

Operant Learning versus Energy Conservation Activity Management Treatments for Patients with Fibromyalgia: A Randomized Controlled Trial

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Introduction

- Activity management (AM) (sometimes referred to as activity pacing) is a treatment widely used in individuals with chronic pain, but its potential benefits remain unproven
- There are two key approaches to AM: operant learning (OL) and energy conservation (EC)¹
- The **Operant Learning** approach uses positively reinforced activity quotas that are time and/or goal contingent²
- The **Energy Conservation** approach focuses on balancing the patient's energy expenditures³
- Fibromyalgia Syndrome (FMS) is a common pain condition associated with considerable suffering that has also been the frequent target of AM methods
- However, the overall efficacy of AM, as well as the relative strengths and weaknesses of the OL and EC models for explaining the mechanisms of AM in individuals with FMS, are not yet known

Objectives

- To investigate the effectiveness and relative benefits of OL and EC activity management treatments on pain and fatigue
- To assess the impact of OL and EC on physical functioning, mental wellbeing and quality of life in patients with FMS

Methodology

Population: FMS participants were recruited from multiple sources including health professionals from primary and tertiary care settings, FMS associations, patient support groups and direct solicitations from the community.

Eligibility criteria:

- Age ≥ 18 years
- Meet the ACR's 1990 or 2010 diagnosis criteria for FMS
- Available to follow a 10-week AM program and follow-up sessions (3 and 6 months)
- Never having received an AM intervention before
- Able to provide informed consent

Study design:

- FMS participants were randomly assigned to one of four treatment groups (OL, Delayed-OL, EC or Delayed-EC) and were blind to study hypotheses
- The delayed groups received the AM treatment 3 months later and served as a Usual Care control group
- Data were collected at delayed, pre- and post-treatment
- Both the OL and EC treatments were given by occupational therapists as 3-month long "stand-alone" interventions, comprising ten weekly 120-minute group sessions with 6-12 participants per group
- Handouts and homework were provided to group participants at every session

Analysis and Results

Sample Description:

- 178 participants were recruited, of which 5 were excluded, 60 dropped out before starting, and 44 dropped out during treatment. This resulted in a final sample of 69 participants, 35 in the EC group and 34 in the OL group
- A set of comparisons (t-test and/or chi-squared test (χ^2)) were first conducted for socio-demographic variables and primary outcome measures
- As shown in Table 1, participants in the OL groups and EC groups did not differ according to their demographic characteristics as well as their average pain and fatigue levels

Treatment Effectiveness:

- A split-plot factorial design (ANOVA for repeated-measures) served as the basis for analyzing these data (OL versus EC, EC vs D-OL and OL vs D-EC) where delayed groups were used as a Usual Control (UC) group
- In order to minimize Type I errors, a p-value of $\leq .01$ and at least a moderate effect size (Partial Eta-Squared $\eta_p^2 \geq .09$) were required for a difference to be statistically significant
- As shown in Table 2, we found no statistical difference between the Usual Care, OL and EC groups for changes in pain and fatigue ratings, physical functioning, and psychological well-being. It is worth noting that we observed non-significant tendencies showing that the OL group did better than the UC group with respect to fatigue interference and depressive symptoms ratings. A similar trend was also found for lower depressive symptoms scores in the EC group when compared to the UC group
- Our results showed that the OL treatment was superior to EC in two SF36v2 domains: Physical Functioning and Social Functioning while a non-significant trend was also observed for the Mental Health domain

- Participants in the OL group fared better than the UC group with respect to improvements within the SF36v2 Physical Role, Bodily Pain, Vitality and Social Functioning scales while the EC group showed no differences from the Usual Care group. However, our results also suggest a non-significant tendency where the EC group showed better health-related quality of life with respect to the SF36v2 Physical Functioning and Bodily Pain domains than the UC group did.

Table 1: Sample characteristics of 69 participants with FMS, pre-treatment

	Operant Learning groups	Energy Conservation groups	P-value
A. Demographic Measures			
Age (mean, SD)	52.9 (10.3)	50.5 (8.9)	0.291
Sex - % of women	94%	97%	0.538
Ethnicity - % of Caucasian	94%	91%	0.667
Marital Status - % in a relationship	59%	60%	0.921
Work Status - % Unemployed or on disability compensation	56%	58%	0.833
Household Income - % Less than 49,999\$	63%	58%	0.674
B. Primary Outcome measures (mean, SD)			
Average pain (0 to 10 - NRS)	6.1 (2.0)	6.5 (1.7)	0.413
Usual fatigue (0 to 10 - NRS)	6.8 (1.8)	6.7 (1.9)	0.846

