

EFFICACY OF AN EARLY BIOPSYCHOSOCIAL INTERVENTION FOR PATIENTS
WITH ACUTE TEMPOROMANDIBULAR DISORDER-RELATED PAIN:
A LONG-TERM FOLLOW-UP STUDY

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DEDICATION

To my son,
husband, and parents

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by

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A long-term follow-up (LTF) study was conducted to further evaluate the efficacy of a biopsychosocial intervention for acute high risk (HR) temporomandibular disorder (TMD) patients. Subjects from Gatchel and colleagues' one-year outcome study (Gatchel, Stowell, Wildenstein, Riggs, & Ellis, 2006) were contacted to assess pain and psychosocial measures at LTF (two to six years post intake). An early-intervention (EI) group had received cognitive behavioral skills training and biofeedback, while a nonintervention group (NI) had received no intervention. Similar to one-year follow-up

findings, EI group subjects had significantly lower levels of self-reported pain and depression at LTF as compared to intake. The EI group was also associated with significantly lower pain and depression scores, relative to the NI group. EI group subjects continued to show a decreasing trend on jaw pain-related health care visits relative to NI group subjects, providing further evidence for reduced costs associated with early interventions. The present study supports and extends the findings of the earlier one-year outcome study, indicating that an early biopsychosocial intervention is beneficial for patients with acute TMD. By receiving treatment during the acute stage of TMD, patients are less likely to develop chronic TMD, and to be impacted long-term by the physical, emotional and financial aspects of TMD.

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LIST OF ABBREVIATIONS

1-Year	One-Year Follow-Up
ANOVA	Analysis of Variance
BDI- II	Beck Depression Inventory- II
χ^2	Chi-Square
CI	Confidence Interval
DSM-IV-TR	Diagnostic and Statistical Manual, Fourth Edition, Text Revision
<i>F</i>	F-ratio
GAD	Generalized Anxiety Disorder
GAF	Global Assessment of Functioning
HR	High Risk
LOCF	Last-Observation-Carried- Forward
LB	Low Back
LR	Low Risk
<i>M</i>	Mean
MDD	Major Depressive Disorder
OR	Odds Ratio
η^2	Partial Eta-Squared
n.s.	Not Significant
PRS	Participant Ratings Survey
RDC	Research Diagnostic Criteria
SCID-I	Structured Clinical Interview for DSM-IV Axis I Disorders

SCID-II	Structured Clinical Interview for DSM-IV Axis II Personality Disorders
<i>SD</i>	Standard Deviation
TMD(s)	Temporomandibular Disorder(s)
TMJ	Temporomandibular Joint
<i>U</i>	Mann-Whitney <i>U</i> -statistic
WOC	Ways of Coping

CHAPTER ONE INTRODUCTION

Temporomandibular disorder (TMD) symptoms impact 75% of the U.S. population, with 5-10% severe enough to require treatment (American Academy of Orofacial Pain, 2004). Researchers (Drangsholt & LeResche, 1999) have calculated that more than 5.3 million Americans within a 6-12-month period request treatment for TMD. In addition to the physical and emotional aspects of TMD, patients are also challenged with rising health care costs. Stowell and colleagues (Stowell, Gatchel, & Wildenstein, 2007) estimated an annual cost of \$4 billion for TMD treatment in the U.S. Alone, traditional treatments have been costly, invasive and in some cases ineffective. The need for an efficacious and cost-effective treatment for TMD is clear.

Research has been done in various areas of TMD, although most studies have focused on chronic subjects and/or have had limited follow-up. Gatchel (Gatchel, Garofalo, Ellis, & Holt, 1996; 2006) and Wright (Wright et al., 2004), concerned with differentiating chronic versus acute, as well as high risk (HR) versus low risk (LR) patients, have investigated both chronic and acute TMD populations. With the ability to classify these patients comes the possibility to create more unique and efficacious treatment interventions (Wright et al., 2004), as well as the opportunity to intervene early and thereby reduce the risk of progression to chronic TMD. In addition to physical and emotional benefits for patients, early intervention reduces health care visits and thus health care costs (Gatchel, Stowell, Wildenstein et al., 2006; Stowell et al., 2007).

In a one-year outcome study of patients with acute TMD, Gatchel and colleagues (2006) found an early biopsychosocial intervention to be effective in reducing pain levels

and emotional distress, while also improving coping abilities for an acute HR TMD study group. Subjects who received early-intervention (EI) were more capable of managing their pain, thus reducing the risk of developing chronic, costly jaw pain. The purpose of the present prospective study was to evaluate subjects' progress long-term post-treatment, and to determine if the benefits achieved at one year were sustainable. The long-term follow-up (LTF) study supports the findings of the one-year outcome study (Gatchel, Stowell, Wildenstein et al., 2006) that an early biopsychosocial intervention is efficacious for patients with acute TMD. This study provides more evidence for early biopsychosocial interventions as part of future treatment protocols for acute TMD.

CHAPTER TWO

REVIEW OF THE LITERATURE

TEMPOROMANDIBULAR DISORDERS (TMDs)

Definition

TMDs are a group of disorders that encompass temporomandibular joint (TMJ) difficulties (pain and limited jaw opening), and masticatory musculature pain (Hansdottir & Bakke, 2004; Rudy et al., 2001; Suvinen, Reade, Kemppainen, Kononen, & Dworkin, 2005). Typically, TMD diagnoses involve degenerative changes of the TMJ, disc displacements, muscle disorders, or internal derangements (Gatchel, 2002). Orofacial pain, joint sounds (grinding, clicks, or popping), pain on masticatory muscle palpation, and limited mandibular movement are common TMD symptoms (S. F. Dworkin et al., 1990; S. F. Dworkin, Turner et al., 2002; Gardea, Gatchel, & Mishra, 2001; Glaros & Glass, 1993). In 1997, The Technology Advancement Conference by the National Institutes of Health (NIH) acknowledged the complex nature of TMD by defining the disorders in terms of pain and psychosocial dysfunction (National Institutes of Health, 1997; 2005). TMDs affect the stomatognathic system which some researchers argue is unique compared to other musculoskeletal systems in that teeth, joints and musculature are involved (Okeson, 1996; Suvinen, Reade, Kemppainen et al., 2005).

Etiology

While the etiology is unclear, most researchers agree that TMDs are a multi-determined group of disorders (Suvinen, Reade, Hanes, Kononen, & Kemppainen, 2005; Wright et al., 2004). Proposed causal factors include: physical mouth structures;

musculature; and psychosocial aspects (Carlson et al., 1993; Gremillion, 2000; Laan, Duinkerke, Luteijn, & Poel, 1988; Macfarlane, Kinney, & Worthington, 2002; Wright et al., 2004). Clenching and grinding related to stress, poor muscle discrimination, and/or unconscious bracing of the orofacial musculature have been considered leading contributors in TMD etiology (Carlson et al., 1993; Simon & Lewis, 2000). In reviewing the etiology of TMD, Suvinen and Reade (2005) examined biomedical concepts and found a focus on TMJs, muscles of mastication, and occlusal factors. In the area of TMJs, functional and structural theories (trauma, internal derangement, mechanical displacement, and osteoarthritic) have been investigated. Suvinen et al. (2005) concluded that TMJ or muscle/myofascial-related TMD are currently viable contributors in TMD etiology.

In a 2007, prospective study (LeResche, Mancl, Drangsholt, Huang, & Von Korff), researchers identified risk factors for onset of TMD in early adolescence. Subjects ($n=1,996$) were evaluated at intake by phone interview and followed for 3 years, with data collected every three months. At any point, if a subject endorsed facial pain, a clinical examination was administered. Outcome was assessed by classifying subjects into three categories: no facial pain; facial pain with RDC/TMD pain diagnosis (upon examination); or facial pain without RDC/TMD pain diagnosis. Researchers found female gender and negative somatic and psychological symptoms (somatization, number of pain complaints, and life dissatisfaction) to be baseline predictors of clinically significant TMD during early adolescence. Based on these results, this team proposed that the development of TMD may be connected to an underlying vulnerability to musculoskeletal pain throughout the body.

