Efficacy of Task-Specific Training on Physical Activity Levels of People With Stroke: Protocol for a Randomized Controlled Trial

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Background. The majority of people after stroke demonstrate mobility limitations, which may reduce their physical activity levels. Task-specific training has been shown to be an effective intervention to improve mobility in individuals with stroke, however, little is known about the impact of this intervention on levels of physical activity.

Objectives. The main objective is to investigate the efficacy of task-specific training, focused on both upper and lower limbs, in improving physical activity levels and mobility in individuals with stroke. The secondary objective is to investigate the effects of the training on muscle strength, exercise capacity, and quality of life.

Design. This is a randomized controlled trial.

Setting. The setting is public health centers.

Participants. Community-dwelling people with chronic stroke.

Interventions. Participants will be randomized to either an experimental or control group, who will receive group interventions 3 times per week over 12 weeks. The experimental group will undertake task-specific training, while the control group will undertake global stretching, memory exercises, and health education sessions.

Measurements. Primary outcomes include measures of physical activity levels and mobility, whereas secondary outcomes are muscle strength, exercise capacity, and quality of life. The outcomes will be measured at baseline, postintervention, and at the 4- and 12-week follow-ups.

Conclusions. The findings of this trial have the potential to provide important insights regarding the effects of task-specific training, focused on both upper and lower limbs, in preventing secondary poststroke complications and improving the participants' general health through changes in physical activity levels.
Efficacy of Task-Specific Training of People With Stroke

Stroke is one of the leading health problems worldwide and an important cause of long-term disabilities,1–3 becoming a challenge for health care systems. Many individuals may experience the recurrence of stroke, which is associated with more disabling conditions.4 The importance of prevention of health complications and proper rehabilitation of individuals with stroke5,5 is well recognized.

A sedentary lifestyle and the presence of disabilities in individuals with stroke contribute to reduced physical activity (PA) levels and increased risks of cardiovascular diseases, declines in aerobic capacity, increased fatigue, and the development of new disabilities.6–9 Thus clinical rehabilitation guidelines recommend the maintenance of adequate PA levels, which are related to general well-being.5,5,10,11

Physical activity refers to any bodily movement produced by the skeletal muscles that results in energy expenditure.12 It includes planned and structured activities (i.e., physical exercises) and unplanned or casual activities such as daily activities at work, leisure, home, or during travel.12,13 Despite recommendations to maintain adequate PA levels, this outcome is not usually assessed in individuals with stroke. Furthermore, interventions rarely focus on PA levels.8 Adequate monitoring of PA levels is important to follow and evaluate the effectiveness of interventions or health initiatives to increase PA levels, promote healthy lifestyles, and prevent the recurrence of stroke and the development of disabilities.4,14

Beyond sedentary lifestyles and the lower PA levels observed in individuals with stroke,8 motor impairments are usually related to mobility limitations.15–17 Mobility refers to “any movement to change the body position or location, to carry, to move or to manipulate objects, to walk, run or climb, or when using different forms of transportation.” Mobility limitations in individuals with stroke may affect the function of the upper and lower limbs and the trunk and lead to important health problems, including functional dependence, falls, and low perceptions of quality of life.15,16

Mobility limitations in individuals with stroke may contribute to their lower PA levels.8,19 Therefore, improvement in mobility is an important goal during rehabilitation interventions.16,20 Studies have demonstrated associations between measures of mobility and PA levels, assessed with pedometers21 and activity monitors.22 Many rehabilitation strategies have been described for improving poststroke mobility.16 Among these is task-specific training, which has important characteristics that favor its clinical applicability.23–25 Although effective in improving mobility, the effects of this training on PA levels in individuals with stroke is not fully understood.

