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Randomized Control Trials on Otago Exercise Program (OEP) to Reduce Falls Among Elderly Community Dwellers in Shahroud, Iran

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Abstract

Background: Fall is a worldwide health problem among elderly people and a known leading cause of disabilities. Fall prevention programs have been implemented in various forms. The Otago exercise program (OEP) is one of the most recent home-base exercise training program.

Objectives: This study was conducted to examine the effectiveness of OEP to reduce falls among elderly people in Shahroud, IR Iran.

Materials and Methods: This randomised control trial was conducted among the elderly community dwellers in Shahroud city of the Semnan province, IR Iran, with experience of falls in the last 12 months. Subjects of the study (n = 317) were recruited from elderly senior citizens at public health centers. Block systematic random sampling was applied to categorize the subjects in experimental and control groups. The experimental group (n = 160) received OEP for six months and was compared with the control group (n = 157) who received general health training. This study was registered with the following ID, IRCT2014012016285N1.

Results: The findings of the study showed that OEP improved physical performance (Berg-Balance-Score with $P > 0.025$, and Timed-Up-Go-Test with $P > 0.017$) and functional capacity (Arm-Curl-Test with $P > 0.00$ and Chair-Stand-Test with $P > 0.01$). In addition, OEP significantly reduced the incidence of falls ($P \leq 0.00$) among senior citizens in the experimental group.

Discussion: The OEP as a home-based exercise is effective for the reduction of the incidence of falls among senior citizens with a history of falls. The OEP can be recommended for elderly homebound people who do not have access to facilities.

Keywords: Otago Exercise, Falls, Elderly, Community

1. Background

Fall is a worldwide health problem among elderly people (1, 2). Approximately 30% of community dwellers aged 65 and older fall annually (3). Falls are not only associated with morbidity and mortality in the older population (3, 4), but are also linked to poorer overall functioning, low quality of life and early admission to hospitals and long term care facilities (5).

Fall prevention programs have been implemented in various forms (2, 6, 7). However, most of the previous fall prevention programs are costly and require a lot of time and effort (8). Moreover, they are implemented by trained personnel at luxurious settings. This means that public availability of most programs is not possible (8-11). Researchers have applied different approaches and strategies to prevent falls among vulnerable elderly people in the community (12, 13). To meet this public need, the necessity for a home-base exercise program has been proposed by some researchers (14-16). For those homebound elderly, application of a home-based exercise training can be an alternative option to prevent falls (14, 17). Therefore, there is growing attention towards the application of home-based exercise programs for the elderly (14, 18-20).

Despite obvious advantages of home-base exercise programs, surprisingly, only a few randomized controlled intervention studies on falls have investigated the effects of home-base training intervention for community-dwelling elderly (20-22). In addition, there have been some drawbacks in previous home-base programs. Most previous home-base interventions still rely on expert personnel who closely supervise their clients (23) and provide them with high standard care at their homes (21, 22). The Otago Exercise Program (OEP) is one of the most recent home-based exercise training programs. The OEP was first introduced in New Zealand (21, 22, 24).

The program is a strength and balance retraining program, combined with walking, known as the OEP (14, 21). The program was designed for three times a week and progressed over time. Four randomized controlled trials, with different settings and timings, disclosed the effects of the program on the elderly.

The first Otago trial addressed female elderly community dwellers, over the age of 80, who were grouped in exercise and control groups. Physiotherapists who were responsible to attend four home visits over the first two months conducted this OEP. They scheduled the program for 30-minute sessions to be conducted three times a week, plus walking outside the home three times a week. For monitoring purposes, regular telephone contacts were done. In the control group, usual home visits were done and usual home visit care was provided for the clients. The results showed that there was no significant difference between the control and experimental groups in Instrumental Activity of Daily Life (IADL) or the physical self-maintenance scale (25).

