISCUSSION

The QOL outcome was more sensitive to fall prevention programs than to the number of falls. Evidence is inconsistent that exercise alone can reduce the risk of falls, and a common explanation is that some studies have made use of exercise of insufficient duration, intensity, and frequency.[40,41] Nonetheless, vigorous exercise empirically increases the cumulative risk of falling for elderly people with osteoporosis,[42] and vigorous elderly groups are more likely to experience serious fall injuries.[43] This quandary may be avoided when the changes in QOL domains resulting from each intervention program are involved in the decision-making process, because greater improvements in multiple QOL domains should indicate that an intervention is acceptable and that older people will adhere to them in the long term compliance.

The results from this study reinforce the need to further examine the meaning of QOL assessments of older adults. First, not all of the generic QOL measures, usually developed for the general population, are suitable for older people. It has been determined that the WHOQOL-BREF is a reliable, valid, and responsive measure of the occurrence of falls in older people.[33] Second, improvements in the physical QOL domain and ADLs in the ED group may have resulted from physical recovery as a consequence of a previous fall, social visits, or the educational program itself. The decline in the social domain of the group was unexpected, and older people may misinterpret the educational advice on fall prevention as meaning activity limitations.[44] Third, differences in the magnitudes of the score changes across the four WHOQOL-BREF domains might reflect the sensitivities of different WHOQOL-BREF domains as well as the effects of different intervention programs. Finally, a meaningful interpretation of changes in QOL scores is usually difficult, because the statistical significance of changes in QOL scores implies little about the clinical significance. The effect-size interpretation used in the study was based on the distribution of the observed data and the variability of the measurements, although if the QOL changes are related to more-familiar or objective measures, clinicians may more easily grasp the anchor-based interpretation of clinical significance in elderly populations. For instance, the score changes in the physical QOL domain in this study were significantly correlated with those in the Tinetti balance

Table 4. Results of the Mixed Model Analysis for Functional Reach, Tinetti Balance and Gait, Activities of Daily Living, Fear of Falling, and Depression Level

Characteristic	Functional Reach	Tinetti Balance	Tinetti Gait	Activities of Daily Living	Fear of Falling	Level of Depression
	Relative Difference (95% Confidence Interval)					
Intercept	12.3 (8.7–15.9)	16.1 (13.5–18.8)	5.9 (4.9–6.9)	18.6 (15.9–21.3)	9.1 (7.6–10.6)	10.8 (9.5–12.0)
Group						
Educational	0.0	0.0	0.0	0.0	0.0	0.0
ET	2.3 (– 0.4–5.0)	2.0 (– 0.1–4.1)	0.7 (– 0.1–1.5)	1.1 (– 1.1–3.2)	– 0.4 (– 1.7–0.8)	– 0.1 (– 1.1–1.0)
HSAM	1.1 (– 2.1–4.2)	0.5 (– 1.8–2.8)	0.6 (– 0.2–1.5)	0.1 (– 2.2–2.4)	0.4 (– 0.9–1.8)	– 0.1 (– 1.1–1.1)
Time	0.4 (– 0.4–1.2)	0.1 (– 0.7–0.8)	0.2 (– 0.1–0.5)	0.9 (0.2–1.7)	– 0.1 (– 0.5–0.4)	0.5 (0.1–1.0)
Group × time						
ET × time	1.5 (0.3–2.6)	1.3 (0.2–2.4)	0.4 (0.1–0.8)	0.5 (– 0.5–1.5)	– 0.8 (– 1.5 to–0.1)	– 0.6 (– 1.2–0.1)
HSAM × time	0.1 (– 0.9–1.2)	1.0 (– 0.1–2.0)	0.3 (– 0.1–0.6)	– 0.1 (– 1.0–1.0)	– 0.1 (– 0.7–0.6)	– 0.9 (– 1.5 to–0.2)

Note: Adjusted for alcohol consumption, marital status, and number of body parts injured in the last fall.
ET = exercise training; HSAM = home safety assessment and modification.

(correlation coefficient (r) = 0.56), Tinetti gait (r = 0.46), ADL (r = 0.63), fear of falling (r = −0.44), and depression (r = −0.55).

There are several limitations to this study. First, the results may be less generalizable to frail older people, because subjects who had poorer health; had serious fall injuries or more body parts injured in the more-recent fall; or were divorced, widowed, or single tended not to participate or remain in the trial. Subgroup analysis confirmed that subjects who had AIS scores of 2 or higher in the most-recent fall had greater improvements in the physical domain of the WHOQOL-BREF than their counterparts (14.0 vs 7.3 points, P = .03). Moreover, despite the WHOQOL-BREF being developed cross-culturally, cultural differences in the meaning and importance of QOL items and domains, the perception of health, the effect of a fall, and expectations of interventions between elderly Taiwanese fallers and those of other countries may still remain and somewhat limit the generalizability of the results. Second, missing values of QOL data in the follow-up assessments for subjects who had died or were bedridden may have reduced the study efficiency; more importantly, they may have also led to biased results, although differences in score changes in each WHOQOL-BREF domain between educational controls and other intervention groups remained unchanged when the minimum possible value was imputed to each item of the WHOQOL-BREF for those subjects, probably because the numbers of missing values across the three intervention groups were similar. Finally, differences in the study outcomes between the HSAM and ED groups may have been overestimated because of different response rates between the two groups (92% vs 80%). A larger sample size of subjects is warranted to guarantee no selection factors between study groups and to reduce the effect of unavoidable attrition in studies of older people. Nevertheless, the response rates did not differ between the ET and ED groups (78% vs 80%), and the comparison of results between the two groups should be robust.

Although not denying the importance of more-objective measures for fall-prevention programs, the QOL reflects not just health status, but also how patients perceive and value the health- and non-health-related aspects of their conditions before and after receiving an intervention. The QOL outcome supported the superiority of exercise training over the other two interventions in older fallers and paralleled those more-objective functional measures.

ACKNOWLEDGMENTS

Financial Disclosure: The Bureau of Health Promotion, Department of Health (DOH92-PH-1103) and the National Science Council (NSC95-2314-B-038–008), Taiwan, Republic of China, supported this work. There was no financial conflict of interest for this study.

Author Contributions: Mau-Roung Lin: study concept and design, acquisition of subjects and data, analysis and interpretation of data, preparation of manuscript. Steven L. Wolf: study concept and design, preparation of manuscript. Hei-Fen Hwang: acquisition of subjects and data, preparation of manuscript. Sheng-You Gong: acquisition of subjects and data, analysis and interpretation of data. Chih-Yi Chen: analysis and interpretation of data.

Sponsor's Role: The National Science Council had no role in this manuscript.

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