Mudge et al26 conducted a randomized controlled trial (RCT) with individuals in the chronic phases of stroke using task-specific training, which was organized in a series of workstations focused on the lower limbs. The control group received social and educational sessions. Physical activity was measured, as the primary outcome, by the number of daily steps obtained with the StepWatch Activity Monitor accelerometer and, as a secondary outcome, by the level of activity assessed by the self-reported Physical Activity and Disability Scale. No changes within and between the groups were found for any of the outcomes.26 Dean et al27 also conducted an RCT with individuals in the chronic phases of stroke using a task-specific intervention organized in series of workstations focused on the lower limbs. The control group received upper limb and cognitive exercises. Physical activity level was measured as a secondary outcome by the number of daily steps with a pedometer Digimax. No changes within and between the groups were found.27 Michael et al28 conducted a pre- and postintervention study with individuals in the chronic phases of stroke using task-specific training focused on the lower limbs and reaching exercises to promote trunk stability. Physical activity was measured as a secondary outcome by the number of daily steps obtained with the StepWatch Activity Monitor accelerometer. No change was found for this outcome.28 Pang et al29 conducted an RCT with individuals in the chronic phases of stroke using task-specific training focused on the lower limbs. The control group received task-specific intervention, strengthening exercises, and electrical stimulation focused on the upper limbs. Physical Activity was measured as a secondary outcome by the Physical Activity Scale for Individuals with Physical Disabilities questionnaire. Within-group improvements were found, but not between the groups.29

Pedometers and accelerometers, the devices that were applied in previous studies, have some disadvantages in measuring PA levels, such as the inability to measure activities that do not involve walking, and have low sensitivity in detecting the low-intensity activities.30 Questionnaires are good options for use within clinical contexts, as they are easy to use and inexpensive. However, they have the disadvantage of subjectivity and can be affected by recall bias.13,14,30 In addition, many questionnaires that measure PA levels in individuals with stroke have limitations regarding their measurement properties, which can influence the obtained results.13,14

Multisensor devices have been found to be more adequate tools for measuring PA levels.13,30 These devices provide more accurate measures of PA levels and energy expenditure, because of the combination of physiological and mechanical sensors, which are able to detect activities of various intensities and tasks that do not involve walking.13,30 In addition, some multisensors are able to measure all 3 PA dimensions, that is, intensity, frequency, and duration.8,13

Previous studies that reported the assessment of PA after task-specific training programs in individuals with stroke often emphasized lower limb tasks, and upper limb training was delivered only to the control group.27,29 Task-specific training focused on both upper limbs and lower limbs could have a greater impact in improving mobility and PA in individuals.
with stroke. Moreover, the tools that were previously used for the assessment of PA levels show limitations and are unable to effectively measure all the relevant dimensions. A more adequate tool, such as a multisensor, should be used to assess possible changes in PA levels after interventions. Thus, it is necessary to investigate the efficacy of task-specific training focused on both upper limbs and lower limbs in improving PA levels.

The main objective of this trial is to investigate the efficacy of task-specific training focused on both the upper limbs and lower limbs in improving PA levels and mobility in individuals with stroke. The secondary objective is to investigate the effects of training in improving muscle strength, exercise capacity, and quality of life.

**Methods**

**Design**

A prospective RCT with concealed randomization and blinded assessments will be carried out in a community-based setting in the city of Belo Horizonte, Brazil. Participants will be screened for eligibility by a trained researcher, who is blinded to the group allocation.

Participants will be randomly assigned to the experimental or control group. Both groups will undertake training sessions of 60 minutes, 3 times per week over 12 weeks. The interventions will be carried out in groups of two to six participants. At baseline, postintervention, and 4- and 12-week follow-ups, outcome measures will be collected by the same researcher (Fig. 1).

This trial is registered at ClinicalTrials.gov (NCT02937480) and we obtained ethical approval from the Institutional Research Ethical Review Board (1.373.837).

**Patient Population: Inclusion and Exclusion Criteria**

Stroke survivors will be eligible if they have a clinical diagnosis of first or recurrent stroke (>6 months); are ≥19 years of age and able to walk 10 m independently, with or without walking devices; have tonus of the elbow flexor muscles <4 on the modified Ashworth scale; are inactive or insufficiently active based on the standards of the Centers for Disease Control and Prevention; and have medical permission for PA.