In the second trial of the OEP, researchers continued telephone contacts to motivate the subjects in the experimental group to keep up the program (25). At this time, the researcher merely measured incidence of falls, falls-induced injuries and subjects' compliance to the exercise program (14, 22). According to the results of this study, 44% of the subjects continued the program for two-years (26). They reported significant reduction in the incidence of falls, although the rate of falls in the first and second year in experimental group was unchanged (25). One of recommendations of this trial was a booster home visit at the end of the sixth month (26). In the third and fourth trials, the OEP was altered to a different model and researchers tried to look at the cost-effectiveness of the program. At this stage the program was delivered by trained district nurses (25, 26), and also included male senior citizens. Moreover, they included subjects of 75 years old and over (25). The content of the exercise program was intact, yet they increased the home visits frequency to weeks one, two, four and eight. Moreover, they planned a booster visit at the end of the sixth month (27). The results of the study revealed that the OEP is beneficial for elderly people. The program failed to decrease the rate of falls in elderly people under 80; however, it successfully reduced the rate of falls among the elderly community dwellers 80 years old and above (22, 25). Moreover, the researchers concluded that the OEP can be cost-effective, especially if trained practice nurses conduct the program (22, 25).

2. Objectives

Despite growing application of OEP, it has not been applied and tested in Middle East countries. The purpose of this study was to examine the effectiveness of OEP to reduce falls among community elderly dwellers in Shahroud city of the Semnan province, IR Iran.

3. Materials and Methods

This study was a randomised clinical trial conducted on senior citizens living in Shahroud, IR Iran. Figure 1 shows the flow chart of the study.

3.1. Sampling

Block random sampling was applied to assign participants into experimental and control groups. In this multicenter study, each public health center was randomly assigned as control or experimental blocks. All subjects at each health center were allocated to control or experimental groups based on their allocated health centers. This prevented data contamination between subjects in the control and experimental groups.

The researchers planned to have at least 150 subjects in each of the control and experimental groups based on the sample size calculation formula. To estimate a sample size for a proportion in a study, three numbers are needed; estimate of the expected proportion (p), desired level of absolute precision (d), and confidence level (e.g. 1.96 for 95% confidence level) (Z).

The sample size formula is presented below:

$$n = \frac{Z^2 \times p(1-p)}{d^2} = \frac{1.96^2 \times 0.28(1-0.28)}{0.05^2} = 310 \quad (1)$$

The inclusion criteria were as follow. All subjects were 60 years old and above, able to walk at least 10 meters long, had permanent residency in an urban area in the last 12 months and had previous experience of falls. Moreover, they had a female family member (to maintain homogeneity) as a caregiver (aged 18 - 50) who had health literacy. Health literacy was tested by reading an instructional booklet and explaining the content to the researchers.

Exclusion criteria were acute or chronic disease, which may restrict exercise for subjects. A physician's approval letter was filled by GPs working at the district health centers. Other reasons for exclusion from the study were being unable to walk independently for 10 m, having previous hip replacement surgery or previous history of lower extremities fracture in the last 12 months, severe articular involvement limiting physical activity and recommendations discouraging participation for any reason by an orthopedic surgeon. In addition, elderly people with high vigorous level of activity in the last 12 months were excluded from the study.

In this study, 12,315 elderly individuals were registered at district health centers, under the health services of Shahroud Medical University (SHMU), IR Iran, from January 2012 to January 2013. Of all registered elderly people, 2,223 subjects attended the district health centers and were interviewed and examined by GPs. However, 1,772 subjects were excluded for different reasons, such as being unwilling to participate in the project, which was either the decision of the client (n = 461) or their caregivers (n = 284), having experience of vigorous activity during the last 12 months (n = 13), not having an eligible caregiver (n = 573),

suffering from an acute disease or not approved to participate in the exercise training by the panel doctor (n = 441). The final number of subjects who were selected to participate in the program was 451.

The number of subjects in both groups who rejected to complete the program at any stage of the program was 144 individuals, of whom 115 were from the experimental group and 119 were from the control group. The total number of subjects who participated in the study for six months was 157 individuals in the control group and 160 in the experimental group, giving a total number of 317 elderly people.

