DOI: 10.1590/1413-81232017221.14262015

Recruitment rate and retention of stroke subjects in cross-sectional studies

Taxa de recrutamento e retenção de indivíduos pós-acidente vascular encefálico em estudos transversais

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Abstract *This article aimed to determine the recruitment rate of chronic stroke survivors to cross-sectional studies and to determine their retention at the two days of assessments. Participants after six months of a unilateral stroke were screened for eligibility and invited to participate in two cross-sectional studies, by telephone. The number of people who were screened, eligible, and successfully recruited was recorded. Retention at the two days of assessments was also recorded. From a list of 654 individuals, 87 were ineligible. Of the 567 left, 216 had wrong contact numbers, 144 refused to participate, and 12 had died. A total of 165 subjects participated in both studies. Out of the 56 who agreed to attend to the second day of assessment, eight did not return. The results showed that individuals with chronic stroke had low rates of recruitment and retention.*

Key words *Stroke, Physical therapy, Cross-sectional study, Patient selection*

Resumo *Este artigo teve por objetivo determinar a taxa de recrutamento de indivíduos pós-Acidente Vascular Encefálico (AVE) em estudos transversais e determinar sua retenção nos dois dias de avaliação, tendo como referencial teórico a Classificação Internacional de Funcionalidade, Incapacidade e Saúde. Participantes após 6 meses a um AVE unilateral foram selecionados de acordo com a sua elegibilidade e convidados a participar em dois estudos transversais, por telefone. Foi obtido o número de pessoas contatadas, elegíveis e recrutadas com sucesso. A retenção nos dois dias de avaliação foi igualmente obtida. De uma lista de 654 indivíduos, 87 não eram elegíveis. Dos 567 restantes, 216 possuíam números telefônicos errados, 144 se recusaram a participar e 12 haviam ido a óbito. Um total de 165 indivíduos participaram dos dois estudos. Dos 56 indivíduos que concordaram em participar do segundo dia de avaliação, oito não retornaram. Os resultados demonstraram que indivíduos pós-AVE crônicos apresentam baixas taxas de recrutamento e retenção.*

Palavras-chave *Acidente Cérebro Vascular, Fisioterapia (Especialidade), Estudos transversais, Seleção de pacientes*

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Introduction

Brazil is an emergent country and is faced with one of the major public health challenges in the world, stroke, which is the leading cause of death and disability in the country[1]. When patients survive a stroke episode they have to keep on living with either partial or complete disabilities, which have a direct impact not only on themselves, but also on their families and society[2]. A previous study reported that the worst the condition of a patient when he starts a rehabilitation program, the longer he tends to stay on the program[3], leading to increased economic demand on public health care services and preventing the enrollment of another patient. Thus, efforts in science have been made to fill the gaps in understanding aspects of stroke rehabilitation. Methodological concerns should be taken into consideration when a research is developed, to provide the best results in terms of avoiding bias and losses of participants. The recruitment is an essential part of the research process, and poor recruitment could result in underpowered results[4]. Additionally, poor recruitment rates could be associated with the length of the study and the increased cost and workload[5].

Farred et al.[6] stated that although the results of clinical trials are used to impact practice with stroke subjects, there is not enough available information regarding the proportion and characteristics of patients recruited for clinical trials. Recently, a study developed in Brazil showed that the retention of stroke survivors in a randomized trial was 76% (SD 23), with the total number of attended sessions being 192 out of possible 276[7]. The most common reported barrier to participate and attend the training sessions was lack of transport[7]. In addition, since in Brazil the individuals are not allowed to receive financial support to participate, i.e., their voluntary nature of participation, in scientific studies according to the Brazilian code of ethics[8], their retention to trials is not entire, even when free treatment is provided during the period of the study.

In this sense, it is possible that the recruitment rates and retention to cross-sectional studies are even lower, considering the lack of direct benefits (no treatment). Although randomized controlled trials are considered the strongest designs, there are specific topics that still need research at cross-sectional levels. At the present moment, there were not found any studies, which investigated the recruitment rate and retention in cross-sectional studies. Thus, the specific research questions of this study were:

1. What was the recruitment rate in cross-sectional studies?

2. What was the retention at the two days of assessments?

Method

Design

This study performed a secondary analysis from the data of two cross-sectional studies with chronic stroke subjects. The first aimed to determine the factors associated with social participation and the second to determine the energy expenditure during daily activities. For the last study, the assessments were performed in two days, seven days apart.

Participants

Individuals with diagnosis of unilateral stroke were recruited from the general community, according to the following criteria: were older than 20 years of age, had a mean time since the onset of the stroke of at least six months, showed clinical signs of hemiparesis, and were able to walk independently, using walking aids and orthoses, if necessary. They were excluded if they had cognitive deficits, as determined by the cut-off scores on the mini-mental state exam[9]; bilateral stroke; and other neurological or orthopaedic disorders.

