Improving Physical Functional Status in Patients with Fibromyalgia: A Brief Cognitive Behavioral Intervention

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ABSTRACT. ***Objective.*** Sustained improvement in physical functional status was the primary goal of a brief, 6 session cognitive behavioral therapy (CBT) protocol for fibromyalgia (FM).

Methods. One hundred forty-five patients with FM were randomly assigned to either (1) standard medical care that included pharmacological management of symptoms and suggestions for aerobic fitness, or (2) the same standard medical treatment plus 6 sessions of CBT aimed at improving physical functioning. Outcome measures included the Medical Outcome Study Short Form-36 Physical Component Score and McGill ratings of pain. Outcomes were treated dichotomously using a preestablished criterion for clinically significant success based upon the reliability of change index from baseline to one year posttreatment.

Results. Twenty-five percent of the patients receiving CBT were able to achieve clinically meaningful levels of longterm improvement in physical functioning, whereas only 12% of the patients receiving standard care achieved the same level of improvement. There were no lasting differences on pain ratings between groups.

Conclusion. Lasting improvements in physical functioning have been among the most difficult outcomes to obtain in studies of FM. These data suggest that the inclusion of CBT to a standard medical regimen for FM can favorably influence physical functioning in a subset of patients. (J Rheumatol 2002;29:1280–6)

Key Indexing Terms:
FIBROMYALGIA CHRONIC PAIN FATIGUE
COGNITIVE BEHAVIORAL THERAPY RANDOMIZED CONTROLLED TRIAL

Fibromyalgia (FM) is a common clinical syndrome defined on the basis of diffuse pain and tenderness[1]. Early attempts to understand FM sought to link the presenting symptoms with a single underlying pathophysiological process, such as inflammation of the muscles or disrupted sleep. It has become clear that FM is a complex entity, with abnormal sensory processing as the primary neurobiological substrate, and that subsets of patients display psychological, behavioral, and other factors that also play a role in symptom expression[2,3].

Given the complexity of the disorder, it is not surprising that the treatment of FM is similarly complex. There is evidence that pharmacological therapy such as tricyclic compounds can lead to modest short term symptomatic improvements[4-6]. Several nonpharmacological interventions have also been shown to be helpful in the management of FM, including aerobic fitness[7-9] and cognitive behavioral therapy (CBT)[10,11].

CBT is recognized as an efficacious treatment for psychiatric concerns such as depression and anxiety[12]. It has also been successfully applied in the management of some medical conditions. For example, in patients who had heart attack, CBT has been shown to reduce the risk of subsequent attacks to an extent greater than standard medical care or exercise[13]. Increased survival rates have also been found in patients with cancer who have used CBT[14]. For many years, CBT has been successfully applied to chronic pain conditions such as low back pain, and rheumatological conditions such as osteoarthritis and rheumatoid arthritis[15-20]. The rationale for using CBT with chronic pain conditions stems from the assumption that

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pain and suffering are the result of complex interplay involving pathophysiology, cognition, affect, and behavior[21]. Modification of any one of these 4 factors can positively or negatively affect the course of an individual's medical condition.

Several investigators have applied CBT in the management of FM. The outcomes have been mixed, but generally modest positive effects have been reported. For example, one study applied a stress reduction based version of CBT in 79 patients with FM compared to a waitlist control group (n = 49)[22]. This study found significant improvements in pain, functional status, and psychological status. A second study that applied a problem solving based version of CBT in combination with exercise and suggestions for healthy lifestyle changes similarly found a 6 month sustained reduction in pain intensity[23]. A third study found reductions in pain intensity along with improvements in life interference, self-efficacy to control pain, and emotional distress[24]. This study and a companion article[25] described that CBT could produce both short (3 weeks) and longterm (30 months) improvements in symptoms of FM.