To recruit and train the executive team, public health Deputy of Dean at SHMU, mobilized general practitioners, nurses and chief health officers in all district health centers participated in a workshop on "Fall in Elderly". The workshop was run by the same instructor and a package of instructions was provided for the participants. The package included a CD with video clips to instruct on how to do all the clinical exams and interview with the clients and how to fill up the forms and questionnaires. All medical tests were performed by a GP, blinded about the program and subjects in both groups. The inter-rater reliability between the two examiners with the same knowledge and skills was conducted and revealed strong reliability (r = 0.94).

Subjects in the experimental group received the OEP for six months in the presence of their family caregivers. All training sessions were held at the client's home. In addition to face-to-face education, participants were given a pictorial booklet of all training exercises. They were instructed on how to use the training booklet. A flexible timetable (based on participants' preference) in a logbook was arranged for the subjects to allocate 45 to 60 minutes for exercise three times a week. Each OEP session consisted of a five- to ten-minute warm-up, 30- to 40-minute strength training, and five- to ten-minute cool-down training. They were instructed to strictly follow sequences of the training as warm up, exercise and cool down. In order to confirm accuracy of the participants and caregivers performance (monitoring and recording), an orientation session and regular home visits (once a month) were planned. The control group received a booklet on general health for elderly people published by the "Iranian Ministry of Health, Treatment and Medical Education". All participants' family members were allowed to call the researcher during the programme to ask their questions. In addition, the researcher called them frequently to assure if they are using their booklet properly.

3.2. Ethics

The proposal of this study was approved and supervised by the research committee and medical ethic committee of Shahroud University of Medical Sciences. In addition, this randomized control trial was registered with the following ID, IRCT2014012016285N1. All participants, elderly people and their family caregivers, filled the informed consent. They were visited by a panel of doctors to approve safety of training for their clients. Participants were encouraged to call their doctors or researcher in case of any query. Moreover, they were assured that any injury during pre and post-tests at the rehabilitation center would be supported by the university hospital. Moreover, they were assured that all the information would be kept confidential and would not be revealed unless for research purposes and in an anonymous form. Participants were allowed to decline participation at any stage of research, yet they were not allowed to switch from either group to another.

3.3. Study Intervention

This study followed the standard OEP to prevent falls. The Otago university formally validated and approved the study to be conducted in Iran via email. The procedure started with five-minute gentle warm up, continued by 30- to 45-minute exercise activity and finished with a 5 - 10 minute cool down exercise. The exercise protocol included strengthening and balance exercises.

3.4. Measurement Outcomes

Demographic characteristics' of the subjects were collected from their health records at the health centers. The outcome measures included "functional capacity", "physical performance" and "incidence of falls". All these outcome variables were examined before and after the exercise training program. The functional capacity included, the Berg balance scale (BBS) and the timed up and go test (TUGT). Chair stand test (CST) and arm curl test (ACT) assessed physical performance for each subject.

3.5. Berg Balance Scale

The BBS contains 14 static and dynamic activities (e.g. transfers, standing unsupported and sit-to-stand) and more difficult tasks (e.g. tandem standing, turning 360° and single-leg stance). For scoring, a five-point scale, ranging from 0 - 4 was used. Zero indicated the lowest level of function and four indicated the highest level of function. The total score varied between 0 and 56. In interpretation of BBS, three levels of low, medium and high risk of falls were categorized. Low risk of falls corresponded to scores 41 to 56; medium risk of falls corresponded to scores 21 to 40 and high risk of falls corresponded to scores 0 to 20 (28).

3.6. Timed Up and Go Test

The TUGT measures the individual's ability to stand up from a standard arm chair, walk a three-meter distance in a flat direction, then turn back and walk to the chair, and sit down in seconds (29, 30). A client with normal ability is expected to accomplish the task in less than 12 seconds. A longer time needed to finish the test is considered as impaired TUGT results (31). The client is instructed to start with the following sentence; "When I say 'go' I want you to stand up and walk to the line, turn and then walk back to the chair and sit down again. Walk at your normal pace" (31, 32).

