CRITICALLY APPRAISED PAPER (CAP)


CLINICAL BOTTOM LINE

The researchers in this randomized controlled trial examined the effectiveness of an educational–behavioral joint-protection program for people with moderate to severe rheumatoid arthritis. Outcomes measured in this study were pain, disability, and health status, including occupational performance in activities of daily living and self-efficacy. According to the researchers, most joint-protection programs include the traditional use of assistive devices, therapeutic activities, therapeutic exercises, alternative biomechanical movement patterns, and splints. These programs tend to fail, however, because of patients’ inability to manage and maintain the items recommended in the programs. This study proposed an alternative approach that helped participants enhance their self-efficacy and self-management by learning and applying new skills in their everyday routine, along with the complementary use of medication.

The occupational therapy intervention sessions addressed six sequential areas. These included (1) the pathophysiology of rheumatoid arthritis, which included the course of the disease and functional changes through pain, joint deformity, and damage; (2) the pain and stress mechanisms (which detailed the connection among pain, muscles, stress, tension, and depression) and cognitive measures of management; (3) the importance of safe exercises with correct biomechanical movements of involved joints, including compensatory techniques to perform exercises, the number of repetitions, and the time of day to exercise to decrease fatigue; (4) rest routines to decrease joint overload and muscle contractions; (5) the use of joint-protection techniques in occupational tasks; and (6) the use of assistive or technical equipment to prevent or decrease joint overload.

The sessions involved teaching information to patients and their partners with use of return
demonstration. Participants also kept a diary and had monthly consultations with the occupational therapist for compliance and motivation.

The researchers used three measures important to occupational therapy interventions: the Visual Analogue Scale (VAS) to assess pain, the Health Assessment Questionnaire (HAQ) to assess functional status, and the Arthritis Impact Measurement Scales 2 (AIMS2) to assess disability and health status among arthritic patients. The outcome scores had a common trend in the experimental group, whereby pain scores decreased and both functional and health status scores increased. The researchers stated that the results did not deviate from similar studies that increased participants’ knowledge of rheumatoid arthritis and use of pain-management methods, because this approach enhances new behaviors among participants. This change in behavior was identified as a possible cause of improvement in activities of daily living with decreased disability and pain.

Limitations noted in the study included lack of data on disease activity, which might have correlated with increased pain; lack of an intermediate assessment during the study; and the absence of measures of dexterity, grip strength, and range of motion. This study can be reproduced in outpatient settings with patients diagnosed with moderate to severe rheumatoid arthritis, using the six sequential methods along with the complementary use of medication.

The study is beneficial because it offers a guide to occupational therapists in designing interventions with rheumatoid arthritis patients. It moves the focus of intervention from deficits and impairments to a new focus on reviewing the impact of pain on function and the importance of using knowledge of various pain-management interventions to produce a behavioral change in the patient. That is, this approach allows the occupational therapist to reflect on integrating knowledge of the disease process and theories of social learning and self-management into the plan of care.

Future studies are required in other settings, such as home-health and skilled nursing facilities, using the same six sequential contents for the sessions to gain psychometric data. In summary, increased knowledge of a disease process along with use of self-management techniques may lead to behavioral changes and improve gains among patients with rheumatoid arthritis.

**RESEARCH OBJECTIVE(S)**

Determine the effects of participation in a joint education–behavioral program on improving pain, disability, health status, and occupational performance for patients with moderate to severe rheumatoid arthritis

**DESIGN TYPE AND LEVEL OF EVIDENCE**
Level I: Randomized controlled trial

PARTICIPANT SELECTION

How were participants recruited and selected to participate?

A total of 91 participants were recruited from a hospital outpatient rheumatology department.

