

ORIGINAL RESEARCH

Four-Step Co-Designing of the Reablement Strategies Targeting Sarcopenia (ReStart-S): An Exercise-Based Multicomponent Program for Older Adults Residing in Long-Term Care Settings

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Background: The prevalence of sarcopenia is concerningly high in long-term care settings (LTCS); yet, no exercise programs specifically targeting older adults living in residential care are available.

Objective: The goal of the present study was to co-design and validate a program named Reablement Strategies targeting Sarcopenia (ReStart-S) for older long-term care residents.

Design: Cross-sectional study with an exploratory phase.

Settings: LTCS in Udupi, Karnataka, India.

Participants: Sarcopenic older adults diagnosed using Asian Working Group for Sarcopenia 2019 criteria.

Material and Methods: The program was designed using a four-step intervention mapping technique involving systematic progression after completing each step. The steps included 1) identifying the appropriate exercise-based intervention for sarcopenia, 2) determining objectives and expected outcomes, 3) seeking expert views through a Delphi consensus approach, and 4) assessing the feasibility of ReStart-S program among older adults living in LTCS.

Results: A comprehensive literature review appraised existing exercise programs for managing sarcopenia. A workshop held with six older adults and one caretaker, decided on morning exercise sessions, recommended 2–7 days/week. The results of the review and workshop were compiled for the Delphi process that had seven experts from 5 countries, achieving a 71% response rate after four rounds. In the last step, a pilot study on eight LTCS residents, two males and six females with a mean age of 78.3 ± 8.3 years, was conducted and the program was found to be feasible.

Conclusion: The ReStart-S program for managing sarcopenia among older adults residing in LTCS incorporates evidence from the literature and the engagement of older adults, caregivers, and experts, making it a contextually appropriate intervention. Our study also provides researchers and healthcare professionals insight into co-designing an intervention program for vulnerable older adults. Finally, the program evaluation indicates that a full-scale trial testing the efficacy of the ReStart-S program is feasible.

Keywords: reablement, sarcopenia, intervention mapping, older adults, long-term care settings

Introduction

Sarcopenia, an age-related condition characterized by abnormally low muscle mass and strength, was recognized as a distinct clinical entity in 2016 within the International Classification of Diseases, Tenth Revision, Clinical Modification ICD-10-CM code (M62.84). The prevalence of sarcopenia varies substantially depending on the operational definition adopted, the tools used for muscle mass and strength assessment, the characteristics of the study population (eg, age, sex, ethnicity), and living arrangement (eg, community, hospital, residential care). However, agreement exists that the

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condition is far more frequent among older adults residing in long-term care settings (LTCS), with prevalence rates ranging from 30 to more than 70%.²⁻⁴ Adverse health consequences associated with sarcopenia are multifaceted and include falls, disability, dysphagia, loss of independence, hospitalization, and mortality. 5-8 Among those living in LTCS, the presence of sarcopenia is also associated with depression, reduced quality of life, and a two-fold greater risk of allcause mortality. Hence, the recognition and management of sarcopenia are crucial to foster well-being and extending health- and lifespan in older adults living in LTCS. 9,10

As per the internationally accepted definition, reablement is a goal-oriented, person-centred holistic approach to enhance an individual's physical and functional abilities for independent daily living regardless of age, medical diagnosis, and setting.¹¹ Research suggests that the most commonly used reablement approach for older adults residing in LTCS is a multicomponent exercise program delivered by physiotherapists. For a longer impact of the reablement approach, stakeholders (including older adults, caregivers, administrators, physiotherapists, and medical professionals) should be consulted while designing the program. ^{12,13} However, programs delivered to LTCS residents typically lack the consultation component to co-design a program. Intervention mapping (IM) may be useful to structure this process and ensure the development and implementation of a feasible, acceptable, and effective intervention.

The IM is a problem- and theory-driven protocol that includes knowledge obtained from the literature and the involvement of key stakeholders. 14-16 The approach has been extensively used for designing health promotion and selfmanagement programs. 17,18 IM-based programs have been designed for older adults with chronic conditions to selfmanage, 19 and increase physical activity. 20 Various consensus groups have provided clinical practice guidelines for managing sarcopenia. 3,21-23 The guidelines indicate strong evidence of efficacy for resistance training either alone or as part of multicomponent exercise interventions. 21-23 However, no robust evidence exists to guide exercise prescription to older adults living in LTCS.²⁴ Furthermore, a multicomponent exercise-based reablement program co-designed with residents and experts to manage sarcopenia in LTCS is currently unavailable. 10

To fill this knowledge gap, the present study was conducted to co-design and validate the Reablement Strategies targeting Sarcopenia (ReStart-S) program in older adults residing in LTCS.

Materials and Methods

This was a Phase 1 study to lay the foundation for a possible full-scale clinical trial that will test the efficacy of the ReStart-S program. The study protocol was approved by the Institutional Ethics Committee, Kasturba Medical College and Kasturba Hospitals, Manipal Academy of Higher Education, Manipal, Karnataka, India [IEC1: 100/2022] and was prospectively registered on the Clinical Trial Registry-India (CTRI) platform. The date of registration was 20/10/2022, and the CTRI registration number is [CTRI/2022/10/046680]. The study duration was from December 2021 (starting of step 1) to July 2023 (completion of step 4).

Study Procedures

The IM technique was used to develop the program's four-step approach. A systematic procedure and step-by-step process were adopted in which progression was done only after completing the previous step. The steps were as follows: (a) The logic model of the problem, including needs assessment, (b) Program objectives and expected outcomes, (c) Program production, and (d) Evaluation.

