DOI: 10.7860/JCDR/2023/64028.18245

Research Protocol

Physiotherapy Section

Effect of Chair Suryanamaskar with Strength Training on Functional Fitness in Frail Older Adults: A Research Protocol for a Randomised Controlled Trial

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ABSTRACT

Introduction: Physical frailty is a syndrome characterised by deterioration in multiple physiological domains, including muscle mass and strength, flexibility, balance, neuromuscular coordination, and cardiovascular function. Evidence suggests that regular exercise provides substantial health benefits, reducing the risk of many chronic diseases and medical costs, especially for frail older adults. However, the effect of exercise on functional status in this population is not well explored.

Need of the study: Population aging in India is rapidly accelerating, and frailty is a significant clinical condition associated with aging. Frailty increases the risk of institutionalisation, morbidity, and mortality. Regular exercise has been shown to improve functional fitness in older adults, but exercises performed while standing unaided can be challenging for individuals with compromised balance and mobility. Chair Suryanamaskar, a form of exercise performed while seated, may be an alternative mode of exercise for this population. Although aerobic and resistance exercises have shown benefits, there is growing interest in exploring the potential benefits of a multicomponent intervention for frail older adults.

Aim: The aim of this study is to investigate the effect of chair Suryanamaskar with strength training on functional fitness in community-dwelling frail older adults.

Materials and Methods: The study will be conducted from March 2021 to March 2024. This two-group parallel single-blind randomised controlled trial will take place at MAEER's Physiotherapy College in TalegaonDabhade, Maharashtra, India. Approximately 400 older adults will be screened for frailty using the Short Physical Performance Battery (SPPB) test. Participants with an SPPB score ≤7 will be considered frail and a total of 108 participants aged 65-84 years will be recruited based on inclusion and exclusion criteria. The participants will be equally divided into two groups (54 participants in each group) using computer-generated random tables. The experimental group (group A) will receive a 45-minute Chair Suryanamaskar with strength training protocol three times a week for 12 weeks. Before the study begins, participants will have two practice sessions of 20 minutes each to become familiar with Chair Suryanamaskar. The control group (group B) will participate in two 20-minute health education program sessions and receive weekly telephonic follow-ups to monitor for adverse events. Additionally, a health education program booklet will be provided. The primary outcome of the study is the Senior Fitness Test (SFT). Assessments will be conducted at baseline (0 weeks) and post-intervention (12 weeks). Intention-to-treat analyses with mixed linear modeling will be used for statistical analysis.

Keywords: Physical frailty, Senior fitness test, Short physical performance battery

INTRODUCTION

Ageing is characterised by a gradual decrease in functional fitness, which serves as a significant and independent risk factor for premature mortality [1]. Reduced fitness among older adults is associated with a higher rate of lean mass decline, increased body fat, abnormal metabolic profile, elevated blood pressure, arterial stiffness, disruptions in autonomic function, and cardiac pressure overload. These factors significantly impact the individual's quality of life [2]. Therefore, muscle mass, muscular strength, muscular flexibility, muscular endurance, and cardiorespiratory fitness play crucial roles in functional fitness for older adults [3]. To assess these components, the SFT was developed by Rikli RE and Jones CJ at California State University. This test helps evaluate key aspects such as flexibility, strength, speed, endurance, and balance [4,5].

The SPPB test includes balance, walking, and rising from chair tasks, which have proven to be useful for predicting physical frailty in clinical practice. A cutoff score of ≤7 points is considered physical frailty in community dwelling older adults [6]. Frailty is associated with an increased risk of functional decline, institutionalisation, morbidity, and mortality [7]. Several studies have demonstrated that regular exercise can enhance functional fitness in older adults [8]. According to the American College of Sports Medicine (ACSM) guidelines, older adults should engage in 20-30 minutes of moderate-to-vigorous aerobic training at least three days a week, along with incorporating resistance training one or two days a week [9]. Some studies have suggested that practicing Suryanamaskar at different speeds can offer various benefits, and when performed rapidly, it can warm up the body and act as a cardiotonic [10]. The research provides compelling evidence that resistance training can help counteract the age-related decline in neuromuscular function and functional capacity. Different forms of resistance training show potential in improving muscle strength, mass, and power output [11,12].