3.7. Chair Stand Test

The Chair Stand Test, or 30 seconds Chair Stand Test, is a physical performance test used to assess the clients' lower-extremity function, which has been shown to predict subsequent development of disability, because it reflects the effects of chronic disease, coexisting conditions and overall physiologic decline. A five-repetition test is a measure of strength while a ten-repetition test is a measure of strength and endurance (33).

3.8. Arm Curl Test

The ACT is used to measure upper extremity strength, which is assessed by the number of times a weight (0.5 Kg for females and 1 Kg for males) can be lifted (on their dominant hand) in a 30-second time period. The goal of this test is to have the client to perform as many biceps muscle curls as possible in 30 seconds (34). This test should be performed on the dominant arm side (or stronger side). The subject sits on the chair, holding the weight in their hand using a suitcase grip (palm facing towards the body) with their arm in a vertically down position beside the chair. The upper arm against the body should be immobilized, so that only the lower arm is moving (35). Interpretation of the test differs based on sex and age category of the subjects. The results are reported as below average, average and above average (34).

3.9. Statistical Analysis

To analyze the data, the SPSS version 21 was applied. Descriptive and inferential statistics were performed by the SPSS software, and the mean, standard deviation, and frequency of variables were obtained. Moreover, t-Test and x^2 were applied in inferential statistical methods. Statistical significance was determined at < 0.05. Normality of the results was tested by skewness of ± 1, indicating that all results were normally distributed.

4. Results

The baseline characteristics of the subjects of the study are summarized in Table 1. It presents the mean (M) and standard deviation (SD) baseline assessment of the 317 subjects in both control (n = 157) and experimental (n = 160) groups. Moreover, the t value, degree of freedom (df) and significance level for comparison of values of control and experimental groups are shown in Table 1.

As presented in Table 1, all variables had significance values more than 0.05, indicating that there was no difference between subjects in the control and experimental groups and they were well matched.

In order to compare homogeneity of groups, the chi-square test for differences between groups regarding demographic parameters including age, sex, activity of daily living (ADL), gender, balance, marital status, cognitive status, living area and living arrangement was conducted. In addition, in this study, cognitive status was measured by the Abbreviated Mental Test Score (AMTS). This test is routinely applied for elderly people (36). In this study neither of the subjects had severe cognitive impairment. This is because of the exclusion criteria, which excluded subjects with severe dementia and very low cognitive status. The P values of characteristics among subjects of this study were all greater than 0.05, indicating that subjects in the control and experimental groups were well matched.

The TUGT and BBS are two tests, which show subjects' functional capacity. The findings of this study regarding TUGT indicated that more than 85% of the subjects in both groups were suffering from moderate to severe gate disturbances. In addition, the P value for TUGT was 0.39, which rejects differences between baseline results of TUGT in control and experimental groups. In addition, the results of the study regarding BBS indicated that 70 to 75 percent of the subjects were at intermediate to high risk of falls due to balance impairment. The P value result for BBS was 0.16, which rejects there being differences between pre-intervention results of BBS in the control and experimental groups. All outcome variables were not significantly different between subjects in the control and experimental group, indicating that these groups were well matched.

To ensure fulfilment of the research objectives regarding the effects of exercise training on physical performance, the chi-square test was applied. Physical performance is evaluated by measurement of ACT and CST. The results of ACT are shown in Table 2. The comparison of post-intervention results of ACT, using the chi-square test, showed that there is a significant difference between post intervention results in the control and experimental groups ($P \leq 0.00$). In addition, the results of CST are shown in Table 2. The results, using the chi-square test showed that there was a significant different between control and experimental groups when comparing the post-intervention results of ACT ($P < 0.00$) and CST ($P \leq 0.001$).

