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Randomized Pilot Trial for a Community-Based Group Stretching Exercise Program for Chronic Low Back Pain

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Abstract

Background: Authors of meta-analyses concluded that exercise therapy appears to be slightly effective at decreasing pain and improving function in adults with chronic low back pain (CLBP), particularly in health-care populations. Similar to health-care settings, community organizations provide wellness and lifestyle modification programs. Different versions of the Young Men's Christian Association (YMCA) Y's Way to a Healthy Back program were offered from 1974 to 2004. Champions of the YMCA program and authors of the pilot study designed a Healthy Back Curriculum to update and reintroduce the program. **Objective:** The research aim of this randomized pilot trial was to investigate the feasibility of a follow-up larger randomized controlled trial on the program's effectiveness for CLBP. The randomized pilot trial addressed subject recruitment, retention, and subject compliance with protocol. **Methods:** The pilot trial employed a 2-arm parallel group randomized design. Seventy-eight subjects aged 18 to 64 years with low back pain on at least half the days over the previous 6 months were assigned to either (1) a group stretching exercise arm with 12 weekly classes or (2) a self-care book arm. **Results:** Sixty participants, 30 in each group, completed the study. Out of the 130 members who accepted invitation, 60% were eligible. Retention rate over the 24-week study in the group stretching exercise arm was 30 out of 43 participants (70%). Participants in the group stretching exercise program attended an average of 5 of the 12 classes (42%). Participants completed baseline and follow-up self-report items with no missing data. **Conclusion:** The pilot study did not prove to be feasible based on the prespecified benchmarks. We suggest that a larger trial should include changes gleaned from the pilot study.

Keywords

chronic pain, randomized trial, public health

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Background

Authors of meta-analyses concluded that exercise therapy appears to be slightly effective at decreasing pain and improving function in adults with chronic low back pain (CLBP), particularly in health-care populations.^{1,2} Similar to health-care settings, community organizations provide wellness and lifestyle modification programs. We conducted a pilot trial of a stretching exercise program with the goal of updating and reintroducing a low back pain program at a community organization.

The Young Men's Christian Association (YMCA) offered different iterations of the Y's Way to a Healthy Back program for low back pain from 1974 to 2004.^{3–5}

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The history of this program began in the 1940s when Dr Hans Kraus and Dr Sonja Weber developed a method of physical fitness testing to assess strength and flexibility of hip, back, and abdominal muscles. Over 3000 patients with low back pain were evaluated by the Kraus–Weber physical fitness tests. Eighty-three percent of the study patients had no structural pathology as a cause of their pain though they demonstrated weakness and/or stiffness of their postural muscles. With therapeutic exercise, 65% became pain-free, 26% reported occasional discomfort, and 9% failed to improve. In 2-to 8-year follow-up of a subgroup of 233 patients, 82% returned to full function without pain. In this follow-up group, symptoms recurred when patients stopped exercising. Symptom resolution was associated with a return to exercise and improved muscle function.^{6–8} The stretching exercise program was refined through clinical practice and became the basis for the Y's Way to a Healthy Back program established in 1974.

By 1982, this YMCA program was offered throughout the United States, Canada, Australia, and Japan with over 150 000 participants. Thirteen thousand participants of the program were evaluated with pre- and postquestionnaires and objective scores on tests of strength and flexibility. Out of 11 809 people who completed all items on the surveys, 9532 (81%) reported improvement. On average, the participants had experienced back pain for 8 years, and duration of pain did not correlate with outcome. Results were similar in a subgroup of 546 people who had continued pain following back surgery. Improvement in pain correlated with adherence to the exercise program and with improvement in objective measures of strength and flexibility.⁹

An exercise protocol inclusive of some stretching exercises from the Y's Way to a Healthy Back programs was studied in a randomized clinical trial of transcutaneous electrical nerve stimulation (TENS) and exercise for CLBP. Four study groups with a total of 125 subjects completed the trial. Although the study demonstrated no benefit of TENS, patients in the exercise groups had significant improvement in pain scores. These benefits were lost in 2-month follow-up after patients had discontinued the exercises.¹⁰

The Y's Way to a Healthy Back program was based on a psycho-socio-biological approach to relieve suffering from low back pain. Kraus postulated that sedentary lifestyle and psychological stress could result in pain from suboptimal muscle health and function. He described muscle dysfunction as the combined impact of muscle tension, muscle deficiency (weakness and/or stiffness), muscle spasm, and trigger points.⁶ Kraus and other champions designed the Y's Way to a Healthy Back program to restore proper muscle function. The program starts with relaxation exercises, then progresses to gentle limbering/warming exercises including core strengthening, followed by gentle stretching to decrease muscle tension, weakness, and stiffness.^{3–5}

Our pilot study investigates a Healthy Back Curriculum that updates and reintroduces the Y's Way to a Healthy Back programs. Nationally, YMCA health and wellness centers work directly with 13 million adults each year to include individuals characterized by low socioeconomic status.¹¹ No national/international standardized exercise program for CLBP is currently available through a community organization such as the YMCA.

