Archives of Gerontology and Geriatrics 59 (2014) 25–31

Contents lists available at ScienceDirect

Archives of Gerontology and Geriatrics

journal homepage: www.elsevier.com/locate/archger

# Strategies to recruit and retain older adults in intervention studies: A quantitative comparative study

Mona Michelet [a,*], Anne Lund [b,c], Unni Sveen [b,c]

[a] Norwegian Centre for Ageing and Health, Vestfold Mental Health Trust, pb. 2136, 3103 Tønsberg, Norway
[b] Oslo and Akershus University College of Applied Sciences, Faculty of Health Sciences, Department of Occupational Therapy, Prosthetics and Orthotics, Oslo, Postboks 4, St. Olavs plass, 0130 Oslo, Norway
[c] Oslo University Hospital, Geriatric Medicine, Pb 4956, Nydalen, 0424 Oslo, Norway

ARTICLE INFO

*Article history:*
Received 17 December 2013
Received in revised form 3 March 2014
Accepted 7 March 2014
Available online 15 March 2014

*Keywords:*
Participation bias
Recruitment strategies
Elderly
Stroke
Dropout
Randomized controlled trials

ABSTRACT

Recruitment and retention of participants in randomized controlled trials (RCTs) drawn from the older population is challenging, and studies have shown that poor recruitment and retention may lead to biased samples and results. Several strategies to improve the participation of older adults in research are outlined in the literature.

The objective was to identify factors associated with participation in an RCT aiming at preventing depressive symptoms and social isolation in a later phase following a stroke, in an older population living in their homes.

Strategies to improve participation were applied in the RCT "Lifestyle intervention for older adults in rehabilitation after stroke: development, implementation and evaluation". Quantitative data collected on participants ($n = 99$) and non-participants ($n = 56$) in the trial were compared using statistical analyses.

The findings are in line with earlier studies in that the participants were younger ($p = 0.01$) and received less help in the home ($p = 0.01$) than did non-participants. The results differ from earlier studies in that participants had a higher rate of depressive symptoms (participation rate was 57% with HAD depression scale score 0–2, 61% with score 3–4, 62% with score 5–6 and 79% with a score 7 or above). The findings also illustrate a poorer health-related quality of life among the participants in the role physical domain on Short Form-36 ($p = 0.01$).

The results indicate that the use of targeted strategies to enhance participation may lead to a less biased sample as well as the inclusion of more subjects who seem to meet the aims of the intervention.


## 1. Introduction

The recruitment and retention of participants in randomized controlled trials (RCTs) is challenging and raises issues of great concern, especially in studies involving the older population (Bayer & Tadd, 2000; Crome et al., 2011; McMurdo, Witham, & Gillespie, 2005). The characteristics of the sample in a given study should as much as possible reflect the characteristics of the population that is the subject of the enquiry. To obtain this, it is necessary to focus also on those who drop out of the studies at different stages and for various reasons. Differences between participants and non-participants might bias the results of an RCT. Biased research may lead to unreliable results, misleading or incomplete evidence (McMurdo et al., 2011). Participation bias is also shown in postal surveys (de Souto Barreto, 2012). Yet, many studies do not account thoroughly for different types of non-participation or discuss the generalizability and external validity of their sample. Thus, there is a need for further investigation into non-participation.

A greater understanding of the factors that lead to or predict non-participation may enable us to identify those at risk of dropping out (Elzen, Slaets, Snijders, & Steverink, 2008; Haring et al., 2009; Jacomb, Jorm, Korten, Christensen, & Henderson, 2002; Slymen, Drew, Elder, & Williams, 1996; van Heuvelen et al., 2005; Young, Powers, & Bell, 2006). Using relevant and targeted strategies to recruit and retain participants may lead to lower

* Corresponding author at: Norwegian Centre for Ageing and Health, Pb 2136, 3103 Tønsberg, Norway. Tel.: +47 91 88 18 65; fax: +47 23 01 61 61.
*E-mail addresses:* mona.michelet@aldringoghelse.no, moic@online.no (M. Michelet).

http://dx.doi.org/10.1016/j.archger.2014.03.002
0167-4943/

drop-out rates (McMurdo et al., 2011; Gardette, Coley, Toulza, & Andrieu, 2007; Treweek et al., 2010), and may also be useful in recruiting and keeping participants in rehabilitation programs and treatment on a general basis. Relevant and targeted strategies should be considered at all stages of the studies, including the design and the approach used in recruiting participants. The traditional means of recruiting participants assumed that people were potentially willing to participate in RCTs, and that non-response to an initial approach could be followed up with further communication. This approach is called 'opt-out', as participants approached in this way actively choose not to take part in the study when they are unwilling to participate. For ethical reasons, the gold standard in recruitment at present is the 'opt-in' approach, where potential participants are informed about the study and then have to communicate their willingness to participate actively; hence, choosing to be included in the study (Junghans, Feder, Hemingway, Timmis, & Jones, 2005; Vellinga, Cormican, Hanahoe, Bennett, & Murphy, 2011). Research has shown that one needs to approach a larger number of potential participants in order to get the required number of participants when applying an opt-in approach, compared to the former opt-out approach (Trevena, Irwig, & Barratt, 2006), and that selection bias can occur with the higher level of consent requirements of the opt-in approach (Buckley, Murphy, Byrne, & Glynn, 2007; Junghans & Jones, 2007; Hewison & Haines, 2006). However, an opt-out approach is often not possible, because of the more stringent ethical regulations imposed in recent years.

