A Randomized Clinical Trial Using Research Diagnostic Criteria for Temporomandibular Disorders-Axis II to Target Clinic Cases for a Tailored Self-Care TMD Treatment Program

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Aims: *To carry out a randomized clinical trial (RCT) contrasting usual conservative treatment of TMD by clinical TMD specialists with a structured self-care intervention, targeted to clinic cases independent of TMD physical diagnosis, who were reporting minimal levels of psychosocial dysfunction; the intervention was delivered by dental hygienists in lieu of usual treatment.* ***Methods:*** *The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) was used to target subjects who exhibited minimal TMD-related psychosocial interference. Criteria for study inclusion were: (1) self-report of facial and/or masticatory muscle pain discomfort for which usual care was prescribed by the clinic TMD specialist; (2) RDC/TMD Axis II graded scale of chronic pain (GCP) score of 0, I, or II-Low. (3) Age 18 to 70 years.* ***Results:*** *On 1-year follow-up, while both groups showed improvement in all clinical and self-report categories measured, patients in the tailored self-care treatment program compared to usual TMD treatment showed significantly: (a) decreased TMD pain, (b) decreased pain-related interference in activity; (c) reduced number of masticatory muscles painful; (d) fewer additional visits for TMD treatment. Groups were comparable with regard to measures of vertical range of motion. The self-care program was associated with consistent, but non-statistically significant, trends towards lower levels of depression and somatization. Ability to cope with TMD, knowledge concerning TMD and patient satisfaction was significantly enhanced for the self-care group. No participating patients experienced physical or personal adverse effects during the 1-year post-treatment follow-up period.* ***Conclusion:*** *Use of RDC/TMD psychosocial assessment criteria can contribute to successful clinical decision-making for the management of TMD.*

J OROFAC PAIN 2002;16:48–63.

Key words: Research Diagnostic Criteria for TMD, self-care, pain

Temporomandibular disorders (TMD) encompass a range of commonly occurring[1,2] orofacial conditions that compromise the comfort and healthy functioning of the hard and soft tissues of the masticatory system. The prime manifestations of these disorders are described as: (1) pain of a persistent, recurring, or chronic nature in the masticatory muscles and/or the temporomandibular joint (TMJ) as well as, less frequently, in adjacent structures; (2) limitations or other alterations in range of mandibular motion, often accompanied by pain; (3) TMJ clicking and/or crepitus sounds produced during mandibular function. Despite an extensive scientific literature extending over several decades, the etiology of the most common forms of TMD remains largely unknown and diagnosis is made largely in descriptive fashion on the basis of pre-

senting signs and symptoms. The TMD pain is frequently accompanied by psychological distress—notably depression and somatization, and can be associated as well with psychosocial disability, including pain-related interference with usual work, home, and interpersonal activities and extensive use of health care services.[3–8]

Pain is unquestionably the most common presenting symptom and, overwhelmingly, the most frequent reason for seeking TMD treatment. TMD pain relief is the primary therapeutic objective for the very wide range of available treatments.[9–11] The available treatments for TMD extend from anti-inflammatory, analgesic, and antidepressant medications, intra-oral occlusal appliances, physiotherapy, occlusal equilibration and reconstruction, TMJ surgery and arthroscopy, to include biobehavioral treatments such as biofeedback, hypnosis, cognitive-behavioral therapy (CBT), and education. While the physically based therapies are dentist-based interventions to modify bodily structures or putative pathophysiologic processes, the biobehavioral treatments rely more heavily on self management, or synonymously, self-care approaches, to relieve the painful symptoms of TMD, restore healthy patterns of jaw use, and modify maladaptive responses to stressors and to the disabling sequelae of both psychological distress and psychosocial disability.[12–14] Despite reported success rates of 80% and higher for many of these TMD treatments, especially the physically based treatments, many TMD patients seek repeated bouts of treatment, often over the course of many years. Additionally, in the extensive TMD literature, there are only a few randomized clinical trials (RCTs) that include adequate follow-up of the efficacy of TMD treatments.[15] As a result, it has proven difficult to disentangle changes in signs and symptoms attributed to treatment effects from spontaneous changes in symptoms associated with the well-documented fluctuating and recurrent course of TMD or from changes associated with such statistical artifacts as regression to the mean.[16] Based on findings from several long-term epidemiologic and clinical case studies, TMD seems best characterized as self-limiting or nonprogressive with regard to the physical disease aspects of the condition(s); additionally, the long-term fluctuating course of TMD signs and symptoms seems to be independent of extent of treatment sought over a 5-year period.[17] For example, well-designed RCTs with adequate (eg, 1-year) follow-up indicate that one of the fairly standard components of a conservative treatment approach, intra-oral flat-plane occlusal appliances fabricated under dentist supervision, are not more efficacious in improving TMD signs and symptoms than placebo controls[18,19] or to "store-bought," largely patient-fabricated appliances, or to no intra-oral appliance at all.[20] It seems fair to say that, for the most part, no over-arching evidence-based rationale for selecting among TMD treatments has emerged, although reversible, noninvasive treatments are generally advocated and have been recommended[21] as the most appropriate initial form of TMD treatment.

Research Diagnostic Criteria for Temporomandibular Disorders

The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) uses a dual axis system for diagnosing and classifying TMD patients.[22] Axis I assigns physical diagnoses of the most commonly occurring masticatory muscle and/or TMJ disorders. Three major physical diagnostic groups are included: Group I, Muscle Disorders; Group II, TMJ Disc Displacements; and Group III, Arthralgia, Arthritis, and Arthroses of the TMJ. Axis II is used to assess behavioral, psychological, and psychosocial factors acknowledged to be relevant to management of the TMD patient: *(1)* pain status variables, including average, current, and worst pain intensity; *(2)* functional mandibular limitations; *(3)* psychological distress, based on SCL-90 subscales,[23] specifically, depression and endorsement of nonspecific physical symptoms suggesting somatization tendencies; and (4) graded scale of chronic pain (GCP),[24,25] which integrates pain intensity and interference into a single 0–IV hierarchical scale to categorize level of pain severity. The RDC/TMD criteria for both Axes I and II have been used in numerous clinical research studies to characterize physical, psychological, and psychosocial factors associated with TMD as well as the relationship among these factors,[17,22,26–28] and the RDC/TMD has been suggested as a model system for the diagnosis and assessment of all chronic pain conditions.[28]

The present RCT is the use of the RDC/TMD Axis II GCP scale to identify psychosocially functional TMD patients, independent of their RDC/TMD Axis I diagnosis. Data relevant to the reliability and validity of GCP have been published.[25,29] Grade 0 identifies patients who do not report TMD pain but who may report symptoms of discomfort, such as jaw stiffness or troublesome TMJ clicking sounds. Grade I identifies patients reporting low pain intensity and low levels of TMD-pain related interference in usual psychosocial activities; Grade II identifies patients reporting

moderate-high levels of pain intensity (≥5 on a 0–10 scale) but low levels of pain-related activity interference. Patients characterized as Grade III (moderate interference) and Grade IV (high interference) show incrementally higher levels of psychosocial interference typically reflected as increased use of both health care and prescription medications.[30] In previous studies,[7,31,32] it was found useful to characterize TMD patients with GCP scores in the I–II range as "psychosocially functional." These patients typically showed minimal psychological distress and pain-related interference in the personal, social, and work domains of their lives.

