Out-patient cognitive-behavioural treatment of fibromyalgia: Impact on pain response and health status

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Out-patient cognitive-behavioural treatment of fibromyalgia: Impact on pain response and health status.
Pain Res Manage 1997;2(3):145-150.

OBJECTIVE: To evaluate a cognitive-behavioural out-patient program for patients with fibromyalgia syndrome.
PATIENTS AND METHODS: A quasi-experimental design was used to evaluate 101 patients who participated in a four-week program that included psychological, family educational, occupational therapy and physiotherapy interventions. After discharge, patients were seen four times over one year for day-long review sessions. Five pain response scales from the Multidimensional Pain Inventory (MPI) and the Fibromyalgia Impact Questionnaire (FIQ) were used to assess treatment effects. Data were analyzed using multivariate ANOVAs followed by multiple comparisons using Tukey's honestly significant difference test.
RESULTS: The overall multivariate effect for the MPI was significant ($P<0.0001$). Subsequent multiple comparisons indicated consistent improvement in pain severity, life interference, control, emotional distress and activity level scores at discharge, but no change during a no-treatment waiting list control interval. These effects were maintained at a 12-month follow-up with the exception of activity level. The multivariate effect across the FIQ scales was significant ($P<0.01$). Multiple comparisons indicated that all variables except physical impairment improved at discharge. Impairment ($P<0.05$), anxiety and well-being ($P<0.01$) improved at follow-up compared with scores at admission.
CONCLUSIONS: Pain response and health status improve following intensive cognitive-behavioural treatment. These effects persist at one year but are generally weaker than at discharge. The largest effects were on indexes that reflect emotional status and general well-being. Implications of these findings for fibromyalgia treatment programs are discussed.

Key Words: *Chronic pain, Cognitive-behavioural treatment, Fibromyalgia*

Traitement ambulatoire de la fibromyalgie basé sur une approche comportementale et cognitive : impact sur la réponse à la douleur et sur l'état de santé

OBJECTIF : Évaluer un programme ambulatoire basé sur une approche comportementale et cognitive pour traiter les patients atteints de fibromyalgie.
MÉTHODES : On a utilisé un plan quasi-expérimental pour évaluer 101 patients qui ont participé à un programme d'une durée de 4 semaines comprenant une assistance psychologique, l'éducation de la famille, des séances d'ergothérapie et de physiothérapie. Les patients ont été revus à leur sortie du programme, quatre fois au cours de l'année pendant des sessions s'étalant sur toute la journée. Cinq échelles sur la réponse à la douleur tirées de l'inventaire de la douleur multidimensionnelle (IDM) et du questionnaire sur l'impact de la fibromyalgie (QIF) ont été utilisées pour évaluer les effets du traitement. On a procédé à des analyses de variance multidimensionnelles suivies par des comparaisons multiples faisant appel au test HSD de Tukey.
RÉSULTATS : L'effet global multidimensionnel pour l'IDM était significatif ($P<0,0001$). Les comparaisons multiples subséquentes indiquaient une amélioration constante des scores de l'intensité de la douleur, de l'intrusion de la douleur dans la vie quotidienne, de la maîtrise de soi, des difficultés émotionnelles et du niveau d'activité physique, à la sortie du programme, mais pas de changements pendant un intervalle de contrôle d'une liste d'attente sans traitement. Les effets du traitement se sont prolongés tout au long du suivi de 12 mois à l'exception du niveau d'activité. L'effet multidimensionnel à travers les échelles du QIF était significatif ($P<0,01$). Les comparaisons multiples indiquaient une amélioration de toutes les variables sauf de la déficience physique à la sortie du programme. Les scores de la déficience physique ($P<0,05$), l'anxiété et la sensation de bien-être ($P<0,01$) s'étaient améliorés pendant le suivi comparativement aux scores à l'entrée dans le programme.

