

Original article

Recruitment of older adults into randomized controlled trials: Issues and lessons learned from two community-based exercise interventions in Shanghai

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Abstract

Background: With the increasing need for high-quality exercise interventions in China, relatively little is known about issues and challenges related to recruitment of older Chinese adults into exercise-based disease prevention interventions. This study aims to describe the recruitment process and outcomes of 2 exercise interventions conducted in Shanghai, China.

Methods: Recruitment information was ascertained from 2 community-based randomized controlled trials for 2 exercise interventions, the first designed to improve health outcomes for older women with knee osteoarthritis and the second to study changes in cognitive function in adults with mild cognitive impairment. Results were summarized in terms of recruitment sources, number screened, screening-to-enrollment ratios, and costs.

Results: Recruitment was primarily achieved through working with local residential divisions (i.e., neighborhood associations and residential committees). Both studies achieved their planned target number of older adults (45 and 46, respectively) within a 1-year time frame, with a screening-to-randomized ratio of 5:1 and demonstrated excellent retention rates (range 87%–93%) at 6 months. The recruitment cost for the 2 studies averaged RMB 189 (about USD 30) per initial recruit and RMB 738 (about USD 119) per participant randomized. Some major issues encountered during the recruitment process included (1) the use of community neighborhoods to support the conduct of the projects, (2) access to participants, and (3) feasibility.

Conclusion: Analysis of the 2 randomized controlled trials has provided valuable insights into the recruitment process and identified resources that can help better planning and recruitment for future interventions. Recommendations aimed at increasing the success of future recruitment efforts are provided.

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Keywords: Community stakeholders; Exercise intervention; Older adults; Participant access; Randomized controlled trial; Recruitment

1. Introduction

With an increase in the aging population and the prevalence of noncommunicable chronic diseases in China,^{1–4} there is an urgent public health need to develop and evaluate interventions that can help prevent the onset and progression of chronic disease in older Chinese adults at risk for health problems. Mounting evidence indicates that exercise can bring about significant health benefits for older adults.^{5–7} In China, researchers in the field of health promotion and disease prevention have recently increased their

efforts to conduct randomized controlled trials (RCTs) of exercise interventions. These RCTs help determine the efficacy and effectiveness of interventions aimed at improving or preventing chronic diseases among older Chinese adults.^{1,8–10}

Despite the growing number of RCTs targeting older Chinese adults, there has been little attention paid to understanding the process by which participants are recruited into these trials. Because the success of most RCTs involving exercise interventions depends primarily on the recruitment and retention of study participants, the extent to which target recruitment and retention goals are met can have a major impact on study costs, outcomes, and subsequent outreach of the intervention to the intended populations.^{11–13} Although the disease prevention literature readily acknowledges the difficulties and challenges inherent in recruiting study participants, especially older adults,^{12,14} knowledge regarding best practices for

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2 reaching populations in China for RCTs involving exercise interventions remains limited. With the pressing need for preventive interventions that might ward off chronic disease and improve the quality of life among older Chinese populations, it is critical that we increase our understanding of how to develop effective recruitment strategies, maximize intervention participation, and ensure the success of interventions.

This article attempts to fill this knowledge gap by describing and analyzing the recruitment process and outcomes of 2 community-based RCTs of exercise interventions involving older Chinese adults in Shanghai, China. In doing so, we summarize many of the recruitment issues encountered and offer recommendations for future studies.

2. Methods

This paper covers 2 previously published RCTs that evaluated 2 distinct exercise interventions conducted in Shanghai between 2012 and 2014. Details of the design, methodologies, and outcomes of each intervention are fully described elsewhere.^{15,16} The protocol for each study was approved by the Shanghai University of Sport Ethics Committee. An informed written consent was obtained from each participant.

2.1. Community neighborhoods and target populations

The study area covered 2 administrative divisions (Wujiaochang Town and Yinhang Neighborhood Association) in the Yangpu district, Shanghai. The 2 divisions comprised 89 residential committees (subdivisions under the jurisdiction of towns or neighborhoods), 10 of which were targeted for participant recruitment by researchers conducting the 2 studies. The selection of these residential committees was based on (1) availability of classroom space for the interventions and (2) participant access to the research facility sponsoring the studies. In both interventions, the town office and neighborhood association were the initial contact points where recruitment approval was sought.

Both trials targeted community-dwelling older adults living in the study area defined. Specifically, the Tai Ji Quan for Osteoarthritis project targeted older women with knee osteoarthritis,¹⁵ whereas the Dumbbell for Healthy Brain project targeted individuals with mild cognitive impairment.¹⁶

2.2. General recruitment strategies

Although most RCTs use either community-wide promotions¹⁷ or referrals for recruiting participants,^{18,19} the 2 studies described here used a top-down approach. That is, local community administrative authorities (i.e., local town offices or neighborhood associations) were first asked for permission to recruit community-dwelling older adult residents living in these neighborhoods.

Once permission was granted from a town office or neighborhood association, recruitment efforts started at the level of local residential committees, which helped coordinate and assist in initial recruitment efforts. Methods of recruitment included phone calls, promotional meetings, in-person contacts, and word of mouth. These efforts resulted in a list of

potential volunteers who expressed an interest in participating. The list was then provided to the researchers, who arranged for screening, recruitment, group assignment, and baseline assessment, all of which took place at a designated research facility. The following provides a detailed description of the recruitment process for each of the 2 RCTs.

2.3. Tai Ji Quan for Osteoarthritis

The local town office was first approached by research staff members, who inquired about the possibility and feasibility of conducting an exercise project in the study area. At the same time, a list of the potential residential committees was compiled in consultation with an administrator, along with information on the number of older adults living in the neighborhoods and the availability of exercise facilities.

After this initial step, research staff contacted representatives at 4 local residential committees to explain the research activities in more detail and to seek permission to conduct the study. After permission was granted, the residential committees, using the recruitment methods described earlier, took the lead in mobilizing the residents at each residential complex by encouraging them to sign up for the research project.

After the sign-up list was generated, research staff used it to conduct a formal prescreening per the study's inclusion and exclusion eligibility criteria. At that time, a medical doctor performed a second screening (including radiography at a local hospital) to verify osteoarthritis. Those who qualified per study criteria were then scheduled to visit a laboratory where the study assessment and intervention activities were further detailed and explained.

On agreeing to participate, each participant signed an informed consent form. Participants were then assigned to either the Tai Ji Quan group or the control group, and a baseline assessment was conducted. A total of 46 participants were needed to achieve an adequate power analysis.¹⁵ To meet this target enrollment number, recruitment was conducted in waves between 2012 and 2013.

Recruitment costs were documented, including project staff time specifically devoted to participant recruitment, diagnosis of knee condition conducted by medical experts as part of recruitment eligibility screening, and remuneration made to neighborhoods and individuals during the recruitment process.

2.4. Dumbbell for Healthy Brain

A recruitment strategy similar to the one used for the osteoarthritis study was used in this study. Specifically, research staff made initial contact with a leader of a local neighborhood association where the study was to be conducted. The leader then contacted 6 local residential committees within the study area and requested that they assist in recruitment for the project. After agreeing to do so, the residential committees took the lead using the recruitment methods described earlier to encourage residents at each residential complex to sign up for the research project.

After a list of potential participants was generated, it was given to research staff members, who made initial contact with

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