

# A Randomized Clinical Trial of a Tailored Comprehensive Care Treatment Program for Temporomandibular Disorders

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**Aims:** To test the usefulness of tailoring cognitive-behavioral therapy (CBT) for patients with temporomandibular disorders (TMD) who demonstrated poor psychosocial adaptation to their TMD condition, independent of physical diagnosis. **Methods:** A randomized clinical trial compared a 6-session CBT intervention delivered in conjunction with the usual TMD treatment to the usual conservative treatment by TMD specialist dentists. For study inclusion, Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), Axis II criteria, were used to target patients with elevated levels of TMD pain-related interference with daily activities, independent of physical diagnosis (ie, Axis I). **Results:** At the post-treatment assessment, about 4 months after the baseline evaluations, the comprehensive care group, when compared to the usual treatment group, showed significantly lower levels of characteristic pain intensity, significantly higher self-reported ability to control their TMD pain, and a strong trend ( $P = .07$ ) toward lower pain-related interference in daily activities. From post-intervention to 1-year follow-up, all subjects showed improvement. At the 1-year follow-up, the comprehensive care group, while not losing any of its early gains, was not significantly different from the usual care group with regard to reported levels of pain, ability to control pain, and levels of interference in activities. For many of these psychosocially disabled TMD patients, pain and interference 1 year after treatment remained at the same or higher levels than those observed at baseline among a group of patients selected for a separate randomized clinical trial on the basis of better psychosocial adaptation. **Conclusion:** The 6-session CBT intervention for patients with heightened psychologic and psychosocial disability was effective in improving pain-related variables over the course of the CBT in conjunction with usual treatment, but was too brief an intervention to result in further improvement after the sessions ended. Patient ratings of treatment satisfaction and helpfulness were high for both groups, but they were significantly higher for the comprehensive care group.

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**Key words:** temporomandibular disorders, cognitive-behavioral therapy, RDC/TMD

Treatments for temporomandibular disorders (TMD) are wide-ranging and directed primarily toward relief from persistent orofacial pain.<sup>1-3</sup> Pain is the cardinal symptom of TMD that causes patients to seek treatment, and pain relief is the major, but not exclusive, criterion by which both patients and clinicians gauge treatment as successful. The most widespread forms of

treatment include a core of so-called conservative treatments. These include reversible, noninvasive treatments using physical medicine methods, non-repositioning splints, and non-prescription analgesics. Numerous invasive and not-so-readily reversible treatments are also described in an abundant literature; these include temporomandibular joint (TMJ) surgery, arthroscopic methods, occlusal equilibration, mandibular repositioning appliances, and craniosacral manipulations.<sup>3,4</sup> Although many of these methods are reported to have high success rates (80% success is commonly reported),<sup>5-7</sup> workers in the field are confronted with the apparent paradox of an abundance of TMD patients who seek repeated treatments for their TMD—principally for their TMD-related pain.<sup>8</sup>

The most commonly treated subtypes of TMD are those diagnosed as primarily masticatory muscle and/or TMJ disorders. Diagnoses of the most commonly occurring forms of TMD are based on clinical findings from a physical examination; the patterns of clinical findings are presumed to reflect pathophysiologic processes that give rise to TMD symptomatology.<sup>1,9</sup> As with any clinical disorder, a major purpose of diagnosis and assessment is to guide a rational plan for clinical management. The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)<sup>2</sup> provide a systematic method for classifying the major subtypes of TMD along a physical disease axis (Axis I). The RDC/TMD Axis I conditions are representative of those managed according to the wide variety of treatment methods that have been partially summarized above. Signs and symptoms that enter into an RDC/TMD Axis I diagnosis include persistent orofacial pain, limitations in mandibular range of motion, pain on masticatory muscle palpation, and detectable sounds in the TMJ during jaw function.

The conceptual basis for our understanding of chronic pain is provided by a biopsychosocial model, which has proven helpful in guiding our epidemiologic, health services, clinical dental, and biobehavioral research, including the present randomized clinical trial (RCT). The model we have developed, which has been applied to illness behavior in general,<sup>10</sup> is a dynamic, ecologic one that views expression of pain and dysfunction as the current resolution of intra- and interpersonal as well as environmental forces operating across time. The model suggests that physiologic activity in the form of nociceptive information in the pain-transmission system is operated upon by higher centers associated with perception, emotion, cognition, overt behavior, and social role levels of psychosocial functioning. The expression of pain can

be described at any of these levels by the appropriate scientific methods and language suitable to each level. The expression of pain at the level of the overtly behaving individual who is suffering and seeking treatment represents the outcome of the complex integration of these biologic, psychologic, and social forces simultaneously at play—hence, a biopsychosocial model. The model suggests the possibility that if personal and environmental factors contribute to the expression of pain and dysfunction at many levels, then perhaps interventions such as cognitive-behavioral therapy (CBT), targeted at cognitive, emotional, and behavioral levels, may be effective in modifying the expression of pain and dysfunction. An extensive scientific literature also repeatedly confirms the presence of significant emotional, cognitive, behavioral, and psychosocial disability in TMD clinic populations.<sup>10-14</sup>

The RDC/TMD also assess the psychologic and psychosocial status of TMD patients along a second axis (Axis II). Axis II allows for the assessment of impaired or maladaptive masticatory muscle function (eg, eating, communicating, bruxism); depression; and non-specific physical symptoms. The extent of psychosocial interference is also assessed on Axis II through the Graded Chronic Pain scale (GCP).<sup>15</sup> One purpose of such an RDC/TMD Axis II assessment is to guide research into the most efficacious treatment and long-term management of the TMD patient. In the present study, RDC/TMD Axis II criteria were used to target TMD patients with TMD pain-related psychosocial interference for a comprehensive treatment program that included a biobehavioral component tailored to their level of psychosocial interference. This component was integrated with usual clinical care provided by TMD specialist clinicians.

Of particular relevance for establishing a comprehensive treatment plan for chronic TMD patients is the well-documented finding that an appreciable number of these patients meet criteria for the diagnosis of major depressive disorder and/or somatoform disorder.<sup>11,16,17</sup> Somatoform disorder is defined as the reporting of multiple physical symptoms, including multiple pain problems, that are not explained by a medical condition.<sup>18</sup> In addition, it is well-established that TMD clinic populations include patients who exhibit many of the important indicators of depressive and somatoform disorders but at levels that do not meet rigid criteria for a formal psychiatric disorder as defined by DSM-IV (Diagnostic and Statistical Manual of Mental Disorders).<sup>18-21</sup> Somatoform disorders have been reported to be an important

predictor of poor response to TMD treatment.<sup>21</sup> Depression is also a risk factor for poor response to medical treatments, and the treatment of depression, when present, is an important component of any multidisciplinary pain management program.<sup>22</sup>

Many TMD patients show, in addition to psychological disturbance, pain-related interference with activities of daily living.<sup>23–25</sup> These patients may have high health-care utilization, reliance on pain medications of all kinds, and an inability to carry out usual functions at work, home, or school. Unfortunately, it is still not known whether psychological disturbance and psychosocial disability precede the onset of TMD signs and symptoms—and thus might be risk factors for TMD onset—or whether such psychological and psychosocial dysfunction is a result of the persistent pain condition—or whether both of these may be true. It is widely believed that the optimal management of other common chronic disabling pain conditions, such as back pain and headache, requires a multidisciplinary approach that integrates the treatment methods of health care disciplines associated with both Axis I (eg, rehabilitation medicine, neurology, anesthesiology, surgery) and Axis II (eg, psychiatry, clinical psychology, behavioral medicine, and health psychology).<sup>26</sup> Although it is not so common for TMD to be managed in such an integrated multidisciplinary fashion,<sup>27</sup> the major university-based orofacial pain centers integrate both assessment and treatment along lines reflected by the dual-axis nature of the RDC/TMD. The RDC/TMD have been identified as a potential model system for the diagnosis and assessment of all chronic pain conditions.<sup>10</sup>

The most common psychologically based therapies included in multidisciplinary management of chronic pain, including TMD, are based on CBT theory and methods.<sup>28,29</sup> CBT aims to restructure how patients view the impact and management of their condition, providing strategies for systematically addressing the emotional, cognitive, and behavioral factors associated with chronic pain. Such therapies especially attend to management of depression and life stresses, so patients can develop more adaptive methods for coping with TMD. The efficacy of CBT has been reviewed for chronic pain conditions<sup>29,30</sup> and for TMD specifically.<sup>31</sup> We have reported on the use of CBT methods in brief therapies for TMD, including group formats.<sup>32</sup> The present report represents a continuation of these efforts to study the efficacy of brief physical medicine<sup>33</sup> and CBT<sup>34</sup> approaches for the management of TMD.

