Efficacy of Static Stabilization Exercises along with Progressive Resistive Exercises on Balance and Quality of Life in Elderly Population: A Study Protocol

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Abstract

Background: Balance impairment is one of the most prevalent concern with increasing age. Globally, One in five older adult experiences balance problem. Prevalence of fall has been estimated at 14-53 %in India. Various intervention has already been use to prevent fall and improve quality of life. Static Stabilization Exercises and Progressive Strength training have proven to be effective as a single intervention however minimal literature is available on combined effect of both. The main objective of study is to find out efficacy of combined Static Stabilization Exercises and Progressive Resistive Exercises on balance and quality of life of elderly population and also establishment of dose response relationship of balance training.

Methods/Design: The study will be designed as experimental study. 100 participants will be selected as per inclusion and exclusion criteria and will be allocated in two groups, Combined Intervention Group (A) and Traditional Balance Intervention group (B). Both intervention include 30-45 min session which will be carried out 3-5 times in week for duration of 8 weeks structured into different components. Outcome will be Balance and Quality of Life and outcome measures will be evaluated at baseline, at midway (4th week) and at the end (8th week) of intervention period. Statistical Analysis will be done using SPSS24. Oversion and p<0.005 will be considered as level of significance.

Discussion: The study protocol details two Physiotherapy Interventions to improve balance and quality of life in elderly population. In current literatures there are minimal evidence on combined effect of Static Stabilization Exercises and Progressive Resistive Exercises on balance and quality of life. Successful Completion of trial will provide evidence for best strategy targeting balance and quality of life and relationship of dose response and balance training.

Key words: Static Stabilization Exercises, Progressive Resistive Exercises, Balance, Quality of life, Elderly, Older adults

Introduction

Postural control (balance control) is the ability of body to control it's position for stability and orientation

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Department of Neurophysiotherapy, Ravi Nair Physiotherapy College, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India- 442001 Email: irshadphysio@rediffmail.com in space. It plays an important role in activities of daily living ⁽¹⁾ Static postural control (static balance control, stability) is the ability to maintain stability and orientation with the Centre Of Mass (COM) over the Base Of Support (BOS) with the body at rest. Dynamic postural control (dynamic balance control, controlled mobility) is the ability to maintain stability and orientation with the COM over the BOS while parts of the body are in motion ⁽²⁾.

Balance control requires interaction of nervous, sensory and musculoskeletal system and is affected by impairment in any of them. Aging and changes in vestibular, visual and somatosensory systems coincides which leads to reduced, improper or irrelevant feedback to higher centres. Similarly, muscle effectors also lack the ability to react adequately in response to postural instability as advancing age results in decline of cross-sectional area and muscle strength. Hence strength of muscle and postural control has direct relationship (

In basic terms, balance loss results when the COM falls out of alignment with the BOS. Age related alteration in postural is well established, significant studies demonstrated increased in postural sway with advancing age ⁽⁷⁾. Globally, one in five elderly individuals experience balance impairment problem.⁽⁸⁾ Prevalence of fall has been estimated at 14-53 % in India ⁽¹⁰⁾

Different types of Traditional Balance Exercises (TBE) have been utilized for balance improvement in older adults. One of Cochrane Systematic Review summarizes these exercises as effective, in enhancing balance in elderly population which includes Coordination exercises, exercises involving functional tasks, Tai Chi, Yoga therapy, General Physical activities etc. Combination of any above exercises as multiple exercise intervention has also been used widely (11).

Studies have shown relationship between strength training and functional abilities in older adults. In Past, various studies and meta-analysis have demonstrated effectiveness of Progressive Resistive Exercises (PRE) as sole intervention on balance and functional abilities in elderly (Gillespie et al., 2012; Liu and Latham, 2009; Westhoff et al., 2000)2016; Liu and Latham, 2009; Westhoff et al., 2000 . However, recent studies suggests strength training when combined with different interventions improves balance and as an isolated intervention it hasn't been shown effective in balance improvement (13,16–18)mean age 80 (SD±3.9

Various components of Static Stabilization Exercises (SSE) had been utilized in different studies as part of intervention and has positive role in improvement of balance in elderly population (19–22). Different types of exteroceptives and proprioceptive stimulation techniques (Sensory Stimulation Techniques) such as

vibration, joint approximation etc. have been found effective in improving static balance (23–25).

In residential care, different approaches aren't found consistent which have been proven effective in reducing falls or enhancing balance in community dwelling older adults. Example, exercise as single intervention prevent falls ⁽¹⁷⁾. For older adults, statistics have been reported of various effective exercise programs for balance enhancement and fall prevention⁽²⁶⁾ however preliminary dose response relationship of balance training hasn't been specified yet ⁽²⁷⁾.

