

Research article

Effect of Reablement Strategies targeting Sarcopenia (ReStart-S) on sarcopenic older adults residing in long term care settings: A protocol for cluster randomized trial

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ABSTRACT

Background: The prevalence of sarcopenia is high among older adults residing in long-term care settings (LTCS). Guidelines to manage sarcopenia cannot be directly implemented among sarcopenic older adults residing in LTCS.

Objectives: To examine the effectiveness of a codesigned Reablement Strategies targeting Sarcopenia (ReStart-S) program on muscle parameters, physical performance, blood biomarkers and quality of life among sarcopenic older adults residing in LTCS.

Methods: The study is a cluster randomized trial that will take place in LTCS. A total of 78 sarcopenic older adults will be included, selected through convenience sampling, and diagnosed using the Asian Working Group for Sarcopenia 2019 criteria. The LTCS clusters will be randomized into intervention and control groups. The participants in the intervention group will receive the ReStart-S multicomponent exercise intervention twice a week for a total of six weeks, while those in the control group will continue with their usual daily activities. The primary outcome will be grip strength, and the secondary outcomes will include a short physical performance battery, muscle mass, C-terminal agrin fragment, and quality of life as assessed through the sarcopenia and quality of life-Kannada version questionnaire. The outcomes will be measured at week 0, week 6, week 12, and week 18.

Conclusion: ReStart-S program if found to be effective could be implemented globally to manage sarcopenia and promote healthy ageing in older adults, enhancing their independence in LTCS.

1. Introduction

Sarcopenia, a geriatric medical condition, is characterized by a gradual reduction in muscle mass, strength, and overall physical ability [1–3]. The prevalence of sarcopenia is on the rise, particularly among older adults residing in long-term care settings (LTCS) [4], which is reported to range from 30 % to 50 % [5–7]. Sarcopenia significantly impacts physical performance, ability to carry out activities of daily living (ADL) and increases the risk of falls and physical disability, thereby affecting the individual's quality of life

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(QoL) [8–13]. Therefore, it is crucial to address sarcopenia among older adults residing in LTCS through timely interventions and reablement strategies [14,15].

As per the internationally accepted definition, reablement is a goal-oriented, holistic approach to enhance an individual's physical and functional abilities for independent daily living regardless of diagnosis or settings [16]. Research suggests that the most commonly used reablement approach for older adults residing in LTCS is a multi-component exercise program delivered by physiotherapists [14]. For a longer impact of the reablement approach, the stakeholders (older adults, caregivers, administrators, physiotherapists, medical professionals) should be consulted while designing a reablement program [17,18]. However, the literature suggests that the programs delivered to LTCS residents lack the consultation component to co-design a program [14].

Co-design is a collaborative approach that involves researchers, end-users, and stakeholders to tailor interventions to the specific needs of the target population [19]. To optimize the implementation of evidence-based interventions according to the priorities and preferences of all stakeholders, enabling designed solutions to achieve maximum feasibility and sustainability, the co-design approach is the mainstay [20,21]. However, the multi-component exercise-based reablement program co-designed with residents and experts to manage sarcopenia is lacking [14,15].

Clinical practice guidelines have been provided by the International Conference on Frailty and Sarcopenia Research (ICFSR) [22], the Australian and New Zealand consensus group [23], and the Singapore consensus group for the management of sarcopenia [24]. The guidelines showed strong evidence of resistance training provided alone or as part of the multi-component exercise interventions to manage sarcopenia [22–24]. However, when comparing older adults in LTCS to those living independently in the community, there are notable differences in their cognitive and physical abilities, QoL, polypharmacy and medical conditions they may have [25–28]. Hence, the recommendation for the treatment of sarcopenia in LTCS should not be drawn only from the current practice guidelines which are certainly more appropriate for community-dwelling older adults, necessitating to have a program relevant to LTCS. However, the exercise based reablement program specific for sarcopenic older adults in LTCS is lacking [15].

There exists a definite challenge, assessing the muscle parameters in the form of participants motivation, evaluator's expertise and portability of the instruments, necessitating the use of biomarkers [29,30]. Hence, as a sarcopenia screening method, a blood-based biomarker C-terminal Agrin Fragment (CAF) could be a more accessible choice [30]. A recent scoping review has reported CAF to be a good biomarker to distinguish between sarcopenic and non-sarcopenic older adults and has recommended an appropriate selection of exercise parameters to be critical in reducing the CAF levels and, eventually, managing sarcopenia [31]. Thus, this study aims to look at the effect of Reablement Strategies targeting Sarcopenia (ReStart-S) program on muscle strength, physical performance, muscle mass, blood-based biomarker, and QoL among sarcopenic older adults residing in LTCS. We hypothesize that the ReStart-S program will improve the muscle parameters (strength and mass), physical performance, QoL, and decrease the biomarker level.

2. Material and methods

2.1. Study design and settings

The present study is a cluster randomized trial with two arms. The trial design has been chosen to prevent contamination of the data. The trial will be conducted on the residents of eligible LTCS for older adults in Udupi and its neighbouring districts in Karnataka, India. This study protocol follows the standard protocol for clinical trials in accordance with the SPIRIT 2013 statement [32]. The CONSORT 2010: extension to cluster randomized trial statement [33], will be followed for reporting to ensure clinical trial transparency. The study is approved by the Institutional Ethics Committee [IEC1: 100/2022]. The trial is registered in the Clinical Trial Registry- India [CTRI/2022/10/046680].

2.2. Study participants and eligibility criteria

2.2.1. Selection criteria for clusters

Clusters will be assessed for their eligibility following the Inclusion and exclusion criteria mentioned below.

Inclusion criteria: (1) LTCS for older adults, (2) Udupi and neighbouring districts (Dakshina Kannada, Uttara Kannada, Chikmagalur, Shivamogga).

Exclusion criteria: The cluster providing (1) adult day care, (2) hospice care, and (3) settings that provide respite care will be excluded.

2.2.2. Selection criteria for participants

Participants will be assessed for their eligibility following the inclusion and exclusion criteria mentioned below.