Inclusion criteria:

- Participants were diagnosed with rheumatoid arthritis according to the 1987 American Rheumatism Association criteria: (1) morning stiffness in and around joints lasting at least 1 hour before maximal improvement; (2) soft-tissue swelling (arthritis) of three or more joint areas observed by a physician; (3) swelling (arthritis) of the proximal interphalangeal, metacarpophalangeal, or wrist joints; (4) symmetric swelling (arthritis); (5) rheumatoid nodules; (6) the presence of rheumatoid factor; and (7) radiographic erosions or periarticular osteopenia in hand or wrist joints. Criteria 1–4 must have been present for at least 6 weeks.
- Participants were receiving treatment with antitumor necrosis factor alpha (anti-TNFα) medication (infliximab).
- Participants were between 18 and 65 years of age.
- Participants presented with no variations in drug therapy in the 6 months before the trial.
- Participants did not present with severe disability that seriously compromised their independence in activities of daily living, such as dressing, walking, or moving.

Exclusion criteria:

- Previous participation in educational training
- Variations in drug therapy at any time during the trial
- Rehabilitation treatment or orthopedic surgery during the trial

PARTICIPANT CHARACTERISTICS

N = 85

<table>
<thead>
<tr>
<th>#/ % Male:</th>
<th>Experimental group: 11/23%</th>
<th>Control group: 13/15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>#/ % Female:</td>
<td>Experimental group: 35/76%</td>
<td>Control group: 57/67%</td>
</tr>
</tbody>
</table>

Ethnicity: Not reported

Disease/disability diagnosis: Rheumatoid arthritis
# INTERVENTION AND CONTROL GROUPS

## Group 1: Experimental group

| Brief description of the intervention | The experimental group continued the same medication regimen as the control group (anti-TNFα medication: infliximab) and participated in an educational–behavioral joint-protection program. The sessions consisted of four meetings, each approximately 3 hours in length, attended by 4–6 participants with one or more family members or a partner. Educational methods included group discussions, problem solving, guided practice, and lectures. Each session began with feedback, continued to discussion on home practices, and concluded with each individual receiving an illustrated program guide with a home guide. The facilitating clinicians called patients monthly to follow up on recommended exercises and to provide encouragement to use the educational guides.  
Educational program topics included  
- Pathophysiology of rheumatoid arthritis to increase knowledge of the disease, with a focus on factors that increase pain, joint damage, and deformity  
- Mechanisms and control of pain and stress, including the relationships among pain, muscle tension, stress, depression, and cognitive methods of pain management (e.g. relaxation)  
- Home exercise program that included upper extremity joint exercises of the participant’s fingers, wrists, shoulders in a seated position, and lower extremity joints in a supine or prone position. Participants were taught to complete the exercises four to five times per week, 10–15 repetitions per set, completing the upper extremity in the morning and the lower extremity in the afternoon to avoid fatigue.  
- Rest to avoid muscle contractions and joint overload  
- Joint protection and energy conservation, which included various joint-protection techniques and homework to identify problem activities and to find solutions based on imparted principles |

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- Use of adaptive equipment designed to avoid joint overload

<table>
<thead>
<tr>
<th>How many participants in the group?</th>
<th>46</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where did the intervention take place?</td>
<td>The authors did not specify where the educational meetings and training were held.</td>
</tr>
<tr>
<td>Who delivered?</td>
<td>The authors did not specify who delivered the educational sessions. The educational program was developed by an interdisciplinary team of an occupational therapist, physical therapist, physiatrist, and rheumatologist.</td>
</tr>
<tr>
<td>How often?</td>
<td>Four sessions, for approximately 3 hours every 3 weeks</td>
</tr>
<tr>
<td>For how long?</td>
<td>8 months</td>
</tr>
</tbody>
</table>

**Group 2: Control group**

<table>
<thead>
<tr>
<th>Brief description of the intervention</th>
<th>The control group received only the anti-TNFα medication (infliximab) and continued with medication monitoring and a medical-management regimen in the follow-up months. No other additional treatments were performed or permitted (including therapies).</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many participants in the group?</td>
<td>39</td>
</tr>
<tr>
<td>Where did the intervention take place?</td>
<td>Standard of care; no intervention occurred</td>
</tr>
<tr>
<td>Who delivered?</td>
<td>Routine care from the participant’s regular care team (e.g., physician, rheumatologist)</td>
</tr>
<tr>
<td>How often?</td>
<td>N/A</td>
</tr>
<tr>
<td>For how long?</td>
<td>8 months</td>
</tr>
</tbody>
</table>

**INTERVENTION BIASES**

**Contamination:**

| YES | NO | The control group did not receive any known rehabilitative therapy or joint-protection education. |

**Co-intervention:**
Neither the experimental nor the control group was noted to receive any other intervention.

Timing of intervention:

The study occurred over 8 months. It is possible that participants made general improvements over such a long period of time.

