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Brief group cognitive-behavioral intervention for temporomandibular disorders

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Summary Temporomandibular disorders (TMD) are currently viewed as an interrelated set of clinical conditions presenting with signs and symptoms in masticatory and related muscles of the head and neck, and the soft tissue and bony components of the temporomandibular joint. Epidemiologic and clinical studies of TMD confirm its status as a chronic pain problem. In this report we present results from a randomized clinical trial which compared, at 3- and 12-month follow-ups, the effects of usual TMD treatment on TMD pain and related physical and psychological variables with the effects of a cognitive-behavioral (CB) intervention delivered to small groups of patients before usual TMD treatment began. The purpose of this study was to determine whether a minimal CB intervention followed by dental TMD treatment enhanced the effects of usual clinical dental treatment. A second purpose of the study was to determine whether patients classified as high in somatization and psychosocial dysfunction would respond less favorably to this minimal intervention than would those low in somatization and dysfunction. Patients who participated in the CB intervention followed by usual treatment showed greater long-term decreases in reported pain level and pain interference in daily activities than did patients who received only usual treatment. The benefits of CB intervention were not seen when the CB and UT groups were compared at 3-month follow-up. During the 3–12-month follow-up interval, however, the UT group maintained essentially the same level of improvement in characteristic pain while the CB group continued to improve, as hypothesized. During this same follow-up interval, the CB group also showed a strong trend toward continued improvement in pain interference. Such effects were not observed for depression, somatization, or clinical measures of jaw range of motion. Additionally, as hypothesized, dysfunctional chronic pain patients did not appear to benefit from the brief CB intervention. Intent to treat analyses were also performed to assess generalizability of the results.

Key words: Temporomandibular disorder; Chronic pain; Cognitive-behavioral; Group; Dysfunction; Somatization; Intent to treat

Introduction

Temporomandibular disorders (TMD) are currently viewed as an interrelated set of clinical conditions presenting with signs and symptoms in masticatory and related muscles of the head and neck, and the soft tissue and bony components of the temporomandibular joint. Although a common condition, with a 6-month prevalence of approximately 12% in the population we studied (Von Korff et al. 1988), the etiology of TMD is poorly understood and its diagnosis is acknowledged to be complex (Bell 1986; Fricton et al. 1987).

Epidemiologic and clinical studies of TMD confirm its fundamental status as a pain problem, more specifically a chronic pain problem (Bell 1986; Fricton et al. 1987; Dworkin et al. 1992b). About 95% of TMD patients seek treatment to relieve pain in the region of

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the ear, the temporomandibular joint (TMJ) and/or the muscles of mastication (Dworkin et al. 1990a). Comparison of TMD with other common chronic pain conditions, such as headache and back pain, for chronicity, intensity, psychosocial profile, and use of health care resources confirms that in all these major respects TMD is essentially a chronic pain condition. Empirical support for this view comes from large-scale longitudinal population-based studies we have conducted (Dworkin et al. 1990a; Von Korff et al. 1993), and from the extensive work of Turk, Rudy and colleagues (Turk and Rudy 1988; Rudy et al. 1990) in a pain clinic setting, as well as psychosocial assessment of TMD patients by numerous workers (Marbach et al. 1983; Keefe and Dolan 1986; Schnurr et al. 1990; McCreary et al. 1991).

Cognitive-behavioral treatments and chronic pain

Cognitive-behavioral (CB) treatment methods have been incorporated into the overall management of the most common chronic pain conditions and their use is especially widespread in pain clinics. CB chronic pain programs typically involve multiple components, including: (1) information to increase knowledge and awareness of factors influencing chronic pain problems; (2) cognitive and behavioral therapies aimed at increasing physical and functional activities, and adaptive responses to pain; and (3) skills training such as the use of relaxation, biofeedback, hypnosis and other self-control strategies to modify perception of pain and related bodily sensations (Fordyce 1976; Turk et al. 1983; Keefe and Gil 1986; Turner and Romano 1990). The importance of addressing psychological and behavioral aspects of chronic pain problems is now widely recognized because physical findings are often not consistent with observed pain behaviors and disability.

Numerous studies have examined the efficacy of CB methods for chronic pain problems. Comprehensive reviews by Turner and Romano (Turner 1982; Turner and Romano 1990) and Turk et al. (1983) support the use of multi-component CB treatments, including the use of group approaches. Some researchers have also found that patients who participate in CB treatment show continued improvement on longer-term follow-up past the end of such treatment (Keel 1982; Turner et al. 1990).

Minimal interventions

A recent innovation based on CB principles, and referred to as minimal intervention or minimal therapy (Glynn et al. 1990; Glasgow et al. 1991), also seems promising as a pragmatic approach to management of chronic pain problems. Minimal interventions emphasize use of information and education in the form of self-care materials coupled with brief professional guidance at critical points and low-cost methods for patient follow-up, such as brief telephone counseling. These minimal interventions involve a smaller number of sessions with trained mental health professionals (e.g., clinical psychologists) than the 8–16 treatment programs that are typical for CB interventions for chronic pain. They are also often characterized as occurring independent of any biomedically based treatments. Most relevant to TMD, a series of studies has shown minimal CB interventions for headache to be effective (Jurish et al. 1983; Richardson and McGrath 1989; Nash and Holroyd 1992). Nash and Holroyd (1992) indicate that CB treatments for headache can be made less costly and thereby more widely available to the degree that self-management skills can be learned with minimal assistance from a therapist.

Although TMD patients are exposed to many forms of treatment, from physically based modalities such as occlusal adjustment (Clark and Adler 1985) and TMJ surgery (Benson and Keith 1985) to behavioral and other psychologically based modalities, such as biofeedback, relaxation and diverse forms of psychotherapy (Moulton 1966; Pomp 1974), the management of TMD is not associated with the same widespread use of CB approaches reported for other common chronic pain conditions. When biobehavioral methods are used, they tend to be limited to biofeedback and, to a lesser extent, relaxation therapies (Okeson et al. 1983; Burdette and Gale 1988). These biobehavioral treatments are delivered on an individual basis and the efficacy of group interventions for TMD has not been evaluated in controlled studies.