In recent times, there has been a growing proposal to use increased physical activity or regular exercise training as a preventive measure for frailty and its adverse consequences [13]. Both aerobic and resistance exercises have demonstrated positive outcomes, targeting distinct features of frailty [14]. The potential benefits of an intervention that combines both exercise components for frail older adults have garnered recent interest. Consequently, this study aims to investigate the effects of chair Suryanamaskar with strength training on enhancing the functional fitness of frail older adults residing in the community.

Objective

Primary objectives: To determine the effect of a 12-week chair Suryanamaskar with strength training intervention, compared to the control group, on the following:

i) Body flexibility, assessed using the chair sit and reach test and back scratch test.

ii) Body strength, assessed using the 30-second chair stand test and Arm curl test.

iii) Agility and dynamic balance, assessed using the 8 Foot up and go test.

iv) Aerobic endurance, assessed using the 2-minute step test and 6-minute walk test

Secondary objectives: To assess the effect of a 12-week chair Suryanamaskar with strength training intervention, compared to the control group, on the frailty status of older adults aged 65-84 years, using the SPPB test [15].

Hypotheses: This study hypothesises that compared with a Health education program (Control), a Chair Suryanamaskar with Strength Training intervention will result in moderate improvements (50-75%) in the functional fitness of community-dwelling frail older adults aged 65-84 years.

REVIEW OF LITERATURE

Brown M et al., conducted a study in which 84 physically frail older adults (mean age, 83±4 years) were randomly allocated to three months of low-intensity supervised exercises (n=48) versus unsupervised home-based flexibility activities (n=36). They found a significant improvement in the exercise group in their primary indicator of frailty, the Physical Performance Test (PPT) (29±4 vs 31±4 out of a possible 36 points), as well as in many of the risk factors previously identified as contributors to frailty, such as reductions in flexibility, strength, gait speed, and poor balance [15].

Sousa N et al., aimed to evaluate the effectiveness of combined exercise training in enhancing functional fitness among older adults. A total of 59 community-dwelling older men were randomly assigned to three groups: an aerobic training group (ATG, n=19), a combined aerobic and resistance training group (CTG, n=20), and a control group (n=20). Both exercise training programs were conducted at a moderate-to-vigorous intensity, with a frequency of three days per week, spanning nine months. The results of the study showed significant differences (p-value <0.001) between both training groups and the control group. However, it was found that the ATG group exhibited improvements only in the chair sit-and-reach and the 30-second chair stand performance, whereas the CTG group showed improvements across all functional fitness tests [16].

Watababe Y et al., conducted a 16-week study to assess the impact of bodyweight resistance training on 39 active elderly individuals. The exercise program included five resistance exercises and four plyometric exercises, all utilising the participants' own bodyweight, with each exercise performed in a single set. The participants were divided into two experimental groups. One group performed the resistance exercises with slow movement and tonic force generation, while the other group performed the same exercises at a normal speed. Following the intervention, both groups exhibited significant improvements in the strength of their upper and lower limbs, as well as in maximum leg extensor power. The study findings suggest that bodyweight resistance training with slow movement and plyometric exercises can effectively enhance physical function in the elderly, even when using a single set for each exercise [17].

Pandya S and Prajapati H conducted a study to investigate the impact of chair Suryanamaskar on blood pressure in individuals with essential hypertension. The study involved 40 participants who were divided into two groups. The experimental group performed chair Suryanamaskar while continuing their medication for four weeks, while the control group only received medication. Analysis of the results demonstrated a significant reduction in systolic, diastolic, and mean arterial blood pressure in the experimental group compared to the control group [18].