Three studies compared CBT for FM against credible active treatment or attention controls, with each revealing positive treatment effects for CBT; but each also failed to prove a clear superiority of CBT over the other interventions. One study found significant improvements in pain coping and pain control, but these improvements were not significantly different from those obtained in an educational control group[26]. A second randomized controlled trial found improvements in depression, pain behaviors, and tenderness when a behaviorally and socially based version of CBT was delivered. Like the previous study, these findings, while positive, were not significantly different from those obtained in the educational control condition[27]. A third randomized controlled trial compared an education control group to 3 versions of active treatment: a relaxation based version of CBT, exercise, and a combination of relaxation and exercise[28]. In this study, the education group showed a modest deterioration over time, whereas the 3 intervention groups each resulted in positive treatment outcomes. The combination group of CBT and exercise showed the best maintenance of functional gains over 2 years.

As is evident from the literature sited, CBT is not a uniform intervention but rather is composed of many different skills that can be offered alone or in combination. While there is little agreement over what skills should be included in a CBT intervention for FM, there is some evidence that CBT works better when specific outcomes are targeted and skills are selected that specifically address those targets. In one study that compared "targeted" versus "nontargeted" outcomes for FM, only the outcomes that were specifically tied to CBT content (i.e., targeted) revealed sustained change[24]. The literature also shows that positive outcomes can be obtained with CBT when as many as 24 or as few as 6 sessions are used[29,30]. There is also evidence suggesting that positive outcomes are possible when CBT is delivered in a group format, which can be more efficient and less costly than individual sessions[29,31].

From the literature, it cannot be stated that CBT cures FM, nor that all who receive it will benefit significantly. It does, however, appear that in this syndrome characterized by chronic pain and diminished functioning, a subset of patients will experience some or even substantial improvements if offered CBT[30,31].

We carried out an initial test of the efficacy of a CBT protocol specifically targeting sustained improvements in physical functional status. A brief 6 session group-formatted intervention was tested, emphasizing CBT skills focused on improving physical functioning and deemphasizing CBT skills that could be applied to more time-consuming aspects of the FM clinical spectrum (e.g., depression).

MATERIALS AND METHODS

Objectives. The primary objective was to determine if a sustained, clinically meaningful improvement in physical functional status could be realized by a greater proportion of patients with FM if they were exposed to a brief 6 session protocol of CBT in addition to their usual and customary medical care. The secondary objectives were to identify similar improvements in pain and to explore the role of treatment adherence in achieving improvements in physical functional status.

Procedures and randomization. All patients who satisfied the eligibility criteria and gave written informed consent were asked to complete baseline assessment questionnaires. Following the baseline assessment, patients were randomized into one of 2 groups: (1) standard pharmacological management of symptoms plus suggestions to engage in aerobic fitness (usual and customary care control group) or (2) usual and customary care plus CBT. Once randomized, if assigned to CBT, treatment began within 30 days and was delivered within a 4 week time frame. Participants in both groups were contacted monthly by phone to track health care use and CBT skill use in patients assigned to CBT. At 12 months posttreatment, a final followup questionnaire similar to that administered at baseline was administered.

Subject selection. Eligible patients were identified from a patient registry of individuals being followed medically in a tertiary care rheumatology clinic specializing in FM. To be included in the study, potential subjects needed to meet the study inclusion and exclusion criteria.

Inclusion criteria. All subjects needed to fulfill the 1990 diagnostic criteria[1] for FM of the American College of Rheumatology (ACR), be 18 years of age, and needed to have been in standard medical care with the clinic for at least 6 months.

Exclusion criteria. Subjects were excluded from participation if they had any of the following: (1) severe physical impairment that precluded receiving cognitive behavioral therapy (e.g., complete blindness or deafness); (2) comorbid medical illnesses capable of causing a worsening of physical functional status independent of FM, e.g., morbid obesity, autoimmune diseases, cardiopulmonary disorders (angina, congestive heart failure, chronic obstructive pulmonary disease, chronic asthma), uncontrolled endocrine or allergic disorders (e.g., thyroid dysfunction, Type I diabetes), and malignancy within 2 years; (3) any present psychiatric disorder involving a history of psychosis (e.g., schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder, etc.), current suicide risk or attempt within 2 years of the study, or substance abuse within 2 years. Subjects with mood disorders were not excluded.