Minimal or Brief Cognitive-Behavioral/ Educational Self-Care Interventions. Structured, manual-based brief educational interventions have been shown efficacious for enhancing self-management and self-care of the most common chronic pain conditions—namely, back pain, headache, and TMD.[33–36] Minimal intervention or minimal therapy[33,37] may increase the feasibility of adapting cognitive-behavioral concepts to interventions tailored for psychosocially functional TMD patients.[38,39] Minimal interventions of this type have been delivered by nurses, social workers, and other nonphysician/dentist health care providers; they emphasize use of information and educational methodology in the form of self-care materials and skills training coupled with brief professional guidance at critical points, and low-cost methods for patient follow-up, such as brief telephone counseling. In an RCT, Mishra et al[40] demonstrated that TMD patients randomly assigned to biofeedback, cognitive-behavioral skills training, and a combination of the two were comparably effective in reducing reported TMD pain and mood compared to a no-treatment group which did not show pain reduction.

In a prior study[36] that influenced the approach taken with the current study, a group approach was used wherein all TMD patients willing to participate in an RCT designed to test the efficacy of a brief, 2-session cognitive-behavioral educational intervention introduced before usual clinical care for TMD began.[38] The group intervention was psychologist-led with a dentist providing basic TMD-related clinical information as part of 1 session. The approach taken emphasized a self-care approach to the management of TMD. To provide a basis for self-care, groups were exposed to information delivered by a psychologist and a dentist about the etiology and maintenance of TMD and the varieties of TMD treatments available. Brief skills-acquisition training was provided for relaxation, monitoring of jaw function, and physical therapy as prescribed by the attending TMD dentist-specialist, as well as an introduction to stress management. Most importantly, the brief intervention emphasized self-management through the development of a structured and formal "personal plan" self-tailored to each patient's clinical problem and to their preferred means for executing the self-care methods presented. At 1-year follow-up, compared to TMD patients randomly assigned to receive only usual clinical care by TMD specialists, statistically significant, albeit modest, reductions in both TMD-related pain levels and in levels of pain-related interference with usual activities was observed; in addition, exploratory analyses indicated that through the 1-year follow-up, reductions in pain and interference were observed for psychosocially functional TMD patients (defined as GCP scores of I and II) but not those with significant psychosocial disability (GCP scores III and IV). Although the studies reviewed have in common the use of CBT-based methods and self-care concepts, these studies did not utilize treatments tailored to the TMD patient's level of psychosocial functioning. Evidence is currently available indicating that such tailoring of treatment according to psychosocial criteria may be an effective therapeutic strategy.[38,39,41]

Study Hypotheses. The present report deals with results from a RCT designed to test the efficacy of a biobehavioral intervention that contrasts usual conservative treatment of TMD by TMD specialist dentists with a structured psycho-educational intervention delivered by dental hygienists in lieu of usual treatment. The conceptual basis for this research is provided by a biopsychosocial model of chronic pain.[42] The model suggests that if biologic, psychologic, and psychosocial factors interact to influence the expression of pain, then interventions targeted to *any* of these factors may modify the expression of pain and dysfunction. The utility of the RDC/TMD Axis II GCP assessment for targeting TMD patients able to maintain reasonable levels of psychosocial functioning despite their persistent pain problem was explored. The hypothesis was put forth that, independent of RDC/TMD Axis I diagnosis, a brief, structured educational self-care intervention tailored to patients identified as having low levels of pain-related activity interference could be delivered, on an individualized basis, by registered dental hygienists in lieu of usual conservative TMD treatment. Furthermore, when compared with usual TMD treatment, the self-care intervention would result in enduring reductions in the major outcome variables under

study—namely, reductions in reported TMD pain and pain-related interference as well as satisfactory mandibular function, with good patient acceptance and minimal to adverse effects.

Methods

Subjects

Study participants were recruited from patients referred for treatment to the Orofacial Pain Clinics in the Department of Oral Medicine, University of Washington School of Dentistry (UW) 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, the region in front of the ear or inside the ear, or report of stiffness or other symptoms of discomfort in the same orofacial region for which usual care was prescribed by the clinic TMD specialist; *(2)* RDC/TMD Axis II GCP score of 0, I or II-Low (defined below); *(3)* age 18 to 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; or presence of significant or debilitating chronic physical or mental illness; and *(3)* necessity for emergency TMD treatment. All participants were recruited into the study after the attending TMD clinic specialist determined eligibility. All study participants provided signed, informed consent in accordance with the National Institutes of Health and University of Washington standards for protection of human research patients.

Of the 196 patients who met study eligibility criteria, 124 (63%) agreed to participate and were assigned randomly to the self-care intervention (SC, n = 61) or to the usual TMD treatment condition (UT, n = 63). A sample size of at least 56 patients per group at the 12-month follow-up was required to detect a 40% detection in characteristic pain intensity at 6- and 12-month follow-ups in the SC group as compared to the UT group with at least 80% power based on a MANOVA at a 0.05 significance level. Interview and clinical examination data were collected at baseline (pretreatment), postintervention (approximately 2.5 months post-baseline, on average), and at 6- and 12-month postintervention follow-ups. Of those randomized, 12-month follow-up data were available for 90% of SC and 97% of UT patients.

Study Measures

Table 1 summarizes the RDC/TMD Axis I clinical physical measures and the Axis II self-report measures gathered in this study. The GCP scores shown in Tables 1 and 2 are defined as follows: Grade 0 indicates no current TMD pain, although other signs and symptoms may be present, such as muscle stiffness, TMJ sounds, limitations in mandibular opening, etc; Grade I indicates low levels of TMD pain of less than 5 on a 0–10 scale, together with zero pain disability points as measured by the GCP, indicating minimal levels of psychosocial interference due to TMD; although measures of psychological status (eg, depression and somatization) do not enter into the assessment of GCP, empirically, Grade I patients show relatively low levels of psychological disturbance. Grade II was divided into low and high groups. Grade II-Low is characterized by orofacial pain rated as 5 or higher on a 0–10 GCP, and as with Grade I patients, zero disability points; levels of psychological disturbance may be low or moderately elevated. Grade II-High is characterized by the same level of pain (characteristic pain > 5) as Group II-Low but with low (ie, < 3) disability points; subjects qualifying as Grade II-High, Grade III, and Grade IV were assigned to an alternative RCT conducted concurrently, and to be reported separately. Table 1 includes additional non-RDC/TMD data gathered that were related to demographics, history, and levels of psychological or psychosocial functioning. Measures of compliance included a measure of health care utilization for TMD pain during and after the treatment intervention. Finally, the study measured changes in knowledge about TMD and its management as well as patient satisfaction. All measures were gathered at baseline, posttreatment, 6- and 12-month follow-up except where otherwise indicated.