The logic model of the problem, including needs assessment: the objective of this step was to synthesize the details of the exercises/exercise program prescribed for the improvement of muscle mass/muscle strength/physical performance among sarcopenic older adults. The investigators (GN and SU) validated a range of appropriate keywords and MeSH terms. A comprehensive literature search was conducted in the five electronic databases: PubMed, Scopus, Embase, Cumulated Index to Nursing and Allied Health Literature (CINAHL), and Web of Science in December 2021. An appraisal of the exercise programs was carried out using a data extraction/ charting form prepared and validated a priory by investigators. Exercises that targeted several domains such as strength, aerobics, balance, agility, and flexibility, and used either individually as single-mode intervention or in combination as a multi-component program were identified. Exercise prescription details such as type, frequency, intensity, and duration, as well as their progression, were also

extracted to appraise the various programs existing in the literature to target muscle mass, muscle strength, and physical performance among sarcopenic older adults. Details of the review methodology can be accessed elsewhere.²⁵

The next step involved framing the program objectives and expected outcomes and also identifying preferences, awareness, challenges, motivations, and barriers for stakeholders (administrators and older adults residing in LTCS) to an exercise-based intervention. A workshop involving administrators and residents of LTCS was conducted to co-design a reablement exercise program adaptable to LTCS. Six LTCS in the Udupi district of Karnataka, India, were randomly selected, and permission was obtained to conduct the study. A list of all the older adults (age >60 years) residing in LTCS and caretakers was prepared. The purposive sampling method was used to identify two older adults (with a minimum of five years of stay) and one caretaker (providing care to older adults for at least one year) each from three LTCS. Following the explanation of the procedure and obtaining the informed consent, the older adults were asked about the duration of their stay, and caregivers were asked about the number of years of providing care to be eligible as per the earlier mentioned inclusion criteria. From the eligible participants, the discussion was conducted with the LTCS administrator to select the most suitable older adults who were used to doing some kind of exercises and could provide valuable suggestions in the workshop to co-design a reablement exercise program adaptable to LTCS. According to the participant's convenience, the time and date were set on December 21, 2022 (10 am-12 pm). The participants were transported to the workshop location (Dr AV Baliga home for senior citizens) after being picked up from their long-term care facilities. Participants were made to sit in a well-lit and ventilated room. All participants were thoroughly informed of the nature and aims of the workshop and gave their consent to participate. To ensure older adults could express their views and opinions without hesitation, they introduced themselves to one another to break the ice, followed by a brainstorming session. A PowerPoint presentation was displayed to make the session more interactive, and the openended questions (eg. Do you know anything about the condition of sarcopenia? What do you think about exercise? How many days a week do you like to exercise? What should be the intensity of the exercise? How long should be the duration of the exercise session in a day? What kind of exercises should be there in the training in your opinion? What motivates you to exercise? What are the challenges/difficulties you face that prevent you from doing exercise? What are your thoughts on doing exercise in a group? Fun-based physical activity should be included in the exercise program. What is your opinion? What are the safety concerns while doing exercise? What is the most suitable time to do exercise? What do you think we should keep in mind while designing the exercise program?) to be discussed during the workshop were shown. For each question, the responses of each participant were recorded by two investigators (PK and GN) along with a video recording of the session (prior consent was obtained from all participants). Participants were asked to freely discuss their preferences, awareness, challenges, motivation, and barriers with each other and the investigators.

In the third step, a Delphi consensus approach was used for program production, which aimed to seek suggestions from seven (n = 7) experts to develop a reablement exercise-based intervention program specific to sarcopenic older adults residing in LTCS. An international panel of sarcopenia experts was identified from the website expertscape.com and among authors of scientific articles on sarcopenia. An expert was defined as an individual with an H-index of >3 (author profile in Scopus or Google Scholar) and at least four years of experience in geriatrics. In identifying experts, attention was given to ensure a wide geographical coverage. Experts were provided with an explanatory statement that informed them of the study's objectives, their roles and duties, and an offer of co-authorship for those completing at least one Delphi round. Google's cloud-hosted survey application (https://www.google.com/forms/about/) was used to create the form and conduct the Delphi rounds. There were four sequential and anonymous online rounds of Delphi.

In round 1, from the identified panel of experts, an e-mail invitation was sent to seven experts seeking their participation along with an attached Google form link, which included the consent section, the section describing their roles and duties, and the component list 1 for round 1. The investigator (PK) prepared the component list-1 (incorporating the points gathered from the review in step 1 and during the workshop in step 2). The list contained 88 items divided into five sections: section 1 (resistance exercise, 31 items), section 2 (aerobic and endurance exercise, 12 items), section 3 (balance exercise, 25 items), section 4 (stretching exercise, 15 items), and section 5 (delivery of exercise, 5 items). Five days from the day of invitation were allowed to reply, followed by a reminder on the fifth day and a last reminder on the seventh day (weekends were not counted as the days in the process). If no response was received from any of the seven contacted experts within the following two days of the last reminder, an Email invitation was sent to the remaining

required number of experts. The process was repeated until all the required seven experts for the Delphi process were included. After obtaining the response from all the experts, two investigators (PK and GN) analyzed the responses to identify the items that reached consensus to be retained (more than or equal to 85%), items that reached consensus not to be retained (more than or equal to 85%), and items with no consensus (less than 85%). Only items with no consensus were carried forward to the next round.

In Delphi round 2, a detailed report of round 1 and component list 2 were sent to the experts. After obtaining the response from the experts, two investigators (PK and GN) analyzed the responses to identify the items that reached consensus to be retained (more than or equal to 80%), items that reached consensus not to be retained (more than or equal to 80%), and items with no consensus (less than 80%). Only items with no consensus were carried out for the next round. The experts who did not respond were not included in the next round. In Delphi round 3, a detailed report of round 2 and component list 3 were sent to the experts. After obtaining the response from the experts, two investigators (PK and GN) analyzed the responses to identify the items that reached consensus to be retained (more than or equal to 60%), items that reached consensus not to be retained (more than or equal to 60%), and items with no consensus (less than 60%). Only items with no consensus were carried out for the next round. In Delphi round 4, the detailed report of round 3 and component list 4 were sent to the experts. The Delphi process was ended after the consensus was reached for all items (more than or equal to 60%) and the ReStart-S program was designed.

As the last step, the ReStart-S program was evaluated in a pilot study to test its feasibility among sarcopenic older adults residing in LTCS. The feasibility study was conducted in line with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement extension to the feasibility study. The program was evaluated in two facilities. Permission was obtained from the LTCS manager, and informed consent was obtained from all participants after a detailed explanation of the procedure was provided. A convenience sampling method was used for participant recruitment. Inclusion criteria were (1) either sex, (2) age ≥60 years, (3) Barthel index ≥60 points, (4) Minicog score ≥3, (5) presence of sarcopenia according to the Asian Working Group for Sarcopenia (AWGS) 2019 criteria.

