

# Effectiveness of the Primary Therapist Model for Rheumatoid Arthritis Rehabilitation: A Randomized Controlled Trial

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**Objective.** To compare the primary therapist model (PTM), provided by a single rheumatology-trained primary therapist, with the traditional treatment model (TTM), provided by a physical therapy (PT) and/or occupational therapy (OT) generalist, for treating patients with rheumatoid arthritis (RA).

**Methods.** Eligible patients were adults requiring rehabilitation treatment who had not received PT/OT in the past 2 years. Participants were randomized to the PTM or TTM group. The primary outcome was defined as the proportion of clinical responders who experienced a  $\geq 20\%$  improvement in 2 of the following measures from baseline to 6 months: Health Assessment Questionnaire, pain visual analog scale, and Arthritis Community Research and Evaluation Unit RA Knowledge Questionnaire.

**Results.** Of 144 consenting patients, 33 (10 PTM participants, 23 TTM participants) dropped out without completing any followup assessment, leaving 111 for analysis (63 PTM participants, 48 TTM participants). The majority were women (PTM 87.3%, TTM 79.2%), with a mean age of 54.2 years and 56.8 years for the PTM and TTM groups, respectively. Average disease duration was 10.6 years and 13.2 years for each group, respectively. At 6 months, 44.4% of patients in the PTM group were clinical responders versus 18.8% in the TTM group ( $\chi^2 = 8.09$ ,  $P = 0.004$ ).

**Conclusion.** Compared with the TTM, the PTM was associated with better outcomes in patients with RA. The results, however, should be interpreted with caution due to the high dropout rate in the TTM group.

**KEY WORDS.** Rheumatoid arthritis; Rehabilitation; Primary therapist model; Physical therapy; Occupational therapy; Randomized controlled trial.

## INTRODUCTION

Health care providers are exploring new service models to meet the demands for arthritis treatment (1–3). In Canada, The Arthritis Society instituted the primary therapist model (PTM) in the province of Ontario in 1994. Under the PTM, physical therapists and occupational therapists function as multiskilled professionals and assume the role

of case managers (4,5). Primary therapists may consult their respective physical therapy (PT) or occupational therapy (OT) colleagues, rather than transferring the patient for completion of the treatment. Disease-specific, cross-disciplinary training is continuously being offered by The Arthritis Society to all primary therapists (6).

The PTM has been used in psychiatric care and pediatric

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special education since the 1980s (7); however, no formal evaluation was available at that time. In 1996, Principi et al (8) described the use of multiskilled physical and occupational therapists in a geriatric rehabilitation assessment unit and found a significant decrease in overlapping assessment procedures. To our knowledge, no study has been conducted to assess the effectiveness of PTM against the traditional treatment model (TTM), which is the standard of most Canadian facilities for arthritis rehabilitation. The TTM uses rehabilitation professionals who are trained as generalists to provide discipline-specific care. One problem associated with this model is the waiting time for patients who need both PT and OT because of gaps in communication among disciplines and administrative processes of the facility. Furthermore, patients living in under-served areas may have difficulties accessing both disciplines. The objective of this randomized controlled trial (RCT) was to evaluate the outcome of patients with rheumatoid arthritis (RA) who were referred to the PTM versus those referred to the TTM.

## PATIENTS AND METHODS

**Design and patient recruitment.** Because the PTM was only used by The Arthritis Society and the TTM was used by most publicly funded agencies, we conducted the RCT within the context of these 2 service environments in Ontario. Eligible candidates were individuals who required PT and/or OT and had not received rehabilitation treatment for RA in the previous 2 years. We excluded persons who received joint replacement surgery in the last 3 months or those who were scheduled to receive surgery in the next 3 months. Patients were stratified by the American College of Rheumatology (ACR) functional classification criteria (9) prior to randomization because baseline physical function has been identified as a prognostic variable in determining disability (10). We assigned eligible patients to the PTM or the TTM at a one-to-one ratio using block sizes of 6. A computer-generated table of random numbers was used for the randomization.

**Treating therapists.** All primary therapists were physical and occupational therapists from The Arthritis Society who completed the Training Program in the Assessment of Polyarthritis (34 physical therapists, 14 occupational therapists) (6,11). Traditional physical and occupational therapists were generalists practicing in hospital outpatient departments (PT and OT), publicly funded clinics (mainly PT), or home care agencies (PT and OT).

There were 2 types of publicly funded PT clinics at the beginning of the study. According to the College of Physiotherapists of Ontario, there were 93 physiotherapist-owned clinics covered under the Ontario Health Insurance Plan (OHIP clinics). In addition, there were physician-owned clinics that employed physical therapists and other health professionals to provide rehabilitation treatments. These clinics were commonly known as “G-code clinics,” because physicians billed OHIP for the treatment using “G” codes in the fee schedule. The number of G-code clinics in the province was unknown.

**Treatment protocol.** We used The Arthritis Society’s triage algorithm to assign the location of treatment (i.e., an outpatient clinic or patient’s home). The length of intervention was set at 6 weeks (12–15). We allowed therapists to decide the number of visits depending on the patient’s needs. All participants continued to receive medical care from their rheumatologists.

As a part of the routine service of The Arthritis Society, patients in the PTM group were contacted by their treating therapists to set up the first visit. Primary therapists might provide one or a combination of the following treatments: education, including the diagnosis, pain management, energy conservation and joint protection principles, and proper footwear; advice on the use of physical modalities/arthritis-specific exercises; advice and prescription for assistive devices/mobility devices (including canes, walkers, wheelchairs, and scooters); upper extremity splints/foot orthoses; and psychosocial support and patient advocacy.

Patients in the TTM group were initially seen by a PT or OT generalist according to the rheumatologist’s referral. We allowed therapists to initiate a cross-disciplinary referral if a patient required both PT and OT interventions. Patients assigned to an outpatient clinic were asked to contact one of the publicly funded facilities from a list we provided. Those assigned to home treatment were contacted by a therapist from a local home care agency. All patients received education on pain management. In addition, physical therapists might provide one or a combination of the following treatments: physical modalities for pain, advice on exercise, and advice and prescription for canes or walkers. OT treatment might include assistive devices (e.g., raised toilet seats), splints, and orthotics; and advice and prescription for mobility aids, including canes, walkers, wheelchairs, and scooters. Therapists in both groups completed a log documenting the treatments provided at each session.