Inclusion criteria: The participants (1) either gender, (2) more than or equal to 60 years of age, (3) Barthel index more than or equal to 60 points, (4) Sarcopenia as per the Asian working group for sarcopenia 2019 (AWGS-2019) guidelines cut-off that is: (a) Skeletal muscle mass: $<7.0 \text{ kg/m}^2$ in men and $<5.7 \text{ kg/m}^2$ in women, (b) Handgrip strength (HGS): $<28.0 \text{ kg}$ for men and $<18.0 \text{ kg}$ for women, and (c) Short physical performance battery (SPPB): ≤ 9 will be included.

Exclusion criteria: Participants will be excluded for the following reasons: (1) critically ill/terminally ill/active infection, (2) presence of pacemaker and any metal implant, (3) bed bound/wheelchair bound, (4) acute onset (less than 30 days) of cardiorespiratory/neurological/renal/orthopaedic disease.

2.3. Study procedure, randomization, and blinding

The LTCS will be identified and checked for eligibility. If found to be eligible, informed consent will be obtained from the authorities of LTCS (cluster-level consent). Following a detailed explanation of the procedure to the participants, written informed consent will be taken (participant level consent), and all the participants will be assessed for eligibility from each identified cluster. As per the number of eligible participants, blocks of 2 clusters (LTCS) will be made (e.g., block-1 having two clusters, 1A and 1B). The clusters in each block will be randomized to the intervention arm and control arm using the lottery method. The number of clusters in each arm may vary and will depend on the number of eligible participants obtained from each cluster (for example, if there are five eligible participants from one cluster having a total of twenty residents, there will be a need for at least eight clusters in each arm to achieve a sample size). After baseline evaluation, the 6-week ReStart-S program will be administered to the individual participants

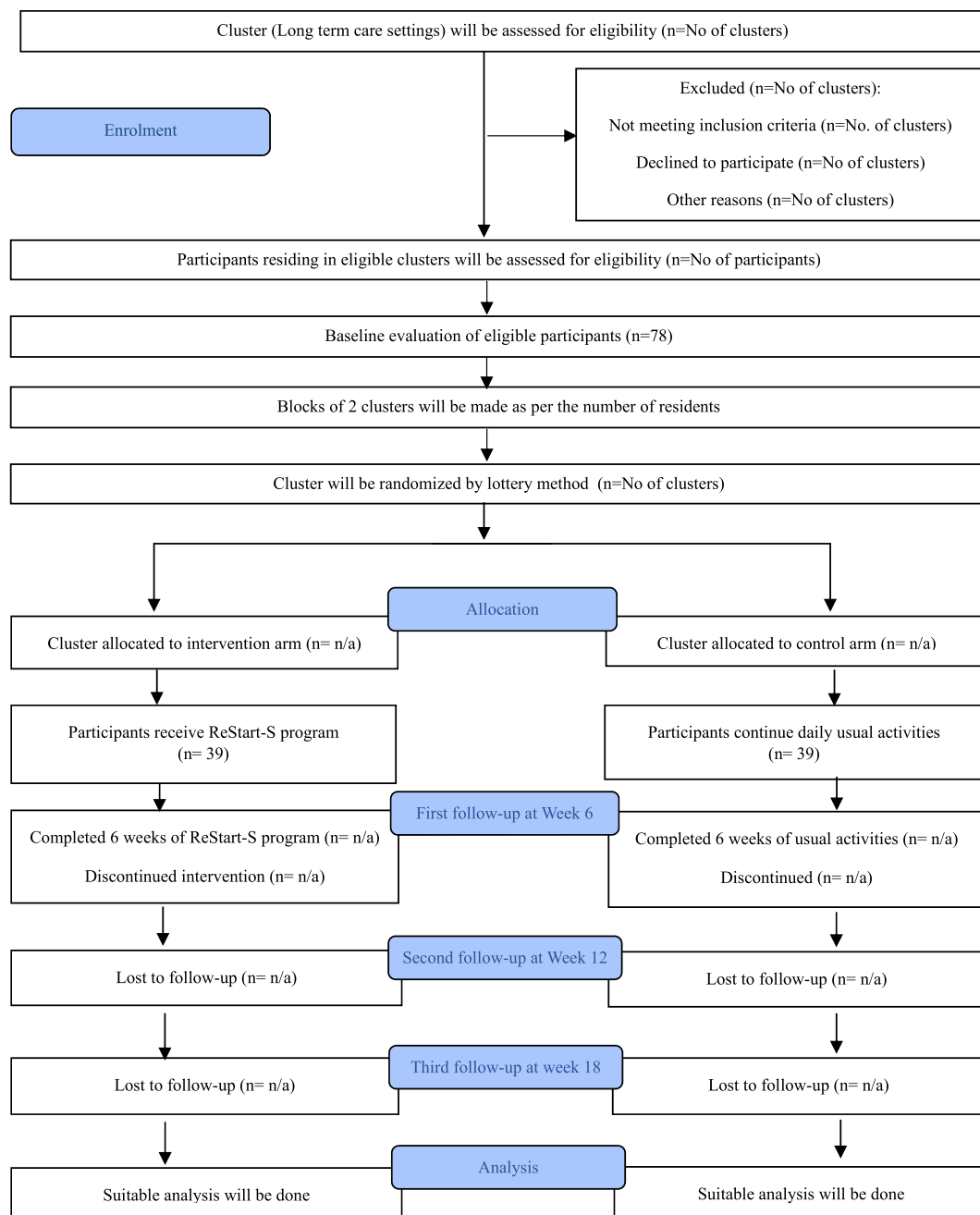


Fig. 1. Participants flowchart of the Study [CONSORT 2010].

residing in those cluster(s) in the intervention arm. Participants in the control arm will be asked to continue their usual daily activities. Upon the conclusion of a 6-week intervention, a thorough assessment of outcome measures will be carried out. Additionally, follow-up evaluations will be conducted at the 12th and 18th-week. It will not be possible to blind the allocation of groups from the therapist responsible for the intervention since the person will be delivering the protocol. It will not be possible to blind the intervention from the participants to whom it would be administered. Key aspects of the participant's flow can be found in Fig. 1.