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**Figure 1.**
Flow diagram of the planned trial pathway for the effects of task-specific training after stroke.
Subjects will be excluded if they have cognitive impairments, as determined by the Mini-Mental State Exam cut-off scores,\(^{46}\) and/or language impairments (comprehensive aphasia);\(^{57}\) a history of severe heart disease and/or uncontrolled blood pressure;\(^{58}\) and pain and/or other adverse health conditions that might affect their performance in the intervention, such as vestibular disturbances, severe arthritis, or other neurological disorders.

All participants will be asked to stop any formal rehabilitation during the 12 weeks of training. A physical therapist, who is experienced in neurological rehabilitation, will be in charge of the interventions.

**Randomization**

The sequence of randomization will be computer generated in blocks of two and maintained in sequentially numbered, sealed opaque envelopes. The envelopes will be prepared prior to the study by a trained researcher, who will not be involved in the study. Eligible participants will be randomly allocated to either the experimental or control group after baseline measures and the contents of the sealed opaque envelopes will be revealed by the treating therapist.

**Interventions**

Tables 1 and 2 show the proposed interventions for both groups, including progression and adaptation strategies.

The experimental intervention, based on the four bilateral tasks of the Test d’Évaluation des Membres Supérieurs de Personnes Agées (TEMPA)\(^ {39}\) and previous published protocols,\(^ {40-43}\) will involve activities related to task-specific training\(^ {44}\) and circuit class exercises\(^ {45}\) (Tab. 1). The task-specific training will progress by increasing the speed, the number of repetitions, and/or the complexity of the task. Individuals will receive feedback regarding their performances and will be encouraged to work as hard as possible and use their paretic limb during the exercises, as much as possible. The therapist will assist the participants to perform the task, when needed. The assistance provided by the therapist will be as minimal as possible. Details about the exercise intensity, as well as any adaptation or task modifications in case a participant is unable to perform the task at each station, will be recorded and will be used to plan progression and feedback for the following session. Between the tasks the participants will be allowed to rest for at least 1–2 minutes and will have time to move between the stations and receive instructions for the next station.

The control intervention will include static global stretching, memory exercises, and health education sessions (Tab. 2).

**Procedures**

Demographic, anthropometric, and clinical information will be obtained, followed by collection of the primary and secondary outcomes. The participant’s stages of motor recovery will be assessed by the Fugl-Meyer scale.\(^ {45}\) The experimental intervention, such as vestibular disturbances, severe arthritis, or other adverse health conditions that might affect their performance in the intervention, such as vestibular disturbances, severe arthritis, or other adverse health conditions.

**Outcome Measures**

**Primary Outcomes**

Primary outcomes will be measures of PA levels and mobility. PA levels will be assessed by direct (multisensory)\(^ {46}\) and self-reported [Human Activity Profile (HAP)] measures,\(^ {37,47}\) whereas mobility will be assessed by the 10-m walk test\(^ {48,49}\) and TEMPA.\(^ {55}\)

The multisensor SenseWear Mini (Body Media, Pittsburgh, PA, USA; software version 8.0) provides objective and accurate measurements of levels of PA.\(^ {56}\) It is a noninvasive and portable device that is placed and adjusted with a velcro strap on the individuals’ nonparetic arm.\(^ {8,14}\) Participants will be instructed to use the device for a week (7 days) and remove it only when having a shower and performing activities in water.\(^ {48}\) Significant and strong associations were already established between the SenseWear and the gold standard (doubly-labeled water) to measure the total energy expenditure (\( r = 0.85, P = .004 \)) in individuals in the chronic phases of stroke.\(^ {50}\)

The HAP provides a subjective measure of PA levels and is low cost and easy to use.\(^ {37,47}\) This questionnaire will be applied by interviews. It consists of 94 activities that are hierarchically graded according to the required metabolic equivalents.\(^ {37,47}\) The activities include personal care, transportation, house maintenance, social and leisure activities, and exercises. The HAP is an appropriate tool to evaluate individuals with different PA levels and has no ceiling or floor effects to assess individuals with disabilities.\(^ {37}\)