With notable exceptions (Stam et al. 1984; Funch and Gale 1986), the tendency to view psychologically based therapies as treatments of last resort seems to prevail in the clinical TMD literature. For example, Clark and colleagues reported research (Clark 1986) which provided TMD patients with a package of CB interventions (e.g., cognitive restructuring, coping methods, relaxation skills training). However, patients receiving this intervention were those who had not succeeded at biologically based TMD therapies. Keefe has advocated early introduction of CB methods into chronic pain management and points, specifically, to the absence of CB programs for the management of TMD (Keefe and Dolan 1986). Scott and Gregg (1980) reviewed psychological aspects of TMD treatment and also suggested early intervention with biobehavioral methods to minimize the likelihood of prolonged TMD pain problems. Because TMD tends to be a chronic recurrent pain condition (Dworkin et al. 1992a), many patients seek repeated bouts of treatment in response to the cyclic nature of the pain condition. Dichotomizing TMD treatments into either physical or behavioral approaches relegates behavioral methods only to 'resistant' cases which may deny many TMD patients opportunities to learn more efficacious methods of

long-term self-management of their problem earlier in the course of the condition.

In this report we present results from a randomized clinical trial which compared, at 3- and 12-month follow-ups, the effects of usual TMD treatment on pain and related physical and psychological variables with the effects of a CB intervention delivered to small groups of patients before usual TMD treatment began. By introducing this intervention prior to the onset of usual treatment, we hoped to test a clinical model that would make apparent the early introduction of biobehavioral methods, along with the more biologically based usual treatments that dentists provide.

The purpose of this study was to determine whether a minimal CB intervention followed by conventional TMD treatment was more beneficial for TMD pain and related limitations in mandibular function than clinical dental treatment alone. A second purpose of the study was to determine whether patients classified as high in somatization and psychosocial dysfunction would respond less favorably to this minimal intervention than would those low in somatization and dysfunction.

Somatization

Increasing attention has been called to the role that reporting of multiple non-specific physical symptoms may have in determining health care behavior (Bridges and Goldberg 1985; Katon 1985). We have shown that somatization, defined for present purposes as the reporting of non-pain-related physical symptoms such as tremors, heart palpitations, etc., is associated with depression in chronic pain patients (Dworkin et al. 1990e) and with increased number of muscle sites tender to palpation in TMD patients (Wilson et al. 1991). Somatization has also been shown to be associated with increased likelihood of seeking treatment from multiple providers (Katon et al. 1986). For example, using norms for populations from which our study samples are drawn, we found that approximately 50% of TMD patients scoring in the top quartile for somatization (SCL-90-R age/sex-adjusted scale scores) reported a history of seeing 5 or more TMD providers, compared to approximately 18% of TMD patients whose somatization scores were in the lowest quartile. McCreary et al. (1992), in a study relating psychological factors to TMD treatment outcome, concluded that unless somatization issues are addressed with TMD patients, successful treatment outcome is threatened.

Psychosocial dysfunction

The assessment of psychosocial functioning in chronic pain patients, including TMD patients, has received appreciable attention (Osterweis et al. 1987; Social Security Administration 1987; Turk and Rudy 1988). Rudy et al. (1989), using methods derived from assessment of pain clinic patients, have demonstrated, for example, that TMD patients characterized as dysfunctional show greater depression and report more physical symptoms than TMD patients categorized as 'adaptive copers', although dysfunctional TMD patients and adaptive copers do not differ in commonly assessed physical signs of TMD.

Using an alternative classification system (Von Korff et al. 1992), dysfunctional chronic pain patients are defined as having high pain intensity and pain-related interference with daily activities. Patients classified as dysfunctional were found to be more depressed, to have higher somatization scores, and to use more medications and health care than non-dysfunctional patients.

Study hypotheses

The present study was designed to introduce a 2-session CB component prior to the onset of the patient's clinical treatment. Because the intervention was designed to be placed before conventional TMD treatment began, no attempt was made to distinguish among the clinical subtypes of TMD when recruiting study subjects. We hypothesized that the CB intervention followed by usual TMD treatment, compared to usual treatment alone, would be associated with greater decreases in pain and pain interference, and with greater improvement in mandibular function and psychological distress. We also hypothesized that patients would show greater improvement at 12-month than at 3-month follow-up in the CB intervention group but not in the usual treatment group. Of secondary interest, we hypothesized that somatization scores and grades of dysfunctional chronic pain would not be lowered by the CB intervention, which was not designed in content or length to address such complex problems.

Methods

Subjects

Subjects potentially available to participate in the study included 395 patients experiencing pain and related symptoms of TMD recruited from the TMJ Clinic of Group Health Cooperative of Puget Sound (GHC) or Orofacial Pain and Dysfunction Clinic at the University of Washington School of Dentistry (UW). Criteria for study inclusion were referral for treatment of TMD with a self-report of facial ache or pain in the muscles of mastication, the TM joint, the region in front of the ear or inside the ear, other than infection. Exclusion criteria included pain attributable to confirmed migraine or head pain condition other than tension headache; acute infection or other significant disease of the teeth, ear, eye, nose or throat; or history of significant or debilitating chronic physical or mental illness. Patients requiring emergency TMD treatment were also excluded from the study. All participants were recruited into the study prior to their initial examination with the TMD dental specialist, by clinical field examiners who were not involved with usual treatment or with the CB intervention.

Of the 395 patients who met eligibility criteria, 185 agreed to participate. Using a block randomization schedule (Pocock 1983), 95 were assigned to the CB intervention and 90 were assigned to the usual treatment (UT) group. Extensive interview and clinical examination data were collected at (pre-treatment) baseline and at 3- and 12-month follow-ups. Of those randomized, 148 (80%; CB = 69 and UT = 79) completed the 3-month follow-up. Outcome data for this report come from the sample of 139 patients (75%; CB = 66 and UT = 73) who completed the entire study through 12-month follow-up. All study participants provided signed, informed consent prior to randomization. Overall, approximately 85% of patients were female, 81% completed more than high school education and 96% were Caucasian. The average age of all participants was 37 ± 10.3 years. More than two-thirds reported experiencing TMD pain for greater than 1 year. Approximately 58% of both the CB and UT groups were composed of GHC patients and 42% of each group were UW clinic patients. CB and UT groups did not differ significantly in age, gender, level of education, race, or pain-related and clinical variables, as summarized in Table I.

Study measures

Clinical measures. Mandibular range of motion measures were obtained to assess the patient's ability to open the jaw without pain and the extent to which the jaw can be assisted open by the attending examiner. Measures were recorded in millimeters (mm) of: (a) unassisted mandibular opening without pain and (b) maximum assisted mandibular opening.

Self-report measures. TMD History Questionnaire inquired into sociodemographic variables, including age, gender, race, income, education and marital status as well as TMD treatment history.

Pain measures. Visual analog scales (VAS) were used to assess present pain intensity, average and worst pain intensity in the past 2 months as well as pain interference with daily activities. Two pain-related measures were analyzed from data gathered.

Characteristic pain. The measure characteristic pain represents the average of VAS scores for average, present and worst pain. This has been shown to be somewhat more reliable than a single measure of average pain (Dworkin et al. 1990d).