The inclusion criteria were chosen to select patients who were taking stable doses of therapy, in contrast to new patients, where changes in medications or the addition of other nonpharmacological therapies such as exercise

could introduce confounding factors. The exclusion criteria were selected so that all subjects would be likely to understand and potentially implement CBT, and to isolate the physical functional impairments caused by FM.

Treatment procedures. Usual and customary care. All patients in both arms of the study received the clinic's usual and customary care. The treating physician and nurse practitioner that were delivering standard care were blinded to group assignment. In this clinic, the usual and customary care consisted of symptom based pharmacological therapy, usually including low dose tricyclic compounds, analgesics, and/or antidepressants. In addition, all patients received instructions on aerobic exercise, and were regularly encouraged to exercise.

Cognitive behavioral therapy. CBT was delivered in a group format. The group leader was a doctoral level clinical psychologist with 5 years' experience conducting CBT groups for chronic pain patients. The therapist followed a standardized session-by-session treatment manual for all groups and met regularly in supervision with the study principal investigator to ensure protocol adherence. The entire therapy was delivered in 6 one-hour sessions during a 4 week time frame. Groups consisted of between 4 and 8 participants.

Each therapy session followed a format that included (1) reviewing the previous session's homework, (2) introducing new content through brief lectures and group discussion, and (3) discussing the homework assignment to be completed before the next session. Each session built upon the content of the previous session and patients were assigned protocol based goals for the use of each skill during the therapy. During the 12 month followup period, participants were given the choice of adhering to the goals for each skill as discussed during therapy or choosing personally tailored goals for each skill.

The content of the sessions (e.g., the skills chosen) was selected because of their ability to be applied in such a manner as to improve physical functioning. While each of the skills can also be applied to treat other concerns with relevance to FM, (e.g., cognitive restructuring for depression), the skills as taught in this study had a primary focus on functional status.

The first session involved introductions, ground rules for group therapy, a rationale for treatment based upon the gate control theory of pain[32], and an introduction to progressive muscle relaxation as a means of learning the relaxation response. Subjects were given a standardized relaxation tape for practice[33] and instructed in its use. Learning the relaxation response has strong support as a method to manage pain and can lead to improved functioning[15,34].

Session 2 focused on methods to gradually increase function without increasing pain or fatigue. This session introduced time based pacing skills (i.e., graded activation)[35,36] based on a model that encourages time cued rest breaks as a means of preventing symptom flares and increasing physical functioning. Visual imagery techniques were also discussed in session 2 as a complementary skill for progressive muscle relaxation[37].

Session 3 introduced pleasant activity scheduling[38]. This was a complementary skill taught with time based pacing in which patients learned to broaden their range of pleasurable activities. Using time based pacing with pleasant activities can be easier to learn than when pacing is attempted first with work responsibilities. Brief relaxation skills (i.e., mini-practices) were also introduced in this session[39]. These briefer forms of progressive muscle relaxation were taught as tools that could be generalized for use throughout the day and in public.

Session 4 introduced communication skills and assertiveness training[40]. These skills provided patients with tools for social interactions that could improve self-confidence, control, and efficacy in the acquisition of needed assistance with factors that can worsen pain and fatigue and serve as barriers to physical functioning. An additional brief relaxation strategy known as the mini-TRIP (tension-reducing imagery practice) was also introduced in this session as a means of gaining control over pain while in public[41].

Session 5 introduced cognitive restructuring principles[42]. These techniques were chosen to provide patients with tools for managing negative automatic thinking processes, appraisals, and beliefs that could sabotage coping attempts and diminish gains in functional status. In a more expanded form than used in this study, this skill can be used in the treatment of depression. For this study, however, this technique was introduced in a very brief form for use specifically with symptoms of FM and to assist in the removal of barriers impeding functional status.

Session 6 focused upon general principles of stress management and problem solving[43]. These skills were taught to assist patients in anticipating and solving problems that might impede future functioning and the use of the skills covered in this therapy. This session also allowed patients to develop their Personally Tailored Symptom Management Plan (PTSMP). This plan allowed patients to select their own goals for using the various CBT skills over the longterm maintenance phase of the study. The importance of maintaining regular practice with their chosen skills was emphasized.