**Primary outcome measure.** We used a modified version of Wilson and Cleary’s health-related quality of life model (16) (Appendix A) to guide the selection of outcome measures. In our opinion, rehabilitation interventions were unlikely to have significant influence on biologic/physiologic, environmental, and nonmedical variables, and therefore we eliminated these variables from the model. We subsequently selected physical function (measured with the Health Assessment Questionnaire [HAQ]), pain (measured with the visual analog scale [VAS]), and disease knowledge (measured with the Arthritis Community Research and Evaluation Unit RA Knowledge Questionnaire) as core clinical measures because they were identified as the top 3 goals for arthritis rehabilitation in a previous chart review (17). The RA Knowledge Questionnaire comprises 31 items covering 7 domains: prognosis, coping strategies, pain management, exercise, medication, joint protection, and energy conservation (18). The questionnaire has demonstrated internal consistency (Cronbach’s  $\alpha = 0.76$ ,  $n = 185$ ), test-retest reliability ( $r = 0.91$ ), and content and construct validity through mail and face-to-face administration (18).

It was difficult to select a primary outcome measure out

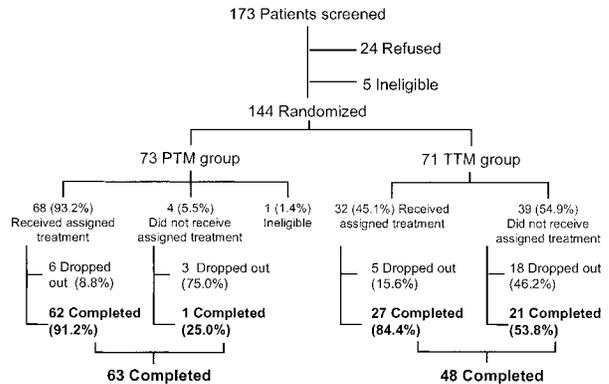
of the 3. Pain was not an appropriate choice because we did not restrict patients' use of medications. In contrast, functional status and disease knowledge had limited ability to detect changes in rehabilitation studies (19–21). Also, each of these measures only evaluated a limited aspect of rehabilitation interventions, and it was unclear which measure was more important from the patient's perspective. We therefore constructed a composite measure that defined the primary outcome as the proportion of patients who experience a  $\geq 20\%$  improvement in 2 of the 3 measures from baseline to 6 months (i.e., clinical responders). This definition was based on the research team's clinical experience and was consistent with the ACR20 criteria, which recommend a 20% improvement in the core measures for pharmaceutical trials (22).

**Secondary outcome measures.** We included 3 secondary measures: the Stanford Self Efficacy Scale (23), the RA disease activity index (RADAI) (24,25), and the Coping Efficacy Scale (26). The latter was a 3-item scale developed to assess patients' confidence in their ability to manage various aspects of their condition (27). The Coping Efficacy Scale correlates moderately with the Arthritis Helplessness Scale ( $r = -0.58$ ). Cronbach's alpha for the measure was 0.79 (26).

All participants received the outcome measure booklet by mail at baseline, discharge, and 6 months after baseline. A research assistant contacted patients by telephone if they did not return the booklet within 1 week. We considered a patient as a dropout if he or she refused to return both the discharge and 6-month booklets after 3 phone calls. The study protocol was approved by the University Health Network Research Ethics Board.

**Statistical analysis.** *Analysis for clinical responders (primary outcome measure).* We used the chi-square test to analyze the association between the treatment group and the proportion of clinical responders. The level of statistical significance was set at  $P < 0.05$ . For patients who only completed the baseline and discharge assessments, we replaced the missing 6-month data by carrying forward the discharge observation. We excluded the dropouts because of the lack of posttreatment data, which hindered the validity of most missing-data handling techniques. Sensitivity analyses were performed within 4 extreme scenarios: all PTM patients with missing data were responders, all TTM patients with missing data were nonresponders; all patients with missing data were responders; all patients with missing data were nonresponders; and all PTM patients with missing data were nonresponders, all TTM patients with missing data were responders.

Logistic regression was used to evaluate the association of treatment group with clinical responses by controlling for the following factors: ACR functional class (class III and IV = 1, class I and II = 0) (9), disease duration ( $\leq 2$  years = 1,  $> 2$  years = 0), age, sex (female = 1, male = 0), education level (completed high school = 1, did not complete high school = 0), average household income ( $> \$20,000 = 1, \leq \$20,000 = 0$ ), and living arrangement



**Figure 1.** Patient recruitment. PTM = primary therapist model; TTM = traditional treatment model.

(living with family = 1, living alone/in nursing home = 0). These variables were controlled in the analysis because they predicted patient outcome according to the literature (10,28) and according to the clinical judgment of the research team.

Blocks of variables were entered into the model in the following order: patient demographic variables (age, sex, education level, average household income), disease-related variables (ACR functional class, disease duration), and treatment (PTM group = 1, TTM group = 0). The level of statistical significance was set at  $P < 0.05$ . The adjusted odds ratio and 95% confidence interval were calculated to determine the magnitude of association between the groups and the primary outcome measure.

*Analysis for outcome measures.* We performed Student's *t*-tests to compare the change scores of each individual outcome measure between PTM and TTM at 2 time frames: baseline to discharge and baseline to 6 months. In addition, repeated-measures 1-way analysis of variance (ANOVA) tests were conducted for each treatment model to explore changes in the outcome measures across time. Post-hoc least significant difference (LSD) tests were performed when statistically significant differences were detected among means ( $P < 0.05$ ).

*Sample size.* A total of 142 patients (71 patients per group) were required in the RCT based on estimates from the pilot study (difference of clinical responders between groups = 25%,  $\alpha$ -level = 0.05, 80% power, 20% attrition rate) (15).

