

# Recruitment, retention, attendance, and adherence of a randomized controlled trial to evaluate the effects of task-specific training with individuals post stroke

*Recrutamento, retenção, presença e adesão de um ensaio clínico aleatorizado para avaliar os efeitos do treino específico da tarefa em indivíduos pós-acidente vascular encefálico*

*Selección, retención, asistencia y adherencia de un ensayo clínico aleatorizado para evaluar los efectos del entrenamiento específico de tareas en sujetos pos-acidente cerebrovascular*

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**ABSTRACT** | Individuals who suffered stroke benefit from different therapeutic strategies whose efficacy has been proved by well-designed randomized controlled trials (RCTs). Understanding study steps may assist researchers in conducting future RCTs. Thus, the objective of this study was to describe the process of recruitment, retention, attendance, and adherence in conducting RCTs with individuals in the chronic phase of stroke in the municipality of Belo Horizonte/MG/Brazil, with the purpose of investigating the efficacy of specific task training for both lower and upper limbs in improving patients' physical activity and mobility. Results showed that, of the 674 potential participants, it was impossible to contact 240 individuals and 384 were excluded from our sample for failing to meet eligibility criteria. In total, 50 individuals participated in clinical evaluations and 14 were excluded from the study for the same reason. Overall, 36 individuals started the interventions, a 5.3% recruitment rate. An 80.6% retention rate was observed. In total, seven individuals left the study, mainly due to lack of interest in the activities. We found an 80.9% attendance rate, and the main reason for missing medical appointments was incompatibility

with treatment schedule. We also observed an 82.7% adherence rate. Of these, 180 interrupted sessions were mainly due to patients leaving early. These results indicate some difficulties found in conducting RCTs with individuals in the chronic phase of stroke, especially regarding specific task training. Despite these difficulties, the proposed intervention can be considered feasible.

**Keywords** | Patient Selection; Treatment Adherence and Compliance; Randomized Controlled Trial; Stroke.

**RESUMO** | Indivíduos acometidos pelo acidente vascular encefálico (AVE) se beneficiam de diferentes estratégias terapêuticas que apresentam comprovação da eficácia por meio da condução de ensaios clínicos aleatorizados (ECA) bem delineados. Compreender as etapas do estudo pode auxiliar os pesquisadores na realização de futuros ensaios clínicos. Dessa forma, o objetivo deste estudo foi descrever o processo de recrutamento, retenção, presença e adesão na condução de um ECA realizado com indivíduos pós-AVE na fase crônica na cidade de Belo Horizonte (MG), Brasil, com o

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This study is part of the project: "Eficácia do treino específico da tarefa no nível de atividade física de indivíduos acometidos pelo acidente vascular encefálico: um ensaio clínico aleatorizado," advised by Professor Christina Danielli Coelho de Morais Faria.

propósito de investigar a eficácia do treino específico da tarefa para membros superiores e inferiores na melhora do nível de atividade física e mobilidade. Nos resultados, foi observado que dos 674 potenciais participantes, não foi possível contatar 240; 384 não foram avaliados por não atenderem aos critérios de elegibilidade. Participaram da avaliação presencial 50 indivíduos e 14 não fizeram parte do estudo pelo mesmo motivo. Apenas 36 indivíduos iniciaram as intervenções (taxa de recrutamento de 5,3%). Uma taxa de retenção de 80,6% foi observada. Sete indivíduos abandonaram o estudo, principalmente por desinteresse pelas atividades. A taxa de presença foi de 80,9%, e o principal motivo para ausência nas sessões foi incompatibilidade de horário com as consultas médicas. A taxa de adesão foi de 82,7%, com 180 interrupções durante as sessões, sendo sair mais cedo o motivo mais comum. Esses resultados indicam algumas dificuldades no processo de condução do ECA com indivíduos na fase crônica do AVE envolvendo treino específico da tarefa. Apesar dessas dificuldades, a intervenção proposta pode ser considerada viável.

**Descritores** | Seleção de Pacientes; Cooperação e Adesão ao Tratamento; Ensaio Clínico Controlado Aleatório; Acidente Vascular Cerebral.

