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An exercise trial for wheelchair users: Project Workout on Wheels

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Abstract

There is growing interest in promoting health for people with disabilities, yet evidence regarding community-based interventions is sparse. This paper describes the design details of a randomized controlled trial (RCT) that will test the effectiveness of a multi-component behaviorally-based, intervention to promote exercise adoption (over 6 months) and maintenance (up to one year) among wheelchair users and includes descriptive data on participant characteristics at baseline. Participants were randomly assigned to either a staff-supported intervention group or a self-guided comparison group. The primary study aim is to assess the effectiveness of the multi-component behaviorally-based intervention for promoting physical activity adoption and maintenance. The RCT will also assess the physical and psychosocial effects of the intervention and the complex interplay of factors that influence the effectiveness of the intervention. Therefore, the primary outcome derives from participant reports of weekly exercise (type, frequency, duration) over 52 weeks. Secondary outcomes collected on four occasions (baseline, 3 months, 6 months, 12 months) included physiological outcomes (VO₂ peak, strength), disability-related outcomes (pain, fatigue, participation), and psychosocial outcomes (exercise self-efficacy, exercise barriers, quality of life, depression, mood). This study will provide evidence regarding the effectiveness of a multi-component behaviorally-based intervention for promoting exercise adoption among people with mobility impairments that necessitate wheelchair use.

Keywords

disability; exercise; randomized controlled trial

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Evidence regarding health disparities between people with and without disabilities [1–9], coupled with the Healthy People Initiative [8] and the Surgeon General's Call to Action [10] point to a strong need for developing and testing health promotion efforts for people with disabilities. Physical activity reduces many health risks among the general population [11, 12] and evidence suggests people with disabilities have the same positive response to exercise [13, 14]. Indeed, physical activity may be even more important for this population [13, 15] because of the potential for increasing function and independence through increased strength and endurance [16].

Nonetheless, nearly two-thirds of people with disabilities are not active enough to achieve health benefits [6]. Reasons for this include unique environmental, programmatic, and attitudinal barriers [17, 18] experienced by those with disabilities. Studies of community-based fitness centers report most do not meet all accessibility guidelines of the Americans with Disabilities Act (ADA) [19–21]. Requirements for parking, ramps, and entrances generally are met, but access is poorer to bathrooms and locker rooms; space around equipment is inadequate to accommodate wheelchair users; and adaptive equipment for wheelchair users is rarely available [20]. Other barriers to physical activity cited by people with disabilities include the availability and affordability of transportation, lack of knowledgeable professionals, and lack of financial resources [22–24]. While the benefits of physical activity for people with disabilities are clear, few studies have examined approaches to promote physical activity for this population [25]. Those that report high retention and adherence rates [26–28] provide intensive professional support [27, 28], numerous behavior change strategies [27, 29], and/or transportation to exercise sessions [28]. Given the health benefits of physical activity and the potential to improve function and independence among people with disabilities, additional research is needed to identify successful strategies for increasing physical activity among this population.

The purpose of this paper is to provide details of the design and methods used in a trial that will test the effectiveness of a home-based behavioral intervention for promoting exercise adoption and maintenance among wheelchair users. The intervention was based on Social Cognitive Theory (SCT) [30] and Relapse Prevention (RP) [31]. While RP was originally developed for negative behaviors such as alcohol abuse, it also has been used to maintain positive behaviors such as exercise [32–34]. SCT posits that human behavior is influenced by the interaction of behavior, personal factors, and the environment. Our intervention draws on the following SCT constructs: self-efficacy (having confidence to perform a behavior under various circumstances); self-regulation (bringing behavioral performance under personal control); behavioral capability (recognizing the role of skill development in successful behavioral performance); and the environment (constituting external factors that can facilitate or pose barriers to behavioral performance). The primary study aim is to test the effectiveness of a multi-component behaviorally-based intervention in promoting exercise adoption and maintenance by wheelchair users. Secondary study aims include (1) assessing the physical and psychosocial effects of the intervention as measured by cardiovascular and muscular fitness, disability-related, and psychosocial health outcomes, and (2) assessing the complex interplay of factors that influence the intervention effectiveness.

METHODS

In this 12-month, home-based exercise trial, participants were randomized to either the maximal intervention group being tested (staff-supported) or the minimal contact comparison group (self-guided). The human subjects committee of the sponsoring institution approved the study (HSC #10053) and all participants signed consent forms. The participant consent process was conducted in two stages. We opted for this approach to avoid alerting

participants to the specific details of the two study groups, which we thought might lead those assigned to the comparison group to be disappointed and withdraw from the study. Therefore, after determining eligibility status, participants signed the first consent that covered the general parameters of enrolling in a home-based exercise program, which included a statement that they would be randomized to one of two exercise groups, the procedures for fitness testing and completing surveys, and approval for study staff to obtain medical clearance from participants' physicians. The second consent was signed after randomization, but immediately before baseline testing. This consent provided details regarding the exercise group to which they were randomly assigned. Clearance also was obtained from participants' primary physician before fitness testing and when indicated, a specialist such as a neurologist or cardiologist. Indications for obtaining a second physician's approval occurred when the primary physician requested a second medical provider be contacted or when the potential participant reported cardiac issues for which they were under the care of a cardiologist. Physician re-approval was obtained if participants had a major health status change between testing time points (e.g., hospitalization). To be eligible to participate, all participants had to have signed medical clearance by their primary healthcare provider and two separate study consent forms.

Recruitment

Participant recruitment involved working with entities that have direct contact with the target population and advertising through numerous outlets. Primary recruitment strategies included placing posters and brochures in physician waiting rooms; mailing study brochures directly to individuals; placing paid advertisements in newsletters and movie theaters and on metro buses, television, and radio; posting fliers; disseminating information via direct mail coupon packets [ValPak®], and through project staff attending community events. Organizations that disseminated study information included hospitals, healthcare facilities, healthcare providers, durable medical equipment suppliers, and disability service agencies such as independent living centers and state vocational rehabilitation services. We also employed a snowball technique. Study enrollees were mailed brochures and invited to share study information with wheelchair using friends or acquaintances. They were offered a \$10 store certificate as a small incentive if someone enrolled based on their referral. A more detailed discussion of recruitment and recruitment challenges was previously published [35].