## RESULTS

Between November 1999 and May 2002, 173 patients with RA were recruited from 25 rheumatologists' offices in Ontario, Canada. Of those patients, 24 refused to participate and 5 were ineligible. The remaining 144 patients were randomly assigned to the PTM group ( $n = 73$ ) and the TTM group ( $n = 71$ ). We considered one patient (PTM) ineligible after randomization because she had received PT treatment  $< 2$  years ago. Nine patients from the PTM group (12.3%) and 23 from the TTM group (32.4%) dropped out, leaving 111 patients (PTM group = 63, TTM group = 48) who were included in the analysis (Figure 1). There was no significant difference in patient characteris-

Table 1. Patient characteristics and baseline clinical measures\*

Variable	PTM group		TTM group		Dropout	
	No. missing	n = 63	No. missing	n = 48	No. missing	n = 33
Age, mean $\pm$ SD years	0	54.19 $\pm$ 14.35	1	56.77 $\pm$ 13.18	13	58.75 $\pm$ 16.08
Disease duration, mean $\pm$ SD years	1	10.60 $\pm$ 11.46	1	13.17 $\pm$ 12.07	12	14.41 $\pm$ 11.80
Sex	0		0		0	
Female		55 (87.30)		38 (79.17)		30 (93.75)
Male		8 (12.70)		10 (20.83)		2 (6.25)
ACR functional class	0		0		0	
I		10 (15.87)		8 (16.67)		6 (18.75)
II		25 (39.68)		19 (39.58)		10 (31.25)
III		23 (36.51)		17 (35.42)		12 (37.50)
IV		5 (7.94)		4 (8.33)		4 (12.50)
>2 comorbid conditions	0	30 (47.62)	0	18 (37.50)	11	6 (27.27)
Education level	0		1		11	
$\leq$ High school		31 (49.21)		21 (44.68)		6 (27.27)
University/college		24 (38.10)		18 (38.30)		14 (63.64)
Postgraduate studies		8 (12.70)		8 (17.02)		2 (9.09)
Marital status	0		1		11	
Married/common law		46 (73.01)		32 (68.09)		15 (68.18)
Separated/divorced		8 (12.70)		7 (14.89)		1 (4.55)
Widowed		8 (12.70)		4 (8.51)		4 (18.18)
Never married		1 (1.59)		4 (8.51)		2 (9.09)
Employment status	0		1		11	
Full time		16 (25.40)		16 (34.04)		8 (36.36)
Part time		5 (7.94)		2 (4.26)		3 (13.64)
Homemaker		10 (15.87)		7 (14.89)		2 (9.09)
Retired		19 (30.16)		17 (36.17)		7 (31.82)
Unemployed		5 (7.94)		1 (2.13)		1 (4.54)
On leave		8 (12.70)		4 (8.51)		1 (4.54)
Average household income	0		1		13	
$\leq$ \$20,000		13 (20.63)		7 (14.89)		4 (20.00)
\$20,000–\$60,000		26 (41.27)		22 (46.81)		4 (20.00)
$>$ \$60,000		15 (23.81)		14 (29.79)		7 (35.00)
Refuse		9 (14.27)		4 (8.51)		5 (25.00)
Living arrangement	0		1		11	
Living with family		49 (77.78)		35 (74.47)		5 (22.73)
Living alone		12 (19.05)		12 (25.53)		17 (77.27)
Living in a nursing home		2 (3.17)		0		0
Received treatment at a clinic	1	46 (74.2)	0	43 (89.6)		NA
Baseline core clinical measure, mean $\pm$ SD	0		0		11	
Pain (0–10)		6.86 $\pm$ 2.43		6.79 $\pm$ 2.34		6.86 $\pm$ 2.04
HAQ (0–3)		0.94 $\pm$ 0.66		0.82 $\pm$ 0.65		1.10 $\pm$ 0.55
Knowledge (0–31)		18.76 $\pm$ 5.71		19.52 $\pm$ 5.46		17.55 $\pm$ 3.52

\* Values are the number (percentage) unless otherwise indicated. PTM = primary therapist model; TTM = traditional treatment model; ACR = American College of Rheumatology; NA = not applicable; HAQ = Health Assessment Questionnaire.

tics and baseline clinical measures between completers and dropouts (Table 1).

Among the participants, 100 started the assigned treatment (PTM group = 68, TTM group = 32) (Figure 1). Most of the patients who opted against the assigned treatment were in the TTM group. In July 2002, the Ontario government passed legislation to delist all the G-code clinics. As a result, the number of publicly funded facilities for patients in the TTM group decreased drastically. Although this did not affect the study design, some patients had difficulty accessing treatment. Of the 39 TTM patients who opted against the treatment, 10 were unable to access a publicly funded facility, 8 refused to see a PT/OT generalist, 7 cited the time commitment as a problem, and 6

cited other health problems. The remaining 8 patients did not provide a reason. Of those in the PTM group who refused treatment (n = 4), 1 cited the clinic location as a problem, 1 did not want to be treated by a primary therapist, and 2 did not offer a reason. Regardless of the treatment status, patients who completed the baseline assessment plus at least 1 of the 2 followup assessments were included in the analysis.

The mean length of rehabilitation treatment in the PTM group was 3.4 visits (median 3, range 0–15), as compared with 5.3 visits reported by the TTM group (median 1, range 0–50). The average number of visits was considerably higher in the TTM group because some patients required treatment from both a PT and an OT generalist. Patients in

Table 2. Chi-square analyses of core measures and clinical responder\*

Measure†	PTM group (n = 63)	TTM group (n = 48)	$\chi^2$	P
HAQ	31 (49.2)	16 (33.3)	2.81	0.09
Pain	32 (50.8)	16 (33.3)	3.38	0.07
Knowledge questionnaire	25 (39.7)	8 (16.7)	6.91	0.01
2 of 3 measures (i.e., clinical responder)	28 (44.4)	9 (18.8)	8.09	0.004

\* Values are the number (percentage) unless otherwise indicated. PTM = primary therapist model; TTM = traditional treatment model; HAQ = Health Assessment Questionnaire.  
†  $\geq 20\%$  improvement from baseline to 6 months.

the PTM group appeared to be slightly younger (mean  $\pm$  SD 54.2  $\pm$  14.3 years compared with 56.8  $\pm$  13.2 years in the TTM group) and had a shorter disease duration (mean  $\pm$  SD 10.6  $\pm$  11.5 years compared with 13.2  $\pm$  12.1 years in the TTM group).