Outcome assessment. Primary outcome measure. The primary endpoint and study outcome measure was the proportion of patients with FM who improved more than 6.5 units at 12 months relative to baseline on the Physical Health Summary Scale (Physical Component Summary Score, PCS) of the 36 item Medical Outcome Study Short-Form Health Survey (SF-36). The SF-36 is a brief, well established, self-administered patient questionnaire for the assessment of health status[44]. The SF-36 measures 8 domains of health status: physical functioning, role limitations because of physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. A summary score for physical functional status (the PCS) can be calculated by combining and weighting the various individual scales. The PCS score has been standardized to have a mean = 50, SD = 10 in the general US population[45]. Internal consistency reliability for the PCS is r = 0.91 with test-retest reliability r = 0.89.

Subjects were grouped into one of 2 categories based upon the direction and magnitude of change in PCS between baseline and 12 months' followup. Categorization followed the method outlined by Ware, *et al*[46], where subjects were considered "better" if their PCS scores improved by 6.5 points or more. Patients were considered "unimproved" if their PCS scores were within 6.5 points of baseline, or declined. The criterion of a 6.5 unit change in PCS is the magnitude of change necessary to exceed the 95% confidence interval for any individual score. The 95% CI is based upon 2 standard errors of measurement (SEM), which incorporate the test-retest reliability and standard deviation of the measure. This criterion, similar to the reliability of change index[47], is highly conservative but given the difficulty in obtaining symptom changes of this magnitude on the PCS, such changes may be assumed to be and have been considered to be clinically and socially relevant[46]. The one-year time point was chosen as the primary study endpoint because previous clinical trials of CBT have shown better longterm than short-term results, and because longterm efficacy has become a common benchmark against which many clinical investigations in this area are being compared.

Secondary outcome measures. Secondary study outcomes explored the effect of brief CBT on sensory and affective symptoms of pain. Pain ratings were measured using the short form of the McGill Pain Questionnaire[48], which measures the quality of pain by asking patients to rate the intensity of 15 verbal descriptors of pain on a 0 to 3 rating scale. Two scores were derived from this instrument for use in this study, a sensory pain score and an affective pain score. In a separate sample of patients with FM, we determined the 4 week test-retest reliability of the McGill short form to be r = 0.57 (SD 6.5) for the sensory scale and r = 0.55 (SD 3.9) for the affective scale (unpublished data). Based upon these figures, the reliability of change index would require a change of 12 points on sensory and a change of 5 points in affective scores to constitute a sustained meaningful change from baseline to 12 month followup. As with the PCS score, patients were dichotomously categorized as "improved" or "unimproved" on these measures of pain between baseline and 12 months posttreatment.

Adherence to treatment measures. All subjects in the CBT group were asked to monitor their use of the 9 CBT skills presented in therapy for 12 months. In the last treatment session, patients were asked to choose a goal for practicing each CBT skill over the followup period. Patients recorded their use of skills on a daily diary form that was relayed to a study research assistant by phone on a monthly basis. From these data, a rating of "met or exceeded the goal" or "under the goal" was calculated on a monthly basis for each skill.

Aggregate ratings were then calculated for each skill that indicated the pattern of adherence to each skill [i.e., "never met the goal in 12 months," "mixed" (met the goals in some months and not in others), and "met the goal every month for 12 months"].

Demographic and disease status measures. Standard demographic data recording sheets were utilized to collect information on demographics and illness characteristics such as illness duration. The Duke University Severity of Illness scale (DUSOI)[49] was used as a standardized physician rating of illness severity at baseline. This checklist employed a complex scoring procedure that allowed for multiple health problems (e.g., comorbidity) and produced an index of health ranging between 100 (poor health) and 0 (excellent health). This instrument has been validated for use by clinicians at the time of patient encounter or by medical records auditors. Patients also identified the number of previous treatments they had tried for FM (e.g., medications, massage, acupuncture, religious counseling, psychological therapy, physical therapy, nerve blocks, manual manipulation, braces, surgery, etc.), as well as any benefit obtained from these previous treatments (i.e., "no benefit," "some benefit").