Participants

Individuals interested in the study either returned a postcard with their contact information (i.e., postage-paid tear off portion from the study brochure) or called the study office. During the initial telephone contact all inquirers were provided a brief study description and those interested were screened to determine eligibility. To be eligible, participants had to meet the following criteria:

- a mobility impairment for $\geq$ six months that necessitates manual or powered wheelchair use for mobility outside of the home;
- between the ages of 18–65;
- not currently physically active (report $<$ 150 minutes of exercise a week);
- sufficient upper arm mobility to use for aerobic exercise;
- physician approval to exercise;

Exclusion criteria included:

- body mass index of 50 or higher;

- medical conditions such as chronic obstructive pulmonary disease, liver or kidney disease, or cardiac problems that their physician identifies as contraindicated for participating in unsupervised exercise;
- significant cognitive impairment that precludes ability to self-direct daily activities; and
- pregnant, or planning to become pregnant.

Design

The study used a stratified, randomized controlled trial design. Participants were stratified based upon their disability type (i.e., whether it is stable, episodic, or progressive) and availability of a support partner to assure groups would be equal on factors that may impact exercise adherence. Both factors were assessed during the telephone screening. Disability type was determined by participants' responses to a question regarding their experience with their impairment, "We want to know about the general nature of your disability—since the onset of your disability, have you experienced it as stable (doesn't change much), episodic (occasionally flares up), or progressive (gets worse with time)?" Availability of a support partner was determined based on responses to the following two-part question, "As part of the study, we are encouraging participants to identify a support partner, a person who will support you in your exercise program and perhaps even exercise with you. Can you think of someone who might be a support partner to you?" When respondents indicated yes, we asked, "What is that person's name?" Those who named a support person were counted as having support for exercise.

Randomization occurred after recruitment and eligibility determination, but before baseline testing. To maximize the likelihood of generating equivalent groups based on participants' disability type and availability of a support partner, we stratified participants into one of six groups (e.g., those with a stable disability and a support partner, those with a stable disability and no support partner, etc.). We then randomly assigned participants to either the self-guided comparison group or the staff-supported intervention group within each of the six strata. While all fitness testers were blinded to group assignment, due to the nature of the intervention, the study staff delivering the intervention could not be blinded to group assignment. However, they were not involved in assessment of any outcome measures.

Exercise Groups

We chose to compare our intervention group to a minimal contact comparison group, rather than a no active intervention group, because of recruitment and retention concerns. Refusals and attrition are often high for exercise trials when assigned to a no exercise group. While others have used a wait-list control design, we believed the delay would negatively impact individuals' decision to remain in the study. When responding to an invitation to join an exercise trial, most people are at the action stage of change and ready to initiate an exercise program. We wanted to avoid the potential scenario of participants' becoming impatient waiting, feeling discouraged, and withdrawing before moving into the intervention phase. Therefore, we decided to provide the comparison group with a minimal intervention that relied primarily on sending educational materials and providing attention, recognizing this creates a tougher test of our intervention. We hypothesized that providing this content to a comparison group, combined with the initial motivation to start an exercise program, would motivate participants in this group to begin exercise, but that it would not be sufficient to sustain their exercise for a year.

The intervention approach was designed to reduce barriers to exercise that are common among people with disabilities (i.e., transportation [36], environmental, and physical

limitations such as an inability to use their legs). To address transportation and cost barriers we allowed participants to exercise in the location of their choice (home, neighborhood, or community) rather than to convene exercise classes at a central facility. Permitting participants to select the location, time, and activity type also was intended to increase the likelihood that they would choose exercise that was appropriate for their functional limitations, that they enjoyed, and that would fit with their schedules.

Several features distinguished the two groups, but the primary between-group differences related to behavioral skills taught and the intensity of support provided for exercise adoption. The specific components provided to each group are described later; this section describes common features provided to both groups. Both groups received binders that contained written information about the importance of exercise, a booklet specifically designed for people with disabilities describing how to start an exercise program, a list of community recreation facilities in the metro region, and latex-free elastic bands of increasing resistance along with pictorial and descriptive information about how to use them for strength training. All participants were asked to self-monitor their weekly exercise participation by completing study logs and all received regular phone calls. Self-monitoring is described in greater detail in the measures section below, but served as both an intervention component and strategy to collect participant self-reports of weekly exercise. The phone call content differed between groups and is described separately for each group. In addition to staff contact via telephone calls, all participants received mailed greetings from the study staff as a strategy to maintain positive rapport—a birthday and a holiday card and acknowledgement for various life events if the staff knew about them (e.g., weddings, births, hospitalizations, employment status changes, or deaths).

The 12 month study was designed to have a six month active intervention phase and a six month maintenance phase during which participants would continue their exercise program and weekly monitoring but would not receive telephone contact or support for exercise. All participants were asked to perform moderate-intensity aerobic exercise and strength training over 12 months and to incrementally increase the frequency and duration of these sessions. Participants also received a brief orientation regarding elastic band use for strength training during their baseline fitness testing appointment. This session taught participants to hold and secure the bands, perform several strength exercises, and practice using the bands.