Exclusion criteria were as follows: (1) the presence of critical or terminal illness (an end-stage disease with an estimated life expectancy of <6 months), acute infection, (2) the presence of a pacemaker and any metal implant, (3) bed bound/wheelchair bound, and (4) acute onset (<30 days) of cardiorespiratory, neurological, renal, or orthopaedic conditions.

Lean body mass was estimated using an Omron Karada Scan HBF-375 Bioelectrical Impedance Analyzer (BIA) and expressed as a skeletal muscle mass index (SMI = [percentage of skeletal muscle mass \times body mass/100] \div height²). The AWGS 2019 cut-off values adopted were <7.0 kg/m² for male participants and <5.7 kg/m² for female participants. Muscle strength (handgrip) was assessed with a JAMAR digital handheld dynamometer. According to AWGS 2019, cutoff values were <28.0 kg for male participants and <18.0 kg for female participants. The grip strength of the dominant hand (the dominant hand was considered to be the one preferred for daily activities like writing or eating) was measured following a standardized procedure. Before the recording, each participant was given a trial to familiarize themselves with the procedure on their non-dominant hand. Short physical performance battery (SPPB) was used to evaluate the physical performance. The SPPB includes balancing in three positions, walking a 4-meter 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. A total score of less than or equal to 9 indicates sarcopenia as per the AWGS 2019 criteria.

Following the screening of all the participants in the identified two LTCS, the eligible participants were categorized into possible sarcopenic, sarcopenic, and severe sarcopenic groups. The ReStart-S program was administered twice weekly for two consecutive weeks, and each session lasted for a minimum of 30 minutes. The exercises were pragmatically delivered for possible sarcopenic, sarcopenic, and severe sarcopenic groups assessed using the AWGS 2019 criteria. The intensity of the exercises was controlled using the Borg rating of perceived exertion (RPE) 6-20 scale.²⁷ The participants performed resistance, aerobic, balance, and stretching exercises under the supervision of the investigator (PK). Exercise equipment like thera bands (yellow, blue, red, and green colour), thera tubes, dumbbells (1/2, 1, 2, and 3 Kg), and sandbags (1/2, 1, and 2 kg) were used. The feasibility outcomes included (a) number of participants found to be eligible as per the eligibility criteria, (b) willingness of eligible participants to be engaged (recruitment rate),

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(c) fidelity of intervention at the level of therapist (time required to explain the procedure (minutes), any challenges identified during outcome measure assessment (outcome measures assessed were SMI, grip strength, physical performance, sarcopenia quality of life questionnaire (SarQoL) Kannada version, a disease-specific patient reported quality of life questionnaire (https://sarqol.org/en/downloads/kannada) comprises 22 questions rated on a 3-, 4-, or 5-point Likert scale in which items are categorized into the following seven domains of dysfunction: physical and mental health, locomotion, body composition, functionality, activities of daily living, leisure activities, and fears, and Katz index of activities of daily living, which is an instrument to discover issues with activities of daily life and the index ranks the adequacy of performance in the six functions of bathing, dressing, toileting, transferring, continence, and feeding. In each of the six functions, respondents are given a yes/no score. Full function is indicated by a score of six, moderate impairment by a score of four, and severe impairment by a score of two or less²⁹), suitable time for implementing the program, safety and risk identification, any adverse events, travelling time (minutes), acceptability of the program among participants), and (d) the fidelity of intervention at the level of the participant about the ReStart-S program as assessed on a 4-point Likert scale for the questions "Is the program comfortable?", "Are you comfortable with the outcome measure assessed?", and "Are the exercises included in the program suitable for you?".

Results

The results are presented per the steps for designing the ReStart-S program.

Step 1: A logic model of the problem: A detailed description of the review has been published elsewhere.²⁵ Resistance exercises were included in all studies, with frequency ranging from 1 to 5/week, intensity ranging from 20 to 80% of 1 repetition maximum (RM), or 6–14 points on ratings of perceived exertion (RPE), and duration per session ranging from 20 to 75 min. The intensity of aerobic exercises ranged from 50 to 70% of the estimated heart rate max or at a level of 7-17 in RPE, ranging from 6 to 30 min per session for 2-5 days/week. For balance exercises, the intensity was mentioned as the level of effort 3 on a scale of 10, and the duration per session ranged from 5 to 30 min, with a frequency of 2/3 per week. The results of the systematic review were published.²⁵ The literature search also revealed that many studies have tested multicomponent physical activity programs among frail older adults. A systematic review has reported moderate quality of evidence that exercise among frail community-dwelling older adults improves muscle strength and physical performance.³ Likewise, a study was conducted among frail older adults residing in LTCS, which utilized a high-intensity resistance training program for lower limb muscles. The program was found to be beneficial in counteracting muscle weakness and physical frailty. A structured physical activity program in Lifestyle Interventions and Independence for Elders (LIFE) study was delivered to sedentary community-dwelling older adults. The intervention was multi-modal but focused mainly on improving walking ability, which is considered as primary mode of physical activity. 31 Similarly, Vivifrail, a multi-modal exercise program, has been developed for the prevention of frailty and falls among community-dwelling older adults.³² The identified trials were conducted in the community setting with frail older adults as the study population. These exercise programs lack the concept of co-designing the program with the involvement of stakeholders, which adds to the novelty of the ReStart-S program. To the best of our knowledge, the IM methodology has not been used in previous trials, which makes the study the first to use the IM methodology to design the program. Also, the categorization of the exercise as per the stage of sarcopenia makes the ReStart-S unique to target the sarcopenic older adults residing in LTCS. Older adults residing in LTCS differ from their community-dwelling counterparts.³³ There are notable differences in their cognitive and physical abilities, quality of life, polypharmacy, and medical conditions they may have. 33-36 Hence, the recommendation for the treatment of sarcopenia in LTCS should not be drawn only from the current practice guidelines, which are more appropriate for community-dwelling older adults, necessitating having a program relevant to LTCS. This justifies the development of a ReStart-S program adaptable to sarcopenic older adults residing in LTCS. As a first step towards designing a program, a thorough review of the existing exercise gerontology literature has helped in co-designing the program as per the severity of sarcopenia.

