Self-management strategies and multicomponent training to mitigate the effects of the physical exercise programs interruption in the pandemic context on functionality, sedentary behavior, physical capacity, mental health, body composition and quality of life in older adults: a blinded randomized controlled study protocol

Ana Farche (anaclaudiafarche@gmail.com)
Universidade Federal de São Carlos: Universidade Federal de Sao Carlos

Gabriela Cassemiliano
Universidade Federal de São Carlos: Universidade Federal de Sao Carlos

Paulo Giusti Rossi
Universidade Federal de São Carlos: Universidade Federal de Sao Carlos

Bianca Ferdin Carnavale
Universidade Federal de São Carlos: Universidade Federal de Sao Carlos

Stefany Lee
Universidade Federal de Sao Carlos

Laura Bonome Message
Universidade Federal de São Carlos: Universidade Federal de Sao Carlos

Vinicius Ramon da Silva Santos
Universidade Federal de São Carlos: Universidade Federal de Sao Carlos

Juliana Hotta Ansai
Universidade Federal de São Carlos: Universidade Federal de Sao Carlos

Natália Duarte Pereira
Universidade Federal de São Carlos: Universidade Federal de Sao Carlos

Eduardo Ferriolli
Universidade de São Paulo: Universidade de Sao Paulo

Miriam Elisa Guerra-Balic
Universitat Ramon Llull

Guillermo Ruben Oviedo
Universitat Ramon Llull
Title

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Names protocol contributors

Ana Claudia Silva Farche¹, Gabriela Cassemiliano¹, Paulo Giusti Rossi¹, Bianca Ferdin Carnavale¹, Stefany Lee¹, Laura Bonome Message¹, Vinícius Ramon da Silva Santos¹ Juliana Hotta Ansai², Eduardo Ferriolli³, Natália Duarte Pereira¹, Guillermo Rúben Oviedo4, Myriam Guerra-Balic4, Maria Giné-Garriga4, Marina Araújo Lopes5 and Anielle Cristhine de Medeiros Takahashi¹.

1. Department of Physical Therapy, Federal University of São Carlos, São Carlos, Brazil
2. Department of Gerontology, Federal University of São Carlos, São Carlos, Brazil
3. Faculty of Medicine of Ribeirão Preto, University of São Paulo, Ribeirão Preto, São Carlos, Brazil
4. School of Psychology, Education and Sport Sciences, Ramon Llull University, Barcelona, Spain
5. Faculty of Pharmacy and Food Science, University of Barcelona, Barcelona, Spain

Abstract

- **Background**: Considering the confinement recommended by the World Health Organization due to the pandemic caused by COVID-19, community physical exercise programs for older adults had their activities cancelled. In this context, proposing strategies to recover possible adverse effects of confinement period are pertinent. The use of self-management strategies associated with regular physical activity reduces the sedentary behavior and improves the physical capacity in older adults. Thus, the purpose of this study was to describe a multicomponent training program combined with self-management strategies protocol to mitigate the effects of the physical exercise programs interruption on functionality, physical capacity, mental health, body composition and quality of life in older adults.

- **Methods**: This will be a blinded, randomized and controlled clinical trial. Eighty older adults will be divided into two groups: multicomponent training(Multi) and multicomponent training+ self-management strategies(Multi+SM). The intervention will be performed in 16-weeks, on three alternate days of every week, with 50-min sessions. The assessment of physical capacity will be performed before the physical
exercise programs interruption (T0- initial assessment-March/2020), pre-intervention (T1- immediately after the exercise program return) and post intervention (T2). The assessments of physical activity level, quality of life, mental health, functionality and body composition will be performed in T1 and T2.

