Recruitment methods and yield rates in a clinical trial of physical exercise for older adults with hypertension - HAEL Study: A study within a trial

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Abstract

Background: Although the prevalence of hypertension is high in older adults, clinical trials' recruitment is a challenge. Our main aim was to describe the HAEL Study recruitment methods and their yield rates. The secondary objectives were to explore the reasons for exclusion and to describe the characteristics of participants enrolled.

Methods: This is a descriptive study within a trial. The HAEL Study was a Brazilian randomized two-center, parallel trial, with an estimated sample of 184 participants. The recruitment strategy was based on four methods: electronic health records, word of mouth, print and electronic flyer, and press media. The yield rate was the ratio of the number of participants who underwent randomization to the total number of volunteers screened, calculated for overall, per recruitment method, study center and by age group and sex. Also, we described the reasons for exclusion in the screening phase and for non-enrolled participants, as well as the demographic characteristics of those enrolled. The data are presented in absolute/relative frequencies and mean ± standard deviation.

Results: 717 individuals were screened, and 168 were randomized over 32 months. The yield rate was higher by word of mouth (30.1%) for the overall sample. However, press media contributed the most (39.9%) to the absolute number of participants randomized in the trial. The coordinating and participant centers differed in methods with the highest yield ratios and absolute numbers of randomized participants. The main reason for exclusion in the screening phase was due to physically active status in study seekers (61.5%). Out of 220 participants included, 52 were non-enrolled mainly because did not meet the eligibility criteria (26.9%). Most of the screened were women (60.2%), between 60-69 years (59.5%), and most of the randomized were caucasian/white (78.0%).

Conclusions: Multiple recruitment methods seem to have been an effective strategy. We observed that approximately every four individuals screened, one was allocated to an

intervention group. Even so, there were limitations in reaching a representative sample of Brazilian older adults with hypertension. Data show an underrepresentation of race and age groups.

Registration: This SWAT was not registered.

Keywords: physical activity; randomized clinical trial; lifestyle intervention; recruitment approaches.

Background

The prevalence of hypertension is rising globally[1]. Approximately 30% of the Brazilian population has hypertension[2], and in older adults, the prevalence is twice as high[3]. Structured physical exercise, as a nonpharmacological intervention, brings about cardiovascular health benefits, and is considered a cornerstone for hypertension management[4–6]. Clinical trials are essential to understand the effectiveness of physical activity as part of anti-hypertensive treatments, but few studies were designed and exclusively included older adults with hypertension.

Although the global number of older individuals with hypertension is substantial, clinical trials' recruitment success is not guaranteed. Identifying and recruiting research participants is a common challenge among studies and is considered a determining factor for trial sucess[7]. Especially in some settings, recruiting participants can be an operational barrier to clinical trials, in particular those conducted in developing countries, as financial costs associated with complex and lengthy administrative processes are an additional barrier for trial completion[8]. In addition, the recruited sample is not always representative, and the external validity of clinical trials remains a great challenge[7, 9].

Many recruitment strategies exist to reach out to research participants, and although some previous studies tried to explore these in different fields[10–13], it is not clear what are the most useful. The effectiveness of recruitment strategies depends on population's factors, such as physical, demographic and clinical characteristics, as well as the trial setting and type of intervention[14]. Hence, analyses of the yield rate of recruitment methods may be highly informative for future studies[10, 11, 13], especially those conducted in scenarios in which a low research budget is available.

To share challenges and outputs, our general purpose was to describe the recruitment strategies for the Hypertension Approaches in the Elderly: a Lifestyle Study (HAEL Study) conducted in southern Brazil. Our primary aim was to describe the yield rates, calculated for overall, per recruitment method and study center, and by age group and sex. Also, we calculated the crude recruitment output. Our secondary objectives were to explore the reasons for exclusion throughout the screening phase and for non-enrolled participants post consent signed. Finally, we describe the demographic characteristics of the participants who underwent randomization.

Methods

Study design

This is a descriptive study within a trial (SWAT). We did not register the study previously, although we had pre-planned to carry out this analysis and therefore collected all data related to the recruitment phase. The participants consented to use the data asked during the telephone screening and baseline assessment. The study was approved by the Ethics Committee/IRB from the Hospital de Clínicas de Porto Alegre (CAAE: 62427616.0.1001.5327) and Universidade Federal de Pelotas (CAAE: 62427616.0.2001.5313).