Staff-supported intervention group—The staff-supported intervention group components were based on Social Cognitive Theory and Relapse Prevention Theory and were designed to increase participants' knowledge of and self-efficacy for exercise, as well as their behavioral capability and self-management. Participants first attended a day-long **educational workshop** designed to increase their knowledge and behavioral capabilities specific to exercise. A professional patient educator from one of the nation's model spinal cord injury centers, who is a physically active wheelchair user, conducted the workshop. Attendees learned about the importance of exercise for health, types of exercises people with disabilities can perform, disability-specific exercise barriers and strategies to overcome these barriers, and self-management techniques (e.g., goal setting, self-monitoring). Attendees engaged in a short, moderate intensity aerobic exercise session and were provided an opportunity to use elastic bands for strengthening. They were taught self-management skills and received relapse prevention training. Attendees also participated in a 60-minute breakout session for developing their individualized exercise plan. Transportation costs were covered and attendees were provided lunch. If schedule conflicts prevented in person attendance, a DVD of the workshop content was provided. The DVD featured the same patient educator who led the in-person workshop and the breakout session content was covered by telephone for DVD recipients ($n=15$.)

During the workshop, intervention specialists presented content in small groups (2–4 people) and then worked one-on-one with each participant to develop an individualized exercise plan. During **goal setting**, participants documented where (exercise location), when (days and times during the week), and for how long (duration) they would exercise (aerobic and strength) each week. Participants were encouraged to set realistic goals based on their current activity level, schedule demands, and access to activities. The intervention specialists also stressed that participants should slowly increase the duration and frequency of exercise over time and revisit their exercise goals as needed. Additional goal sheets were provided for this purpose. Participants also completed **Relapse Prevention** sheets that required writing down high risk situations when they would not exercise and creating an action plan to get back on track. Participants also completed support sheets to identify other people (e.g., family or friends) who might **support their exercise efforts** and to specify what each person could do to provide support.

Exercise support throughout the study was provided by intervention specialists who were graduate students in clinical disciplines (psychology and social work). Training for these specialists included a session on clinical skills used to promote behavior change and ongoing consultation and feedback with a clinical health psychologist with experience delivering clinical guidance to individuals undertaking health behavior change. Participants received regular phone calls from the intervention specialist to support their exercise program. Calls occurred weekly for 2 months, every other week for months 3 and 4, and once a month over months 5 and 6. Calls were scheduled as a standing appointment, with flexibility to accommodate schedule changes as needed. These calls provided support for exercise, assistance with problem solving, and gentle guidance to resume progress if and when necessary. The calls followed a semi-structured format with 11 targeted topics (refer to Table 1 for the topic list) to address at some time over the 15 scheduled calls. The scripts for specific topics were flexible to maximize callers' ability to meet individuals' experiences and needs during each phone call. In addition, callers either thanked participants for returning their weekly exercise log or reminded them to do so and asked about the occurrence of any new exercise-related injury.

This intervention group also received **monthly newsletters** by mail. Each two-page, color newsletter contained four articles. Page one featured an article focused on an aspect of starting and sticking with an exercise routine (topics listed in Table 1) accompanied by an article that highlighted an aerobic activity, a resource, or equipment accessible for wheelchair users. Page two profiled active wheelchair users who described what they do for exercise, how they got into that activity, and the benefits they experienced from being active. Another article provided a brief summary of a useful resource for wheelchair users, which did not necessarily relate to being active. All newsletter content was written by the study staff.

Self-guided comparison group—Participants assigned to the comparison group did not attend the educational workshop and received a minimal contact, self-guided intervention. This included both educational content and telephone calls. Participants in this group received the same printed educational materials provided to the staff supported intervention group. However, participants received this binder through the mail and were oriented to its content during a single phone call.

Participants in the self-guided comparison group received regular **phone calls** from an intervention specialist provided on the same schedule as for the staff-supported intervention group to provide comparable staff attention to that given to the intervention group. These calls also were arranged as standing appointments, with the flexibility for changing as needed. The group's initial call was more extensive than subsequent calls, to accommodate

orienting participants to the educational binder content. However, subsequent calls were limited to 1) thanking the participant for returning their log or requesting return of a missing log and 2) inquiring about the occurrence of exercise-related injuries that may have happened since our last contact. Callers were friendly, but kept conversations to a minimum as they were instructed not to provide support for exercise during these calls. When necessary they deflected comments soliciting support for exercise by stating, “Unfortunately, the study protocol does not allow me to discuss that.” However, to maintain a positive rapport with participants assigned to this group, callers were encouraged to resonate with participants’ feelings or experiences when shared. For example, a caller’s response in a situation where a participant reported their father was admitted to the hospital would be, “I’m so sorry to hear that, it sounds like you are going through a difficult time.”

Outcome Measures

The main outcomes to be assessed are changes in participant self-reported exercise (validated with actigraph measures), physical fitness (aerobic/muscular), and self-reported perceptions of exercise and health. The frequency and timing of data collection is presented in Figure 1. Testers were blinded to group assignment.

Self-reported weekly exercise—Participants’ binders included 52 weeks of pre-printed exercise logs. Logs were printed on non-carbon copy paper, to allow for a replica of each completed sheet and both copies were pre-labeled with the study week and date. Participants returned one copy of their exercise log in a pre-addressed, postage-paid envelope to the study office and kept the other for their records. To increase the return of exercise logs, participants received a \$5 store coupon on five occasions (months 2, 4, 6, 9, and 12) if compliant with returning logs and received phone and mail reminders for late or missing logs. Staff requested return of missing logs during regular phone calls and mailed reminders for up to three consecutive weeks. Post cards were sent for two weeks and a formal letter was sent the third week to encourage log return. Those noncompliant beyond three consecutive weeks were not sent further reminders, and data were considered missing.