We received the therapist log of 75 patients (PTM = 62, TTM = 13). Range of motion exercise (90.3%) and education (88.7%) were the most frequently used treatments in the PTM group. Furthermore, 58% of PTM patients obtained splints and 37% received mobility aids and assistive devices. Approximately 85% of the TTM group were taught range of motion exercise and  $\sim 70\%$  received RA education. Both groups offered education on disease management (PTM = 88.7%, TTM = 62.9%), joint protection and energy conservation principles (PTM = 88.7%, TTM = 84.6%), and pain control (PTM = 79.0%, TTM = 69.2%). However, results from the TTM group should be interpreted with caution because only 40% of treatment logs were returned.

**Analysis of clinical responders.** We found that 44.4% of the PTM group and 18.8% in the TTM group met the clinical responder criterion ( $\chi^2 = 8.09$ , 1 degree of freedom [df],  $P = 0.004$ ) (Table 2). Sensitivity analyses were performed to examine the robustness of the result. Four extreme scenarios were used for handling the 11 patients with a missing 6-month assessment (Appendix B). The results showed a significantly higher proportion of responders in the PTM group in all scenarios, except when all PTM patients with missing data were treated as nonresponders and all TTM patients with missing data were treated as responders. These findings suggest that the current results are relatively stable.

Among the individual clinical measures, 39.7% of the PTM group improved  $\geq 20\%$  between baseline and 6 months in disease knowledge compared with 16.7% in the TTM group ( $\chi^2 = 6.91$ , 1 df,  $P = 0.01$ ) (Table 2). However, there was no statistically significant difference on the HAQ (PTM = 49.2%, TTM = 33.3%;  $P = 0.09$ ) or the pain VAS (PTM = 50.8%, TTM = 33.3%;  $P = 0.07$ ). We performed Student's *t*-tests to compare the change scores of each core measure between treatment groups and found a greater improvement in disease-specific knowledge in the PTM group at both discharge and 6 months ( $P < 0.01$ ) (Table 3).

A total of 108 patients were included in the logistical regression analysis because 3 patients did not provide demographic information at baseline. The results showed that being in the PTM group increased the odds of meeting

the clinical response criterion by 3.98 times after adjusting for patient characteristics and disease-related variables (Table 4). The total variance explained by the full model ranged between 19.1% (Cox and Snell  $R^2$ ) and 26.5% (Nagelkerke  $R^2$ ).

**Analysis of secondary outcome measures and exploratory analysis.** We found no significant between-group difference in the change scores of the secondary outcome measures except for coping efficacy, which showed a 4.6% decline in the PTM group at 6 months and a 4.2% improvement in the TTM group ( $P = 0.03$ ) (Table 3). Exploratory repeated-measures ANOVA tests were performed to assess changes in each outcome measure over a 6-month period (Table 5). Statistically significant differences were found in pain for both the PTM group ( $F[2,174] = 3.78$ ,  $P = 0.025$ ) and the TTM group ( $F[2,130] = 3.58$ ,  $P = 0.031$ ). Post-hoc LSD tests indicated that the discharge and 6-month scores were significantly better than the baseline scores for both groups. We did not find a significant difference in other measures over time.

## DISCUSSION

The objective of this study was to examine the outcome of patients with RA who were referred by their rheumatologists for treatment provided by a primary therapist versus that provided by a traditional physical and/or occupational therapist. Ideally, an intent-to-treat analysis should be conducted to assess the effectiveness of the treatment (29). This was, however, not possible because 22.9% of patients dropped out without completing any followup assessment. As a result, the findings should be interpreted with caution due to the potential for attrition bias (30).

This study used a number of sources to develop the primary outcome measure. The strength of the composite measure was that it was based on a conceptual framework and on information from patients. The measure also increased the power of clinical trials because it drew on information from multiple outcome measures. In our case, we estimated a sample size of 142 patients using the composite measure. If we based the calculation on pain, for example, we would have needed close to 6,000 patients (mean  $\pm$  SD difference 0.17  $\pm$  2.06,  $\alpha = 0.05$ , 80% power, 20% attrition rate) for the RCT (15). We used the 20% improvement as the cutoff point because it has shown the best discriminatory power in drug trials (22); however,