Step 2: Program objectives and expected outcomes: One hundred seventeen (n = 117) residents and thirty-one (n = 31) caregivers were screened in six LTCS. Thirty-nine (n = 39) older adults and twenty-three (n = 23) caregivers were found to be eligible as per the inclusion criteria. Out of the six LTCS, the investigator selected three (n = 3) LTCS depending on the feasibility of conducting the workshop. Among the eligible caregivers, three (n = 3) head caregivers

and/or administrators of the LTCS were purposively chosen for the workshop. The investigator discussed with the head caregiver and/or administrator the suitable older adults who can be included to be part of the workshop. Two (n = 2) older adults each from three LTCS were chosen to take part in the workshop and could provide valuable suggestions and feedback for the ReStart S program. A total of six older adults, two men and four women, and one caretaker participated in the workshop. Due to health reasons, the two caretakers were eventually unable to participate.

All participants lacked knowledge of sarcopenia. For the question related to exercise frequency, there was a variability ranging from 2 to 7 days a week, with the majority (n = 3) of older adults favouring 7 days weekly. All agreed on morning exercise sessions. Tiredness, post-exercise pain, and joint pain were the difficulties complained by participants. Responses were mixed for the questions related to the aspects the therapist should consider while designing the exercise program. Some respondents mentioned any previous fall, surgical history, and hesitancy to engage in a group among the items to consider during program design. The responses of the participants have been summarized in Table 1. Details of the workshop can be found in Supplementary Material 1 and findings of the review and workshop in Supplementary Table 1.

Step 3: Program production: A Delphi process was undertaken for program production. Invitations were extended to seven experts, with subsequent communication rounds being initiated based on their acceptance, rejection, or non-

Table I Summarization of the Responses from the Workshop Conducted to Co-Design a ReStart-S

Question No.	Question Discussed	Participants Response	Theme Generated	Investigator Action
Question I	Do you know anything about the condition of Sarcopenia?	Never heard of the term sarcopenia	Lack of knowledge	The condition was introduced to the participants.
Question 2 What do you think about exercise?		Improvement in strength Improves ability to walk Improves flexibility Ease in carrying out activities Feels active	Appreciate the importance of exercise	Additional benefits of doing exercise were discussed.
Question 3	How many days a week do you like to exercise?	Three (n=3): 7 times/ week One (n=1) each for 2, 3, 5, and 6 times/week	Willingness	The investigator introduced the concept of Frequency (part of the FITT principle)
Question 4	What should be the intensity of the exercise?	Four (n=4): Tailored as per person's fitness level Three (n=3): 5 on a scale of 0 to 10 and stepwise progress	Capacity	Explained about the Intensity (part of the FITT principle) The participants were asked to rate the exercise intensity on a scale of zero (nil) to ten (maximum intensity).
Question 5	How long should the exercise session be in a day?	Four (n=4): 30 minutes/day, 1–3 times/day Two (n=2): start with 30 minutes and progress to 60 minutes	Duration	Participants responses about the time/day of exercise (including different modes and rest periods)
Question 6	What kind of exercises should be there in the training, in your opinion?	Strengthening exercises Aerobic exercises Balance exercises Stretching exercises	Type of exercise	The investigator displayed photographs of a few exercises to the participants to help them understand the question.

Table I (Continued).

Question No.	Question Discussed	Participants Response	Theme Generated	Investigator Action
Question 7	What motivates you to exercise?	Reduce dependency on tablets To be active and feel better Decrease tiredness	Self- determination	The investigator noted the responses
Question 8	What are the challenges/ difficulties you face that prevent you from exercising?	Stones Uneven walkway Pets	Barrier	Discussed solutions/alternatives
Question 9	What are your thoughts on doing exercise in a group?	Group	Positivity	The investigator noted the responses
Question 10	Fun-based physical activity should be included in an exercise program. What is your opinion?	Two (n=2): Throwing a ball Reasoning and mental abilities Two (n=2): Dance Two (n=2): games plus exercise One (n=1): laughing	Exercise is fun; do not consider it a burden	The investigator noted the responses
Question 11	What are the safety concerns while doing exercise?	Two (n=2): Tiredness Three (n=3): joint pain One (n=1): blood pressure fluctuations One (n=1): headaches	Safety concerns	The investigator noted the responses
Question 12	What is the most suitable time to do exercise?	Morning	Preference	The investigator noted the responses
Question 13	What do you think we should keep in mind while designing the exercise program?	Age Surgical history Fear of fall Acute exacerbation of medical condition Fear of group (some inmates show hesitancy to take part in a group)	Thoughts	The investigator noted the responses

response. This process continued until the seven experts had accepted the invitation, resulting in a total of 22 experts being contacted during this course of action. Of them, twelve (n = 12) did not respond, three (n = 3) did not give consent, and seven (n = 7) accepted to participate. The seven experts were from geographically diverse regions of the world (India [n = 2], Sweden [n = 1], Singapore [n = 1], Taiwan [n = 1], Italy [n = 1], and the Netherlands [n = 1]) and represented the following disciplines: public health (n = 1), endocrinology (n = 1), geriatric medicine (n = 3), nutritionist (n = 1), and surgery (n = 1). Across experts, there was expertise in working with older adults clinically as well as in the research, with four (n = 4) experts having an h-index in the range of ten to twenty and the remaining three (n = 3) with an index ranging from forty to seventy. All seven completed round 1 and five completed round 2, round 3, and round 4 (response rate 71%). Those who did not participate in round 2 were not invited for the further rounds. Figure 1 summarizes the results