HAEL study *(host study)*

This SWAT is nested within the HAEL Study, which was a randomized, single-blinded, multicenter, two-arm, parallel, superiority trial. The study was designed to evaluate the

efficacy of a combined aerobic and resistance exercise training program on reducing blood pressure levels compared with a control group undergoing health education in older patients with hypertension (≥ 60 years old). The study was prospectively registered (Clinicaltrials.gov NCT03264443), and the complete protocol is published[15]. Recruitment data were collected at both centers where the study was conducted, located in southern Brazil. The coordinator center (CC) was based in Porto Alegre, the largest city in the state of Rio Grande do Sul, at the Hospital de Clínicas de Porto Alegre. The participant center (PC) was based in Pelotas, the fourth most populous city in the Rio Grande do Sul, located 168 mi from Porto Alegre, at the Universidade Federal de Pelotas. The recruitment period was from August/2017 to March/2020. In the PC, the recruitment ended in March/2019.

Sample size

All individuals who were screened for HAEL study eligibility by telephone were included in this study. The HAEL study sample estimation, based on two studies[16, 17], was a total of 184 participants (i.e., 92 per center), for providing power values of 0.79 and 0.92 to detect differences of 2.5 mmHg and 3.0 mmHg between the two groups mean values for the 24-h systolic blood pressure, considering an expected standard deviation of 6.0 mmHg. A two-sided significance level of 0.050, obtained from a mixed-effects model fit without the treatment-by-center interaction, was considered. More details about the sample size calculation are in the HAEL study protocol[15].

Eligibility criteria and reasons for exclusion

In the telephone screening and after signing the consent form, for participants not enrolled, the reasons for exclusion were counted either according to the eligibility criteria or other reasons that were identified during the baseline test period. Inclusion criteria were as follow: 1) Diagnosis of hypertension as assessed by a previous ambulatory BP monitoring (no later than six months) or current use of antihypertensive drugs; 2) Age ≥ 60 years old; 3) Unchanged pharmacological scheme for four weeks prior enrollment; 4) Willingness to participate in either intervention group. Exclusion criteria included 12 characteristics which could increase the cardiovascular risk during exercise (e.g., cardiac event within the 12 recent months) or modify (increasing or decreasing) intervention adherence due to external factors. Additionally, the exclusion criterion "to be physically active" was not described in the study protocol[15], but was considered in the eligibility process. Those who performed ≥ 30 min of physical activity at moderate intensity, at least three days/week, in the last three months before screening were excluded.

Recruitment methods

The recruitment strategy was based on four pre-planned approaches: 1) *Electronic health records from public healthcare units*; 2) *Word of mouth*; 3) *Print and electronic flyer*; 4) *Press media*. For the *electronic health records*, the lists of patients registered in one/two basic care units of the public health system were accessed. The *word of mouth* method comprises word-of-mouth referrals from friends, relatives, or professionals. Professional referrals were considered when specialist professionals (i.e., cardiologists, gerontologists, etc.) indicated the study. The *print and electronic flyer* method corresponded to disseminating flyers with standard information about the research and contact. Flyers were distributed in print on the streets, and flyer posters were hung in pharmacies and

grocery shops. Also, the flyer was released in digital format on social media (i.e., Facebook and Instagram) and WhatsApp Messenger. Finally, *press media* was a method of recruitment through free advertisement in local and widely circulated newspapers. During the telephone screening, potential participants were asked how they got to know the study's recruitment to compute which method reached them. Although the same approaches have been used in both centers, each center was free to decide which methods would be prioritized.

Participants demographic characteristics assessment

Participants fulfilled questionnaires to self-identify their sex (i.e., man or woman), race/ethnic group, and age in years. From the characteristics of the participants, the categories of race/ethnic were created as follows: Caucasian/white, Black/Afro-descendants, Asian, Indigenous, Other/mixed.