Mobility will be assessed by tests that have been previously applied and recommended for the assessment of individuals with stroke.\(^ {51}\) Only one trial, after familiarization, will be employed for all the tests.\(^ {52}\) The tests have shown adequate measurement properties and good clinical applicability for the assessment of individuals with stroke.\(^ {39,48,52,53}\)

Gait speed will be assessed using the 10-m walk test.\(^ {48,49}\) Participants will be instructed to walk at both comfortable and maximal speeds in a 14-m hallway, using their walking devices, usual shoes, and orthoses.\(^ {48,49}\) The instructions will be standardized.\(^ {54}\)

The TEMPA will be applied for the assessment of upper limb function in a standardized way by performing tasks that represent daily living activities.\(^ {39}\) In this study, only the following bilateral tasks of the TEMPA will be assessed: open a pot and take a coffee spoon, open a lock and open a bottle containing pills, write an address and paste a stamp, and shuffle cards.\(^ {49}\) Each task will be timed from the moment the hands of the participant leave the platform until the moment the task is completed. The final score will be the sum of the time required to perform the four tasks. When the subject is unable to perform the task, he/she will be assigned a score of 120 seconds, since this is the maximum time allowed for the individual to try to accomplish the task.

**Secondary Outcomes**

Secondary outcomes will be muscle strength, exercise capacity, and quality of life. Muscle strength will be assessed bilaterally by portable dynamometers,\(^ {55,56}\) exercise
### Efficacy of Task-Specific Training of People With Stroke

#### Table 1.
Experimental Group Intervention Training: 11-Station Task-Specific Training, Progression, and Initial Adaptation When a Participant Is Unable to Perform the Task

<table>
<thead>
<tr>
<th>Activity</th>
<th>Time</th>
<th>Progression and Adaptation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limb Exercises*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sitting position: open covered pots of different sizes and transfer flour to a cup with a spoon, then close the pot</td>
<td>5 min</td>
<td>Progression: Increase the speed and the number of repetitions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Increase the diameter of the spoon and release cover pots</td>
</tr>
<tr>
<td>Sitting position: pick up coins and cards on the table and put the coins in a pot and gather the cards</td>
<td>5 min</td>
<td>Progression: Increase both the speed and the number of coins and cards on the table</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Slide the coins and cards on the table</td>
</tr>
<tr>
<td>Sitting position: write and/or draw pictures on a piece of paper</td>
<td>5 min</td>
<td>Progression: Increase the number of words or pictures as well as the degree of difficulty of the pictures to be drawn</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Increase the diameter of the pencil</td>
</tr>
<tr>
<td>Sitting position: open a safe box with a key, pick up small objects inside the box, and transfer them to a pot, then lock the safe box</td>
<td>5 min</td>
<td>Progression: Increase both the speed and the number of objects inside the box</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Increase the thickness of the key and/or the size of the objects</td>
</tr>
<tr>
<td>Sitting position: pick up and transfer jars, bottles, and glasses of different sizes and weights located on a table. Transfer the liquid contents from jars and bottles to glasses</td>
<td>5 min</td>
<td>Progression: Increase the speed as well as the distance from the object to be reached</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Reduce the volume of liquid in the jars and bottles</td>
</tr>
<tr>
<td>Sitting position: throw and catch balls (in pairs)</td>
<td>5 min</td>
<td>Progression: Increase both the speed and the distance from the players</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Throw balls in a shorter distance or catch balls on the ground</td>
</tr>
<tr>
<td>Lower Limb Exercises</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sit-to-stand from chair by placing the paretic foot behind</td>
<td>5 min</td>
<td>Progression: Reduce the height of the chair, hand support, and increase speed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Place the feet in an autoselected position</td>
</tr>
<tr>
<td>Step forward onto a step with the paretic limb</td>
<td>5 min</td>
<td>Progression: Increase the height of the step and speed and reduce the hand support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Step forward with the paretic limb on the ground</td>
</tr>
<tr>
<td>Step up onto a step, starting with the paretic limb, and step down, starting with the nonparetic limb</td>
<td>5 min</td>
<td>Progression: Increase the height of the step and speed and reduce the hand support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Start with the nonparetic limb when stepping up and down the step</td>
</tr>
<tr>
<td>Standing position: heel raise while putting an object on a higher shelf</td>
<td>5 min</td>
<td>Progression: Increase the height of the shelf and speed and reduce the hand support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: Perform the activity with the paretic limb on a step</td>
</tr>
<tr>
<td>Over-ground walking with auditory stimulus: walk while listening a metronome beat</td>
<td>10 min</td>
<td>Progression: The metronome beat will start with 20 pulses/minute and will be incremented 20 pulses/minute every 2 minutes until it reaches 100 pulses/minute</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adaptation: none</td>
</tr>
</tbody>
</table>