Historically, various psychosocial aspects have also been investigated, including psychodynamic concepts, personality concepts, emotional and affective states, and behavioral factors (Suvinen, Reade, Kemppainen et al., 2005). Wright and colleagues' (2004) study highlighted the importance of psychosocial factors and the role they may play in TMD etiology. In that study, psychopathology was more prevalent, and coping skills were poorer, in subjects who were HR versus subjects who were LR.

Suvinen et al. (2005) proposed a conceptual model of psychophysiological aspects of TMD pain and dysfunction. Adapted from both the biopsychosocial model created by Turk and Rudy (1987) and information processing theory, the model begins with a "peripheral event" leading to a structural/functional impairment (interacting with TMJs and muscles) and a pain perception (interacting with psychological, physiological factors). The result of this process is TMD.

Diatchenko and colleagues (Diatchenko, Nackley, Slade, Fillingim, & Maixner, 2006) suggested that pain amplification and psychological distress are two important pathways of vulnerability for developing an idiopathic pain disorder (IDP) such as TMD. The authors discussed how pain amplification and psychological distress, mediated by genetics and environment, are determinants of the onset and persistence of TMD. In two recent studies, researchers discussed their work on finding genes associated with pain sensitivity and psychological disorders (Diatchenko, Anderson et al., 2006; Diatchenko et al., 2005). In their earlier study, Diatchenko and colleagues (2005) implicated the gene encoding COMT (catechol-O-methyltransferase), an enzyme related to catechol and estrogen metabolism, in the onset of TMD. In their 2006 study, they linked three common haplotypes of the COMT gene to heightened pain sensitivity and risk for TMD

(Diatchenko, Anderson et al., 2006). Based on these findings, Diachenko and colleagues (2006) recommended analyzing the interactive effects of polymorphic variants of multiple functionally-related candidate genes as a way to efficiently approach genetic marker identification for IDPs and TMD.

In 2007, this research team (Nackley et al.) also demonstrated that low COMT activity leads to increased pain sensitivity by way of a β_2 - and β_3 - adrenergic process. Declining COMT activity results in increased norepinephrine and epinephrine activity, which triggers β_2 - and β_3 - adrenergic receptors. Based on these findings, researchers believe that pain conditions such as TMD, which appear to be related to low COMT activity and/or elevated catecholamine levels, may benefit from medications which block the β_2 - and β_3 - adrenergic receptors.

Future research, sponsored by the National Institute of Dental and Craniofacial Research (NIDCR), is tasked with researching TMD treatment, psychosocial and physiological risk factors. One specific study is titled OPPERA (Orofacial Pain: Prospective Evaluation and Risk Assessment) and aims to investigate genetic polymorphisms that influence pain amplification and psychosocial profiles in subjects who develop TMD. The \$19.1 million project will follow 3,200 healthy volunteers over 3 to 5 years, and examine how many subjects from this group develop TMD.

Diagnosis

Since the development of Dworkin and LeResche's (1992) Research Diagnostic Criteria for Temporomandibular Disorders (RDC-TMD) for the NIDCR, diagnosing TMD has become more standardized. The RDC has become the most widely accepted

system for diagnosing TMD, and it has addressed the issue of classifying such a heterogeneous pain population (Gatchel, 2002; Mishra, Gatchel, & Gardea, 2000; Suvinen, Reade, Kemppainen et al., 2005). The RDC offers a way to systematically delineate the clinical subtypes of TMD via a physical disease axis (Axis I; S. F. Dworkin, Turner et al., 2002), and a psychological, psychosocial axis (Axis II). Axis I is comprised of three groups: Group I (muscle disorders); Group II (disk displacements); and Group III (arthralgia/arthritis/arthrosis; S. F. Dworkin & LeResche, 1992; Gatchel, 2002). Axis I diagnoses may include one Group I diagnosis, up to two Group II diagnoses (one for each joint), and up to two Group III diagnoses (one for each joint). Axis II allows for evaluation of depression, nonspecific physical symptoms, pain intensity, and pain-related disability (S. F. Dworkin, Huggins et al., 2002; S. F. Dworkin & LeResche, 1992; S. F. Dworkin, Turner et al., 2002; Gatchel, 2002). The RDC has been translated into 18 languages and is used by a consortium of 45 RDC/TMD-based international researchers (John, Dworkin, & Mancl, 2005). A recent study (Reiter, Eli, Gavish, & Wincour, 2006), examining the ethnic differences in TMD between Jewish and Arab populations in Israel using the RDC, highlights the importance of culture and other social factors. While the RDC may be available in many languages, these researchers recommended cross-cultural calibration of RDC Axis II and proposed creating an Axis III to cover the social component of TMD.

While the RDC is widely used, a recent study by John and colleagues (John et al., 2005) addressed the issue of reliability in diagnosing. This study concluded that the RDC exhibits sufficiently good reliability for most TMD diagnoses. Ten international clinical centers, encompassing 30 clinical examiners and 230 subjects, provided the data for this

study. Fair to good reliability was found using intraclass correlation coefficients (ICCs): myofascial pain with limited opening, 0.51; myofascial pain without limited opening, 0.60; arthralgia, 0.47; disc displacement with reduction, 0.61. Other RDC diagnoses were too limited in order to run ICCs, but percent agreement was greater than 95% (disc displacement without reduction, osteoarthritis, osteoarthrosis). ICCs improved when diagnoses were grouped by pain and non-pain, (0.72), as well as for finding any diagnosis versus no diagnosis, (0.78).

John and colleagues (John, Reissmann, Schierz, & Wassell, 2007) also investigated how to characterize and measure the impact of TMD on oral-health related quality of life (OHRQoL) using the German version of the Oral Health Impact Profile (OHIP; Slade & Spencer, 1994). Researchers utilized the OHIP summary score to characterize the OHRQoL, and then created an OHRQoL description for the 8 RDC/TMD Axis I diagnoses and Axis II measures. Differences were found between the TMD patients and the general populations for both RDC/TMD Axis I and Axis II. However, the greatest differences were found on the Axis II measures. In particular, the Graded Chronic Pain Scale (GCPS) scores showed the greatest association with OHRQoL with jaw disability and somatization also related; however, depression was only weakly correlated with the OHRQoL.

In addition to the RDC, other methods have been suggested for diagnosing. Klasser and Okeson (2005) conducted a review of recent literature on the use of surface electromyography (SEMG). Their analysis suggested that reliability, validity, sensitivity and specificity are difficult to attain and, as such, EMG provides little value clinically in

diagnosing TMD. The researchers found SEMG potentially useful in controlled research settings where data can be standardized.

In an effort to determine which symptoms and signs are characteristic of TMD , Cooper and Kleinberg (2007) reviewed data from 4,528 TMD patients seen by a single dentist over a 25-year period. The researchers found that all of the patients endorsed some symptoms in an intake questionnaire with the following symptoms most prevalent: pain (96.1%); headache (79.3%); temporomandibular joint discomfort or dysfunction (75%) and ear discomfort or dysfunction (82.4%); joint sounds / pain in TMJ / limited ability to open mouth (75%); and throat symptoms (42.4%). Ninety-six percent of patients showed signs upon clinical examination with the following most prevalent: tenderness to palpation of the lateral pterygoid muscles (85.1%); tenderness to palpation of the medial pterygoid muscles (62.8%); tenderness to palpation of the temporomandibular joints (62.4%); and discomfort on palpation of the anterior temporalis (50.0%). These findings further support the usefulness of the RDC which requires examination of many sites including the lateral pterygoid muscles and the anterior temporalis.