- **Discussion:** The results from this MC+SM protocol will allow to contribute with clinical support to evaluate the variables analyzed, and to guide future public health policies, aiming at minimizing the possible deleterious effects arising from the physical exercise interruption periods caused by epidemics and pandemics

- **Trial registration:** Prospectively registered.
- **Registry Name:** Use of self-management strategies combined with multicomponent training to mitigate the effects of social distance from COVID-19 on capacity, physical capacity, mental health and quality of life in the older adults - A blind, randomized and controlled clinical trial.

  - Registration Number: RBR-10zs97gk
  - Date of Registration: 17Jun2021
  - URL: https://ensaiosclinicos.gov.br/rg/RBR-10zs97gk

### Keywords

*Covid-19; confinement; older adults; multicomponent exercise; self-management.*

### Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see [http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/](http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/)).

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| Author details (5a) | Ana Claudia Silva Farche¹, Gabriela CasSEMILIANO¹, Paulo Giusti Rossi¹, Bianca Ferdin Carnavale¹, Stefany Lee¹, Laura Bonome Message¹, Vinicius Ramon da Silva Santos¹ Juliana Hotta Ansai², Eduardo Ferrioli³, Natália Duarte Pereira¹, Guillermo Rúben Oviedo4, Myriam Guerra-Balic4, Maria Giné-Garriga4, Marina Araújo Lopes5 and Anielle Cristhine de Medeiros Takahashi¹.  
1. Department of Physical Therapy, Federal University of São Carlos, São Carlos, Brazil  
2. Department of Gerontology, Federal University of São Carlos, São Carlos, Brazil  
3. Faculty of Medicine of Ribeirão Preto, University of São Paulo, Ribeirão Preto, São Carlos, Brazil  
4. School of Psychology, Education and Sport Sciences, Ramon Llull University, Barcelona, Spain  
5. Faculty of Pharmacy and Food Science, University of Barcelona, Barcelona, Spain |
| Name and contact information for the trial sponsor (5b) | Ana Claudia Silva Farche, PhD.  
Department of Physical Therapy, UFSCar – Federal University of São Carlos, R. Washington Luiz, km 235, Zip Code: 13565-905, São Carlos, SP, Brazil.  
Email: anaclaudiafarche@gmail.com |
| Role of sponsor (5c) | Each author and co-authors met all four criteria:  
1) Substantial contributions to the conception or design of the work, or acquisition, analysis or interpretation of data for the work;  
2) Drafting the work or revising it critically for important intellectual content;  
3) Final approval of the version to be published; |
4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Introduction

Background and rationale {6a}

The Covid-19 pandemic is a health crisis, that forced the world’s population to live in confinement for several months in an attempt to delay transmission, avoid rapid advances of the disease, and minimize the collapse of intensive care units in hospitals. Social restriction recommendations may be a health challenge for the population, due the confinement can reduce physical activity levels, which has important impacts on muscle, cardiovascular, metabolic, endocrine and nervous systems. Among the populations most affected by these restriction measures, the older adults stand out. During aging, there are numerous physiological changes, and the consequent reduction in physical performance as well as in the individual’s ability to maintain homeostasis. Thus, the older adults are considered more vulnerable when compared to other confined groups for the onset or worsening of sarcopenia, frailty and cardiometabolic diseases, possibly leading to increased morbidity and mortality of this population. In addition, individuals who present chronic comorbidities also have a greater predisposition to aggravate the disease which affects the most part of population over 60. Although confinement is an effective measure and must be strictly followed, the literature shows negative outcomes for older adults, especially on physical capacity and mental health. The lack of social contact is related to a greater risk of depression and anxiety, especially during a pandemic situation, as many older adults experience insecurities, increased concern for family members, and grieving processes. In addition to psychological symptoms, these measures may lead to a decline in functionality, physical capacity and consequent markers of inactivity, such as cardiovascular, respiratory, neurocognitive, musculoskeletal problems, and increased dependence and risk of falls. Schrempf et al. (2019) observed that social isolation for older adults is related to a low physical activity level and longer time in sedentary behavior. Therefore, the authors suggest that physical inactivity could contribute to the increase of risk factors related to social isolation.