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Received for publication April 14, 1997. Accepted June 20, 1997

CONCLUSIONS : La réponse à la douleur et l'état de santé se sont améliorés après un traitement intensif basé sur une approche comportementale et cognitive. Les effets de ce traitement persistent pendant un an mais sont de manière générale moins prononcés qu'à la sortie du programme. Les effets les plus marqués ont été observés sur les indices qui reflètent l'état psychologique et la sensation de bien-être globale. Les implications de ces résultats pour les programmes de traitement de la fibromyalgie sont discutés.

Interventions used to treat fibromyalgia syndrome (FS) include tricyclic drugs, muscle relaxants, nonsteroidal anti-inflammatory agents (1,2), electromyography (EMG) biofeedback training (3), aerobic exercise (4), hypnotherapy (5), education plus exercise (6), multimodal group therapy (7) and cognitive-behavioural therapy (CBT) (8,9). Some of these approaches are only effective for short periods of time whereas others, particularly the two latter programs, appear to promise long term effects. CBT has been recommended as a useful therapeutic measure in the treatment of FS (10), and preliminary data (8,9) from a CBT in-patient program have been encouraging. Randomized controlled trials (RCTs) of CBT present considerable difficulties and are even considered by some as unnecessary (11,12). Vlaeyen et al (13) conducted the only RCT using cognitive-behavioural techniques but had limited success; they suggest that their results may have been better had they embedded their cognitive-behavioural strategies within a more comprehensive program.

In-patient treatment of FS is prohibitively expensive and does not appear to offer a clear advantage over out-patient care. FS patients do not require 24 h nursing care and hence in-patient care is not cost-effective. The present study used a quasi-experimental design to provide an initial evaluation of the effectiveness of a multidisciplinary CBT day care program for patients with FS.

PATIENTS AND METHODS

Participants

Patients who met the American College of Rheumatology criteria for FS (14) were admitted if they continued to function poorly after receiving basic education about FS and appropriate medications. Exclusion criteria included major psychological or medical illness, unwillingness to discontinue narcotic analgesics and lack of fluency in English. Patients on compensation or involved in litigation were not excluded. Of 127 consecutive patients admitted, five dropped out or were asked to leave and 21 had missing data on one of the assessment instruments (see below) for at least one of the follow-up sessions. Thus, 101 patients entered the study. Sixty-seven also completed an additional assessment instrument (Fibromyalgia Impact Questionnaire [FIQ]). Average age of participants was 44.9 years (SD 8.1, range 20 to 60); 93 (92.1%) were female, 53.5% were currently working and 87 (86.1%) were living with a significant other (including children).

Treatment

Patients were admitted in small groups (normally six per group but size ranged from four to six patients) for a four-week day care program that included CBT (cognitive restructuring, reduction of pain behaviours, assertiveness training, relaxation training, EMG biofeedback and education about FS), physical therapy (stretching, strengthening and low impact aerobic exercises) and occupational therapy (principles of energy conservation and pacing). Follow-up sessions were provided at one, three, six and 12 months postdischarge and were designed to review and reinforce skills acquired during the four-week intensive portion of the program. During the four-week day care period, family members attended weekly group sessions that provided them with basic education about FS and the program. With the exception of family and pain behaviour interventions, the specific treatment components were similar to those employed in the authors' previous study (9) but were adapted to a group format. The treatment team comprised a psychologist, a psychometrist, two rheumatologists, a physiotherapist, a kinesiologist, an occupational therapist, an occupational therapy assistant and a social worker.

Design

A simple quasi-experimental pretest/post-test design was used (15) to provide a no-treatment baseline. Patients were initially assessed at the beginning (preadmission) and end (admission) of a waiting period before entering the treatment program (mean 10.8 weeks; range one to 46). Although this design did not control for all possible confounding factors, it was assumed that if participants did not change during this interval they would also be unlikely to change over the treatment interval in the absence of treatment. In addition to the two pretreatment assessments, participants were evaluated at discharge and at a 12-month follow-up.