Prevalence

TMD symptoms impact 75% of the U.S. population with 5-10% severe enough to require treatment (American Academy of Orofacial Pain, 2004). While prevalence rates for TMD are inconsistent, Drangsholt and LeResche (1999) previously estimated that TMD pain annually affects 10% of women and 6% of men; roughly 20 million adults (Gatchel, Stowell, Wildenstein et al., 2006; Wright et al., 2004). Drangsholt and

LeResche (1999) further calculated that more than 5.3 million Americans within a 6-12-month period request treatment for TMD. An earlier study reported that 22% of the U.S. population experienced orofacial pain on multiple occasions in a 6-month period (Lipton, Ship, & Larach-Robinson, 1993). Dworkin and colleagues (1990) estimated a lifetime prevalence rate of 65-85% for TMD symptoms in the U.S. population. Researchers estimated that 5-12% of the population may progress from acute to chronic TMD (Duckro, Tait, Margolis, & Deshields, 1990; S. F. Dworkin et al., 1990; Lipton et al., 1993; Svensson & Graven-Nielsen, 2001). Prevalence rates appear to be higher in women than in men (Dao & LeResche, 2000; Lipton et al., 1993). In fact, one study cited prevalence rates of 8-15% for women, and 3 -10% percent for men (Dao & LeResche, 2000).

Cost

With health care costs becoming more of an issue for patients as well as health care providers, researchers are investigating and finding that some behavioral treatments offer a medical cost-offset effect (Chiles, Lambert, & Hatch, 1999). Stowell and colleagues (2007) estimated an annual cost of \$4 billion for TMD treatment in the U.S. Annual managed care treatment costs for orofacial pain individually can range from \$12,000 to \$20,000 (Brotman, 1997). Von Korff and colleagues (2007) observed 372 TMD patients over a 3 year period, and found this pain population made more visits than controls. Clearly, in addition to the medical and psychological benefits in preventing patients from progressing from acute to chronic TMD, there is a cost benefit. Early identification and intervention can help minimize potential for costly multiple treatments

and lost wages (Stowell et al., 2007; Von Korff, 1995). Chronic TMD impacts patients socially, vocationally, and emotionally, and can become seriously debilitating (Garro, Stephenson, & Good, 1994; Greco, Rudy, & Harlich, 1998; Stowell et al., 2007; Von Korff, Ormel, Keefe, & Dworkin, 1992). For example, several studies have found that TMD patients have higher usage of health care services (Gatchel, Stowell, Wildenstein et al., 2006; Shimshak & DeFuria, 1998; Shimshak, Kent, & DeFuria, 1997; White, Williams, & Leben, 2001).

An additional challenge for TMD patients is coverage of treatment costs by insurance companies. As TMD may involve medical (physical and mental) and dental aspects, often insurance companies pass the liability of TMD to each other, resulting in no coverage for the patient (Stowell et al., 2007). Stowell and colleagues (Stowell et al., 2007) found reduced health care expenditures for acute high risk TMD patients who received a cost-effective, biopsychosocial treatment.

Acute versus Chronic Pain

Acute pain is characterized by a well-defined cause and sudden onset with a typical course, ending with the completion of treatment (all lasting less than six months). Acute pain is typically associated with anxiety while chronic pain is related to depression (Gatchel et al., 1996). Gatchel and colleagues (1991; 1996) have developed a conceptual model to explain the transition from acute to chronic pain. In Stage 1, initial emotional reactions and psychological distress (fear, anxiety, and worry) are a direct product of the patient's perception of the acute pain. As the patient continues to experience pain past the acute period (2-4 months), Stage 2 begins and psychosocial problems develop or are

exacerbated (depression, distress-anger, somatization, learned helplessness, substance abuse). By Stage 3, the patient has accepted the sick role and abnormal behavior is perceived as normal by the patient.

Several studies have highlighted the need to address acute and chronic TMD as unique subgroups (Epker, Gatchel, & Ellis, 1999; Garofalo, Gatchel, Wesley, & Ellis, 1998). By differentiating these groups, patients receive more appropriate treatment, thereby increasing their chances of recovery and reducing the risk of chronic TMD. With fewer chronic TMD patients, health care expenditures will be reduced.

Garofalo and colleagues (Garofalo et al., 1998) developed an algorithm to delineate risk factors in acute TMD patients who progress from acute to chronic TMD. Their study, utilizing the RDC (S. F. Dworkin & LeResche, 1992), found a number of physical and psychological variables which differentiated between members who became chronic versus those who became symptom free. At six month follow-up, chronic TMD subjects were characterized by an increase in the following: Axis I – Group I disorders; Axis II GCPS; nonspecific physical symptoms; and Characteristic Pain Intensity (CPI; S. F. Dworkin & LeResche, 1992) score (pain measure). The results of this study paved the way for Epker and colleagues' (1999) work. They refined the algorithm created by Garofalo and colleagues (1998) which had allowed for correct classification of 77% of subjects. Epker and colleagues (1999) identified 2 variables that allowed them to accurately predict 91% of subjects who progressed to chronic TMD. The presence or absence of myofascial pain and the CPI score were found to be significant predictors based on a logistic regression analysis.

Wright and colleagues (Wright et al., 2004) further researched the differences between acute TMD patients identified at HR and LR for progressing from acute to chronic pain. Functional and psychosocial measures were assessed for subjects who were categorized as HR or LR based on Epker and colleagues' (1999) algorithm. The HR subjects endorsed more psychopathology, had poorer coping skills, and greater self-reported pain. Six factors allowed researchers to correctly classify 77 % of the subjects as being in the HR group: Beck Depression Inventory-II total score (BDI-II; Beck, Steer, & Brown, 1996); the Ways of Coping research edition Avoidance scale (WOC; Folkman & Lazarus, 1988); presence or absence of West Haven-Yale Multidimensional Pain Inventory (MPI; Kerns, Turk, & Rudy, 1985) adaptive coping style; presence or absence of MPI interpersonally distressed coping style; and presence of Axis I or Axis II diagnoses using the Structured Clinical Interview for DSM-IV (SCID I; First, Spitzer, Gibbon, & Williams, 1995) and Structured Clinical Interview for DSM-IV Personality Disorders (SCID-II; First, Spitzer, Gibbon, Williams, & Lorna, 1994).

Psychosocial Aspects

The acknowledgement of the relationship between psychosocial factors and pain dates back to the development of Melzack and Wall's (1965) *gate control theory*. Today, a diathesis-stress model is considered to be the leading theoretical perspective (Gatchel & Dersh, 2002) of pain and related psychological disorders. Psychopathology is postulated to result from diatheses, (i.e. preexisting characteristics of a person), which are activated by a significant stressor. Several studies have examined psychosocial aspects in TMD patients to better understand how to treat this unique pain population (Gatchel et al.,

1996; Wright et al., 2004). As early as 1992, researchers identified certain psychosocial disorders prevalent in chronic TMD patients (Kinney, Gatchel, Ellis, & Holt, 1992).

Kinney and colleagues (1992) found that chronic TMD subjects had higher current and lifetime rates of DSM-III-R Axis I and Axis II psychological disorders than the general population. Excluding somatoform disorders, 84 % and 46% of the chronic TMD subjects in their study met lifetime and current criteria, respectively, for Axis I disorders. Higher rates of depression, anxiety, and somatoform disorders were also observed. Axis II disorders were also found to be more prevalent in the chronic TMD subjects, with 40% meeting criteria for a personality disorder. Paranoid, obsessive-compulsive, and borderline personality disorders were the most commonly diagnosed Axis II disorders.

Gatchel and colleagues (1996) investigated major psychological disorders in both acute and chronic TMD subjects. Similar to Kinney et al. (1992), this study found higher lifetime prevalence rates for DSM-III-R Axis I and II psychological disorders, relative to the general population. For Axis I, Anxiety disorders (52.9%) were the most common diagnosis for the acute group, then affective disorders (45.1%) and substance abuse disorders (25.5%). In the chronic group, affective disorders (78%) were most diagnosed, followed by somatoform disorders (50%) and substance abuse disorders (30%; Gatchel et al., 1996). Current Axis I diagnoses prevalence rates were as follows: acute (anxiety disorders: 47.1%; affective disorders: 11.8%) and chronic (somatoform disorders: 50%; affective disorders: 34%; anxiety disorders: 12%). Additionally, 80% of acute and 86% of chronic subjects met criteria for an Axis I diagnosis prior to experiencing TMD symptoms. Many Axis II diagnoses were more common in chronic than acute subjects; higher rates were observed in both groups relative to the general population. Paranoid

personality disorder was most common diagnosis for the acute (15.7%) and chronic (18%) groups, followed by histrionic personality disorder in the acute group (7.8%) and obsessive-compulsive personality disorder in the chronic group (10%).