2.4. Demographic characteristics and baseline assessment

All the participants who will provide consent will be screened for eligibility. Screening proforma will include the following demographic characteristics: Gender, Age (years), Weight (Kg), Height (cm), Hand dominance (the dominant hand will be considered the one preferred for daily activities like writing or eating), presence of any of the factors which would cause exclusion of the participant and assessment as per the AWGS 2019 criteria. The eligible participants will be assessed for additional baseline clinical characteristics, including Marital status (Not married/married/widow/divorced), education level, years of stay in LTCS, family visits/year, and activities of daily living and other variables which are reported in Table 1.

2.5. A detailed description of the intervention

Control arm: The eligible participants residing in the clusters (control arm) will be asked to continue their usual daily activities.
Intervention arm: The ReStart-S program, codesigned specifically for the sarcopenic older adults residing in LTCS, consists of

Table 1
Details of Demographic characteristics.

Variables	Subcategory
Age (Years)	60-70/71-80/81-90/91-100
Gender	Male/Female
Weight (Kg)	NA
Height (cm)	NA
BMI (Kg/m ²)	Male/Female
Education level	Primary level/Secondary level/Higher level
Marital status	Not married/Married/Widow/Divorced
LTCS (Years of stay)	NA
Family visits/year	NA
Independence in activities of daily living	1 (independent)/0 (required assistance)
Bathing	
Dressing	
Toileting	
Transferring	
Continence	
Feeding	
History in the past 1 year:	Yes/No
Smoking	
Alcohol	
Falls	
Fracture	
Hospitalization	
Physical activity	
Any co-morbidities and medications	Names of the conditions and medication
Body composition	Values of body composition parameters
Fat (%)	
Resting metabolic (kcal)	
Visceral fat (Level)	
Subcutaneous fat (%)	Values of subcutaneous fat parameters
Whole body	
Trunk	
Arms	
Legs	
Skeletal muscle (%)	Values of skeletal muscle parameters
Whole body	
Trunk	
Arms	
Legs	
Skeletal muscle index (Kg/m ²)	Male/Female
Hand grip strength (Kg)	Male/Female
Short Physical performance battery	Male/Female
Blood biomarker	Male/Female
C-terminal agrin fragment	
Sarcopenia Quality of Life questionnaire	Male/Female

resistance, aerobic and endurance exercises, balance exercises, and stretching exercises. The development of the program content was meticulously executed through an extensive process of reviewing relevant literature [34], gathering feedback from participants (through the workshop), and consulting with experts (through the Delphi agreement) [35]. The program will be administered to the eligible participants residing in the LTCS under the intervention arm. After the initial assessment of the participants, the sarcopenic status will be determined, and they will be stratified into (a) a possible sarcopenia group, (b) a sarcopenia group, and (c) a severe sarcopenia group based on the guidelines given by the AWGS-2019 [36].

The intervention will be delivered at a frequency of two times per week for six weeks, followed by the follow-up in 6th-week and the 12th-week post-intervention. The exercise will be supervised and delivered by the PhD research scholar who has completed a Master of Physiotherapy. Two LTCS (clusters) will be visited in one day to deliver the ReStart-S program. After a one-day gap, the second visit

Table 2

Proposed ReStart-S program for severe sarcopenics.