A focus has recently emerged on developing treatments for chronic pain, including TMD, that

target specific patient populations.<sup>35–37</sup> An innovative approach (and perhaps provocative in an already controversial field) has been to target TMD patient subgroups based on their ability to cope or adapt successfully to their TMD condition, independent of their physical or RDC/TMD Axis I diagnosis, and to deliver TMD treatment programs tailored to such subgroups. Initial attempts at tailoring TMD treatments were conducted by Turk, Rudy, and colleagues, who found that integrating CBT methods with components of usual TMD care in patient/treatment-matching paradigms was effective for both well-adapting<sup>38</sup> and dysfunctional<sup>36</sup> TMD patients.

In a recent report<sup>34</sup> the present authors described an RCT conducted to evaluate the efficacy of a brief self-care treatment program for TMD. The program was targeted for TMD patients who showed minimal TMD-related psychosocial interference, independent of physical diagnosis. The self-care treatment program consisted of 3 sessions with 2 telephone follow-ups and was delivered by a registered dental hygienist. Patients were randomized either to the self-care program or to usual TMD care delivered by university-based TMD clinical specialists. At the 1-year follow-up appointment, while both groups showed improvement in all clinical and self-report categories measured, those participating in the tailored self-care treatment program showed significantly decreased TMD pain, pain-related interference with activities, and number of masticatory muscles painful on clinical examination, as compared to those randomized to receive usual TMD treatment. Both the self-care and usual treatment groups improved comparably on measures of vertical range of mandibular motion. The self-care program was associated with non-statistically significant trends over time toward lower levels of depression and somatization as compared with the usual care group. Self-care was associated with significantly fewer dentist visits in the post-treatment period. Patient satisfaction with treatment, reported ability to cope with pain, and level of TMD knowledge were significantly enhanced for the self-care group. No patients participating in the RCT experienced physical or personal adverse effects.

### Use of the RDC/TMD Axis II in Clinical Trials Research

The present study was part of a programmatic longitudinal research effort investigating the validity and clinical utility of RDC/TMD in identifying

sub-samples of TMD clinic cases. In previous studies,<sup>39-41</sup> it was found useful to characterize TMD patients with RDC/TMD Axis II GCP scale scores of Grades I or II as “psychosocially functional.” These patients typically show minimal psychologic distress and pain-related interference in the personal, social, and work domains of their lives. In contrast, we have previously demonstrated that patients classified as Grades III and IV show psychologic and psychosocial disability. Data relevant to the reliability and validity of GCP have been published.<sup>15,42</sup>

The RDC/TMD have been extended to identify TMD clinic cases that could be targeted for TMD management using brief, tailored treatment approaches that incorporated CBT theory and methods, either alone or in combination with usual TMD clinical care. The research approach separated TMD patients into 2 subject pools according to their GCP score. A critical element was the use of the RDC/TMD Axis II GCP scale to assess the level of psychosocial interference, independent of RDC/TMD Axis I diagnosis. Those patients whose GCP score placed them in the psychosocially functional range were invited to participate in the RCT summarized above.<sup>34</sup> Contemporaneously appearing patients with GCP scores indicative of psychosocial dysfunction were targeted for the concurrently conducted RCT described in this report.

## Study Hypotheses

This RCT was designed to compare a treatment approach incorporating CBT methods tailored to higher levels of TMD-related disability with usual clinical care for TMD. Treatment assignment was independent of RDC/TMD Axis I diagnosis. Our primary hypothesis was that a relatively brief (6-session) CBT designed for dysfunctional TMD pain patients and integrated into usual care would reduce pain intensity and psychosocial interference to a significantly greater extent than would usual TMD treatment. We also hypothesized that, both after the CBT and at the 12-month follow-up, the cognitive-behavioral intervention group would have increased perceived control over TMD, lower levels of depression and somatization, and greater overall satisfaction with treatment. Finally, for both primary and secondary outcome measures, we hypothesized that changes observed would not be linear over time, but that most reported change would come early in the study, and for the comprehensive care group this would be temporally

associated with the cognitive-behavioral intervention; hence our major analyses examined outcomes post-treatment and at a 1-year follow-up appointment.

## Materials and Methods

### Subjects

Study participants were recruited from patients referred to the Orofacial Pain Clinics in the Department of Oral Medicine, University of Washington (UW) School of Dentistry, for assessment of pain and related symptoms of TMD. Criteria for study inclusion were: (1) self-report of facial ache or pain in the muscles of mastication, the TMJ, or the region in front of the ear or inside the ear; (2) RDC/TMD Axis II GCP score of II-High (defined below), III, or IV; (3) age between 18 and 70 years. Patients who met these criteria were invited to participate in the study if the attending dentist, after a baseline clinical examination and history evaluation, judged the patient to require treatment for TMD, regardless of pain level or Axis I physical diagnosis. Exclusion criteria included: (1) pain attributable to confirmed migraine or head pain condition other than tension headache; (2) acute infection or other significant disease of the teeth, ears, eyes, nose, or throat; (3) debilitating physical or mental illness; (4) necessity for emergency TMD treatment; and (5) inability to speak or write English. All study participants provided signed, informed consent in accordance with US National Institutes of Health and UW standards for protection of human research subjects.

Of the 186 patients who met study eligibility criteria, 117 (62.9%) agreed to participate and were assigned randomly to a comprehensive care (CC,  $n = 59$ ) or usual TMD treatment (UT,  $n = 58$ ) condition. A sample size of at least 56 patients per group was required to detect a 40% reduction in characteristic pain intensity and pain interference (see Study Measures) at the 6- or 12-month follow-up in the CC group as compared to the UT group with at least 80% power, based on a repeated-measures multivariate analysis of variance (ANOVA) at a .05 significance level. Interview data were collected at baseline (pretreatment), post-intervention (approximately 4 months post-baseline, on average), and at 6- and 12-month post-intervention follow-ups. Clinical examination data were gathered at baseline and at 6- and 12-month follow-ups.

**Table 1** Study Measures Examined

Measures <sup>2</sup>	Description
RDC/TMD Axis I measures (not collected at post-treatment follow-up) <sup>2</sup>	
Physical examination	Range of vertical mandibular motion, number of extra- and intraoral masticatory muscles painful to palpation
RDC/TMD Axis II measures <sup>2</sup>	
Characteristic pain intensity <sup>43</sup>	The average of 0–10 ratings of: present pain, worst pain, and average pain in past month
Pain interference score <sup>15</sup>	Average of 0–10 ratings of pain-related interference with work, social activities, and overall activities in past month
Chronic pain grade <sup>15</sup>	Category based on characteristic pain intensity, pain interference score, and days kept from usual activities due to pain in past month
SCL-90 depression and somatization scales <sup>57</sup>	Age- and sex-adjusted scale scores (population mean = 0)
Self-report measures	
Days in pain	Days pain was present in prior 6 months
Ability to control pain <sup>68</sup>	Average of 0–6 rating of ability to control TMD-related pain
Process of care ratings (post-treatment and 12-month follow-up)	0–10 scales to assess perceived helpfulness and global satisfaction
Demographics (baseline only)	Age, gender, education, income

SCL-90 = Symptom Checklist 90.