**RESUMEN** | Las personas afectadas por accidente cerebrovascular (ACV) tienen a su disposición diferentes estrategias terapéuticas que muestran evidencia de eficacia a través de la realización de ensayos

clínicos aleatorizados (RCT) bien diseñados. Conocer las etapas del estudio puede ayudar a los investigadores a realizar futuros ensayos clínicos. Así, el objetivo de este estudio fue describir el proceso de selección, retención, asistencia y adherencia de un RCT realizado con individuos post-ACV en fase crónica en la ciudad de Belo Horizonte (Brasil), para investigar la efectividad del entrenamiento específico de tareas para las extremidades superiores e inferiores en la mejora del nivel de actividad física y la movilidad. En los resultados se observó que, de los 674 potenciales participantes, no fue posible contactar a 240; y 384 no fueron evaluados por no cumplir con los criterios de elegibilidad. Cincuenta personas participaron en la evaluación presencial y 14 no formaron parte del estudio por la misma razón. Solo 36 personas empezaron las intervenciones (tasa de selección del 5,3%). Se observó una tasa de retención del 80,6%. Siete personas abandonaron el estudio, principalmente por falta de interés en las actividades. La tasa de asistencia fue del 80,9%, y el principal motivo de ausencia a las sesiones fue la incompatibilidad de horario con las citas médicas. La tasa de adherencia fue del 82,7%, con 180 interrupciones durante las sesiones, y la salida anticipada fue la razón más frecuente. Los resultados apuntan algunas dificultades en el proceso de realización del RCT con individuos en fase crónica del ACV con relación al entrenamiento específico de tarea. A pesar de esto, la intervención propuesta puede considerarse viable.

**Palabras Clave** | Selección de Paciente; Cumplimiento y Adherencia al Tratamiento; Ensayo Clínico Controlado Aleatorio; Accidente Cerebrovascular.

## INTRODUCTION

Most individuals who survived strokes deal with serious disabilities<sup>1</sup>. These people benefit from different therapeutic strategies<sup>2</sup>, such as task-specific training, which effectively improves functionality<sup>3,4</sup>. The principle of this strategy is the repeated performance of functional and significant activities<sup>5,6</sup>, e.g., opening bottles, transferring their liquid to glasses and closing them<sup>7</sup>, sit to stand<sup>8</sup>, and gait training<sup>9</sup>.

Well-delineated randomized clinical trials (RCTs)<sup>10</sup>, which establish a cause-and-effect relation between variables<sup>11</sup>, prove the efficacy of these therapeutic strategies. Conducting RCTs involves recruitment, retention, attendance, and adherence<sup>12</sup>. Understanding these stages can aid specialists in conducting future trials. Few studies have reported RCT stages involving task-specific training. Among the few found, none reported the aforementioned four stages.

Scianni, Teixeira-Salmela, and Ada<sup>12</sup>, authors of one of these studies, analyzed the effectiveness of a muscle

strengthening and specific gait training program and reported the challenges in recruitment, attendance, and adherence to an RCT with individuals in the post-stroke acute phase (<6 months). However, individuals in the chronic phase may show different behaviors. Moreover, the challenges involved in conducting an RCT related to task-specific training for both upper and lower limbs are yet to be investigated.

Thus, this study aimed to describe the recruitment, retention, attendance, and adherence to an RCT with individuals in post-stroke chronic phase to investigate the effectiveness of task-specific training directed at upper and lower limbs to improve physical activity and mobility levels.

## METHODOLOGY

This is a descriptive study of an RCT conducted in Belo Horizonte (MG), Brazil at the School of Physical Education, Physical therapy and Occupational Therapy

at the Universidade Federal de Minas Gerais (UFMG) and in a Basic Health Unit (UBS) in the Sanitário Nordeste district. The previously published<sup>13</sup> RCT protocol was registered on ClinicalTrials.gov (NCT02937480).

Patients who received a clinical stroke diagnosis at least six months prior to this study were included; those who were aged 19 years or older; were able to walk 10 meters with or without the aid of gait devices<sup>14</sup>; showed an elbow flexor muscle tone of less than four on the modified Ashworth scale<sup>15</sup>; were inactive or insufficiently active based on Centers for Disease Control and Prevention criteria<sup>16</sup>; and had been medically cleared for physical activity. Patients who showed the following were excluded: suspicion of cognitive deficit according to the mini-mental state examination<sup>17</sup>; aphasia<sup>18</sup>; history of severe heart disease and/or uncontrolled arterial hypertension<sup>19</sup>; and pain and/or other health conditions that could affect the performance of tests and interventions.