In this context, due to the pandemic scenario, the physical exercise programs for groups had to be discontinued, and the older population was very affected. While confinement of older adults is important to minimize the pandemic situation, measures for immediate recovery after returning to ...
activities and the implementation of preventive strategies for further damage are needed. Thus, regular physical exercise for older adults, especially of a multicomponent (resistance, aerobic, flexibility and balance), is related to benefits and preservation of physical, functional and cognitive capacity; and reduction of anxiety, risk of depression and falls. Besides, the multicomponent training increases expectation of living independently and improves quality of life. However, despite a regular practice of moderate-vigorous exercises, the time spent in sitting or lying position that generates energy expenditure \( \leq 1.5 \text{ MET} \) can reduce the functional independence and increase the mortality.

Besides that, self-management (SM) policies have been prominence on literature. Previous authors have shown SM strategies in which individuals empower themselves with self-care, while professionals instruct patients to take care of their own health, encouraging the development of their autonomy. These SM programs are described as a primary mechanism for effective chronic disease management. These programs aim to establish goals for the patients, record their progress and plan their activities. All work is recorded and maintained with the patient, facilitating the personal record of goals, progress and strategies used. Among the themes addressed by SM strategies, there is the focus for reducing sedentary behavior, which may have been aggravated due to social distancing caused by the COVID-19 pandemic. In this context, considering a possible decrease on physical capacity, mental health, physical activity levels and functionality, the association of SM strategies with multicomponent exercises can be a good strategy to mitigate the negative outcomes of social distance period for older adults.

**Objectives**

The present study protocol aims to describe the design and methods of the proposed intervention based on SM strategies and multicomponent training for older population.

**Trial design**

This study is a blinded randomized controlled trial, approved by the research ethics committee of the institution (ID: xxxxxxx/2020), and registered in a Clinical Trial Registration Platform (REBEC ID: xxxxxxx). This protocol follows the standardized guidelines proposed by the Consolidated Standards of Reporting Trials (CONSORT) and SPIRIT. The assessments will be performed at three stages: pre-physical exercise programs interruption (T0- initial assessment performed in March 2020), pre-intervention (T1- immediately after the physical exercise programs return) and post intervention (T2- immediately after the intervention protocol) (Figure 1).
After the physical exercise program interruption period, the participants will be randomized to one of the two study arms by an independent researcher using the Random Allocation Software. According to the sequence generated by randomization, each participant will correspond to a sealed and opaque envelope, and then, will be allocated in two groups: a) Multicomponent Training group (Multi); b) Multicomponent Training + SM group (Multi+SM).

**Methods: Participants, interventions and outcomes**

**Study setting** {9}
Eighty participants were recruited and tested before the lockdown. As all the community programs were cancelled, no one was able to follow these programs. After the quarantine finishes, a systematic exercise program will be offered to all of them, after signing an informed consent. Later, all of them will be randomized and allocated in two groups by an independent researcher using the Random Allocation Software (version 2.0, Albuquerque, United States). One group will follow a multicomponent exercise program and the other will follow a Multi plus the self-management (SM) intervention.

The sample size calculation was carried out through the G*Power (version 3.1.3, Kiel, Alemanha), and suggested that a sample containing 38 participants would carry a power of 80%, with an effect size of 0.25 and alpha of 0.05.

**Eligibility criteria** {10}
Inclusion criteria are: participants aged $\geq 60$ years old, who were enrolled in the physical exercise program “Geriatric Revitalization”, coordinated by the Institution, previous to the pandemic interruption. They have agreed to participate. Exclusion criteria include: indication of cognitive deficit, which will be assessed by Mini-Mental State Examination (MMSE) scores $<18$, and physical limitations that make it impossible to participate in any of proposed assessment tests and physical activity programs.

The assessments will be blinded to the allocation of the participants to all researchers. The two intervention groups will start the protocol activities after the physical exercise programs return to be opened. If the intervention program is effective for the Multi+SM group, the Multi group will also be invited to participate of SM strategies.