All participants received instruction for completing the exercise logs. The logs provided space to record daily the type and duration of aerobic exercise, exercise heart rate, rating of perceived exertion (RPE, [37]) for aerobic activity, whether they engaged in strength training and the associated effort (i.e., low, medium, and high), and mood ratings (positive and negative). Participants reported weekly whether they received support for exercise from a family member/friend, from the study staff, and whether they experienced any disability-related health problem. The logs also had space for writing open-ended comments, where they could report an array of issues, including their reasons for not exercising, notes to their caller, information about life events, or positive effects of exercise. To increase participant accuracy in recording their exercise heart rate, participants received instruction to measure their pulse at the radial or carotid sites during the initial fitness test appointment, with opportunities to practice and receive feedback to increase their accuracy. This helped participants obtain their exercising heart rate values at home. Training included participants’ taking one resting and two exercise heart rates while wearing an electrocardiogram lead (EKG) or Polar monitor so their measurement accuracy could be determined. Study testers provided feedback and additional opportunities for practice if needed. Due to the potential for inaccurate self-reporting, actigraph monitors were provided to participants on three occasions (in first 3 months, again around 6 months, and finally at 9 months) during the trial to assess validity between self-reported exercise minutes and objective movement counts.

Physical Fitness—Fitness testing was conducted in the exercise lab of a university based General Clinical Research Center within the medical center. Testers were blinded to group

assignment and worked in separate buildings from the staff who delivered the intervention. Testing was scheduled for baseline, 3 months, 6 months, and 12 months after program initiation. Participants received \$25 for completing each testing session and those who attended all four test periods received an additional \$20 at the final appointment. Transportation costs were covered either by participant reimbursement for mileage to/from the testing site or through study-provided taxi service. Just over half of the sample did not drive themselves, and nearly one-quarter (21.1%) used the staff arranged transportation option at least once.

Body **weight** was measured using an accessible Seca scale (Seca #664). Participants were weighed in their wheelchair and then their chair was weighed separately to subtract that amount from the first weight.

Participants with medical clearance to perform the **maximal strength** test and who reported no shoulder, elbow, or wrist pain or injuries completed a one-repetition maximum bench press. Before the test, participants warmed up on an arm crank ergometer for five minutes, and cranked at a speed of 50 rpm at 10 watts. A metronome set the pace at 50 rpm, which also provided practice for maintaining the 50 rpm cranking pace used for the aerobic test. Participants then transferred to a mat table and laid down to perform the bench press with the aid of a Smith machine. The Smith machine allowed participants to lift the weight bar vertically between two steel rails and has safety stops that stop the bar at approximately 12" above the mat table, well above the participant's chest. A tester stood on either side of the participant to load weight plates, assisted participants by raising the bar to an appropriate starting height and lowering the bar after the lift, and monitored form and other safety issues.

Participants received instruction on safe lifting techniques and performed one practice lift using only the weight bar (50 lbs). Those unable to start at that weight ($n=14$), used a lighter 15 pound weight bar onto which additional weight was added. Participants then rated how challenging the lift was based on a 1–10 scale (1=very light effort, 10=maximal effort) to help determine their starting weight. Participant rating and tester's observation of their difficulty with the lift were used to select the starting weight. Participants rested one to two minutes between lifts. Lift attempts with increasing weight continued until the participant was unable to complete the lift using the proper technique or based on their report of being unable to continue. Testers added weights with the goal of completing the test in 3–5 lifts. Starting weights at subsequent test periods were determined based upon the participant's previous highest weight lifted and self-reported condition of their shoulder, elbow, and wrist joints.

Participants whose physician provided medical clearance to perform the **peak aerobic capacity test** completed a graded discontinuous arm crank test on a SciFit Pro I Upper Body ergometer. The electrocardiogram was monitored continuously and an Advanced Cardiac Life Support (ACLS) certified staff was present for a peak aerobic capacity tests. A medical monitor was available during exercise testing for participants with moderate or high risk for cardiovascular events as determined by American College of Sports Medicine (ACSM) standards[38]. Participants performed the test from their wheelchair, with the ergometer adjusted to assure proper biomechanical positioning for the torso and arms. The electronic metronome helped participants maintain cranking speed at 50 rpm, and the tester urged them to speed up or slow down as necessary. The test included a one minute warm up at 10 watts with two-minute progressive increases of wattage until participants became too fatigued to continue or the test was terminated due to an adverse physiologic or orthopedic response. Ratings of Perceived Exertion, using the 11 point Borg rating scale [37] was assessed during the last 30 seconds of each stage and blood pressure was measured every 4 minutes at the

end of every other stage. Blood pressure measurement required that participants stop cranking so the tester could manually obtain their brachial arterial pressure in the right arm. The tester then assisted participants to resume the 50 rpm crank speed at the increased wattage. Work load was increased incrementally to achieve volitional fatigue within 8 to 12 minutes. Oxygen consumption was measured continuously using a ParvoMedics' True One® 2400 metabolic cart calibrated according to the manufacturer's instructions. The highest oxygen consumption observed was considered peak aerobic capacity.

Aerobic exercise target heart rate zones (THR) were calculated using the heart rate reserve method: Heart rate reserve (HRR) = maximal heart rate (MHR) – resting heart rate (RHR). MHR was determined using one of two methods: 1) the individual's maximal heart rate achieved during baseline aerobic capacity testing, or 2) estimating maximal heart rate based on $220 - \text{age}$. Once an individual's MHR was determined, THR was calculated within a range of 55–75% of HRR plus RHR.

Self-reported perceptions of exercise and health—Participants completed paper and pencil surveys at each of the four testing periods (baseline, 3, 6, and 12 months). Surveys were mailed before fitness appointments to be completed at home and returned at the appointment. **Demographic** data were collected at baseline and included the respondent's birth date, sex, race, ethnicity, primary etiology of their mobility impairment, date of impairment onset, marital status, education, employment status, healthcare coverage, and income category.

The **PARTS** [39] was developed to evaluate mobility-impaired individuals' participation in daily life. The PARTS measures participation in 5 domains (personal care, moving around, work-related, recreation/leisure, and social activities) and assesses multiple components of participation (temporal, evaluative, health-related limitations, and support required to engage in events). We modified the PARTS question structure to ask only four of the nine questions per item for this study to capture areas most likely to be affected by the intervention: time spent in the activity per day, satisfaction with performance, how much help was needed from another person, and how often special equipment was used. These items provided measurement of three components of participation: temporal (frequency and duration), evaluative (choice, satisfaction, and importance), and support (help from someone else or assistive devices). These three components were combined into a total participation score.