Measures

Assessment materials included five scales from the Multidimensional Pain Inventory (MPI), a measure of response to pain (16); eight scales from the FIQ, a health status measure (17); and the Pain Experience Scale, a measure of distorted thinking and pain-related worry (18). MPI scales related to spouse responses were excluded from these analyses because, first, many patients were unmarried and, second, these scales were less related to expected treatment effects. FIQ scales related to work were excluded because only about half of the participants (53.5% at admission) were working outside the home before or after attending the program. These data were also not meaningful at discharge because patients were not working while attending the program. However, in order for these data to be easily compared with other studies using the FIQ, work-related scales were included in the calculation of FIQ total scores, following the scoring criteria provided by Burckhardt et al (17). The total score data were subjected to a separate repeated-measures ANOVA.

Tender points were evaluated according to the protocol of Wolfe and colleagues (14). The number of tender points could range from 11 to 18 at preadmission (diagnosis required minimum of 11 tender points) and zero to 18 for the remainder of the evaluations. Total myalgic score (TMS) was also obtained. TMS is the sum of tenderness ratings determined for each point by the application of a spring-loaded dolorimeter (Pain Diagnostics and Thermography; Italy) and was recorded as kg/cm^2. The points assessed were the insertion of the ligamentum nuchae just below the occipital protuberances, midtrapezius, lateral epicondyles of the humeri,

TABLE 1
Multidimensional Pain Inventory results

Scale	Pre-admission	Admission	Dis-charge	12 months postdischarge
Pain severity	4.16	4.21	3.70*	3.83*
Life interference	4.44	4.50	4.15*	4.11*
Life control	3.08	2.87	3.85*	3.41*
Affective distress	3.58	3.79	2.88*	3.27*
General activity	2.34	2.23	2.49*	2.26

*$P<0.001$

greater trochanters and medial fat pads of the knees (total 10 points). An increase in TMS reflected improvement.

Analysis

Data were analyzed using repeated-measures multivariate ANOVAs followed by multiple comparisons using Tukey's honestly significant difference (HSD) test (19) to control for type I error. Pillai's criterion (V) was used to the overall multivariate effect because it is the most robust of available test statistics (20). Estimates of strength of association (η^2) and statistical power ($1-\beta$) were also calculated. η^2 provides an index of the proportion of variance in the dependent variable attributable to the treatment effect (ie, magnitude of the treatment effect) (21). All analyses are based on a sample size of 101 except those related to the FIQ. The FIQ was introduced later and was completed by a subgroup of 67 participants.

RESULTS

Pain response

Multivariate ANOVA indicated an overall change across time for the MPI variables (Pillai's V[15,894]=7.76, P<0.0001). Subsequent HSDs (q) indicated that all these variables improved significantly at discharge, and all but activity level remained improved at the 12-month follow-up (Table 1). At discharge, the strongest treatment effects were obtained for life control and emotional distress. Pain severity and life interference showed more moderate effects, and general activity showed the smallest effect. At follow-up, treatment effects were generally smaller, with emotional distress, life control and life interference showing the strongest effects. The reduction in pain severity was less strong. None of these variables changed significantly between preadmission and admission assessments (ie, during the no-treatment condition). The moderate η^2s obtained were stronger for admission/discharge than admission/12-month comparisons (Table 2).

TABLE 3
Fibromyalgia Impact Questionnaire results

Scale	Pre-admission	Admission	Discharge	12 months postdischarge
Impairment	4.79	5.13	4.73	4.68*
Feel good	7.65	7.68	5.64**	6.59**
Pain	6.86	7.00	5.75**	6.45
Fatigue	7.81	8.31	7.28**	7.80
Rest	8.04	8.08	7.24**	7.63
Stiffness	7.52	7.29	5.98**	6.87
Anxiety	6.43	7.18	5.00**	6.06**
Depression	4.69	5.30	3.27**	4.93

