# A Randomized Controlled Trial to Evaluate the Efficacy of Community Based Physical Therapy in the Treatment of People with Rheumatoid Arthritis

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***ABSTRACT.*** ***Objective.*** To evaluate the short term efficacy of a community based physical therapy (PT) program for people with rheumatoid arthritis (RA) through a single blind randomized controlled trial.

***Methods.*** Adults with active RA were referred by their physician for community based PT. Participants were randomized to either an immediate intervention group [experimental group (EG)] or a wait list control group (CG). The intervention was a standardized program of education and exercise consisting of at least 4 visits or 3 h of PT over 6 weeks. Baseline, 6, and 12 week assessments were by a blinded independent assessor. The primary outcome instrument was the Stanford Arthritis Self-Efficacy Scale (SES) and secondary outcome measures included the ACREU Rheumatoid Arthritis Knowledge Questionnaire (KQ) and visual analog scale for pain (VAS). Duration of morning stiffness, grip strength, and tender joint count were also collected at each assessment. Outcome analysis was conducted using analysis of variance.

***Results.*** Of 150 eligible and randomized participants, 127 completed the study according to protocol. Baseline analysis showed no differences between the EG and CG for demographics, disease status, or other characteristics. At the 6 week assessment, primary outcome analysis for those who completed the protocol identified a mean change (improvement) of 13.5% in the EG and 5.8% in the CG, representing a 7.7% difference in change scores between the 2 groups [$F(1,121) = 6.03$; $p = 0.015$]. A statistically significant difference in change scores was also identified for the KQ [$F(1,120) = 6.67$; $p = 0.011$], but not for the VAS. Disease status measures did not change, except for duration of morning stiffness, which improved by 68.8 min in the EG and 8.3 min in the CG ($F(1,121) = 4.50$; $p = 0.036$].

***Conclusion.*** Four hours of a community based PT intervention delivered over 6 weeks significantly improved self-efficacy, disease management knowledge and morning stiffness in people with RA. (J Rheumatol 1998;25:231–7)

*Key Indexing Terms:*
PHYSICAL THERAPY
RHEUMATOID ARTHRITIS
COMMUNITY BASED THERAPY
RANDOMIZED CONTROLLED TRIAL

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disease characterized by musculoskeletal findings that include joint pain, swelling, and stiffness. From population survey data from several countries, it is estimated that 1% of Canadians would meet diagnostic criteria for RA[1,2]. The course of the disease is variable, often with alternating periods of exacerbation and remission, and both the disease and response to pharmacotherapy vary considerably from person to person. In a review of the socioeconomic effect and longterm prognosis for persons with RA, it was estimated that people with RA have 6 times the probability of severe activity limitation, 4 times as many restricted activity days, and 10 times the work disability rate of the general population[3]. There is also cumulative evidence that in a progressive disease such as RA, loss of functional ability, chronic pain, and economic costs to people with RA and society will increase over time[4–7].

A comprehensive approach to the management of people with RA is essential. Often a combination of pharmacotherapy and surgery is used, together with education, physical therapy (PT), and occupational therapy. PT aims to restore optimal function, reduce deformities, and prevent physical limitation. The use of traditional PT modalities (e.g., ice and heat) to relieve pain and swelling and exercise

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to improve joint mobility, muscle strength, and endurance may result in improvement of both function and quality of life[8–19]. Increasingly, community based PT services have also developed specialized programs that focus on patient education regarding the nature of disease, the need for balancing rest and appropriate activity, and methods to protect joints from trauma and overuse. Community based PT can be delivered in almost any setting, including the home. Care in the home may be advantageous for many people, as physical limitations and other factors (including fatigue and transportation problems) may limit an individual's access to ambulatory care facilities[20].

We evaluated the short term efficacy of a specialized community based PT program delivered in the home for people with RA.