We also created a **disability severity index** using participant reports of degree of assistance needed (1) from someone else or (2) with assistive equipment to perform seven personal care activities (grooming, dressing, bathing, meal preparation, eating, bladder care, bowel care). Participant responses were recoded to generate a score (0=no help, 1= some help, 2=a lot of help) on each of the 14 questions. These scores were then summed to create a severity score, the scores ranged from 0 to 28, with higher scores indicating greater severity based on needing more assistance. We used the following ranges to indicate disability severity: 0–9 requires little assistance and low severity, 10–18 requires moderate assistance and moderate severity, and 19–28 requires substantial assistance and high severity.

The 18-item **Lee Fatigue Scale** (LFS)[40]measured perceived fatigue. Scale items were rated from 1 to 10, anchored with extremes relevant to the specific items, e.g., 1 'not all tired' to 10 'extremely tired.' The LFS was developed for use in sleep disorder research and originally used a visual analog scale. It has been used subsequently with a numeric rating scale and in a variety of populations with various chronic diseases. It has demonstrated strong internal consistency reliability (Cronbach alpha of .91–.96 across different populations for both the full scale and the subscales[40, 41],and good sensitivity to

discriminate within subject changes. Concurrent validity has been demonstrated with high correlations between the LFS and the Stanford Sleepiness Scale [40] and the Profile of Mood States [40, 41].

The two item **Bodily Pain** subscale from the Short Form-36 [42] also was used. The items asked how much bodily pain has been experienced in the past four weeks and how much pain interfered with their normal work (both outside and inside the home). Responses were scored on a Likert-type scale ranging from 'none' or 'not at all' to 'very severe' or 'extremely severe.' Scale scoring followed the traditional scoring of the SF-36.

The 20 item, self-report **Center for Epidemiology Scale for Depression (CES-D)** measured depressive symptomatology [43]. Participants rated how often over the past week they experienced each of 20 symptoms on a 4-point Likert-type scale ranging from 0 'rarely' to 3 'most of the time'. Although the CES-D was originally designed for general population use, it has also been extensively used with well and chronically ill populations [44]. Psychometric evaluation supports use of the CES-D with people with physical disabilities [45].

The 66-item **Quality of Life Index (QLI)**[46] measured participants' self-rated quality of life by assessing their *satisfaction* with and the *importance* of 33 life areas in four domains: health and functioning, psychological/spiritual, social and economic, and family. Scale items were rated on a 6-point Likert-type scale. The satisfaction scale ranged from 1 'very dissatisfied' to 6 'very satisfied' and the importance scale ranges from 1 'very unimportant' to 6 'very important.' The satisfaction ratings were weighted by the importance ratings to yield a total quality of life score and a score for each domain. The QLI has high internal consistency across healthy and ill groups (Cronbach alpha of .93 and .90, respectively) and strong test-retest correlations (.81 over 2 weeks and .87 over 1 month) [46]. The scale has been widely used in the general population and among people with various chronic illnesses, including mobility-limiting disorders such as spinal cord injury, multiple sclerosis, and stroke, and has been found to have strong psychometric properties [47–49], including sensitivity to change [50–52].

The 42-item **Inventory of Felt Energy and Emotion in Life (I FEEL)** assessed general positive and negative affect[53]. The I-FEEL referenced the last two weeks, and asked participants to rate how they felt on 42 single-words (e.g., 'happy') or short phrases ('like no one likes me') using a 7-point Likert-type scale ranging from 1 'not at all' to 7 'all the time.' The I FEEL assessed feelings of loneliness, negative self-evaluation, somatic complaints, lack of energy, and various anxiety dimensions (hostile anxiety, fearful anxiety, and nervous anxiety). The I FEEL also assessed positive affective states such as feelings of social connectedness, active energy, calmness, and positive self-evaluation. Each dimension has demonstrated high levels of internal consistency (Cronbach alpha of .83–.95 with a median of .91). The dimensions also have demonstrated high-levels of concurrent and predictive validity [54].

Participant self-reports of engaging in **moderate and vigorous physical activity** were obtained using several physical activity questions from the Behavioral Risk Factor Surveillance Survey [55, 56]. Participants reported whether they engaged in moderate and vigorous physical activity and how many days per week and minutes per day they did so. The scale allowed for calculating the total weekly minutes spent in moderate and vigorous activity.

The 16-item **Barriers to Exercise for Disabled Persons (BHADP)**[57] measured exercise barriers, including those of concern to people with disabilities. Participants rated how frequently each issue interferes with their health on a 4-point Likert-type scale that ranged

from 1 'never' to 4 'routinely.' The BHADP has high internal consistency (Cronbach alpha of .82) and good discriminant validity between individuals with and without disabilities [57]. Factor analysis resulted in two subscales, the Motivation subscale (Cronbach alpha of .81 for 7 items) and the External Barrier subscale (Cronbach alpha of .69 for 9 items).

The **Self-Rated Abilities for Health Practices Scale (SRAHP)**[58] assesses a variety of health practices among people with disabilities (exercise, nutrition, health practices, and psychological well being) and includes issues of specific concern to a disabled population. We used only the 7-item Exercise subscale. Items were rated on a 5-point Likert-type scale, ranging from 0 'not at all' to 4 'completely', and scores ranged from 0–28 with higher scores indicating higher exercise self-efficacy. The scale has demonstrated high reliability and validity for those with and without disabilities[58]. Internal consistency among people with disabilities was high with Cronbach alpha of .94 for the total 28 item scale and .89 for the Exercise subscale. Test-retest reliability was acceptable with Pearson correlation of .69 between two week administrations of the Exercise subscale. Convergent and divergent validity of this scale have been established with the Health Promoting Lifestyles Profile [59] (Pearson correlation of .69) and Barriers to Health-Promoting Activities Scale [57] (Pearson correlation of $-.55$).

