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Challenges in recruitment, attendance and adherence of acute stroke survivors to a randomized trial in Brazil: a feasibility study

Desafios no recrutamento, presença e adesão ao protocolo de intervenção em um ensaio controlado aleatorizado com sobreviventes de AVE agudo no Brasil: um estudo de viabilidade

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Abstract

Background: There is a high demand for stroke rehabilitation in the Brazilian public health system which should make undertaking clinical trials straightforward. **Objectives:** The aims of this study were to 1) determine the rate of recruitment of community-dwelling stroke survivors into a randomized trial of the effects of strength training in addition to task-specific gait training, 2) compare the effectiveness of various recruitment strategies on accrual rates, and 3) determine the attendance at training sessions and adherence to the intervention protocol. **Methods:** Participants within six months of a stroke were screened for eligibility and invited to participate. Recruitment strategies were classified as advertisement or referral. The number of people who were screened, eligible and recruited for each strategy was recorded. Attendance at training sessions and adherence to the intervention protocol were recorded. **Results:** Over the first 14 months, 150 stroke survivors were screened, 10 were recruited, and 35 (23%) were eligible. Twenty-five of these patients (71%) were unable to participate with lack of transport given as the most common reason. The most successful strategy was referral via hospital-based physical therapists (50%). Overall attendance was 72% with lack of transport being the most common reason for non-attendance. Overall adherence to the protocol was 97% with feeling unwell being the most common reason for non-adherence. **Conclusions:** Recruitment of stroke survivors was inefficient. Lack of transport was the most common barrier to participate in and attend training sessions. Funding for transport is essential to make carrying out trials in Brazil feasible. Trial Registration ACTRN12609000803291.

Keywords: randomized controlled trial; muscle strength; stroke; walking; physical therapy.

Resumo

Contextualização: O sistema de saúde pública no Brasil apresenta uma alta demanda para a reabilitação de indivíduos após acidente vascular encefálico (AVE). Consequentemente, a condução de ensaios clínicos com essa população deveria ser simples. **Objetivos:** Determinar a taxa de recrutamento de sobreviventes de AVE para ensaio controlado aleatorizado sobre os efeitos do fortalecimento muscular em adição ao treino específico de marcha; comparar a eficácia de várias estratégias de recrutamento e determinar a presença nas sessões de treinamento assim como a adesão ao protocolo de intervenção. **Métodos:** Sobreviventes de AVE há menos de seis meses foram triados para elegibilidade e convidados a participar do estudo. Estratégias de recrutamento foram classificadas como propagandas ou encaminhamento. O número de pessoas triadas, elegíveis e recrutadas por cada estratégia assim como presença nas sessões e adesão ao protocolo de intervenção foram registrados. **Resultados:** Durante 14 meses, 150 indivíduos foram triados e dez, recrutados. Trinta e cinco (23%) eram elegíveis; 25 deles (71%) eram incapazes de participar do estudo, sendo a falta de recursos para transporte a principal razão. Encaminhamento por meio de fisioterapeutas de hospitais representou a estratégia de recrutamento de maior sucesso (50%). A taxa de presença foi de 72%, e a taxa de adesão foi de 97%. A falta de transporte representou a principal razão para falta nas sessões de intervenção. **Conclusões:** A falta de recursos para o transporte representou a principal barreira à participação e presença. Portanto, o financiamento de transporte torna-se essencial para a condução de ensaios clínicos viáveis no Brasil. Registro de Ensaios Clínicos ACTRN12609000803291.

Palavras-chave: ensaio controlado aleatorizado; força muscular; AVE; marcha; fisioterapia.

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Introduction

Recruitment is often a major problem in randomized trials. It has been reported that failure to reach target sample size occurs in half of all clinical trials[1]. One of the most important methodological concerns in randomized trials is the recruitment and retention of a sufficient number of participants. Failure to recruit or retain enough participants to satisfy the target sample size may decrease the statistical power of the trial and lead to invalid or inconclusive results, increase the trial length and costs, or result in premature termination of the trial.

