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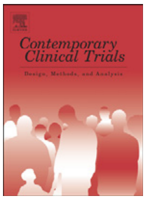

Recruitment issues in a randomized controlled exercise trial targeting wheelchair users[☆]

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ABSTRACT

This paper describes recruitment challenges and lessons learned in conducting a randomized controlled exercise trial in the absence of direct access to a clinical population. One-hundred thirty-five wheelchair users were enrolled in a home and community-based intervention to promote exercise adoption and maintenance. Over 44 months of recruitment, 355 individuals inquired about the study and 323 completed the screening process. Nearly half were determined ineligible (150/323, 46.4%), typically due to having restricted arm movement, cognitive impairment, or medical conditions that are contraindicated for unsupervised exercise. Respondents cited paid media advertisements and recruitment materials placed in health care providers' offices most frequently as being how they learned about the study. RCT participant recruitment, particularly in the absence of direct access to a clinical population, required far more time and resources than anticipated to achieve sufficient enrollment. Nurturing relations with key gatekeepers, creating a visible public profile, and maintaining ongoing recruitment activities were essential to success.

Participant recruitment is essential but increasingly difficult for randomized controlled trials (RCTs) [1–3], causing many trials to proceed without sufficient participant numbers [4]. Avoiding low participation rates, however, frequently requires more resources than initially anticipated [5] — a situation especially problematic in an era of reduced biomedical research funding [6]. Recruitment is particularly challenging for investigators lacking access to a clinical population since a patient's personal health care provider is typically most successful at study recruitment [7]. Despite these challenges, there are limited empirical data on effective recruitment strategies to guide investigators [8]. Moreover, data are particularly limited on recruiting from understudied populations, such as those with disabilities, despite calls for increased inclusion of these populations [9–11].

People with disabilities experience significant barriers to research participation, including lack of transportation [2], complex health problems [12], cognitive impairments or low literacy, and financial stress [7]. Recruiting those with disabilities can be more challenging when studies enroll participants on the basis of functional impairment, rather than by their diagnosis. Many individuals living with disabling conditions perceive their condition-related problems as unique, and seek health promotion information that addresses their specific condition [13]. Similarly, some researchers suggest that patients with disabilities, such as spinal cord injury, have unique needs [2]. Nonetheless, others have suggested that defining intervention groups by "non-disease" commonalities,

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such as mobility impairment, fatigue, or chronic pain, appropriately focuses on general wellness principles rather than specific disease management strategies. [13] Doing so, however, increases the difficulty of identifying and recruiting participants, even when using electronic medical record searches or computerized programs such as Research Match (https://www.researchmatch.org/) developed by the NIH Clinical and Translational Research Award Consortium.

Achieving cultural competence in working with people with disabilities as a minority population also may be critical to recruitment success [12]. Establishing rapport and a sense of collaboration [14,15] and eliminating barriers to research participation [2] can facilitate connections with the target population.

This article describes the recruitment challenges and lessons learned during a large randomized controlled exercise trial for wheelchair users when the investigators did not have direct access to the clinical population. The paper provides evidence for overcoming recruitment barriers frequently documented by researchers when enrolling participants from underserved populations.

1. Background

Recruitment targeting 180 participants began after receiving approval from the principal investigator's institutional Human Subjects Committee (HSC) for a randomized controlled trial to assess a multi-component behavioral intervention for adopting and maintaining exercise among wheelchair users (NIH #R01 HD048628). Recruitment focused on seeking individuals who require the use of a wheelchair as their primary method of mobility outside the home, regardless of the etiology causing mobility impairment.

Specific eligibility criteria included: permanent mobility impairment for ≥six months that necessitated manual wheelchair use outside of the home; sufficient upper extremity mobility for upper body exercise; not regularly physically active in the past six months (assessed by questions regarding participation in moderate and vigorous physical activity over the past six months); physician consent to exercise; between 18 and 60 years old; and able to speak, read, and write English. Exclusion criteria included: body mass index of ≥50 (added after safety concerns were raised given the number of extremely obese persons who inquired); medical conditions their physician identified as contraindicated for unsupervised exercise (e.g., certain cardiac problems, and chronic obstructive pulmonary disease); taking beta-blockers; cognitive impairment that precluded self-directing daily activities; and pregnant, or planning to become pregnant.

Recruitment began in May of 2006. Because none of our interdisciplinary research team is a direct service provider, recruitment required working with clinical providers and other groups in regular contact with the target population. Study information also was broadly disseminated across the metro region.

Initial efforts followed a recruitment plan that anticipated enrolling 60 participants in three cohorts. Experience recruiting for the first cohort, however, led to altering and expanding of the original recruitment plans. The revised plans, vetted and approved by the HSC, included increasing the number of cohorts and altering eligibility criteria. Making these changes early was important for consistent sampling and recruitment over the entire project. The initial small cohort that prompted these changes was designated pilot data to preserve overall project integrity. While beyond the scope of this paper, adding cohorts with differing start dates may have an effect on study outcomes and should be considered when analyzing findings.

Eligibility criteria were revisited to assess what could be changed to achieve a greater sample size without compromising scientific rigor. Issues that resulted in exclusions from our initial efforts were reviewed and four specific criteria were altered. The upper age limit was increased to 65 years, using a powered wheelchair was acceptable if there was sufficient upper arm mobility for exercise, those on beta-blockers with pharmacologically controlled heart rates and physician consent were no longer excluded, and those randomly assigned to the treatment group but unable to attend the one-day workshop were provided a DVD of the content so they would receive the intervention content of the workshop and could remain in the study. To mitigate against creating a selection effect for educational content delivery method, everyone assigned to the intervention arm was strongly encouraged to attend the workshop. Individuals were informed of the DVD only in the event they reported a conflict would prevent their workshop attendance. We then focused on strategies to reduce participation burden and enhance retention. Specific recruitment and retention strategies are described next.

2. Recruitment and retention

A catchy study name (Project Workout on Wheels or Project WOW) and a logo (Fig. 1) were developed for all study materials (flyers, brochures, posters, pens, magnets, and data collection sheets) to establish project identity. Study brochures and advertisements provided a phone number and address for interested individuals to contact study staff. The study brochure included a pre-printed, addressed and postage-paid tear off that could be completed and returned. Upon initial telephone contact, the study was described and those interested in enrolling were formally screened for initial eligibility.

2.1. Recruitment strategies

Recruitment efforts included working with entities that have direct contact with the target population. Strategies ranged from meeting with hospitals, healthcare facilities, healthcare providers, and durable medical equipment suppliers to place posters and brochures in waiting rooms; working with disability service agencies such as independent living centers and social and rehabilitation services to mail study brochures directly to individuals; placing paid advertisements in newspapers, newsletters, fliers, direct mail coupon packets (ValPak), movie theaters, and on metro buses; using media outlets such as television, radio, and the internet; and having project staff attend community events such as health fairs and informational fairs for disability groups. Additionally, the research team built upon ongoing collaborative relationships with local disability leaders developed through previous studies. For example, several