## Study Measures

Table 1 summarizes the RDC/TMD Axis I clinical physical measures and the Axis II self-report measures gathered in this study. Characteristic pain intensity represents the mean scores (0 to 10 scale) for average pain in the past month, current pain, and worst pain in the past month. Characteristic pain intensity has been shown to be a more reliable measure of TMD pain than any of the components taken separately.<sup>43</sup> GCP is defined as follows: Grade 0 indicates no current TMD pain, although other signs and symptoms (such as muscle stiffness, TMJ sounds, and limitations in mandibular opening) may be present. Grade I indicates levels of TMD pain of less than 5 (0 to 10 scale). Although measures of psychologic status (eg, depression and somatization) do not enter into the assessment of GCP, empirically, Grade I patients show relatively low levels of psychologic disturbance. Grade II was divided into low and high groups. Grade II-Low is characterized by orofacial pain rated as 5 or higher (0 to 10 scale) and zero disability points, indicating no pain-related interference with daily activities; Grade II-High is characterized by the same level of pain as Grade II-

Low (ie, 5 or higher) but with 1 to 3 disability points, reflecting slight interference with daily activities due to TMD pain. Grades III and IV are defined as showing moderate to high levels of pain-related activity interference (including work interference), independent of pain level. Previous research has shown that Grades III and IV are associated with high levels of pain (over 5 on a 0 to 10 scale) and moderate to high levels of psychologic disturbance.<sup>15,39,44</sup> Table 1 includes additional measures gathered related to demographics, history, and psychologic/psychosocial functioning. Finally, we measured patient satisfaction and perceived helpfulness of TMD treatment.

## Procedures

All patients were evaluated by the attending dentist at baseline with a complete physical examination and history questionnaire. This evaluation included the RDC/TMD Axis I and II measures and calibration of dental examiners.<sup>2</sup> Attending dentists documented TMD treatments they prescribed for each patient on a DDS Treatment Checklist form at the conclusion of their examination. Patients in both study conditions continued

to receive prescribed conservative treatments from 1 of 6 UW Orofacial Pain Clinic specialists. Patients assigned to the CC condition were also randomly assigned to 1 of 4 clinical psychologists in the Department of Oral Medicine Orofacial Pain Clinic for 6 visits and 3 telephone calls between visits over a 4-month period. For patients who declined to participate or who dropped out prior to randomization, baseline demographic and clinical examination data were obtained with the patients' consent. All patients who dropped out from the study prior to completion of the 12-month follow-up were asked to provide minimal data about pain and pain-related interference to allow intent-to-treat analyses. All analyses present results for patients who were randomized and for whom data are available, although there are small differences in numbers of patients across some analyses. All patients in both groups paid customary and usual clinic fees for their usual care as provided by attending TMD clinicians. Patients incurred no additional treatment charges from psychologists associated with the CC study intervention and were paid up to \$150 for completing the study measures.

**Usual Treatment Group.** Patients randomized to UT received customary TMD treatment, typically described as conservative because the treatment approach emphasizes noninvasive and reversible physical medicine treatments together with medications. The treatments prescribed in this RCT at the discretion of the attending dentist typically included:

1. Physiotherapy: passive and active jaw range-of-motion and stretching exercises and application of heat or cold packs
2. Patient education: parafunctional oral behaviors, diet, nature of the condition, and rationale for treatment
3. Medications: analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, antidepressants
4. Intraoral flat-plane occlusal appliances: typically fabricated by the dentist from heat-cured acrylic, which resulted in a hard, individually fitted splint; or adjustments were made by dentists to pre-existing adequately functioning appliances as necessary

Typical dentist-prescribed usual treatment components also included behavioral self-care regimens for reduction of bruxism, soft food diet, and jaw exercises. Those aspects of the dentist-prescribed treatment that implicated self-care behav-

iors on the part of patients were recorded on a Patient Instruction Checklist and given to patients at the end of their initial clinical visit. A copy was retained in the clinic chart; for CC patients, an additional copy was provided to the appropriate clinical psychologist. There were no limitations on numbers of visits or additional treatments that could be provided by the attending dentists. All treatments prescribed at the initial visit or subsequently delivered were recorded on the Treatment Checklist at each clinic visit.

**Comprehensive Care Group.** A manual-based 6-session intervention that included 3 telephone calls interspersed among the sessions was delivered on an individual basis by the study's clinical psychologists. Subjects simultaneously received usual treatment from their attending TMD clinic specialist. The CC intervention included 1 joint session involving the patient, his/her dentist, and the clinical psychologist. The CC intervention was based on CBT and methods commonly employed in multidisciplinary management of chronic pain.<sup>28,45</sup> It included an emphasis on patient education and self-care, training in the identification and modification of maladaptive thought patterns related to pain, training in relaxation and other pain management coping skills, and discussion of relapse prevention and long-term maintenance of gains achieved in treatment. In addition, because psychosocially disabled TMD patients frequently hold largely physically based explanatory models for their condition<sup>46-49</sup> and present with multiple somatic complaints, widespread pain, and depression, the CC intervention also included modules designed specifically to address somatization and depression when present. To address the problems of pain and inability to use the jaws comfortably, the psychologists reinforced the attending dentists' prescription of self-care behaviors as recorded on the Patient Instruction Checklist. The overall course of the CC treatment program delivered by the psychologists is outlined below.

*Stage I: Engagement (Session 1).* The goals of the Engagement phase were to: (1) defuse negativity and resistance to approaches other than biomedical ones; (2) introduce alternatives based on patient-generated information concerning strengths, competencies, and interests; (3) introduce patients to the self-instructional materials.

*Stage II: Educational and Cognitive-Behavioral Treatment Program (Sessions 2 to 5).* The goal of this phase was to address patients' explanatory models for pain and health care utilization and to teach pain coping skills based on well-accepted

cognitive and behavioral methods.<sup>29</sup> Homework was assigned and reviewed by the clinical psychologist; homework assignments were designed to maximize use of limited appointment time available. The principal components of the intervention (organized into a patient handbook) included:

1. Behavioral/Relaxation: Monitoring of symptoms, attention to mandibular postures and habits, jaw stretching exercises, and training in abdominal breathing and progressive muscle relaxation.
2. Cognitive Coping: Monitoring of pain-related situations, thoughts, and feelings; learning and practicing skills for challenging negative thoughts. In addition, the clinical psychologists could introduce depression and/or somatization treatment modules as appropriate.
3. Explanatory Model: Provision of a biopsychosocial model for TMD to help patients better understand the interaction of physical, behavioral, and stress-related factors in the etiology and maintenance of the condition. Significant emphasis was placed on instilling explanatory models that stressed realistic expectations about the fluctuating and recurrent nature of TMD and other somatic symptoms. Following from methods suggested by several workers,<sup>45,48,50</sup> a “rehabilitation” model rather than a “curative” model was emphasized and was coupled with a focus on distinguishing bodily sensations that can be monitored and then managed safely through self-care from those requiring professional intervention.
4. Health Care: Provision of instruction and feedback in facilitating long-term relationships with all health care providers by enhancing positive and accurate communication. All patients met with their attending dentist and psychologist in a joint session. The health care component was especially emphasized for somatically focused patients with histories of excessive and unsuccessful seeking of care from multiple providers.
5. Personal Plan: Integration of all of the components of the CC treatment program through the use of a Personal Plan format successfully applied in our biobehavioral intervention studies.<sup>34</sup> The Personal Plan is a form on which the patient records strategies to be used on a scheduled (typically, daily) basis for (1) managing TMD and other symptoms; (2) communicating with health care providers to optimize the use of professional health care; (3) managing difficul-

ties and relapses; and (4) reversing the negative impact of pain on daily activities.