Systematic reviews examining recruitment for clinical trials have pointed out that time, transport, costs and procedures are barriers to participation[2,3]. Strategies have been suggested to overcome these barriers, such as telephone calls, monetary incentives and informing the participants about group allocation[2,3]. After stroke, the main reasons given for difficulty in recruitment to clinical trials include unwillingness to participate, complex protocols and eligibility criteria and trial fatigue by the investigators[4,5]. Additionally, stroke survivors may have motor and cognitive disabilities that interfere with their ability to participate. After discharge from hospital, it is even more difficult, as they need to travel to the site of trial.

The aim of this study was to investigate the feasibility of running a randomized trial examining the effect of strengthening exercises in community-dwelling stroke survivors in Brazil. Stroke survivors who need assistance in physical activities after discharge from hospital are referred for rehabilitation from a health professional from a primary care unit or a specialist physician from the public health system. Treatment is then, scheduled in one of the public system own units, or in a non-public clinic contracted by the public service. Since demand for rehabilitation is higher than supply, there is usually a long waiting list. For this reason, we believed that recruitment to our randomized trial would not be very difficult since it offered immediate rehabilitation. The specific research questions were:

1. What was the rate of recruitment?
2. What was the level of attendance at training sessions?
3. What was the level of adherence to the intervention protocol?

Methods

This study was a feasibility study of a prospective randomized trial with concealed randomization and blinded assessment. Stroke survivors, who were living at home and attending physical therapy outpatient clinics in the city of Belo Horizonte, MG, Brazil were recruited and randomized into either a control group (task-specific walking training, three times per week for 10 weeks) or an experimental group (targeted strength training plus task-specific walking training, three times per week for 10 weeks). The inclusion criteria were: i) clinical diagnoses of first stroke, which resulted in walking deficits; ii) living at home for less than six months, after being discharged from the hospital; iii) older than 20 years of age; iv) clinical diagnoses of hemiparesis or hemiplegia; v) ability to walk 10 meters independently, using walking aids or orthoses, if necessary, with or without supervision; vi) muscular weakness (≤3 on Manual Muscle Test) in at least 50% of the 12 lower limb muscles; and vii) walking speeds between 0.4 and 0.8 m/s (limited community)[6]. They were excluded if they had severe cognitive and/or language deficits or had adverse health conditions, which precluded them from participation in strength and walking training. The recruitment target for the first 15 months of the current trial was set at 40 participants. Two staff members were engaged in the recruitment process. Informed consent was obtained from all participants.

The study was registered prior to the allocation of participants by the Australian New Zealand Clinical Trials Registry-ACTRN (ACTRN12609000803291) and ethical approval was obtained from the appropriate Human Research Ethical Committee (ETIC 120/09), Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, MG, Brazil. The protocol of this randomized trial was published previously[7].

Measurement of recruitment

Throughout the recruitment process, records were kept regarding the number of people screened for entry to the trial, and the source by which the person became aware of the trial. If not admitted to the trial, the reason why the person was ineligible for inclusion was recorded. Similarly, if eligible, the reason for a person declining to participate was noted.

Once recruitment for the first 10 participants had ceased, a review of the information related to recruitment was conducted. The records were sorted based on the source of recruitment and summed to gain the total number of people screened from each source. This was then compared with the recruitment source of the participants who were actually admitted to the clinical trial. Recruitment sources were classified as advertisement or referral. Advertisement sources were from i) physical flyers distributed in public places such as churches, gyms, universities and stores; ii) electronic flyers distributed in non-governmental organizations and hospital websites. Referral sources were from i) clinical neurologists working in private clinics; ii) physical therapists working in rehabilitation clinics, iii) physical therapists working in metropolitan hospitals and iv) other researchers. All sources were contacted at least once a week via telephone or e-mail. The most *successful* recruitment

source was determined by the total number of participants recruited to the trial from an individual source. The most *efficient* recruitment sources were defined in three ways: i) the highest number of people eligible for the trial as a proportion of those screened; ii) the highest number of people recruited as a proportion of those screened; and iii) the highest number of people recruited as a proportion of those eligible.