As discussed earlier, Wright and colleagues (2004) investigated differences between HR and LR acute TMD patients. As compared to the LR group, the HR group was 11 times more likely to have a DSM-IV Axis I diagnosis, and 3 times more likely to have a DSM-IV Axis II diagnosis. Consistent with previous studies, a high rate of Axis I and II diagnoses were found in both acute and chronic TMD subjects (Gatchel et al., 1996; Kinney et al., 1992). Seventy-one percent of the HR subjects and 18% of the LR subjects met criteria for Axis I diagnoses, while rates of 59.6% and 27.3%, respectively, met criteria for Axis II diagnoses. In Gatchel and colleagues' (1996) study, anxiety disorders were most prevalent among acute TMD subjects. However, in that study, HR subjects were most commonly diagnosed with somatoform disorders (51.9%), followed by affective disorders (46.2%) and anxiety disorders (38.5%). LR subjects were most commonly diagnosed with affective disorders (22.7%), followed by somatoform disorders (13.6%). With respect to Axis II diagnoses, higher rates were observed in the HR group as compared to the LR group for Cluster C personality disorders (avoidant, obsessive-compulsive, dependent), particularly obsessive-compulsive personality disorder. No significant differences were found for other Axis II personality disorders. Wright and colleagues (2004) hypothesized that TMD patients, characterized by a more anxious aspect to their illness, are more likely to be at high risk versus those patients with a more depressive aspect who are more likely to be at low risk for developing chronic TMD. Anxious type patients may be less aware of their feelings and/or deny any

unpleasant emotions (Wright et al., 2004). Depressive-type patients, on the other hand, may be more insightful and aware of their emotional distress prompting them to seek help or find other ways to cope with their discomfort. In fact, when compared to an acute low back (LB) pain population, researchers (Edwards, Gatchel, Adams, & Stowell, 2006) found greater depression among LB subjects versus greater anxiety among TMD patients. LB subjects had a significantly higher rate of dysthymia while TMD subjects had a significantly higher rate of generalized anxiety disorder (GAD). TMD subjects also had lower BDI and CPI scores, as well as higher Global Assessment of Functioning (GAF) scores. In addition, TMD subjects were more likely to use benzodiazepines to manage their pain versus Schedule II narcotics used by LB subjects.

A 2005 study investigated a subtyping approach and compared physical, psychosocial, and psychological variable of TMD patients (Suvinen, Reade, Hanes et al., 2005). Subjects were assessed for physical symptoms, coping style and effectiveness, and illness behavior using the Temporomandibular Pain Dysfunction Questionnaire. Additionally, subjects were given the BDI and Beck Anxiety Inventory (BAI; Beck, 1961), as well as the MPI. The researchers identified the following three TMD subtype clusters using an iterative partitioning method, k-means cluster analysis: *simple* (22%), *intermediate* (41%), and *complex* (37%). While there were no significant differences on physical measures, the following variables were significant: coping style and coping effectiveness; disease conviction and affective disturbance; daily interference; social satisfaction; work satisfaction; and family satisfaction. The *simple* subtype subjects primarily endorsed physical symptoms, but not psychosocial variables; the *intermediate* subtype subjects endorsed physical and psychosocial variables, but were able to cope

with their difficulties; the *complex* subtype subjects endorsed psychosocial dysfunction regardless of physical severity level. The *complex* group also exhibited the following characteristics: prominent depression, considerable anxiety, and dysfunctional coping style. This study concluded that subtyping of patients by using physical, psychological, and psychosocial factors is useful in guiding management of TMD.

While several studies have investigated psychological factors such as depression and anxiety, a recent study looked at the association between optimism and facial pain (Sipila, Ylostalo, Ek, Zitting, & Knuuttila, 2006). Researchers found an inverse relationship between subject's level of optimism and self-reported facial pain when controlling for depression. This study concluded that optimism was an independent variable and should be considered in treatment planning. Optimism was measured via postal questionnaire with the Life Orientation Test (LOT: Scheier, Carver, & Bridges, 1994), while facial pain was measured with a self-report computer-aided questionnaire completed by subjects at a clinical examination.

Treatment

In keeping with the traditional biomedical model of pain, physical treatments have been commonly used to treat TMD (Gatchel, 2002). Pharmacological agents, such as tranquilizing medications, corticosteroids, muscle relaxants, and placebo drugs, have been prescribed for patients (Gatchel, 2002). Interocclusal appliances, nocturnal alarms, physical therapy, surgery, occlusal calibration, patient education, soft diet, massage, and heat have also been used in TMD treatment (Gatchel, 2002; Gatchel, Stowell, Wildenstein et al., 2006).

Truelove and colleagues (Truelove, Huggins, Mancl, & Dworkin, 2006) examined the use of splint therapy for the treatment of TMD. Two-hundred TMD subjects were randomized into three groups: usual conservative treatment (UT); UT plus a conventional flat-plane hard acrylic splint (HS); and UT plus a soft vinyl splint (SS). UT consisted of jaw relaxation, reduction of parafunction, thermal packs, NSAIDS, passive opening stretches, suggestions about stress reduction, and self-care strategies. HS and SS subjects also received the UT treatment in addition to their respective splints. Follow-up data were collected at 3, 6, and 12 months, although only 3-month and 12-month outcomes were reported for this study. Researchers hypothesized that in the short term (at 3 months), the HS and SS subjects would show greater improvement than the UT subjects; however, over long-term (at 12 months), all 3 groups would show equivalent improvement. Several outcome measures were utilized, with CPI score designated as the primary outcome measure. No differences were found among groups at intake, 3-month, or 12-month. Significant differences, however, were found on average CPI score from intake to 12-month follow-up (means: 5.5 to 3.1), with all 3 groups showing similar decreases in pain across the study. In addition, all 3 groups had fewer subjects with RDC/TMD Axis I Group I diagnoses. Researchers concluded that UT was just as effective as HS or SS in treating TMD, thus prompting the question of whether costly (hard acrylic) or less costly (soft vinyl) splint therapy is necessary. All groups did receive UT and did improve, which suggests some elements of this treatment are helpful for TMD patients.

As TMD has been shown to be biopsychosocial in nature, an integrated approach to treatment is most promising for TMD patients (Suvinen, Reade, Kemppainen et al.,

2005; Wright et al., 2004). Various biobehavioral treatments have been investigated, including cognitive-behavioral approaches, biofeedback and progressive muscle relaxation (Gatchel, 2002). Dworkin and colleagues (1994) investigated a brief cognitive behavioral therapy (CBT) intervention for patients with TMD. At three-month follow-up, no differences were found between a CBT group and a treatment as usual group. However, improvement in characteristic pain and pain interference was found from 3 to 12 month follow-up for the group receiving the CBT. Additional research by Dworkin and colleagues (2002) showed contrasting results; significant differences were found for follow-up immediately after treatment, while one-year follow-up showed no significant differences. This study (S. F. Dworkin, Turner et al., 2002) tested a six-session CBT tailor-made for TMD patients with poor psychosocial adaptation. Treatment assignment was independent of RDC Axis I diagnosis. Level of psychosocial disability was assessed using the RDC Axis II Graded Chronic Pain Scale (GCP) score. Subjects were included if they had a GCP of II-High, III, or IV. The CBT group received a combination of six sessions of CBT and usual conservative treatment for TMD. The control group received usual treatment, which included the following: physiotherapy, patient education, medication, and intraoral flat-plane occlusal appliances. At four months (post-treatment assessment), the CBT group showed significantly lower levels of pain intensity (RDC Axis II: CPI), significantly higher ability to control TMD pain (self-reported), and lower pain-related interference in daily activities (RDC Axis II; pain interference score), as compared to a treatment as usual group. At one-year follow-up, the CBT group continued to show improved CPI scores, higher ability to control TMD pain, and lower pain-related interference with daily activities; however, statistically significant

differences were not found between the CBT treatment group and the control group. This research team concluded that, at post-treatment, the CBT intervention combined with usual treatment was more efficacious. However, further improvement was limited as the CBT intervention was thought to have been too brief.

