Research Article

Efficacy of an exercise program on balance and lower limb functional level among elderly population of Gujarat, India: A randomized controlled trial to prevent falls

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ABSTRACT

Background: Altered balance and lower limb muscle weakness are the common risk factors associated with falls in elderly. **Objectives:** The purpose of this study was to assess the efficacy of an exercise program on balance and lower limb functional level in elderly population with moderate risk of fall. **Materials and Methods:** An exercise program, including warm-up exercises, balancing exercises, strengthening exercises, flexibility, and cool-down exercises, was designed for this interventional study. A total of 50 participants were selected by simple random sampling method from the physiotherapy department of the hospital, Ahmedabad, and they were randomly allocated into an interventional group of 25 and a control group of 25 participants. The inclusion criteria included, age: 60–80 years, both men and women, and Berg balance scale (BBS) score of ≤45. The intervention group received the exercise program for 4 times/week for up to 6 weeks and the control group was kept in waiting period. Pre- and post-exercise programs, a comparison of all measures was done with focus on BBS and lower extremity functional scale as primary outcome measures to find out the efficacy of the treatment protocol. The general linear model: Repeated measures analysis of variance and the independent *t*-test was used for analysis and values of $P < 0.05$ were considered statistically significant. **Results:** A total of 50 participants including 28 females and 22 males aged 60–80 years with an average age of 69.2 ± 6.6 years were included in the study. The balance and lower limb functional level of the intervention group were significantly higher than the baseline values with large effect size. Furthermore, the intervention group showed statistically significant improvement in balance and lower limb function when compared with the control group. **Conclusion:** The randomized controlled trial indicated that the designed exercise program for elderly was effective, and there was a significant improvement in balance and lower limb functional level in participants who received the exercise program. This study suggested that elderly people with moderate risk of fall can minimize falls and related fractures by better balance and strength with exercises.

KEY WORDS: Balance; Elderly; Exercises; Lower Limb Function

INTRODUCTION

Falls and their sequelae are potentially preventable and hence, understanding the risk factors and utilizing them for prediction, prevention, and management of falls and fractures would be of utmost importance in the elder age group. Fracture prevention can be done basically by enhancing bone strength and preventing falls, which requires an evidence-based treatment plan. Muscle weakness and reduced balance are significant factors responsible for the increased risk of falls in elderly people. Physical therapy by means of exercises can increase the strength and balance and thereby can minimize falls and fractures.

Various physical activities and exercises increase bone strength in early and young age, maintain this strength throughout life and reduce falls in elderly. Furthermore, exercises alone

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can reduce falls and related complications.[1,2] The dynamic exercises are more effective in fall prevention.[3] The group exercise as well as home exercise program has been proven effective in minimizing fall risk.[4] Exercise intervention that includes strengthening and balancing exercises has been found effective in fall prevention.[5]

The most common risk factor for falls in older adults is altered balance. The Berg balance scale (BBS) is a valid and reliable clinical tool used to test balance and risk of fall.[6] Moreover, lower limb muscle weakness is also associated with falls.[7] Early identification and prevention of functional decline in elderly people are of utmost importance.[8] Functional ability is associated with the quality of life and that's why it is important to assess the functional level of an individual in routine examination.[9] Lower extremity functional status can be assessed by the lower extremity functional scale (LEFS).[10] The LEFS was translated from English to Gujarati as a part of this study for the convenience of Gujarati population and to incorporate the use of Gujarati LEFS in clinical practice by physical therapists.[11]

As per the American College of Sports Medicine's (ACSM) guidelines for elderly, an exercise protocol should include aerobic training, muscle strengthening or/and endurance exercises, balancing exercises, and flexibility exercises.[12] To enhance the balance, the customized exercise program should be designed for patients at risk. Balance training is important to help decrease the risk of falls. Older people can make a significant improvement in strength if adequate strength training is provided. Strength training plays a key role in restoring independence and functionality. Flexibility exercises help in improving joint range of motion and preventing injuries. Walking as an exercise is very easy to do and has many health benefits in aged population. The Otago Exercise Program was developed and assessed for falls prevention. This program has been proven to reduce falls in elderly. It includes various balancing and strengthening exercises with walking program.[13] Research should be carried out to explore the exercises with the standard dosage to improve balance and lower limb functionality which may help in minimizing fall risk in older adults.