Measurement of attendance

According to the current trial protocol, each participant in the experimental and control group was required to participate in training, three times per week for a period of 10 weeks. The exact number of training sessions available to each cohort of participants varied slightly due the occurrence of public holidays during the intervention periods.

Throughout the intervention phase, information regarding attendance at the training sessions was collected by the physical therapist delivering the training. If a participant did not attend a session, the reason for non-attendance was noted (when given by the participant). Once the intervention phase had ceased, the number of sessions each participant attended was added up. Participants who attended less than 50% of training sessions were classified as "poor attenders".

Measurement of adherence

According to the trial protocol, each participant in the experimental group was required to participate in 60 minutes of training (targeted strength training plus task-specific walking training) and each participant in the control group was required to participate in 30 minutes of task-specific walking training (task-specific walking training).

Throughout the intervention phase, information regarding adherence to this protocol was collected by the physical therapist delivering the training. The number of sessions where the participant completed the full 30 minutes of walking training and the reasons for not completing the 30 minutes, were also noted. This information was used to determine: i) the number of sessions where the participant completed the full training; and ii) the reasons for not completing the full training protocol.

Results

Recruitment to trial

A total of 150 stroke survivors were screened for eligibility to the current trial in the period from July 2009 to October 2010. Of these, 115 (77%) were excluded because they did not meet the inclusion criteria and the reasons for exclusion are given in Table 1. The most common reason for exclusion was that the walking speed was outside the range of 0.4-0.8 m/s. Twenty-five (17%) stroke survivors were eligible for admission to the trial but declined to participate. The reasons for declining to participate included lack of money to pay for transport to the site of intervention (44%); other physical therapy services (once a week or month) available near home (28%); lack of interest (20%); caregiver/partner did not want to accompany the participant to the site of intervention (4%); and dislike of exercise (4%). Ten (7%) stroke survivors were both eligible to take part in the study and consented to participate. These represented 25% of the target of 40 participants for this period.

The number of participants recruited from each source is presented in Table 2. The most successful source of recruitment was referral from hospital-based physical therapists with 5 (50%) participants recruited from this source. Referral was determined by the most efficient recruitment strategy. The least successful source of recruitment was advertisement. Although clinical neurologists referred the highest proportions of eligible participants from an individual source, this only resulted in one participant.

Attendance at training sessions

Attendance at the intervention sessions is summarized in Table 3. The overall attendance was 76% (SD 23), with the total number of sessions attended being 192 out of a possible 276 sessions. Five (50%) participants attended ≥89% of available sessions. There were two (20%) poor attenders who attended less than 50% of intervention sessions. Reasons for not attending sessions are shown in Table 4. The most common reason for non-attendance at the intervention sessions was illness, followed by transport problems. The two poor attenders accounted for 40 (48%) of the missed intervention sessions. When these participants were excluded, the most common reason for not attending was illness.

Table 1. Number (%) of stroke survivors screened but excluded.

Reason	Excluded n=115
Walking speed slower than 0.4 m/s	45 (39)
Walking speed faster than 0.8 m/s	32 (28)
More than one stroke event with gait deficits	14 (12)
No hemiparesis/hemiplegia	13 (11)
Muscle strength >3 (0-5 MMT) on 7 or more of the 12 lower limb muscle groups	5 (4)
More than 6 months after stroke	2 (2)
Unstable cardiorespiratory condition	2 (2)
Insufficient cognition/language	1 (1)
Barrier to undertaking rehabilitation	1 (1)

Adherence to intervention protocol

Of the 192 sessions attended by participants, 187 (97%) sessions were of the complete training that was prescribed. There were five (3%) sessions where participants did not complete the full training. Two of these sessions were not completed by experimental participants and three by control participants. The reasons for non-completion are given in Table 5. The most common reason was illness.