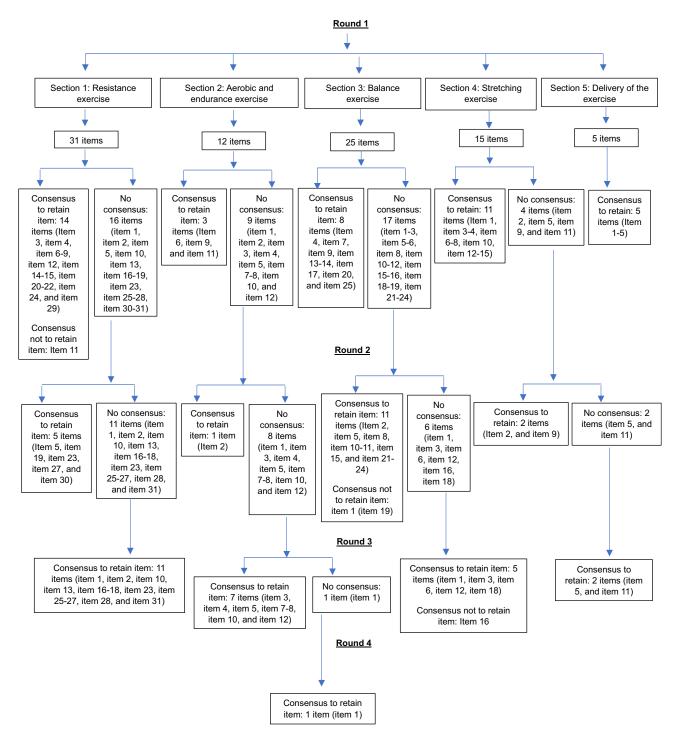


Figure I Flow chart of the Delphi process.

of individual rounds of the Delphi and the flow of items throughout the process. The Delphi was conducted for four rounds, and after each round, a component list was refined according to the responses obtained.

In the first round of the Delphi process, experts reached a consensus to retain 41 items (more than or equal to 85%), while only one item was not recommended for retention (more than or equal to 85%). However, no consensus was reached for the remaining 46 items (less than 85%), which were then carried forward to the second round. During the first round, experts agreed that exercises for older adults should be tailored to their fitness level and performed under

supervision in a group setting. Verbal motivation was also identified as an important factor in maintaining engagement, and enjoyable activities were recommended to improve adherence. The military press exercise was the only type of exercise that reached a consensus not to be included. The items included in the component list and details of the report of the Delphi round first can be found in <u>Supplementary Table 2</u>.

In the second round of the process, 18 items were recommended for retention (more than or equal to 80%), and only one item was recommended not to be retained (more than or equal to 80%). However, the experts did not reach a consensus on 27 items (less than 80%), which were then carried forward to the third round. During the second round, the complex cross-over stepping activity in the balance section was the only item that reached a consensus not to be included. The items included in the component list and details of the report of the Delphi round second can be found in Supplementary Table 3.

In the third round, only one item did not reach a consensus (less than 60%) and was carried forward to the fourth round. The item under the section on balance exercises that discussed the use of the vibration platform also reached a consensus not to retain (more than or equal to 60%). The items included in the component list and details of the report of the Delphi round third can be found in <u>Supplementary Table 4</u>. After the experts reached a consensus to retain one item in the fourth round (more than or equal to 60%), the Delphi process was concluded.

Step 4: Evaluation: All the residents of the two LTCS, which were twenty-four (n = 24) were screened for eligibility based on a priory decided inclusion criteria and exclusion criteria mentioned in the methods section. After screening, eight (n = 8) participants were found to be eligible and were included (two males and six females). Reasons for exclusion were as follows: wheelchair-bound (n = 2), hemiparesis due to a stroke (n = 2), refusal to participate (n = 3), acute exacerbation of cardiorespiratory disorder (n = 3), mini-cog score <3 (n = 3), bed bound (n = 1), and absence of sarcopenia (n = 2). The mean age of participants was 78.3 ± 8.3 years (males: 71.0 ± 14.1 , females: 80.7 ± 5.4). None of the participants had a history of alcohol abuse, smoking, or fracture in the previous two years. All participants were right-handed and regularly engaged in physical activity. Commonly reported physical activity by participants was light walking and general active movements for 30 minutes daily. The demographic characteristics of participants are presented in Table 2 and the flowchart of participants in Figure 2.

The eligible participants were categorized and made to sit in the group as per their sarcopenic status, with one (n = 1) possible sarcopenic, three (n = 3) sarcopenic, and four (n = 4) severe sarcopenic. The ReStart-S was delivered for four sessions (two times per week) for two weeks. The exercises were delivered and tailored as per the participant's capacity

Table 2 Demographic, Clinical, and Performance Characteristics of the Participants (n = 8)

Domain	Values
Age (Years)	78.25 ± 8.35
Gender	Male= 2 (25%) Female= 6 (75%)
Weight (Kg)	55.44 ± 10.31
Body mass index (Kg/m²)	23.81 ± 4.12
Education level	Primary level= 5 (62.5%) Secondary level= 1 (12.5) Higher level= 2 (25%)
Hand dominance	Right= 8 (100%), Left= 0
Years of stay	Less than one year= 2 (25%) Two to three years= 1 (12.5%) More than three years= 5 (62.5%)
Marital status	Married= 3 (37.5%) Widow= 5 (62.5%)

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Table 2 (Continued).

Domain	Values
Family visits	Yes= 6 (75%) No= 2 (25%)
Frequency of visits (in a year)	1.63 ± 1.41
History of falls (in the last two years)	Yes= 2 No= 6
History of hospitalization (in the last two years)	Yes= I No= 7
History of comorbidities (in the last two years)	Yes= 6 No= 2
Comorbidities (in the last two years)	Hypertension= 5 (62.5%) Diabetes and hypertension= 2 (25%) Hypertriglyceridemia= 1 (12.5%)
History of medication (in the last two years)	Antihypertensive drugs= 2 (25%) Diabetic drugs= 1 (12.5) Sedatives= 1 (12.5%) Antihypertensive and diabetes drugs= 2 (25%) No medication= 2 (25%)
Sarcopenia status	Possible sarcopenia= 1 (12.5%) Sarcopenia= 3 (37.5%) Severe sarcopenia= 4 (50%)
Skeletal muscle index (Kg/m²) Males Females	5.22 ± 1.09 6.18 ± 0.47 4.89 ± 1.05
Hand Grip Strength (Kg) Males Females	17.10 ± 7.23 27.95 ± 5.58 13.48 ± 2.04
Short physical performance battery score Males Females	8.38 ± 2.13 10.50 ± 2.12 7.66 ± 1.75
Katz index	6.00 ± 0.00

under the supervision of a physiotherapist. The intensity of the exercise was low-moderate (6–8 RPE) with 1–2 sets of 5–7 reps/set with the type of exercises performed varied as per the sarcopenic status. After the completion of the two-week programs, feasibility outcomes were assessed. Eight out of twenty-four participants screened were eligible with a ratio of eligible to non-eligible of 1:3. All the eligible participants expressed their willingness to participate in the program.