Statistical analyses. *Baseline comparability.* To insure that the demographic and illness characteristics associated with each group were comparable, comparisons of these variables were completed at the close of subject recruitment. Continuous variables were compared via t tests and categorical variables were compared by chi-square analysis.

Analysis of primary outcome measure. The primary study endpoint was the proportion of patients who improved their PCS by more than 6.5 points at one year relative to baseline. Odds ratios evaluated by chi-square were used to detect significant differences in the proportion of patients showing improvement between the 2 groups.

Exploratory post-hoc analyses dismantled the PCS score into its scale score components and used paired t tests (with appropriate Bonferroni correction to the alpha level) to identify which functional domains accounted for treatment successes and treatment failures in each group (CBT vs control).

Analysis of secondary outcome measures. Secondary outcomes (i.e., sensory and affective pain) were treated in an identical manner as the primary outcome measure using the dichotomous cutoff values for "success" and "failure" associated with each respective measure.

Adherence to treatment. Treatment adherence was measured in 2 ways. The first was a simple tally of the number of sessions attended (out of 6) by each participant. The second was a measure of adherence to the CBT skills given as homework assignments. Individual adherence ratings (i.e., goal attainment) by skill and by month were used to assess the pattern of goal attainment over the 12 month period. This measure of adherence pattern (i.e., never meeting goals, sometimes meeting goals, always meeting goals) was used to analyze the relationship between adherence and outcomes in physical functional status using chi-square tests.

RESULTS

Sample selection and patient characteristics. Consecutive clinic patients who met the study criteria were recruited over a 24 month period. This resulted in the study sample (n = 145) of 130 women and 15 men with an average age of 47.7 years (SD 11.4). The majority of subjects were white (not of Hispanic origin — 88%), the remainder of the sample being black (not of Hispanic origin — 9%), Hispanic (2%), and Asian American (1%). The average education level of the sample was 16 years or the equivalent of a college education, and 60% of the sample were married. Compensation was present or pending in 28% of the sample. The average reported duration of FM in the sample was 8.6 years (range 6 months–40 years) and the average severity of illness rating on the DUSOI was 54.8 (SD 15.2) (e.g., 100 being poorest health). In this sample, patients had tried an average of 8.6 (SD 3.6) treatment modalities before starting the trial, with 7.2 (SD 4.1) of the interventions reported as being of at least some benefit. The mean PCS score at baseline was 28.6 (SD 8.9), suggesting an overall low level of self-reported functioning in this sample. The mean McGill sensory pain score was 14.8 (SD 6.8) and the mean affective pain score was 4.6 (SD 3.1).

Subjects were randomly assigned to one of the 2 treatment conditions (n = 69 controls, n = 76 CBT) and were comparable to one another on the baseline characteristics. Of 145 patients who joined the trial and were randomized, 23 (15%) dropped out over the course of the year (14 treatment condition, 9 controls), leaving 122 subjects with complete data. The primary reported reasons for dropping out were moving out of the region or losing interest in continuing the study over the 12 month followup period. There were no differences of demographic characteristics or pretreatment assessment measures between subjects completing the study and dropouts.

Primary outcome (physical functioning). Twenty-five percent of the patients receiving CBT realized a clinically meaningful and sustained improvement in physical functional status. The number of patients realizing this level of change was significantly greater than the standard care control group, in which only 11.6% realized the same degree of improvement during the same time period. These conditional percentages translate into an odds ratio of 2.9 (chi-square = 5.30, $p < 0.05$), suggesting that this level of improvement was nearly 3 times more likely to occur in the CBT condition than in standard care (Figure 1).