**Who will take informed consent?** {26a}
The study procedures will be presented individually to participants by an investigator and all doubts will be
clarified. After that, the Informed Consent Form will be signed voluntarily by both parties.

Additional consent provisions for collection and use of participant data and biological specimens {26b}
N/A no biological specimens were collected as part of this trial

Interventions

Explanation for the choice of comparators {6b}
N/A

Intervention description {11a}
When the physical exercise programs return to be set up, both groups will be invited to a meeting, and they will receive information about sedentary behavior. At the end of the meeting, an informative material with these topics will be offered.

The Multicomponent Training will be performed both by the Multi and Multi+SM groups. The design of the program follows the American College of Sports Medicine (ACSM) recommendations and considers the previous physical exercise program, combining muscular strengthening, flexibility and balance exercises ⁶. A 16-week training protocol will be performed on three alternate days of every week, with 50-min sessions (Table 1). During the sessions, all participants will use a heart rate monitor (Polar® H10) in order to monitor HR values and so, the exercises intensity.

Self-Management Strategies
The self-management techniques to minimize the sedentary behavior will be performed by a single researcher, based on “self-management strategies (SMS)” protocol of the SITLESS multicenter study ¹⁶.

Initially, the responsible researcher will perform a remote meeting (familiarization stage) with each participant of Multi+SM group. The main objectives of this meeting will be to introduce the SM protocol and establish a researcher-participant relationship. Participants and researcher will establish together the functional goals for the participant to be more active every day, especially on days when multicomponent exercises are not developed. These goals will be based on ACSM 2021 guidelines for walking or similar aerobic activities ²⁵, for 150 minutes a week. Participants will receive an activity diary to record daily activities and goals achieved.

Besides, the Multi+SM group will also receive a pedometer (Decathlon OnWalk 500 Geonaute, France) for use during the self-management intervention, in order to count data steps, and motivate and encourage the participants. For this, the researcher will provide an information material with instructions for use ¹⁶.

After initial contact, the SM protocol will be follow up weekly by a telephone contact, with calls lasting up to 20 minutes. The objective of these contacts is to question the participants regarding the daily activities performed, the number of steps achieved in each activity, and to encourage the reduction of sedentary behavior. The SM protocol will be added concomitantly with the Multi-protocol for 16 weeks.
Criteria for discontinuing or modifying allocated interventions {11b}
N/A

Strategies to improve adherence to interventions {11c}
Regular telephone calls will be performed by a physiotherapist with the participants to reinforced the importance of this program.

Relevant concomitant care permitted or prohibited during the trial {11d}
N/A

Provisions for post-trial care {30}
At the end of the intervention, in case of positive results, both groups will be invited to participate in a program of SMS

Outcomes {12}
The outcomes are described in Table 2.

Participant timeline {13}
The study procedures will be performed at three stages: pre-physical exercise programs interruption (T0- initial assessment performed in March 2020), pre-intervention (T1- immediately after the physical exercise programs return) and post intervention (T2- immediately after the intervention protocol) (Figure 1).

Sample size {14}
The sample size calculation was carried out through the G*Power (version 3.1.3, Kiel, Alemanha), and suggested that a sample containing 38 participants would carry a power of 80%, with an effect size of 0.25 and alpha of 0.05.

Recruitment {15}
Participants will be recruited from a public and regular physical activity program for older adults

Assignment of interventions: allocation

Sequence generation {16a}
All participants will be randomized and allocated in two groups by an independent researcher using the Random Allocation Software (version 2.0, Albuquerque, United States). One group will follow a multicomponent exercise program and the other will follow a Multi plus the self-management (SM) intervention.
Concealment mechanism {16b}
N/A

Implementation {16c}
N/A

Assignment of interventions: Blinding

Who will be blinded {17a}
The professionals responsible for assessing all outcomes and data analysts will be blinded

Procedure for unblinding if needed {17b}
N/A

Data collection and management

Plans for assessment and collection of outcomes {18a}

Anamnesis and body composition
When physical exercise programs return, all participants will participate in an interview structured by a multidisciplinary team. In this anamnesis, it will be collected: demographic data (age, years of study, ethnicity, and sex), comorbidities, smoking and alcohol habits prior Covid-19 diagnosis, and hospitalizations in the last year. The use of medications will be evaluated by a pharmacist.