Week Wise Progression	Description
Components of resistance training within the ReStart-S program	
First week	The resistance training starts with low to moderate intensity (RPE 6–8), focusing on simple exercises like dynamic quadriceps contractions, ball squeezes, seated heel raises, and biceps curls using a theraband. Participants perform one set of 5–7 repetitions per exercise, and the session lasts about 10 min.
Second week	The intensity remains low to moderate, but the volume increases to two sets of 5–7 repetitions. Additional exercises are introduced, such as biceps curls with dumbbells and dynamic quadriceps contractions with a sandbag, building upon the previous week's exercises.
Third week	This week sees an increase in intensity to moderate to somewhat high (RPE 9–10), with participants performing two sets of 8–10 repetitions. The same exercises from the second week are repeated, but the overall session duration is increased to 20 min.
Fourth week	The intensity remains moderate to somewhat high, but participants now perform three sets of 8–10 repetitions. Two new exercises are added: seated hip abduction using a theraband and shoulder flexion with dumbbells. The overall session lasts 20 min.
Fifth week	During this week, the intensity increases to somewhat high to high (RPE 11–12), and participants perform three sets of 10–12 repetitions. New exercises, such as seated knee raises and horizontal shoulder abduction with a theraband, are added, and the session extends to 30 min.
Sixth week	The final week maintains a high intensity (RPE 11–12), with participants performing three sets of 12–15 repetitions. The same exercises from the fifth week are repeated, with the session continuing to last 30 min.
Components of Aerobic & endurance training within the ReStart-S program	
First week	Aerobic training begins with low to moderate intensity (RPE 6–8), focusing on self-paced walking. Participants walk for 30 s and repeat this 2–4 times, with a total session duration of 1–2 min.
Second week	The second week maintains the same intensity, but the walking duration increases to 50 s, still repeated 2–4 times. The overall session time increases to 3–4 min, building on the previous week.
Third week	In the third week, the intensity rises to moderate to somewhat high (RPE 9–10). Participants walk for 50 s, but the number of repetitions increases to 5–6, resulting in a session lasting 4–5 min.
Fourth week	The intensity remains moderate to somewhat high, with walking duration increasing to 60 s and 7–8 repetitions. Additionally, repetitive anterior stepping for 10 s is introduced. This week adds new movements, such as anterior, lateral, and posterior stepping, with the session lasting 6–12 min.
Fifth week	The intensity increases to somewhat high to high (RPE 11–12), and walking time extends to 70 s with 9–10 repetitions. Repetitive stepping in both anterior and lateral directions for 10 s is added to the routine, resulting in a session duration of 11–15 min.
Sixth week	The final week maintains high intensity (RPE 11–12), with walking lasting 80 s and repeated 11–12 times. Repetitive stepping in all directions is increased to 15 s, with the session lasting 16–20 min.
Components of Balance training within the ReStart-S program	
First week	Balance training begins with low to moderate intensity (RPE 6–8), focusing on broad base standing. Participants maintain the position for 20 s and perform it three times, resulting in a total session length of 1 min.
Second week	The intensity remains the same, but the exercises become more challenging. Participants stand with their feet together, using one finger for support for 10 s (repeated six times), followed by standing without support for 5 s (repeated three times). The session duration increases to 2–3 min.
Third week	The third week maintains moderate intensity (RPE 9–10) and repeats the exercises from Week 2. The session duration extends to 3–4 min, helping participants strengthen their balance further.
Fourth week	In this week, participants are introduced to a semi-tandem stance, where the heel of one foot touches the toes of the other. They hold this position for 10 s, repeating it twice. The session lasts 4–6 min, with moderate to somewhat high intensity (RPE 9–10).
Fifth week	The intensity increases to somewhat high to high (RPE 11–12), with participants performing a full tandem stance, standing heel-to-toe for 10 s, repeated twice. The session duration increases to 6–8 min, challenging their balance significantly.
Sixth week	The final week repeats the exercises from Week 5, maintaining the same intensity (RPE 11–12) and session duration of 6–8 min.
Components of Stretching exercises within the ReStart-S program	
First week	Stretching exercises begin with low to moderate intensity (RPE 6–8). Participants perform one set of wrist flexor/extensor and seated plantar/dorsiflexor stretches, holding each stretch for 10–12 s and repeating twice. The session lasts 1 min.
Second week	The intensity remains low to moderate, but the stretches are held for a longer duration of 13–15 s. An additional neck extensor stretch is introduced, and the session duration increases to 1–2 min.
Third week	In the third week, the intensity rises to moderate to somewhat high (RPE 9–10). Participants now perform two sets of stretches, each held for 13–15 s, and seated lateral trunk stretches are added. The session lasts 2–3 min.
Fourth week	The same intensity (RPE 9–10) is maintained, with participants repeating the stretches from Week 3. A neck rotator stretch is introduced, and the session duration extends to 3–4 min.
Fifth week	In this week, the intensity increases to somewhat high to high (RPE 11–12). Participants perform two sets of each stretch, holding them for 13–15 s and repeating them three times. Bicep and tricep stretches are added, and the session duration increases to 4–5 min.
Sixth week	The final week maintains a high intensity (RPE 11–12), with participants performing three sets of stretches, each held for 13–15 s and repeated three times. Shoulder abductor and neck lateral flexor stretches are added, with the session lasting 5–6 min.

will be made. Thus, four LTCS with two visits for each setting will be made in a week. The eligible participants will be asked to sit in the group according to their sarcopenic status in a well-lighted and ventilated hall. For each group, a tailored set of multi-component exercises will be delivered. The proposed intensity, volume & progression, and type of exercise customized from 1st-week to 6th-week for each group are shown in Table 2, Table 3, and Table 4.

All the required equipment/materials (thera band/sandbags/water bottle) will be provided to the participants. Participants will be motivated while exercising using verbal motivation vocabulary, such as doing good, great go on, etc. The participants will be involved in fun-based activities (like ball throwing/catching, ball kicking, throwing a ball to the target, and hitting the ball to the target using the wand) to ensure retention for the intervention period. To ensure complete reporting of intervention, a Consensus on Exercise Reporting Template (CERT) [37] has been used in Table 5.

Table 3
Proposed ReStart-S program for sarcopenics.