Table 3. Clinical measures at baseline, discharge, and 6 months\*

Measure	PTM group (n = 63)			TTM group (n = 48)			P†
	Missing	Mean ± SD	Difference from baseline (SD; % change)	Missing	Mean ± SD	Difference from baseline (SD; % change)	
HAQ (0–3, lower = better)							
Baseline	0	0.94 ± 0.66	—	0	0.82 ± 0.65	—	NA
Discharge	5	0.80 ± 0.64	-0.07 (0.36; -7.2)	7	0.78 ± 0.54	-0.07 (0.42; -8.5)	0.97
6 months	7	0.92 ± 0.75	-0.05 (0.42; -5.3)	4	0.81 ± 0.60	-0.01 (0.46; -1.2)	0.53
Pain (0–10, lower = better)							
Baseline	0	6.86 ± 2.43	—	0	6.79 ± 2.34	—	NA
Discharge	5	5.78 ± 2.53	-0.98 (2.79; -14.3)	7	5.80 ± 2.25	-0.95 (2.41; -14.0)	0.95
6 months	7	5.73 ± 2.72	-1.17 (2.66; -17.1)	4	5.57 ± 2.40	-1.20 (2.27; -17.6)	0.96
Knowledge questionnaire (0–31, higher = better)							
Baseline	0	18.76 ± 5.71	—	0	19.52 ± 5.46	—	NA
Discharge	5	20.86 ± 5.21	1.84 (3.40; 9.8%)	7	19.54 ± 6.08	-0.15 (3.15; -0.8)	< 0.01
6 months	7	20.88 ± 6.06	2.14 (4.16; 11.4%)	4	19.07 ± 5.60	0.05 (3.14; 0.3)	< 0.01
RADAI (0–10, lower = better)							
Baseline	0	5.08 ± 2.03	—	0	4.98 ± 1.99	—	NA
Discharge	12	4.25 ± 1.95	-0.67 (2.16; -13.2)	12	4.43 ± 2.04	-0.72 (2.04; -14.5)	0.91
6 months	21	4.24 ± 2.26	-0.74 (2.04; -14.6)	15	3.97 ± 1.89	-1.17 (2.15; -23.5)	0.43
Self-efficacy scales (1–10, higher = better)							
Self-management behavior							
Baseline	2	6.41 ± 1.56	—	0	6.44 ± 1.62	—	NA
Discharge	12	6.96 ± 1.58	0.27 (1.55; 4.2)	12	6.55 ± 1.81	-0.04 (1.05; -0.6)	0.31
6 months	21	6.71 ± 1.72	0.16 (1.60; 2.5)	15	6.50 ± 1.81	-0.02 (1.19; -0.3)	0.59
Disease management							
Baseline	0	6.69 ± 2.06	—	0	7.27 ± 1.56	—	NA
Discharge	12	7.11 ± 1.66	0.15 (1.96; 2.2)	12	7.17 ± 1.77	-0.23 (1.24; -3.2)	0.32
6 months	21	6.97 ± 1.82	-0.06 (1.79; -0.9)	15	6.90 ± 1.76	-0.38 (1.76; -5.2)	0.43
Achieve outcome							
Baseline	0	5.64 ± 1.95	—	0	6.08 ± 2.03	—	NA
Discharge	12	6.39 ± 1.94	0.45 (1.88; 8.0)	12	6.01 ± 1.98	0.04 (0.97; 0.7)	0.19
6 months	21	5.74 ± 2.28	-0.04 (1.80; -0.7)	15	6.22 ± 2.21	0.18 (1.17; 3.0)	0.54
Coping efficacy scale (1–5, higher = better)							
Baseline	0	3.70 ± 0.88	—	0	3.80 ± 0.73	—	NA
Discharge	12	3.97 ± 0.73	0.06 (0.81; 1.6)	12	3.86 ± 0.90	0.02 (0.65; 0.5)	0.81
6 months	21	3.72 ± 0.93	-0.17 (0.71; -4.6)	15	3.97 ± 0.72	0.16 (0.60; 4.2)	0.03

\* PTM = primary therapist model; TTM = traditional treatment model; HAQ = Health Assessment Questionnaire; NA = not applicable; RADAI = Rheumatoid Arthritis Disease Activity Index.  
 † Student's t-test was used for comparing mean difference scores between groups.

**Table 4. Association between study group assignment and clinical response: hierarchical logistic regression\***

Variables	Adjusted OR	95% CI	Wald test	P
Block 1 entered				
Age	0.98	0.94–1.01	2.17	0.14
Education (some university = 1, no university = 0)	2.15	0.85–5.46	2.58	0.11
Family income (>\$20,000 = 1, ≤\$20,000 = 0)	0.49	0.18–1.32	2.00	0.16
Sex (female = 1, male = 0)	0.44	0.15–1.32	2.15	0.14
Block 2 entered				
Age	0.98	0.95–1.01	1.37	0.24
Education (some university = 1, no university = 0)	2.10	0.81–5.49	2.31	0.13
Family income (>\$20,000 = 1, ≤\$20,000 = 0)	0.44	0.16–1.25	2.36	0.12
Sex (female = 1, male = 0)	0.59	0.19–1.89	0.78	0.38
ACR (class III & IV = 1, class I & II = 0)	0.47	0.18–1.22	2.39	0.12
Disease duration (≤2 years = 1, >2 years = 0)	1.79	0.67–4.77	1.35	0.25
Block 3 entered				
Age	0.98	0.95–1.02	0.76	0.38
Education (some university = 1, no university = 0)	2.28	0.84–6.21	2.58	0.11
Family income (>\$20,000 = 1, ≤\$20,000 = 0)	0.54	0.18–1.62	1.22	0.27
Sex (female = 1, male = 0)	0.43	0.12–1.51	1.73	0.19
ACR (class III & IV = 1, class I & II = 0)	0.45	0.17–1.21	2.51	0.11
Disease duration (≤2 years = 1, >2 years = 0)	1.73	0.62–4.82	1.10	0.29
Treatment group (PTM group = 1, TTM group = 0)	3.98	1.47–10.78	7.38	0.007

\* OR = odds ratio; 95% CI = 95% confidence interval; ACR = American College of Rheumatology; PTM = primary therapist model; TTM = traditional treatment model.

further testing is needed to demonstrate the same in rehabilitation studies.

Some of our findings concur with previous reports involving physical therapists and occupational therapists who completed The Arthritis Society training program (12,13). For example, both our study and Helewa et al's study (13), which involved trained occupational therapists, observed only a modest change in the HAQ among patients with RA. Although this might suggest the lack of effect from treatments provided by therapists, the recent literature has also questioned the use of the HAQ in rehabilitation trials. Physical functional disability, as measured with the HAQ, is mainly determined by disease activity, structural damage, and pain. Stucki estimates that these disease-related variables explain 50–70% of the overall variance in HAQ scores, whereas muscle strength only accounts for an additional 12% of the variance (31). The relatively small contribution of rehabilitation-related variables (e.g., muscle strength) to disability might explain why it was difficult to demonstrate clinically and statistically important improvements in HAQ scores in rehabilitation trials. A thorough understanding of the relationship between RA disability and variables influenced by rehabilitation will be essential for improving the selection of outcome measures in future studies.

Pain relief was identified in 2 recent surveys as the most important goal for persons living with arthritis (32,33). In the current study, we observed a significant improvement in pain over time in both the PTM and TTM groups. This finding was matched by the RADAI scores, which showed a 15% and 24% improvement in the PTM group and TTM group, respectively. Similarly, in an RCT comparing patients treated by a rheumatology-trained physical therapist and waiting list controls, Bell et al reported a 19% improvement in pain in the trained PT group and 17% in the

control group (12). The results might be due to the fact that both studies did not restrict the use of physician-prescribed medications. Because medications have a direct impact on the disease activity and inflammatory process, it is expected that they play the major role in pain control, whereas rehabilitation serves as an adjunctive treatment. Consequently, the results are a realistic reflection of the patient outcome in clinical practice. Although pain intensity and disease activity should be evaluated in future rehabilitation trials, they should not be used as the sole primary outcomes in studies that allow patients to continue their usual medical treatment. Furthermore, other dimensions of pain, such as pain perception, should be explored as outcome measures for future studies of rehabilitation interventions.