Pain interference. Pain interference with daily activities in the previous 2 months was measured by a 0–10 point scale anchored by 0 = no interference and 10 = as unable to carry on any activities. Pain interference has been shown to be a useful measure of the impact of chronic pain on ability to perform usual daily activities (Von Korff et al. 1992).

Psychosocial variables. These variables were assessed by items from the Symptom Checklist 90-Revised (SCL-90-R) (Derogatis 1983) Depression and Somatization scales. Age- and sex-adjusted standardized scale scores were computed for each subject using population norms (Von Korff et al. 1988; Dworkin et al. 1990e) derived from a random sample survey of the community population from which approximately 60% of the present clinical study sample was drawn.

Dysfunctional chronic pain. We used a 0–IV scale developed by Von Korff et al. (1992) to grade patients as functional or dysfunctional. The scale incorporates characteristic pain level, degree of interference due to pain and number of days of activity lost due to pain. The reliability and validity of this graded chronic pain scale have been established with separate samples of headache, back pain and TMD patients and the scale has been shown to be useful for relating pain-related dysfunction to psychological, psychosocial and clinical variables (Graff-Radford et al. 1991; Von Korff et al. 1992). For present purposes, functional TMD patients were defined as those whose characteristic pain was less than 50 on a 0–100 scale and whose combined pain interference and activity limitation scores were 30 or below on 0–100 scale. Dysfunctional patients were those who scored above these cut-off points (see Von Korff et al. 1992 for detailed description of methods to compute scores for determining functional and dysfunctional chronic pain status). The quantitative criteria used allow functional TMD patients to be reliably defined as minimally impacted by their pain condition, reporting low-moderate pain which is not highly persistent (i.e., present on many days), and not associated with activity limitation. The composite measure of graded chronic pain is included in the study analyses even though it incorporates measures of characteristic pain and pain interference, which are also analyzed separately as major dependent variables in the study because it extends the measurement of chronic pain to a multi-dimensional assessment which directly quantifies the impact of TMD pain on important behaviors in daily living. We were interested in observing the potential for the minimal intervention to differentially affect pain-related variables of interest when they were analyzed unidimensionally and when incorporated into a multidimensional measurement.

Self-rating of change in TMD condition and response to treatment. This is a single item assessed at 3- and 12-month follow-up whether patients viewed their TMD condition as improved, stabilized or worsened. A series of items inquired into evaluation of TMD treatment received, knowledge regarding factors thought to exacerbate TMD and methods used for self-management of the condition.

TABLE I

BASELINE CHARACTERISTICS OF CB AND UT GROUPS: DEMOGRAPHIC AND DEPENDENT MEASURES

	CB (n = 66)	UT (n = 73)
Demographics		
Age (± SD)	38.4 (± 11.34)	35.9 (± 9.21)
Gender (% females)	83	86
In Pain > 1 year (%)	66.7	72.6
Completed High School (%)	97.0	98.6
Dependent measures	$\bar{X}$ (± SD)	$\bar{X}$ (± SD)
Characteristic Pain (0–10)	5.2 (± 1.97)	4.5 (± 1.90)
Pain Interference (0–10)	3.4 (± 2.37)	3.1 (± 2.72)
Somatization (age/sex standardized)	0.6 (± 1.55)	0.75 (± 1.45)
Depression (age/sex standardized)	0.19 (± 1.08)	0.26 (± 1.18)
Unassisted Opening (mm)	35.1 (± 10.49)	36.4 (± 11.95)
Maximum Assisted Opening (mm)	43.4 (± 9.38)	46.5 (± 8.27)

All group differences n.s.

Finally, CB participants were asked to evaluate their satisfaction with the CB intervention and its perceived usefulness.

Procedures

CB intervention. The CB intervention was delivered in a small group format of from 2 to 7 (mode = 4) TMD patients. The CB groups met for two 2-h sessions spaced 1 week apart. For most patients, group sessions began before onset of dental treatment. The groups were team-led by a study dentist and study psychologist. The teams were drawn from a panel of 4 dentist-specialists and 4 clinical psychologists, all experienced in the treatment of chronic pain patients. Such teams used a detailed manual and set of materials to provide information concerning the nature and typical course of TMD; biomedical and biobehavioral management of TMD; the relationships among jaw muscle fatigue, muscle tension, and the psychophysiologic aspects of stress; the basics of pain physiology with an emphasis on chronic pain; how to self-monitor TMD signs and symptoms; and an introduction to cognitive and behavioral pain and stress-coping strategies. Patients learned and had an opportunity to briefly practice a progressive relaxation method and a simple physiotherapy exercise for jaw muscles. Patients also developed a daily personal plan for adherence to these pain and stress reduction and physiotherapy exercises. Each patient was provided a personalized notebook containing study materials and forms, a relaxation (audio) tape, reminder cards containing exercise schedules and brief descriptions, and an annotated list of relevant articles and books. The psychologist called participants between the CB sessions to clarify and/or reinforce the group discussion content and called 1 month after the second session to discuss the patient's progress in implementing the daily personal plan. CB patients also received usual treatment by their dentist TMD-specialist following the 2-session intervention.

Psychologists and dentists were provided with a detailed therapist's manual with scripts for each of the 2 sessions. Psychologists and dentists were trained together in the use of study materials and methods, practicing first in groups among themselves and then with non-patient clinic personnel and finally with pilot testing of study conditions using several groups of TMD patients. Psychologists and dentists rotated in their team composition to insure consistency of presentation and regular discussions among all clinician-researchers insured acceptable consistency among those conducting the 2-session interventions. Since several combinations of dentist-psychologist were employed, inadequate sample sizes precluded formal statistical analyses of outcomes by intervention team.

UT condition. Dental 'treatment-as-usual' was delivered by one of the study dentist/TMD specialists at the TMJ Clinic of Group Health Cooperative or the Orofacial Pain and Dysfunction Clinic of the Department of Oral Medicine, University of Washington. Usual treatment was conservative and typically included use of flat-plane occlusal splints, non-steroidal anti-inflammatory medications, passive and active range of jaw motion exercises, modification of parafunctional and/or dietary habits and regular use of cold and heat packs. No attempt was made to influence patient dental treatment.