Week Wise Progression	Description
Components of resistance training within the ReStart-S program	
First week	Participants engage in resistance exercises twice weekly, with an intensity of low to moderate (6–8 on the RPE scale). The volume consists of one set of 5–7 repetitions per exercise, lasting approximately 10 min. The exercises include shoulder abduction with a dumbbell, chest press, abdominal crunches while seated, and standing back extensions.
Second week	The frequency remains at twice weekly with the same low to moderate intensity (6–8 RPE). However, the volume is increased to two sets of 5–7 repetitions per exercise over 10 min, with the addition of standing abduction of the hip with support and performing flexion/extension exercises in standing.
Third week	The intensity increases to moderate to somewhat high (9–10 RPE), with two sets of 8–10 repetitions per exercise, lasting 20 min. New exercises include hip abduction with sandbags and triceps extensions along with seated rows.
Fourth week	Participants perform three sets of 8–10 repetitions per exercise at a moderate to somewhat high intensity (9–10 RPE), with a session lasting 20 min. Additional exercises are standing knee bends (hamstrings) with support and heel raises.
Fifth week	The intensity rises to an 11–12 rating of RPE which is defined as somewhat high to high, with three sets of 10–12 repetitions per exercise, lasting 30 min. Squats with support, knee bends with sandbags and sit-to-stand exercises are introduced.
Sixth week	Participants perform three sets of 12–15 repetitions per exercise, maintaining a high intensity (11–12 RPE) with a 30-min duration. New additions include wall push-ups and knee raises in standing.
Components of Aerobic & endurance training within the ReStart-S program	
First week	Aerobic exercises are performed twice weekly at a low to moderate intensity (6–8 RPE). The volume is 5 s of step marching, repeated 2–3 times, with each session lasting 1–4 min. Step marching is performed with support.
Second week	The volume increases to 10 s of step marching, repeated 2–3 times, lasting 5–7 min while maintaining the same intensity (6–8 RPE).
Third week	Introduces moderate to somewhat high intensity (9–10 RPE), with step marching for 10 s, repeated 4–5 times, and the session extending to 8–10 min.
Fourth week	The intensity remains at 9–10 RPE, but the volume increases to 20 s of marching for 1–2 times, with the session lasting 11–13 min. Stationary cycling is added.
Fifth week	Participants perform 20-s intervals of aerobic exercises, repeated 2–3 times, at somewhat high to high intensity (11–12 RPE), with sessions lasting 14–16 min.
Sixth week	Aerobic sessions consist of 30-s intervals, repeated 3–4 times, lasting 16–20 min, while maintaining the same intensity (11–12 RPE).
Components of Balance training within the ReStart-S program	
First week	Balance exercises are conducted twice weekly at a low to moderate intensity (6–8 RPE). Participants hold positions for 10 s, repeating them 6 times, with sessions lasting 1 min. Exercises include heel raises and toe raises with support, as well as single-leg standing with support.
Second week	The intensity remains the same, but participants hold positions for 10 s and repeat them 3 times per exercise. Sessions extend to 2–3 min, and new exercises include heel, and toe raises without support and standing on foam.
Third week	The intensity increases to a nine to ten rating of RPE, which is moderate to somewhat high. Participants maintain the position and walk for 10 s, repeating this three times for each exercise, with total session durations of 4–6 min. Additional exercises include standing reach-outs, heel walking with assistance, and tandem walking forward and backward with support.
Fourth week	Participants walk for 10 s, repeating four times per exercise, with the intensity remaining at 9–10 RPE. Sessions last 7–8 min, and the new exercises include figure of eight walking and heel walking without support.
Fifth week	The intensity rises to somewhat high to high (11–12 RPE), and participants perform walking and obstacle clearance exercises over 8–10 min. Toe walking with support is added.
Sixth week	Participants perform toe walking and stair climbing exercises for ten to 13 min, maintaining the high intensity (11–12 RPE), with toe walking done without support.
Components of Stretching exercises within the ReStart-S program	
First week	Stretching exercises are done twice weekly at a low to moderate intensity (6–8 RPE). Participants complete one set, repeating it twice, holding stretches for 10–12 s. Sessions last 1 min and involve seated arm stretches.
Second week	The same intensity and set structure are maintained, but stretches are held for 13–15 s. Sessions extend to 1–2 min, with the addition of standing lateral trunk muscle stretches.
Third week	The intensity increases to moderate to somewhat high (9–10 RPE), and participants perform two sets, repeating them twice, holding stretches for 13–15 s, with sessions lasting 2–3 min.
Fourth week	The same intensity and volume are maintained, but new exercises include seated trunk rotator stretches, and sessions last 3–4 min.
Fifth week	The intensity increases to somewhat high to high (11–12 RPE), with participants performing two sets, repeating them three times, holding stretches for 13–15 s. Sessions last 4–5 min and sit-to-reach stretches are added.
Sixth week	Participants perform three sets, repeating them three times, with stretches held for 13–15 s, and sessions lasting 5–6 min. The new exercise is standing stretches of gastrocnemius and soleus muscles with support.

Table 4
Proposed ReStart-S program for possible sarcopenics.

Week Wise Progression	Description
Components of resistance training within the ReStart-S program	
First week	In the first week, participants engage in resistance exercises twice a week, starting with low to moderate intensity (RPE 6–8), performing one set of 5–7 repetitions for each exercise. The focus is on lunges with support and standing pelvic tilts, lasting around 10 min per session.
Second week	The frequency remains the same, but the volume increases to two sets of 5–7 repetitions. The exercises from the first week continue, with the addition of seated leg presses.
Third week	In the third week, the intensity rises to moderate to somewhat high (RPE 9–10), with two sets of 8–10 repetitions per exercise. This week adds double-arm pull-downs to the routine, extending the session to 20 min.
Fourth week	During the fourth week, the intensity is maintained at the same level, but participants progress to three sets of 8–10 repetitions, incorporating forward-bend rows into the workout
Fifth week	In the fifth week, the intensity increases to somewhat high to high (RPE 11–12), with three sets of 10–12 repetitions. Latissimus dorsi pull-downs are introduced, and the session duration extends to 30 min.
Sixth week	By the sixth week, participants continue with three sets, now performing 12 to 15 repetitions, with the addition of supine chest presses, maintaining a somewhat high to high intensity (RPE 11–12) for 30 min.
Components of Aerobic & endurance training within the ReStart-S program	
First week	The aerobic component in the first week begins with step marching twice a week at low to moderate intensity (RPE 6–8), performed for 5 s at a time, repeated 2 to 3 times, for a total duration of 1–4 min.
Second week	In the second week, the step marching progresses to 10-s intervals, maintaining the same frequency and intensity, but the duration extends to 5–8 min.
Third week	In the third week, slow running is introduced, with 10-s runs performed 1 to 2 times, increasing the session length to 9–11 min, while maintaining moderate to somewhat high intensity (RPE 9–10)
Fourth week	By the fourth week, participants perform 10-s slow runs 2 to 3 times, extending the total session duration to 11–14 min.
Fifth week	In the fifth week, agility ladder drills are added, with participants performing one set of forward and sideward steps, increasing the duration to 14–17 min while working at a somewhat high to high intensity (RPE 11–12).
Sixth week	In the final week, participants progress to performing two sets of forward and sideward drills, increasing the session to 18–20 min.
Components of Balance training within the ReStart-S program	
First week	For balance exercises, week one introduces crossing obstacles twice a week at low to moderate intensity (RPE 6–8), performing 2 sets of 10 repetitions, lasting 1–2 min per session.
Second week	In the second week, backward counting while walking is added as a cognitive task, with the session duration extending to 2–3 min.
Third week	By the third week, manual tasks are incorporated, with participants walking for 10 s twice, while carrying out a manual task, at moderate to somewhat high intensity (RPE 9–10), for 4–6 min.
Fourth week	In the fourth week, ramp walking is introduced, with participants walking uphill for 5 s twice, extending the session to 6–8 min.
Fifth week	In the fifth week, backward ramp walking is added, increasing the intensity to somewhat high to high (RPE 11–12), with the session lasting 8–10 min.
Sixth week	In the sixth week, participants practice quick directional changes, performing two sets of front and sideway movements, for 8–10 min.
Components of Stretching exercises within the ReStart-S program	
First week	In week one, stretching exercises focus on standing trunk rotations, performed twice a week at low to moderate intensity (RPE 6–8), with one set of stretches repeated twice, holding each for 10–12 s, lasting 1 min in total.
Second week	During the second week, participants repeat the same exercises but extend the hold to 13–15 s, increasing the session duration to 1–2 min.
Third week	In the third week, seated Achilles stretches using a towel are introduced, with two sets of stretches, repeated twice, for 13–15 s each, lasting 2–3 min at moderate to somewhat high intensity (RPE 9–10).
Fourth week	By the fourth week, participants perform pectoral muscle wall stretches, extending the session to 3–4 min.
Fifth week	In the fifth week, supported quadriceps stretches are added, with participants repeating the stretches three times, holding each for 13–15 s, increasing the duration to 4–5 min.
Sixth week	In the sixth week, participants continue with three sets of stretches, repeated three times, holding each for 13–15 s, for a total of 5–6 min, while working at a somewhat high to high intensity (RPE 11–12).

