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Enrolling Older Adults with Cognitive Impairment in Research: Lessons from A Study of Tai Chi for Osteoarthritis Knee Pain

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Abstract

Exercise is an adjunct intervention for treating osteoarthritis (OA) knee pain, but many elders, especially those who with cognitive impairment, refuse to participate because of their frailty. Tai Chi (TC) is a gentle alternative to Western style aerobic exercise. We report recruitment experience based on elders' comments recorded by the staff and staff's observations/reports in a pilot randomized controlled trial (RCT) using TC as an intervention to reduce OA knee pain in a cognitively impaired elderly population. Challenges in recruitment included issues with retirement apartment site staff, the elders, study criteria or study design, and insufficient research staff. Strategies included networking and staying connected with site staff, using various recruiting approaches, providing incentives/motivation, and using informal leaders or residents as a venue to recruit participants. Finally, modifying strict study criteria, securing staff for recruiting, and considering alternative designs to classical RCT can also assist in overcoming the recruitment challenges.

Introduction

Up to 33% of elders have pain from knee osteoarthritis (OA) (World Health Organization and the Bone and Joint Decade, 2001; Zhang *et al.*, 2001). The rate of OA in elders with cognitive impairment (CI) is comparable to that in elders without CI (The Canadian Study of Health and Aging, 1994), and knee OA pain accelerates CI elders' functional decline (Ng *et al.*, 2006; Spiers *et al.*, 2005). Pharmacological interventions for knee OA pain have limited efficacy (Buffum *et al.*, 2004) and produce severe side effects (Curhan *et al.*, 2004; Desai & Chibnall, 2004; Forman *et al.*, 2005). Studies have shown, however, that exercise generally benefits elders with OA knee pain (O'Reilly *et al.*, 1999) (Thomas *et al.*, 2002).

Tai Chi (TC), a low-impact aerobic exercise and a non-pharmacological adjunct for pain relief, has shown promise in reducing pain in elders without CI (Adler, 2000; Hartman *et al.*, 2000; Lee *et al.*, 2001; Song *et al.*, 2003), and has the endorsement of the United States Arthritis Foundation and the American Geriatrics Society (American Geriatrics Society Panel on Exercise and Osteoarthritis, 2001; Arthritis Foundation, 2005). TC is superior to other forms of exercise for elders because it involves slow stretching of the limbs and trunk and gradually improves muscle strength and range of motion without exacerbating OA pain, as other exercises may do (Kirsteins *et al.*, 1991; Taylor, 2003). It requires less physical strength than strenuous exercise and can be modified to allow physically frail elders to practice in a small space, at any time, individually or in groups, regardless of weather conditions.

Given the high prevalence of CI and OA in elders and the side effects of pain medication, non-pharmacological adjunct interventions such as TC should be beneficial in reducing OA pain in these elders. However, studies investigating the effect of TC on health outcomes have often excluded elders with CI (Li *et al.*, 2001; Song *et al.*, 2003; Wolf *et al.*, 2003). In addition, there are obstacles to motivating elders to initiate physical activity, including their perceptions of the chance of success (such as self-efficacy, perceived control over their health, co-morbidities and other behavioral factors), the perceived importance of the goal (includes beliefs and education and the importance of health), and perceived costs (such as access problems and cost factors related to specific demographic groups) as well as the inclination to remain sedentary (Phillips *et al.*, 2004). There are also obstacles to adherence to an exercise regimen. Self-efficacy is the most important predictor of exercise adherence (Brassington *et al.*, 2002), but elders tend to exhibit less exercise self-efficacy than other age groups (Conn, 1998). If deficits resulting from CI have not impaired elders' ADLs, their level of exercise self-efficacy may not be different from those without CI. On the other hand, elders with moderate to severe CI frequently experience difficulties in ADLs and thus may have low level of exercise self-efficacy, which may prevent them from participating and maintaining a regular exercise program. In addition, their cognitive deficits may interfere with formulating an accurate expectation of ability to exercise. However, no research study has investigated the association between cognitive impairment and exercise self-efficacy. Factors facilitating the practice of TC by the elderly include encouragement from others and positive health outcomes, but many feel too weak to practice (Chen *et al.*, 2001).

Recruitment of elders for a study of TC's effects is a challenge. This challenge is even greater when we need to recruit from among the elderly with CI. No studies to date have reported recruitment issues for a TC exercise study designed for elders with CI. We therefore report our recruitment experience in a pilot randomized controlled trial (RCT) using TC as an exercise intervention to reduce OA knee pain in this neglected population. The information is designed to help others who plan to initiate similar research projects.