Clinical and demographic data of the participants were obtained. After evaluation, individuals were randomized into two groups: the experimental one, performing task-specific training with activities for upper and lower limbs; and the control one, performing global static stretching and memory exercises, and receiving guidance on health care. In total, 36 one-hour sessions were held in groups three times a week. Intervention details have been previously published<sup>13</sup>. Our RCT was completed as originally planned<sup>13</sup>.

## Recruitment

Our recruitment strategies were referrals, which consisted of phone numbers obtained from directories of other research projects and health professionals from clinics, hospitals, and UBSs; and advertisements, which consisted of physical pamphlets distributed in public places, such as universities and health centers, and electronic pamphlets published on social networks. Recruitment rate was obtained by the ratio between the total number of participants who started the interventions and the total number of screened individuals.

## Retention

Our retention strategies were encouraging participants to attend the sessions; providing snacks at the end of each week; calling participants in case of absences; and giveaway draws every 15 days. Retention rate consisted of the ratio between the total number of participants who finished the 36 sessions and the total number of participants who started the interventions.

## Attendance

Our attendance strategies were the same as the ones to ensure retention. Attendance rate was estimated by the ratio between the number of sessions performed and the number of sessions offered. Each participant's reasons for and number of absences were recorded.

## Protocol adherence

Our adherence strategies were the same as the ones to ensure retention. Participation rate consisted of the ratio between the number of sessions performed in full and the number of sessions attended by participants. Participants' reasons for not completing the sessions were recorded.

## Statistical analysis

Variable normality was assessed by the Shapiro-Wilk test. Normally distributed variables were described by mean and standard deviation and abnormally distributed ones via median and interquartile intervals. Categorical variables and information on the stages of RCT were reported using absolute and relative frequencies.

## RESULTS

### Recruitment

We screened a total of 674 individuals from June 2016 to November 2017. Referrals (n=633; 93.9%) were the most effective recruitment strategy. We found most participants via research project lists (n=331; 52.3%) and the remaining, by health professionals (n=302; 47.7%). Advertisements allowed the identification of 41 (6.1%) individuals.

It was impossible to contact 240 (35.6%) individuals due to errors in phone registries or unanswered calls. Among the remaining 434 (64.4%) patients, 384 (88.5%) were not evaluated face-to-face. Table 1 shows these individuals' reasons for non-participation. Failing to meet eligibility criteria (n=159; 41.4%) and lack of interest/refusal to participate (n=103; 26.8%) were the main reasons for non-participation.

In total, 50 (11.5%) individuals were evaluated face-to-face. Out of these, 14 (28%) failed to participate in the study, most (n=10; 71.5%) for unmet eligibility criteria. Table 1 shows reasons for exclusion.

Table 1. Absolute and relative frequencies of the reasons for non-participation in this study before (n=384) and after face-to-face evaluation (n=14)

Reason	n (%)
<b>Before face-to-face evaluation (n=384 individuals)</b>	
Failed to meet eligibility criteria	159 (41.4%)
Unable to walk 10 meters with or without the assistance of gait devices	65
Other health conditions	42
Classified as active*	26
Not showing a >6-month stroke diagnosis	18
Elbow flexor muscle tone >4**	4
Suspected cognitive impairment	3
Lacking medical clearance for physical activity	1
Lack of interest/refusal to participate	103 (26.8%)
Unavailability to participate	85 (22.1%)
Transportation barriers	29
Lack of caregivers	24
Works	17
Lives in another state	12
Travel	3
Death	37 (9.7%)
<b>After face-to-face evaluation (n=14 individuals)</b>	
Failed to meet eligibility criteria	10 (71.5%)
Classified as active*	4
Other health conditions	3
Lacking medical clearance for physical activity	2
Elbow flexor muscle tone >4	1
Lack of interest/refusal to participate	2 (14.3%)
Unavailability to participate	1 (7.1%)
Changed residences	1
Refused to complete the initial evaluation	1 (7.1%)

\*Classification based on Centers for Disease Control and Prevention criteria; \*\*Patients reported sufficient information to attest that they failed to meet this inclusion criterion: "incapable of moving the affected upper limb;" "able to slightly move the elbow but not the wrist," "short range of motion of the affected upper limb;" "incapable of moving the affected upper limb."