*Stage III: Maintenance (Session 6).* This summarized and reinforced progress, with emphasis placed on compliance with the Personal Plan, realistic expectations, and relapse prevention.

All study psychologists, who were faculty members in the UW Department of Oral Medicine and/or the Department of Psychiatry and Behavioral Sciences, were experienced with the methods outlined, including self-monitoring of TMD signs and symptoms and the simple exercises for jaw stretching and jaw muscle relaxation. In addition, all the study psychologists were experienced in the use of CBT methods with a wide variety of chronic pain patients. Each psychologist followed a written manual for each session. Major points to be covered in each session were indicated in the manual, and the psychologist checked off these points as they were covered. Also, after the first session, the psychologist reviewed the patient-completed personal plan at each session and provided positive feedback for practice and application of skills taught in the program. When subjects failed to complete “homework” as assigned, reasons were explored and the psychologist helped the patient to find other ways to perform the assigned therapeutic tasks.

All clinical baseline and follow-up study data collection were performed by calibrated and reliable clinical examiners not participating in the RCT and blinded to the study group to which patients were assigned.

### Statistical Analyses

Two main considerations motivated our overall analytic strategy: (1) the change over time for the primary outcomes of pain intensity and pain interference would not be linear over time (most reported change would occur early in the study), and (2) for the intervention to be considered successful, we wanted to demonstrate reduction in pain intensity and interference following treatment and 1 year after treatment, because we explicitly hypothesized that the intervention would reduce pain intensity and pain interference following treatment and 1 year after treatment.

Accordingly, ANOVAs were used for the major outcome analyses to compare the 2 patient groups at post-treatment (approximately 4 months after baseline) and at the 12-month post-treatment follow-up on the primary outcomes of characteristic pain intensity and pain interference. Again, this

**Table 2** Patient Baseline Characteristics

	Comprehensive care (n = 59)			Usual treatment (n = 58)			P
	Mean	Percent	SE	Mean	Percent	SE	
Demographic							
Age (y)	38.6		1.3	39.3		1.4	.72
Female		81.4%			84.5%		.65
Education level (>high school)		72.9%			72.4%		.95
Income (> \$50000/annually)		27.1%			37.5%		.23
Characteristic pain intensity	6.8		0.2	6.8		0.2	.91
Pain interference score	5.0		0.3	4.9		0.3	.74
Axis I measures (see also Table 3 and Fig 4)							
Unassisted opening, no pain (mm)	36.0		1.5	34.0		1.4	.33
Unassisted opening, pain (mm)	44.6		1.4	43.4		1.2	.53
Maximum assisted opening (mm)	48.5		1.3	47.6		1.2	.58
Group I diagnosis (muscle disorders)		94.9%			94.7%		.97
Group II diagnosis (disk disorders)		86.4%			84.5%		.67
Group III diagnosis (TMJ disorders)		67.8%			69.0%		.85
Axis II measures							
Depression*	1.4	44.8%	0.2	1.5	42.9%	0.3	.81**
Somatization*	1.1	52.5%	0.2	1.3	55.4%	0.3	.47**
Graded Chronic Pain Scores							
Grade II-High		25.4%			36.2%		
Grade III		30.5%			24.1%		
Grade IV		44.1%			39.7%		

\*Age/sex-adjusted scores<sup>56</sup>; population mean = 0; depression scores: < 0.54 = normal; 0.54–1.05 = moderate; > 1.05 = severe. Somatization scores: < 0.50 = normal; 0.50–1.00 = moderate; > 1.00 = severe.

\*\*P value for mean differences.

approach was based on our assumption that the change over time in pain intensity and pain interference would not be linear; we expected that most change would occur by time of the post-treatment follow-up. We also believed that, in evaluating a treatment, it is important to demonstrate reduction in pain intensity and interference both following treatment and longer-term (eg, 12 months after treatment). Data at the 6-month follow-up were also reported to help clarify the course of change over time. For several of the secondary outcome measures (eg, depression and somatization), the change over time was approximately linear, and for these outcomes, in addition to ANOVAs, we also conducted trend analyses using data from all available time points to compare the rate of change between patient groups. We found no meaningful differences between the ANOVAs and trend analyses for depression and somatization.

In addition to intent-to-treat analyses,<sup>51,52</sup> it can be useful to examine the results of analyses that exclude subjects who drop out of the study intervention<sup>53</sup> without participating in all of the 6 intervention sessions (n = 6).<sup>54</sup> Such analyses were also conducted (it should be noted that no sub-

jects who dropped out of the CC group were changed to inclusion in the UT group). For all such analyses, results favored the hypothesized outcomes somewhat more strongly than the intent-to-treat analyses (results are reported for pain intensity and interference), but the differences were not statistically or clinically meaningful in this study; hence for all other outcomes, only the results of intent-to-treat analyses are reported.

## Results

### Baseline Comparisons of Groups

As is commonly reported in TMD clinical studies, 85% of study participants were women.<sup>55</sup> The subjects had a mean age of 38.8 years (SD = 10). There were no statistically significant differences between CC and UT patients at baseline in age, gender, level of education, pain intensity, RDC/TMD Axis I clinical physical variables, or distribution of Axis I diagnoses or Axis II measures. The results of these baseline analyses are summarized in Table 2.



**Comparison of Study Participants and Non-participants.** Of the 186 eligible patients, 36.9% ( $n = 69$ ) declined to participate or dropped out prior to randomization. The most common reasons given for declining to participate in the study were time, distance, and related considerations ( $> 50\%$ ); 13% refused any further participation after initial consent, and only 3% ( $n = 2$ ) refused to see a psychologist. There were no statistically significant demographic or clinical differences at baseline between those who declined to participate or dropped out prior to randomization and the study participants.

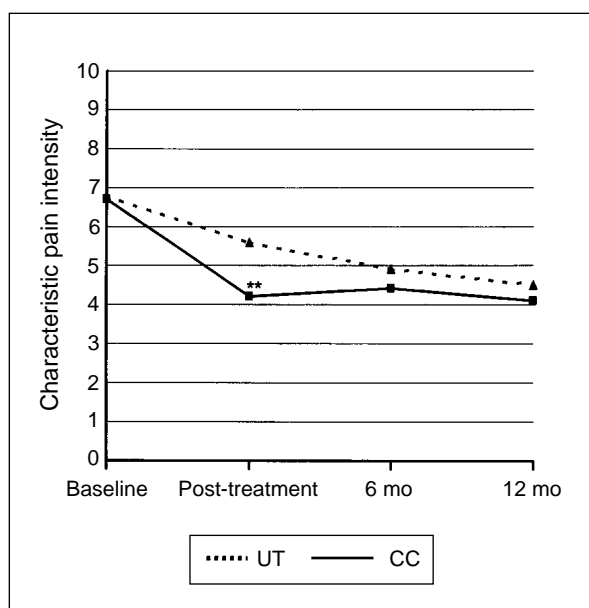
**Comparison of Study Completers and Dropouts.** Of those randomized, post-treatment data were available for 88% ( $n = 52$ ) of CC and 84% ( $n = 49$ ) of UT patients, and 12-month follow-up data were available for 95% ( $n = 56$ ) of CC and 88% ( $n = 51$ ) of UT patients. There were no statistically significant demographic or clinical differences at baseline between patients lost from the study and the study participants. However, it should be noted that the statistical power to detect significant differences is low due to the small number of study dropouts.