Fidelity of intervention at the level of the therapist: The therapist was able to prescribe the exercises tailored to the participant's capacity in accordance with the protocol. It took 7–10 minutes to explain the procedure to each participant. The evaluation of outcome measures was not particularly challenging but did require a significant amount of time. Each participant's assessment took approximately 20–25 minutes, with the majority of the time being spent on completing the questionnaire. After analyzing the data related to the ADL it was observed that the Katz index of ADL exhibited a ceiling and floor effect. Delivery of the program in the morning was deemed appropriate. Participant safety was assessed in terms of the number and severity of adverse events attributable to the intervention that occurred during the study. The

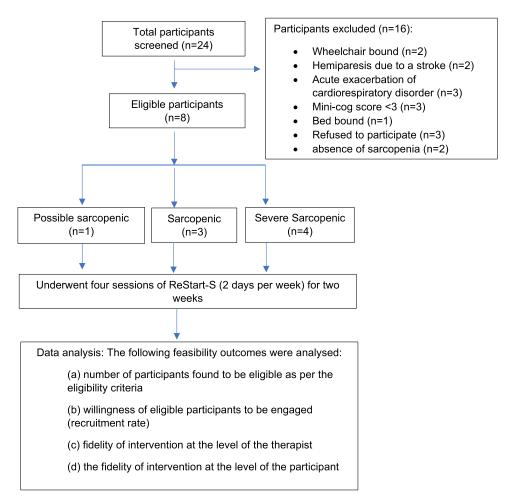


Figure 2 Flowchart of the participant in the pilot study (step 4) to test ReStart-S feasibility among sarcopenic older adults residing in LTCS.

therapist did not identify any safety/risk and/or no adverse events associated with the program; however, the supervised delivery of the program was perceived as important. The travel time to reach the LTCS was on average 40–45 minutes. All participants completed the four sessions of the ReStart-S program, which was found to be highly acceptable.

Fidelity of intervention at the level of participants: The participants rated their satisfaction with the ReStart-S on the 4-point Likert scale. All participants were very comfortable with the ReStart-S. Seven participants reported that they were "very comfortable" with the outcome measures assessed, while one reported to be "comfortable". All participants reported that the exercise included in the ReStart-S was overall very much suitable.

Detailed information on the program can be found in Tables 3-5.

Discussion

The study was conducted to co-design an exercise-based multicomponent reablement program, which we named ReStart-S. The development of the ReStart-S was carried out methodically and systematically.

The four steps of IM were chosen to develop the program. Among the existing methods to design a multi-component intervention, the IM was selected as it provides a systematic and step-by-step decision-making framework. As part of the first step of the need assessment, we conducted a literature review to identify existing exercises used for the management of sarcopenia in older adults. With this background, in the second step, a workshop was conducted with older adults and caregivers to discuss the objectives of the exercise-based reablement program. The evidence supports such an approach as the involvement of key stakeholders or patients in the planning process that enables the development of more successful interventions.

Table 3 Proposed ReStart-S Program for Severe Sarcopenics

Week Wise Progression	Frequency/ Week	Intensity	Volume & Progression	Duration (min)/Session	Exercises
Resistance exer	cise components	of the ReStart-S pro	ogram for severe sarcopenics		
Ist week	2/week	Low-moderate (6–8 RPE)	I set with 5–7 repetitions/set	10 min	Dynamic quads, ball squeeze, sitting heel raise, biceps curls using thera band
2nd week	2/week	Low-moderate (6–8 RPE)	2 sets with 5–7 repetitions/set	10 min	Ist week + biceps curls with dumbbells, dynamic quads with sandbag
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	2 sets with 8–10 repetitions/set	20 min	2nd week
4th week	2/week	Moderate- somewhat high (9–10 RPE)	3 sets with 8–10 repetitions/set	20 min	3rd week + sitting hip abductor using thera band, shoulder flexion with dumbbells
5th week	2/week	Somewhat high- high (11–12 RPE)	3 sets with 10–12 repetitions/set	30 min	4th week + sitting knee raises, horizontal shoulder abduction using thera band
6th week	2/week	Somewhat high- high (11–12 RPE)	3 sets with 12–15 repetitions/set	30 min	5th week
Aerobic & endu	ırance exercise c	omponents of the R	eStart-S program for severe sarcopenics		
Ist week	2/week	Low-moderate (6–8 RPE)	30 sec self-paced walking 2–4 times	I–2 min	Self-paced walking
2nd week	2/week	Low-moderate (6–8 RPE)	50 sec self-paced walking 2–4 times	3–4 min	Week I
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	50 sec self-paced walking 5–6 times	4–5 min	Week 2
4th week	2/week	Moderate- somewhat high (9–10 RPE)	60 sec self-paced walking 7-8 times and 5 repetitive stepping in anterior direction 10 sec 2 times	6–12 min	Week 3 + anterior/ lateral/posterior stepping
5th week	2/week	Somewhat high- high (11–12 RPE)	70 sec self-paced walking 9–10 times and repetitive stepping anterior + lateral 10 sec 2 times for each direction	11–15 min	Week 4
6th week	2/week	Somewhat high- high (11–12 RPE)	80 sec self-paced walking 11–12 times and repetitive stepping 15 sec 2 times for each direction	16–20 min	Week 5

Table 3 (Continued).