*$P<0.05$; ** $P<0.01$

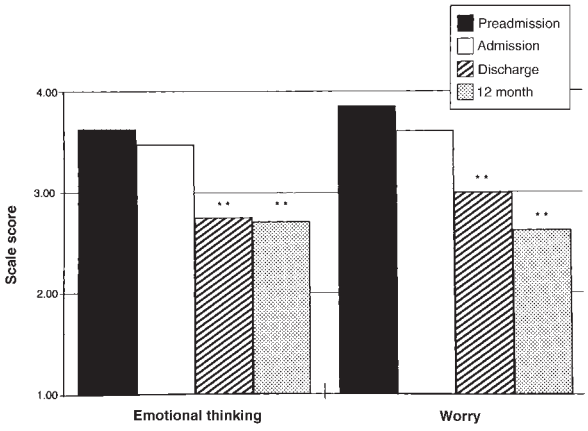

Figure 1) Pain Experience Scale. **Tukey's honestly significant difference test: P<0.01

TABLE 2
η^2s and powers for Multidimensional Pain Inventory (MPI) and Pain Experience Scale (PES) variables

	η^2		Power at P=0.05	
Scale	Admission/discharge	Admission/12 months	Admission/discharge	Admission/12 months
MPI pain severity	0.25	0.11	1.00	0.93
MPI life interference	0.23	0.18	1.00	1.00
MPI life control	0.45	0.19	1.00	1.00
MPI emotional distress	0.40	0.19	1.00	1.00
MPI general activity	0.22	0.00	1.00	0.05
PES emotional thinking	0.31	0.36	1.00	1.00
PES worry	0.21	0.46	1.00	1.00

TABLE 4
η^2s and powers for Fibromyalgia Impact Questionnaire (FIQ) variables

	η^2		Power at P=0.05	
Scale	Admission/discharge	Admission/12 months	Admission/discharge	Admission/12 months
FIQ Impairment	0.00	0.06	0.05	0.71
FIQ Feel good	0.42	0.17	1.00	0.99
FIQ Pain	0.22	0.05	1.00	0.57
FIQ Fatigue	0.20	0.08	1.00	0.80
FIQ Rest	0.14	0.06	0.98	0.69
FIQ Stiffness	0.22	0.02	1.00	0.36
FIQ Anxiety	0.35	0.17	1.00	0.99
FIQ Depression	0.26	0.02	1.00	0.24

TABLE 5
Tender point and total myalgic score data

	Mean	SD	Minimum	Maximum
Tender point count				
Admission	16.36	2.20	5*	18
Discharge	16.17	2.70	3	18
12 months	16.52	2.28	6	18
Total myalgic score				
Admission	24.90	9.93	7.4	55.3
Discharge	24.87	12.59	1.9	85.3
12 months	24.43	13.47	10.0	64.9

**All patients met the American College of Rheumatology diagnostic criteria, including a minimum of 11 of 18 tender points, at initial assessment for the program. At admission, two patients had tender point counts less than 11 (2% of the total sample)*

Emotional thinking and worry

Improvements in the emotional thinking and worry scales of the Pain Experience Scale were found between admission and discharge, and between admission and 12 months, consistent with the MPI results. In addition, the worry scale continued to improve after discharge such that patients indicated less worried cognitions at 12 months than they did at discharge (Figure 1). As depicted in Table 2, moderately strong η^2s were obtained for both variables at discharge, with emotional thinking showing a somewhat stronger treatment effect. In contrast, at follow-up the treatment effect on the worry scale was greater than that on the emotional thinking scale. The former scale also showed much stronger treatment effects at the 12-month assessment than at discharge.

Health status

Multivariate ANOVA indicated a significant effect across time, collapsing across the eight FIQ scales (Pillai's V[24,579]=3.20, P<0.0001). Table 3 illustrates means and HSDs for individual scales. All variables except physical impairment improved between admission and discharge. As depicted in Table 4, the strongest improvements were for the feel good and anxiety scales. More moderate changes occurred on the depression, stiffness and pain scales. The weakest, albeit significant, effects occurred with respect to fatigue and rest.