Procedures

All patients were evaluated by the attending dentist at baseline with a complete physical examination and history questionnaire, which included, but was not limited to, the RDC/TMD Axis I and II measures. Attending dentists noted TMD treatments prescribed for each patient on a Treatment

Table 1 Study Measures

Variable	Brief description
RDC/TMD measures [24]	
Axis I: physical examination measures	Range of vertical mandibular motion, number of extra- and intraoral masticatory muscles painful to palpation
Axis II measures	
Characteristic pain intensity	The average of 0–10 ratings of: 1, pain right now; 2, worst pain; and 3, usual pain
Pain interference score	Average of 0–10 ratings of pain-related interference with work, social, and overall activities
Pain-related disability days	Disability days in the prior 6 months
Chronic pain grade	Composite of 1, 2, 3 above
SCL-90-R scales: Mean and age-sex adjusted scores [25]	Scale scores for depression and number of non-specific physical symptoms. Population mean = 0.
Self-report measures, non-RDC/TMD	
Days in pain	Days in pain was present in prior 6 months
Number of pain sites	Number of co-occurring pain problems
Pain-related visits	(Baseline, posttreatment and 12-month follow-up, only) Documented UW clinic visits for TMD pain and self-reported visits to any health care provider for TMD pain
Process of care ratings	(Posttreatment and 12-month follow-up, only) 0–10 scales to assess global satisfaction; compliance, participation and visit content
Coping and perceived control	(Baseline, 12-month follow-up) Pain beliefs, coping and behaviors scale 0–5 rating scales of ability to control pain
Demographics	(Baseline, only) Age, gender, marital status, race, level of education attained, employment and insurance/litigation status

Table 2 Patient Baseline Characteristic Adjusted for Level of Education

	Self-care (n = 61)		Usual treatment (n = 63)		
	Mean/*Median**	SE/*IQR**	Mean/*Median*	SE/*IQR**	*P*
Demographics					
Age, years	37.4	4.2	38.0	3.6	.75
% Female	88.5%		81%		.32
Education level (% > high school)†	91.8%		66.7%		.00
Income (% > $50,000/annually)	49.2%		42.6%		.98
Characteristic pain intensity	4.4	0.3	4.4	0.3	.92
Pain interference score	1.21	0.25	0.91	0.1	.25
Axis I measures					
Unassisted opening, no pain (mm)	41.5	1.4	42.4	1.4	.64
Unassisted open, pain (mm)	49.6	1.1	50.6	1.0	.48
Maximum assisted open (mm)	52.3	0.9	53.0	1.0	.61
# Painful extraoral muscles* *(median, IQR)*	*/3.5*	*/1.0–6.0*	*/3.0*	*/2.0–6.0*	.8
Axis II measures‡[23]					
Depression	0.45	0.20	0.20	0.20	.40
Somatization	0.45	0.20	0.35	0.20	.63
Graded chronic pain scores					
Grade 0	8%		4%		0.30
Grade 1	57%		48%		
Grade 2 – Low	35%		48%		
Grade 2 – High, 3 or Grade 4	0%		0%		

* IQR: Interquartile Range = 25th – 75th percentiles. †Unadjusted values.

‡ Age-sex scores [23]; population mean = 0; depression scores: < 0.5 = normal; somatization scores: < 0.428 = normal; 0.48 > score < 0.857 = moderate.

Checklist form at the conclusion of their initial (ie, baseline) examination. Patients randomized to the UT group continued to receive prescribed conservative treatments from 1 of 6 UW Orofacial Pain Clinic specialists while patients assigned to the SC group saw 1 of 2 registered dental hygienists for 3 visits and 2 telephone calls between visits over a 2.5-month period. Data are reported from study visits which included questionnaire administration and an RDC/TMD examination, conducted at baseline, posttreatment, approximately 3 months from the initial clinic visit, and at 12 months after the posttreatment evaluation. All patients who dropped out from the study prior to completion of the 12-month follow-up were asked to complete the study questionnaire inquiring into the status of their pain and jaw function, in order to allow intent to treat analyses of all patients.[43–45] Patients incurred no treatment charges associated with the study intervention and were reimbursed up to $150 for completing the study measures.

Usual Treatment (UT Group). Patients randomized to the UT group received customary TMD treatment typically described as conservative because the treatment approach emphasizes noninvasive and reversible physical medicine treatments together with medications. The 6 attending dentists participating in this RCT based their usual treatment on the initial TMD treatment prescription list, and indicated the treatments to be provided for management of the patient's presenting TMD condition. The treatments prescribed in this RCT at the discretion of the attending dentist typically included:

1. *Physiotherapy*—including passive and active jaw range of motion and stretching exercises and application of heat or cold packs
2. *Patient education*—concerning parafunctional oral behaviors, diet, nature of the condition, and rationale for treatment
3. *Medications*—including analgesics, muscle relaxants, and 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

Components of the dentist-prescribed usual treatment typically included behavioral self-care requirements—eg, reduction of bruxism, soft food diet, jaw exercises, etc. Those aspects of the dentist-prescribed treatment that implicated self-care behaviors on the part of the patient were recorded on a Patient Instruction Checklist and given to each patient at the end of their initial clinical examination and evaluation appointment. A carbon copy was retained in the clinic chart; for SC patients an additional copy was provided to the appropriate hygienist. 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 a DDS treatment prescription checklist at each clinic visit.

Self-Care (SC) Group. A manual-based individual 3-session intervention emphasizing education and self-care for TMD and incorporating cognitive-behavioral methods was delivered by 1 of the 2 dental hygienists, in lieu of dentist-delivered usual TMD care. One hygienist was experienced in conducting research with TMD patients but not in the biobehavioral domain; the second hygienist had no prior experience with delivering interventions of any type in a RCT. Although both hygienists were experienced as clinicians and survey interviewers, neither had any prior formal training in the management of TMD. The first session was 75 minutes long, followed by a second session 2 weeks later, lasting 50–60 minutes with an intermediate 10-minute telephone contact; telephone contact was made 2 weeks after the second session; the third (final) session of 50–60 minutes duration occurred 1 month after the second session. SC patients were informed they were free to make a clinic appointment to see their TMD clinic specialist at any time during the course of the intervention or follow-up, if they so desired. The major components of the SC group emphasized education delivered in brief mini-seminar fashion, together with skills training provided by demonstration, between-session exercises, and structured feedback during sessions and telephone contacts, including the following elements:

- *Education* about the biopsychosocial model of TMD, chronic pain, the multifaceted aspects of TMD etiology, management methods, and the rationale for self-management.
- *Guided reading with structured feedback,* using patient completed forms to explore the patient's understanding of and identification with major themes such as rationale for breathing and relaxation methods, knowledge about TMD, communicating with health care providers, emotions, and bodily changes.
- *Relaxation and stress management training,* including training in abdominal breathing, gen-

eral muscle relaxation methods, and specific methods for relaxation of head, neck, and masticatory muscles. An initial introduction was also provided concerning the role of stress and negative psychological states as potential factors in exacerbating or maintaining painful TMD symptoms; methods for detecting and managing stress were briefly engaged.