Study Methods

This ongoing pilot study, funded by the National Institute of Nursing Research in 2007, is a 20-week cluster-RCT with two arms (TC and attention control) using a convenience sample with mild CI. The study sites are high rise housing facilities, continued care facilities and independent living facilities around Little Rock, Arkansas. We have randomized the intervention by sites. The minimum class size is 5 and the maximum is 10. Inclusion criteria are: 1) age ≥ 60 years; 2) a MMSE score of 18-28 indicating mild CI; 3) diagnosis of knee OA based on medical history reviewed with elders or family members/staff or confirmation from the physician/advanced practice nurse; 4) self-report of knee OA pain ≥ 2 on the Verbal Descriptor Scale, or pain ≥ 3 on the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index pain subscale, indicating mild pain; 5) ability to speak English; 6) physician's/advanced practice nurse's permission to participate; 7) no regular exercise program

in the past one month; 8) ambulation without assistance from staff or a walking device for 50 meters indicating the physical strength to participate; and 9) ability to stand and maintain balance for 1 minute without a walking device. Exclusion criteria are 1) uncorrectable moderate or severe hearing or vision deficits; 2) Parkinson's disease; 3) cancer pain; 4) other severe chronic pain; 5) diabetic neuropathy; 6) arthroscopic surgery or total knee- or hip-replacement surgery in the past 6 months; 7) fractures in the past 6 months; 8) major psychiatric disorder or positive screen for depressive symptoms (GDS-15 score ≥ 5) without taking medication; 9) history of falls in the past 3 months; or 10) vertigo in the past month.

The experimental groups receive three sessions of Sun TC per week for 20 weeks on site (20 to 40 minutes exercise plus a 5-minute rest per session). The attention control activity groups receive information on medical topics and various cultures, play games, make crafts, learn about indoor planting, and share family pictures. We are collecting data on knee pain in both the TC and attention control groups at baseline and then every month for 5 months (T1-T6). Elders' comments regarding participating in the study and reasons for not participating were recorded episodically by the research assistants on 2 documents: the site recruiting summary (6 sites) and individual screening result summary (146 residents). Staff's observations and reports provide additional information on recruitment issues for this paper.

Recruitment results

As of today, we have contacted eight sites and have been given permission to recruit participants at six sites. We have completed four groups (two TC and two attention control), and are working with one TC group at this point. We are recruiting two additional groups from these 6 sites. We have contacted 456 elders through presentations and at information booths. Because an elder may be contacted through both means, the actual number of elders contacted may be less than 456. We have obtained 146 permission slips to contact elders again and prescreen them by asking whether they have knee pain, memory problem and other health conditions related to pain and whether they were able to walk and had recent history of falls. Among these, The informed consent procedure was completed and formal screening was done in 75 elders and we have enrolled 41 in the program. We did not have enough participants at two sites, and thus two participants from these 2 sites were not assigned to groups. We are still actively conducting the study, which will conclude in 2010.

Challenges to recruitment

The challenges to recruitment of elderly with CI are organized into challenges from site administrators and the elderly individuals themselves, factors associated with the study design and project staffing issues.

Site staff

When we introduced our research to site administrators, some of them gave us positive responses immediately. However, there were occasions when we were greeted with less enthusiasm during these initial contacts. In one case, the administrator was new to the position and was fully occupied by administrative duties. She did not want to invest her time and energy doing a study that did not appear rewarding to her. At another site, we were told that the facility was being renovated and could not provide us with the space needed for the project. In addition, the site managers often mentioned that they were already conducting various activities for their residents and they did not find it possible to include our research in their busy schedules. This was especially true when we contacted them during the holiday season. Finally, one facility had an established research relationship with a local hospital, and the administrator felt uncomfortable in allowing a study conducted by a research team from a university with an

affiliated medical center. This sense of competition prevented her from signing up for the study initially.

Elderly individuals

In these facilities, we saw two groups of elders. One group had poor physical function and was home-bound. This group usually did not meet the inclusion criteria for the study. Even if they were eligible, fear of “falling” or “losing balance” often discouraged them from joining the study. The other group was actively involved in various activities, inside or outside the facilities, and they were usually too busy to engage in other activities. Inviting them to participate in a study and allocate time for something new, such as the TC exercise, was difficult. Even if they signed the “permission to contact” slip, it was still a big challenge to get an appointment with them, so that the research staff could visit them and screen them for eligibility.