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*aAll exercises will be performed with involvement of both upper limbs.

*bSpending extra time on tasks is not allowed, even if a participant has a task that is more difficult to perform.

*cAdaptation will be performed only if a participant is unable to perform the task. The therapist will assist the participant to perform the task, when needed. The principle of progressive training will be applied in each session, aimed at reducing and removing the initial adaptation and the assistance of the therapist.

Chair characteristics or specifications: backrest chair, without armrest, seat 42 cm wide. Chair height will be adjusted to the participant’s leg length.

Step characteristics or specifications: minimum height 11 cm, length 70 cm.

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Handgrip strength will be measured using the model SH5001 hydraulic handgrip dynamometer (Saehan, Changwon, South Korea) and the strength of the knee extensor muscles by the Micro- fet2 digital hand-held dynamometer (Hoggan Health Industries, Drapper, UT, USA). To perform the handgrip test, the participant will be seated in a chair without armrests, with the shoulder in adduction and neutral rotation, elbow flexed at 90°, forearm in a neutral position.

capacity by the 6-minute walking test, and quality of life by the Stroke Specific Quality of Life (SSQOL) Scale. All tests have shown adequate measurement properties for the assessment of individuals with stroke.
position, and wrist in slight extension (between 0° and 30°). To perform the knee extensor strength test, the individual will remain seated on a stretcher, with legs perpendicular to the floor, knee flexed at 90°, and hands resting on the thighs. The researcher will hold the dynamometer stable at the extremity to be tested or use a belt to promote better stability as the participant exerts force on the equipment. One trial, after familiarization, will be performed.

The 6-minute walking test is a simple, low-cost, easy-to-apply test that does not require advanced training and is widely clinically used with individuals with stroke. The test will be applied on a flat surface, following the recommendations of the American Thoracic Society, for a distance of 25 m.

The SSQOL scale is a simple measure that is applied by interviews. It includes 12 domains with 49 questions: energy, family roles, language and communication, mood, personality, self-care, social roles, thinking, upper extremity function, vision, and work/productivity. The minimum possible score is 49 (worst) and the maximum is 245 (better perception of quality of life).

**Data Monitoring**

An independent researcher, who will be blinded to the group allocation, will be responsible for database management and statistical analyses. The treating therapists will monitor the doses and compliance with training.

**Sample Size**

The sample size was calculated to detect a between-group difference of 0.15 m/s in gait speed, with 80% power, at a two-tailed significance level of 0.05. In an RCT with a similar population and intervention, gait speed for the control and experimental groups at baseline was 0.78±0.14 m/s and 0.84±0.13 m/s and after were 0.78±0.15 m/s (P=0.8) and 0.93±0.14 m/s (P<0.001), respectively. Based on these values, 15 participants per group will be required (a total of 30 participants). Assuming a dropout rate of 15%, a total of 36 participants will be recruited (18 per group).

**Statistical Analyses**

Data analyses will be performed using SPSS for Windows (release 17.0; SPSS, Chicago, IL, USA). Descriptive statistics will be determined for all outcome variables. Differences between the groups at baseline will be investigated with the independent Student’s t-test or chi-square test for all variables related to the demographic and clinical characteristics. If differences between the groups at baseline exist, analysis of covariance will be used to eliminate the influence of extraneous factors.