Discussion

This study revealed a problem of slow recruitment for this Brazilian clinical trial. One hundred and fifty stroke survivors were screened for eligibility and 10 (7%) agreed to participate. This number represents only 25% of the target of 40 participants. Low levels and slow recruitment imply longer duration of the trial. Problems with the funds intended for the original study and the possibility of low statistical power if the recruitment target is not achieved, may compromise the results of the trial. In addition, there are further implications on the quality of clinical care, since this delay means more time without the knowledge of the most effective intervention. Gul and Ali[8] reported that one of the biggest mistakes in recruitment to clinical trials is the tendency for researchers to overestimate the number of available patients who meet the inclusion criteria ("recruitment funnel"). Evidence suggests that only 10% of subjects "survive" to the "recruitment funnel"[9].

Recruitment

According to the database of the Brazilian National Health System (DATASUS)[10], approximately 14,349 people with stroke were admitted to public hospitals of the State of Minas Gerais, Brazil in a period of nine months from July 2009 to April 2010. Of these patients, 2,831 were admitted in the metropolitan area of Belo Horizonte, MG, Brazil[10]. Additionally, 1953 (69%) of these stroke survivors live in Belo Horizonte, Brazil. Since the eligibility criteria included those who had a stroke within the

Table 2. Number (%) of participants screened, eligible and recruited for each source.

Source	Success			Efficiency		
	Screened n (%)	Eligible n (%)	Recruited n (%)	Eligible n (% screened)	Recruited n (% screened)	Recruited n (% eligible)
Advertisement						
Physical flyers	6 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Electronic flyers	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Referral						
Clinical neurologists	1 (1)	1 (3)	1 (10)	1 (100)	1 (100)	1 (100)
Physical therapists working in rehabilitation clinics	26 (17)	8 (23)	2 (20)	8 (31)	2 (8)	2 (25)
Physical therapists working in metropolitan hospitals	113 (75)	24 (68)	5 (50)	24 (21)	5 (4)	5 (21)
Other researchers	3 (2)	2 (6)	2 (20)	2 (67)	2 (67)	2 (100)
Total	150	35	10	35	10	10

Table 3. Attendance at intervention sessions.

Participant	Group	Sessions available	Sessions attended	% sessions attended
1	Experimental	30	10	33
2	Control	27	25	93
3	Experimental	28	26	93
4	Control	28	25	89
5	Control	28	25	89
6	Experimental	27	17	63
7	Control	26	19	73
8	Experimental	27	24	89
9	Experimental	27	7	26
10	Control	28	14	50

Table 4. Number (%) of training sessions not attended for each reason.

Reason	All participants n=10	Excluding poor attenders n=8
Illness / sickness	30 (36)	30 (68)
Transport problems	27 (32)	7 (16)
Away (on holidays)	6 (7)	6 (14)
Caregiver problems	1 (1)	1 (2)
No reason given by participant	20 (24)	0 (0)
Total	84 (100)	44 (100)

Table 5. Number (%) of participants who did not complete training for each reason.

Reason	n=10
Feeling generally unwell, pain	3 (60)
Emotional crisis	1 (20)
Fatigue	1 (20)
Total	5 (100)

previous six months and who resided in the community of Belo Horizonte, it was originally concluded that there was a large number of stroke survivors who could be recruited.

A number of obstacles were encountered during the recruitment process. One was the lack of direct access to stroke survivors in the community. Privacy laws and the need to maintain confidentiality of patient data prevented the physical therapists based on hospitals and on physical therapy clinics providing details of potential participants. There is a growing tendency to depend on clinicians to be the connection between researchers and research participants. However, with demands on their time (eg, supervision, administration, improvement of service quality and security), the workload of clinicians is currently high and a demand for additional assistance with recruitment for clinical trials may compromise the quality of clinical care. Since most hospitals and physical therapy clinics do not have staff available to assist in the recruitment process, recruitment efforts at these sites became extremely difficult. In an attempt to overcome this barrier, we sought to recruit participants from the community. Flyers were published on websites related to the care of stroke survivors and one researcher was responsible for coordinating the distribution of a large number of flyers to the community. Despite several attempts, advertisement was not a satisfactory recruitment strategy for this population.