Data collection procedures. A previously developed and standardized interview and clinical examination (Dworkin et al. 1988) was used in this study to gather extensive data on the most common clinical signs associated with TMD as well as self-report data related to pain and dysfunction, psychosocial variables, treatment history, self-management and coping behaviors and satisfaction with treatment. A subset of the most commonly assessed clinical and psychosocial variables associated with TMD and relevant to the experimental hypotheses was selected for analysis. All clinical and self-report data were gathered at baseline and at 3- and 12-month follow-up by dental hygienist examiners blind to the subject's original random assignment to the CB or UT study conditions. Dental hygienists who served as TMD field examiners/interviewers were trained according to standardized protocols and calibrated to acceptable levels of reliability for assessing the variables covered by the examination. The training protocol, calibration and reliability of the dental hygienist TMD clinical examiners have been described previously (Dworkin et al. 1988, 1990b).

All subjects who dropped out from the study prior to completion of the 12-month follow-up were asked to complete an abbreviated questionnaire inquiring into the status of their pain and jaw function in order to allow intent to treat analyses of all subjects (Turk and Rudy 1990a; Lee et al. 1991; Peter et al. 1992).

Results

Baseline comparisons

GHC vs. UW patients. Approximately 60% of subjects were drawn from the TMJ Clinic of GHC and 40% from the Orofacial Pain and Dysfunction Clinic, UW. Analyses of baseline clinical and demographic data revealed no significant differences (t tests for independent means, $\alpha < 0.05$) between the GHC and UW groups (e.g., characteristic pain was 4.8 vs. 4.9, respectively, for the GHC and UW groups; unassisted vertical opening was 36.3 vs. 34.1 mm; SCL-90-R-depression score was 0.2 vs. 0.4; and age was 37.5 vs. 37.1 years).

Non-participants and study drop-outs vs. study completers. Of those refusing to participate in the study, 77% gave either the time or the location of sessions as their reason for non-participation (sessions were scheduled in the evening at sites other than UW and GHC clinics. Of these refusals, 58% agreed to answer 3 key questions regarding their pain condition over the past 2 weeks: (1) number of days of facial pain in last 2 months, (2) number of days of limited activity in last 2 months, and (3) average pain intensity in last 2 months (VAS).

There was no significant difference between groups for numbers of days of facial pain, with 52% of subjects in both groups reporting the maximum of 60 days in pain. More refusals (84%) reported no activity-limited days compared to 72% of subjects participating, a statistically significant difference. In contrast to this finding, refusals showed a trend to have higher pain intensity levels (mean = 5.29) compared to those participating (mean = 4.80, $P = 0.07$) in the study.

Baseline analyses were performed comparing those subjects who completed the study (through 12-month follow-up, n = 139) with those who dropped out after baseline assessment (n = 46) on 50 clinical and demographic variables. Analyses (t tests for independent means for continuous variables, chi-square analyses for categorical variables) yielded some significant differences. Study dropouts reported significantly lower income ($P = 0.003$) and had more recent onset of pain, with a median of 3.5 years pain duration in the completed study group vs. 1.4 years in the drop outs

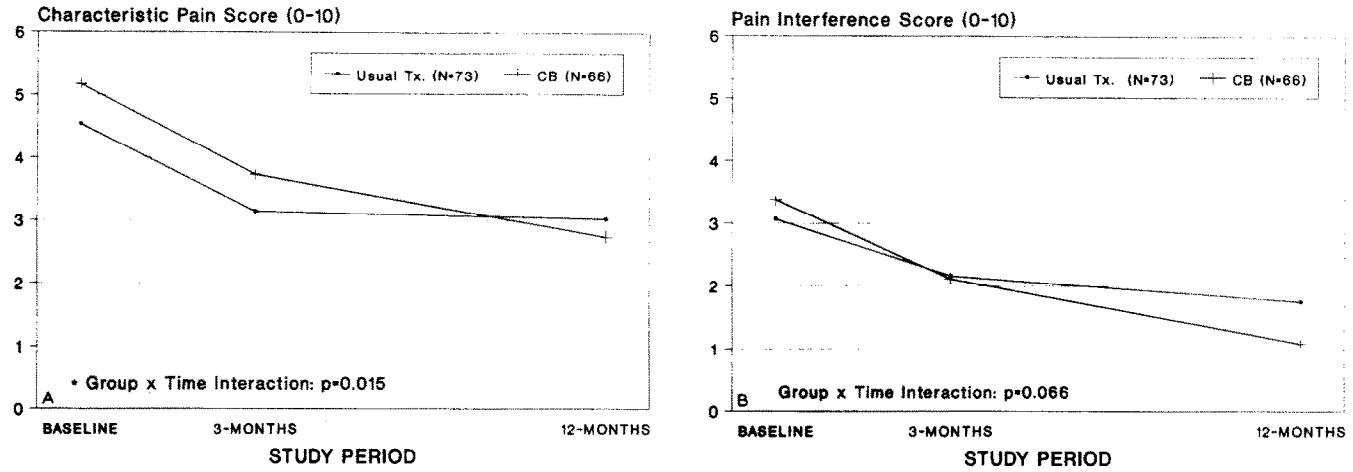

Fig. 1. A: characteristic pain (0–10): group CB vs. UT. Baseline, 3- and 12-month follow-ups (±SEM), respectively, for UT 4.54 (0.22), 3.14 (0.28), 3.03 (0.27), and 5.17 (0.25), 3.73 (0.31), 2.74 (0.32). B: pain interference score (0–10): group CB vs. UT. Baseline, 3- and 12-month follow-ups (±SEM), respectively, for UT 3.07 (0.32), 2.16 (0.29), 1.75 (0.31), and 3.38 (0.29), 2.11 (0.31), 1.09 (0.22).

($P = 0.05$). We also observed that 47% of those failing to complete the study were assigned to the UT vs. 64% to the CB group ($P = 0.05$).

CB vs. UT groups (study completers). Baseline comparisons of the CB and UT groups on relevant demographic and dependent variables revealed no significant differences between the groups, as summarized in Table I. Similarly, preliminary analyses did not reveal systematic differences between those subjects who received both sessions before usual treatment began, and those who (for logistic reasons) may have completed the second group session shortly after an initial clinical treatment visit.

Follow-up comparisons of CB and UT

The initial set of major analyses compared the UT and CB groups at 3- and 12-month follow-up for differences from baseline in characteristic pain level, vertical range of jaw motion, depression, and pain interference, using repeated-measures analyses of variance (ANOVA) with 2 Groups (CB, UT) ×3 Time Points (baseline, 3-month, 12-month). As in previous research (Rudy et al. 1989), weak relationships among pain or psychological measures and clinical signs of TMD were observed. For example, in the present study characteristic pain was correlated 0.05 with maximum assisted jaw opening and −0.13 with unassisted jaw opening. Similarly, somatization was correlated −0.01 with maximum assisted opening and −0.13 with unassisted opening. The same pattern was observed for the relation between pain interference scores and clinical signs. Thus, multiple univariate ANOVAs were performed rather than an overall multivariate analysis of variance (MANOVA) followed by post-hoc univariate analyses, because there was no theoretical interest in analyzing the changes on all the dependent variables as a group (Huberly and Morris 1989).