In total, 36 individuals (mean age of 55±14 years and mean stroke time of 65±64 months) started the interventions, resulting in a 5.3% recruitment rate (Figure 1). Most participants were women (n=21; 58.3%) who suffered ischemic strokes (n=29; 80.6%) and had right hemiparesis (n=19; 52.8%) and either a marked (n=16; 44.4%) or moderate motor impairment degree (n=13; 36.1%).

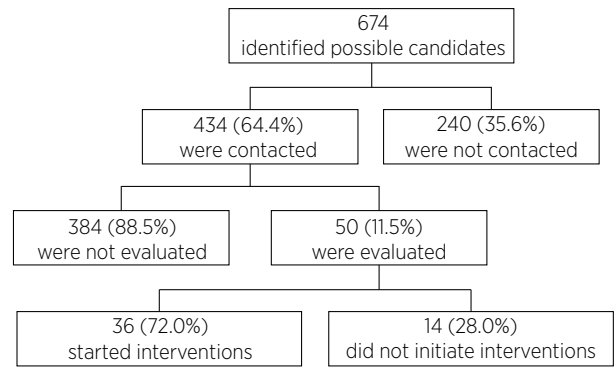


Figure 1. Recruitment flowchart

### Retention

In our sample, seven (19.4%) individuals abandoned this study due to lack of interest in the activities (n=3; 42.8%), health problems (n=2; 28.6%), beginning of treatment at another site (n=1; 14.3%), and barriers to transportation (n=1; 14.3%). In total, 29 individuals finished our protocol, resulting in an 80.6% retention rate.

### Attendance

We expected all 36 individuals to perform 36 sessions, totaling 1,296 sessions. However, 1,157 sessions were performed, resulting in an 89.3% attendance rate. The 29 individuals who were retained attended 845 sessions, resulting in an 80.9% attendance rate. The seven individuals who abandoned the study attended 61 sessions, resulting in a 24.2% attendance rate. Table 2 describes the reasons for the absence of participants who finished the sessions but abandoned this study.

Table 2. Absolute and relative frequencies of reasons for absence from sessions (n=36 subjects)

Reason	Finished this study (n=29)	Abandoned this study (n=7)
Sessions	50 (25.2%)	6 (11.5%)
Indisposition	45 (22.6%)	9 (17.3%)
Another commitment	28 (14.1%)	1 (2.0%)
Lack of caregivers	22 (11.1%)	0 (0%)
Transportation barriers	17 (8.5%)	6 (11.5%)
Travel	13 (6.5%)	18 (34.6%)
Unreported	11 (5.5%)	5 (9.6%)
Tardiness	8 (4%)	0 (0%)
Home visits	5 (2.5%)	7 (13.5%)

## Protocol adherence

Out of the 845 sessions attended by the individuals who initiated the interventions (n=36), 699 were performed in full, resulting in an 82.7% participation rate. Thus, 146 (17.3%) were partially performed,

with 133 interruptions. Among these, 108 (81.2%) showed no properly registered reason for it. Table 3 shows the 25 (18.8%) registered reasons that prevented the session from being fully performed, showing that leaving the session earlier was the most prevalent one (n=9; 36%).

Table 3. Absolute and relative frequencies of the recorded reasons for failing to perform sessions (n=25 records)

Reason	n (%)
Need to leave the session early	9 (36%)
Vertigo	5 (20%)
Pain	5 (20%)
Fatigue	2 (8%)
Malaise	2 (8%)
Injury during session	1 (4%)
Fall	1 (4%)

## DISCUSSION

This study is the first to describe the recruitment, retention, attendance, and adherence to an RCT performed with individuals in post-stroke chronic phase to investigate

the effectiveness of task-specific training directed at upper and lower limbs to improve physical activity and mobility levels. RCT was completed as originally planned<sup>13</sup>.

Chart 1 summarizes the information from the studies that will be used to discuss our results.