The aim of this study was to assess the efficacy of an exercise program on balance and lower limb functional level in elderly population. It was hypothesized that there would be a significant effect of an exercise program on balance and lower limb functional level in elderly population.

MATERIALS AND METHODS

Ethics committee approval was obtained from the ethics committee. An interventional study was conducted from November 2017 to January 2018. The intervention program was developed on the basis of the current evidence and published guidelines. The sample size formula used was, $n_1 = (\sigma_1^2+\sigma_2^2/K)\ (z_{1-\alpha/2}+z_{1-\beta})^2/\Delta^2$, $n_2 = K*n_1$, where, $\Delta = |\mu_2-\mu_1| =$ absolute difference between two means, σ1, σ2 = variance of mean 1 and 2, n_1 = sample size for Group 1, n_2 = sample size for Group 2, α = probability of Type I error (0.05), β = probability of Type II error (0.2), z = critical Z value for a given α or β, k = ratio of sample size for Group 2 to Group 1. Accordingly, $n_1 = (5^2+5^2/1)\ (1.96+0.84)^2/4^2 = 25$ and $n_2 = K*n_1=25$, a total of 50 participants were selected by a simple random sampling method from the physiotherapy department of the hospital, Ahmedabad. The inclusion criteria included: (a) Age: 60–80 years (b) both men and women (c) BBS score of ≤45, and (d) elderly persons who were independent and ready to participate in the study. Participants were educated about the study and written informed consent was obtained from all the participants included in the study. The assessment of all participants was done. BBS and LEFS were the primary outcome measures. The participants were then randomly allocated to an interventional group of 25 participants and a control group of 25 participants. Group A was the intervention group and Group B was the control group.

An exercise program, including warm-up exercises, balancing exercises, strengthening exercises, flexibility, and cool-down exercises, was designed for this study. Furthermore, walking was advised as a home exercise program. The personalized exercise program was designed for the participants depending on their capabilities. The dosage of exercises was in the form of frequency, intensity, type, and time as per the ACSM's guidelines. Tables 1 and 2 show the exercise protocol and list of exercises, respectively. The exercise program was given for 4 times/week for up to 6 weeks to Group A. Each participant of Group A was provided with a leaflet including pictures of all exercises. Group B was kept in waiting period.

Table 1: Exercise protocol

Exercises	Frequency	Intensity	Time	Type	Progression
Endurance	4 days/week	Usual pace	30 min/day	Walking-home exercise program	Walk indoors advance to walking outdoor
Strengthening	4 days/week	Moderate	1 set of 10 repetitions	Progressive weight training/ weight bearing	Increase from 1 to 2 sets of repetitions
Balancing	4 days/week	Moderate	2–5 Repetitions of each exercise 10 min/session	Static and dynamic balancing exercises	Supported exercise to unsupported exercise
Flexibility	4 days/week	Moderate	3–5 repetition of each exercise with 30–60 s hold for stretch	Static stretching exercise	Passive to self-stretching

Table 2: List of exercises

Type of exercises	Exercises
Warm-up exercises	Head movements
	Neck movements
	Shoulder movements
	Trunk movements
	Back movements
	Ankle movements
Strengthening exercise	Knee extensors: High sitting knee extension
	Knee flexors:
	Standing knee bending
	Hip abductors: Standing hip abduction
	Hip extensors:
	Standing hip extension
	Planter flexors: Standing heel raises
	Dorsiflexors: Standing toe raises
Balancing exercise	Sit to stand
	Sideways walking
	Backward walking
	Walk and turn
	One-leg stand
	Heel to toe stand/tandem stance
	Heel to toe walking/tandem walking
	Heel walking
	Toe walking
Flexibility and cool-down exercises	Calf stretch
	Hamstrings stretch
	Diaphragmatic breathing exercise
	Relaxation

All participants were advised to stay safe and a leaflet of advice in Gujarati language was designed for them.