Characteristic pain. As depicted in Fig. 1a, a significant Group × Time interaction was observed for characteristic pain ($F = 4.23$, $df = 2,272$, $P = 0.015$). The CB group continued to decrease in characteristic pain between the 3- and 12-month follow-ups at a significantly greater rate than did the UT group; the latter group's mean characteristic pain level remained essentially constant from the 3- to the 12-month follow-up. Thus, while no significant main effects were observed — that is, differences in characteristic pain level between the groups were not significant at baseline, 3- or

TABLE II

MEAN VALUES OF UT (n = 73) AND CB (n = 66) GROUPS FOR CLINICAL AND PSYCHOLOGICAL VARIABLES

Repeated-measures ANOVA for Group effects (CB vs. UT); Time effects (baseline, 3- and 12-month follow-ups); Group × Time interaction.

Dependent variables	Baseline		3 Months		12 Months		*P*		
	UT	CB	UT	CB	UT	CB	Group	Time	Group × Time
Maximum assisted mandibular opening	46.5	43.1	46.9	45.2	46.9	45.6	n.s.	0.05	n.s.
Unassisted mandibular opening	36.4	35.1	38.9	38.1	38.5	39.2	n.s.	0.001	n.s.
Depression score *	0.26	0.12	−0.06	0.04	−0.20	−0.06	n.s.	0.001	n.s.
Somatization score *	0.75	0.86	0.54	0.59	0.44	0.44	n.s.	0.001	n.s.

* SCL-90-R scores age/sex-adjusted and standardized to population norms.

12-months — the significant interaction indicates those receiving the minimal CB intervention preceding usual TMD treatment showed a continuing benefit in pain reduction past the 3-month follow-up that was not seen with those receiving only usual treatment.

Pain interference. Results were somewhat comparable, as seen in Fig. 1b, for the measure of pain interference. There was a strong trend for the CB group only to continue to decrease in pain interference through the 12-month follow-up period. However, the Group (CB, UT) × Time interaction just failed to reach statistical significance at the 0.05 level ($F = 3.04$, $df = 2,272$, $P = 0.066$).

Clinical and psychological measures. Clinical physical measures of vertical range of jaw opening (unassisted opening and maximum assisted opening) and measures of psychological status (depression and somatization) all showed improvement over time that was comparable for the CB and UT groups. Baseline, 3- and 12-month mean values for these variables are summarized in Table II. Thus, the CB intervention did not enhance the effect of usual treatment on these physical and psychological parameters.

TMD pain dysfunction. In addition to the analyses just described, a secondary set of repeated-measures ANOVA included functional vs. dysfunctional graded chronic pain status as an additional variable because it was of interest to examine if functional vs. dysfunctional chronic pain status influenced responses to the CB intervention. Results of these analyses of 2 groups (CB, UT) × 3 time periods (baseline, 3-month, 12-month follow-ups) × 2 levels of chronic pain grade (functional, dysfunctional) are depicted in Fig. 2a–c. Characteristic pain (see Fig. 2a) was analyzed as a dependent variable only to demonstrate that this variable, which enters into the criteria for defining func-