- *Self-monitoring of signs and symptoms,* providing patients with the ability to detect changes in their physical status in order to reinforce positive self-care behaviors and to call attention to negative factors that might be modified through self-care methods (eg, detecting effects of parafunctional oral behaviors).
- *Development of a "Personal TMD Self-Care Plan,"* a central component of the self-care intervention, which allowed the patient, with guidance and assistance from the hygienist, to develop a regular schedule of individually tailored coping behaviors to correct and/or ameliorate specific physical, psychological, or emotional factors that could exacerbate or maintain TMD symptoms (eg, specifying times when relaxation, jaw stretching exercises, or monitoring of symptoms would be performed).
- *Supervised practice and reinforcement of dentist prescribed self-care treatments,* eg, observing patient performance of prescribed exercises during regularly scheduled self-care sessions and providing feedback and positive support; using follow-up telephone contacts to elicit changes in symptomatology and compliance with regimens prescribed.
- *Maintenance and relapse prevention,* to foster recognition of obstacles to maintaining the self-care Personal Plan and to introduce self-initiated corrective behaviors to overcome or reduce such obstacles.

Two manuals were developed: One was for the hygienists' use, to guide their conduct during each session and the intervening telephone contacts. The hygienist's manual allowed standardized methods to be applied to all patients and contained all the necessary hygienist "scripted" materials, readings and reading feedback forms, exercises, symptom monitoring forms, and personal care plans. A patient manual, called *A Patient's Guide to Self Care for TMD,* was given to each patient and contained patient education and reading materials and blank forms.

A central feature of the approach taken by the hygienist in delivering the self-care intervention was to carefully structure and integrate the self-care aspects of treatment prescribed by the attending dentist into the interaction with patients. A copy of the dentist-prepared Patient Instruction Checklist was also incorporated into the hygienist's manual to allow reinforcement of the specific self-care treatments prescribed by the attending dentist.

Special Precautions for Detecting and Managing Adverse Effects. Prior to the onset of the RCT, all attending clinic TMD specialists agreed upon a set of questions and clinical probes that hygienists were to use routinely in order to detect any clinical relapse or other change in the patient's TMD condition which required the attention of the dentist. These "red flags" were incorporated into the hygienist's manuals for ready reference at each self-care session and telephone contact. Commencing with the onset of the RCT, each visit with the dental hygienist began with a review of "red flags" to determine if there was any degradation in symptoms that warranted clinical attention as defined, a priori, by the attending clinic TMD specialists. Any symptoms or clinical findings qualifying as a possible adverse effect were to be immediately reported to the attending dentist. Over the course of the study this precautionary procedure was in fact almost never required; in no case was it necessary to consider removing any patient from the RCT protocol due to any adverse effect arising in the interval when SC patients were not under the regular care of a dentist.

Training of Hygienists to Deliver the SC Group Intervention. Registered dental hygienists are well recognized for their role as educators of dental patients.[46,47] A significant portion of the training curriculum for dental hygienists is devoted to enhancing their effectiveness as educators and skills trainers.[46] Their educational role relates largely to better informing dental patients concerning the nature of the most common dental and oral diseases, including caries, periodontal disease, and oral malignancy.[48,49] As patient educators and trainers, they are expected to serve as change agents, providing dental patients both the motivational basis for changing toward healthy and preventive oral health behaviors and then delivering effective skills training to accomplish those prevention and health behaviors.[48] The present RCT capitalizes on the extensive training and experience of hygienists in clinical settings as behavior change agents and sought to extend their role as patient educators to the clinical problem of TMD. Eight total hours of instruction were provided to the hygienists by the team of study authors. Topics covered included TMD etiology, pathophysiology,

and clinical management, as well as delivery of educational materials and behavioral skills training.

The study hygienists delivered all their educational and training services to study patients under the direct supervision of licensed dentists; in no instance did hygienists create clinical diagnoses or institute any treatment strategy with regard to educating study patients or training them in behavioral changes that were not specifically recommended by an attending dentist. Formal notes were entered in each patient's clinical chart by the hygienist to keep attending dentists apprised of patient status.

Results

Comparison of Groups: Baseline and Demographic Data

As is commonly reported in TMD clinical studies, 85% of patients were female. They had a mean age of 37.5 years (SE = 1.09). There were no statistically significant differences between SC and UT groups at baseline in age, gender, ethnicity, pain intensity, pain duration, RDC/TMD Axis I clinical physical variables, and Axis II measures. However, the SC and UT groups did differ significantly ($P < .001$) in highest level of education attained, with 91.8% of SC compared to 67.7% of UT reporting post-high school education. Therefore the baseline comparisons between the SC and UT groups, adjusted for education level, were repeated. The results of these adjusted baseline analyses are summarized in Table 2.

Comparison of Non-Participants and Study Dropouts with Study Completers

Of 196 eligible patients, 63.3% agreed to enroll in the RCT. Of those who declined, about 40% gave time, distance, and related considerations as the basis for their refusal, while about 15% declined to participate in any clinical research. Patients either refusing participation or dropping out after the study began were asked to provide at least minimal data about pain and pain-related interference. All analyses present results for patients for whom data are available although there are small differences in numbers of patients across some analyses. Of those who were randomized to the SC group and began the RCT, 5 patients dropped out of the intervention: Two attended only the first session and 3 patients attended only the first 2 sessions. Eight patients in the SC group changed their mind after randomization but before the study began and did not attend any sessions; all 13 of these SC patients had only the initial dentist visit. Similarly, in the UT group, 8 patients had only the initial baseline clinic visit, while 4 other UT subjects discontinued usual care after 1 to 2 additional clinic visits. All patients who dropped out of either the SC or UT groups were included in the intent-to-treat longitudinal analyses reported as available follow-up data allowed.