2.6. Participant withdrawal and harms

If at any point a participant wishes to withdraw the consent, they are free to do so without any consequences. Additionally, the primary researcher may remove a participant from the study if necessary for their safety or if they are unable or unwilling to follow the study's procedures. The primary researcher will record the reasons for the withdrawal. During the study, participants must report any harm or adverse effects that may prevent them from continuing the intervention, regardless of whether it relates to the study procedure. The principal investigator will ensure that the participant receives appropriate medical care. Any adverse effects will be documented and reported promptly to the institutional review board and ethics committee.

2.7. Outcome measures and assessments

Primary and secondary outcomes will be measured at individual participants level on four evaluation time points at week 0 (baseline), first follow-up at week 6 (post intervention), second follow-up at week 12, and third follow-up at week 18, shown in Table 6.

2.7.1. Primary outcomes

The primary outcome measure is a change in the HGS (Kg) during the study period. HGS will be measured using a JAMAR Plus Digital Hand Dynamometer, Patterson Medical Ltd. HGS is a strong predictor of disability, morbidity, and mortality and one of the

Table 5
Consensus on exercise reporting template (CERT).

Item category	Item No.	Abbreviated item description
What: materials Who: provider How: delivery	1	Thera band, Thera tubes, dumbbell, sandbags
	2	PhD research scholar
	3	Exercises will be performed in the group
	4	Exercises will be performed under the supervision
	5	Measurement and reporting of adherence to exercise: NA
	6	Verbal motivation will be used
	7a	Detailed description of the decision rule(s) for determining exercise progression: The exercise progression will depend on the RPE the individual reporting at the intensity
	7b	Resistance training: Raising both the number of repetitions and the number of sets.
		Cardiovascular and endurance workouts: Enhancing the rate of perceived exertion (RPE).
		Balance training: Making the exercises more difficult by increasing their challenge.
	8	Flexibility exercises: Customized to meet individual needs.
		The resistance exercises for the upper limbs include movements like bending and straightening the elbow joint, raising the forearm from the elbow and lifting it above the head (to target the triceps muscle), pull-down exercises using both arms, shoulder exercises like taking the arm away from the body or lifting in front, chest presses, seated rows, bent-over rows, seated latissimus pull-downs, front raises, push-ups using the wall, and exercises of the hand musculature such as intrinsic hand movements, pumping the hand by closing and opening the fist, and squeezing the rubber ball. For the lower limbs, the exercises involve bending and straightening the knee joint, taking the whole leg away and close to the body (abduction and adduction), leg presses in a seated position, squatting, raising the heels and standing on toes, kicking back, lunges, tilting the pelvis, bridging exercises, and leg raises. Trunk exercises focus on abdominal crunches and back extensions. In terms of aerobic and endurance training, activities include walking, slow jogging, step marching, cycling on a stationary bike or fixed cycle ergometer, repetitive stepping in different directions (anterior, posterior, and lateral), and agility ladder drills.
		Balance exercises incorporate both static and dynamic components. Static balance involves broad-base standing, standing with feet together, semi-tandem and tandem standing, heel-up and toe-up positions, and one-leg standing. Dynamic balance exercises include heel and toe raise, heel-to-toe walking, multi-directional stepping, quick directional changes, functional reaches in various directions, walking on ramps forwards and backwards, figure of eight walking, and walking with added tasks, either cognitive or manual. Stretching exercises cover the upper limbs, including stretches for the biceps, triceps, shoulder abductors, neck (flexion, rotation, side flexion), pectorals, and fingers. Lower limb stretches focus on the hamstrings and calves, while trunk stretches involve rotating the trunk with arms crossed and stretching the side flexors.
	9	Participants will be asked to continue with their daily usual activity
	10	Describe whether there are any non-exercise components: NA
	11	Any adverse event, if occurred will be noted and reported to IEC within 24 h of happening
Where: location	12	The exercise will be performed in long term care settings
When How much: dosage	13	A detailed description of the exercises (e.g., sets, repetitions, duration, intensity): Individually tailored exercise volume will be delivered
Tailoring: what, how	14a	Describe whether the exercises are generic (one size fits all) or Tailored: Tailored as per the fitness level of the individual
	14b	A detailed description of how exercises are tailored to the Individual: RPE will be used as the guide scale for tailoring the exercise
How Well: planned, actual	15	Describe the decision rule for determining the starting level: The participants fitness level at a particular point in time
	16a	Describe how adherence or fidelity is assessed/measured: NA
	16b	Describe the extent to which the intervention was delivered as Planned: N/A

Table 6
Timeline for the measurement of primary and secondary outcomes of the study participants.