The research aim of this randomized pilot trial was to investigate the feasibility of a follow-up larger randomized controlled trial (RCT) on the program's effectiveness for CLBP. The pilot trial addressed subject recruitment, retention, and subject compliance with protocol.

Methods

Trial Design

The pilot trial employed a 2-arm parallel group randomized design. The participants within each recruitment cohort were randomized to 2 treatment arms in a ratio of 1:1 (group stretching exercise intervention at YMCA: self-care book). Quorum Institutional Review Board approved trial protocol and procedures.

Participants

Eligibility criteria were 18 to 64 years of age and low back pain occurring at least half the days over the previous 6 months. The diagnostic criteria for CLBP were based on recommendations of the National Institutes of Health (NIH) Task Force on research standards for CLBP.¹²

Exclusion criteria included individuals whose back pain was attributed to systemic or specific disease such as known cancer, spinal infection, fracture, or ankylosing spondylitis. Patients with complex conditions did not participate in the study (eg, sciatica, medicolegal issues, or a previous back surgery). Individuals who were unable to attend classes or unwilling to do home practice were excluded. Pregnant women were not permitted in the study as well. All aspects of the study were conducted in English.

Between September 2014 and September 2017, e-mail invitations were sent to members at YMCA facilities in Wilton, Connecticut, and New Canaan, Connecticut, to participate in the trial. Participants gave oral consent before telephone eligibility screening and baseline interview. Eligible participants provided written informed consent prior to study enrollment.

Interventions

Participants were randomized to a group stretching exercise program at the YMCA or a self-care book arm. Participants received stretching exercise sessions and

self-care books at no cost. No other incentive was provided to participants. Participants in both the group stretching exercise and self-care book arms continued to have access to any other medical care for their CLBP.

Stretching exercise. From June 2013 to March 2014, authors of the randomized pilot trial and stakeholders of the Y's Way to a Healthy Back program created a Healthy Back Curriculum based on the different iterations of the historical program for low back pain. Features that differentiated the Healthy Back Curriculum from other exercise programs offered by health care and community-based organizations included the following: (1) relatively brief weekly sessions that lasted from 15 to 30 minutes, (2) a graded activity program to prevent participants from falling behind and dropping out of the study if they missed sessions, (3) a companion audio and participant manual to guide daily home stretching exercises as instructed in class each week, (4) a mind-body component that included guided imagery and breathing techniques, (5) sequence of stretching exercises characterized as relaxing—limbering (warming-up)—stretching—limbering—relaxing movements, and (6) stretching exercises designed to increase flexibility and strength of postural muscles (online Appendix 1).

Four group stretching exercise sessions were held at Wilton Family Y and 3 sessions at New Canaan YMCA from September 2014 through December 2017. Sessions were facilitated by a health and fitness staff member after training by an author (MB). Weekly e-mails reminded the participants to attend the group stretching exercise classes. Participants who were assigned to the group stretching exercise arm were asked to do the stretching exercises at home each day that they had learned each week in class.

Self-care book. Participants assigned to the comparative intervention arm received The Back Pain Helpbook with information on the causes of back pain and advice on exercising, making appropriate lifestyle modifications, and managing flare-ups.¹³ Participants had full ownership on how to use the book and received no specific instructions. Weekly e-mails to participants tracked the 12 weeks of self-care book arm. The rationale for using the self-care book was to compare data from the pilot study with the results of recent CLBP studies which included exercise and the same self-care book treatment arms.^{14,15}

Outcomes

Outcomes to primary objectives were as follows: (1) number of YMCA members who accepted invitation to participate in the research, (2) percentage of recruited members who met eligibility criteria, (3) retention rates

of the group stretching exercise participants at 6-, 12-, and 24-week follow-up, and (4) number of sessions on average that participants in the group stretching exercise arm attended over the 12-week intervention.