Interestingly, of the 150 survivors of stroke who were screened for admission into the clinical trial, 10 (7%) agreed to participate. There is a difficulty to compare this recruitment rate with other studies[11-14], since few studies reported the number of participants screened for eligibility[15-18]. Recently, Cooke et al.[15] reported a 10% rate of recruitment of acute stroke patients for a clinical trial investigating the efficacy of a six-week program of functional strength training on motor function of lower limbs. Unfortunately, the authors did not report the time taken to recruit participants as well as the strategies implemented for this task. Blanton et al.[19] evaluated the aspects of recruitment and retention of participants during a clinical trial investigating the efficacy of constraint-induced therapy in hemiplegic patients after stroke. They screened 3,626 patients in six different cities in the United States of America during a period of two years. Two hundred and twenty-two patients (6%) were enrolled in the study. This recruitment rate was similar to the rate of the current study (7%), although the number of patients screened and enrolled was higher. Importantly, the participants of the cited study were reimbursed per visit for transportation, parking and food. This cost ranged from US$ 20.00 to US$ 50.00 per participant per session.

Once stroke survivors were identified as eligible, a major barrier to recruitment emerged. Of the 35 stroke survivors who were eligible for the clinical trial, 11 (31%) could not participate because of lack of provision of transportation to the site of intervention. This finding is consistent with Rimmer's, Wang and Smith[20] findings on barriers to exercise after stroke. Fifty-seven percent of the patients interviewed did not have any means of transport to an activity center. Providing transport should, therefore, increase the rate of recruitment as well as the attendance at the training sessions[21]. This was found to be the case in another study with stroke survivors which provided funding for transportation, where the recruitment rate was more effective (51%) than in the present study (7%)[22].

Given the barriers experienced in recruitment to this clinical trial, researchers need different strategies in recruiting people from the community. First, a national or state database of stroke survivors willing to participate in research could help recruitment. Researchers also need to ensure sufficient funds to finance staff to carry out the recruitment. Finally, providing funding for transport should increase recruitment rates.

Attendance

This clinical trial showed a moderate rate of attendance. The data from this study has produced important information about the availability and willingness of stroke survivors to undertake exercise in Brazil. The attendance rate of 76% was lower than the rate reported by Ada et al.[23] with an attendance rate of 92%. However, in that study, participants had to attend sessions for a period of only four weeks rather than 10 weeks in the current trial.

A total of 84 sessions were not attended during this study. Thirty sessions (36%) were not attended due to illness or flu symptoms. Two participants were hospitalized for a short duration (1-3 days), one due to respiratory infections (participant 4) and the other due to fall in the domestic environment (participant 10). Falls are a common problem in stroke survivors. Approximately one third of these patients fall within six months of rehabilitation[24]. Therefore, prevention of falls in stroke survivors is critical not only to prevent injuries, but also to ensure that these patients enroll on exercise programs in the community. Participants did not attend 27 sessions (32%) due to difficulties with transportation. To increase attendance at intervention and measurement sessions, provision of transport is essential for conducting this trial.

Adherence

Adherence to the intervention protocol was 97% for all participants and 99% for participants in the experimental group. Obviously, once participants attended the training sessions, they were committed to exercising. Although the intervention was implemented at the individual level, it was common to treat more than one participant at the same time. This means

that there was opportunity for social interaction among participants as well as between family members, caregivers and people from the community. Physical therapists involved in implementing the intervention protocol encouraged each participant individually in an attempt to maintain adherence to the intervention protocol. These strategies may have helped to gain the high adherence rates found in this trial.

A number of barriers were encountered during the recruitment for this trial. The absence of communication between university researchers and stroke survivors living in the community was one barrier. Funding for transport and recruitment personnel should be considered when designing clinical trials with stroke survivors.

The results of this feasibility study served as rationale to request funds to provide participants transportation to the intervention site. The government agency *Conselho Nacional de Desenvolvimento Científico e Tecnológico* (CNPq), Brasília, DF, Brazil, will fund the transportation costs to complete the ongoing trial (Process 4768902010-1 CNPq, Brazil).

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