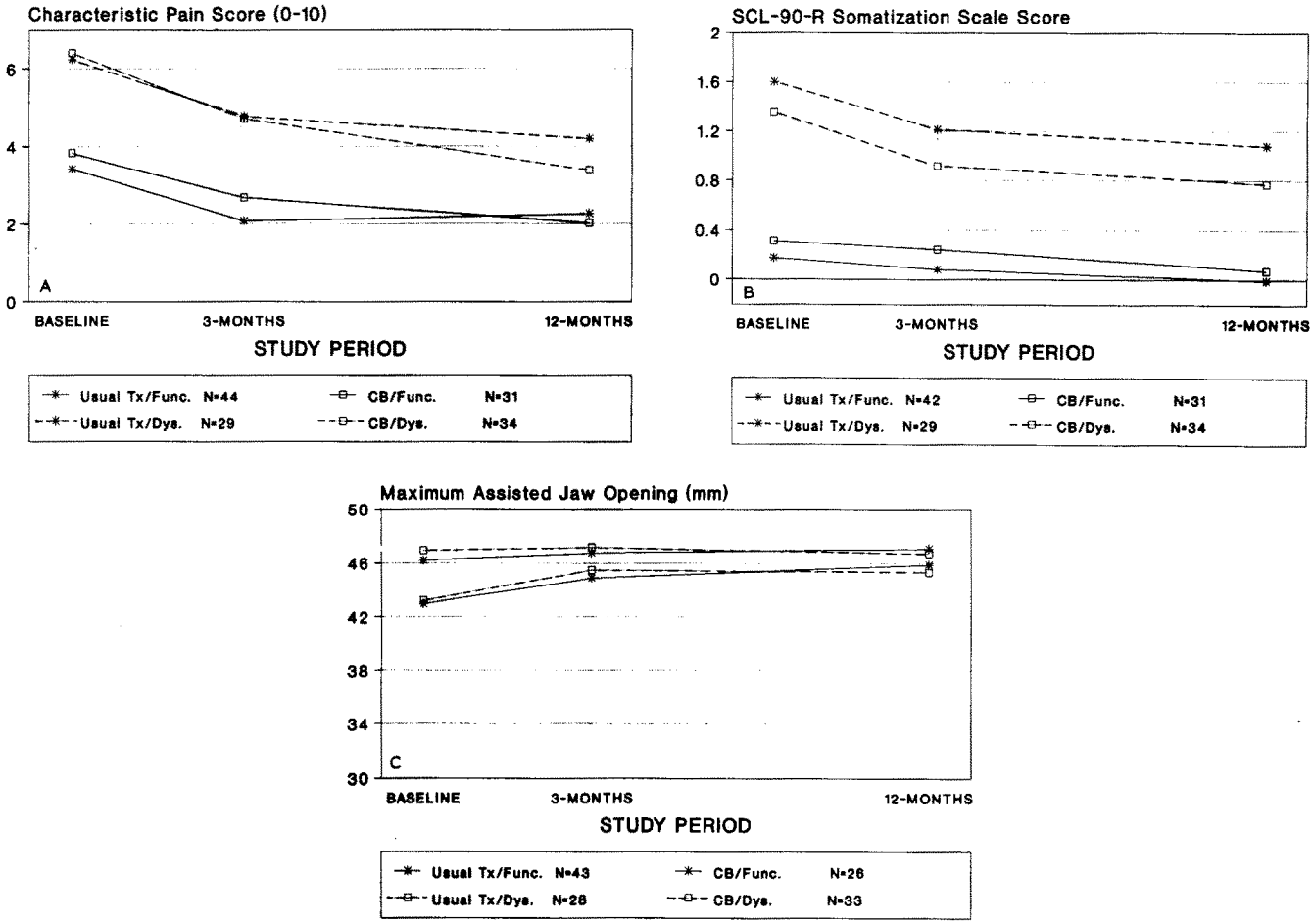

Fig. 2. a: Characteristic pain (0–10): group CB vs. UT by functional and dysfunctional patients (±SEM). Baseline, 3- and 12-month follow-ups, respectively, for UT Functional (3.42 (0.20), 2.07 (0.29), 2.26 (0.33)); CB Functional (3.83 (0.32), 2.67 (0.38), 2.02 (0.40)); UT Dysfunctional (6.24 (0.24), 4.76 (0.40), 4.19 (0.38)); and CB Dysfunctional (6.40 (0.20), 4.71 (0.41), 3.39 (0.46)). b: Somatization score for group CB vs. UT by functional and dysfunctional patients (±SEM). Baseline, 3- and 12-month follow-ups, respectively, for UT Functional (0.17 (0.15), 0.08 (0.14), −0.01 *P* (0.13)); CB Functional (0.31 (0.18), 0.24 (0.20), 0.07 (0.15)); UT Dysfunctional (1.60 (0.29), 1.21 (0.28), 1.08 (0.26)); and CB Dysfunctional (1.35 (0.28), 0.92 (0.26), 0.77 (0.33)). c: Maximum assisted jaw opening for group CB vs. UT by functional and dysfunctional patients (±SEM). Baseline, 3- and 12-month follow-ups, respectively, for UT Functional (46.19 (1.27), 46.74 (1.24), 47.05 (1.21)); CB Functional (43.00 (2.11), 44.88 (1.78), 45.88 (1.72)); UT Dysfunctional (46.93 (1.57), 47.14 (1.36), 46.68 (1.39)); and CB Dysfunctional (43.24 (1.47), 45.48 (1.25), 45.30 (1.25)).

tional vs. dysfunctional chronic pain level, does indeed separate patients into functional and dysfunctional sub-groups. Mean baseline, 3- and 12-month follow-up levels of characteristic pain are significantly different (t tests for independent means, baseline $t = 8.02$, $df = 295$, $P < 0.01$; 3-months, $t = 7.12$, $P < 0.01$; 12-months, $t = 4.71$, $P < 0.01$), when functional and dysfunctional patients are compared at each time point.

Somatization scores were examined as a dependent variable because it was of interest to observe how these scores were related to chronic pain grade and to observe how they changed for the CB and UT groups. Somatization score does not enter into the determination of functional vs. dysfunctional status, yet Fig. 2b reveals a pattern of significant differences in somatization scores between functional and dysfunctional patients at each time point (baseline: $t = 5.82$, $df = 223$, $P < 0.01$; 3 months: $t = 4.28$, $df = 223$, $P < 0.01$; 12 months: $t = 4.19$, $df = 223$, $P < 0.01$). By contrast, maximum assisted jaw opening, selected for these analyses because it is one of the few clinically relevant and objective physical signs associated with TMD that is not dependent on self-report, shows no significant differences at any time point, for either the functional or dysfunctional TMD patients, as shown in Fig. 2c (baseline: $t = 0.03$, n.s.; 3 months: $t = 0.14$, n.s.; 12 months: $t = 0.47$, n.s.). For example, while somatization returned to the population mean for functional patients at 12-months, this decline was from only slightly elevated baseline levels. For dysfunctional patients, while somatization did lower from baseline levels, at 12-month follow-up somatization levels still remained high (i.e., 75th percentile, see Fig. 2b), according to normative values derived from our studies of the general (i.e., non-TMD clinic) population with demographic characteristics (Von Korff et al. 1988; Dworkin et al. 1990e) comparable to the clinic sample studied here. The maximum assisted jaw opening measure remained relatively constant from baseline through 12-month follow-up (see Fig. 2c).

Additional analyses for between-group differences at baseline, 3- and 12 month follow-up also compared functional and dysfunctional patients for changes over time. We observed no significant interaction effects between chronic pain grade (functional vs. dysfunctional) and group assignment (CB vs. UT) for somatization or for maximum assisted opening. Although the sample sizes in all these secondary analyses were small, and power to detect significant differences were low, these exploratory analyses are provocative and, at the least, consistent with our hypothesis that the minimal CB intervention would not influence somatization.

Analyses by intent to treat. These analyses allow determination of the effectiveness of the CB intervention for all patients randomized to the CB and UT conditions, regardless of whether they actually received

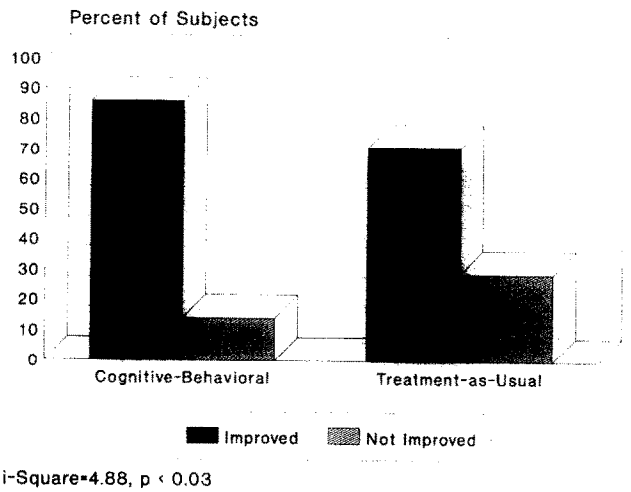

Fig. 3. Self-reported improvement in TMD. Condition: baseline to 12-month follow-up (some/much improved vs. no change/worse).

the assigned treatment. Analysis by intent to treat protects against possible bias introduced by differential drop-out rates in CB vs. UT groups. Analyses by intent to treat, although commonly reported for *biomedical* randomized trials (Lee et al. 1991), are rarely reported in randomized clinical trials of *biobehavioral* interventions.