Procedure

The exercise program began with 5 min of warm-up exercises to prepare the body for further exercises. It was followed by 10 min of lower limb strengthening exercises which included major muscles of lower limb such as hip extensors and abductors, knee flexors and extensors, ankle dorsiflexors, and plantar flexors. The exercises were progressive in nature. Most of the participants started the exercises with 1 kg of ankle weight cuff and progressed to 2 kg. Those who were not able to start with weight were exercised using their own body weight against gravity. It was started with one set of 10 repetitions for each exercise and progressed to two sets. However, it varied among the participants. The participants were instructed to not to hold the breath during exercises and they were asked to exhale during exertion and inhale on relaxation. Adequate rest period was given after each exercise. After strengthening exercises, balancing exercises were done for about 10 min including 2–5 repetitions of each exercise. They were started with support and progressed without support. The exercises were selected and progressed as per the individual's balance and functional level. The exercise program ended with 5 min of flexibility and cool-down exercises. In this phase, static stretching of hamstrings and calf muscles was performed which began with passive stretching and progressed to self-stretching with 3–5 repetitions of each and 30–60 s hold. At last participants were asked to do diaphragmatic breathing exercise and relax in a comfortable position. The entire class lasted for about 30 min.

Pre- and post-exercise program, a comparison of all measures was done with focus on BBS and LEFS as primary outcome measures to find out the efficacy of the treatment protocol within the group as well as between the groups. On completion of intervention phase, the participants were recommended to carry on with their exercise program as prescribed. The participants in Group B were also given the exercise intervention, once the study was over.

Statistical Analysis

The normality of variables was assessed using Shapiro-Wilk's test. The data distribution was found to be normal. The general linear model: Repeated measures analysis of variance (ANOVA), was used to analyze the effects of exercises within the groups as well as between the groups. To test the assumption of sphericity, the Mauchly's test of sphericity was used. Furthermore, the independent *t*-test was used to compare the groups. The difference was interpreted statistically significant with $P < 0.05$.

RESULTS

A total of 50 participants including 28 females and 22 males aged 60–80 years with an average age of 69.2 ± 6.6 years were included in the study. The details of descriptive data are shown in Table 3. The analysis was done by a repeated measure ANOVA and independent sample *t*-test. The difference found was statistically significant with alpha level 0.05.

A statistically significant main effect for Time (pre/post) was seen for both BBS score ($F [1, 48] = 309.96$, $P < 0.001$, $\eta^2p = 0.87$) and LEFS score ($F [1, 48] = 289.97$, $P < 0.001$, $\eta^2p = 0.86$). Statistically significant Group × Time effect was also seen for BBS score ($F [1, 48] = 309.96$, $P < 0.001$, $\eta^2p = .87$) and LEFS score ($F [1, 48] = 237.37$, $P < 0.001$, $\eta^2p = 0.83$). This indicated that the difference was significant between groups and the change in scores over time was different depending on group, with large effect size. Moreover, there was no significant difference between intervention group and control group before exercise program for BBS (M = 1.7, SD = 2.2) ($t [48] = 0.000$, $P = 1.00$) and for LEFS (M = 47.2, SD = 6.8) ($t [48] = 1.39$, $P = 0.17$). However, there was a statistically significant difference between intervention and control group after exercise program for BBS (M = 43.2, SD

Table 3: Basic characteristics of participants

Variable	Age (year)	Height (cm)	Weight (kg)	BMI kg/m²	BBS pre	BBS post	LEFS pre	LEFS post
Range	20	38	57	25	9	12	33	33
Minimum	60	140	45	18	36	36	33	33
Maximum	80	178	102	43	45	48	66	66
Mean	69.2	160.4	67.1	25.9	41.7	43.2	47.2	48.8
Std. Deviation	6.7	8.8	13.5	4.7	2.2	2.7	6.8	7.3

BMI: Body mass index, BBS: Berg balance scale, LEFS: Lower extremity functional scale

Table 4: Pre- and post-exercise BBS and LEFS score between and within groups

Primary outcome measures	Intervention group Mean±SD	Control group Mean±SD	*P*
BBS pre	41.68±1.93	41.68±2.43	1.0
BBS post	44.64±2.02	41.68±2.43	0.000
LEFS pre	48.48±6.27	45.84±7.14	0.17
LEFS post	51.68±6.20	46.00±7.23	0.004

BBS: Berg balance scale, LEFS: Lower extremity functional scale, SD: Standard deviation