To assess improvement of functional capacity, the results of TUGT and BBS were compared for subjects' post intervention results in the control and experimental groups. The TUGT results, as shown in Table 2, present significant differences between control and experimental groups when comparing the post-intervention results of TUGT ($x^2 = 36.99$, df = 2, P-value = 0.017). In addition, BBS results, as are shown in Table 2, present significant differences between control and experimental groups when comparing the post-intervention results ($x^2 = 21.31$, df = 2, P-value = 0.025).

Figure 2 shows the change in means of measures for incidence of fall before and after intervention in both control and experimental groups.

According to the results for comparing the mean in the control group the mean of fall incidence raised from 1.58 to 1.64 from pre to post intervention assessment. On the other hand, in the experimental group the means of fall incidence declined from 1.58 to 1.26 from pre to post intervention assessment. As it is indicated from the abovementioned results, OEP can improve outcome variables such as TUGT, FES, BBS and ABCS. In addition, the OEP reduced the frequency of falls among subjects of the study.

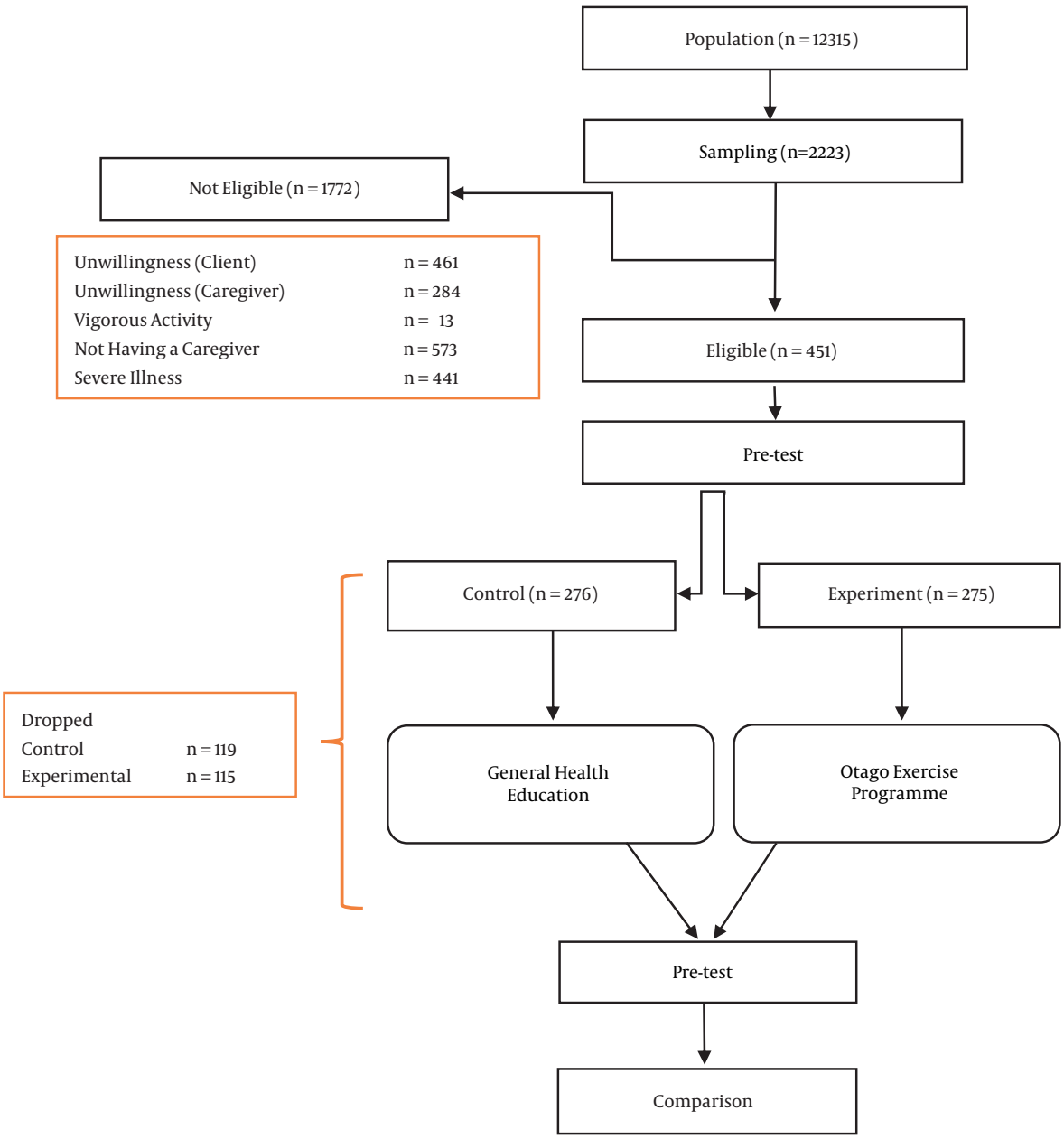

Figure 1. Flow Chart of the Study

Table 1. Comparative Characteristics of Subjects in the Control and Experimental Groups

Variables	Control (n = 157)	Experimental (n = 160)	t	df	P Value
Age	70.06 ± 5.20	70.60 ± 5.80	-0.88	315	.382