### Compliance with Intervention

Of the 59 patients who were randomized to CC, 6 did not attend any sessions, 2 attended only the first session, and 8 attended 2 or 3 sessions. No subjects dropping from the CC intervention were changed to inclusion in the UT group. Also, analyses to examine for effects of psychologists and/or dentists indicated few to no observable differences among psychologists or dentists with regard to patients' characteristic pain at baseline or at 12-month follow-up—that is, no significant differences at baseline, post-treatment, or at the 1-year follow-up were observed in any outcome measures as a function of either dentist or psychologist seen by patients in either group.

### Characteristic Pain Intensity

Characteristic pain intensity levels (Fig 1) were identically high at baseline for both groups (mean  $> 6.7$  on a 0 to 10 scale). At post-treatment, mean characteristic pain intensity levels for the CC group fell to 4.2 (about a 35% decrease), significantly below the mean level of 5.6 (about an 18% decrease) shown by the UT group ( $P = .02$ ). From post-treatment to the 1-year follow-up, the CC group continued to show a decline in characteristic pain intensity levels, but not as sharply.

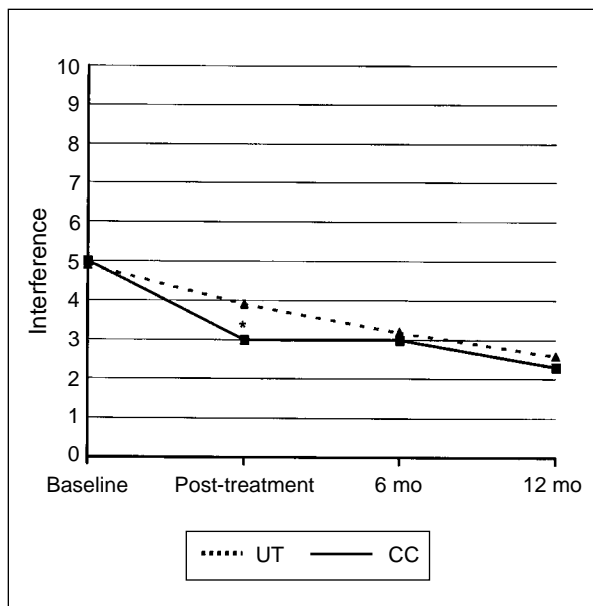


**Fig 1** Comprehensive care versus usual treatment: Mean characteristic pain intensity (scale of 0 to 10). \*\* $P = .02$  (ANOVA comparing groups at post-treatment and 1-year follow-up).

At the 1-year follow-up, the difference between groups in mean level of pain intensity was not statistically significant (CC mean = 4.1 versus UT mean = 4.5,  $P = .38$ ). Exclusion of CC subjects who did not attend all 6 intervention sessions gave only a slightly larger difference in pain intensity levels between the CC group (mean = 3.9) and the UT group (mean = 4.5;  $P = .28$ ) at the 1-year follow-up.

### Pain-Related Activity Interference

Interference with daily activities was relatively high at baseline for these patients due to study inclusion criteria. CC and UT groups changed differentially over time (Fig 2), with the CC group showing about a 40% decrease from baseline at post-treatment compared to about a 20% decrease for the UT group. The mean level of pain-related interference in the CC group was lower than that in the UT group; this difference approached statistical significance (mean post-treatment interference = 2.7 versus 3.9 on a 0 to 10 scale;  $P = .07$ ). Levels of pain interference continued to decrease after the post-treatment assessment for both groups. Although the CC group continued to show lower levels of interference than did the UT group 1 year after treatment, the difference was not statistically



**Fig 2** Comprehensive care versus usual treatment: Mean pain-related activity interference (scale of 0 to 10). \* $P = .07$  (ANOVA comparing groups at post-treatment and 1-year follow-up).

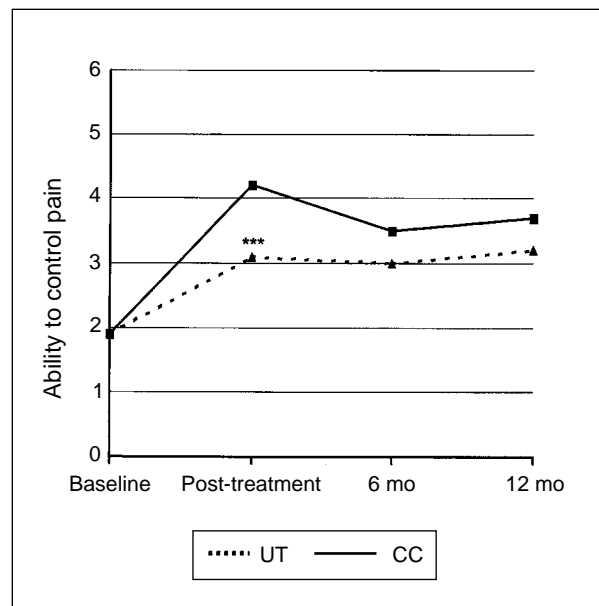
significant ( $P = .62$ ). The difference between groups was still not significant when CC subjects not attending all 6 intervention sessions were excluded (CC mean = 2.1 versus UT mean = 2.6;  $P = .39$ ).

### Ability to Control Pain

Self-reported ability to control TMD pain, measured on a scale of 0 to 6, was identically low for both groups at baseline (mean = 1.9) (Fig 3). Post-treatment, the ability to control pain had increased significantly more for the CC group (mean = 4.1) compared to the UT group (mean = 3.1;  $P < .001$ ). At the 1-year follow-up, the CC group declined slightly in perceived ability to control pain, while the UT group showed modest improvement. As a result, at the 1-year follow-up, the 2 groups did not differ significantly in self-reported ability to control TMD pain ( $P = .12$ ).

### RDC/TMD Axis I Measures

**Vertical Range of Jaw Motion.** Figure 4 summarizes findings for vertical range of mandibular motion measures. These include unassisted jaw opening with no pain, maximum unassisted opening even if accompanied by pain, and maximum

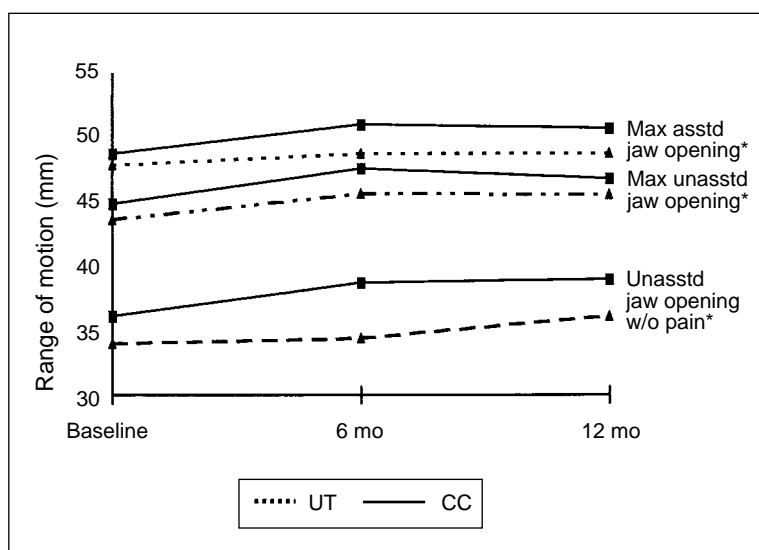


**Fig 3** Comprehensive care versus usual treatment: Mean ability to control pain (scale 0 to 6). \*\*\* $P < .001$  (ANOVA comparing groups at post-treatment and 1-year follow-up).

assisted mandibular opening. For each of these measures, no statistically significant or clinically meaningful differences were observed between patients in the 2 conditions and no meaningful trends were detected in the intervals from baseline through post-treatment and the 1-year follow-up.