The effects of the interventions will be analysed in two ways, namely from the data collected and by intention-to-treat analyses, where the last available value in the dropouts will be carried forward to represent the missing data. Analyses of variance with repeated measures (2×4) will be employed to investigate the mean and interaction effects between the groups (intervention×control) and the time (preintervention, postintervention, and follow-up) for the primary and secondary outcomes. Group descriptions will be presented as mean (SD) and effect sizes with 95% confidence intervals (CIs) will be reported.

The effect sizes will be calculated to determine the magnitude of the differences between the groups. The differences between the two mean values will be expressed in units of their SD, expressed as Cohen’s d, or mean results for the experimental group minus the mean results for the control group, divided by the SD of the control group. Effect sizes between 0.2 and 0.5 will be considered small; between 0.5 and 0.8, medium; and >0.8, large.

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**Table 2.** Control Intervention Training

<table>
<thead>
<tr>
<th>Activity</th>
<th>Time</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global stretching, 3 sets of 30</td>
<td>40 min</td>
<td>Static stretching of the following muscle groups:¹&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Sitting position: head and neck flexor/extensors and lateral flexors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Sitting position: trunk flexors and lateral flexors; lying position: trunk extensors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Standing position: wrist flexors; sitting position: wrist extensors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Sitting position: elbow extensors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Standing/lying position: knee flexor; lying position: knee extensors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. Sitting position (mats): hip adductors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. Lying position: plantar flexors</td>
</tr>
<tr>
<td>Memory exercises and health education</td>
<td>20 min</td>
<td>Memory games using images, reminding the sequence of the objects, bingo using charts with pictures, speak names of fruits or animals starting with a specific letter. Information about stroke and general health.</td>
</tr>
</tbody>
</table>

<sup>¹</sup>If a participant is unable to perform static self-stretching, the therapist will assist.

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Discussion
The majority of individuals with stroke have mobility limitations, which may reduce their levels of PA. Task-specific training has been shown to be effective in improving mobility in individuals with stroke. However, little is known about the impact of this intervention on levels of PA. Furthermore, the effects of task-specific training focused on both upper limbs and lower limbs on mobility or PA outcomes is unknown. The planned activities of the task-specific training in this trial have been found to be feasible, meaningful, and relevant to patients’ functionality. Therefore, the findings have the potential to provide important insights regarding the efficacy of task-specific training in improving both PA levels and mobility in individuals with stroke. Patients, physical therapists, and public health systems may ultimately receive important positive economic and social impacts from the results.

Although adequate PA levels have been recommended to prevent the recurrence of stroke and the development of disabilities, as well as to promote healthy lifestyles, it is unclear if task-specific training can be applied to increase PA levels in people with stroke. Furthermore, previous studies on the effects of task-specific training on PA levels did not use instruments, such as the multisensor, which provides objective and accurate information regarding all 3 PA dimensions (i.e., intensity, frequency, and duration), which limits the usefulness of their conclusions.

Author Contributions and Acknowledgments
Data collection: J.C. Martins
Project management: J.C. Martins, S. Nadeau, and C.D.C.M. Faria
Providing participants: C.D.C.M. Faria
Providing facilities/equipment: C.D.C.M. Faria

Clerical/secretarial support: C.D.C.M. Faria
Consultation (including review of the manuscript before submitting): J.C. Martins, S. Nadeau, L.F. Teixeira-Salmela, A.A. Scanni, and C.D.C.M Faria
The guarantor of this study is Dr. Faria. All authors contributed to the conception and design of the study and provided final approval of the version to be published.

Ethics Approval
This clinical trial is being conducted in accordance with a relevant ethical framework. Ethical approval was obtained from the Universidade Federal de Minas Gerais and Health-Care Secretariat of Belo Horizonte (Minas Gerais, Brazil) Institutional Research Ethical Review Board (#1.373.837).

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Disclosures and Presentations
The authors declare that they have no competing interests.

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Clinical Trial Registration
This trial is registered with ClinicalTrials.gov (NCT02937480).

References
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