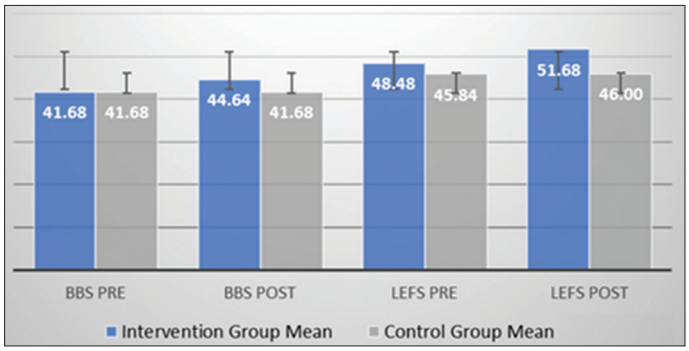

Figure 1: Pre- and post-exercise berg balance scale and lower extremity functional scale score between and within groups

= 2.7) (t [48] = 4.68, $P < 0.001$) and for LEFS (M = 48.8, SD = 7.3) (t [48] = 2.98, $P = 0.004$). Table 4 shows pre- and post-exercise BBS and LEFS score between and within the groups.

To summarize, there was a statistically significant difference found in the intervention group in pre- and post-exercise values of outcome measures. The balance and lower limb functional level of the intervention group were significantly greater than the starting values with large effect size. Furthermore, the intervention group showed statistically significant improvement in balance and lower limb functional level compare to the control group. Figure 1 shows pre- and post-exercise BBS and LEFS score between and within groups.

DISCUSSION

The purpose of this study was to evaluate the efficacy of an exercise program in elderly population of Gujarat. The population included had BBS score ≤45. An exercise program, including warm-up exercises, balancing exercises, strengthening exercises, flexibility, and cool-down exercises, was designed for this study. Furthermore, walking was advised as a home exercise program. The results of this study demonstrated that this exercise program is feasible for the elderly population, providing preliminary support to improve balance performance, lower limb function, and strength. All participants of the intervention group improved from pre-test to post-test on BBS, LEFS as well as lower limb muscle strength. Furthermore, significant difference in balance and lower limb function was found between intervention group which was provided with the exercise program and control group which was not on exercises.

The results of this study were consistent with earlier studies that have shown benefits from this type of exercise protocol for falls prevention. Gardner *et al*. (2000) concluded in their study that various risk factors lead to falls, but weakness of muscles and affected balance were the key factors for majority of falls. Furthermore, they mentioned that strengthening and dynamic balancing exercises increased strength and balance and thereby reduced the fall risk.[14] Moreover, Maritz *et al*. (2013) in their research work with group exercise program including strengthening, flexibility, and mobility and balancing exercises showed improvement in lower extremity strength and functional mobility among elderly population.[15] Furthermore, the present study showed remarkable improvement in lower limb functional level and strength which was consistent with a previous study done by Thiamwong and Suwanno (2014), which had shown improved stability during walking and other functional activities as a result of balance training.[16] Furthermore, Lee and Park (2014) found that increase in lower limb muscle strength enhanced the balance in older adults.[17] Besides that a previous extensive review by Ishigaki *et al*. (2014) concluded that lower limb muscle strengthening exercises can minimize the frequency of falls among aged people.[18] In the current study, the participants who followed the walking exercise program at home as per the advice showed improvement in balance and functional level. A previous study by Mızrak *et al.* (2015) suggested that aerobic exercise in the form of walking was useful in improving dynamic balance and gait in elderly.[19] Likewise, Sherrington *et al.* (2017) in their systemic review found that walking, high impact balance exercises and strengthening exercises improve balance and minimize the risk of falls. However, they also recommended that individuals with risk of fall should not be advised for brisk walking programs.[20] In present study, flexibility exercises played an important role,

as participants reported improved mobility in their daily activities. Similarly, Reddy and Alahmari (2016) concluded in their study that lower limb muscle stretching exercises can increase balance and may help to reduce falls.[21]

The sample size, with no missing data, is one of the strong points of this study. There were few limitations too. This study combined different exercises so the independent effect of each exercise was not found. Furthermore, the long-term follow-up and the rate of falls need to be assessed. The efficacy of this exercise program should be assessed in other age groups as well in future studies.

CONCLUSION

The randomized controlled trial indicated that the designed exercise program for elderly was effective and there was a significant improvement in balance and lower limb functional level in participants who received the exercise program. Furthermore, the difference was significant between intervention and control group. This study suggested that elderly people with moderate risk of fall can minimize the falls and related fractures by better balance and strength, gained due to regular exercises as advised.

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