There were no statistically significant demographic or clinical differences between those who declined to participate or dropped out and study participants, but study decliners endorsed greater control over pain ($P = .044$) and greater ability to decrease pain ($P = .001$). At the 12-month follow up, there were no observed significant differences on any study measure between study completers and dropouts, except that those who dropped out tended to have a smaller maximum unassisted jaw opening (45.0 mm, SE = 6.2 versus 50.4 mm, SE = 0.8; $P = .073$); it should be noted that statistical power to detect significant differences is very low due to the relatively small number of non-completers.

Longitudinal Analyses Comparing the SC and UT Groups

Analyses of covariance (ANCOVA) were the major longitudinal analyses conducted; to reduce the risk of spurious statistically significant findings from multiple analyses, we limited ANCOVAs to those comparing baseline and posttreatment results and baseline and 12-month postintervention follow-up results. ANCOVAs were controlled for group differences in education level and for baseline levels of the variable under analysis. Intent-to-treat analyses were conducted to examine differences between the SC and UT groups on the outcome measures. In determining the data analytic approach to be reported, an analysis of trends over time was considered. In fact, all the analyses were conducted both ways and no meaningful differences between the ANCOVA and the trend analyses were found, except for the Axis I measure of number of muscle sites painful to palpation and Axis II measures of depression and somatization. In those instances, the results of both analyses are presented to facilitate the clarity of the results observed for interested readers. Trend analyses were performed using generalized estimating equations to test for a linear trend and to compare groups over time.[50]

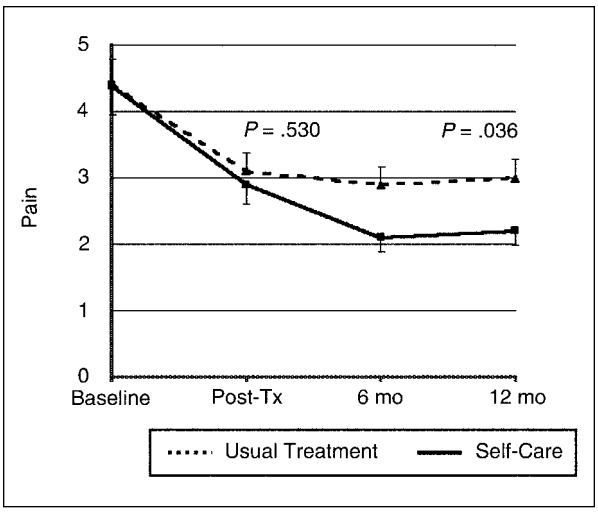

Fig 1 Mean (± SE) Characteristic pain intensity on a scale of 0–10. Self-care group (SC) versus usual treatment for TMD group (UT), analyzed by ANCOVA (adjusted for baseline levels of pain intensity and education).

We have also recommended that, in addition to reporting outcomes based on intent-to-treat analyses, it could be useful to report "simpler" analyses which ignored principles of intent to treat, related to incorporating into data analyses those subjects who drop out of the study.[51] Such analyses not using the intent-to-treat principle were also conducted; it should be noted that no subjects dropping from the SC group switched to the UT group. For all such analyses, results favored the hypothesized outcomes somewhat more strongly than the intent-to-treat analyses, but the differences were not statistically significant or clinically meaningful in this study; hence only the results of intent-to-treat analyses are reported.

Characteristic Pain. Characteristic pain intensity levels, depicted in Fig 1, adjusted for baseline education and pain levels, were identical at baseline, and dropped for both groups in the interval from baseline to posttreatment with the groups diverging slightly. However, the SC group continued a more marked decline compared to the UT group over the year following treatment. At the 12-month follow up, the SC group reported significantly lower levels of characteristic pain, compared to the UT group.

Pain-Related Activity Interference. Interference with daily activities was relatively low at baseline for these patients due to study inclusion/exclusion criteria. Nevertheless, both the SC and UT groups changed differentially over time, as Fig 2 depicts, with the SC group showing a fairly sustained decrease in pain-related interference over the entire study period, after controlling for baseline levels of education and interference. By contrast, the UT group tended to decline more gradually over the first 6 months and then showed significantly greater interference associated with TMD pain at 12 months.

RDC/TMD Axis I Physical Measurements: Vertical Range of Jaw Motion. Figure 3 summarizes findings for vertical range of mandibular motion measures (mm), for unassisted jaw opening with no pain, maximum unassisted opening even if accompanied by pain, and maximum 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.

Number of Extraoral Masticatory Muscles Painful to Standardized Palpation Examination. As can be seen in Fig 4, although the (adjusted) number of painful muscles is comparable between the groups at baseline, the number of extra-oral masticatory muscle sites painful to palpation on examination (RDC/TMD Axis I) declines continuously for the SC group but fluctuates within a narrow band around the initial baseline level for the UT patients such that the number of painful muscles is significantly higher for the UT group compared to the SC group at 1 year. Repeated ANOVA measures to analyze trends confirmed that the difference between the groups at 12 months is due to the SC group improving (decrease of 1.3 painful muscle sites, $P = .002$) while the UC group showed no significant improvement (decrease of 0.2 painful muscles sites, $P = .61$).

RDC/TMD Axis II Psychological Measurements: Depression and Somatization. The data confirmed our expectation that elevated psychological distress would not be associated with GCP scores of II-Low and below, and replicated findings from other population-based and clinical studies.[36,52] Nevertheless, as can be seen in Fig 5, the SC group tended to decrease in psychological distress over the course of this study compared to the UT group. The SC group showed a gradual decline in depression scale scores adjusted for age and sex, while the UT group tended toward higher depression scores by the 1-year follow-up. The difference in trends between the groups was only marginally significant ($P = .085$), with the SC group showing a decrease in

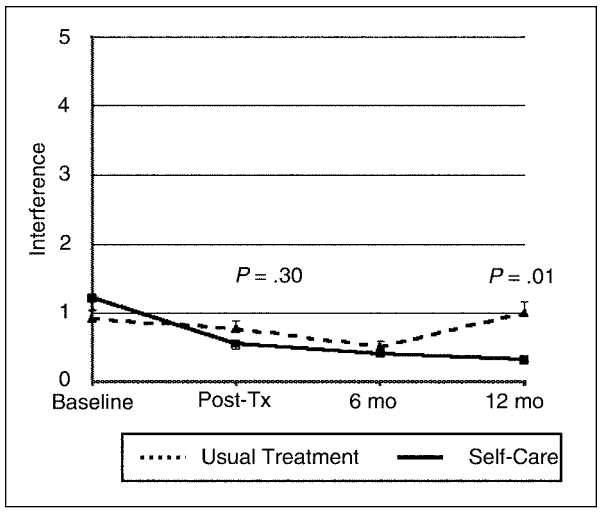

Fig 2 Mean (± SE) pain-related activity interference on a scale of 0–10. Self-care group versus usual treatment for TMD group, analyzed by ANCOVA (adjusted for baseline levels of interference and education).