Site of intervention:

Not specified for the experimental group or the control group

Use of different therapists to provide intervention:

Baseline equality:

Both the control group and the experimental group were taking the anti-TNFα medication (infliximab). These two groups were also comparable at baseline in terms of sociodemographic characteristics, clinical variables, and outcome scores.

MEASURES AND OUTCOMES

Measure 1: Arthritis Impact Measurement Scales 2

<table>
<thead>
<tr>
<th>Name/type of measure used:</th>
<th>Arthritis Impact Measurement Scales 2 (AIMS2), Italian Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>What outcome is measured?</td>
<td>• Evaluates disability and health status</td>
</tr>
<tr>
<td></td>
<td>• Five subscales (Physical Function, Symptoms, Work, Psychological Dimension, and Social Interaction)</td>
</tr>
<tr>
<td>Is the measure reliable (as reported in the article)?</td>
<td>YES ☐ NO ☐ Not Reported ☒</td>
</tr>
<tr>
<td>Is the measure valid (as reported in the article)?</td>
<td>YES ☐ NO ☐ Not Reported ☒</td>
</tr>
<tr>
<td>When is the measure used?</td>
<td>For the experimental group, the measure was administered at baseline, every 4 weeks, and at the end of the program. The control group completed this measure at baseline and at the end of the study.</td>
</tr>
</tbody>
</table>

Measure 2: Health Assessment Questionnaire
Name/type of measure used:  | Health Assessment Questionnaire (HAQ)  
---|---
What outcome is measured?  | The HAQ is a 20-item self-administered scale consisting of eight subscales (Dressing and Grooming, Arising, Eating, Walking, Hygiene, Reach, Grip, and Other Activities) that evaluate physical function during activities of daily living.
Is the measure reliable as reported in the article?  | YES ☐ NO ☐ Not Reported ☒
Is the measure valid as reported in the article?  | YES ☐ NO ☐ Not Reported ☒
When is the measure used?  | For the experimental group, this measure was used at each session. The control group completed this measure at baseline and at 8 months postintervention.

**Measure 3: Visual Analogue Scale**

Name/type of measure used:  | Visual Analogue Scale (VAS)  
---|---
What outcome is measured?  | • Pain intensity is measured on a 100-mm scale (0 = no pain, 100 = maximum pain).
• Participants mark a point on the line to describe their average degree of hand pain during normal activities.
Is the measure reliable (as reported in the article)?  | YES ☐ NO ☐ Not Reported ☒
Is the measure valid (as reported in the article)?  | YES ☐ NO ☐ Not Reported ☒
When is the measure used?  | The experimental group completed the measure at baseline, every 4 weeks, and at the end of the program. The control group completed this measure at baseline and at the end of the study.

**MEASUREMENT BIASES**

Were the evaluators blind to treatment status?  | The evaluators conducting assessments did not have knowledge of participant group placements.
---|---
YES ☒ NO ☐

Was there recall or memory bias?
Participants completed the VAS, AIMS2, and HAQ assessments every 4 weeks during the study, which increased the potential for the participant to recall prior responses and possibly inflate responses.

Other measurement biases:

None.

RESULTS

List key findings based on study objectives:

Participants in the educational–behavioral joint-protection program significantly improved their self-management of activities of daily living and disease management after the 8-month intervention, compared with the participants who received standard-of-care medication-management only.

HAQ scores improved in the experimental group ($p = .1$) and worsened in the control group ($p = .09$).

AIMS2 scores improved in the areas of symptoms ($p = .02$), physical function ($p = .05$), and social interaction ($p = .04$) for the experimental group, with no significant changes for the work ($p = .31$) and psychological dimensions ($p = .19$). The control group scores worsened in symptoms ($p = .44$), physical function ($p = .36$), social interaction ($p = .39$), work ($p = .55$), and psychological dimensions ($p = .64$).