Mishra and colleagues (Mishra et al., 2000), recognizing the trend toward cognitive behavioral skills training (CBT), evaluated the efficacy of three biopsychosocial treatments (Gatchel, Stowell, Wildenstein et al., 2006). Chronic TMD patients were assigned to one of four groups: biofeedback (BFB), cognitive-behavioral skills training (CBST), combined (BFB/CBST), or no-treatment. Significantly reduced pain scores on the CPI were found for all three of the treatment groups at three months, but not for the no-treatment group. The BFB group showed greater improvement than either of the other two treatments. Mood states, assessed with the Profile of Mood States (POMS; McNair, Lorr, & Dropelman, 1981), were also greatly improved by all three of the treatments.

Gardea and colleagues (2001) conducted a one-year follow-up of the Mishra and colleagues' study (2000). At 12 months, the combined BFB/CBST treatment group showed the most comprehensive benefit across all outcome measures, while all three treatments resulted in improvements in subjective pain, pain-related disability, and mandibular functioning. As in the original study, the no-treatment group did not experience such improvements (Mishra et al., 2000). Analysis of these two studies suggested that BFB may show greater impact immediately after treatment because this modality focuses on the physical pain, whereas the BFB/CBST combined treatment addresses both physical pain (BFB) and lifestyle issues (CBST).

In two concurrent studies, researchers (Turner, Mancl, & Aaron, 2006; 2005) evaluated the efficacy of CBT for patients with chronic TMD. Turner and colleagues' 2005 study assessed patient's daily electronic ratings of several outcomes and process variables (Turner et al., 2005). Outcomes included: activity interference, pain intensity, jaw use limitations, and negative mood. Process variables included: pain-related beliefs, catastrophizing, and coping. Subjects were randomly assigned to one of two groups: the first, receiving cognitive-behavioral pain management training (PMT), and the second, slated as an education/attention control condition with self care management (SCM). Subjects attended four biweekly sessions for their respective groups and filled out electronic interviews three times daily over the eight week period of treatment. PMT treatment subjects showed a greater improvement as compared to SCM control subjects in the following daily process variable areas: pain-related beliefs, catastrophizing, and coping. Daily electronic outcome measures showed no significant differences. Despite this, greater proportions of PMT subjects than SCM subjects showed improvement on activity interference and jaw use limitations.

In the previous study, Turner and colleagues (2006; 2005) based their outcome measures on electronic diaries collected three times daily during the eight weeks of the study. For their 2006 study, data were collected via questionnaires completed at baseline, 3 months (post-treatment), and again at 6-12-months. Subjects either mailed in the questionnaires or returned them in person. The PMT group had significantly greater improvement at all three follow-up periods on outcome, belief, and catastrophizing measures. Three times as many subjects in the PMT group versus the SCM group reported no interference at 12 months. As a percentage, more PMT subjects had

statistically and clinically significant improvement on pain intensity, masticatory jaw function and depression.

Recently, this research team (Turner, Holtzman, & Mancl, 2007) examined mediators, moderators, and predictors of treatment effects for a subset of subjects from the previously mentioned study (Turner et al., 2006). Turner's team found that perceived pain control accounted for the greatest percentage of the total treatment effect supporting the belief that cognitive-behavioral interventions which address modification of specific pain-related beliefs are beneficial for TMD patients. Based on Turner and colleagues' (2007; 2006; 2005) work, it can be stated that a brief CBT intervention can improve outcomes and is sustainable even at one year follow-up.

While research has validated the efficacy of CBT approaches for TMD patients, most studies have utilized subjects with chronic TMD (S. F. Dworkin et al., 1994; Gardea et al., 2001; Mishra et al., 2000). Chronic and acute TMD patients differ and thus require unique treatments (Gatchel et al., 1996; Grzesiak, 1991). Gatchel and colleagues (2006) addressed this issue by investigating the efficacy of combined CBT/BFB treatment for acute TMD patients. Subjects were classified as HR or LR using an algorithm developed in previous studies (Epker et al., 1999; Wright et al., 2004). The HR subjects were randomly assigned to one of two groups: early intervention (EI) or nonintervention (NI). Pain and psychosocial measures were collected at intake and one-year follow-up. At one-year follow-up, researchers found the following: subjects in the EI group reported significantly lower levels of self-reported pain and depression than subjects in the NI group; EI group subjects had improved coping abilities; NI group subjects had utilized health care resources for jaw pain more than the EI group members; and NI group

subjects were more likely than EI group subjects to carry certain SCID Axis I diagnoses (12.5 times for somatoform disorders, 7 times for anxiety disorders, 2.7 times for affective disorders). Also, subjects who received early-intervention (EI) were more capable of managing their pain, thus reducing the risk of developing chronic, costly jaw pain.

Gatchel and colleagues (Gatchel, Stowell, & Buschang, 2006) also examined the relationships among depression, pain, and masticatory functioning within the EI group. No significant differences were found on self-reported pain levels (CPI) between depressed subjects and non-depressed subjects at intake as well as at one-year follow-up. This suggests that the treatment was effective regardless of any pre-existing depression. In addition, these findings further support the importance of early intervention and the need to prevent conversion to chronic TMD.

PURPOSE OF THE PRESENT STUDY

Research has been conducted in various areas of TMD. However, a thorough literature review (CINAHL-Cumulative Index to Nursing & Allied Health Literature, Ovid MEDLINE(R), PsychINFO, PubMed; May 28, 2007) reveals that most studies have focused on chronic subjects and/or have limited follow-up. Turner (2006) and Dworkin (2002) looked at the effectiveness of CBT interventions for TMD patients at one-year follow-up; however, both of these studies utilized chronic TMD subjects. Gatchel (1996; 2006) and Wright et al (2004), concerned with differentiating chronic versus acute, as well as HR versus LR patients, have investigated both chronic and acute

TMD populations. With the ability to classify these patients comes the possibility to create more unique and efficacious treatment interventions (Wright et al., 2004), as well as the opportunity to intervene early and thereby reduce the risk of progression to chronic TMD. In addition to physical and emotional benefits for patients, early intervention reduces health care visits and thus health care costs (Gatchel, Stowell, Wildenstein et al., 2006; Stowell et al., 2007).

In the one-year outcome study of patients with acute TMD, Gatchel and colleagues (2006) found an early biopsychosocial intervention to be effective in reducing pain levels and emotional distress, while also improving coping abilities for an acute HR TMD study group. Subjects who received early-intervention (EI) were more capable of managing their pain, thus reducing the risk of developing chronic, costly jaw pain. The purpose of the present prospective study was to evaluate subjects' progress long-term post-treatment and determine if the benefits achieved at one year were sustainable. In a Letter to the Editor (Stowell & Gatchel, 2007) regarding Stowell and colleagues' recent cost article (Stowell et al., 2007), a reader highlighted the need for a long-term follow-up (LTF) of these initial acute subjects, post one-year follow-up. In response to this letter, the researchers (Stowell & Gatchel, 2007) agreed that an LTF would be groundbreaking. With LTF results supporting one-year outcome study results, this study was planned to provide more evidence for early biopsychosocial interventions as part of future treatment protocols for acute TMD (Gatchel, Stowell, Wildenstein et al., 2006).

HYPOTHESES

As this study was a follow-up to an earlier study (Gatchel, Stowell, Wildenstein et al., 2006), it was expected that the LTF study would replicate the one-year outcome study results, demonstrating the maintenance of one-year gains. Hypotheses are stated accordingly.