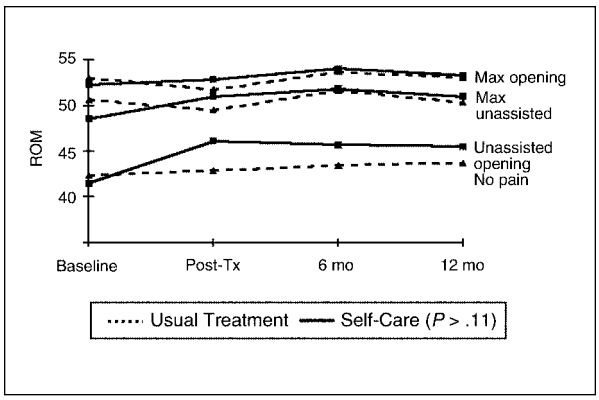

Fig 3 Mean (± SE) vertical jaw range of motion (ROM, mm). Self-care group versus usual treatment for TMD group, analyzed by ANCOVA (adjusted for baseline levels of ROM and education).

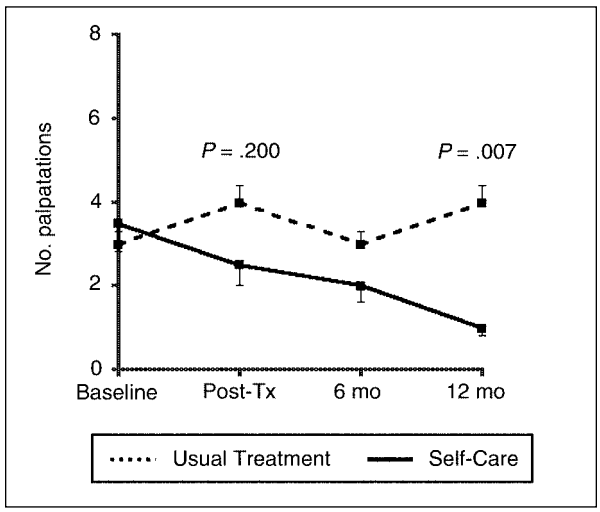

Fig 4 Median (± SE) number of painful extraoral muscle palpations on a scale of 0–16. Self-care group versus usual treatment for TMD group, analyzed by ANCOVA (adjusted for baseline levels and education).

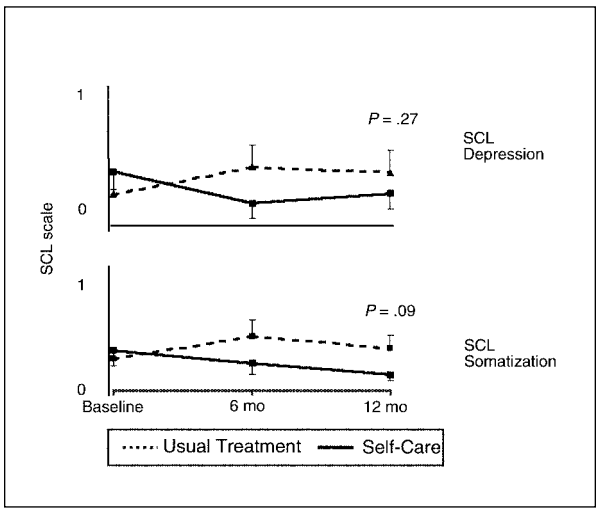

Fig 5 Self-care versus usual treatment for TMD: ANCOVA (adjusted for baseline levels and education) depression and somatization (age-sex adjusted SCL-90 mean [± SE]) Scores.

depression score of 0.17 while the UT group increased by 0.15. With regard to somatization (the tendency to report nonspecific physical symptoms such as numbness or tingling, hot or cold spells, etc, as worrisome), the differences between groups over 12 months are somewhat more distinct. The SC group showed a continual decline in the number of nonspecific physical symptoms reported as bothersome, while the UT group tended to fluctuate. At 12-month follow-up, the UT somatization scores were higher than those for the SC group, but the difference was not statistically significant. There was a significant difference in trend for somatization for scores between the groups (P = .002) with SC showing a 0.25 decrease over 12 months in somatization score (P = .001) while the UT group showed a 0.12 increase (P = .37) over the 12-month follow-up period.

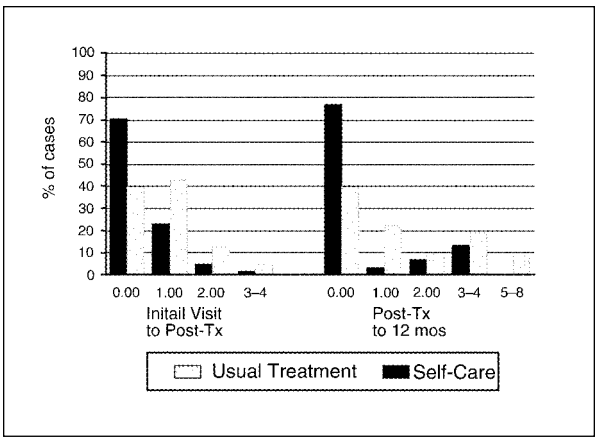

Fig 6 Number of dental visits for TMD after baseline visit (% of cases). Self-care group (n = 63) versus usual treatment group (n = 61).

Compliance, Treatment Helpfulness, Satisfaction, and Knowledge

Number of Dentist Visits for TMD. Patients enrolled in the SC group were not expecting to receive TMD care from their attending dentist during the interval of approximately 2.5 months they were participating in the self-care intervention. Patients were, of course, free to seek care from their dentist during the study period. The SC group showed overall compliance with the expectation of no usual care treatment visits to a clinic dentist in the baseline through postintervention period (median SC clinic dentist visits, excluding baseline visit, during the baseline to posttreatment interval = 0.0 compared to UT median dentist clinic visits excluding baseline visit = 1.0; P = .004). Of course, those patients in the SC group had 3 hygienist session visits, so that the median for total number of hygienist plus dentist visits during the study intervention phase for the SC group = 3.0 while the median number of clinic visits for the UT group = 1.0 ($P < .0001$). In the posttreatment through 12-month follow-up period, the median for all documented UT TMD clinic dentist visits plus self-reported visits to any dentist for TMD treatment for the SC group = 0.0 (Inter-Quartile Range, 25th–75th percentile; IQR = 0.0–2.0) versus UT = 2.0 (IQR = 1.0–4.0), P = .001. Additional analyses, depicted in Fig 6, indicate that in the initial visit to posttreatment interval, about 70% of the SC patients had no dental visits while only 40% of the UT group made no visits to a dentist for TMD treatment after their initial visit. In the following interval, from posttreatment to the 12-month follow-up, the disparity between groups in terms of visits for TMD treatment is more striking. Almost 80% of those in the SC group compared to around 40% of the UT patients who sought no further TMD treatment from their attending dentist. In this posttreatment interval, the contrast is most striking for those making more than 2 dentist visits for TMD: Almost 30% of the UT patients made more than 2 TMD visits to their dentist, with a maximum of 8 visits reported by about 9% of the UT patients; fewer than 15% of the SC patients made 2 or more visits and no SC subject sought more than 4 visits.