In the present study, randomization was originally performed on 185 TMD patients and resulted in comparable numbers of patients assigned to the CB and UT groups. Results of the data analyses presented so far were for 139 (CB = 66; UT = 73) patients who completed the 12-month follow-up. Of the remaining 46 (185 − 139) patients, baseline and 12-month follow-up data on the major dependent variables were available for 25 patients. Repeated-measures 2 Groups (CB, UT) × 2 Time periods (baseline, 12-month follow-up) ANOVA were performed on the resulting sample of 164 (139 + 25) patients who were originally randomized to CB (n = 83) and UT (n = 81). Results revealed a significant Group × Time interaction for characteristic pain ($F = 5.79$, $df = 1,161$, $P = 0.017$), as was found with the sample of 12-month study completers. The Group × Time interaction was not significant for any other dependent variable (pain interference, somatization or depression and the clinical measures of mandibular opening).

Assessment of self-reported improvement. At 12-month follow-up, as shown in Fig. 3, significantly more patients in the CB group (86.4%) than in the UT group (70.1%) reported improvement in their TMD condition compared to their baseline status. Conversely, more than twice as many UT subjects (29.9%) as CB patients (13.6%) reported no improvement or worsening of their condition at 12-month follow-up ($\chi^2 = 4.88$, $df = 1$, $P = 0.027$).

TABLE III

KNOWLEDGE OF POSITIVE AND NEGATIVE FACTORS INFLUENCING TMD

Comparison of CB and UT groups for 'agree', 'disagree', 'don't know' (%). At 12-month follow-up.

TMD item	Patients reporting (%)						*P*
	Agree		Disagree		Don't know		
	CB	UT	CB	UT	CB	UT	
Oral habits (nail biting, clenching or grinding teeth) are often significant in the development of TMD. (agree = correct response)	94	74	5	4	1	22	0.001
All individuals with clicking joints should have treatment. (disagree = correct reponse)	20	15	56	38	24	47	0.019
Relaxation treatments are an effective treatment for TMD. (agree = correct response)	89	79	6	1	5	19	0.013
Bite adjustment is an essential treatment for TMD. (disagree = correct response)	26	35	47	21	27	44	0.005
Crooked or missing teeth, or a poor fit of the upper teeth to the lower teeth is a primary cause of TMD. (disagree = correct response)	24	32	50	21	26	47	0.001
The normal relaxed resting position for the mouth is to have the upper and lower teeth touching. (disagree = correct response)	11	17	87	54	2	29	0.001

Evaluations of TMD treatment received and knowledge concerning TMD and self-management. All patients responded to questionnaire items inquiring into evaluation of TMD treatment received. For CB patients, this included the combination of the CB intervention plus usual treatment; for UT patients, responses reflected evaluation of only TMD usual treatment provided by the dentist-specialist. For the item, 'how helpful has treatment been for your face and jaw pain', using a 0–10 scale anchored with 0 = not at all helpful and 10 = extremely helpful, data were analyzed by comparing CB and UT groups at 12-month follow-up. Responses were collapsed into 3 categories: (a) 0–2 = not at all to minimally helpful; (b) 3–7 = moderately helpful; and (c) 8–10 = very to extremely helpful. Significantly more favorable responses were given by the CB patients. The disparity in evaluations of overall TMD treatment between UT and CB groups was most striking at the positive and negative extremes. Approximately two-thirds of CB patients, compared to only one-third of UT patients, evaluated their TMD treatment as 'very/extremely helpful'; conversely, about twice as many UT patients (21%) as CB patients (11%) viewed their overall TMD treatment as 'not at all/minimally helpful' ($\chi^2 = 10.5$, $df = 2$, $P < 0.005$).

When 12-month responses were analyzed for knowledge of factors thought to negatively influence TMD and/or positive self-management strategies thought to be helpful in ameliorating pain and discomfort, CB patients were significantly better informed about the TMD condition and how patients might help themselves. Table III summarizes these data and indicates that for each item, CB patients were significantly (chi-square analyses) better informed than UT patients about factors such as oral habits that were likely to exacerbate their condition, as well as about useful

TABLE IV

POST-TREATMENT SATISFACTION WITH THE CB TREATMENT PROGRAM

	Percentage subjects (n = 70)		
Usefulness of:	Not useful	Somewhat useful	Very useful
Developing personal plan	0	12.9	87.1
Stress management methods	2.9	8.6	88.5
Jaw exercises	4.3	20.0	75.7
Relaxation methods	1.4	12.9	85.7
Confident about ability to apply program methods for:	Not confident	Somewhat confident	Very confident
Self-monitoring of TMD	4.3	21.4	74.3
Maintaining correct jaw posture	0	12.9	87.1
Muscle relaxation	7.1	14.3	78.6

self-management strategies and preferred customary jaw position to reduce risk of increased TMD pain and discomfort.

Patient satisfaction with the CB program. Given the positive implications of the data concerning CB vs. UT group evaluations of TMD treatment and knowledge about self-management, we would expect overall satisfaction with the CB program. Data gathered by post-program questionnaires, self-administered immediately after the second session, did indicate very high satisfaction with the program. Table IV summarizes patient global assessment of the program as well as assessment to selected components. In addition, overall, 94% were extremely satisfied with the program, 6% were somewhat satisfied and none were dissatisfied. About 86% indicated they would be 'very likely' to recommend the program to a friend and about 14% indicated a 'fair' likelihood to do so; again, no one indicated they would 'not recommend' the CB program.

Discussion

A 2-session CB intervention was designed to increase knowledge of etiology and treatment of TMD as well as provide skills in self-monitoring the condition and in use of behavioral strategies to manage chronic TMD pain. This intervention was introduced before usual clinical treatment for TMD began. Our hypothesis that patients who participated in the CB intervention followed by usual treatment would show greater long-term decreases in reported pain level and pain interference in daily activities than would patients who received only usual treatment was confirmed. The benefits of CB intervention were not seen when the CB and UT groups were compared at 3-month follow-up. At this time, both groups showed comparable and fairly steep improvement from baseline. During the 3–12-month follow-up interval, however, the UT group maintained essentially the same level of improvement in characteristic pain while the CB group continued to improve, as hypothesized. During this same follow-up interval, the CB group also showed a strong trend toward continued reduction in pain interference.

A similar pattern was not observed for relevant clinical variables involving range of mandibular motion, or for the psychological variables of depression and somatization. The improvement in all these variables was significant over time, independent of CB or UT group assignment. Thus, our hypothesis that patients in the CB group would show significantly greater improvement in vertical range of motion than would the UT group was not confirmed. Our expectation that the modest CB intervention would not have a significant impact on somatization and dysfunctional chronic pain grade was borne out.