Safety Monitoring

To assure participant safety, everyone was regularly asked to report exercise-related injuries by phone and on their exercise logs. During the six month active intervention, participants were explicitly asked over the phone whether they experienced any exercise-related injuries since the last conversation and they were reminded to record this information weekly on the exercise logs. During maintenance (months 7–12), participants continued reporting events on their exercise logs and completed Health Event forms monthly. All health events reported, regardless of their relation to exercise, were reviewed by the study safety monitor and principal investigator.

Treatment Fidelity

Fidelity of intervention delivery will be assessed by tracking workshop attendance by those in the staff-supported treatment group, phone call delivery for both groups, and provision of exercise support to the staff-supported treatment group and not provided to the self-guided comparison group. Phone call tracking includes the number of call attempts, number of calls completed, percent of completed calls, number of scripted topics delivered, and percent of scripted topics completed for the staff-supported group. All phone calls were audio recorded with participants' permission to assess provision of exercise support. Reliability of appropriate exercise support provision will be conducted by listening to a random sample (30%) of each intervention specialists' calls.

A Priori Power Analysis

Our power calculations were based on similar studies reported in the literature [60–63] and on results from a previous pilot study [29]. From these sources, effect sizes were observed in the small to large range (Cohen's d of 28–1.03) and we noted that the small effect sizes were for non-central outcome measures (e.g., VO_2 max. which had a median effect size of .39). For variables that are similar to our primary outcomes (e.g., physical activity, activity adherence), the median effect size was relatively large ($d=.69$). Given the several design features of our study, such as regular contacts, no wait-list control to delay intervention participation, monetary incentives, and overall validity improvements of the measures, we anticipate that the effect sizes obtained for the intervention will be at least as large as these rough estimates.

We estimated that the sample of 180 participants would be adequate to maintain 80% power for addressing our study aims. For mixed modeling, power of 80% or greater was expected to be achieved with effects greater than .44 (a reasonable, clinically meaningful effect), a conservatively assumed high correlation of .70 among repeated measures (higher correlations generally yield lower power when other conditions are the same), and attrition rates as high as 37% (i.e., complete data on at least $n=113$) (see [64]). With an attrition rate of 13% (i.e., complete data on $n=156$), which is about the typical attrition rate reported in the literature for studies that include regular follow-up contact, the minimum detectable effect size was .37. These estimated effect sizes are smaller than the effect sizes we anticipate for the intervention. For structural equation modeling (SEM), our planned models were expected to provide greater than 80% power for rejecting the null hypothesis of acceptable fit (RMSEA of .10) in favor of close fit (RMSEA of .05) with the complete data on as low as 150 participants (> 13% attrition rate) (see [65]).

Proposed Data Analyses

We will analyze our longitudinal data using mixed modeling (also called hierarchical linear modeling) to handle non-independence of the data, where the intervention outcomes were repeatedly measured over the six month exercise adoption period and following the six month maintenance period. We will simultaneously estimate the error covariance components, growth trajectory (i.e., linear change over time), and intervention effect (i.e., group contrast) on each of the primary and secondary outcomes. Health event (yes/no) and season (Spring/Summer/Fall/Winter) will be considered model covariates to account for differences in these factors and thereby further increase power to detect the intervention effect. We will also conduct two-group, longitudinal SEM analyses to assess the complex interplay of factors that influence the intervention effectiveness. More specifically, an individual differences model will be fitted to examine the mediation relationships (i.e., indirect paths) among self-efficacy, perceived barriers, disability-related health outcomes, and physical activity adoption and maintenance. This multiple-group approach provides the advantage of using the statistical power of the whole sample while allowing us to make direct comparisons between the intervention and comparison groups.

We will use maximum likelihood (ML) estimation algorithms for our intent-to-treat analyses with the incomplete data—restricted maximum likelihood (REML) for mixed modeling and full information maximum likelihood (FIML) for SEM. The theoretical benefits of ML estimation are widely known [66, 67] and empirical studies have shown that ML estimation accurately recovers the missing information due to attrition or nonresponse, especially compared to ad-hoc missing data techniques (e.g., list-wise or pair-wise deletion; citation, 2010). Prior to analysis, we examine whether the patterns of missing observations were associated with demographic characteristics or other attributes (i.e., the MAR missing data mechanism). Following Enders (2010), we found no evidence of NMAR and conducted all analysis under MAR and MCAR missing data assumptions.

Baseline Findings

Three-hundred and fifty-five individuals were screened and 173 were determined to be eligible (refer to CONSORT, Figure 2). Of these, 38 declined to participate and 135 enrolled in the study. The initial cohort of 7 participants was used to pilot the intervention and methods, and thus were excluded from subsequent analyses, leaving 128 in the sample.

There were no significant differences between intervention and comparison group demographics (Table 2), confirming that randomization achieved the goal of a balanced distribution of socio-demographic characteristics and disability profiles between the two groups. On average, participants were 44.5 ± 12.5 years old, lived with their disabling

condition for 22.3 ± 15.9 years, and needed little assistance (disability severity index of 7.7 ± 5.2 on a 0–28 scale) to perform their ADL activities. Most participants reported having some college or more education (74.2%), with about one-third (36.4%) being employed. The most common etiology of participants' mobility impairment was spinal cord injury (46.1%), followed by cerebral palsy/spina bifida (20.3%), multiple sclerosis (7.8%), and other (7.8%). In terms of health status, 16% were current smokers, a third (35.2%) reported having hypertension, a third (32.2%) reported having high cholesterol, and nearly 8% reported having diabetes.

Participant baseline data from fitness testing and self-reports are presented in Table 3. There were no significant between group differences on the outcome measures at baseline. All blood pressures and resting heart rates were in the normal ranges. Maximal strength in the bench press was 69.4 ± 28.8 kg. Peak aerobic capacity was 13.2 ± 4.4 (mL/kg) at an average maximum heart rate of 145 beats/minute.