MATERIALS AND METHODS

This study will be an experimental, two-group parallel, single-blind randomised controlled trial. Assessments of outcome measures and the intervention will be conducted at the designated facility of MAEER's Physiotherapy College, Talegaon Dabhade, Maharashtra, India. Considering that one out of four older individuals is frail, based on the prevalence of 26% physical frailty in community-dwelling older adults in Pune city [19], screening of approximately 400 older adults for frailty using the SPPB test will be conducted. A cutoff score of ≤7 points is associated with an increased risk of disability and mortality and is suggested to define frailty, while 8-9 points is associated with an intermediate risk of adverse outcomes and is suggested to define prefrailty [6].

The study protocol has been approved by the Institutional Ethics Committee (IEC) of MAEER's Physiotherapy College, Talegaon Dabhade (Ref. No. EC/NEW/INST/2019/377/61), and Pravara Institute of Medical Sciences, Loni (Approval number: PIMS/Ph.D/289). The trial is prospectively registered with the Indian Council of Medical Research Trial Registry CTRI/2021/03/032277.

Sample size estimation: The sample size was calculated using WinPepi software version 11.65, and the estimated sample size was 44 participants in each group. Considering a dropout rate of participation in the yoga intervention, the final sample size was determined to be 108 participants, equally divided into two groups (54 in each group) using computer-generated random tables. All eligible participants will receive detailed information about the study in the language best understood by the participants, and the principal investigator will obtain written informed consent from the participants before assessment. Each participant will be given an individual unique identity trial number to ensure confidentiality.

Eligibility Criteria

Inclusion criteria:

i) Individuals aged between 65 and 84 years.

ii) Those who score 3 to 7 on the SPPB test [6].

iii) Those who are fit to do the exercises as determined by the physician.

iv) Those who score ≥24 on the Hindi Cognitive Screening Test (HCST) scale [20].

Exclusion criteria:

i) Individuals who exercise regularly.

ii) Those with physical impairments for whom exercises are contraindicated.

iii) Those with uncontrolled hypertension (BP ≥160/100 mmHg).

iv) Those with uncontrolled diabetes (≥200 mg/dL).

v) Those with benign paroxysmal positional vertigo.

vi) Those with prolapsed intervertebral disc or disc herniation.

vii) Those with recent upper limb, lower limb, or spinal fractures.

viii) Those with neurological involvement such as stroke, Parkinsonism, etc.

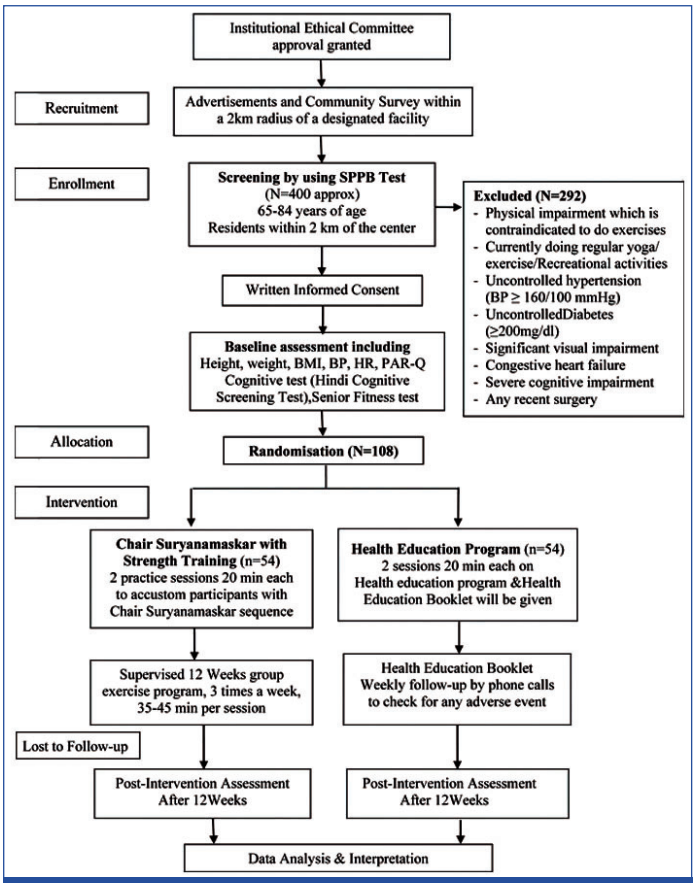
ix) Those with recent surgery such as hip and/or knee replacement surgery.