Improved disease knowledge was one of the top 3 goals identified by patients with arthritis receiving rehabilitation (17). Our study demonstrated a significant improvement in RA knowledge after interventions from a primary therapist, but not from a PT or OT generalist. Similarly, Bell et al reported an 18% improvement in the PT group at discharge versus 7% in the control group (12). Education was a major component in both studies regardless of the process of service delivery (i.e., multiskilled primary therapists or discipline-specific physical therapists). In our study, rheumatology-trained primary therapists reported a notably higher use of education as compared with the traditional PT/OT generalists. This suggests that therapists' training in arthritis might be a major factor in improving patients' knowledge, and that there might be an advantage to advanced rheumatology training and specialization for rehabilitation therapists working in the field.

We observed an unexpected, statistically significant change in coping efficacy, with a mild deterioration in the PTM group and a mild improvement in the TTM group

**Table 5. Repeated measures analysis of variance for within-group effects for sequential assessments of outcome measures (baseline, discharge, 6 months)\***

	PTM group			TTM group						
	Sum of squares	df	Mean squares	F	P	Sum of squares	df	Mean squares	F	P
HAQ disability										
Between groups	0.64	2	0.32	0.68	0.51	0.05	2	0.02	0.07	0.94
Within groups	81.06	174	0.47			46.61	130	0.36		
Total	81.69	176				46.66	132			
Pain VAS										
Between groups	49.40	2	24.70	3.78	0.03+	38.94	2	19.47	3.58	0.03+
Within groups	1,136.78	174	6.53			707.15	130	5.44		
Total	1,186.18	176				746.09	132			
ACREU RA knowledge questionnaire										
Between groups	180.06	2	90.03	2.80	0.06	6.23	2	3.12	0.10	0.91
Within groups	5,594.45	174	32.15			4,226.97	130	32.52		
Total	5,774.51	176				4,233.20	132			
RADAI										
Between groups	25.46	2	12.73	2.97	0.05	20.42	2	10.21	2.61	0.08
Within groups	642.19	150	4.28			446.36	114	3.92		
Total	667.65	152				466.77	116			
Self-efficacy scale, self-management behaviors										
Between groups	8.68	2	4.34	1.68	0.19	0.26	2	0.13	0.04	0.96
Within groups	391.35	151	2.59			342.19	114	3.00		
Total	400.03	153				342.45	116			
Self-efficacy scale, disease management										
Between groups	5.27	2	2.63	0.75	0.47	2.76	2	1.38	0.49	0.62
Within groups	534.85	153	3.50			323.19	114	2.84		
Total	540.12	155				325.96	116			
Self-efficacy scale, achieve outcomes										
Between groups	17.34	2	8.67	2.08	0.13	0.78	2	0.39	0.09	0.91
Within groups	636.74	153	4.16			482.65	113	4.27		
Total	654.08	155				483.43	115			
Coping efficacy scale										
Between groups	2.26	2	1.13	1.56	0.21	0.57	2	0.29	0.47	0.63
Within groups	110.73	153	0.72			70.11	114	0.62		
Total	112.99	155				70.68	116			

\* df = degrees of freedom; VAS = visual analog scale; ACREU = Arthritis Community Research and Evaluation Unit; RA = rheumatoid arthritis; see Table 3 for additional definitions.  
 + P < 0.05.

from baseline to 6 months. This suggests that the TTM patients felt more confident in coping with their condition over time. There are 2 possible explanations for this finding. First, patients' expectations about their prognosis may have changed as their knowledge about RA improved. This phenomenon of response shift has been described by Sprangers and Schwartz (34) as a change in the meaning of a person's evaluation of a construct due to an adjustment of internal standards of measurement (i.e., recalibration), a change in the definition of the target construct (i.e., redefinition), and/or a change in the importance of the domains constituting the construct (i.e., reprioritization). Using our study as an example, knowledge about the chronic nature of RA may cause someone to readjust their expectation from full recovery to a partial improvement. As a result, patients may reprioritize their treatment goals and reconceptualize their ability to cope with the condition. When they respond to the postintervention assessment, they may use this new framework and report a lower level of coping efficacy because coping has a whole different meaning to them than previously. The highlight of our explanation is not that knowledge decreases patients' confidence in coping, but that instead, knowledge may facilitate a more realistic assessment of one's coping efficacy. We encourage further research to examine this hypothesis.

It is also possible that changes have occurred in patients' social support and life circumstances over the 6-month period, which may or may not have any relationship with the therapy intervention. Coping efficacy has previously been shown to be associated with self efficacy in pain management (35), perceived control, satisfaction with social support, and coping style (36). Changes in social support can potentially alter the frame of reference on which individuals rated their ability to cope with the disease. Unfortunately, this study could not verify the assumption because we did not gather postintervention personal and demographic information. Such data should be collected in future trials evaluating coping efficacy in order to allow for better understanding of the results.

There were several limitations to this study. First, ~23% of patients dropped out without completing any followup assessment. The missing data might have resulted in potential biases of the estimates. Second, more than half of the TTM group did not initiate treatment after consenting to participate in the study. The unexpectedly poor treatment adherence hindered comparison between the PTM and TTM groups. Approximately 26% of these patients cited challenges in accessing rehabilitation services in publicly funded facilities as their reason for not adhering to treatment. It should be noted that the PTM group was contacted by The Arthritis Society to set up the first visit, whereas patients in the TTM group were asked to contact a local outpatient clinic. This might also have created a barrier for TTM patients to access the service.