1. At LTF, no significant differences would be found in demographic variables between EI group subjects and NI group subjects, for those subjects able to be contacted.
2. At LTF, no significant differences would be found in demographic variables between those subjects with LTF data and those without LTF data.
3. At LTF, EI group subjects would have utilized outside health care for jaw-related pain less than NI group subjects.
4. At LTF, EI group subjects would have significantly lower levels of self-reported pain (CPI) than the NI group subjects.
5. At LTF, EI group subjects would have significantly lower levels of self-reported pain (CPI) as compared to intake.
6. At LTF, EI group subjects would have significantly improved coping abilities (WOC) as compared to the NI group subjects.
7. At LTF, EI group subjects would have significantly improved coping abilities (WOC) as compared to intake.
8. At LTF, EI group subjects would have significantly lower levels of self-reported depression (BDI-II) than the NI group subjects.

9. At LTF, EI group subjects would have significantly lower levels of self-reported depression (BDI-II) as compared to intake.
10. At LTF, EI group subjects would have fewer DSM-IV-TR Axis I diagnoses than the NI group subjects.
11. At LTF, EI group subjects would have fewer DSM-IV-TR Axis II diagnoses than the NI group subjects.

CHAPTER THREE METHODOLOGY

Subjects

This LTF study utilized the subject pool of the one-year outcome study conducted by Gatchel and colleagues (2006), in addition to other patients within the study who had since completed the study. HR subjects (those at risk for progressing to chronic TMD) were identified at intake using an algorithm developed in previous studies to predict risk status (Epker et al., 1999; Wright et al., 2004). Of the 101 HR acute jaw pain subjects who participated in the one-year outcome study, there were 81 females (80%) and 20 males (20%). The mean age for the total sample was 37.76 years, with a range from 18.00 to 61.45 years. Subjects were referred by dentists and oral surgeons in the area, as well as recruited via fliers at local universities or advertisements placed in local newspapers for participation in the TMD Clinical Research Project at The University of Texas Southwestern Medical Center at Dallas. Adults with acute jaw or facial pain of less than six months were randomly assigned to an early-intervention (EI) or nonintervention (NI) group using an Urn Randomization Method. Exclusion criteria included comorbid pain-exacerbating physical conditions (such as fibromyalgia or cancer), a prior history of jaw pain or non-English speaking. At LTF, 112 high risk subjects were entered in the study, this included the 101 in the original one-year outcome study (2006) and an additional 11 subjects who had completed the one-year follow-up since that study, with 62 in the EI group and 50 in the NI group. The goal of the LTF study was to assess all 112 subjects post one-year follow-up.

Procedure

The purpose and procedures of the study were reviewed with subjects at intake by a research personnel team member. In addition, informed consent was explained and obtained during intake to subjects of the study. The initial phase took approximately 2.5 hours, and subjects were compensated \$70 for their time. The intake protocol was based on a previous study by Wright and colleagues (2004), and included a physical examination, as well as self-report and clinician administered psychosocial measures. An abbreviated version of the RDC (S. F. Dworkin & LeResche, 1992) was performed in order to assess for the presence or absence of myofascial pain (Epker et al., 1999). Specifically, Axis I-Group 1a of the RDC, which involves palpation of 20 muscle sites and the subject's response to question number three of the RDC history questionnaire, ("Have you had pain in the face, jaw, temple, in front of the ear, or in the ear in the last month?") was utilized in determining diagnosis of myofascial pain. Psychosocial measures included the following: a general information questionnaire, the BDI-II, the WOC, the SCID-I and SCID-II, and the CPI.

Consecutive subjects were randomly assigned to the EI group or the NI group. The EI group received a combined cognitive behavioral therapy /biofeedback (CBT/BFB) treatment based on a previous study (Mishra et al., 2000), provided by doctoral and master's level study personnel (A.W.S./L.W.). Psychosocial, pain, and physical measures were assessed again at one year. All subjects were instructed to continue treatment as usual with their own health care providers as needed. The same psychosocial, pain, and physical measures collected at the one-year evaluation were collected again for the LTF study (Gatchel, Stowell, Wildenstein et al., 2006). Also, a

participant ratings survey (PRS) was given to all LTF participants in order to collect additional information in the following areas: skills and techniques; jaw pain-related symptoms; and program evaluation and feedback. Subjects were offered compensation for participating in the LTF study with amounts ranging from \$20-\$100, dependent upon reimbursement needs, i.e. travel, childcare, etc.

Instruments and Outcome Measures

General Information Questionnaire. At intake, all subjects were given a questionnaire covering the following areas: demographic information (name, gender, age, marital status, contact information, referral source, occupation, education), physical health, medication, history of jaw pain (onset, date of treatment, type of treatment).

Beck Depression Inventory-II (BDI-II; Beck et al., 1996). The BDI-II is a 21 item measure that serves as an indicator of the occurrence and severity of the physical and emotional symptoms of depression. The BDI-II is a self report measure that utilizes a four point scale (0 to 3) for each item. The sum of the 21 items is compared to cut score guidelines in order to establish an interpretive range (Beck et al., 1996). Suggested cut scores are as follows: <10 absence of depression; 10-18 mild to moderate depression; 19-29 moderate to severe depression; and >29 severe depression. The BDI-II is appropriate for use in subjects 13 years of age and up.

The BDI was first developed in 1961 and has become a gold standard for medical and psychological research (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). The latest version, the BDI-II, contains DSM-IV criteria for depression (Beck et al., 1996). Good validity and reliability have been established for the BDI-II, [Reliability: the BDI-

II yields a coefficient alpha of .92 and a test-retest correlation of .93 (Beck et al., 1996). Validity: this measure is positively correlated with the Hamilton Psychiatric Rating Scale for Depression ($r = .71$) and the Beck Hopelessness Scale ($r = .68$) (Beck et al., 1996)]. In addition, studies have supported the validity of the BDI-II as a measure of depression in chronic pain patients (Geisser, Roth, & Robinson, 1997; Novy, Nelson, Berry, & Averill, 1995). A limitation of the BDI-II is a confounding of somatic items with pain symptoms (Wesley, Gatchel, Polatin, Kinney, & Mayer, 1991). Relative to pain patients, studies recommend removal of some items and/or modification of cut scores (Geisser et al., 1997; Wesley, Gatchel, Garofalo, & Polatin, 1999).

Ways of Coping (WOC; Folkman & Lazarus, 1988). The WOC is a 66-item questionnaire developed to assess the coping style used by individuals in stressful situations. Styles may be either adaptive or maladaptive and include the following -- Adaptive: *Problem-focused* and *Seeks Social Support*; Maladaptive: *Blame-self*, *Wishful Thinking*, *Avoidance*. Encounters are described by the subject and may be used as the focus of the questionnaire. The scoring method utilized in this study was developed by Vitaliano and colleagues (1985; 1987), and assesses a participant's coping style by providing a percentage of coping effort by style. The benefit to this method is that interrelationships among styles are considered. A Cronbach's alpha of .53 to .80 was found for within-scale item correlations.

Characteristic Pain Intensity (CPI; S. F. Dworkin & LeResche, 1992). The CPI is a measure of pain severity for TMD derived from the RDC's History Questionnaire (S. F. Dworkin & LeResche, 1992). The CPI is scored from 0 to 100 with 100 being the most pain. The mean score of questions 7 to 9 (pain right now, worst pain, average pain)

are taken and then multiplied by 10. Since the development of the RDC, the CPI has been used in many TMD studies (Gardea et al., 2001; Garofalo et al., 1998; Gatchel, Stowell, Wildenstein et al., 2006; Mishra et al., 2000).

Structured Clinical Interview for DSM-IV (SCID-I; First, Spitzer, Gibbon et al., 1995). The SCID-I was developed to assess the presence or absence of DSM-IV Axis I disorders. A semi-structured interview, the SCID-I captures the following information: current and lifetime diagnoses; history of physical or sexual abuse; time line of psychiatric diagnosis and pain symptoms; and global assessment of functioning (GAF). The SCID-I is administered by a trained professional who may use clinical judgment and ask any questions necessary to reach a differential diagnosis.