Interventions

The intervention group (group A) will participate in chair Suryanamaskar with strength training three times per week for 12 weeks at a designated physiotherapy facility. Participants in group A will receive two practice sessions (20 minutes each) of the exercise program to become familiar with the sequence of chair

Suryanamaskar. The exercise program will be conducted as a group exercise session, with approximately 6-8 participants in each group. Both males and females will be included in the same class.

The control group (group B) will receive two sessions (20 minutes each) of a health education program. Additionally, a health education program booklet will be provided. Weekly follow-up phone calls will be conducted to check for any adverse events [Table/Fig-1].



[Table/Fig-1]: Design and participants flow chart according to SPIRIT 2013 guidelines (Standard Protocol Items: Recommendations for Interventional Trials). BMI: Body mass index; BP: Blood pressure; HR: Heart rate; PAR-Q: Physical activity readiness-questionnaire

Intervention Description

Chair Suryanamaskar with strength training (group A)

Proposed Exercise Program

Warm-up exercises (10 minutes): The warm-up exercises will include chair marching and active movements of the upper limbs (shoulder and wrist rotation), spine (neck and trunk rotation, trunk side bending), and lower limbs (ankle rotation).

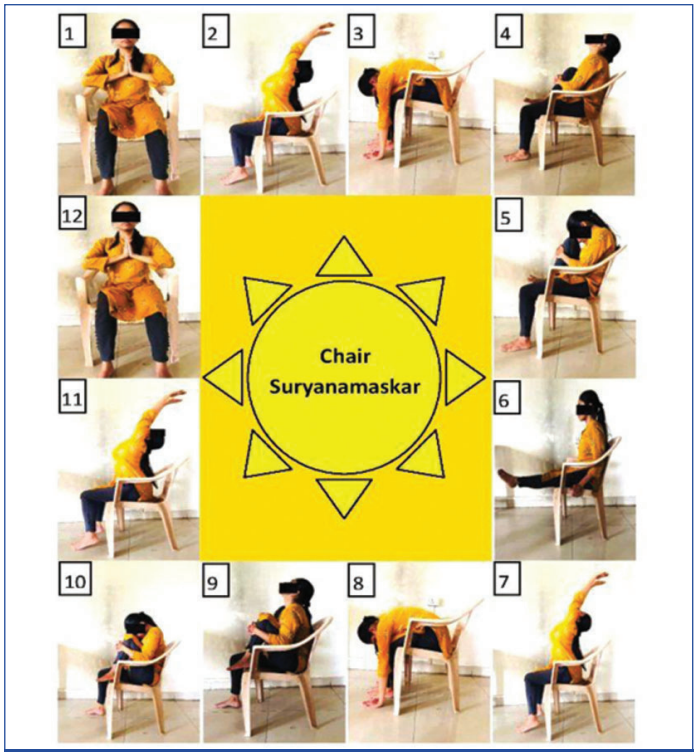
Prescription of Chair Suryanamaskar (10-20 Minutes) [18,21]: The Chair Suryanamaskar session will consist of 12 physical postures (asanas) performed in the following order each time [Table/Fig-2]:

1) Pranamasana→ 2) Hasta Uttanasana→ 3) Hasta Padasana→ 4) Anjaneyasana→ 5) Ek Padhastasana→ 6) Dandasana→ 7) Hasta Uttanasana→ 8) Hasta Padasana→ 9) Anjaneyasana→ 10) Ek Padhastasana→ 11) Hasta Uttanasana→ 12) Pranamasana.

Chair Suryanamaskar will be performed to metronome beats at 32 beats per minute. Initially, it will be performed for 10 minutes and gradually progress to 15 minutes from the 4th week to the 8th week, and then progress to 20 minutes from the 8th week to the 12th week.