At follow-up, scores from the physical impairment, feel good and anxiety scales were significantly improved over admission levels. These effects were of smaller magnitude than those seen at discharge, with the feel good and anxiety scales reflecting somewhat stronger effects than the weak effect shown for impairment.

The FIQ total score reflected a moderately strong admission to discharge treatment effect (q[HSD]=7.79, P<0.01; η^2=0.338; 1–β=1.00), which was marginally significant at 12 months (q[HSD]=3.62, P<0.06; η^2=0.100; 1–β=0.776). No preadmission/admission difference was found for this variable.

Tender point count and TMS

No significant changes occurred in either tender point count or TMS across time (P>0.10) (Table 5).

DISCUSSION

Pain response and health status improved among FS patients following intensive cognitive-behavioural intervention. These changes persisted but were generally less strong at one year following treatment, indicating a decline in treatment effectiveness over the one-year follow-up. Changes seen in this study at four weeks are comparable with those previously reported at three weeks in our in-patient program (9). There were no significant differences on any of the outcome measures between preadmission and admission that suggest that the severity of symptoms and their effects were relatively constant during that interval. The largest magnitude treatment effects were for indexes that reflected emotional status and general well-being. The absence of significant changes in tender point counts and TMS in our patients may appear surprising; however, other published trials of various therapeutic interventions have also often failed to show a response to physician-assessed measures of pain (2). Bennett et al (7) showed a reduction in tender point counts but also used trigger point injections (7). Tender point counts, TMS and similar measures of pain either may not be sufficiently sensitive to change or may be inappropriate in assessing responses to CBT.

These results raise a number of questions concerning validity, generalizability and cost effectiveness. We used a quasi-experimental design that compared admission/discharge and admission/follow-up effects with a preadmission/admission interval. Although random assignment of patients to treatment and control conditions is optimal, considerable logistical difficulties are inherent (12). Bradley (10) suggested two ways of dealing with this problem. One is to use waiting time to admission as a control, as we have done. The other is to compare the CBT component with exercise or medication alone, or the latter two components with support and educational groups. Although Vlaeyen and co-workers (13) compared a cognitive intervention with support and education, their cognitive treatment protocol was less intense and of shorter duration than ours. Results of trials comparing our type of program with shorter, less intensive programs of physical exercise or education would be interpretable only if the latter programs were found to be equal or better. The feasibility of conducting a study in which patients are subjected to interventions of exercise or education that are of the same duration and intensity as in our cognitive group is questionable. Equating groups along these dimensions would likely reduce patient acceptance and create differentially higher drop-out rates. That is, artificially prolonging an educational comparison group simply so that it is of the same duration as the CBT treatment group would likely reduce its credibility because patients would recognize that little additional information was being conveyed. This awareness would, in turn, undermine the intervention and increase drop-outs. Merely exchanging one type of interpretive problem (ie, suboptimal control group) for another (ie, treatment credibility and differential drop-out confounds) would offer no overall advantage.

There is little standardization in the literature regarding how a 'cognitive-behavioural' or 'multidisciplinary' treatment program is defined. The specific components of such programs, their intensity, duration and staffing vary enormously. For example, in our study patients were seen for 6 h daily, five days/week for one month and then at four follow-up visits. The program of Bennett et al (7) involved weekly sessions of 90 mins' duration for six months; the program of Vlaeyen et al (13) involved 12 sessions of 90 mins each.

Medications were apparently allowed in all programs. In the program of Bennett et al (13), those not taking antidepressants were started on tricyclics, selective serotonin reuptake inhibitors or both. As noted previously, Bennett et al also included trigger point injections in their treatment regimen. Gainful employment varied somewhat among the three program populations, with the lowest percentage of patients doing paid work in the group studied by Vlaeyen et al (13) (34.1%). Unlike our program, the study by Bennett et al excluded patients who had litigation pending with respect to their FS.