Data analysis

Descriptive statistical analyses were used to assess the study results. Continuous data are presented as means and standard deviations. Categorical data are presented in absolute and relative frequencies. We calculated the yield rate by the ratio of the number of participants who underwent randomization to the total number of volunteers that were screened (i.e., yield rate = individuals randomized/individuals screened). Firstly, we calculated the overall yield rate of the trial. Secondly, we calculated the yield rate per recruitment method and study center. Lastly, the yield rate was estimated per recruitment method, stratified by age group and sex. In addition to the yield rate, we calculated the

crude recruitment output by the ratio of who underwent randomization per method to the total number of participants randomized (i.e., crude recruitment output = individuals randomized per each method / total of individuals randomized). Exclusion reasons were counted for all contacts made in the telephone screening and for those who were not enrolled in the study after signing the consent form. We had missing data because some participants refused to answer the form completely during the telephone screening or due to failure to complete it. The missing data were treated as undefined. All descriptive analyses were generated in the software Microsoft Excel, 2016 (Microsoft Inc., Redmond, WA, USA), and IBM SPSS Statistics version 21.0 (IBM SPSS Inc., Chicago, IL, USA).

Results

The study flowchart per recruitment method is described in Figure 1. Throughout the study enrollment process, 717 individuals were telephone-screened for eligibility. On average, over the 32 months of the study, 22 to 23 individuals were screened each month, and five to six were randomized. Most individuals were screened by the CC (487; 67.9%) compared to the PC (210; 29.5%), and 20 (2.7%) had an undefined center. Between telephone screening and face-to-face interviews, 69.3% (CC, n= 326; PC, n=151; undefined center, n=20) were excluded or declined to participate, and 220 (30.6%) signed the consent form. Through baseline data collections and before allocation, 52 individuals were excluded or declined to participate. In total, 168 participants were randomized, 119 (70.8%) in the CC and 49 (29.2%) in the PC.

For CC and PC, 244 (50.1%) and 36 (17.1%) individuals screened were reached by *press media*, respectively. *Printed and electronic flyer* reached 139 (28.5%) and 14 (6.6%) screened individuals, while *word of mouth* reached 92 (18.9%) and 50 (23.8%)

individuals for CC and PC, respectively. *Electronic health records* accounted for nine individuals (1.8%) screened in the CC and 110 (52.4) in the PC.

<<FIGURE 1 HERE>>

Demographic characteristics of enrolled participants

For participants who underwent randomization, the overall sample age range was from 60 to 84 years old and most of them were women (61.9%) and caucasian/white (78%) (Table 1).

<<TABLE 1 HERE>>

Yield rate

The overall yield rate was 23.4% (Figure 2). Separately, the yield rate was 24.4% for the CC and 23.3% for the PC. Twenty and seven individuals had center and recruitment method undefined, respectively, and were excluded from stratified yield rate analysis. The yield rate per recruitment method was higher by *word of mouth* (30.1%) for the overall study and by *printed and electronic flyer* for the CC (25.2%) and the PC (42.9%). The lowest yield rate was by *electronic health records*.

<<FIGURE 2 HERE>>

Yield rate per sex and age range

For 10 and 13 individuals screened, sex and age, respectively, were undefined. Most of the screened individuals were women (432; 60.2%), compared to men (275; 38.3%). Relative to age range, 427 (59.5%) individuals ranged from 60 to 69 years, 221 (30.2%) from 70-79 years, 40 (5.6%) from 80-97 years and 16 (2.2%) were aged out of eligibility, between 42-59 years (Table 2). Thirteen individuals with undefined ages were not counted.

Press media was the method that most reached men (56.0%) and women (31.7%). For women, the method with the highest yield rate *was word of mouth* (32.4%), whereas for men, it was *printed and an electronic flyer* (28.0%). The lowest yield rate strategy was *electronic health records* for both women (15.3%) and men (3.4%). For the age groups of 60-69 years and 80-97 years, the *word of mouth* method had the highest yield rate (34.5% and 33.3%, respectively). The age group ranging from 70-79 years had the highest value with *printed and electronic flyer* (34.1%).

<<TABLE 2 HERE>>

Crude recruitment output per method

The method that contributed most to the total participants who underwent randomization was *press media* (39.9%) (Figure 3). Considering centers separately, for the CC also was *press media* (48.7%), while for PC was *word of mouth* (42.9%). The lowest crude output was *electronic health records* for the overall study (8.3%) and for the CC (0.8%). For the PC, *printed and electronic flyer* had the lowest crude recruitment output (12.2%).