## MATERIALS AND METHODS

*Participant selection.* Our single blind, randomized, controlled trial included adults with a diagnosis of RA (based upon American Rheumatism Association criteria)[21] who met the eligibility criteria listed in Table 1. Potential study participants were referred for PT to selected offices of the Consultation and Therapy Service (CTS) of The Arthritis Society, Ontario, Canada, between September 1993 and July 1995. The CTS delivers community based rehabilitative services throughout the province of Ontario. The CTS is funded through the Ontario Ministry of Health, and the service is provided at no cost to people with arthritis (clients). Most services provided by the CTS are delivered in the home by physical therapists. The CTS serves people with moderate to severe arthritis, usually on the referral of a rheumatologist[22]. In addition to client education, the CTS interventions focus on strengthening and range of motion exercises, pain control strategies, and drug monitoring. CTS offices with at least one full time physical therapist participated in this trial.

*Study design.* Referral forms for all clients with RA were forwarded by fax to the coordinating center in Toronto. Eligible clients were screened by the study coordinator to obtain verbal consent for a home or workplace (community) visit by an independent assessor. Clients who were deemed ineligible for the study or who could not be contacted within 48 hours of referral received usual care. Eligibility was confirmed and written consent was collected by the independent assessor. Participants were stratified and randomly allocated equally, in blocks of 4, to the experimental or the control groups. Three factors were used for stratification: (1) stable or unstable medications; (2) disease duration; less than or equal to 2 years or greater than 2 years; and (3) Steinbrocker Functional Classification II or III[23] to create 8 strata. Medication stability was defined as no changes in methotrexate within the past 3 months or all other disease modifying antirheumatic drugs (DMARD) within the past 6 months. Disease duration was calculated from time of diagnosis (vs onset of symptoms). Functional classification was determined by administration of a standardized series of questions about current function. Randomization was concealed from the persons making eligibility assessments.

Once randomized, hospitalization or participation in any other rehabilitation program for arthritis was considered a protocol violation. These participants were followed and their data were analyzed in an intent-to-treat analysis. When possible, randomized participants who refused therapy were also followed as intent-to-treat participants. Aside from hospitalizations and other rehabilitation programs, usual medical care, including medication changes, was allowed in both groups for the duration of the trial.

Study treatment was provided by experienced physical therapists (therapists) employed by the CTS who are specially trained in the physical assessment and treatment of inflammatory arthritis[24]. The experimental intervention was standardized to include: (1) a total evaluation of disease activity (effused/tender/damaged joints, grip strength, sensation, range of motion, muscle strength) and level of function (domains of: dressing, hygiene, feeding, reaching/bending, hand activity, mobility, household management, communication, work/leisure/school); (2) the distribution and review of a set of 5 educational brochures covering the RA disease process, general principles of RA disease management, medications, nutrition and exercise, and access to community resources; and (3) individual goal setting. Therapists tailored their interventions to meet these goals and were required to record the goals and interventions on a study checklist that listed common CTS PT interventions[25]. The therapists were blinded to the participant's randomization group and were required to treat all clients with RA as experimental group participants.

Upon randomization, the experimental group received the community based PT intervention for 6 weeks, while the control group received no treatment for 6 weeks. The control group waiting time of 6 weeks approximated the usual wait time for referrals to CTS at the time the study was designed[22,25,26]. The length of the experimental intervention also approximated usual care at the time the study was designed[22,25,26]. The experimental intervention required at least 3 hours of treatment or 4 therapist visits within the 6 week study time frame. The wait list control group received PT for the second 6 weeks of the study (Weeks 6 to 12) and the experimental group continued with PT treatment as required.

Eighteen nonmedical, trained interviewers were employed as independent assessors[27] to perform a joint examination and to administer the study questionnaires at 0, 6, and 12 weeks. The independent assessors were required to pass a joint examination training program and reliability testing was performed regularly. The independent assessors remained unknown to the treating therapists and referring physicians and had no knowledge of the participant's group identity, nor the objectives and results of the study.

Following an extensive review of reliable and valid outcome measures used to evaluate change in an arthritis population[28] the primary outcome measure chosen was the change in the combined Pain Control and Other Symptom domains measured by the Stanford Arthritis Self-Efficacy Scale (SES), over the 6 week treatment period[29]. The SES asks respondents to rate their confidence in performing 11 arthritis self-efficacy tasks on a scale from 0 (totally uncertain) to 100 (totally certain) and a total mean score is calculated. The SES was developed to measure changes in self-efficacy that could be attributed to the Arthritis Self Management Program, a program that promotes the same self-management principles as the CTS program[30]. Secondary outcome measures included: (1) the ACREU Rheumatoid Arthritis Knowledge Questionnaire (KQ) developed and validated for use in this study[31]. The KQ asks people to agree or disagree to 31 RA disease management knowledge statements for a total score of 31; (2) a self-reported pain assessment with a 100 mm visual analog scale (VAS)[32]. The VAS asks respondents to rate joint pain yesterday from 0 (none) to 100 (maximum imaginable). Disease activity was also monitored at each assessment (duration of morning stiffness today, grip strength, and tender joint count).