BMI	27.40 ± 2.97	27.03 ± 3.05	1.12	315	.263
Medication Number	5.33 ± 1.47	5.35 ± 1.49	-0.11	315	.910
Special Medication	1.29 ± 0.10	1.27 ± 0.87	0.12	315	.905
TUGT	25.78 ± 5.34	25.40 ± 5.71	0.68	315	.495
BBS	30.97 ± 8.12	30.54 ± 7.22	0.48	315	.629
FES	53.13 ± 15.45	52.91 ± 16.45	0.22	315	.823
ABCS	76.12 ± 22.20	77.28 ± 21.03	0.07	315	.946
Falls Frequency	1.56 ± 0.66	1.58 ± 0.63	-0.29	315	.775

Abbreviations: ABCS, Activity-specific Balance Confidence Scale; BMI, Body Mass Index; FES, Falls Efficacy Scale; TUGT, Timed Up and Go Test.

Table 2. Comparison of Outcome Variables Between Post-intervention Results in the Control and Experimental Groups[a]

Outcome Variables	Groups		X^2	df	P Value
	Control	Experimental			
ACT			22.32	1	.00
Below	79 (49.68)	41 (25.6)			
Average	77 (49.05)	109 (68.1)			
Above	1 (00.27)	10 (06.3)			
CST			55.65	2	.001
Weak	57 (31.90)	23 (14.4)			
Strong	78 (68.10)	81 (50.6)			
Strong and Endurance	22 (14)	56 (35)			
TUGT			36.99	2	.017
Mild Impairment	21 (13.38)	71(44.38)			
Moderate	98 (62.42)	65 (40.62)			
Severe	38 (24.20)	24 (15)			
BBS			21.31	2	.025
Low risk	33 (16.60)	45 (28.1)			
Medium Risk	88 (68.80)	107 (66.9)			
High Risk	36 (14.60)	8 (5)			
Frequency of Falls			21. 19	3	.00
None	3 (1.90)	22 (11.87)			
One	56 (35.70)	76 (44.37)			
Two	92 (58.60)	60 (42.50)			
Three	6 (3.80)	2 (1.25)			

Abbreviations: ACT, Arm Curl Test; CST, Chair Stand Test; TUGT, Timed Up and Go Test; BBS, Berg Balance Scale.
[a]Data are presented as No. (%).