	Measurement	Week 0 (Baseline)	First follow-up at Week 6 (Post intervention) period	Second follow-up at Week 12	Third follow-up at week 18
Primary outcome	Hand grip strength	×	×	×	×
Secondary outcomes	Short physical performance battery	×	×	×	×
	Skeletal muscle mass	×	×	×	×
	C-terminal Agrin Fragment	×	×	×	×
	Sarcopenia Quality of Life questionnaire	×	×	×	×

components of AWGS 2019 guidelines to diagnose sarcopenia [3]. Participants will be asked about their dominant hand (the dominant hand will be considered the one preferred for daily activities like writing or eating). Prior to the recording, each participant will be given a trial to familiarize them with the procedure on their non-dominant hand. The reading obtained on the dominant hand will be recorded following standard procedure [38]. Grip strength assessments in healthy older persons have previously been shown to have excellent intra-tester reliability (ICC = 0.94 to 0.98) and inter-tester reliability (ICC = 0.98) [39]. The minimum clinically important difference (MCID) was found in the range of 0.04 kg–6.5 kg [40]. We hypothesize that the intervention would lead to an increase in the HGS.

2.7.2. Secondary outcomes

The secondary outcomes are changes in physical performance, muscle mass, biomarker levels, activities of daily living, and quality of life. The SPPB will evaluate physical performance. It is a standard test used to assess the balancing ability, strength of the lower extremities, and walking speed of older adults. The test includes balancing in three positions, walking a 4-m course for time, and performing five sit-to-stand repetitions as quickly as possible. The test score ranges from zero to twelve; each component's maximum score is four [41]. A total score of less than or equal to 9 indicates sarcopenia as per the AWGS 2019 criteria [3]. Research suggests the test has high sensitivity but low specificity to diagnose sarcopenia [42]. An improvement of 0.4–1.5 points is clinically significant [43].

Skeletal muscle mass will be estimated using Omron Karada Scan HBF- 375 Bioelectrical Impedance Analyzer (BIA) measurements and expressed as skeletal muscle mass index (SMI, Kg/m²) ($SMI = [\text{percentage of skeletal muscle mass} \times \text{body mass}/100] \div \text{height}^2$). Participants will be asked to void urine, not have any food, drink at least 2 h before the recording, and do no physical exercise for 8 h. The BIA platform will be cleaned using an alcohol rub. The required inputs like age, gender, and height will be entered. Participants will be asked to stand on the foot marks and hold the hand device at 90-degree shoulder flexion for 5–10 s [44]. Once the procedure is completed, the participant will ask to step off the device, and the obtained readings will be noted.

A blood-based biomarker will be measured for C-terminal Agrin Fragment (CAF, pg/ml). A recent scoping review has reported that sarcopenia is associated with a higher level of CAF [31]. An expert from the Department of Medical Laboratory Technology will perform the procedure. Participants will be requested to do an overnight fast. In the morning, blood samples will be drawn via the cubital vein using vacutainers with an anticoagulant called Ethylenediamine tetraacetic acid (EDTA). The vacutainers will be stored at a controlled temperature. They will be transported to the laboratory, where the sample will be centrifuged for 10 min at 4000 g and 4 °C temperature for plasma separation. The plasma obtained will be kept for analysis [45].

Sarcopenia is associated with reduced QoL [10], the participants QoL will be assessed using the self-administered Sarcopenia quality of life questionnaire- Kannada version (SarQoL-Kannada) [46]. The questionnaire comprises 55 items translated into 22 questions rated on a 4-point Likert scale. These items are organised into seven domains of dysfunction: Physical and mental health, Locomotion, Body composition, Functionality, Activities of daily living, Leisure activities and Fears. The minimum score is zero, and the maximum score countable is a hundred [47]. A questionnaire printout will be provided to the participants so they can enter their responses. The responses of each participant will be encoded in the online account on the SarQoL website. The SarQoL-Kannada questionnaire has high internal consistency (Cronbach's alpha coefficient was 0.904) with excellent test-retest reliability (intraclass correlation coefficient was 0.97, 95 % CI 0.92–0.98) [46]. We hypothesize that the intervention would lead to an increase in the SPPB score, improvement in muscle mass, reduction in the CAF concentration, and better QoL.

2.8. Sample size

The study has been powered according to the primary outcome: HGS. To determine the sample size, we used a comparison of the mean formula $(2 \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times (\sigma^2/(\mu_d)^2)$ and considered the standard deviation of grip strength (4.5 kg) and the minimum clinically important difference (3.90 kg) based on previous randomized controlled trials [48,49]. With a significance level ($Z_{1-\alpha/2}$) of 5 % and power ($Z_{1-\beta}$) of 80 %, we arrived at a sample size of approximately 21 participants per arm. However, after factoring in a design effect of 1.5, the estimated sample size increased to around 32 participants per arm. Accounting for a potential drop-out rate of 20 %, we arrived at a total of 39 participants in each arm as an adequate sample size for the study.

2.9. Statistical analysis

The results will be analysed by IBM Statistical Package for Social Sciences 20. To ensure that the data is distributed uniformly, the Kolmogorov-Smirnov test will be utilised. The demographic details of the individuals will be summarized using descriptive statistics. If there are dropouts during the follow-up, the intention to treat analysis will be used. For both within-group and between-group comparisons, the analysis of variance will be utilised. A significance level of ≤ 0.05 will be set. If a statistically significant difference is found, post hoc analysis (Bonferroni correction and Tukey's HSD) will be carried out. In case of missing data, multiple imputation analyses will be done, assuming that the data are missing at random (MAR). Multiple imputations will involve creating multiple complete datasets by imputing missing values based on observed data patterns and relationships and then analyzing each dataset using the same statistical methods. The results will be pooled to obtain unbiased parameter estimates and valid standard errors that reflect the uncertainty due to missing data. Sensitivity analyses will be conducted to assess the robustness of the findings to different missing data assumptions. Additionally, we will perform a complete case analysis and compare the results with those obtained from multiple imputations to evaluate the potential impact of missing data on our conclusions. The proportion and patterns of missing data will be reported, and any deviations from the MAR assumption will be explored through appropriate diagnostics. This comprehensive approach aims to minimize the bias introduced by missing data and enhance the robustness of the trial findings. Cox proportional hazards regression analysis will be carried out if any untoward event occurs.