*Sample size determination.* Sample size was estimated using pilot study results that identified a 10% change in the SES at 6 weeks[26]. Using an analysis of variance F test, an alpha level of 0.05 and a beta level of 0.10, a clinically important difference in change scores of 10% between the groups, and a standard deviation of 16.5, the calculated sample size per group was 58. To allow for dropouts and protocol violations the sample size was expanded to 68 per group, for a total of 136.

*Statistical methods.* The major endpoint in the assessment of efficacy was the change score for SES after the 6 week experimental intervention. Change scores were calculated by subtracting the baseline score from the 6 week score for each individual. Efficacy analysis was performed on the data from all participants who completed the study protocol. Effectiveness (intent-to-treat) analysis was performed for all participants randomized into the study. Because of the stratification for medication stability, disease duration, and functional classification, outcome analysis was conducted using analysis of variance (ANOVA) taking into account these stratification

factors. Clinically important change in knowledge was estimated using effect sizes, calculated as [(mean change score experimental group – mean change score control group)/standard deviation of the mean change score control group]. An effect size of at least 0.3 was considered clinically important for an education intervention[33]. For reporting purposes, change scores listed in the accompanying tables have been recoded so improvement is always a positive score and worsening is always a negative score.

## RESULTS

*Accrual and baseline characteristics.* Six hundred ninety-eight of the 897 eligible participants referred to the CTS were considered unsuitable for the trial because of inactive disease (n = 166), concurrent participation in a rehabilitation program (n = 125), inability to make timely contact (n = 115), language barriers (n = 91), limited intervention required (n = 79), and other reasons (n = 122). Forty-nine individuals refused participation. The 150 remaining eligible and consenting participants were randomized equally to the experimental group or the control group. Attrition occurred when 8 participants refused to continue in the study and 10 violated protocol by commencing participation in nonstudy rehabilitation. In addition, 2 participants randomized to the control group required immediate care and 3 participants randomized to the experimental group were hospitalized for uncontrolled disease. In total, 127 participants completed the study protocol.

Baseline analysis showed no clinically important differences between the experimental and control groups for demographics, drug stability, disease activity measures, or other characteristics as measured by the outcome instruments (Table 2). Participants were predominantly female (80.0%) and middle aged. The mean disease duration was 7.5 years; tender joint count was 31 out of a maximum of 66; grip strength was 110 mm Hg (maximum 300); and duration of morning stiffness was 163 minutes. All participants were under the care of a rheumatologist and at baseline 85.3% of participants were taking daily medication for their arthritis.

*Table 1.* Inclusion and exclusion criteria.

| |
|---|
| Inclusion criteria |
| Referral is for a physical therapy intervention. |
| Diagnosis of RA, 1987 revised ARA criteria[21] confirmed by reference to the referring physician for details of laboratory and clinical findings. |
| Disease onset after age 18 years. |
| First referral to CTS for the client. |
| Ability to independently read, write, and speak English. |
| Ability to understand the purpose of the study and provide informed consent. |
| Determined to require ≥ 4 visits or ≥ 3 hours of intervention from a CTS physical therapist. |
| Available for followup for the full length of the study. |
| At least 3 of 12 potential areas identified for improvement. |
| At least 6 tender and painful joints. |
| At least 45 minutes of morning stiffness. |
| Functional Classification II or III[23]. |
| Exclusion criteria |
| Involvement in the feasibility pilot[26] for the study intervention. |
| Determined to require urgent care. |
| Current or past participation in a similar program. |

ARA: American Rheumatism Association; CTS: Consultation and Therapy Service.