Outcomes to secondary objectives were as follows: (1) To compare the outcome measure of the proportion of participants who reached $\geq 50\%$ improvement on Roland-Morris Disability Questionnaire (RDQ) score at 12-week follow-up relative to baseline between group stretching exercise and self-care book arms and (2) data collection of all key outcome domains at 6-, 12-, and 24-week follow-up as described by the NIH Task Force.¹² An author (MB) conducted the baseline and follow-up telephone interviews.

Investigators had specific feasibility and acceptability guidelines. For primary objective, the criteria were as follows: (1) ≥ 84 YMCA members would accept invitation to participate in the research, (2) $\geq 80\%$ of recruited members who accepted invitation to participate in the research would meet eligibility criteria, (3) participants in the stretching exercise group would demonstrate $\geq 80\%$ retention rates at 6-, 12-, and 24-week follow-up, and (4) participants in the stretching exercise group would attend ≥ 6 sessions over the 12-week intervention.

Feasibility and acceptability cut-off guidelines for secondary objectives were $\geq 50\%$ of the stretching exercise group would improve by $\geq 50\%$ in RDQ score at 12 weeks relative to baseline and $\leq 15\%$ of the self-care book group would improve by $\geq 50\%$. For the key domains at 6-, 12-, and 24-week follow-up as described by NIH Task Force,¹² feasibility and acceptability cut-off guideline was $\leq 10\%$ missing data.

As a feasibility study, a formal sample size calculation is not required. As a secondary objective, we explored the proportion of participants in each group who reached $\geq 50\%$ improvement in RDQ score at 12 weeks relative to baseline to represent clinically meaningful change. In a previous low back pain study that included an exercise and self-care book arm, 52% (95% CI: 41%–63%) of the exercise arm met this cut-off and 23% (95% CI: 14%–38%) of the self-care book arm met this cut-off. The exercise and self-care book arms in the benchmarked study showed no significant difference at $\geq 30\%$ improvement in RDQ score at 12-week follow-up relative to baseline to represent “minimal improvement.”¹⁴

Power calculations were based on the secondary objective to test the hypothesis of a 70% difference between the stretching exercise group and self-care arm for the outcome measure of $\geq 50\%$ improvement in RDQ at 12 weeks relative to baseline. The study required 27 subjects in each arm at Alpha = 0.05, Beta = 0.2, and Power = 0.8. With an anticipated trial drop-out rate of 20%, the study protocol projected enrollment of 68 participants for the study. These numbers of subjects were

also deemed suitable to test the secondary objective of testing compliance with data collection of the key outcome domains at 6-, 12-, and 24-week follow-up as described by NIH Task Force.¹²

Randomization and Blinding

Treatment assignments were randomly generated by computer. The author (MB) who oversaw treatment assignments was blinded prior to randomization of the participants. The author (WB) who generated the

random assignments and performed statistical analysis of the data was blinded to the study.

Results

Numbers Randomized and Analyzed

One hundred thirty YMCA members accepted the invitation to participate in the study, 78 were randomized to participate, and 60 completed the study. Forty-three