Both studies were approved by the Institution ethical review board and all participants provided written consent, prior to data collection.

Recruitment

The contact and clinical information of the potential participants were obtained on medical records and lists of previous research projects. The recruitment was performed by telephone by three trained research assistants, when the individuals were informed about the purpose and procedures of the studies, and invited to participate. The assessments were scheduled according to the participants' availability. They also received a phone call from the research assistants one day before the scheduled date, to remind them of their appointment.

In the present study, the recruitment rate was defined as the proportion of invited patients who agreed to participate[7] and the retention was determined by the number of individuals who participated at the two days of assessment[10].

Data analysis

Throughout the recruitment process, the records regarding the number of people, who were recruited and screened for entry to the studies, were kept. If not included, the reason why the individual was ineligible was recorded. Similarly, if eligible, the reason for declining to participate was recorded. The rate of recruitment rate was determined by the number of people, who were contacted and agreed to participate, whereas the retention by the number of people, who were invited and returned to the second day of assessments.

Results

Recruitment rate

The flow of the recruitment process is shown in Figure 1. From a list of 654 individuals, 87 (13%) did not meet the inclusion criteria, for several reasons, such as cognitive deficits, other disabling health conditions, bilateral stroke, or aphasia. Of the 567, 372 (57%) potential participants were excluded for various reasons, including incorrect contact information (n = 216), refusals (n = 144), and death (n = 12). The most frequent reasons for refusals were lack of interest (n = 45), health problems (n = 35), and lack of transportation (n = 29) (Table 1). Out of the 195 subjects, who agreed to participate, 30 did not show up, despite prior confirmation. Thus, 165 subjects completed the first assessment.

Retention

Out of 165 participants, 56 were invited to attend the second day of assessment and 48 (86%) returned.

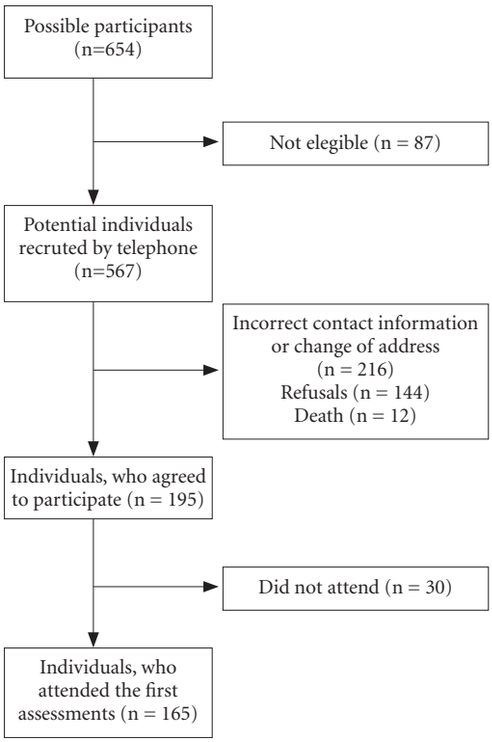

Figure 1. Flow of the recruitment process.

Table 1. Most frequent reasons for participants' refusal to participate in the study (n = 144).

Reasons for refusal	n (%)
Lack of interest	45 (31)
Health conditions	35 (25)
Distance and transportation	29 (20)
Difficulty on locomotion	17 (12)
Lack of companion	6 (4)
Avoidance of getting out of the house	6 (4)
Busy or lack of time	6 (4)

Discussion

To the best of our knowledge, this was the first study that investigated the recruitment rate and retention of stroke survivors in cross-sectional studies. The low recruitment rate (57%) of the eligible subjects was due to two main reasons: Incorrect contact information and refusals. In addition, eight individuals did not return to the second day of assessment. It is important to point out that this scenario reflects, in part, the voluntary nature of participation in scientific studies, since in Brazil the individuals are not allowed to receive financial compensation for participation in scientific studies[6].

This poor recruitment rate is an example of what frequently happens in the scientific world. When factors, such as ineligibility and drop-outs combine, they deeply impact the results, since they might lead, amongst other things, to

invalid or inconclusive results and increase the length and costs of the study[7]. Thus, better understanding regarding recruitment and having a solid strategy, while doing so, is of major importance for rehabilitation scientists, since high recruitment rates are crucial to research and evidence-based practice[11]. For example, even though the researchers from the present study had a long list of contacts (654 subjects), only 25% (165 subjects) of them actually participated, demonstrating the difficulty in carrying-out the recruitment process.