*Table 2.* Participants' baseline characteristics.

| | Experimental Group, n = 76 Mean (SD) | Control Group, n = 74 Mean (SD) |
|---|---|---|
| Age, yrs | 57.6 (11.1) | 54.3 (15.1) |
| Disease duration, yrs | 7.6 (11.0) | 7.4 (10.0) |
| SES | 49.6 (19.2) | 48.8 (20.3) |
| KQ | 15.8 (5.2) | 15.7 (4.4) |
| VAS | 58.5 (25.3) | 65.3 (21.9) |
| Morning stiffness, min | 171.1 (160.8) | 154.5 (152.4) |
| Grip strength, mm Hg | 111.8 (54.4) | 108.6 (65.3) |
| Joint count | 30.4 (16.0) | 32.4 (16.3) |
| | n (%) | n (%) |
| Female | 59 (77.6) | 61 (82.4) |
| Married/common law | 57 (75.0) | 52 (70.3) |
| Did not complete high school | 35 (46.0) | 31 (41.9) |
| Household income < $19,999/yr | 26 (37.1) | 23 (33.3) |
| Functional classification II | 61 (80.3) | 62 (83.8) |
| Daily arthritis medication | 66 (86.8) | 62 (83.8) |
| Stable DMARD | 21 (27.6) | 16 (21.6) |

SES: Stanford Arthritis Self Efficacy Scale; KQ: ACREU Rheumatoid Arthritis Knowledge Questionnaire.

*Intervention characteristics.* In total, 23 therapists from 11 offices treated participants in 86 Ontario cities, towns, and villages. The mean length of the therapeutic intervention was 4.0 hours, similar for both the experimental group (Weeks 0 to 6) and the control group (Weeks 6 to 12) [$F(1,125) = 0.13$; $p = 0.718$]. Two hundred fifty-nine treatment goals were identified by participants in the experimental group, while 184 goals were identified by the control group. Improvement in disease management knowledge and pain control were the most frequently cited goals for therapy in both groups. Improvement in activities of daily living ranked third in the experimental group, and improvement in stiffness ranked third in the control group. All participants received education and modalities of treatment, which included participant specific exercises. In addition, 65.2% of the experimental group and 56.1% of the control group were prescribed assistive devices and adaptations, while 36.2% of the experimental group and 41.4% of the control group were referred to community resources (to commence after study Week 12). Therapy was continued beyond the 6 week experimental intervention for those who required it; 39.4% required at least 2 additional visits (44.9% of the experimental group and 32.7% of the control group).

*Table 3.* Primary outcome analysis (scores at completion of intervention are underlined).

| | Protocol Completers | | Intent-to-treat | |
|---|---|---|---|---|
| | Experimental, n = 69 Mean (SD) | Control, n = 58 Mean (SD) | Experimental, n = 76 Mean (SD) | Control, n = 74 Mean (SD) |
| Baseline SES score | 51.0 (19.7) | 52.5 (18.8) | 49.6 (20.0) | 48.8 (20.3) |
| 6 week SES score | 63.9 (18.4) | 58.4 (19.5) | 63.2 (18.4) | 57.7 (20.7) |
| 12 week SES score | 67.6 (17.6) | 64.1 (20.3) | 66.8 (18.0) | 64.2 (20.2) |
| 0 to 6 week change score | 13.5 (16.3) | 5.8 (18.4) | 13.3 (16.4) | 8.2 (20.0) |
| 0 to 12 week change score | 15.7 (17.5) | 11.5 (19.0) | 16.0 (17.5) | 14.2 (21.0) |

*Outcome analyses.* Primary outcome analyses data are presented in Table 3. The mean change (improvement) for the experimental group protocol completers after 6 weeks was 13.5% and the mean change for the control group was 5.8%, representing a 7.7% difference in change score between the 2 groups [$F(1,121 = 6.03$; $p = 0.015$]. Intent-to-treat analysis identified a mean change (improvement) of 13.3% in the experimental group and 8.2% in the control group for all participants [$F(1,134) = 2.64$; $p = 0.106$]. For protocol completers, the improvement in the experimental group was maintained to 12 weeks and analysis of the 12 week data showed no difference between experimental and control group change scores [$F(1,12) = 0.37$; $p = 0.543$]. The difference between the 6 week experimental group mean change score and the 12 week control group mean change score was not statistically significant [$F(1,122) = 1.65$; $p = 0.202$].