**Number of Sites Painful to Palpation.** As Table 3 indicates, the number of muscle or joint sites painful to palpation did not show any statistically significant or clinically meaningful change in either group from baseline through the 1-year follow-up ( $P > .15$ ).

**Axis I Diagnoses.** At baseline, both groups showed comparable distribution of RDC/TMD Axis I diagnoses (see Table 2). While the distribution of baseline Axis I diagnoses was different from that observed at the 1-year follow-up, both groups showed comparable changes, resulting in non-significant differences between the CC and UT groups in the distribution of Axis I diagnoses at the 1-year follow-up. For example, for the most common diagnostic categories, at baseline, 94.9% of CC and 94.7% of UT patients had an RDC/TMD Axis I, Group I (muscle disorder) diagnosis; and at the 1-year follow-up, 83.0% of CC and 75.6% of UT patients had an Axis I, Group I diagnosis. Similarly, an RDC/TMD Group IIIa (arthralgia) diagnosis was present at baseline for



**Fig 4** Comprehensive care versus usual treatment: Comparison of vertical range of jaw motion (in mm) for unassisted jaw opening, no pain; maximum unassisted jaw opening; and maximum assisted jaw opening. \*All *P* values > .15 (ANOVA comparing groups at post-treatment and 1-year follow-up).

**Table 3** No. of Extraoral and Intraoral Masticatory Muscle Sites and TMJ Sites Painful to Palpation

Time/site	No. of painful palpation sites (mean and SE)		
	Comprehensive care	Usual Treatment	<i>P</i>
Baseline			
Extraoral muscles (0–16)	7.6 (0.5)	8.2 (0.6)	.48
Intraoral muscles (0–4)	3.1 (0.2)	2.8 (0.2)	.29
TMJ (0–4)	2.0 (0.2)	2.1 (0.2)	.65
One-year follow-up			
Extraoral muscles (0–16)	7.2 (0.6)	7.5 (0.8)	.76
Intraoral muscles (0–4)	2.8 (0.2)	2.7 (0.2)	.62
TMJ (0–4)	1.5 (0.2)	1.2 (0.2)	.85

56.9% of the CC group and 56.4% of the UT group, which had changed at the 1-year follow-up to 39.2% and 42.9% for CC and UT groups, respectively.

#### RDC/TMD Axis II Measures

**Depression and Somatization.** The data confirmed our expectation that elevated psychologic distress would be associated with GCP scores of II-High, III, and IV, replicating findings from other population-based and clinical studies.<sup>56,57</sup> Moreover, as can be seen in Fig 5, both the UT and CC groups

tended to remain high in age/sex-adjusted levels of depression and somatization throughout the course of the study.

**Normal, Moderate, and Severe Depression and Somatization.** We also examined the relationships between baseline levels of normal, moderate, and severe depression and somatization, as assessed by RDC/TMD Axis II criteria<sup>2</sup> and baseline and 12-month levels of characteristic pain intensity and interference. Table 4 presents baseline and 1-year follow-up characteristic pain intensity and pain interference scores for patients in the normal, moderate, and severe categories of depression scale

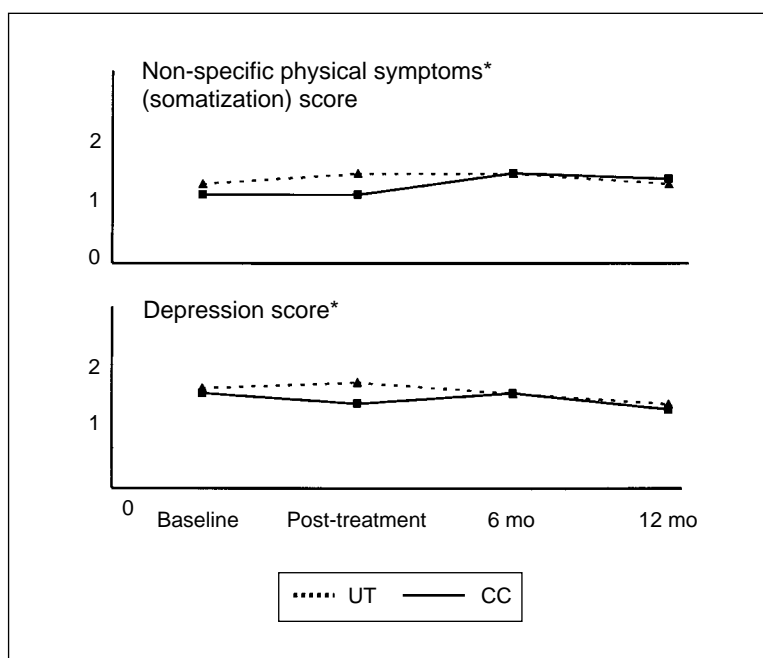


Fig 5 Comprehensive care versus usual treatment: Depression and somatization (age- and sex-adjusted SCL-90) mean scores. \*All *P* values > .22; population mean (age/sex-adjusted) = 0 (ANOVA comparing groups at post-treatment and 1-year follow-up).

**Table 4** Comparison of Normal, Moderate, and Severe Levels of Depressive Symptom Severity (Based on SCL-90 Depression Scale Score) with Characteristic Pain Intensity and Pain Interference (n = 114)

	Baseline depressive symptom severity (mean and SE)			<i>P</i> *
	Normal (27%)	Moderate (29%)	Severe (44%)	
Characteristic pain intensity				
Baseline	6.3 (0.3)	6.6 (0.3)	7.2 (0.2)	.053
One-year follow-up	3.7 (0.4)	4.2 (0.4)	4.8 (0.4)	.200
Pain interference				
Baseline	3.7 (0.3)	4.7 (0.5)	5.9 (0.3)	<.001
One-year follow-up	1.7 (0.4)	2.3 (0.4)	3.0 (0.4)	<.093

\*One-way ANOVA.

scores at baseline. Table 5 presents baseline and 1-year follow-up pain intensity and interference scores for groups of patients categorized as having normal, moderate, and severe somatization score levels at baseline. Baseline data shown in Tables 4 and 5 reveal that severe levels of both depression and somatization scale scores were common among these patients (selected initially on the basis

of pain intensity and pain-related interference), with about 44% of subjects showing severe depression scores and about 55% showing severe somatization scores at baseline. In addition, characteristic pain intensity levels at both baseline and the 1-year follow-up were significantly higher for those with severe somatization scores compared to those with normal levels, while a strong trend in

**Table 5** Comparison of Normal, Moderate, and Severe Levels of Non-Specific Physical Symptom Severity (Based on SCL-90 Somatization Scale Score) with Characteristic Pain Intensity and Pain Interference (n = 114)

	Baseline non-specific physical symptom severity (somatization) (mean and SE)			<i>P</i> *
	Normal (12%)	Moderate (33%)	Severe (55%)	
Characteristic pain intensity				
Baseline	6.3 (0.4)	6.2 (0.2)	7.2 (0.2)	.012
One-year follow-up	2.4 (0.4)	3.9 (0.3)	5.5 (0.4)	< .001
Pain interference				
Baseline	3.9 (0.6)	4.5 (0.4)	5.5 (0.3)	.025
One-year follow-up	1.0 (0.4)	2.2 (0.3)	2.9 (0.4)	.033

\*One-way ANOVA.

the same direction was shown with severe depression scores. A similar pattern was observed for TMD pain-related interference. Both at baseline and at the 1-year follow-up, the level of interference was significantly higher for those with severe depression and severe somatization scores.