It is also worthwhile to mention that there were no differences in HAQ and AIMS2 scores between the 24 experimental group participants who completed exercises four times per week and the 12 control group participants who exercised only twice per week. The VAS scores, however, were significantly less in the experimental group ($p = .04$), whose participants exercised four times per week, than in the control group ($p = .10$).

Was this study adequately powered (large enough to show a difference)?

The researchers did not report on statistical power calculations required to trust findings. The sample sizes of 46 and 39 in the two groups may be adequately powered to show true statistical difference.

Were the analysis methods appropriate?

The researchers used the Wilcoxon matched-pairs signed ranks to identify changes between baseline and final scores for each measure in the control and experimental groups. They used the unpaired $t$ test to test the baseline characteristics of the control group and experimental group for interval data. The chi-square test was used for the baseline characteristic for the categorical data. The researchers used the Mann–Whitney $U$ test to identify
significant differences in gains for each measure (VAS, HAQ, AIMS2) in the two groups at 8 months and also the baseline characteristics of participants in groups for the ordinal data. The researchers used the Statistical Package for Social Sciences (SPSS version 11.5; SPSS, Chicago) to process the statistical data, which included interval data, ordinal data, and categorical data, with the statistical data set at \( p \leq .05 \). This was appropriate for comparing the two groups to determine whether change was a result of the intervention and not due to change.

Were statistics appropriately reported (in written or table format)?

| YES ☒ | NO ☐ | The results were reported statistically in three tables as well as in text format:
|       |       | • Patient demographic and clinical characteristics
|       |       | • Baseline scores, indicating the mean score and standard deviations
|       |       | • Outcome variables and averages in score changes for both groups

Was participant dropout less than 20% in total sample and balanced between groups?

| YES ☒ | NO ☐ | The participant dropout rate was 17%. The number of participant dropouts was 15, because of modification of ongoing medical treatments, the need for rehabilitation treatment, and the abandonment of the study for other reasons not mentioned.

What are the overall study limitations?

- The researchers did not account for disease activity during the program duration to capture changes in pain and disability, which might have affected activities of daily living in both the control group and the experimental group.
- An intermediate outcome measure should have been used to capture disease trends, such as pain and disability.
- Measurements of dexterity and assessments of the various range of motion and grip strength were not included.

CONCLUSIONS

State the authors’ conclusions related to the research objectives.

People with moderate to severe rheumatoid arthritis attending an 8- month educational–behavioral joint-protection program, in combination with medication, demonstrated less pain and disability with improved health status, compared with people with rheumatoid arthritis who took medication alone. An important factor mentioned in the study’s conclusion is the importance of behavioral changes in correlation to self-efficacy. The authors described self-efficacy as the participants’ perception of their capabilities to organize and execute actions that are relevant to daily routines. Self-efficacy, however, requires that participants learn about the
disease process so they can become independent in their activities of daily living and remain compliant with recommendations for improved health outcomes in pain and disability related to rheumatoid arthritis.

Knowledge about rheumatoid arthritis also helps participants to integrate joint protection into their habitual or routine biomechanical movement patterns, through problem-solving and simplification strategies. The authors also mentioned that success in the program included keeping participants motivated to perform exercises and therapeutic strategies through the use of diaries, supportive telephone calls, and involvement of relatives or partners.

Hence, on the basis of evidence presented in this study, an educational–behavioral joint-protection program was found to be effective in decreasing pain and disability and increasing participation in activities of daily living and other domains of occupation necessary for improved quality of life for individuals with rheumatoid arthritis at the various stages of the disease. The participants needed to participate in all aspects of the program and interventions taught during the sessions to gain and maintain positive results, however.

This work is based on the evidence-based literature review completed by Stacey Scott, PPOTD, OTR/L, and Sarah Smith, DSc, OTR/L, faculty advisor, Creighton University.


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For more information about the Evidence-Based Literature Review Project, contact the American Occupational Therapy Association, 301-652-6611, x2052.