<<FIGURE 3 HERE>>

Reasons for exclusions

Out of 497 (69.3%) individuals excluded between telephone screening and face-to-face interview, 229 (46.1%) did not meet eligibility criteria. The main eligibility criteria that caused exclusion were: 1) To be physically active (141; 61.5%); 2) Age < 60 years old (15; 6.5%); 3) No diagnosis of hypertension assessed according to the study's criteria (12; 5.2%); 4) Myocardial infarction, revascularization procedures, deep vein thrombosis, cerebrovascular events or pulmonary embolism (12; 5.2%). Eligibility criteria were undefined for 15 individuals. Other exclusion criteria, such as cancer, heart failure, pulmonary disease, kidney disease or neurological disease, unwillingness to participate in either one or both of the intervention groups, excessive consumption of alcoholic drinks, or another person from the same household/family participating in the study, were less frequent (i.e., 1 to 6 individuals). Also, 58 (11.7%) individuals were not interested in the study, 59 (11.9%) had pain or physical disability, and 55 (11.1%) had no time available. Other reasons account for 4.4% of exclusions (n=22) and the reasons were undefined for 46 (9.2%) participants.

Reasons for non-enrollment

After signing the consent form and at baseline data assessments, 52 (23.6%) of the 220 participants were not enrolled. Fourteen individuals (26.9%) did not meet the eligibility criteria (i.e., one had individual plans to move to another city during the period of participation; 10 had medical reports indicating moderate or high risk for exercise-related

events based on the initial maximal exercise test and clinical evaluation; three were physically active). Seven individuals (13.5%) had different medical reasons for exclusion, and eight (15.4%) were restrained from continuing the study due to the restrictions of the COVID-19 pandemic. Five individuals (9.6%) had physical disability or pain, five (9.6%) had no time available, and three were no longer interested in participating (5.8%). Other reasons account for 9.6% (n=5) of exclusions, and five individuals (9.6%) had undefined exclusion reasons.

Discussion

The general purpose of this study was to assess the recruitment strategy in the HAEL study. We observed that approximately every four individuals screened, one was allocated to an intervention group. The yield rate was higher with the *word of mouth* (30.0%), but the *press media* had the highest crude recruitment output (39.8%). The highest yield rate approaches were *printed and electronic flyer*, *word by mouth,* and *press media*, in this order, for both centers separately. Oppositely, *electronic health records* was the approach with the lowest yield rate.

Interestingly, *press media* was the main driver of absolute screening and recruitment at the CC, which may be related to: (i) newspapers' reach in which the recruitment was advertised; and (ii) especially due to a highly active support from the hospital's communication division at the CC, which favored the contact with several newspapers. To note, newspapers do not usually charge fees to advertise notes of study recruitment in the state where the study was located. At the PC, the *electronic health records* method contributed to many individuals being screened, which was apparently facilitated by

existing relationships between university researchers and health services professionals, who were more readily engaged to identify potentially eligible individuals.

For the overall study sample, the method with the highest yield rate was *word of mouth*. In addition, by assessing the crude randomization output, which ultimately makes the necessary study sample to be completed, both *press media* and *word of mouth* were important sample sources for CC and PC, respectively. Thus, consistent with previous studies[13, 18], it was essential to use varied recruitment approaches to reach the estimated number of individuals in our trial. We highlight that the *word of mouth* method resulted in a high yield rate as well as crude recruitment output at the PC. This might suggest referrals are relevant and a more effective approach than *press media* in smaller cities.

Some recruitment approaches used in our trial, such as the use of *electronic flyers* or *press media*, were implemented with little initial effort. However, all methods except *electronic health records* required potential participants to take the initiative to contact the research team. This could have biased the sample towards individuals highly motivated to exercise or healthy, which may partly reduce the results' generalizability. Even using three widely disseminated recruitment approaches (*press media, word of mouth, printed or electronic flyers),* approximately 60% of the individuals screened were women and were between 60-69 years old (both sexes), whereas few individuals aged between 80-97 years were screened (n=40) or randomized (n=6). The chance of having health complications and limitations to participate in a clinical trial is greater as aging progresses. Furthermore, older individuals may have more barriers (e.g., regarding willingness or commuting) to take part in clinical trials[19]. Also, most of the randomized participants self-identified as caucasian/white (78%), while a minority were black (16.7%). So, these data show an

underrepresentation of race and age groups that may not properly reflect the target population[20, 21].