The percentage of eligible individuals (567 subjects), who refused to participate was one fourth of the eligible participants (144 subjects; 25%), which is considered to be a moderate rate of drop-outs. In this sense, the lack of interest appeared to be one of the main reasons for not getting enrolled. This picture was also observed in other two Brazilian trials, which also investigated the recruitment rate and retention with individuals with neurological disorders, even though treatment was provided to the volunteers[7,12]. The first was a proof-of-concept design study with individuals with Parkinson Disease (PD), who were recruited in public health services[12]. The results showed that lack of interest was as one of the main obstacle while recruiting[12]. Similarly, Scianni et al.[7] conducted a clinical trial with acute stroke survivors (< 6 months), who were recruited from physical therapy out-patient clinics. One hundred and fifty stroke subjects were screened for eligibility and 93% refused to participate, due several reasons, such as lack of interest (20%)[7].

Other aspects regarding refusals were related to the comorbidities, impairments, and functional limitations commonly demonstrated by stroke subjects[13-15], which may prevent them from getting out of their house. In a study conducted by Goljar et al.[13], approximately 50% of the participants reported limitations in walking and moving around in different locations. In addition to these changes in functionality, the associated changes with the occurrence of comorbidities, such as hypertension, heart disease, and *diabetes mellitus*[16], which are correlated with functional outcomes[17], could contribute to the refusals observed in the present study.

Lack of transportation was also an important obstacle to the recruitment rate and retention of the subjects[12]. Similarly, Scianni et al.[7] found that 44% of the participants could not afford transportation to the training site. Even though these subjects had experienced the onset of the stroke for a shorter period of time, compared to the current participants, their findings concur with the present results, since problems with transport were frequent reasons for refusals.

Regarding the retention, 14% of the subjects, who agreed to attend the second day of assessment, did not return. Even though this would not be considered a high rate of drop-outs, it is important to consider that eight individuals could not be well assessed. Oppositely, previous studies with stroke individuals conducted in other countries, such as Australia[18] and United States[19] reported retention of 90%. A possible explanation for the drop-outs in the present study could be due to nature of the study design, i.e., the subjects did not receive any sort of direct benefit and, thus, were less motivated. Importantly, at the first contact, all potential participants received information regarding the purpose of the assessments. Although, in the present study, the subjects did not get any financial compensation to get involved, it is important to note that in a previous study which provided reimbursement for transportation, parking, and food (cost ranged from US$ 20.00 to US$ 50.00 per session), low retention was also observed[11].

In this sense, since cross-sectional studies usually tend to show lower retention rates, strategies should be adopted to reduce the drop-outs. A possible way would be providing to the potential subjects information regarding the importance of participating in scientific studies, not only for themselves, but also for the community, besides fulfilling the gap on the patients' knowledge about their eligibility[20,21]. Working together with other health professionals might be, as well, useful to reinforce this idea on a daily basis, since clinicians tend to not refer their patients to participate in research studies[19]. These ideas are reinforced by the findings of previous studies, which observed that the familiarity and trust of the subjects with the researchers[22,23] and the research setting turned out to be successful recruitment weapons[23]. The development of partnerships with the community has shown to greatly facilitate research recruitment[24].

Another important issue that directly impacts the recruitment process and should be taken into consideration while designing any study, is the inclusion criteria. Rigid eligibility criteria usually tend to be major problems for the development of any study, since researchers tend to overestimate the number of participants, according to their characteristics and availability[25]. In the present study, the exclusion of 13% of the potential volunteers due to the cognitive deficits,

other disabling health problems, bilateral stroke, or aphasia, which are commonly observed in stroke survivors, could reduce the external validity of the present findings.

Some subjects could not be contacted, due to incorrect information, as their personal data were initially extracted from the medical records and lists of previous research projects. Hence, 38% of the eligible individuals could not be reached. This might be considered an important limitation of the present study since, 216 potential participants, who could have met the inclusion criteria, could not be reached. In order to have better control over the collection of personal data out of medical records and lists of previous research projects, researchers and health professionals should be careful in doing so. In addition, periodical update of the data is also important, since the individuals can move to other places and change their contacts.

Recruitment and retention are two of the greatest research challenges, especially when dealing with cross-sectional studies, in which the subjects do not get any form of direct compensation to be involved. Low recruitment rates and retention are serious concerns in the scientific world, since they may affect the validity of the observed results[25,26]. Having an organized and well established strategy of recruitment and retention might be possible ways to keep a satisfactory number of participants enrolled. Within this context, efforts, such as specific training of the staff and improving the communication methods with the patients should be made, while recruiting volunteers to improve the external validity of the results[10,27,28].

Conclusions

The results of these two cross-sectional studies with individuals with chronic stroke found low rates of recruitment and retention. Thus, efforts to overcome these problems have to be considered when designing a study.

Collaborations

JC Polese, I Faria-Fortini, ML Basílio e GS Faria worked on the research, methodology, conception and on the final writing. LF Teixeira-Salmela worked on the conception and on the final writing.

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Artigo apresentado em 29/07/2015
Aprovado em 08/10/2015
Versão final apresentada em 10/10/2015