Prescription of strengthening exercises (10 Minutes) [17]: Bodyweight will be used as resistance for strength training in frail older adults. The strength training protocol will be as follows and is shown in [Table/Fig-3].

Cool down exercises (5 minutes) [22]: The cool-down exercises will consist of muscle stretching exercises for the Calf, Hamstrings, Shoulders, Triceps, and Pectoral muscles.



[Table/Fig-2]: Steps of chair suryanamaskar.

Exercises	Sets	1-4 weeks	5-8 weeks	9-12 weeks
Forward lunge	1 set	8 repetitions	10 repetitions	12 repetitions
Double leg calf raise	1 set	8 repetitions	10 repetitions	12 repetitions
Chair squats	1 set	8 repetitions	10 repetitions	12 repetitions
Hip abduction	1 set	8 repetitions	10 repetitions	12 repetitions
Wall push-ups	1 set	8 repetitions	10 repetitions	12 repetitions

[Table/Fig-3]: Shows strength training protocol using body weight as resistance for frail older adults.

Health Education Program (Group B)

The comparison group (group B) will receive two sessions (20 minutes each) on a health education program. The first session will provide information on the importance and benefits of exercise, while the second session will involve a demonstration of exercises focused on stretching, strengthening, and mobility, conducted by a qualified physiotherapist. Additionally, a health education program booklet will be provided.

Criteria for Discontinuing or Modifying Allocated Interventions

Participants will be discontinued from the study if they begin a different exercise protocol at another center or if they permanently relocate to another city. Participants have the freedom to withdraw from the study at any time and for any reason without notification.

Strategies to Improve Adherence to Interventions

Low adherence to physical exercise training in the elderly age group has been observed in the literature [23]. To minimise participant dropout, two 20-minute face-to-face sessions will be conducted before the start of the project, during which the researcher will address any queries or concerns from participants. Participants will have access to free emergency medical care at all times. All assessments (pre and post), exercise training sessions, and health education programs will be provided free of charge. Study participants will be recruited within a 2 km radius of the facility to minimise travel time. If specifically requested, the researcher will arrange for a pickup and drop facility. Daily attendance of participation will be recorded.

Relevant Concomitant Care Permitted or Prohibited during the Trial

No guidance or restrictions will be given regarding daily walking.

Outcomes

Primary outcomes: The primary outcome measures will include the SFT, which consists of the following components: i) Arm curl test for upper body strength, ii) Back scratch test for upper body flexibility, iii) 30-second chair stand test for lower body strength, iv) Chair sit and reach test for lower body flexibility, v) 8-feet up and go test for agility/dynamic balance, and vi) 6-minute walk test and 2-minute step test for aerobic capacity [Table/Fig-4]. These six components of the SFT have been shown to have good reliability and validity [4,5].

Secondary outcomes: The secondary outcome measure will be the SPPB, which combines the results of the gait speed, chair stand, and balance tests to evaluate lower extremity function and mobility in older adults [6].

Participant timeline: Evaluations will be conducted at various time points throughout the study, including during the screening process, at baseline, post-intervention, and during follow-up.

Sample size and recruitment: The sample size was determined based on the effect size reported in a previous four-month-long Randomised Controlled Trial (RCT) that compared combined exercise (aerobic and strength) training with a control group [16]. In that study, the primary outcome measure, the 6-minute walk test, showed a mean difference (effect size) of 42 between the intervention and control groups. With 80% power and a significance level of 5%, the estimated total sample size required for this study was 88 participants (44 in each group), calculated using WinPepi software version 11.65. To account for potential dropout rates, an expected dropout rate of 23% over three months was considered based on findings from a systematic review and meta-analysis of yoga interventions [23]. Therefore, a total of 108 participants were recruited at the beginning of the study, with an equal distribution of 54 participants in each group.