3. Discussion

The global population of elderly individuals is on the rise, leading to a corresponding increase in the prevalence of sarcopenia and associated healthcare cost [50,51]. Sarcopenia is a significant health concern that various communities are striving to prevent and address [52]. Among the pharmacological and non-pharmacological options available for managing sarcopenia, the most substantial evidence exists for a multi-component program involving exercises as the mainstay [53,54].

Rapid urbanization, the rise of the nuclear family, a lack of social support, and child migration to other cities and countries have all contributed to a reduction in traditional familial and social support, resulting in huge demand for elderly care with a subsequent rise in the number of LTCS in India [55–58]. However, health care in India is concentrated more on hospitals/health care facilities and not much on LTCS, which lacks proper regulations [59]. Despite a plethora of research into the area of sarcopenia, there is little conclusive evidence available for the sarcopenic older adults residing in LTCS [15].

To the best of our knowledge, this study is the first cluster randomized trial to test the effectiveness of the ReStart-S program on muscle strength, muscle mass, physical performance, QoL, and levels of CAF among sarcopenic older adults residing in LTCS. The focus on intervention effectiveness rather than the views and preferences of the residents is concerning and a potential barrier to the longer-term impact and scalability of the multi-component exercise-based reablement programs [14]. Thus, after conducting a thorough literature search on exercise prescriptions for sarcopenic older adults [34], the ReStart-S program has been co-designed with the involvement of the older adults residing in LTCS and experts in sarcopenia care [35]. Thus, applying the ReStart-S multi-component exercise program for sarcopenic older adults in LTCS would be a significant step forward.

In addition to exercise, older adults nutritional status, particularly protein and energy intake, plays a critical role in managing sarcopenia. The European Society for Clinical Nutrition and Metabolism (ESPEN) 2022 practical guideline recommends a minimum daily protein intake of 1.0 g per kilogram of body weight for healthy older adults. This requirement can increase to 1.2–1.5 g per kilogram in individuals with chronic illnesses, and up to 2.0 g per kilogram in those with severe conditions [60]. Although the nutritional status of older adults in this study would not be assessed directly; however, as a proxy measure, the weight and other measures of body composition using BIA would be recorded at each time point to reflect potential changes in nutritional intake over time. This will allow us to observe any trends that could influence the study outcomes. Additionally, the lack of assessing the protein intake of the older adult participants would be addressed as the study limitation, and its potential impact on the results would be acknowledged. Moreover, to partially address dietary protein intake, future studies could incorporate validated dietary assessment methods, such as the Mini Nutritional Assessment (MNA) or Food Frequency Questionnaire or Simplified Nutritional Appetite Questionnaire (SNAQ) for assessing the risk of malnutrition or Protein Screener 55⁺ (Pro⁵⁵⁺), to provide a more comprehensive evaluation of protein and energy intake among older adults [61–64].

Studies had reported an improvement in the physical capacity of community-dwelling frail older adults when the exercise program was delivered as per the frailty status [65]. Older adults can be categorized into groups per their sarcopenic status of possible sarcopenia, sarcopenia, and severe sarcopenia [2,3]. The multi-component exercise-based ReStart-S program will allow prescribing the exercise according to the sarcopenic status, which will be tailored and progressed per the participants fitness level. If this cluster randomized trial confirms our hypothesis, it may be possible to introduce the ReStart-S program to older adults with sarcopenia who reside in LTCS worldwide. Finally, the ReStart-S program could be implemented easily in LTCS to have a far-reaching impact. Its implications may include reducing the health care burden of sarcopenia, improving the well-being of sarcopenic older adults residing in LTCS, and contributing to sustainable development goal 3.

4. Conclusion

With the increase in the population of older adults, it is of utmost importance to incorporate strategies to promote independence in daily life activities for older adults for as long as possible and to reduce disability-adjusted life years. Thus, this study will evaluate the effectiveness of the ReStart-S program among sarcopenic older adults residing in LTCS. The program may help counter sarcopenia by improving muscle strength, muscle mass and physical performance. By reversing the sarcopenia triad, the program may help to promote healthy ageing and enhance the independence of older adults in LTCS. If the ReStart-S program is found to be beneficial, it can be incorporated into geriatric rehabilitation programs in LTCS worldwide.

CRediT authorship contribution statement

Prabal Kumar: Writing – original draft, Project administration, Methodology, Conceptualization. **Shashikiran Umakanth:** Writing – review & editing, Supervision. **Olivier Bruyère:** Writing – review & editing, Supervision. **Girish N:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Informed consent

Participants will receive oral information to fully understand study risks and benefits in compliance with the Helsinki declaration [66].

Data availability statement

Data associated with the study has not been deposited into a publicly available repository because no data was used for the research described in the article.

Ethics statement

The study is approved by the Kasturba Medical College and Kasturba Hospital Institutional Ethics Committee [IEC1: 100/2022] and

is registered on the Clinical Trial Registry-India (CTRI) platform [CTRI/2022/10/046680].

Ethics committee approval

The study protocol has been approved by the Institutional Ethics Committee (IEC), Kasturba Medical College and Kasturba Hospitals, Manipal Academy of Higher Education, Manipal, Karnataka, India; Reference Number IEC1: 100/2022.

Clinical trial registration

The study was prospectively registered on October 20, 2022 on the Clinical Trial Registry-India (CTRI) platform. Trial registration number CTRI/2022/10/046680. The trial can be accessed: <https://ctri.nic.in/Clinicaltrials/showallp.php?mid1=71007&EncHid=&userName=CTRI/2022/10/046680>.

Trial status

All the necessary approvals have been obtained; data collection has not started.

Protocol amendments

Any amendments to the protocol will be reported to the institutional review board, institutional ethics committee, and participants and updated on the trial website.

Confidentiality

Confidentiality of all participants data will be maintained, and information by which a participant could be identified will not be disclosed to a third party. Information from the study records will be kept confidential and reviewed only by the ethics committee or regulatory bodies.

Dissemination

The study's results will be published in peer-reviewed journals, PhD theses, and conferences regardless of the outcome. All participants will receive the results, and authorship will follow strict criteria from the International Committee of Medical Journal Editors.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2025.e42174>.

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