Secondary outcome analysis of data from the protocol completers (Table 4) identified a statistically significant difference in change scores for the KQ at 6 weeks [$F(1,120) = 6.67$; $p = 0.011$]. The effect size for change in knowledge was 0.48. Analysis of the KQ data at 12 weeks identified the maintenance of improvement in the experimental group, which did not differ from improvement in the control group at 12 weeks [$F(1,121) = 0.16$; $p = 0.687$]. The difference between the 6 week experimental group mean change score and the 12 week control group mean change score was not statistically significant [$F(1,120) = 0.15$; $p = 0.695$]. The change in VAS did not differ between the groups at 6 weeks [$F(1,118) = 0.003$; $p = 0.957$]; however, both groups showed improved VAS scores from baseline. Analysis of the VAS data at 12 weeks identified the maintenance of improvement in both groups, and this improvement was not different between the groups [$F(1,120) = 1.13$; $p = 0.290$]. The difference between the 6 week experimental group mean change score and the 12 week control group mean change score was not statistically significant [$F(1,118) = 3.58$; $p = 0.061$].

Analysis of the 6 week disease activity measures (Table 4) identified a statistically significant improvement in the duration of morning stiffness for the experimental group

*Table 4.* Secondary outcome analysis and disease activity measures (scores at completion of intervention are underlined).

| | Protocol Completers | |
|---|---|---|
| | Experimental, n = 69 Mean (SD) | Control, n = 58 Mean (SD) |
| KQ score | | |
| Baseline | 15.8 (5.2) | 15.5 (4.6) |
| 6 week | 18.5 (5.6) | 16.7 (5.0) |
| 12 week | 19.2 (5.5) | 18.7 (5.8) |
| Change score | | |
| 0 to 6 week | 2.8 (3.8) | 1.1 (3.5) |
| 0 to 12 week | 3.4 (4.0) | 3.1 (4.8) |
| VAS score | | |
| Baseline | 57.3 (25.2) | 64.4 (22.8) |
| 6 week | 46.3 (26.8) | 53.3 (24.7) |
| 12 week | 41.5 (27.9) | 44.2 (26.0) |
| Change score | | |
| 0 to 6 week | 10.7 (26.4) | 10.5 (25.0) |
| 0 to 12 week | 14.9 (27.3) | 20.4 (29.9) |
| Morning stiffness, min | | |
| Baseline | 154.5 (147.0) | 142.3 (139.1) |
| 6 week | 88.6 (114.5) | 135.4 (167.7) |
| 12 week | 84.8 (120.0) | 91.8 (135.2) |
| Change, min | | |
| 0 to 6 week | 68.8 (133.5) | 8.3 (181.7) |
| 0 to 12 week | 72.8 (161.56) | 51.9 (189.3) |
| Grip strength, mm Hg | | |
| Baseline | 113.9 (56.2) | 115.8 (69.8) |
| 6 week | 130.1 (59.9) | 129.3 (74.6) |
| 12 week | 140.4 (63.9) | 146.5 (75.5) |
| Change, mm Hg | | |
| 0 to 6 week | 17.5 (42.4) | 12.8 (34.2) |
| 0 to 12 week | 27.4 (39.4) | 32.3 (53.6) |
| Joint count | | |
| Baseline | 29.5 (16.1) | 32.4 (16.4) |
| 6 week | 24.8 (18.5) | 28.7 (20.0) |
| 12 week | 21.3 (16.9) | 24.7 (19.6) |
| Change | | |
| 0 to 6 week | 4.7 (12.8) | 3.8 (12.5) |
| 0 to 12 week | 7.7 (12.2) | 8.2 (14.2) |

(reduction of 68.8 min) compared to the control group [reduction of 8.3 min; $F(1,121 = 4.50$; $p = 0.036$]. Analysis of the morning stiffness data at 12 weeks identified maintained improvement in the experimental group that did not differ from improvement in the control group [$F(1,122) = 0.44$; $p = 0.510$]. The difference between the 6 week experimental group mean change score and the 12 week control group mean change score was not statistically significant [$F(1,121) = 0.33$; $p = 0.565$]. Grip strength improved in both groups, but the differences in change scores between the groups were not statistically significant at 6 weeks [$F(1,119) = 0.44$; $p = 0.510$] or 12 weeks [$F(1,120) = 0.36$; $p = 0.564$]. Tender joint count also improved in both groups; however, the difference between groups was not statistically significant at 6 weeks [$F(1,121) = 0.16$; $p = 0.693$] or 12 weeks [$F(1,122) = 0.03$; $p = 0.858$].