Reliability has been proven to be good in the following areas: test-retest kappa greater than .60 for Major Depressive Disorder (MDD), Bipolar Disorder, and Schizophrenia (Williams et al., 1992); interrater agreement greater than 80% for MDD and GAD (Riskind, Beck, Berchick, Brown, & Steer, 1987; Skre, Onstad, Torgersen, & Kringlen, 1991). Joint interview studies where a subject is interviewed by one clinician, while a second clinician observes (in person or by tape), produced even better reliability coefficients for MDD (.90; Segal, Kabacoff, Hersen, V.B., & Ryan, 1995; Zanarini & Frankenburg, 2001). Validity has been more difficult to assess in the SCID-I as agreement on a “gold standard” for psychiatric diagnosis has not been possible. In lieu of a “gold standard”, studies have looked at validity using “best estimate diagnosis” and found superior validity over standard clinical practices (Basco et al., 2000; Kranzler, Ronald, & Burleson, 1995).

In the one-year study, SCID-I diagnoses were categorized as current (experiencing the disorder), past (previously experienced but not currently experiencing), or lifetime (combination of current and past) (Gatchel, Stowell, Wildenstein et al., 2006). Current diagnoses included: current, sub-current, and current & lifetime. Past diagnoses included: lifetime and sub-past. The LTF study also employed the same SCID-I diagnoses categories.

Structured Clinical Interview for DSM-IV Personality Disorders (SCID-II; First et al., 1994) . The SCID-II was developed to assess the presence or absence of DSM-IV Axis II disorders. The SCID-II is a semi-structured interview that includes 11 DSM-IV Personality Disorders and is administered following the SCID-II Personality Questionnaire (SCID-II-PQ). Subjects are asked to complete the 120-item questionnaire prior to the interview so that the clinician may focus on only those items answered “yes”. By having a screening tool, clinicians can direct their efforts more economically.

Reliability has been proven to be fair in the following areas: test-retest kappa range from .50 to .80 for most Axis-II diagnoses (Dreesen & Arntz, 1998; First, Spitzer, & Gibbon, 1995); and interrater agreement for joint interview studies ranges from .60 to .98 for most Axis-II diagnoses (Dreesen & Arntz, 1998; Maffei et al., 1997). Validity studies for the SCID-II face the same challenge as the SCID-I; there is no “gold standard” for psychiatric diagnoses. While the SCID-II has been shown to have concurrent validity (Hueston, Mainous, & Schilling, 1996; Skodol, Rosnick, Kellman, Oldman, & Hyler, 1988) other studies have found diagnostic power to vary by diagnosis (Skodol et al., 1988).

In Gatchel and colleagues' one year study (2006), SCID-II diagnoses were utilized by cluster. The DSM-IV delineates the following three clusters for Axis II personality disorder diagnoses: Cluster A (Schizoid, Paranoid, Schizotypal); Cluster B (Antisocial, Narcissistic, Histrionic, Borderline); and Cluster C (Obsessive Compulsive, Dependent, Avoidant). Research supports the use of clusters for categorizing patients in general, as well as with pain patients (Reich & Thompson, 1987; Widiger, Trull, Hurt, Clarkin, & Frances, 1987). The LTF study also employed the same SCID-II diagnostic clusters.

Participant Ratings Survey (PRS). At LTF, all subjects were given a 7-question participant ratings survey covering the following areas: skills and techniques, jaw pain-related symptoms, and program evaluation and feedback. Questions 1-6 were developed using a 5-point Likert scale while Question 7 was designed for an unstructured response (Material 1).

Intervention

The intervention for the one-year outcome study was developed from Mishra and colleagues' (2000) study (Gatchel, Stowell, Wildenstein et al., 2006). The combined CBT/BFB treatment, which yielded significant results in a previous study, was shortened to six one-hour sessions for the one-year outcome study (Gardea et al., 2001; Gatchel, Stowell, Wildenstein et al., 2006). A standardized treatment protocol manual was developed to ensure treatment delivery in a structured manner. Subjects were made aware that the treatment protocol was a general program targeted at stress-related problems throughout the six sessions via discussion of the link between stress and

persistent medical and dental difficulties. A modified version of Lewinsohn's (1984) CBT program for depression served as the basis for the CBT protocol, while skill components were integrated from some pain management programs. The following topics were included in the protocol: education regarding the mind-body relationship with an emphasis on stress and the body's reaction to stress; relaxation training in ideal and everyday settings; use of distraction and pleasant activity scheduling as a means of reducing the impact of pain on activities; cognitive restructuring; and self-instructional training and skills maintenance.

The BFB aspect of the protocol, developed by one of the authors (R.J.G.) and investigated in earlier studies (Gardea et al., 2001; Mishra et al., 2000), was shortened from 12 visits to 6 visits for Gatchel and colleagues' prior study (2006), as in other studies (Arena & Blanchard, 1996; Gatchel, 1997; Glass, Glaros, & McGlynn, 1993). Electromyogram (EMG), respiration, and temperature biofeedback units were used in the sessions. EMG BFB electrodes were placed over frontales muscles for all subjects.

In typical CBT fashion, subjects were given workbooks with reading assignments and homework. Subjects were asked to make-up missed sessions in order to maintain session sequencing. Missed or extra sessions were noted by research personnel. Therapists who conducted training received individual, group training, and were supervised weekly by a senior member of the research team, licensed psychologist (A.W.S). Treatment sessions were audio-taped and randomly reviewed to ensure reliable administration.

Statistical Analyses

Analyses were carried out to detect significant differences in demographic variables between EI and NI subjects with LTF data, and between subjects with LTF data and those without LTF data. The following were included: gender, race, marital status, employment status, referral type, health insurance, dental insurance, years of education, age, days of pain and income. Pearson Chi-Square (χ^2) analyses were used for categorical variables (gender, race, marital status, employment status, referral type, health insurance, dental insurance), while one-way analysis of variance (ANOVAs) were used to compare years of education, age, days of pain, and income. When data did not meet criteria for use of one-way ANOVA, the nonparametric Mann-Whitney test was utilized. Due to the differing numbers across time, a repeated-measures ANOVA was conducted on jaw pain-related health care visits for subjects in the EI and NI groups. Type of intervention was designated as the between-groups factor and time interval was considered the repeated measure (intake, one-year, and LTF).

Psychosocial change was assessed with variables from the following measures: WOC, BDI-II, SCID-I and SCID-II, while self-reported pain change was assessed with CPI scale scores. The CPI, BDI-II, and subscales of the WOC were analyzed using a repeated-measures ANOVA, with type of intervention as the between-groups factor and time interval as the repeated measure (intake, one-year, and LTF). All analyses were screened for violations of the sphericity assumption using Mauchly's Test of Sphericity. When this assumption was violated (only for the BD-II), the Huynh-Feldt correction for degrees of freedom was applied to the analysis, signified by degrees of freedom values that are expressed as real numbers instead of the standard round numbers. Significant

group-by-time interactions were decomposed using simple effect contrasts expressed as the linear trend for time at the level of each group. Effect sizes were also reported for all significant results. Partial eta-squared (η^2), the effect size reported in this study, can be interpreted as the variance accounted for by the effect in question, ignoring systematic variance due to other factors in the analyses. Descriptive magnitudes of this effect size are as follows: .010 for small effect; .059 for medium effect; and .138 for large effect.

Prevalence of DSM-IV-TR Axis I and Axis II pathology was analyzed with Pearson Chi-Square (χ^2) analyses to assess any differences in number and types of diagnoses between groups. Means and standard deviations were calculated to analyze Questions 1-6 of the PRS. In addition, the nonparametric Mann-Whitney test was utilized to assess differences between groups on Questions 3-5.