Week Wise Progression	Frequency/ Week	Intensity	Volume & Progression	Duration (min)/Session	Exercises
Balance exercise	e components of	the ReStart-S progr	ram for severe sarcopenics	•	
Ist week	2/week	Low-moderate (6–8 RPE)	Stand in the position for 20 sec and repeat it 3 times	Imin/session	Broad base standing
2nd week	2/week	Low-moderate (6–8 RPE)	Stand with feet together with the support of one finger 10 sec and repeat it for 6 times, followed by without support 5 sec and repeat it for 3 times	2–3 min	Ist week + feet together
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	Week 2	3–4 min	2nd week
4th week	2/week	Moderate- somewhat high (9–10 RPE)	Stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds, 2 times	4–6 min	3rd week + semi tandem
5th week	2/week	Somewhat high- high (11–12 RPE)	Stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds, 2 times	68 min	4th week + tandem
6th week	2/week	Somewhat high- high (11–12 RPE)	Week 5	6–8 min	5th week
Stretching exerc	cise components	of the ReStart-S pro	ogram for severe sarcopenics		
Ist week	2/week	Low-moderate (6–8 RPE)	I set, repeat 2 times, I0–I2 sec hold	I min	Wrist flexor/extensor stretch, sitting plantar/ dorsi flexors stretch
2nd week	2/week	Low-moderate (6–8 RPE)	I set, repeat 2 times, I3–I5 sec	I–2 min	Ist week + neck extensor stretch
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	2 set, repeat 2 times, 13-15 sec	2–3 min	2nd week + sitting lateral stretch of the trunk musculature
4th week	2/week	Moderate- somewhat high (9–10 RPE)	Week 3	3–4 min	3rd week + neck rotators stretch
5th week	2/week	Somewhat high- high (11–12 RPE)	2 set, repeat 3 times, 13–15 sec	4–5 min	4th week + biceps and triceps stretch
6th week	2/week	Somewhat high- high (11–12 RPE)	3 set, repeat 3 times, 13–15 sec	5–6 min	5th week + shoulder abductor stretches, neck lateral flexor stretch

The IM approach involves circling back to the previous steps throughout the process, which allows for re-designing and addressing all the objectives.³⁸ The literature review of step one, followed by the older adults and caregivers' involvement in the second step, allowed us to proceed with the third step of program production. The Delphi process was considered for program production. The Delphi method is a systematic approach to achieving consensus among experts through the

Table 4 Proposed ReStart-S Program for Sarcopenics

Week Wise Progression	Frequency/ Week	Intensity	Volume & Progression	Duration (min)/Session	Exercises
Resistance exer	cise components	of the ReStart-S pr	ogram for sarcopenics		
Ist week	2/week	Low-moderate (6–8 RPE)	I set with 5–7 repetitions/set	10 min	Standing shoulder abduction with the dumbbell, sitting chest press, sitting abdominal crunch, standing back extension
2nd week	2/week	Low-moderate (6–8 RPE)	2 sets with 5–7 repetitions/set	10 min	Ist week+ Standing hip abduction with support, standing flexion/extension
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	2 sets with 8–10 repetitions/set	20 min	2nd week + hip abduction with sandbags, triceps extension and seated row
4th week	2/week	Moderate- somewhat high (9–10 RPE)	3 sets with 8–10 repetitions/set	20 min	3rd week + standing knee bend (hamstring) with support, heel raise with the support
5th week	2/week	Somewhat high- high (11–12 RPE)	3 sets with 10–12 repetitions/set	30 min	4th week + squatting with support, knee bend with support with a sandbag, sit to stand
6th week	2/week	Somewhat high- high (11–12 RPE)	3 sets with 12–15 repetitions/set	30 min	5th week + wall pushups, standing knee raise
Aerobic & endu	ırance exercise c	omponents of the R	eStart-S program for s	arcopenics	
Ist week	2/week	Low-moderate (6–8 RPE)	5 sec steps marching 2–3 times	I-4 min	Step marching with support
2nd week	2/week	Low-moderate (6–8 RPE)	10 sec steps marching 2-3 times	5–7 min	Week I
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	10 sec steps marching 4–5 times	8–10 min	Week 2
4th week	2/week	Moderate- somewhat high (9–10 RPE)	20 sec I–2 times	11–13 min	3rd Week + stationary cycling
5th week	2/week	Somewhat high- high (11–12 RPE)	20 sec 2–3 times	14–16 min	Week 4
6th week	2/week	Somewhat high- high (11–12 RPE)	30 sec 3–4 times	16–20 min	Week 5
Balance exercise	e components of	the ReStart-S progr	am for sarcopenics		
Ist week	2/week	Low-moderate (6–8 RPE)	Hold position for 10 sec, 6 times	I min	Heel raise with support, toe raise with support, single leg standing with support
2nd week	2/week	Low-moderate (6–8 RPE)	Hold position for 10 sec, 3 times each exercise	2–3 min	Ist week + heel raise/toe raise without support, standing on foam
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	Hold and walk 10 sec, 3 times each exercise	4–6 min	2nd week+ standing reach out, heel walking with support, tandem walk with support forward/ backwards

Table 4 (Continued).

Week Wise Progression	Frequency/ Week	Intensity	Volume & Progression	Duration (min)/Session	Exercises
4th week	2/week	Moderate- somewhat high (9–10 RPE)	Walk for 10 sec, 4 times each exercise	7–8 min	3rd week + figure of 8 walk, heel walk without support
5th week	2/week	Somewhat high- high (11–12 RPE)	Walking and clearing hurdles	8–10 min	4th week + tow walking with support, obstacle clearance
6th week	2/week	Somewhat high- high (11–12 RPE)	Toe walks and climbing stairs	10–13 min	5th week + toe walk without support, stair climbing
Stretching exerc	ise components	of the ReStart-S pro	ogram for sarcopenics		
1st week	2/week	Low-moderate (6–8 RPE)	I set, repeat 2 times, 10–12 sec hold	I min	Sitting arm stretch
2nd week	2/week	Low-moderate (6–8 RPE)	I set, repeat 2 times, I3–I5 sec	I–2 min	1st week + standing lateral muscles of trunk stretch
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	2 set, repeat 2 times, 13–15 sec	2–3 min	2nd week
4th week	2/week	Moderate- somewhat high (9–10 RPE)	Week 3	3–4 min	3rd week + sitting trunk rotator stretch
5th week	2/week	Somewhat high- high (11–12 RPE)	2 set, repeat 3 times, 13–15 sec	4–5 min	4th week + sit to reach
6th week	2/week	Somewhat high- high (11–12 RPE)	3 set, repeat 3 times, 13–15 sec	5–6 min	5th week + standing Achilles stretch with support

Table 5 Proposed ReStart-S Program for Possible Sarcopenics

Week wise progression	Frequency/ Week	Intensity	Volume & Progression	Duration (min)/Session	Exercises
Resistance exerc	cise components o	of ReStart-S program	for possible sarcopenics		
Ist week	2/week	Low-moderate (6–8 RPE)	I set with 5–7 repetitions/set	10 min	Lunges with support, standing pelvic tilt
2nd week	2/week	Low-moderate (6–8 RPE)	2 sets with 5–7 repetitions/set	10 min	1st week + sitting leg press
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	2 sets with 8–10 repetitions/set	20 min	2nd week + double arm pulls down
4th week	2/week	Moderate- somewhat high (9–10 RPE)	3 sets with 8–10 repetitions/set	20 min	3rd week + forward bend row

Table 5 (Continued).