An exploratory attempt was made to determine which elements of the PCS score differentiated the treatment successes from the treatment failures. Paired t test comparisons using a Bonferroni correction to alpha (alpha = 0.05/8 = 0.006) were performed on the subscales of the SF-36 for the successes and for the failures in each arm of the study between baseline and

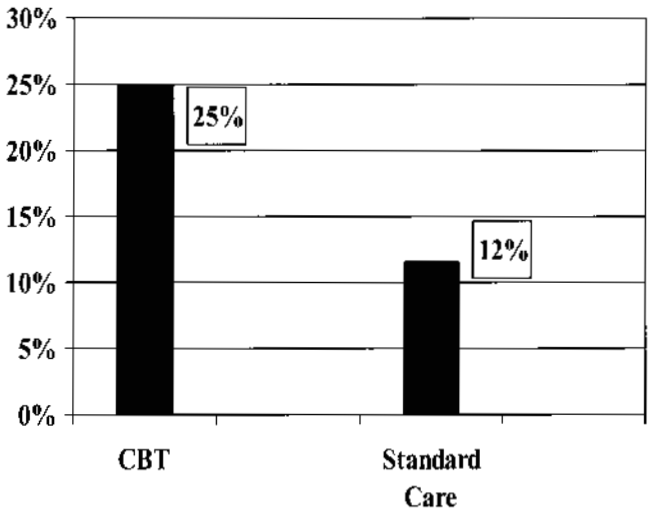

Figure 1. Improvement in physical functioning: brief CBT vs standard care over 12 months. N = 122, OR 2.9, $p < 0.05$.

12 month followup. Treatment failures in the control condition showed no significant improvements on any subscale of the SF-36, but did have significant worsening of scores on physical role functioning, $t = -4.80$, $p < 0.006$, and on energy $t = -3.39$, $p < 0.006$. In contrast, treatment failures in the CBT group showed no significant worsening or improvements on any scale, suggesting the possibility that CBT buffered against worsening in this group. Treatment successes in the controls were due exclusively to a significant improvement in physical role functioning, $t = 4.43$, $p < 0.006$, whereas improvement in the CBT group was due to significant improvements in physical role functioning, $t = 3.03$, $p < 0.006$, general physical functioning, $t = 4.57$, $p < 0.006$, and pain as assessed by the SF-36, $t = 5.88$, $p < 0.006$.

Secondary outcomes (sensory and affective pain). The percentage of patients reporting clinically meaningful and sustained improvements on the McGill sensory and affective pain scales between baseline and 12 month followup did not differ significantly between the CBT and control groups. Improvements in sensory pain were realized by 3.9% of the CBT group and by 7.2% of the controls. Improvements in affective pain were realized by 9.2% of the CBT group and 8.7% of controls.

Adherence to CBT treatment. The median number of sessions attended by patients was 4 (range 2–6). For the 9 CBT skills, patients were given the choice of adhering to the goals set by the therapist for the 12 month followup period or choosing their own goals for skills usage. Given the choice, over 50% of the participants chose to retain the goals set by the therapist. Those choosing to set their own goals were evenly split between raising and lowering the goal. Although underpowered, an exploratory series of chi-square tests was used to examine the percentage of successes and failures using personally chosen goals versus therapist established goals. Although none of these tests were significant, the direction of the relationship favored improved outcomes for those patients who chose personally tailored goals.

Over the 12 month period, participants were evaluated each month on whether they met their stated goals for using each of the 9 CBT skills taught in the therapy. Thirty-eight percent of participants never had a month in which they met their stated goals. Forty-seven percent of subjects exhibited a mixed pattern of goal attainment, with goals being reached some months and not others; and 15% of participants consistently reached their stated goals each month over the entire year. Contrary to expectations, using chi-square tests, there were no statistically significant relationships between goal attainment category and outcome status on physical functioning (i.e., successful–failure). Thus success in improving physical functioning was not directly associated with level of adherence.