Comparisons between participant self-assessed and objective measures of heart rate (EKG or Polar heart rate monitor) demonstrated that among the 82 participants able to measure their own heart rate (86% of total participants) 75% were within 10 beats/min of the objective measure (mean difference = 0.5 ± 4.2 beats/minute). However, among the 25% ($n = 28$) of participants whose accuracy exceeded 10 beats/minute the mean difference between participant and objective heart rate was 25.1 ± 25.9 beats/minute.

Participants reported moderate levels of fatigue (72.7 ± 23.8); moderate levels of pain (56.7 ± 25.1); and some depressive symptoms, yet still below 16, which is the value indicative of depression (13.5 ± 9.7). Participants reported high quality of life (20.3 ± 5.2) and higher positive (4.0 ± 1.2) than negative (2.5 ± 1.1) mood. Participants reported some exercise barriers (29.6 ± 6.5) and high self-efficacy for exercise (SRAHP 22.1 ± 4.4).

Lastly, at baseline, one third (31.6%) reported doing some strength training, 50% reported doing some moderate physical activity, and almost 30% reported doing some vigorous exercise. Participants reported engaging in 197.7 ± 504.3 minutes of moderate and vigorous physical activity per week.

Discussion

Substantial research has been devoted to investigating effective approaches for promoting physical activity adoption and maintenance [68, 69], including among older adults [70] and individuals with arthritis [71], diabetes [72], and cancer survivors [73]. Little research, however, has focused on people with disabilities, despite recognizing that this population can be healthy and benefit from exercise. This randomized controlled trial will assess the effectiveness of a multi-component behaviorally-based intervention in helping individuals with severe mobility impairments who require wheelchair use for mobility to adopt and maintain aerobic exercise and strength training.

Recruitment for this study was more labor intensive, expensive, took longer than initially planned [35], and ultimately yielded fewer participants than intended. However, with a total of 128 enrolled participants, the study retains 80% power for detecting medium-large effects in the key outcome measures. Interest in the study was high, as more than 355 people contacted the study staff to be screened for inclusion—suggesting this is a willing population for future studies. The overwhelming response was indicative of the lack of programs and opportunities for exercise that target and are available for people with more severe mobility impairment. Many reported not knowing where to get information about appropriate and safe exercise for people with disabilities and expressed being pleasantly

surprised to learn of the study and thankful for the opportunity to be considered for participation.

Enrollees in our study represented individuals who were long-term wheelchair users and who had experienced substantial heterogeneity in terms of cause of mobility impairment. Data from baseline testing suggest that these participants have much to gain from getting regular exercise as they are overweight, have low fitness, and many reported having high blood pressure and high cholesterol. Additionally, the sample reported experiencing some pain and fatigue. At the trial start, participants reported high self-efficacy for exercise and reported that they sometimes encountered exercise barriers, with lack of convenient facilities cited as the greatest barrier.

Most published exercise studies conducted among people with disabilities have focused on specific health benefits achieved following short term bouts of regular exercise [25]. Much work is still needed to develop an evidence base for effective approaches for promoting exercise adoption and maintenance for people with disabilities. This study will contribute valuable empirical evidence regarding the effectiveness of a multi-component, behaviorally-based, approach for promoting exercise adoption among people with mobility impairments that necessitate wheelchair use.

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Figure 1.
Study overview

Figure 2.
The CONSORT Flowchart

Table 1

List of topics addressed with the staff-support intervention group via phone calls and monthly newsletters

Intervention phone calls	Newsletter: lead articles about making behavior changes	Newsletter: articles highlighting accessible exercise activity/equipment
Getting started in your exercise program	Making exercise a priority	Seated aerobics video
Measuring and achieving your target heart rate zone	Generating support for exercise	Pedal exerciser
Making exercise a priority	Fitting exercise into your schedule	Hand cycling
Having fun with exercise	Goal setting	Vita glide
Positive benefits of exercise	Busting barriers	Wheelchair basketball
Enlisting support for exercise	Benefits of exercise	Wheelchair softball
Overcoming roadblocks to exercise	Relapse prevention	Aqua jogger swimming shoes
Revisiting exercise goals	Advocating to address environmental barriers	Creative workouts-wheelchair fencing, tennis, kayaking, rowing, dance classes, water/snow skiing
Positive effects of exercise	Keeping it Real	Accessible places to wheel
Revisiting social support for exercise	Changing Seasons/Changing Workouts	Exercise videos – chair dancing, sit tight, wheelchair workout
Planning for exercise without phone support	Tracking Changes	Wheelchair dancing
	Keep it Up	Wheelchair tennis

Table 2

Participant demographics

Variable	Full sample			Self-guided comparison group			Staff-supported intervention group			
	N	M	SD	N	M	SD	N	M	SD	p
Age	128	44.5	12.5	59	42.9	13	69	46	12.1	0.17
Years live with disability	124	22.3	15.9	58	21	15.7	66	23.3	16	0.42
Age at disability onset	124	22.4	18.1	58	21.7	19.5	66	22.9	17	0.71
Disability severity	117	7.7	5.1	53	8.4	5.3	64	7.1	4.9	0.27
	N		%	N		%	N		%	p
Gender										0.70
Male	64		50		26	44.1		38	55.1	
Female	64		50		33	55.9		31	45.9	
Race/Ethnicity										0.70
White	99		77.3	47		79.7	52		75.4	
Black	15		11.7	5		8.5	10		14.5	
Asian	7		5.5	3		5.1	4		5.8	
Other	5		3.9	3		5.1	2		2.9	
	2		1.6	1		1.7	1		1.4	
Education ¹										0.82
>/= HS	27		22.1	12		21.4	15		22.7	
Some college/Bachelors	63		51.6	31		55.4	32		48.5	
Some graduate/Graduate degree	32		26.2	13		23.2	19		28.8	
Employment ²										0.72
Employed (full/part)	44		36.4	18		32.1	26		40.0	
Unemployed	47		38.8	22		39.3	25		38.8	
Other (student/retired/volunteer)	30		24.8	16		28.6	14		21.5	
Primary disability										0.06
SCI	59		46.1	24		40.7	35		50.7	
CP/SB	26		20.3	18		30.5	8		11.6	
MS	10		7.8	6		10.2	4		5.8	
Other	10		7.8	4		6.8	6		8.7	