Although OA pain is one of the most important risk factors for disability (Campbell *et al.*, 1994), OA pain is often overlooked by elders. We have heard residents say that OA pain is a chronic condition and they simply adapt to it. Or they compare it to other severe life threatening health conditions, and decide that OA pain can be dealt with at a later time. Also, elders tend to have co-existing pain conditions that are more severe than the knee pain; the most often mentioned is low back pain and this overshadows the knee pain. For these reasons, the elders we approached might not have found a study focusing on knee OA pain important.

Finally, some elders, especially those with more advanced CI, were hesitant to get acquainted with new faces, including the research team. Some of them did not want to deal with physical activity issues in old age. What we often heard is “I am too old for this.” In addition, some family members had instructed the elders not to pick up the phone or talk to strangers, which added another layer of obstacles to recruitment.

Study criteria

This study is recruiting CI elders who are physically fit but do not participate in any regular exercise programs, have no other severe chronic pain conditions and are willing to let us collect outcome data six times during 5-month period. As noted above, those who are frail usually do not qualify for the study. On the other hand, those who are physically fit often take part in some type of exercise program offered by the facility and/or carry a busy schedule. If elders show interest, the most common reasons for excluding them are severe low back pain and a history of falls. Many elders have severe pain in their lower back, and falling is very common in this population.

The design of the study

Elders might be interested in joining TC, but not the activity group. When we presented our study during recruitment, we stressed the importance of random assignment and stated that participants could not choose a particular group in which to participate. As a result, elders who wanted to learn TC and would not consider doing other activities refused to sign up for the study.

Recruiting elders for a long (5-month) research project has also been difficult. We learned from site managers that many elders preferred to take one day at a time and wanted to prepare their lists of “to-do” things on a daily basis. Thus, some elders refused to participate because they did not want to commit their time for 5 months. In addition, committing a few days of the week during particular hours might complicate their daily schedule.

Research Staffing issue

This is a 2-year pilot research project that employs one full-time and one half-time staff member in addition to two almost 50% (20-25% paid and 25-30% contributed) investigators' efforts working closely with participants. Since we are working with elders at risk of falling, the testing and the intervention require the involvement of 2-3 persons. Thus, devoting one staff member to recruitment in a timely manner is difficult. It took about 3 months for a half-time staff to complete recruiting at one site in addition to her many other duties.

Strategies for meeting the challenges

Networking with site staff

It is important to have staff who are able to gain access to administrators and secure key staff to work within the facilities. In our experience, if our staff had a previous acquaintance with the site administrator or staff, introducing our study and performing recruitment became easier. Sometimes this even helped with recruitment at other sites. For example, as a result of our good working relationship with one site, the site administrator took her own personal initiative to introduce us to other potential study sites. Because of her effort, we were able to secure a site that originally refused to participate given its existing affiliation with another hospital.

Use of various recruiting strategies

We gave presentations and demonstrations to each site since TC was unknown to many elders and our team was also new to them. Demonstrations of TC helped them to visualize what Tai Chi is. The smooth and graceful movements of TC usually attracted their attention immediately and generated great interest. When our research at one site was reported by a local TV station, we used the news footage for subsequent recruitment. This turned out to be a very powerful recruitment tool because it was a piece of information coming from local reporters that elders knew well. This greatly reduced the suspicion they might have had about the research team.

Most facilities had large dining areas, which could be used for a presentation/demonstration. Distribution of flyers a few days before the presentation/demonstration usually helped with turnout. It was also helpful to incorporate the presentation as part of the program in the residents' monthly meetings or special events. However, the presentation needs to be short and quickly get to the point. We have given presentations and demonstrations while elders were having their lunch or dinner in one site. However, it was not encouraged by some administrators because elders wanted to have quality meal time. Some elders did not participate in the meal program offered by the site or in resident meetings and seldom went to the common dining area. As a result, they could miss our presentation and demonstration.

Setting up a booth in a hallway with good traffic either close to the dinner area, the mail box or the parking garage gave residents opportunities to learn about the project and ask questions. We usually set the booth up for a week or more, so the residents could get to know the staff and not feel afraid to talk with staff and ask questions. This also gave us an opportunity to get acquainted with the elders.

Providing incentive/motivation

As noted earlier, some elders were interested in learning TC, but would not join the study if they were assigned to the control group. We thus modified the study to provide a short TC course for those assigned to the control group. This greatly helped our recruitment. Another incentive we provided to participants was a gift card for local stores. While the monetary reward helped to compensate for the time and effort provided by residents, offering the gift cards had no significant effect on recruitment. Finally, some residents signed up for the study in order to help others. We also emphasized this in our presentations.