The current study is part of an RCT which evaluated the effect of a lifestyle intervention program on well-being, activity and social participation for persons over the age of 65 in a later stage of recovery after a mild to moderate stroke (Lund, Michelet, Sandvik, Wyller, & Sveen, 2012). The main aims of the study were to prevent depressive symptoms and social isolation among older persons with stroke resident in their own homes. The intervention started approximately three months after the stroke. All the participants were offered physical exercise in groups at senior centers once a week, while half of the participants, randomly selected, were to receive a group-based lifestyle intervention program once a week, in addition to the physical exercise. Several strategies were used to improve inclusion and retention in the study in an effort to obtain a representative study sample.

Initially, an opt-out approach could not be used for ethical reasons. Stroke survivors had to consent explicitly before being approached by a researcher and having their medical records read. Thus, in this study of older stroke survivors, inclusion was performed in three steps further described in Section 2, in an attempt to reduce the barriers to participation. The aim of the study was to identify factors associated with participation in an RCT involving older stroke survivors.

## 2. Materials and methods

### 2.1. Strategies used

Throughout the RCT, different strategies to enhance participation were applied in the routines and in communication with the participants. We attempted to lower the demands made on potential participants wanting to opt into the study, by including in three steps, wherein the researchers (AL and MM) initiated the contact at all times. Among the strategies used to retain the participants once they had been included in the study, were: close contact with the recruits being kept by only two researchers; creating a project identity; giving thorough information that is easily understood; as well as running the groups at easily accessible local senior centers, and offering transport.

The inclusion criteria for the RCT were: at least 65 years of age, diagnosed with stroke or TIA, believed to be able to function in their own home eventually, and assumed ability to consent. Subjects who met these inclusion criteria were identified with the help of contact-persons in six hospitals in two communities in Norway. Fig. 1 shows the flow of the participants in the RCT.

Subjects identified by contact nurses at six different hospitals, who met the inclusion criteria, and consented to be contacted, were approached by one of the researchers (AL or MM), were given oral and written information and were asked if they agreed to receive a phone call 2–3 months after discharge. This was the first step of the inclusion, and 204 subjects gave their written consent to be contacted at step 2 (more than 95% of those who were approached). At step 1, participants did not actually consent to take part in the intervention or even the baseline interview, and it was made clear that they could leave the study at any time and that refusal would not result in negative consequences for them. Step 2 of the inclusion took place 2–3 months after step 1, when the researchers contacted the participants by phone to ask if they would take part in a baseline-interview including tests and questionnaires focusing on activity, depressive symptoms and anxiety, health related quality of life and functioning. The final 3rd step was consenting to be randomized into the intervention or the control group.

During the step-wise inclusion, the researchers were able to stay in close contact with the participants and use several strategies to enhance participation. Such strategies are also outlined in the literature (Treweek et al., 2010; McMurdo et al., 2011; Gardette et al., 2007). During inclusion, stressful evaluations were avoided, the information given was clear and easy to understand. Also, attempts were made to create a project-identity for the participants, i.e. by drawing attention to the fact that this project was designed to aid stroke survivors and that the participants could contribute from their own experience as well as benefit personally. After initiating inclusion at step 2, frequent and personal contact was made with the participants with only two researchers working in the project at this stage. To maintain contact, track was kept of those patients who had moved or had stays at rehabilitation facilities. If the participants said they might go on to step 2 or 3, but not at that particular time, permission was asked to call again. When permitted, the researchers initiated all the phone calls, sometimes repeated calls during weeks or months until each participant chose either to be included in the next step, or to leave the study.

Baseline interviews were conducted in the participants' homes, avoiding travel problems for the participants on this occasion. These appointments were arranged taking into account the participants' schedules, i.e. fixed visits from home carers, and written confirmation and follow up calls were made to make sure the appointments were at a convenient time. To reduce the travel distances, the groups were held at local senior centers and every participant was offered transport to get to the centers.

The efforts made to improve participation resulted in 155 participants at step 2 – baseline, and of these 99 also consented at step 3 – randomization. Even if this was not required, most of the 56 who opted out between step 2 and step 3 explained their reasons for opting out, and these reasons were recorded. All the 99 who chose to participate at step 3 are considered as participants regardless of how long they stayed in the project after randomization. All the 56 who left the study at this step were treated as one group in the analyses, regardless of reason stated for not participating.

### 2.2. Measures at inclusion and at baseline (interviews) evaluation

Data for the purpose of the current study were collected at time of inclusion (close to discharge from hospital) and the baseline evaluations (approximately 2–3 months post stroke). All the questionnaires were filled in under the guidance of the researchers (AL and MM), to make sure there were no misunderstandings, and that missing data would be kept at a minimum. At inclusion,