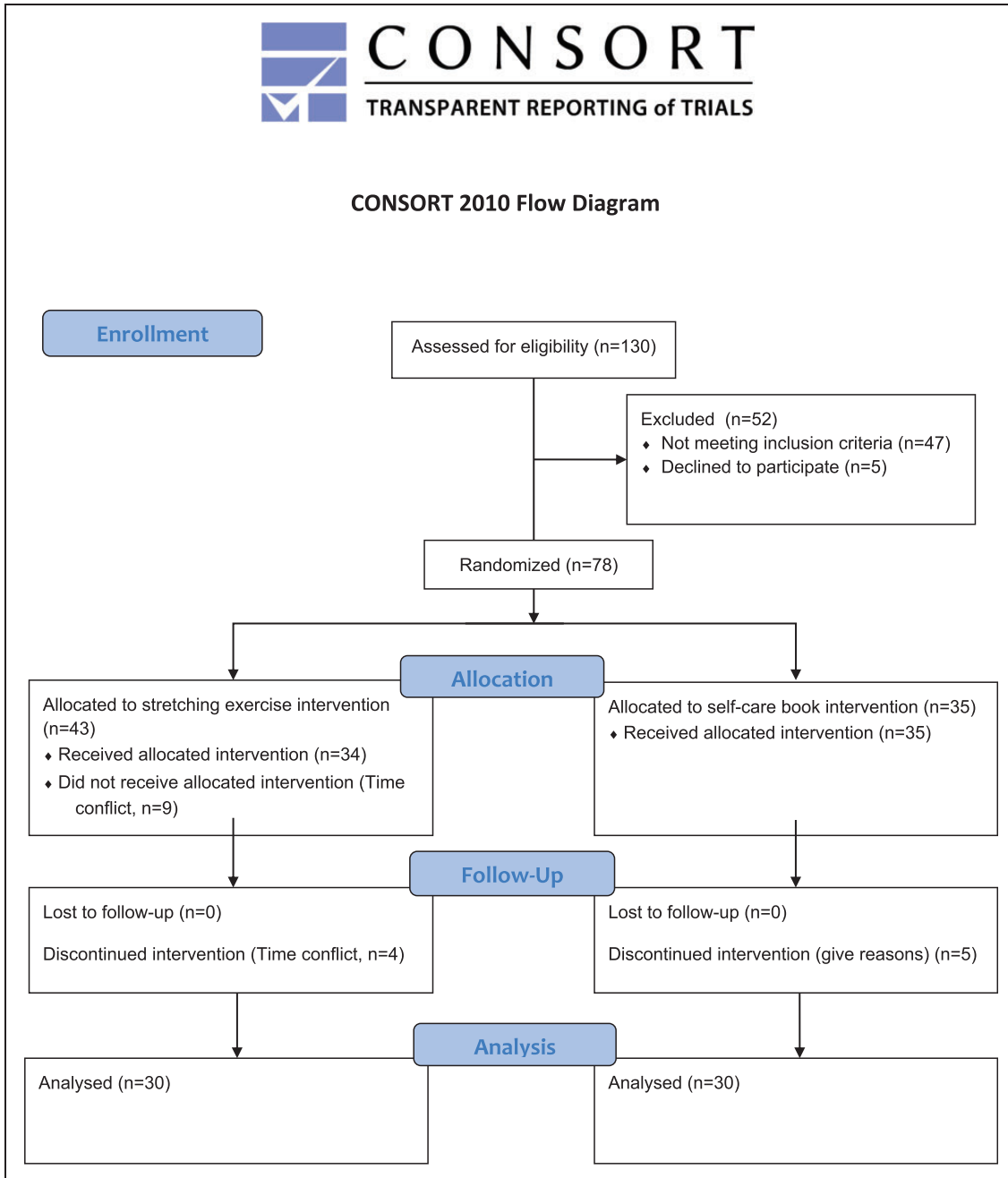


Figure 1. CONSORT Flow Diagram.

participants were assigned to the group stretching exercise arm and 35 participants to the self-care book arm. Thirteen participants declined follow-up in the group stretching exercise arm, and 5 declined follow-up in the self-care book arm. All study dropouts in both arms occurred in the first 6 weeks, and all dropouts declined at 6-, 12-, and 24-week follow-up. All study dropouts in both arms were due to time constraints to participate in the trial. A total of 60 participants, 30 from each group, were included in the analysis. As recommended by Consolidated Standards of Reporting Trials (CONSORT), a diagram describes the flow of participants through the trial (Figure 1).

Outcomes

Out of the 130 members who accepted invitation, 60% were eligible. The majority of noneligible members (47/52) were over 65 years of age or had previous surgery. Baseline demographic, work status, education, comorbidity, and previous treatment data as recommended by NIH Task Force¹² are described for the group stretching exercise and self-care book arms (Table 1).

Retention rate over the 24-week study in the group stretching exercise arm was 30 out of 43 participants (70%). Of the 13 dropouts in the stretching exercise

group, 9 participants did not attend a single session and declined to complete any of the follow-up surveys because of time constraints. Participants in the group stretching exercise program attended an average of 5 of the 12 classes (42%).

For secondary objectives, 57% of the group stretching exercise arm demonstrated $\geq 50\%$ improvement in RDQ score at 12 weeks relative to baseline, and 47% of the self-care book arm demonstrated this degree of improvement. Key self-report domains were physical function, depression, sleep disturbance, and catastrophizing. A subset of the full data set collected on Patient Reported Outcomes Measurement Information System (PROMIS), STarT Back, and Research Task Force (RTF) items recommended by NIH Task Force is reported (Table 2). The NIH Task Force did not make recommendations about standardized composite outcome measures for low back pain studies.¹² All items were completed by all participants with no missing data.