Table 2: Comparisons of activity management treatment effectiveness

Outcome variables	Treatment Groups (mean (SD))				Operant Learning vs Energy Conservation		Operant Learning vs Usual Care		Energy Conservation vs Usual Care	
	Operant Learning Pre Treatment	Operant Learning Post Treatment	Energy Conservation Pre Treatment	Energy Conservation Post Treatment	P-Value	ηp^2	P-Value	ηp^2	P-Value	ηp^2
A. Primary outcome measures										
Average pain (0 to 10 - NRS)	5.93 (2.0)	5.9 (1.9)	6.7 (1.8)	5.9 (1.9)	0.193	0.028	0.534	0.008	0.062	0.061
Usual fatigue (0 to 10 - NRS)	6.7 (1.8)	5.9 (2.2)	6.8 (1.9)	6.5 (1.9)	0.292	0.018	0.622	0.005	0.083	0.053
B. Secondary outcome measures										
Brief Pain Inventory (BPI)	47.5 (16.0)	40.3 (16.5)	47.3 (14.2)	45.2 (12.6)	0.098	0.043	0.099	0.058	0.160	0.034
Brief Fatigue Inventory (BFI)	48.3 (13.0)	42.0 (16.5)	46.4 (16.8)	45.5 (15.8)	0.137	0.035	0.038	0.090	0.370	0.014
Medical Outcomes Study - Sleep scale (MOS)	36.6 (8.3)	38.3 (7.2)	34.4 (9.5)	37.4 (10.4)	0.424	0.011	0.479	0.011	0.727	0.004
Hospital Anxiety and Depression Scales										
- Depression scale	16.0 (2.0)	15.3 (1.9)	15.5 (1.7)	15.5 (2.3)	0.174	0.030	0.028	0.101	0.021	0.161
- Anxiety scale	17.0 (2.2)	17.3 (2.3)	16.6 (2.3)	16.7 (2.6)	0.727	0.002	0.886	0.000	0.921	0.000
SF36v2 Health Survey										
- Physical Functioning	31.0 (8.8)	33.9 (9.0)	31.8 (7.7)	30.2 (8.2)	.009*	.108*	0.295	0.024	0.018	0.098
- Role Physical	28.2 (6.6)	33.9 (7.3)	29.0 (6.0)	31.3 (6.0)	0.062	0.056	.009*	.140*	0.350	0.016
- Bodily Pain	31.7 (6.4)	34.2 (5.2)	30.0 (6.3)	33.3 (5.7)	0.518	0.007	.014*	.125*	0.029	0.084
- General Health	37.2 (11.2)	38.7 (9.7)	34.3 (8.0)	35.9 (8.3)	0.919	0.000	0.737	0.002	0.116	0.044
- Vitality	31.9 (7.4)	37.8 (8.1)	34.7 (8.8)	36.4 (9.6)	0.62	0.056	.000*	.236*	0.141	0.039
- Social Functioning	30.0 (7.4)	36.2 (10.0)	31.1 (11.0)	31.0 (8.7)	.010*	.104*	.008*	.143*	0.213	0.028
- Role Emotional	33.5 (8.9)	38.2 (11.1)	33.1 (11.8)	34.6 (12.2)	0.296	0.018	0.197	0.036	0.940	0.000
- Mental Health	39.6 (8.3)	44.5 (8.9)	39.0 (10.7)	39.9 (9.9)	0.046	0.063	0.023	0.108	0.539	0.007

Conclusions

- This study seems to support using activity management within an operant learning theoretical model over energy conservation in treating individuals with FMS
 - Even though we did not observe any improvement in pain and fatigue ratings, our results suggest that operant learning treatments can be beneficial for patients with FMS in improving their quality of life
 - More research with larger sample sizes and with patients suffering from different pain conditions will be needed to determine the reliability and generalizability of these findings, which could have important implications for health care efficacy, resource allocation and expenditures
- Main study limitations:**
- low responses rates and high dropout rates
 - small sample size reducing the statistical power
 - results cannot necessarily be generalized to a general population of FMS patients, since most of our referrals came from tertiary care centres (Rheumatology department or the Pain Clinic)

Acknowledgements and Disclosures

Thanks are due to the contributions of the Rheumatology Day Program occupational therapists: Joan Laxamana, Tammy Rice and Stacey Gicante. We also want to acknowledge the work of our research volunteer Sandra Leckie and of Martin-Luc Girard for his editing work and design of patient websites. This study and Dr. Mélanie Racine's salary was supported by a bequest from the estate of Mrs. Beryl Ivey to Dr. Warren R. Nielson. Dr. Mélanie Racine's research project was also funded by The Earl Russell Trainee Grant in Pain Medicine, Western University, London, Ontario.

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