Week wise progression	Frequency/ Week	Intensity	Volume & Progression	Duration (min)/Session	Exercises
5th week	2/week	Somewhat high- high (11–12 RPE)	3 sets with 10–12 repetitions/set	30 min	4th week + latissimus dorsi pull- down
6th week	2/week	Somewhat high- high (11–12 RPE)	3 sets with 12–15 repetitions/set	30 min	5th week + supine chest press
Aerobic & endur	ance exercise cor	nponents of ReStart-	S program for possible sarcopenics		
1st week	2/week	Low-moderate (6–8 RPE)	5 sec steps marching 2–3 times	I–4 min	Step marching without support
2nd week	2/week	Low-moderate (6–8 RPE)	10 sec steps 2–3 times	5–8 min	Week I
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	10 sec slow running 1–2 times	9–11 min	Week 2 + slow running
4th week	2/week	Moderate- somewhat high (9–10 RPE)	10 sec slow running 2–3 times	II-I4 min	Week 3
5th week	2/week	Somewhat high- high (11–12 RPE)	One time each in forward and sideward	14–17 min	Week 4 + agility ladder
6th week	2/week	Somewhat high- high (11–12 RPE)	2 times each in a forward and sideward direction	18–20 min	Week 5
Balance exercise	components of R	eStart-S program for	possible sarcopenics		
Ist week	2/week	Low-moderate (6–8 RPE)	Object clearance 2 set, 10 times/	I–2 min	Crossing obstacle
2nd week	2/week	Low-moderate (6–8 RPE)	10 sec walks with backward counting	2–3 min	Ist week + cognitive task while walking
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	10 sec walks, 2 times, manual task with walk	4–6 min	2nd week + manual task while walking
4th week	2/week	Moderate- somewhat high (9–10 RPE)	Forward walk on ramp, 5 sec, 2 times	6–8 min	3rd week + upward ram walking
5th week	2/week	Somewhat high- high (11–12 RPE)	Backward walk on the ramp, 5 sec, 2 times	8–10 min	4th week + downward ramp walking
6th week	2/week	Somewhat high- high (11–12 RPE)	2 times front, sideways	8–10 min	5th week + quick direction change exercise
Stretching exerc	ise components o	f ReStart-S program f	or possible sarcopenics		
1st week	2/week	Low-moderate (6–8 RPE)	I set, repeat 2 times, I0–I2 sec hold	l min	Standing trunk rotator stretch
2nd week	2/week	Low-moderate (6–8 RPE)	I set, repeat 2 times, 13–15 sec	I–2 min	1st week

Table 5 (Continued).

Week wise progression	Frequency/ Week	Intensity	Volume & Progression	Duration (min)/Session	Exercises
3rd week	2/week	Moderate- somewhat high (9–10 RPE)	2 set, repeat 2 times, 13–15 sec	2–3 min	2nd week + seated Achilles stretch using a towel
4th week	2/week	Moderate- somewhat high (9–10 RPE)	Week 3	3–4 min	3rd week + pectoral muscle wall stretches
5th week	2/week	Somewhat high- high (11–12 RPE)	2 set, repeat 3 times, 13–15 sec	4–5 min	4th week + With support quadriceps stretch
6th week	2/week	Somewhat high- high (11–12 RPE)	3 set, repeat 3 times, 13–15 sec	5–6 min	5th week

independent completion of sequential questionnaires that are refined based on feedback, resulting in a convergence of opinion and eventual consensus.³⁹ Independent and anonymous participation, controlled feedback between rounds, and removal of geographical limitations make the Delphi method a better option to choose over other consensus techniques.^{39,40} Four rounds of the Delphi process resulted in the consensus for the items to be included in the ReStart-S.

We circled back to the results of all the previous steps and the ReStart-S development was completed, followed by step four of the program, which is evaluation to test its feasibility. The feasibility study is an important step to be conducted before proceeding with a larger trial to test the effectiveness of the designed program. In the feasibility study, floor and ceiling effects were found for the Katz index of ADL, which limits the instrument's responsiveness and suggests its removal from the list of outcome measures in a future full-scale trial. The majority of participants reported enjoying the program and appreciated its novelty in being personalized according to the participant's capacity, ease of performing, and the use of a variety of exercise equipment. Participants also appreciated the well-planned progression of exercises. These results indicate that a larger-scale trial may be designed.

Strength and limitations: The major strength of the present study resides in its systematic approach to designing the ReStart-S. The program's adaptability to LTCS settings and the co-designing process that involved stakeholders added a novel dimension to the study. However, the research has some limitations that warrant attention. Specifically, the intervention mapping theory-based change step was not incorporated, given that the study aimed to investigate factors other than behavioural change. Additionally, the ReStart-S was pilot-tested in a small sample of the population, which calls for further scrutiny. Feedback of older adults who do not perform exercises has not been included, which could be considered in any future co-designing study. Furthermore, the participation of a limited number of experts adds to the limitation. While the intervention lasted for two weeks, which could be seen as a limitation, it should be noted that the primary objective of the intervention was not to elicit any change in the outcome measures, but rather to ascertain the feasibility of the program. A larger trial is planned to be conducted to evaluate the effectiveness of the ReStart-S program among older adults in LTCS.

Conclusion

The newly developed ReStart-S to manage sarcopenia among older adults residing in LTCS incorporated evidence from the literature and the engagement of older adults, caregivers, and experts, making it a contextually appropriate intervention. This study also provides researchers and geriatric healthcare professionals insights into co-designing a program. The program evaluation through an ad hoc designed feasibility study provided evidence to support the design of a full-scale clinical trial.

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Data Sharing Statement

The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request.

Ethical Approval and Informed Consent

This study was conducted in line with the principles of the Declaration of Helsinki. Approval was granted by the Kasturba Medical College and Kasturba Hospital Institutional Ethic Committee (IEC1: 100/2022). All participants gave their written informed consent before enrolment.

Clinical Trial Registration

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

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