We also observed that at the 1-year follow-up, approximately 44% of subjects showed severe somatization score levels, again accompanied by a relatively high mean ( $\pm$  SE) characteristic pain intensity level ( $5.5 \pm 0.4$ ). At the 1-year follow-up, about 21% showed normal somatization score levels, accompanied by a relatively low mean characteristic pain intensity score ( $2.4 \pm 0.4$ ). Comparable relationships at the 1-year follow-up were shown between heightened levels of depression and heightened characteristic pain intensity scores; pain interference scores also showed the same relationships as characteristic pain intensity to both somatization and depression at the 1-year follow-up.

### Satisfaction and Helpfulness of Treatment

Subjects rated the helpfulness of treatment in reducing pain and enhancing ability to cope with pain, as well as overall treatment satisfaction. Overall, patients in both groups reported being helped and being satisfied with their TMD treatment. At the post-treatment follow-up, the CC group rated their treatment as significantly more helpful in reducing pain, compared to the UT group (CC mean =  $7.4 \pm 0.4$  versus UT mean =  $6.2 \pm 0.4$ ;  $P = .03$ , *t* test). Also at the 1-year follow-up, the CC group showed a strong trend toward

greater overall satisfaction with treatment ( $P = .06$ ), but the 2 groups did not differ in ratings of treatment helpfulness in increasing their ability to cope with pain ( $P = .11$ ). There were no differences between groups during the treatment stage with regard to number of clinic visits or types of treatments and medications received from TMD dentists providing usual care to both groups.

### Discussion

A tailored 6-session CBT intervention in combination with the usual conservative treatment was targeted to psychosocially disabled TMD clinic patients, independent of physical diagnosis. Post-intervention, the CC treatment program was significantly more efficacious in reducing TMD pain and in increasing patient-perceived ability to control pain than was the UT for TMD. There was a strong trend toward a statistically significant advantage for the CC treatment over UT in decreasing pain-related interference with daily activities. These results confirmed hypotheses related to the initial effects of the tailored CC treatment. It was also hypothesized that significant differences in improvement between the 2 groups would be sustained over time. Patients in the CC group showed an early and rather rapid improvement associated with the duration of the CBT component, compared to the more gradual rate of improvement for patients receiving only UT. However, when the CBT component ended after 6 sessions, the CC group, while not losing any of its gains, did not sustain its initial marked rate of

improvement. As a result, fairly comparable levels in all physical, psychological, and psychosocial variables were observed for both groups at 1 year after treatment. The extent to which this overall improvement in both groups at the 1-year follow-up was due to the efficacy of usual treatment versus factors such as natural history cannot be determined from the present study. We should also note that the TMD clinical specialists evaluating both groups of patients in this study generally hold a biopsychosocial view of chronic pain and may have communicated some aspects of the cognitive-behavioral model to patients. It is thus possible that differences between the UT condition and the CC condition were decreased somewhat by virtue of both the dentists and the psychologists conveying comparable components in their respective interventions. Future research should elucidate more clearly the components of the TMD specialist-patient interaction that constitute cognitive-behavioral methods similar to those used by psychologists and as described in the present study's therapist manuals and checklists.

The present data, together with the concurrently conducted RCT targeted to well-adapting TMD patients,<sup>34</sup> lend support to the notion that psychological distress and psychosocial interference, independent of RDC/TMD Axis I clinical diagnosis, constitute a powerful set of variables that are strongly associated with long-term TMD clinical treatment outcome. In the separately reported self-care RCT we observed that well-adapting TMD patients exhibited long-term lowering of pain, interference, and even psychological disturbance to levels approximating norms for the general population,<sup>56</sup> even though self-care, rather than professionally delivered care, was the major treatment intervention. By contrast, in the present study, although pain and interference levels decreased for patients in both arms of the RCT, at the end of 1 year the pain levels were still high, and psychological disturbance—depression and somatization—was still at severe levels for a significant proportion of patients. One possible interpretation of the patterns observed in the present study is that the profoundly psychosocially disabled patients exposed to the CC intervention initially responded positively, but then, in the absence of the supportive biobehavioral intervention, returned to functioning in a manner comparable to that exhibited by patients in the UT group. Again, although these patients, initially targeted for their psychosocial disability, did improve as a group from baseline to post-treatment and over the 1-year follow-up period, pain and interference levels and the ability

to control pain remained unchanged for the subgroup. In other words, both for patients who received usual care only and for patients who received usual care plus CBT, there were some patients who failed to respond, although on average there was improvement at the 1-year follow-up. For example, at baseline, about half the patients showed severe levels of depression and somatization; improvement was seen only for some at the end of the follow-up year. Moreover, those with high somatization scores at the 1-year follow-up also showed high levels of pain and interference at the 1-year follow-up. The same pattern followed with regard to depression, but the findings were not so robust as for somatization. Taken together, these findings support the speculation that somatization—the tendency to report multiple non-specific physical symptoms—is associated with failure of patients with chronic pain conditions such as TMD to respond to brief interventions or usual treatment and/or to sustain the effects of either usual treatment or the type of brief interventions we introduced. Perhaps heightened somatization (and perhaps depression as well) indicates a level of perturbation in the body that constitutes an obstacle to easy resolution of persistent symptom states such as TMD and other chronic pain conditions.

The present data regarding distribution of severe depression and somatization are consistent with the TMD literature, which contains numerous reports documenting the prevalence and distribution of significant psychopathology and psychosocial disability in all chronic pain populations, including TMD clinic cases.<sup>10–14,58</sup> Underreported, however, are accounts of how severely impacted the lives of TMD patients, such as those included in the present RCT, can be as a result of psychological disturbance or psychosocial disability. Patients in the present study included a 60-year-old woman who was divorced from an alcoholic and abusive husband, lived alone, had just experienced the death of a young adult son from AIDS, and was coping with resolving the estrangement of a daughter recently diagnosed as HIV-positive; a mother of 2 young children whose husband had recently been re-imprisoned after violating parole for prior criminal convictions; a patient confronted with the requirement for psychiatric hospitalization due to suicidal tendencies associated with severe depression; and a nurse practitioner no longer able to practice her profession due to multiple somatic symptoms, most not associated with confirmable medical diagnoses, who abused narcotic pain medications obtained by presenting lim-

ited versions of her somatic complaints to multiple health care providers who, in turn, attempted to provide relief by narcotic prescriptions. In our experience, these individuals do not represent isolated cases. Instead, they are typical of an appreciable segment of the TMD clinical population—burdened with major depression, social isolation, and numerous physical symptoms, their extensive treatment-seeking results in only intermittent or partial success, despite multiple treatments over periods of years and even decades.

We offer these clinical anecdotes as supplements to the present account of a carefully executed RCT to support the contention that, in the context of major psychologic and psychosocial dysfunction, presently available treatments that focus on only 1 segment of the patient's multiple and interconnected problems may not succeed, or may not succeed for very long. Such patients are prone to seek care repeatedly, without being able to experience appreciable reductions in intensity or duration of symptoms. Again, without imputing or denying causality, it may be that the co-existence of heightened psychologic and psychosocial turmoil, in perhaps as many as one-third to one-half of specialty referral TMD patients,<sup>11,14</sup> mitigates against all but modest resolution of physical factors that generate the signs and symptoms of TMD. It seems reasonable to suggest that both the brief CBT intervention and the usual care provided by expert clinicians were inadequate for a subgroup of these patients—perhaps inadequate, specifically, in allowing the body to re-establish and then maintain a more quiescent state. Our accumulated experience cautions us to conclude that, while physical treatments directed at reducing observable pathophysiology are certainly indicated, brief CBT programs of the type used in the present study are likely to have limited long-term efficacy due to their time-constrained inability to direct sufficient attention to the emotional and psychosocial adaptation of TMD patients. These issues include, as others have noted, childhood neglect and abuse,<sup>59,60</sup> current interpersonal and socioeconomic stressors, and psychologic disturbance such as anxiety, depression, and somatization. Longer-term CBT and other empirically supported psychotherapies used in many chronic pain clinics are more likely to have better opportunity to address the complexities of chronic pain, psychosocial interference, anxiety, depression, and somatization when they are manifest in the same individual.