## DISCUSSION

We have shown that a 4 hour community based PT intervention that included education and exercise delivered over a 6 week period improved self-efficacy, disease management knowledge, and morning stiffness in people with established RA who were experiencing moderate to severe disease activity at the time of referral. Participants who were randomized into the study had very active disease, as represented by the mean baseline joint count of 31 and duration of morning stiffness of 163 minutes, which was much more severe than the minimum allowed by the eligibility criteria (Table 1). While the mean disease duration for participants was similar to the mean for the clients with RA served by the CTS, study participants represented the moderate to severe end of the spectrum[22].

The between-group difference in the primary outcome measure, the SES, was statistically significant for the efficacy analysis of data from protocol completers, but was not statistically significant in the intent-to-treat analysis. While the experimental group surpassed the expected change of 10%, an unexpected finding was the improvement in SES in the wait list control group, which reduced the differences between the groups. The improvement in the SES of 8.2% in the intent-to-treat control group might be in part due to the number of participants randomized to that group (12%) who received concurrent community rehabilitation during the "waiting time" of the study. At the time this study was designed, there were no data on placebo effect measured by the SES. However, since this time the Canadian ASMP evaluation has identified a placebo effect of about 4.4% in their comparison groups[34], which was similar to the change in our control group. In designing future randomized controlled trials for rehabilitation interventions, sample size calculations must take into account the potential improvement in the control group. Overall, the effect of the 4 hour experimental intervention resulted in similar improvement to that found for other studies using multiple professionals and longer and more intensive interventions[35,36], as well as the Arthritis Self Management Program, which is a 12 hour, 6 week group intervention led by trained lay instructors[30,34,37].

It remains unclear whether the SES is an appropriate measure for evaluating the effect of a short term comprehensive in-home PT program. In planning this study, our review of possible outcome measures did not identify other measures that might capture short term change in this population. This is an area requiring further study. In addition, a more intensive or longer intervention may be needed to confirm a significant change in the SES. This is suggested by the 39.4% of clients requiring at least 2 visits beyond the 6 week experimental intervention. While an estimate of clinically important change using the SES has never been published, the improvement in the experimental group that was measured by this instrument is appreciable, considering the disease severity of the participants and that all were concurrently under supervision by their rheumatologist.

Education is generally recognized as an important part of treatment for people with RA. In this study, education about disease management was one of the most often cited goals for therapy. It has been suggested that in chronic conditions such as RA, education is one way of enhancing both physical and psychosocial outcomes. Studies of educational programs have shown decreases in pain, depression, and disability and increased compliance and knowledge, as well as improved management behaviors believed to positively affect health status in individuals with arthritis[38–48]. In some cases, these effects have been shown to occur above and beyond any improvement due to standard medical care, including medications[39,42]. In our study the effect size for change in knowledge was 0.48, which surpassed the recommended effect size for arthritis education interventions of 0.30. This significant improvement in disease management knowledge supports other research findings.

There was no significant difference in improvement of pain between the 2 treatment groups. This may be attributed to the short duration of therapy for participants who had relatively severe disease. In addition, all participants were allowed medication changes, which may have influenced their self-reported pain levels, which continued to improve in both groups at the 6 and 12 week assessments.

Duration of morning stiffness is not only a measure of disease activity but also a symptom that can be modified by a PT intervention. The dramatic improvement in duration of morning stiffness experienced by the experimental group during their first 6 weeks of treatment may be attributed to the PT intervention they received.

As an adjunct to regular medical care, 4 hours of a community based PT intervention that included education and exercise significantly improved self-efficacy, disease management knowledge, and morning stiffness in people with established moderate to severe RA who completed the study protocol.

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