Variable	Full sample			Self-guided comparison group			Staff-supported intervention group			p
	N	M	SD	N	M	SD	N	M	SD	
Amputation	8	6.3			4	6.8	4	4	5.8	
Orthopedic	5	3.9			0	0		5	7.2	
Post Polio	4	3.1			2	3.4		2	2.9	
Fibromyalgia/Lupus	3	2.3			1	1.7		2	2.9	
Stroke/TBI	3	2.3			0	0		3	4.3	
Disability Status										0.57
Stable	90	70.3			39	66.1		51	73.9	
Episodic	14	10.9			8	13.6		6	8.7	
Progressive	24	18.8			12	20.3		12	17.4	
Chronic Conditions										
High Blood pressure	45	35.2			21	37.5		23	33.3	0.81
High Cholesterol	38	32.2			20	36.4		18	28.6	0.37
Diabetes	10	7.8			6	10.2		4	5.8	0.36
Smoking	20	16.4			8	14.0		12	18.5	0.51

¹ Education data missing from 6 people

² Employment data missing from 7 people

Table 3

Baseline data of trial participants

Outcomes	Full sample			Self-guided comparison group			Staff-supported intervention group			
	N	M	SD	N	M	SD	N	M	SD	p
Physiological										
Weight (kg)	127	86.7	26.2	59	90.9	29.6	68	83.1	22.5	0.100
BMI	115	31.4	8.6	53	33.1	9.3	62	30.0	7.9	0.057
Systolic BP _{rest} (mmHg)	128	123.9	16.5	59	124.5	14.2	69	123.4	18.3	0.721
Diastolic BP _{rest} (mmHg)	128	74.9	10.5	59	74.9	9.5	69	74.9	11.4	0.995
Resting heart rate	128	79.8	13.0	59	80.0	12.5	69	79.5	14.0	0.844
Max. exercise heart rate	101	145.0	25.5	46	149.5	24.6	55	141.3	25.9	0.112
VO ₂ max (mL/kg)	100	13.2	4.4	45	13.8	4.0	55	12.7	4.7	0.242
Max. 1-repetition weight (kg)	97	69.4	28.8	42	74.9	29.0	55	65.2	28.1	0.099
Exercise targets										
Target exercise HR-low end	128	114.2	16.6	59	116.2	16.7	69	112.5	16.3	0.219
Target exercise HR-high end	128	126.7	19.8	59	129.2	20.2	69	124.5	19.4	0.181
Disability-related										
PARTS (-3 - 3)	122	0.05	1.19	55	.25	1.17	67	-0.11	1.19	0.102
LFS (18–180)	122	72.7	23.8	55	73.6	25.0	67	72.0	22.9	0.525
SF-36 pain index (0–100)	122	56.7	25.1	55	55.4	23.2	67	57.7	26.7	0.606
CES-D (0–60, 16 cutoff)	121	13.5	9.7	55	14.6	9.0	66	12.6	10.3	0.257
QLI (0–30)	121	20.3	5.2	55	19.9	4.5	66	20.6	5.6	0.446
Health and Function	121	18.4	5.8	55	18.2	5.2	66	18.5	6.2	0.801
Social and Economic	121	21.6	5.6	55	21.4	5.1	66	21.7	6.0	0.802
Psychological/Spiritual	121	20.5	6.5	55	19.3	6.4	66	21.5	6.4	0.064
Family	114	24.1	4.8	51	23.6	4.9	63	24.4	4.8	0.390
I FEEL										
Positive affect (0–7)	122	4.1	1.2	55	4.0	1.2	67	4.2	1.2	0.386
Negative affect (0–7)	122	2.5	1.1	55	2.5	0.9	67	2.4	1.2	0.580
Anxiety (0–7)	122	2.4	0.9	55	2.4	0.9	67	2.4	0.8	0.724
Physiological (0–7)	122	1.9	0.8	55	1.9	0.7	67	2.0	0.9	0.720

Outcomes	Full sample			Self-guided comparison group			Staff-supported intervention group				
	N	M	SD	N	M	SD	N	M	SD	p	
	N			N			N			p	
Exercise-related											
Do strength	37		31.6		19		36.5	18		27.7	0.591
Do moderate PA	60		50.0		26		49.1	34		50.7	0.983
Do vigorous PA	35		29.4		17		32.1	18		27.3	0.714
	N	M	SD	N	M	SD	N	M	SD	p	
Strength days/week	122	1.1	1.8	55	1.2	1.8	67	0.9	1.8	0.437	
Moderate days/week	122	1.9	2.3	55	1.8	2.3	67	1.9	2.4	0.726	
Vigorous days/week	122	0.8	1.4	55	0.9	1.5	67	0.7	1.3	0.633	
Moderate PA (min/week)	122	143.4	383.7	55	120.1	278.4	67	162.5	453.5	0.546	
Vigorous PA (min/week)	122	54.3	150.4	55	67.1	188.2	67	43.8	110.7	0.397	
Exercise: MVPA	122	197.7	504.3	55	187.2	448.9	67	206.3	548.9	0.860	
BHADP (16–64)	122	29.6	6.5	55	29.9	5.5	67	29.4	7.3	0.653	
Motivation subscale (4–28)	122	12.9	3.4	55	13.0	3.1	67	12.8	3.6	0.751	
External Barriers (4–36)	122	16.7	4.2	55	16.9	3.4	67	16.6	4.7	0.662	
SRAHP (0–28)	122	22.1	4.4	55	21.5	4.3	67	22.6	4.4	0.185	