Finally, this study did not include privately funded PT clinics for providing traditional therapy in the TTM group. In Ontario, >50% of PT outpatient clinics are privately owned. Patients who use these clinics are required to pay out of pocket or through third-party insurance. The latter is usually available to those who are covered under their full-time employment or their spouse's employment. Also,

some retirees have limited coverage from their former employers. The socioeconomic status of these individuals is likely to be different from those who rely on public rehabilitation services. Also, the definition of the traditional therapy model in the private sector may be different from its publicly funded counterpart. However, because private clinics are only affordable to some individuals, a comparison involving only these clinics will not be generalizable to all patients requiring rehabilitation services for RA in Ontario. This problem could have been addressed by conducting a 3-group comparison (PTM, publicly funded TTM, and privately funded TTM); however, this would have required a much larger sample size, which would have diminished the feasibility of the project.

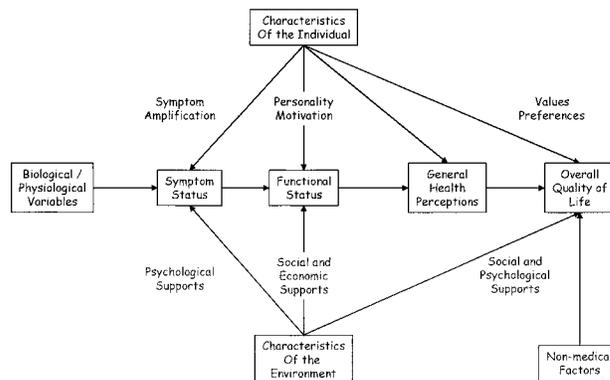
This study is one of the few that have evaluated comprehensive rehabilitation treatment for RA (12,13,37–41), and it is the only one that compared service models. We demonstrated that patients who were referred for treatment provided by a primary therapist had a higher chance of achieving better outcomes than those who were referred to traditional PT/OT generalists. The results should be interpreted with caution due to the high attrition rate. Nonetheless, our findings match those of previous studies in which treatments were provided by a rheumatology-trained physical or occupational therapist. Further research should be directed to understand the effectiveness and the economic value of rheumatology-trained rehabilitation professionals under different models of care, such as the therapist practitioner model and telemedicine.

## REFERENCES

1. Vliet Vlieland TP. CARE: international conference on multidisciplinary care in rheumatoid arthritis. *Int J Adv Rheumatol* 2003;1:34–6.
2. Petersson IF, Bremander A, Klareskog L, Stenstrom CH. Who cares about team care? Conference report from CARE II: Spen-shult, Sweden, 18–20 September 2003. *Ann Rheum Dis* 2005; 64:644.
3. Li LC, Backman C, Bombardier C, Hammond A, Hill J, Iversen M, et al. Focusing on care research: a challenge and an opportunity. *Arthritis Rheum* 2004;51:874–6.
4. Lineker SC, Wood H, Badley EM, Stegna L, Wilkins A. Evaluation of the primary therapist model of service delivery as implemented by the Arthritis Society, consultation and rehabilitation service: phase 1: therapist survey. In: Working Paper 98-5. Toronto, Ontario: Arthritis Community Research & Evaluation Unit; 1998.
5. Hurst K. Multi-skilled health carers: nature, purpose and implications. *Health Manpow Manage* 1997;23:197–211.
6. Stokes BA, Helewa A, Lineker SC. Total assessment of rheumatoid polyarthritis: a postgraduate training program for physical and occupational therapists: a 20 year success story. *J Rheumatol* 1997;24:1634–8.
7. Rainforth B. The primary therapist model: addressing challenges to practice in special education. *Phys Occup Ther Pediatr* 2002;22:29–51.
8. Principi E, Lever J, Vertesi A, Molloy DW, Tuttle IM. Use of multiskilled assessors on an interdisciplinary geriatric team. *Physiother Can* 1996;48:127–30.
9. Hochberg MC, Chang RW, Dwosh I, Lindsey S, Pincus T, Wolfe F. The American College of Rheumatology 1991 revised criteria for the classification of global functional status in rheumatoid arthritis. *Arthritis Rheum* 1992;35:498–502.
10. Guillemin F, Briancon S, Pourel J. Functional disability in rheumatoid arthritis: two different models in early and established disease. *J Rheumatol* 1992;19:366–9.