The yield rates from recruitment methods differed between sexes, with *word of mouth* resulting in more women being randomized (nearly 1 out of 3), whereas *printed and electronic flyer* resulted in more men (nearly 1 out of 4). It is noteworthy that even using four recruitment methods, *press media* accounted for 56% of screened men. In age groups of 60-69 and 80-97 years, the *word of mouth* method had the highest yield rate, whereas *printed and electronic flyer* achieved higher rates among individuals between 70-79 years. To understand that methods vary regarding sex and age may be useful to targeted recruitment in future studies.

Even using a 32-month recruitment period, the pre-trial calculated sample size (N = 184) was not fully reached, lacking inclusion/randomization of 16 individuals. Based on the CC yield rate (24.4%), roughly 65 additional individuals would need to undergo the eligibility screening. Due to the COVID-19 pandemic, the trial was terminated after a careful assessment that included external advice. However, other difficulties also made the recruitment challenging. The PC found more barriers to carrying out the study and ended the recruitment process sooner than expected. Apparently, barriers were mainly related to the institutional contrasts to support clinical studies, infrastructure, and human resources (team size). We reason that strategies specific to each study center and recruitment monitoring could mitigate these barriers and reduce differences between centers.

The number and restriction of eligibility criteria for clinical trials may limit recruitment[22]. As an attempt to recruit a representative sample, we minimized exclusion criteria to characteristics that would represent a risk factor for exercise. The main reason for exclusion at telephone screening was due to individuals declaring to be

physically active, comprising 20% of the individuals seeking information about the study. Other usual reasons for exclusion were the occurrence of pain, physical disability, and not having time available. Even though the training program allowed some tailoring, depending on the level of physical disability, individuals could not comply with protocol fully, so this was listed as an exclusion criterion. Therefore, anticipating the main sources of exclusions may help to design recruitment notes and objectively address such criteria in eligibility screening.

Finally, almost 25% of the individuals who signed the consent form were non-enrolled. Some individuals showed cardiovascular conditions identified only when the stress test was performed. Other cases were individuals who omitted crucial information during the face-to-face interview, such as being physically active or just leaving the study without clarifying the reason. The non-enrollment of participants is routine in any trial, but it can be disadvantageous as there is an investment of financial and human resources. So future studies may try to refine the initial eligibility process, before baseline testing starts, to avoid wasting resources.

The present study is not free of limitations. First, we have not estimated costs for each method, which is important considering that many groups would face costs to advertise in press media, which was not the case in our trial. Second, although we contrasted methods between centers in this report, there were differences not exhaustively explored regarding the opportunities to advertise the trial in each center. Third, although not related to our methods, we experienced limitations in reaching a representative sample of Brazilian older adults with hypertension. We speculate that with wider access to *electronic health records* we would have reached greater diversity of participants, however, this needs further assessment.

Conclusions

In summary, using multiple methods for participant recruitment contributed to reaching older adults to participate in the HAEL Study, in which calls in *press media* and *word of mouth* were valuable approaches in both study centers. However, none of the methods had visible advantage to yield randomization of older (>70 years old) or black participants. We believe that our experience can help future studies in the physical exercise field, which need to recruit older adults with hypertension.

List of abbreviations

CC: coordinator center

HAEL: The Hypertension Approaches in the Elderly

PC: participant center

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee/IRB from the Hospital de Clínicas de Porto Alegre (CAAE: 62427616.0.1001.5327) and Federal University of Pelotas (CAAE: 62427616.0.2001.5313). The study obtained written informed consent from all research participants.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests. The funders had no role in the design of the study at any stage.

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Authors' contributions

CEB, LPS e DU designed the study, analyzed the data, and drafted the manuscript; DU and SSP were the principal investigators of the study centers; CEB, LPS, BGM, RBM, ENW, MLBG took part in the recruitment screening and baseline assessments; All authors took part in the interpretation of the data, revised critically, and approved the final version of the manuscript.

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Figure 1. Flowchart of the recruitment process for the HAEL Study.

Table 1. Demographic and clinical characteristics of randomized participants.

Figure 2. Yield rate per recruitment method. CC= coordinator center; PC= participant center.

Table 2. Yield rate per recruitment methods by sex and age group.

Figure 3. Crude recruitment output per recruitment methods. CC= coordinator center; PC= participant center.