Self-Reported Treatment Helpfulness and Satisfaction

At posttreatment follow-up, subjects used 0–10 rating scales to rate the helpfulness of treatment received in reducing pain, enhancing ability to cope with pain, and increasing knowledge with regard to the causes and management of TMD; a similar measure using a 1–5 graded chronic pain scale assessed overall treatment satisfaction in both groups. These (education-adjusted) posttreatment results are summarized in Table 3. At 1-year follow-up, using the same rating scales, the self-care intervention was reported as significantly more helpful in reducing pain and significantly more helpful in overall coping with TMD pain compared to usual care; the SC group also reported significant increases in their level of knowledge about TMD after 1 year. Finally, on 12-month follow-up, although overall satisfaction with both usual care and self-care treatment remained high, mean rating of treatment satisfaction was statistically significantly higher in the SC group compared to the UT group.

Discussion

Results from this RCT confirm that: *(1)* a subset of TMD clinic cases could be identified through the use of RDC/TMD Axis II criteria who exhibited low TMD-related psychosocial interference without regard to Axis I diagnosis. Targeted patients successfully completed an RCT which contrasted usual treatment for TMD delivered by clinical

Table 3 Posttreatment Measures of Helpfulness of Self-Care and Usual TMD Treatment Received for Reducing TMD Pain, Increasing Ability to Cope with Pain, and Increasing TMD Knowledge, and Overall Treatment Satisfaction (Adjusted for Education Level)

	Self-care		Usual treatment		
Self-report measure	Mean	SE	Mean	SE	*P*
How helpful was treatment you received in reducing pain (0–10)	7.6	0.5	5.7	0.4	.0002
How helpful was treatment you received in ability to cope with pain (0–10)	8.4	0.5	5.4	0.4	< .0001
How much did treatment increase your knowledge about TMD (0–10)	9.1	0.3	7.2	0.3	< .0001
How satisfied were you with the treatment you received (1–5 scale)	4.5	0.2	4.1	0.1	.0280

attending TMD specialists with a brief cognitive-behaviorally oriented educational treatment program tailored for TMD patients showing minimal pain-related psychosocial interference and delivered by registered dental hygienists in lieu of usual TMD treatment; *(2)* at 1-year follow up, while both groups showed improvement in all clinical and self-report categories measured, those participating in the tailored self-care treatment program (the SC group), compared to those randomized to receive usual TMD treatment (the UT group), showed: *(a)* decreased TMD pain; *(b)* decreased (from already low levels at baseline) pain-related interference in activities of daily living; and *(c)* reduced number of masticatory muscle sites painful on clinical examination. Both groups improved comparably with regard to all measures of vertical range of mandibular motion. While appreciable levels of psychological distress are not typically shown by patients with GCP scores in the 0 to II-low range, the self-care program over time was associated with consistent, but nonstatistically significant, trends toward lower levels of self-reported symptoms of depression and somatization. The results observed in this RCT were obtained with no physical or personal adverse effects reported by patients or clinicians and, for the self-care group, significantly fewer additional visits to a dentist for TMD treatment during the 1-year posttreatment follow-up period. Perceived ability to cope with TMD and knowledge concerning TMD were significantly enhanced for the SC group when compared to the UT group. Patient satisfaction with treatment received, while high for both groups, was nevertheless significantly higher for the SC group.

The use of the RDC/TMD to identify targeted groups of TMD patients to receive selected treatments is consistent with the overall rationale for developing the RDC/TMD[22]—namely, to make an evidence-based diagnostic and assessment instrument available for TMD researchers. The present study lends support to the RDC/TMD as a reliable, valid, and clinically useful research instrument by demonstrating its ability to identify clinically meaningful subtypes of TMD patients who could be targeted for treatment clinical trials using Axis II criteria, similar to the more common tendency to target interventions based on Axis I criteria. These results extend comparable findings of Turk and Rudy,[43] who reported on the efficacy of tailoring treatments for TMD through the use of the Multidimensional Pain Inventory. The present study extends their observations with regard to tailoring treatments for TMD patients by using a simpler and perhaps more direct method for targeting patients in primary dental care, especially those who can receive a minimal, tailored TMD treatment regimen.

Because the major components of the self-care intervention are derived from a treatment prescription list the TMD clinical specialist uses to guide usual TMD treatment, it may be useful to consider possible reasons that the SC group had more favorable longer-term outcomes than those who received usual treatment. We observed that although most dentists treating TMD conservatively include biobehavioral interventions in their

clinical armamentarium for managing TMD, including recommendations for masticatory muscle exercise, muscle relaxation, and/or reduction of parafunctional oral behavior, such treatments do not appear to be delivered by dentists in a structured fashion. Dentists may not pay careful attention to providing feedback and reinforcement for sustained efforts at behavior change or for management of behavioral relapses. The self-care intervention, by contrast, focused specifically on the use of trained dental patient educators—registered dental hygienists in the present study—because of hygienists' clinical training and experience with structuring and reinforcing educational and oral health behavior changes for dental patients. We reasoned it may be more efficacious to teach hygienists who are proven patient educators something about TMD than it might be to change dentist behaviors in clinical practice in such significant ways as: modifying the amount of time a dentist would spend on patient education, skills training, motivation, relapse prevention, and reinforcement of behavioral gains. The latter set of behavior changes characterizes much of the hygienists' 1-on-1 activities with TMD patients in the present RCT.

There is no reason to doubt that dentists interested in acquiring and then implementing the knowledge and competencies to become effective health care educators would perform as well as the hygienists did in the present study. There may, however, be very real constraints on the amount of time dentists could spend in delivering self-care education programs. Additionally, it would likely be less cost-effective if dentists provided such self-care programs themselves versus delegating that role to dental hygienists. While it is intuitively appealing to suggest that the costs of dentists delivering a self-care program as described in this report would appear to be substantially higher than when hygienists delivered the same treatment program, the determination of relative cost-effectiveness was beyond the scope of the present RCT. The methods employed in the present self-care intervention were designed with thought given to their adaptability into real-world clinical settings where dentists manage TMD. Data from our population base[25,30] and clinical studies,[55] as well as data from the present RCT, indicate that at least 40% of patients seeking treatment for TMD in our tertiary care clinic would qualify as RDC/TMD Axis II chronic pain grades 0, I, or II-low—the criteria used to identify the target group for this RCT. Thus, it seems conservative to suggest that the present findings are generalizable to almost half of the full spectrum of treatment-seeking TMD patients, meaning, that subset of patients who could have their TMD managed with the self-care methods used in this study, even if those management strategies were delivered by an hygienist working under the supervision of an attending dentist and not a dentist per se.