11. Helewa A, Smythe HA, Goldsmith CH, Groh J, Thomas MC, Stokes BA, et al. The total assessment of rheumatoid polyarthritis: evaluation of a training program for physiotherapists and occupational therapists. *J Rheumatol* 1987;14:87-92.
12. Bell MJ, Lineker SC, Wilkins AL, Goldsmith CH, Badley EM. A randomized controlled trial to evaluate the efficacy of community based physical therapy in the treatment of people with rheumatoid arthritis. *J Rheumatol* 1998;25:231-7.
13. Helewa A, Goldsmith CH, Lee P, Bombardier C, Hanes B, Smythe HA, et al. Effects of occupational therapy home service on patients with rheumatoid arthritis. *Lancet* 1991;337:1453-6.
14. Helewa A, Smythe HA, Goldsmith CH. Can specially trained physiotherapists improve the care of patients with rheumatoid arthritis? A randomized health care trial. *J Rheumatol* 1994;21:70-9.
15. Li LC, Davis AM, Lineker S, Coyte PC, Bombardier C. Outcomes of home-based rehabilitation provided by primary therapists for patients with rheumatoid arthritis: a pilot study. *Physiother Can*. In press.
16. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life: a conceptual model of patient outcomes. *JAMA* 1995;273:59-65.
17. Lineker S, Wilkins A. A retrospective chart review of the CTS goal oriented recording systems. 95-5. Toronto, Canada: Arthritis Community Research & Evaluation Unit; 1995.
18. Lineker SC, Badley EM, Hughes EA, Bell MJ. Development of an instrument to measure knowledge in individuals with rheumatoid arthritis: the ACREU rheumatoid arthritis knowledge questionnaire. *J Rheumatol* 1997;24:647-53.
19. Lineker SC, Bell MJ, Wilkins AL, Badley EM. Improvements following short term home based physical therapy are maintained at one year in people with moderate to severe rheumatoid arthritis. *J Rheumatol* 2001;28:165-8.
20. Maravic M, Bozonnat MC, Sevezan A, Gasqueres D, Pastor J, Pere M, et al. Preliminary evaluation of medical outcomes (including quality of life) and costs in incident RA cases receiving hospital-based multidisciplinary management. *Joint Bone Spine* 2000;67:425-33.
21. Ronen R, Braun Z, Eyal P, Eldar R. A community-oriented programme for rehabilitation of persons with arthritis. *Disabil Rehabil* 1996;18:476-81.
22. Felson DT, Anderson JJ, Boers M, Bombardier C, Furst D, Goldsmith C, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. *Arthritis Rheum* 1995;38:727-35.
23. Lorig K, Stewart A, Ritter P, Gonzalez V, Laurent D, Lynch J. Outcome measures for health education and other health care interventions. Thousand Oaks (CA): Sage Publications; 1996.
24. Stucki G, Liang MH, Stucki S, Bruhlmann P, Michel BA. A self-administered rheumatoid arthritis disease activity index (RADAI) for epidemiologic research: psychometric properties and correlation with parameters of disease activity. *Arthritis Rheum* 1995;38:795-8.
25. Fransen J, Langenegger T, Michel BA, Stucki G. Feasibility and validity of the RADAI, a self-administered rheumatoid arthritis disease activity index. *Rheumatology (Oxford)* 2000;39:321-7.
26. Gignac MA, Cott C, Badley EM. Adaptation to chronic illness and disability and its relationship to perceptions of independence and dependence. *J Gerontol B Psychol Sci Soc Sci* 2000;55:P362-72.
27. Wang PP, Badley EM, Gignac M. Activity limitation, coping efficacy and self-perceived physical independence in people with disability. *Disabil Rehabil* 2004;26:785-93.
28. Guillemin F, Suurmeijer T, Krol B, Bombardier C, Briancon S, Doeglas D, et al. Functional disability in early rheumatoid arthritis: description and risk factors. *J Rheumatol* 1994;21:1051-5.
29. Fuhrer MJ. Overview of clinical trials in medical rehabilitation: impetuses, challenges, and needed future directions. *Am J Phys Med Rehabil* 2003;82 Suppl:S8-15.
30. Shadish WR Jr, Cook TD, Campbell DT. Statistical conclusion validity and internal validity: experimental and quasi-experimental designs for generalized causal inference. New York: Houghton Mifflin Company; 2002. p. 33-63.
31. Stucki G. Understanding disability. *Ann Rheum Dis* 2003;62:289-90.
32. Koehn C, Dooley A, Hofstetter C, Qualman A. Determining the research priorities of people living with arthritis. The Arthritis Society; 2002. URL: [www.arthritis.ca/look%20at%20research/cap/patient/default.asp?s=1](http://www.arthritis.ca/look%20at%20research/cap/patient/default.asp?s=1).
33. Li LC, MacKay C, and the CARE III Local Planning Committee. CARE III online patient survey: summary of preliminary analysis. The Arthritis Society; 2005. URL: [www.arthritis.ca/look%20at%20research/surveys/caresummary/default.asp?s=1](http://www.arthritis.ca/look%20at%20research/surveys/caresummary/default.asp?s=1).
34. Sprangers MA, Schwartz CE. Integrating response shift into health-related quality of life research: a theoretical model. *Soc Sci Med* 1999;48:1507-15.
35. Lefebvre JC, Keefe FJ, Affleck G, Raezer LB, Starr K, Caldwell DS, et al. The relationship of arthritis self-efficacy to daily pain, daily mood, and daily pain coping in rheumatoid arthritis patients. *Pain* 1999;80:425-35.
36. Tsay SL, Halstead MT, McCrone S. Predictors of coping efficacy, negative moods and post-traumatic stress syndrome following major trauma. *Int J Nurs Pract* 2001;7:74-83.
37. Kraaimaat FW, Brons MR, Geenen R, Bijlsma JW. The effect of cognitive behavior therapy in patients with rheumatoid arthritis. *Behav Res Ther* 1995;33:487-95.
38. Gerber L, Furst G, Shulman B, Smith C, Thornton B, Liang M, et al. Patient education program to teach energy conservation behaviors to patients with rheumatoid arthritis: a pilot study. *Arch Phys Med Rehabil* 1987;68:442-5.
39. Mowat AG, Nichols PJ, Hollings EM, Haworth RJ, Aitken LC. A comparison of follow-up regimes in rheumatoid arthritis. *Ann Rheum Dis* 1980;39:12-7.
40. Buljina AI, Taljanovic MS, Avdic DM, Hunter TB. Physical and exercise therapy for treatment of the rheumatoid hand. *Arthritis Rheum* 2001;45:392-7.
41. Hansen TM, Hansen G, Langgaard AM, Rasmussen JO. Long-term physical training in rheumatoid arthritis: a randomized trial with different training programs and blinded observers. *Scand J Rheumatol* 1993;22:107-12.

## APPENDIX A. WILSON AND CLEARY'S QUALITY OF LIFE MODEL (16)



APPENDIX B. SENSITIVITY ANALYSIS OF CLINICAL RESPONDERS USING EXTREME SCENARIOS*				
Scenario	PTM group (n = 63)	TTM group (n = 48)	$\chi^2$	P
Scenario 1†				
Clinical responder	31 (49.2)	9 (18.8)	10.06	0.001
Non-clinical responder	32 (50.8)	39 (81.3)		
Scenario 2‡				
Clinical responder	31 (49.2)	13 (27.1)	5.57	0.018
Non-clinical responder	32 (50.8)	35 (72.9)		
Scenario 3§				
Clinical responder	24 (38.1)	9 (18.8)	4.88	0.027
Non-clinical responder	39 (61.9)	39 (81.3)		
Scenario 4¶				
Clinical responder	24 (38.1)	13 (27.1)	1.49	0.223
Non-clinical responder	39 (61.9)	35 (72.9)		
<p>* Values are the number (percentage) unless otherwise indicated. PTM = primary therapist model; TTM = traditional treatment model; missing case = a patient with incomplete assessment in any of the core measures at discharge and 6 months.</p> <p>† Missing PTM cases = responders, missing TTM cases = nonresponders.</p> <p>‡ All missing cases = responders.</p> <p>§ All missing cases = nonresponders.</p> <p>¶ Missing PTM cases = nonresponders, missing TTM cases = responders.</p>				