Use of informal leaders or residents to recruit participants

We found that it was a good strategy to use a participant who was an informal leader to recruit additional participants. In addition, identifying residents who were a part of the study to promote the study greatly improved residents' comfort level talking to us. In addition, their positive experiences with us greatly relieved the uncertainty that other residents might feel about our research activity. However, this only worked for elders without advanced CI. For elders with more advanced CI, the site staffs have introduced the research staff to residents and family members. Meeting with family members to introduce the study to them seem to be more useful for recruiting. When family members approved the study and took the initiative to talk to with the elders, the elders tended to agree with the family members' decision.

Staying connected with people

Staying connected to the residents and all the staff members of a study site helped the recruitment in the long run. Our research team often stayed in one facility more than 7 months. We became acquaintances of many elders and staff members in the facilities. Getting to know staff members-- for example, staff who served the lunch, janitors, activity directors, and receptionists, in addition to the administrator, helped us to identify potential participants since they were working with elders daily. The activity director at one site, for example, has referred several residents for research staff to make contact. In addition, the elders saw that we maintained close relationships with the site staff, and this promoted a sense of family. Our connections contributed to our success in subsequent recruitment in the facility. We found that getting people to sign the "permission to contact" slip became much easier the second time we did recruitment. In addition, the administrators genuinely appreciated our study and offered to help. Their skepticism ceased and they felt we were there to help them.

Revising criteria and considering alternative study design

Because of our strict study criteria in the original study design hindered recruitment, we adjusted some criteria to facilitate the recruitment. For example, we changed one of the inclusion criteria, the MMSE score, from the original 24-28 to 18-28. This helped to enlarge our pool of participants. We also allowed elders with depression ≥ 5 on the GDS to join our study as long as they take medications treating the depression. However, a major problem is that some elders were unwilling to be assigned to the control group. A classical RCT requires participants to be randomly assigned to groups with full compliance, and no missing data should occur (Long *et al.*, 2008). Obviously, this is not always possible with our study population. Although not implemented for the current study, we will consider other alternative options, such as hybrid intervention trials, in future studies. The simplest approach is to ask participants' treatment preference and use this information as a covariate. Other more radical approaches include the "partial randomized preference trial" in which participants who are willing to be randomly assigned are done as usual. For those who are unwilling to be randomly assigned will be assigned to their preference group. There are pros and cons with each hybrid design (West *et al.*, 2008). However, it is important to note that these designs will allow us to estimate the preference effect and the impact of this effect on treatment outcome, which we cannot obtain from a classical RCT (Long *et al.*, 2008).

Securing staff for recruitment effort and training

Funding for additional staff may be one way to speed up recruitment but this was not possible for us. In our case, the two major investigators devoted additional time to the study to allow staff time for recruitment. We recommend at least a research staff with 50% effort should be devoted to this effort for adequately recruiting participants. Adequate research personnel dedicating to recruiting effort should be described and budgeted when applying for funding.

To prepare and train recruiters, assistance from an already trained person is critically important; further the PI should make sure that the recruiters stay focused and motivated.

Conclusion

This is an ongoing study and to date we have recruited 41 participants. Over the last 18 months we have learned that with limited availability of staff for recruitment, it took approximately 3 months to complete recruitment at one facility. Our recruitment strategies included demonstrations and setting up booths, in addition to presentations and flyers. Connecting well with the site administrator and staff and with residents, and using formal and informal leaders help initial recruitment and subsequent recruitment were helpful. Providing a monetary incentive was not as important for the purpose of recruitment as offering a short program of TC to the control group. In recruiting elders with advanced CI, assistance from staff and approval of family are important in order to convince elders to participate. Finally, modifying strict study criteria, securing staff for recruiting, and considering alternative design to classic RCT will promote recruiting.

Physical inactivity is a leading cause of morbidity and preventable death (Schnohr *et al.*, 2003; U.S. Department of Health and Human Services, 2002). Physical activity has many potential benefits, including treatment for various medical conditions, such as cardiovascular disease and osteoarthritis (Hurley & Scott, 1998; Rodriguez *et al.*, 1994). Thus, designing an exercise study that promotes physical activity to prevent or manage health problems is important for the elderly. Paying adequate attention to recruitment is the first step to promote the success of such study programs. TC is an alternative to other Western style aerobic exercise for elders and an adjunct to pharmacological intervention. If TC can reduce knee pain and promote mobility and independence in elderly with CI, we might be able to maintain their functional capacity longer and keep them residing in the community longer.

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