An additional evidence-based conclusion that supported our willingness to conduct this RCT indicates that TMD is most usefully understood as a fluctuating, self-limiting, recurrent chronic pain condition.[15,17,56] For the overwhelming majority of clinic cases, TMD is not associated over time with readily documented physical changes indicating deterioration of structures, loss of physiologic function, or progression of disease status. In the present RCT, after baseline assessment and diagnosis, patients in the SC group for the most part had no further contact with a TMD dentist over the period of 1 year. No adverse effects were noted nor were any significant deleterious clinical changes observed—the same observations about patient safety and absence of adverse effects obviously applies equally to patients in the UT group, who did receive care from a TMD dentist. Patients improved over time in both groups, an observation reported in other controlled longitudinal TMD treatment outcome studies[17,27,40] and in longitudinal studies examining the relationship between TMD symptoms and extent of treatment.[17]

Limitations of the present study necessitate caution when interpreting data from this single RCT and it also seems prudent to proceed cautiously with regard to generalizing results of this study to clinical practice. The present study represents a first of its kind, rigorously designed and carefully executed RCT into the use of the RDC/TMD to target clinic cases amenable to a cognitive behavioral therapy (CBT)-related educational, skills training, and behavior change intervention which is tailored to level of psychosocial functioning—that is a treatment targeted to an Axis II "diagnosis," so to speak, instead of a physical Axis I TMD diagnosis. However, it must be pointed out that the RDC/TMD itself still needs further reliability and validity assessment. The RDC/TMD provides operational definitions and examination specifications for the most commonly occurring forms of TMD but is not all-inclusive at present in this regard. In addition, although more than 60% of eligible patients enrolled in the RCT, and our long-term follow-up rates were above 90%, more information is needed about the fate of those who did not choose to enroll and those who decided to drop out, whether early or late, from either the SC or UT groups.

Another limitation of the present study relates to the study design. We chose to offer consecutively appearing TMD patients 1 of 2 separate RCTs, depending on RDC/TMD Axis II criteria of graded chronic pain level (ie, GCP score of 0, I, or II-low versus a score of II-high, III, or IV) and to introduce into each RCT a treatment intervention hypothesized to be suitable for the targeted group. Thus, subjects with a GCP score of II-high, III, or IV were offered enrollment in another trial involving more intensive CBT intervention conducted by a clinical psychologist over 6 sessions and integrated into usual TMD care. It would seem reasonable to argue that a stronger study design would have used a single RCT designed to randomize all TMD patients into 1 of 3 arms: *(1)* the self-care treatment intervention reported here; *(2)* the more complex CBT intervention tailored to the more impaired TMD cases; or *(3)* usual treatment. By excluding the more psychosocially impaired cases from the present study, it is not possible to conduct as strong or direct a test of the efficacy of tailoring treatments according to groups of TMD cases targeted by RDC/Axis II criteria. While a theoretical case could be made for employing such a single RCT design, we gave careful consideration to the issues involved and rejected the design in favor of 2 separate RCTs for very practical and clinically meaningful reasons. A single RCT randomizing both well-adapting and poorly adapting chronic TMD patients would, in effect, mean that those coping reasonably well with TMD, showing little or no psychological disturbance or TMD-related interference in activities of living, could be assigned to the lengthier 6-session CBT intervention, while TMD patients experiencing significant psychological and psychosocial distress and typically reporting higher levels of pain would be assigned to an intervention in which they would not be expected to see a TMD dentist and would receive instead a minimal treatment intervention stressing education and skills training delivered by a hygienist. The chronic pain literature contains several excellent accounts[43,57] that document the well-known difficulties in recruiting and retaining chronic pain patients into RCTs. The abundant clinical research and treatment experience of the study by dentists and psychologists supported the view that well-functioning TMD cases assigned the lengthier and more complex cognitive-behavioral therapy intervention might view such a requirement as excessive and drop out of the trial after randomization. Similarly, TMD cases more heavily impacted by their chronic pain problem would likely view the presently described intervention as too minimal for their complicated problem and they, too, would drop out of the study after randomization in numbers sufficient to threaten the integrity of the intent-to-treat requirements for analyzing RCT data.[39,57,58]

The standard methods used in this study for randomizing subjects to experimental and control groups resulted in a disparity between the groups with regard to mean baseline highest level of education obtained. Because the self-care intervention relied heavily on educational methods to convey information and conduct skills-acquisition training, it was especially important to control for this difference in education status when we analyzed the study data so that we could be confident that results obtained were not simply a function, for example, of more experience with educational materials or differences in reading levels. A well-accepted method for exercising such statistical control is the use of ANCOVA, as described above. If we had not exercised such statistical control, the contrasts between self-care and usual treatment would likely have been even more striking, albeit biased.

Finally, we noted with great interest that over the 1-year period following the end of the self-care intervention phase, significantly less care from a dentist was sought by those in the SC group compared to the UT group. As mentioned earlier, within the constraints of the present study we were not able to obtain cost data. It is clear that the perceived need for additional treatment varied across individuals in both groups and while we found no clinical differences among cases to explain this difference in treatment-seeking behavior, others have suggested (and the present data does not refute the possibility) that treatment-seeking may be associated with such nonphysical clinical parameters as depression and somatization. McCreary et al[59] have asserted, for example, that unless the issue of somatization is addressed, success of TMD treatment cannot be assured. In the present targeted subset of reasonably well-functioning TMD cases, we did not observe sufficient instances of more extensive psychological or psychosocial disturbance to adequately explore this provocative aspect of the factors associated with TMD treatment-seeking.

Within the limitations of the present study, results from this RCT are consistent with our prior study[36] investigating the efficacy of brief CBT interventions that emphasize education and skills training for the self-management of TMD. Taken together, our prior[36] and current research indicate that for the overwhelming majority of TMD cases,

risk for serious physical deterioration is absent or minimal; both this RCT and the prior RCT lend strong reinforcement to the notion that carefully structured minimal interventions emphasizing self-management of TMD may offer real benefit to a significant number of TMD patients.

Acknowledgments

The authors wish to express full acknowledgment of the strong support and cooperation offered in the conducting of this RCT by TMD clinicians in the Department of Oral Medicine, University of Washington, including Drs. M. Drangsholt, B. Gandara, M. Martin, M. Schubert, E. Sommers, and especially to Melinda Lane, RDH, BS. Gratitude is also expressed to the staff members of our Orofacial Pain Research Group, especially to Gayle Garson for her superb effort on behalf of data management and statistical analysis, Gregory Mueller for the outstanding administration of study logistics needed to conduct this complex RCT, and Kathy Lanier for production of study manuals and editing. This research was supported by NIDCR Grant # DE-10766.

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