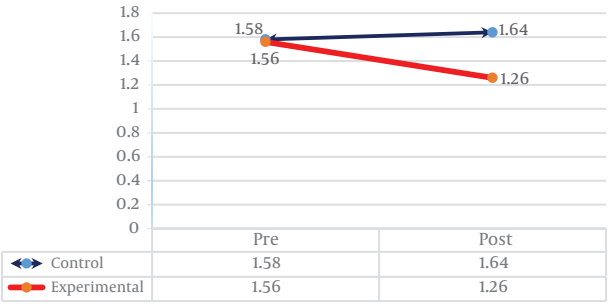

Figure 2. Trend of Falls Incidence Before and After Intervention in Control and Experimental Groups

5. Discussion

The purpose of this study was to examine the effects of OEP to decline the incidence of falls among elderly community dwellers. The main advantage of this study was that the investigation was conducted on a normal community population covering all elderly people from both sexes and both rural and urban communities. The study followed standardized procedures for recruitment of participants, sampling, data collection and baseline assessment for clinical tests and follow-up of the outcomes, using trained research staff. The other advantage of this study was that the study was conducted in a developing country. There are scarce data regarding elderly people in developing countries. Moreover, the key subject of this study was falls. Based on the current knowledge, this is the first RCT on falls prevention in Iran.

Subjects of the study were recruited from a population of elderly people with experience of at least one episode of fall. Previous falls is a risk factor and predisposing variable for falls among elderly community dwellers (37). The OEP as a home-based exercise designed to be applied for elderly people (38), can be used for those senior citizens who cannot benefit from luxurious institutional rehabilitation instruments (39). The OEP is a combination of muscle strengthening, balance training, and walking programs for the reduction of falls among senior citizens (40).

The results of this study add to the evidence on the effectiveness of the OEP for senior citizens in Iran. In other words, the results of this study support the hypothesis that a six-month home-based exercise training program, with supervision of a trained family member as a caregiver, can improve physical functioning and functional balance among elderly community-dwellers with a pre-

vious history of falls. The findings of this study are in accordance with the results of the systemic review and meta-analysis of Thomas et al. This study was six months in duration; however, the results are consistent with the study of Campbell et al. (14), which showed that the benefits of OEP can last at least for two years.

In this study, the OEP was conducted by trained nurses and health officers. Robertson et al. (2001) recommended that OEP should be delivered by nurses (22). It can be as effective as when conducted by physiotherapists yet more cost-effective when nurses deliver the program to the community (22, 27). Moreover, this study did not report any major and/or sever complaint due to exercise. The findings of this study were similar to a research conducted by Matsuda et al. (41) which showed that home-based exercise training was completely safe.

Balance as an important outcome of the study improved in subjects of the experimental group (38). It is likely that impaired balance is a stronger risk factor for falls (Sherrington et al. 2011) (23). This was confirmed by Steadman et al. (2003) (42), indicating that exercise improves balance and mobility and prevents falls among senior citizens. This study showed that OEP as a home-based exercise can improve functional capacity (BBS and TUGT), as a good predictor for balance. In addition, this study confirmed that OEP can increase subjects' physical performance, which is measured by ACT and CST. Rikli and Jones (1999) (33) stated that CST is a valid instrument for predicting falls among elderly community dwellers, and concluded that strength in lower extremities (measured by CST) is more important than upper extremities in prevention of falls in elderly people. This study measured both upper and lower extremities before and after OEP and the results suggested that OEP can improve physical performance in elderly people.

There were some limitations that may affect the outcome of this study. The primary limitation of the study was the application of falls self-report profiles. In the data collection, self-reported data are condemned to be reluctant regarding their validity. In some cases, in order to validate falls, the researcher asked the clients' caregivers to approve occurrence of falls. In addition, the health condition of the majority of the subjects played a deterrent role for participation in the program.

This study supports the effectiveness of OEP to improve balance and prevent falls among elderly people. The findings of this study can be more applicable for homebound senior citizens and especially feasible as an alternative for costly high-tech exercises.

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Footnotes

Authors Contribution: Ali Dadgari and Tengku Aizan Hamid were responsible for all related activities of the study, writing of the manuscript and supervision. Reza Chaman, Mohammad Nazrul Hakim, Seyed Abbass Mousavi, Lim Poh Hin. Leila Dadvar contributed to the writing of the proposal and data analysis.

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