Recruitment

Approximately 400 older individuals will be screened for eligibility using the SPPB test, assuming that every fourth older person will be eligible and interested in participating in the study. The recruitment of participants will be conducted at least two times during the course of the study, with 26-28 participants enrolled in each group each time until the required number is achieved. This phased recruitment of participants will help make the intervention process more manageable and feasible.

Assignment of interventions: Allocation

Sequence Generation

Individuals who meet all selection criteria and agree to participate in the study will be assigned to either the intervention or control group using a 1:1 allocation ratio. The allocation will be determined by computer-generated randomisation, using block sizes of 6 and 8.

Concealment Mechanism

The computer-generated allocation sequence will be concealed in sequentially numbered opaque, sealed, and stapled envelopes. These envelopes, containing the allocation sequence, will be stored in a locked drawer, with the key held by an investigator who is not involved in recruiting participants.

Implementation

The principal investigator will be responsible for enrolling participants in the study. A research assistant, who is not directly involved in the implementation of the intervention, will prepare the sequence generation and envelopes. The principal investigator will open the envelopes only after the enrolled participant completes all baseline assessments. The time between allocation and baseline assessments will not exceed seven days. The envelopes will contain information about the assigned interventions for each participant.

Study timeline					
	Enrolment	Baseline	Intervention	Postintervention	Close-out
Time point	Week-1	Week-0	Week 1-12	Week 12	Week 12+1
Eligibility screening					
SPPB test	✓				
Physical activity readiness	✓				
(PAR-Q) questionnaire	✓				
Hindi cognitive screening test	✓				
Informed consent	✓				
Allocation of participants	✓				
Intervention					
Chair suryanamaskar with strength training			→		
Health education program			→		
Study outcome	**Methods for assessment**				
Demographic data	Socio-economic questionnaire	✓			
Cardio-metabolic risk	Blood pressure, resting heart rate, BMI, WHR	✓			
Senior Fitness Test (SFT)					
i) Upper body flexibility	Back scratch test (Distance in cm)	✓		✓	
ii) Lower body flexibility	Chair sit and reach test (Distance in cm)	✓		✓	
iii) Upper body strength	30 sec arm curl test (No. of arm curl)	✓		✓	
iv) Lower body strength	30-sec chair stand test (No. of chair stand)	✓		✓	
v) Agility/dynamic balance	8 feet up and go test (Time in sec)	✓		✓	
vi) Aerobic endurance	2 min step test (No. of steps)	✓		✓	
vii) Aerobic endurance	6 min walk test (Distance covered in m)	✓		✓	
Follow-up	To check modifications in health-seeking behaviour/Any adverse events	Weekly phone calls from week 1 to week 12			
Feedback	Feedback and participant satisfaction				✓

[Table/Fig-4]: Schedule of enrolment, interventions, and assessments according to SPIRIT 2013 guidelines (Standard Protocol Items: Recommendations for Interventional Trials).
BMI: Body mass index; WHR: Waist hip ratio

Assignment of interventions: Blinding

Who will be Blinded?

The allocation of participants into the two groups, as per the computer-generated random tables, will be done by an external statistician. The baseline assessment will be conducted by a qualified physiotherapist who will be blinded to the participant's intervention assignment. Participants will be informed of their allocation to group A or group B, but the allocated group will be kept confidential from the physiotherapist conducting the follow-up assessments. Participants will be instructed not to disclose any information about the treatment they received during the follow-up assessments to minimise bias. The statistician involved in the analysis will also be blinded to the group allocation.

Data Collection and Management

Plans for assessment and collection of outcomes: Primary and secondary outcomes will be measured at baseline (0 weeks) and post-intervention (12 weeks). The assessments will include basic demographic and socio-economic information, anthropometric measurements, and measurements for primary and secondary outcomes [Table/Fig-4].

Baseline assessment: After obtaining informed consent from participants, a qualified physiotherapist, who will be blinded to the intervention, will conduct a baseline assessment. The Senior Fitness Test (SFT), developed by Rikli RE and Jones CJ, is a simple and effective tool for assessing six important "functional fitness" parameters in the elderly, including lower and upper body strength, lower and upper body flexibility, aerobic endurance, and agility/dynamic balance [5]. The baseline assessments are expected to take approximately 30-45 minutes to complete.