Need For Study

Balance impairment has been identified worldwide as one of the leading causes of morbidity and mortality amongst the elderly. Various interventions have proven to be effective in balance improvement. Several literatures have identified that progressive resistive exercises and static stabilization exercises are effective in improving balance but there are minimal studies on combination of both. Purpose of this study is to incorporate PRE and static stabilization exercises together to determine its effect on balance in elderly population.

Aim & Objective

Study aims to find out the efficacy of combined Static Stabilization Exercises and Progressive Resistive Exercises on balance in elderly population and to establish dose-response relationship of balance training

Methodology

Study setting:-

The trial will be carried out in the two Geriatric Homes of Wardha city (Matoshree and Mahila Ashram) and if participants lacks community dwelling older adults will be recruited from Sawangi M., Wardha, after approval from Institutional Ethics Committee of Datta Meghe Institute Of Medical Sciences, Deemed to be University.

Study design and Sample size:-

The design of study is experimental, which will include two different intervention groups (SSE-PRE and TBE) of elderly individuals. The participants number, enrolled in the experimental study will be 100 (n = 100).

Randomization of participants will be done in a 1:1 ratio, Group A (Static Stabilization Exercises & Progressive Resistive Exercises) and Group B (Traditional Balance Exercises) each for the duration of 8 weeks. The informed consent will be obtained, subjective information will be gathered and initial assessment will be done and after that eligible individuals as per inclusion and exclusion criteria will be recruited. Recruited participants will be explained about the type of study in their own language and written patient consent form will be taken. The study procedure is shown in Figure 1 and the schedule of enrolment, screening, assessment, allocation, intervention, post intervention assessment and followup of the study (as recommended by Standard protocol items: recommendation for intervention trials) (28) reporting, and external review of clinical trials. However, the completeness of trial protocols is often inadequate. To help improve the content and quality of protocols, an international group of stakeholders developed the SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials is illustrated in Figure 2.

Participants

Inclusion criteria of participants

Age above 60

Both genders

Individuals willing to participate

MMSE score 24-30

Bergs Balance Score < 41/56

Functional Reach Test score < 11 inches

Dynamic Gait Index score < 22/24

Time UP and GO score > 14 second

Exclusion criteria of participants

Individuals with Cognitive impairments

Individuals with Neurological issues

Individuals with Musculoskeletal issues

Individuals with visual deficit

Individuals with hearing deficit

PARTICIPANT TIMELINE:

Study duration is of 6 months and intervention duration is 8 weeks so participant will be enrolled during first 3 months of study so 8 week intervention will be completed successfully. Assessment will be done on 1st day of visit then in midway (4th week) and last (8th week) of intervention.

Implementation

Research coordinator and principal investigator will supervise randomization. Participants will be asked to manually select from the envelope, sealed group allocation for the recruitment into either group.

Blinding

Tester(s) will be blinded to assign the subjects to the group. To ensure binding, subjects will be mandated not to reveal any details of their treatment to the tester.

STUDY PROCEDURE:-

Participants will be allocated in two groups

Intervention of Group A (SSE & PRE):

Participants of this group will be going to perform Static Stabilization Exercises (SSE) starting from day one of 1st week and Progressive Resistive Exercises (PRE) starting from day one of 2nd week of intervention in graded progressive manner for 30-45 mins each day, 3-5 days a week, continue for duration of 8 weeks. SSE will include selection of different postures (functional, antigravity), utilization of different tools to facilitate static stabilization (quick stretch, joint approximation, resistance etc) and sequential transition of movements. Complexity will be increase progressively. Progressive Resistive Exercise program will be designed on basis of FITT principle which will include warm-up, conditioning and cool down period. Exercises will mainly focus on targeting key muscles of lower limb (Hip flexors, knee extensors, ankle dorsiflexors etc.). Intensity will be based on REPITATION MAXIMUM (RM) and progression will be according to DeLorme and Watkins protocol.

Intervention of Group B (TBE):

Traditional Balance Exercises OR Conventional Balance Exercise group will be performing TBA, 45

minutes a day, 3-5 sessions per week for the duration of 8 weeks. TBA program comprises include 8 components (sitting balance exercises, standing balance, weight shifts, tandem standing, one leg standing, figure of eight walking, crossover walking, backward and sideways walking). Based on ability of participants complexity will be increased.

PROGRAM VARIABLE	DOSAGE
Sets	3 sets (per exercise, per muscle group)
Repetition	10 repetition in a set
Intensity	REPETITION MAXIMUM
Frequency	3-4 times in weekly
Modality	Free weights

Outcome measures:

Balance: -

Outcome measures will be evaluated by Bergs Balance Scale (BBS), Functional Reach Test (FRT), Dynamic Gait Index (DGI), Time Up and Go Test (TUG)

BBS is a clinical tool to access balance (static and dynamic). The scale contains fourteen everday functional tasks. Scoring is based on a 5-point ordinal scale. A maximum score of 56 points is possible. Inter-rater reliability (ICC = 0.98) and intra-rater relative reliability (ICC = 0.97) of BBS have proven to be excellent.