Chart 1. Characteristics of previous studies used to discuss the results of this study

Characteristic	Gomes et al. <sup>11</sup>	Scianni, Teixeira-Salmela, Ada <sup>12</sup>	Brkic et al. <sup>20</sup>	Lima <sup>21</sup>
Sample	Chronic post-stroke (>6 months)	Acute post-stroke (>6 months)	Acute post-stroke (up to 14 days of stroke)	Chronic post-stroke (>6 months)
Session location	Florianópolis/Brazil	Belo Horizonte/Brazil	Multicentric/England	Belo Horizonte/Brazil
Intervention	Study I EG: mirror training associated with specific task training GC: unreported Study II EG: bilateral task specific training CG: conventional physiotherapy	EG: gait-specific training associated with muscle strengthening CG: gait-specific training	GE: upper limb task-specific training CG: habitual post-stroke rehabilitation	EG: modified constraint-induced therapy with torso restriction CG: modified constraint-induced therapy
Number of sessions	Study I: 12 Study II: 10	30	20	10
Duration of each session	1 hour in both studies	EG: 1 hour CG: 30 minutes	Practice unassisted activities for up to 20 repetitions twice a day.	3 hours
Recruitment rate	25.2%	6.7%	2.2%	7%
Retention rate	100%	—	—	95.5%
Attendance rate	Study I: 84% Study II: 97.5%	76%	—	100%

EG: experimental group; CG: control group; -: information not provided by the study.

## Recruitment

This study showed a low recruitment rate similar to most previous studies on this theme<sup>12,20,21</sup> (Chart 1). Gomes et al.<sup>11</sup> reported a higher rate, which may be related to the strategic recruitment performed, i.e., in clinics and

rehabilitation centers in Florianópolis and an extension project for the population affected by stroke. Other solutions to increase this rate would be the creation of a registration system to facilitate access to individuals' information and the population and professionals' awareness of the importance of research<sup>11,12</sup>. Gomes et al.<sup>11</sup> also faced barriers

to recruit participants, such as wrong phone numbers or unanswered calls, which could be avoided by updating the information and correcting contact registration<sup>11</sup>.

Participants' failure to meet eligibility criteria was also a challenge (n=159; 41.4%) in similar studies<sup>11,12,21</sup>, possibly due to the need to make the RCT sample more homogeneous<sup>12</sup>. Unlike other studies<sup>11,12</sup>, transportation barriers were not the main challenge faced, possibly because this study offered interventions in two places in the municipality.

Scianni, Teixeira-Salmela, and Ada<sup>12</sup> reported that referrals were the most effective recruitment strategy (100%), as observed in this study (93.9%). Research dissemination could be more effective if made by media, such as radio and television, strategies that can be used in future work.

## Retention

Similar previous studies, and others conducted in Brazil<sup>11,21</sup>, reported higher retention rates (Chart 1). A possible explanation for this difference is the greater number of sessions in our study, necessary due to the characteristics of the intervention program offered, following current recommendations<sup>22-24</sup>. Moreover, Gomes et al.<sup>11</sup> reassigned absences by changing their session schedule, ensuring a 100% retention rate. In this study, these strategies were not adopted to ensure that all sessions were held in groups.

## Attendance

Our attendance rate was similar to that described in previous studies<sup>11,12</sup> (Chart 1). The literature lacks a definition of the appropriate attendance rate for research done with individuals who have suffered a stroke. A study conducted with older women suggested that intervention programs may fail to show an attendance rate below 85%<sup>25</sup>. This study showed a higher rate: 89.3%.

The main reasons for absence in this study were having appointments at the time of the intervention (25.2%), also mentioned by Gomes et al.<sup>11</sup>; and indisposition (22.6%), also mentioned by Scianni, Teixeira-Salmela, and Ada<sup>12</sup>. Offering sessions in two shifts could reduce absences but would require greater use of physical space, more time, and a larger research team.

## Protocol adherence

Adherence shows different operationalizations<sup>10,12,25</sup>. Only Scianni, Teixeira-Salmela, and Ada<sup>12</sup> used a

definition similar to the one in this study. They reported a 97% rate. The reasons reported for failing to complete the sessions were malaise, pain, emotional crisis, and fatigue<sup>12</sup>. This study showed an 82.7% participation rate, and the main reason recorded for failing to complete the sessions was the need to leave sessions early. A limitation of this study was the lack of adequate registration of more than half of the reasons given by participants for uncompleted sessions. This information is important for researchers to develop strategies to ensure protocol compliance.

## CONCLUSION

Our results showed the challenges faced in conducting an RCT with individuals in post-stroke chronic phase in Belo Horizonte (MG), Brazil involving task-specific training for lower and upper limbs. Our recruitment rate was low but similar to that of most similar studies found. This study showed good attendance, retention, and adherence rates, characterizing the feasibility of the proposed intervention for this population.

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