Body composition will be evaluated by a Dual-energy X-ray absorptiometry (DXA) system (Discovery A; Hologic Inc. - Bedford, MA, USA), according to the protocol described by Bijlsma et al. Measurements of lean mass and relative muscle mass [appendicular lean mass/height² (kg/m²)] will be obtained.

Functionality
The functionality assessment will be obtained through the World Health Organization (WHO) Disability Assessment Schedule (WHODAS 2.0). This assessment instrument was developed by WHO to provide a standardized method of measuring health and disability cross-culturally. The evaluate domains are: cognition, mobility, self-care, interpersonal relationships, living and household activities and participation. For this study, the version administered by respondents will be used.

Physical capacity
Physical capacity will be assessed by the Timed Up and Go (TUG) test; handgrip strength; 30-second sit and stand test; unipodal test; and 6-minute walk test. These assessments will be carried out according to the structure presented in the Table 2.

**Mental health**

Mental health will be assessed with instruments validated for Brazilian population considering depressive symptoms and perceived stress. The assessment of depressive symptoms will be performed using the Geriatric Depression Scale (GSD-15). This scale has a sensitivity of 87% and a specificity of 82% for the cutoff score of 4/5. Volunteers reaching 5 points or more will be considered as indicative of depressive symptoms.

The Brazilian version of the “Perceived Stress Scale” (PSS-10) will be used to assess the level of perceived stress in the previous month. The final score ranges from 0-40 points, with higher scores denoting a higher degree of stress.

**Physical activity level and sedentary behavior**

In order to verify the physical activity level and sedentary behavior, an accelerometry system will be used, using the activPAL3TM actigraph (PAL Technologies Ltd., Glasgow, UK) at assessments moments T1 and T2. The participant will receive a guidance and will be instructed to use the monitor continuously for a week. The accelerometer data are transferred via a USB interface to the specific software activPAL version 7.2.32, which analyses data and estimates energy expenditure in MET/hour. This variable will be expressed as the average activity per day, excluding days that do not register the full 24 hours. The means of transference from sitting-to-standing during each day will also be presented, as well as the time spent in each posture. The sedentary behavior will be defined by the time spent per day at sitting and waking postures. In addition, the walking time, number of steps/day and cadence of steps will be calculated.

**Life Space Assessment**

In order to verify the confinement adopted by participants, the Life-Space Assessment (LSA) questionnaire, translated and validated version for the Brazilian population, will be used. The Brazilian translated and validated version showed adequate reproducibility (internal consistency of 0.92, reliability with ICC of 0.97 (95%CI 0.95 to 0.98), standard error of measurement: 4.12 points – 3%). This questionnaire can be applied to the participant or the caregiver.

**Plans to promote participant retention and complete follow-up**

N/A

**Data management**

N/A

**Confidentiality**
All sensitive data of participants will be archived in a repository of the Institution following the GDPR. Each participant will receive a numerical code and personal data will be obliterated in the analysis.

**Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use (33)**

N/A

**Statistical methods**

**Statistical methods for primary and secondary outcomes (20a)**

Descriptive for all variables will be obtained. Initially, the Shapiro-Wilk test will be used to verify the normality of the data distribution. The paired t test or Wilcoxon will be used to assess changes in physical capacity on confinement, contrasting T0 and T1. Regarding the intervention, to compare participants characteristics (age, years of study, MMSE, body composition) between groups in T0 the independent t test or Mann-Whitney test will be used, respectively, with the normality or not of the data. The two-way ANOVA with repeated measures will be applied to assess the effect of interventions between groups and moments (T1 and T2) on functionality, quality of life, physical capacity, mental health, physical activity levels, life space, body composition and sedentary behavior. The effect size will be calculated by eta partial square ($\eta^2_p$), and values 0.02, 0.06 and 0.14 will be considered as small, medium and large effects, respectively. The results will be presented in confidence intervals and the analysis will be performed by intention to treat. If any participant presents Covid-19 diagnosis, a linear regression will be performed to verify the contribution of this data in the results obtained.

**Interim analyses (21b)**

N/A.

**Methods for additional analyses (e.g. subgroup analyses) (20b)**

N/A.

**Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data (20c)**

N/A.

**Plans to give access to the full protocol, participant level-data and statistical code**
Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}
N/A

Composition of the data monitoring committee, its role and reporting structure {21a}
N/A

Adverse event reporting and harms {22}
All Serious Adverse Events will be reported by investigators to Ethics Committee in the partial reports, following according the described in the ICF

Frequency and plans for auditing trial conduct {23}
N/A

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}
N/A

Dissemination plans {31a}
N/A

Discussion

It is expected that the self-management strategies combined with a multicomponent training will be effective in minimize possible negative outcomes resulting from social distancing in physical capacity, mental health and quality of life of older adults. Besides, we hope that physical intervention combined with SM can reduce participants’ sedentary behavior. The protocol design was adapted for European success studies and focuses on the main physical domains, considering the local population and individuality of each participant. For the current study, the protocol is easily replicable, as it uses accessible and low-cost materials.

In the long term, it is expected that self-management and health education techniques can help to provide and monitor public physical activity programs in primary care centers, maximizing the benefits and increasing
the number of older adults cared involved in self-care at the end of the activity protocol. In addition, we expect that these techniques can be used in the monitoring of older adults who need to be absent from physical training programs for various reasons, such as in epidemics or pandemics, or even in particular cases, such as absence due to health conditions, transport/locomotion problems, among others. Thus, if self-management strategies are effective, physical activity programs can be implemented associated with health education programs, reducing public health expenses, and assisting in the care of a greater demand.

The authors consider the absence of accelerometry assessment, body composition, functionality, and quality of life measurements as a study limitation. These data were not assessed at T0 once it was not part of the quarterly assessment of physical exercise program before the pandemic. However, these variables can be compared at T1 and T2 to verify the effect of the intervention, as the main objective of this study.

**Trial status**

Protocol Version: v01 approved on 11Oct2021
Date recruitment began: 29Nov2021
Approximate date when recruitment will be completed: September, 2022.

**Abbreviations**

**Declarations**

**Acknowledgements**

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**Authors’ contributions {31b}**

Each author and co-authors met all four criteria:

1) Substantial contributions to the conception or design of the work, or acquisition, analysis or interpretation of data for the work;

2) Drafting the work or revising it critically for important intellectual content;

3) Final approval of the version to be published;
4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

**Funding {4}**

This study has been funded by Fundação de Amparo à Pesquisa do Estado de São Paulo – FAPESP (Process 2020/05471-5), Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – CAPES

**Availability of data and materials {29}**

N/A.

**Ethics approval and consent to participate {24}**

This study was approved by the research ethics committee of the Federal University of São Carlos (ID: xxxxxxx/2020)

**Consent for publication {32}**

All authors are in agreement and consent for publication.

**Competing interests {28}**

The authors declare no conflict of interest.

**Authors’ information (optional)**

N/A.

**References**

3. Narici, M. *et al.* Impact of sedentarism due to the COVID-19 home confinement on


Figure 1

Study timeline. All participants were assessed three times: once before the pandemic confinement (T0: baseline), a second time after PA programs return to be opened (T1), and a third time after sixteen weeks’ interventions (T2: Multi and Multi+SM).