Postintervention assessments: Post-intervention assessments will be conducted after 12 weeks. These assessments will be similar to the baseline assessments and will be performed by the same qualified physiotherapist.

Plans to promote participant retention and complete follow-up: Participants who are unable to attend a session due to health reasons will be visited by the principal investigator on the same day to document the events. In group B, all participants will be contacted telephonically by the principal investigator once a week to document any adverse events. The blind evaluator will conduct the post-intervention assessment at 12 weeks as per the schedule.

Data management: The principal investigator will be responsible for record-keeping, timely backups, and ensuring the safety and confidentiality of participants' data. Participants' information will be collected using a pre-designed case report form and documented in a master chart on Microsoft Excel 2011. The data will be analysed using appropriate statistical software.

STATISTICAL ANALYSIS

Statistical Analysis for Primary and Secondary Outcomes

Based on the normality test of the data, appropriate parametric tests (Student's t-test) and non-parametric tests (Mann-Whitney U test and Kruskal-Wallis test) will be used to compare the outcome measures at baseline with the post-intervention assessment. The Statistical Package for the Social Sciences (SPSS), version 26.0, will be used for statistical analysis. A significance level of 5% will be adopted for all analyses. In cases of dropouts or withdrawal from the study, intention-to-treat analysis will be performed.

Oversight and Monitoring

Composition of the data monitoring committee, its role and reporting structure: The Institutional Research Committee (IRC) of MAEER's Physiotherapy College, TalegaonDabhade, will monitor the data, interventions, and any adverse events. The principal investigator will report any adverse events and the actions taken by the IRC.

Adverse Event Reporting and Harms

In this study, the potential risks of adverse events are minimal. The most frequently anticipated adverse events include muscle strains, muscle soreness, lightheadedness, and the reoccurrence of prior lower back pain or neck pain problems [24]. Participants will have continuous access to emergency medical care throughout the study. A team of qualified physicians will carefully screen all potential participants to identify any health issues that could contraindicate their involvement. Participants with health problems posing risks to their well-being will be excluded from the study for safety reasons. All adverse events will be recorded and followed-up by the principal investigator.

Frequency and Plans for Auditing Trial Conduct

The researchers involved in the study will conduct meetings from time to time to discuss the study's progress and address any doubts. A report will be submitted every six months to the IRC. If there are any changes to the protocol or study, the IEC, the Clinical Trials Registry of India (CTRI), and the Journal will be immediately notified.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees): All amendments to the protocol will be communicated and approved by the IEC, Pravara Institute of Medical Sciences (Deemed University). Trial participants will be fully informed of any changes to the trial and will be required to sign an informed consent form before participating.

Provisions for Post-Trial Care

Participants who experience injury or harm as a result of their participation in the study will be provided with appropriate remedies and care. In accordance with ethical considerations, the intervention that produces the best results will be offered to the other group at the conclusion of the study.

Trial Status

The protocol version 2 registration was approved on March 05, 2021, and was registered with CTRI on March 24, 2021. Recruitment was initially scheduled to begin on April 15, 2021, but was postponed due to the COVID-19 pandemic. Recruitment began in January 2022, and the study is expected to be completed in March 2024.

Authors' contributions: Nikhade NS is the Chief Investigator and has contributed to the conception and design of the research, literature search, protocol development, and a significant portion of the manuscript. Phalke VD has contributed to the study design, the development of the methodology, and the critical revision of the manuscript. All authors have read and approved the final version of the manuscript.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Mar 15, 2023
- Manual Googling: may 24, 2023
- iThenticate Software: Jun 20, 2023 (23%)

ETYMOLOGY: Author Origin

EMENDATIONS: 8

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Mar 11, 2023**
Date of Peer Review: **Apr 26, 2023**
Date of Acceptance: **Jun 22, 2023**
Date of Publishing: **Aug 01, 2023**