FRT is clinical screening tool of balance problems in elderly population. Normative value with reference to age has been given. It has shown good validity and correlates with speed of walking, walking with one foot in front of other, and one leg standing in community dwelling elderly. Reliability: Inter-rater and test-retest-has shown to be excellent for 20 – 87 years of age group.

DGI examines a ability of an individual to perform different alterations in walking with respect to command. The scale consists of 8 tasks with maximum possible score of 24. The DGI appears to bensensitive in predicting likelihood for falls with older adults .

TUG is quick and easy test used to assess mobility

of a person. It has been proven to have excellent interrater (intraclass correlation coefficient [ICC] = .99) and intrarater reliability (ICC = .99).

For Quality Of Life: - SF 36 (36 Item Short Form Survey)

The SF-36 contains 36 items based on questions used in the RAND Health Insurance Study. SF-36 is a set of comprehensive, rational, simple and easy to administer measures. The SF-36 demonstrated high reliability and validity (correlation coefficients ranging from 0.81 to 0.88).

Data Collection And Management

Data collection

Information about study given at time of recruitment (elaborating the purpose, nature, procedure, benefits and after effects of the intervention) with all baseline tests and assessment will be repeated on 2 more occasions.

2nd – midway of intervention (4th week), 3rd- end of intervention (8th week)

Data will be collected in designed database and Primary Investigator will supervised study and make sure t accuracy, precision, authenticity of data and safety of participants. All the data (hard copies of assessment forms, signed consent forms, etc.) will be stored securely in the study setting. The administrator access rights will lie with the principal investigators (PI).

Data management

Principal investigators will supervise documentation & data collection. For precision and accuracy brief evaluation of the study documentation will be done. After completion of study, Excel spreadsheet will be released to an allocation blinded statistician for conducting the analysis, following which unblinding of the groups will be done.

Statistical Analysis Plan

Effect of training interventions on outcome measures will be determined via linear mixed affect model across 'time' (pre-intervention vs post-intervention) and 'group' (Experimental vs Control). To assess which intervention will result in effective improvement. Data

analysis will be done by using descriptive and inference statistics using Chi-square test and student's unpaired t test.

Discussion

Balance impairment and fall has been estimated as one of key factor deteriorating Quality Of life and cause of mortality amongst elderly. Our Study aims to estimate the efficacy of combined static stabilization exercises and progressive resistive exercises on balance in elderly population and dose-response relationship of balance training. According to study by Horlings et al., loss of balance in elderly population involves multiple risk factors where muscle weakness tends to be a significant risk factor for falling and strength training can improve weakness, particularly when given as a component of a multifactorial intervention (29). Multiple studies found that a program consisting multiple intervention (mobility, strength and balance training) found to be the prime approach for enhancing functional independence (gait, balance and strength) and reducing fall rates in older adults (16,26).

Despite abundance of research in domain of falls and balance impairment, there are few which concluded effective ways and dose response. As per study of Lesinski et al., even though numerous studies have been conducted in this area very few provides detailed information hence, preliminary dose response relationship of balance training hasn't been proven and specified vet (27)evidence-based dose-response relationships in BT modalities (i.e., training period, training frequency, training volume. Again, Literatures suggests Static Stabilization Exercises as an effective intervention for balance (30) but very few studies has utilized it as sole intervention or as part of multiple intervention. This study is incorporating PRE and static stabilization exercises together for determining its effect on static as well as dynamic balance in elderly population. Outcome measures will access efficacy of intervention and successful completion of trial will provide evidence for best strategy (detailed and effective) targeting balance and quality of life and establishing relationship of dose response of balance training in elderly.

Ethical Approval and Dissemination: The participant individuals of the study and DMIMSU who will fund it will be able to retrieve findings of study. Enrolled subject's data will be stored securely for atleast

5 years. After completion of study and publication of results data will be stored in the DMIMSU data repository

Patient Consent

Principal Investigators will obtain the written informed consent from the participant on a printed form (local language) with signatures and give the proof of confidentiality.

Confidentiality

The study program will be explained to the participant, the principal investigator will take subjective information. The consent form will include the confidentiality statement and signatures of the principal investigator, patient and a witnesses. If required to disclose some information for the study, consent will be taken from the patient with complete assurance of his confidentiality.

Author's contribution

MIQ suggested the design of the study. SM and MIQ led to the creation and design of the study. SM wrote the manuscript of this article.NC gave final touches to the manuscript. MIQ read and approved the final manuscript for publication

Declaration of Interests: The authors declare no conflicting interest.

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