Thus, the present data may shed light on the nature of TMD as a chronic pain condition resistant to long-term beneficial effects of treatment for

many sufferers. It is a well-known and paradoxical clinical fact of life, alluded to earlier, that although many TMD treatments are reported as highly successful, many patients repeatedly seek treatment despite exposure to such initially “successful” treatments. It seems fair to conclude from studies examining predictors of TMD treatment response that there are few such predictors in the domain of clinical signs and symptoms (ie, Axis I). The clinical parameters of TMD (including range of mandibular motion, muscles painful to palpation, and TMJ sounds), which are critical to the diagnosis of muscle, disc, or TMJ subtypes of TMD, have not been identified as dependable predictors of either treatment outcome or outcome over time independent of treatment.<sup>61</sup> Ohrbach and Dworkin<sup>62</sup> have reported that clinical course seems largely independent of amount of treatment received and that physical factors commonly associated with TMD seem unrelated to long-term TMD outcome. By contrast, several studies have pointed to psychologic and psychosocial parameters as predictors of outcome.<sup>63–65</sup> McCreary and colleagues,<sup>21</sup> for example, have concluded that somatization constitutes a predictor of poor TMD treatment outcome. Of course, the relationships observed between psychologic factors and TMD outcomes imply a critical need to better understand the temporal relationships of which came first: the onset of a chronic pain condition, which represents a risk factor for subsequent psychosocial disturbance, or the onset of psychologic or psychosocial disturbance, which serves as a risk factor for the subsequent onset of a chronic pain condition. It is also quite possible that for some patients, the onset of psychologic and TMD pain problems occurs simultaneously, or, alternatively, that psychologic disturbance may precede TMD onset, but then increase after TMD onset. The present RCT was not designed to shed light on this critical issue.

Without losing sight of the significance of the post-treatment efficacy of the CC program, the failure to observe significant differences between the CC and UT groups at the 1-year follow-up in the present study may reflect on an important aspect of our overall research approach. Consistent with a long-term program of research examining the possibilities of brief interventions for TMD, we utilized only a 6-session CBT intervention in the present study. The early steeper rate of improvement for those patients in the CC program tracked the length of the CBT component of the program; once the psychologically based component of chronic pain treatment ended, the

longer-term trajectory for the CC group was about the same as that for the UT group. This and the other RCT<sup>34</sup> that we conducted in tandem reinforce the dual conclusions that 6 CBT sessions, even when integrated into usual treatment for TMD, are not enough for psychosocially disabled patients, whereas 6 sessions of self-care or perhaps any other form of treatment might even be more than is required for most of those comprising the better-adapting segment of the TMD clinic population. Most CBT programs for chronic pain delivered in clinical settings range from 12 to 24 sessions.<sup>22</sup> We now believe that we underestimated the duration of an effective course of CBT for chronic TMD pain patients selected on the basis of high levels of pain and psychosocial disability.

A limitation of this study is the lack of an experimental condition to control for non-specific effects of the CBT intervention, such as attention and concern from the psychologist. The study design does not allow conclusions concerning the relative role of such effects versus effects of the cognitive and behavioral components of the CBT program. This was not the goal of the present study, which focused on evaluating the efficacy of the CBT program as it might be generalized to application in clinical settings, rather than on identifying active or necessary and sufficient ingredients. However, attention to this issue in the design of future trials of CBT is recommended.

It is important to conclude by emphasizing that the views offered concerning the role of non-physical parameters in chronic pain also allow for physical factors to play a critical role in shaping TMD outcomes. Similarly (and this point warrants emphasis in the lingering climate of controversy among some non-evidence-based clinical schools of thought regarding the diagnosis and management of TMD), the view that psychologic and psychosocial factors are critical influences on TMD outcomes is not equivalent to saying that psychologic distress or psychosocial disability is the cause of TMD—to maintain the latter would be a direct misinterpretation of the views being stated here. Rather, as conventional wisdom and current understandings of health and illness confirm, restoration and maintenance of health and well-being can be profoundly negatively influenced by untreated psychologic distress, such as debilitating anxiety, depression, or post-traumatic stress disorder,<sup>66,67</sup> or by powerful psychosocial factors, such as childhood neglect or physical and sexual abuse<sup>59,60</sup> or substance abuse.<sup>66</sup> It seems entirely reasonable to suggest that such potent forces can mitigate against effective relief from a chronic pain

condition, independent of whatever etiologic factors—physical, genetic, developmental, infectious, malignant, traumatic, and even psychologic—may have originally given rise to the condition or may continue to contribute to its chronicity and periodic exacerbation.

The dynamic, ecologic model for chronic pain,<sup>68</sup> adapted to guide understanding of the etiology, maintenance, and management of TMD and all chronic pain and illness conditions,<sup>42</sup> maintains that in our complex world and in our complex bodies, chronic pain conditions represent the current resolution of biologic (physical) factors imbedded in a matrix of psychologic and psychosocial factors that yield an expression of chronic pain that is unique and specific to each person. No single factor alone is likely to account for individual expression of disease or illness; nor will single factors considered in isolation contribute much to our understanding of how clinicians evolve treatment decisions or how patients evolve long-term responses to treatment of chronic pain conditions such as TMD.

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7.4.3.2. Conventional-Risk Patients . . .e95.Â The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient. Thus, there are situations in which deviations from these guidelines may be appropriate.Â comprehensive review of the literature relevant to carotid and vertebral artery interventions through May 2010. The recommendations listed in this document are, when-ever possible, evidence-based. STUDY DESIGN: A prospective, randomized trial of 169 women was conducted. Baseline evaluation occurred at 24-28 weeksâ€™ gestation, with follow-up at 33 weeksâ€™ gestation. Primary outcomes were the Numerical Rating Scale (NRS) for pain and the Quebec Disability Questionnaire (QDQ).Â The group that received standard obstetric care demonstrated no significant improvements. CONCLUSION: A multimodal approach to low back and pelvic pain in mid pregnancy benefits patients more than standard obstetric care. Key words: back pain, exercise, manipulation, pregnancy. Cite this article as: George JW, Skaggs CD, Thompson PA, et al. A randomized controlled trial comparing a multimodal intervention and standard obstetrics care for low back and pelvic pain in pregnancy. 212 No randomized clinical trial has been published yet exploring adjuvant therapies; no studies 213 comparing quality of life after different treatment modalities were found. We included six 214 studies that assessed the effect of mitotane on recurrence and mortality (36, 58, 90-93). See 215 Appendix 4 for details and Appendix 5 for risk of bias assessment. Platelet Concentrate Treatments for Temporomandibular Disorders: A Systematic Review and Meta-analysis. JDR Clin Trans Res. May 28 2020: 2380084420927326. PMID 32464073. 30. Sousa BM, Lopez-Valverde N, Lopez-Valverde A, et al. Different Treatments in Patients with Temporomandibular Joint Disorders: A Comparative Randomized Study.Â Use of sodium hyaluronate in treating temporomandibular joint disorders: a randomized, double-blind, placebo-controlled clinical trial. J Oral Maxillofac Surg. Mar 1993; 51(3): 232-42. PMID 8445463. 36. Vos LM, Huddleston Slater JJ, Stegenga B. Lavage therapy versus nonsurgical therapy for the treatment of arthralgia of the temporomandibular joint: a systematic review of randomized controlled trials.