DISCUSSION

Studies of the natural history of fibromyalgia suggest that this disease is associated with persistent levels of abnormal functioning and pain over time[50]. Historically, both pharmacological and nonpharmacological interventions have been partially successful at symptom management, but have been unable to produce much in the way of meaningful and lasting improvements in the functional status of patients with FM[10]. This study described an intense but brief nonpharmacological intervention, cognitive behavioral therapy, that resulted in participants being nearly 3 times more likely to achieve meaningful and lasting improvements in physical functional status compared to controls receiving standard symptom based pharmacological treatment. These findings are thought to be robust given the highly conservative criteria used to determine a successful case (i.e., use of the reliability of change index over a 12 month period in a randomized controlled clinical trial).

The form of CBT used in this study appeared to influence physical functional status but did not appear to affect the primary symptom of FM (i.e., pain). Previous trials of CBT have reported changes in pain but have not tended to find substantial changes in functional status[10]. Two primary differences between this study and others are the length of the intervention and the goal of the intervention, which was to specifically target CBT skills designed to improve physical functional status. CBT for pain management is typically offered in 8–12 session blocks[19,51] where multiple pain coping skills are covered in depth and multiple pain related outcomes are assessed. Because of the brief duration of this intervention, and the fact that physical function was targeted rather than pain, we were not surprised that the 2 McGill scores did not change significantly for either group. This finding is also consistent with the well documented imperfect relationship between pain and functional status characteristic of the chronic pain literature[52–56].

Our sample had a relatively high average education level (16 years). This is in contrast to most of the literature in this area, where education is at the high school level or lower[26]. Thus it could be argued that the advanced education level of our sample contributed to the patients being better able to learn and take advantage of the CBT skills being taught. If this were true, then expectations for this level of improvement in physical functional status would not generalize beyond patients with greater education. The latter argument, however, is not supported by data from our sample. In our sample, CBT treatment successes and failures were proportionately equal across education levels [chi square (8 df) = 5.70, $p > 0.10$].

This study did not monitor medication usage in the 2 groups. While it could be argued that the CBT group improved more than the control group because it received more medications, several factors argue against this interpretation. First, there is no empirically based reason to suspect that any known medication for FM would produce this type of functional improvement in outcome. Second, all participants were randomly assigned to groups, thus medications and dosages should have been roughly equal between groups.

Third, if the CBT group had been given more pain medication than the control group, then improvements in sensory pain levels would be expected to be greater in the CBT group than in the controls. This was not the case (CBT 3.9% improvement vs control 7.2% improvement).

Adherence to CBT skills over an extended period of time has historically posed problems for therapeutic researchers interested in behavioral change. This study offered patients a choice — to pursue a personally tailored goal for skill use or to follow the therapist's recommendation for goal setting. It was hoped that personalizing the goal setting process would be associated with improved outcomes. But this hypothesis was not supported by the data. Similarly, the pattern of adherence (i.e., never meeting goals, sometimes meeting goals, always meeting goals) was not significantly related to positive outcome, suggesting that other factors beyond adherence were more importantly associated with success in improving physical functioning (e.g., rapport with the therapist, motivation for change, belief in having a sense of control, etc.). Clearly, more work in this area of adherence is needed.

This study did not utilize an attention-placebo control group, where the same therapist met with a group of participants for the same amount of time but did not deliver CBT. Had this group been included, there could be greater confidence that the superiority of CBT over the standard care control group was due only to the CBT content rather than to personal characteristics of the therapist or to attention to patients by the therapist. Given the strength of the findings in this study, an attention-placebo controlled trial would be an obvious next step in this line of research.

In summary, this study supports the use of cognitive behavioral therapy as a nonpharmacological therapeutic approach to the treatment and management of fibromyalgia. This study supports the notion that physical functional status can be improved in a sustainable manner in a subset of persons with this disease, perhaps in combination with instruction in aerobic fitness and symptom based pharmacological management[57]. Future studies will refine the CBT protocol to expand the percentage of patients achieving success, explore the factors associated with achieving success, and tailor CBT to influence pain more consistently, as well as functional status. While this intervention was brief (6 sessions), it is unknown whether the addition of several more sessions could have affected more individuals or expanded the domains in which patients received benefit. These studies and studies into broadening the availability of CBT to the larger population with FM mark the challenges and exciting next steps in this area of research.

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