Although the overall rate of self-reported improvement was high, which is typical for studies reporting on the efficacy of a wide variety of TMD treatments (Greene and Marbach 1982), significantly more CB than UT patients reported an overall improvement in their TMD condition 1 year after baseline. It was also encouraging to note the high rate of acceptance of the CB component among those attending the groups. The dentist introduced biobehavioral concepts in the dentist-psychologist conjointly led groups, perhaps enhancing patient acceptance of the applicability of these non-biomedical approaches to their TMD condition. A central feature of the CB program was the emphasis placed on developing a personal plan for managing TMD, which each patient was required to prepare in the second group session. At 1-year follow-up, 72% of CB participants reported that they were still following their personal plan while about 28% indicated they used it rarely or not at all. Similarly, 81% of the CB patients evaluated the personal plan as 'somewhat' to 'very important' in the management of their TMD condition (19% said it was of little to no importance). Interestingly, only 65% of patients in this CB followed by UT group thought that dental treatment was somewhat to very important and 35% thought dental treatment was of little or no importance to the management of their TMD condition at 1-year follow-up. Also, at 1 year, we observed that CB patients demonstrated more knowledge than did UT patients about the nature and self-management of their condition. Moreover, they also seemed more positive than UT patients about the rest of their usual TMD treatment, as provided by the 2 specialized clinics engaged in this study. Taken together, these data support the view that the CB program was not only well received by the majority of patients but was also experienced as beneficial in helping them improve their TMD condition.

Despite these positive outcomes, results from the present study must be interpreted with important reservations. The effects of CB vs. UT, although present after a reasonable follow-up, are modest in size. For pain interference, while a strong trend is noted, clear statistical significance was not demonstrated. In addition, a longer follow-up would have allowed us to determine if the trend towards continued improvement shown only in the CB group after 3 months reflected an enduring pattern that extended beyond the 1 year follow-up to which the present study was limited. It is well known that clinical trials of this type are difficult to conduct and many practical as well as experimental design problems have been described (Lee et al. 1991). Some of these involve subjects dropping from the study at differential rates for experimental and control groups (Turk and Rudy 1990a), the design of appropriate control groups (Whitney and Von Korff 1992), and issues in outcomes assessment (Dworkin et al. 1990b).

These issues have received increased recent attention in the chronic pain literature (Turk and Rudy 1990b; Peter et al. 1992) and our experience confirmed that logistic problems encountered in conducting clinical research with groups of patients could be formidable. Analyses by intent to treat are not commonly reported in biobehavioral trials. However, they have been advocated by clinical trials methodologists and were described in this paper to enhance interpretation of the generalizability of these findings.

Another methodologic strength of the present study is its relatively large sample size (139 subjects across both groups with complete data available for analyses after 12-month follow-up), yielding adequate statistical power to conduct the planned statistical comparisons. For our treatment group sizes, for example, there is 84% power to detect significant between-group differences of at least 0.5 SD at the $\alpha = 0.05$ level. Thus, we feel confident that the effect sizes we observed are what can reasonably be expected with interventions of this type, but that clinical trials seeking to demonstrate such effects will require comparably sized experimental and control groups.

With regard to issues of diagnosis, subjects were randomly assigned to CB and UT conditions without consideration of their clinical TMD (muscle, internal derangement or degenerative joint disease) diagnostic status. We have been intensely interested in the problems of diagnosis (Dworkin et al. 1990c) and have recently (Dworkin and LeResche 1992) contributed to making available empirically derived and operationally defined research diagnostic criteria for TMD (RDC/TMD). However, these criteria were not available to the study's TMD dentist-clinicians when the present study was designed and undertaken and reflect a limitation of our present analyses. Since a number of dentists participated in this clinical trial and they did not have available an agreed upon set of diagnostic criteria and standardized examination procedures, it was deemed most advisable not to include for analyses TMD diagnoses based on clinical data gathered in non-standardized fashion. Our subsequent clinical TMD research includes these research diagnostic criteria for classifying TMD subjects.

Dysfunctional chronic pain — associated with self-reports of more intense and persistent pain and manifestations of depression and maladaptive coping behaviors, but poorly correlated with physical pathology — has been documented as present in appreciable numbers of chronic pain patients seen in pain clinics (Turk and Rudy 1988; Rudy et al. 1989) and identified in population-based studies (Von Korff et al. 1990, 1991). The CB intervention was not targeted towards changing levels of dysfunctional chronic pain (or of somatization). It was, however, of additional interest in this study to observe the presence of differential responses to our intervention and to elucidate possible mechanisms of action to account for the patterns of response observed. For example, we observed that dysfunctional TMD patients showed significantly higher levels of somatization at baseline than did functional patients. For this group, somatization did decrease somewhat over the 12-month follow-up of this study, but remained at levels in the top quartile for somatization using norms for the population from which the present study are largely drawn. By contrast, somatization scores for functional patients returned to the mean values for the population (age/sex-adjusted population mean for somatization is equal to zero). Our data have an important limitation with regard to somatization, in that they are limited to self-report of non-specific physical symptoms on the SCL-90-R and behavioral data with regard to health care utilization are lacking.

Nevertheless, our data supports the concern of McCreary et al. (1992) that somatization may have an important negative influence on outcomes of treatment for chronic pain. The observation that self-report measures of pain and somatization seem to change over time (Fig. 2a,b) while an objective physical finding (e.g., maximum assisted jaw opening), which does not involve self-report does not show either time- or group-related changes (Fig. 2c), may also have implications for the kinds of changes one can expect chronic pain patients to accomplish. In a similar vein, the present study supports the notion that dysfunctional chronic pain patients might not respond readily to modest CB interventions which do not address the more complex aspects of their pain dysfunction, such as somatization. These initial conclusions with regard to: (1) the role of chronic pain dysfunction and its resistance to usual TMD treatment with and without minimal CB interventions, and (2) the potential for somatization to influence treatment outcomes, require more extensive investigation to validate their applicability to TMD and to determine whether patterns observed in chronic TMD pain patients are generalizable to other pain conditions.

In summary, the present study supports the utility of a brief group CB intervention, placed before conventional clinical treatment for TMD began, to ameliorate the report of TMD pain. The effects observed from such a biobehavioral intervention seem long-lasting, albeit modest in size. Further research is needed to explicate which components of CB interventions such as those used here are most powerful, e.g., the use of small groups, placement of the CB components before usual clinical dental treatment and the efficacy of having the dentist identified with biobehavioral methods as well as biomedical treatments. It also appears that biobehavioral treatments, like biomedical treatments, are not equally effective across the spectrum of chronic pain patients. Present evidence indicates that

somatization tends to correspond with dysfunctional chronic pain status. Findings presented with regard to somatization as a potentially critical variable need to be extended to determine if the readiness to report multiple non-specific physical symptoms is a predictor, or 'marker' variable, capable of identifying individuals who resist biobehaviorally based methods for coping with pain while engaging in excessive health care utilization.

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