Harms

Adverse effects were limited to mild muscle soreness reported by 13% of group stretching exercise arm and 10% of self-care book arm. Participants reported no serious adverse effects.

Table 1. Baseline Characteristics of Group Stretching Exercise and Self-care Book Arms.

	Stretching Exercise Group (N = 30)	Self-care Book Group (N = 30)
Demographics		
Age in years, mean (SD)	49.87 (8.74)	48.03 (10.10)
Women, N (%)	21 (70)	17 (57)
College graduate, N (%)	27 (90)	28 (93)
White, N (%)	30 (100)	27 (90)
Hispanic, N (%)	2 (6.7)	1 (3.3)
Asian, N (%)	0	3 (10)
Lifestyle		
Employed, N (%)	19 (63)	23 (77)
Smoker, N (%)	0	0
Body mass index, mean (SD)	24.97 (4.14)	24.93 (4.63)
In past year, have you drunk or used drugs more than you meant to? N (%)	1 (3.3)	1 (3.3)
In past year, have you felt you wanted to cut down on your drinking or drug use? N (%)	2 (6.7)	2 (6.7)
Pain history		
Off work > 1 month for back pain, N (%)	1 (3.3)	0
In past 4 weeks have you been bothered by stomach pain? N (%)	4 (13.3)	2 (6.7)
In past 4 weeks, have you been bothered by pain in arms, legs, or joints other than your back? N (%)	13 (43)	12 (40)
In past 4 weeks, have you been bothered by headaches? N (%)	6 (20)	7 (23)
In past 4 weeks, have you been bothered by widespread pain? N (%)	1 (3.3)	4 (13.3)
Pain management		
Have you used opioids at any time for back pain? N (%)	4 (13.3)	3 (10)
Opioids currently, N (%)	1 (3.3)	0
Injection treatment, N (%)	4 (13.3)	1 (3.3)
Exercise therapy, N (%)	19 (63)	23 (77)
Psychological counseling, N (%)	1 (3.3)	0

Table 2. Subset of Full Data Set of Secondary Objective Outcome Measures.

	Stretching Exercise Group (N = 30)	Self-care Book Group (N = 30)
Roland-Morris Disability Questionnaire, mean (SD)		
Baseline	5.63 (3.04)	6.93 (4.50)
6 weeks	4.26 (3.39)	5.00 (4.14)
12 weeks	3.56 (3.72)	3.93 (3.85)
24 weeks	3.06 (3.42)	3.30 (3.87)
Average pain over last 7 days on 0 (no pain) to 10 (worst imaginable pain) scale, mean (SD)		
Baseline	4.33 (1.92)	4.4 (2.59)
6 weeks	3.70 (2.18)	3.27 (1.39)
12 weeks	2.90 (2.39)	3.03 (1.87)
24 weeks	3.06 (2.36)	2.27 (1.44)

Discussion

We found benefits of a community-based exercise program similar to other published studies from a clinical setting.^{14,15} Strengths of the study include the well-characterized stretching exercise intervention. Multiple cohorts at multiple sites were included in the study.

Pilot trial limitations include small sample size. The 70% retention rate of the stretching exercise group was lower than the predicted 80% rate and leads to a risk of bias. Class attendance of 42% was lower than the 50% predicted rate and may have caused heterogeneous treatment within that group. The study failed to reject the null hypothesis of a 70% difference between the group stretching exercise and self-care arms in achieving $\geq 50\%$ improvement in RDQ score at 12 weeks relative to baseline. This trial describes data from 2 YMCAs and may not generalize to YMCAs in other communities or other community-based organizations.

The goal of this randomized pilot trial was to investigate the feasibility of a follow-up RCT on the program's effectiveness for CLBP. The pilot study did not prove to be feasible based on the pre-specified benchmarks. We suggest that a larger trial should include the following changes: (1) eliminate age restrictions and past surgery to increase recruitment, (2) provide financial compensation for time to participate in the each of the arms of the study and complete surveys to increase compliance, (3) change comparative self-care book arm which was used in previous studies that informed this pilot trial but is not an active control or standard of care, (4) measure compliance of comparative arm as well as daily home exercises in the YMCA stretching exercise group to better describe adherence to the programs, (5) use minimal significant change of $\geq 30\%$ improvement in back-related function, (6) incorporate quantitative data on secondary objectives of this pilot trial to inform outcomes and predict sample size of

the definitive RCT with caution given the small sample size, and (7) apply intent-to-treat analysis with statistical tests of the difference between arms in all outcomes.

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Supplemental material

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