The severity of FS among various treatment programs is also difficult to assess because a variety of partially overlapping methodologies are used. Lack of consistency there further obfuscates comparison of outcomes. The absence of standardization of treatment makes it difficult to compare meaningfully various programs with each other. The plethora of outcome measures being used in the FS literature generally (2) creates additional cross-program comparison problems.

Programs also vary according to the amount of individual attention patients receive. Vlaeyen et al (13) suggested that their results may have been poor partly due to the lack of individualized treatment. Bennett et al (7) provided individual therapy for depression. Our program falls between these two extremes; in our study therapists would speak with patients individually if they were experiencing difficulty with a particular program element.

Of concern was the average level of self-rated depression (FIQ depression scale) at the 12-month follow-up assessment. Although the extent to which ratings on a single visual analogue scale are related to clinical depression is unclear, the average self-rated depression result represents an increase in negative affect that is inconsistent with our expectations. Because affective disorders are common among individuals with FS, this is an area that warrants further investigation within the context of the general cognitive-behavioural approach. Perhaps programs of this type should provide treatment components that specifically address depressive disorders. Moreover, it may be concluded that although multicomponent programs such as these generally appear efficacious, it is not possible to attribute improvement to one treatment component or another. The factor(s) that produce improvement remain obscure.

The improvements obtained in this study were modest. One factor that may have restricted the magnitude of treatment effects is individual differences in treatment response. Although patients on average improved, there were patients who relapsed or did not improve as a result of treatment. Indeed, it may be naive to treat FS patients as a homogeneous group that will respond to any treatment in a uniform manner. Just as some FS patients (approximately 80%) (1) do not respond to low dose amitriptyline treatment, not all patients are likely to benefit from cognitive-behavioural programs. Treatment effectiveness is likely to be optimized when subgroups of patients with FS who respond differentially to various interventions can be identified, and the appropriate treatments selected. For example, Turk and associates (22) identified three clusters of FS patients based upon behavioural and psychosocial characteristics and suggested that different treatment strategies may apply to each subgroup. The variability of treatment response suggests that future research should examine whether subgroups of patients respond better to this type of treatment. Failure to consider such subgroup characteristics could not only jeopardize treatment effects but may also limit our understanding of mechanisms underlying the disorder.

While patients appear to benefit from multidisciplinary treatment programs, their cost effectiveness can be questioned. Educational intervention alone appears to be a less costly alternative (23). However, in one study where the effects of education were evaluated using the FIQ, no significant treatment effects were found (6). Similarly, Vlaeyen and colleagues (13) concluded that their educational program for patients with long-standing FS was "too superficial to sufficiently meet the needs of disabled patients...."

Exercise programs have shown short term improvement (4,24). Burckhardt et al (6) found a modest improvement in FIQ scores in a combined education-exercise group compared with a no-treatment control group and an education-only group (6). Because physical exercise and education are elements of multidisciplinary treatment programs for FS, notwithstanding the difficulties noted above, it may be useful to compare an education-exercise intervention with multidisciplinary cognitive-behavioural treatment using a randomized controlled trial. Data from such a study would be useful from a cost effectiveness perspective and would add to our knowledge con-

cerning what is and is not helpful in treating FS. Such a complex study would still not yield the apparently clear results of drug RCTs, although even those are not without significant interpretive limitations (25).

Subsequent research should also focus on improving the physical and functional aspects of multidisciplinary treatment programs. The results of our study suggest that issues of adherence and maintenance of treatment gains must be addressed because effect sizes generally decreased at 12 months despite intermittent postdischarge follow-up sessions. Efforts should be directed toward developing techniques that would improve the maintenance of treatment effects over the long term, especially because the literature suggests that the symptoms of FS patients seen in rheumatology clinics are generally unchanged or worsen over time (26,27). As Jensen (28) suggested, techniques adapted from other behavioural change areas (eg, smoking cessation, weight loss or addiction) may well enhance the effectiveness of multidisciplinary pain treatment programs.

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