CHAPTER FOUR

RESULTS: DEMOGRAPHIC CHARACTERISTICS

Descriptive Analyses

LTF data were collected from 45 out of 112 HR subjects originally enrolled in the earlier reported Acute Jaw Pain Study (Gatchel, Stowell, Wildenstein et al., 2006). With subjects two-six years out from intake, it was a challenge to contact subjects and collect data. All of the 112 subjects were attempted to be contacted, but data could not be collected from 67 subjects for the following reasons: could not reach ($n = 45$); refused to participate ($n = 7$); and expressed interest but were unable to participate ($n = 15$). Of the 45 LTF subjects, 29 were in the EI group and 16 were in the NI group. Data were collected from 16 subjects (EI, $n = 11$; NI, $n = 5$) by a combination of phone, email and mail, while 29 subjects (EI, $n = 18$; NI, $n = 11$) were seen in-person. One subject was excluded from LTF as this subject had received the study treatment intervention post one-year follow-up per subject request prior to the decision to conduct the LTF study. Of the 44 remaining LTF subjects, 29 were in the EI group and 15 were in the NI group (Figure 1). At LTF, subjects' time since intake ranged from approximately 2 to 6 years (Table 1).

Analyses were run to compare the following: LTF EI versus NI subjects; subjects with LTF data versus subjects without LTF data; and subjects with LTF data versus subjects without LTF data within the EI and NI groups. Variables analyzed included: gender, race, marital status, employment status, referral type, health insurance, dental insurance, years of education, age, days of pain and income. Pearson Chi-Square (χ^2) analyses were used to compare group subjects on categorical variables, while ANOVAs were used to compare groups as continuous variables. When data did not meet

criteria for a one-way ANOVA, the nonparametric Mann-Whitney test was utilized. A repeated-measures ANOVA was conducted on jaw pain-related health care visits for subjects in the EI and NI groups with intervention as the between-groups factor and time interval as the repeated measure (intake, one-year, and LTF).

Comparison of LTF Early Intervention (EI) versus Non-Intervention (NI) Subjects

No significant differences were found between LTF EI and NI group subjects on the following variables: gender, race, employment status, referral type, health insurance, dental insurance, years of education, age, days of pain and income. A significant difference was only found for marital status [$\chi^2(2, 44) = 10.77, p = .01$]. Specifically, there were more subjects married / living together as married in the EI group (72.4%) versus in the NI group (33.3%), and thus less single subjects in the EI group (27.6%) versus the NI group (40.0%). In addition, none of the EI subjects were divorced/separated (0.0%), while more than a quarter of the NI subjects (26.7%) fell into this category. Results are summarized in Table 2.

Comparison of Subjects With LTF Data versus Subjects Without LTF Data

No significant differences were found between subjects with LTF data versus subjects without LTF data on the following variables: gender, race, marital status, employment status, referral type, health insurance, dental insurance, age, and income. Significant differences were found for days of pain, $F(1, 110) = 3.84, p = .05$, and for years of education, $F(1, 110) = 7.72, p = .01$. Mean number of days of pain were significantly less for subjects with LTF data ($M = 87.52$), as compared to subjects

without LTF data ($M = 105.59$). Mean years of education were significantly higher for subjects with LTF data ($M = 16.07$) as compared to subjects without LTF data ($M = 14.97$). Results are summarized in Table 3.

When examining subjects with LTF data versus subjects without LTF data within EI and NI groups, similar findings occurred. No significant differences were found within the EI group between subjects with LTF data versus subjects without LTF data on the following variables: gender, race, marital status, employment status, referral type, health insurance, dental insurance, age, days of pain and income. A significant difference was found for years of education, $F(1, 60) = 7.72, p = .01$. Mean years of education were significantly higher for subjects in the EI group with LTF data ($M = 15.90$), as compared to subjects in the EI group without LTF data ($M = 14.55$). Results are summarized in Table 4.

No significant differences were found within the NI group between subjects with LTF data versus subjects without LTF data on the following variables: gender, race, employment status, referral type, health insurance, dental insurance, age, years of education, and income. Significant differences were found for marital status, $[\chi^2(2, 50) = 6.35, p < .05]$, and days of pain $U = 155.00, z = -2.28, p = .02$. Specifically, there were fewer subjects married / living together as married in the NI group with LTF data (33.3%) versus in the NI group without LTF data (71.4%). Thus less single subjects in the NI group without LTF data (17.1%) versus the NI group with LTF data (40.0%), and less divorced or separated subjects in the NI group without LTF (16.0%) versus the NI group with LTF data (26.7%), was found. Mean number of days of pain were

significantly less for NI subjects with LTF Data ($M = 77.87$) as compared to NI subjects without LTF data ($M = 108.03$). Results are summarized in Table 5.

Comparison of Jaw Pain-Related Health Care Visits for EI and NI Subjects

No significant main effects were found for group or time on jaw pain-related health care visits. However, the group-by-time interaction was significant, $F(1, 20) = 4.49, p = .05, \eta^2 = .18$. Although an increasing trend for visits was associated with the NI group over time, simple linear trend contrasts on the interaction trend failed to reach significance beyond the overall interaction term. Figure 2 illustrates the nature of the interaction between groups and time on mean visits. Table 6 presents the number of jaw pain-related health care visits by subject. Results are summarized in Table 7.

CHAPTER FIVE

RESULTS: SELF-REPORTED PAIN VARIABLES

Pain: CPI

CPI scores were analyzed using a repeated-measures ANOVA, with type of intervention as the between-groups factor and time interval as the repeated measure (baseline, one-year, and long-term follow-up). Significant group-by-time interactions were decomposed (observed effect of time within each of the groups individually) using simple effect contrasts, expressed as the linear trend for time at the level of each group. No significant main effect for group on CPI scores was found. However, significance was found for the main effect of time, with a decreasing linear trend of CPI scores between intake and LTF, $F(1, 41) = 58.35, p < .01, \eta^2 = .59$. In addition, the group-by-time interaction was significant, $F(2, 82) = 4.02, p = .02, \eta^2 = .09$. Simple linear trend contrasts of the interaction effect indicated a decreasing linear trend of CPI scores across time for the EI group, $F(1, 27) = 86.73, p < .01, \eta^2 = .76$. There was also a decreasing linear trend of CPI scores across time for the NI group, although not as great as the EI group, $F(1, 14) = 8.21, p = .01, \eta^2 = .37$. Figure 3 illustrates the nature of the interaction between groups and time.

Intake and one-year follow-up CPI scores were examined for subjects with LTF data and subjects without LTF data. No significant differences were found within the EI Group between subjects with LTF data versus subjects without LTF data, or within the NI group between subjects with LTF data versus subjects without LTF data. Results are summarized in Tables 8 and 9.

CHAPTER SIX

RESULTS: PSYCHOSOCIAL VARIABLES

Coping Measures: WOC

WOC subscale scores were analyzed using a repeated-measures ANOVA, with type of intervention as the between-groups factor and time interval as the repeated measure (baseline, one-year, and long-term follow-up). Significant group-by-time interactions were decomposed using simple effect contrasts, expressed as the linear trend for time at the level of each group. No significant differences were found between groups or across time periods. EI group subjects improved on average from intake to LTF on all five subscale coping styles, while NI group subjects only improved on average on one of the subscale coping styles. Results are summarized in Table 8.

Mood and Personality Measures: BDI

BDI-II total scores were analyzed using a repeated-measures ANOVA, with type of intervention as the between-groups factor and time interval as the repeated measure (baseline, one-year, and long-term follow-up). BDI-II analyses were screened for violations of the sphericity assumption using Mauchly's Test of Sphericity. This assumption was violated, and the Huynh-Feldt correction for degrees of freedom was applied to the analysis, signified by degrees of freedom values that are expressed as real numbers instead of the usual round numbers. Significant group-by-time interactions were decomposed using simple effect contrasts, expressed as the linear trend for time at the level of each group.

No significant main effects were found for group or time on the BDI scores. However, the group-by-time interaction was significant, $F(1.82, 72.88) = 3.33, p = .05, \eta^2 = .08$. Simple linear trend contrasts on the interaction indicated a decreasing linear trend of BDI scores across time for the EI group, $F(1, 27) = 4.09, p = .05, \eta^2 = .13$. The linear trend of BDI scores across time for the NI group failed to reach significance. Figure 4 illustrates the nature of the interaction between groups and time.

Intake and one-year follow-up BDI-II total scores were examined for subjects with LTF data and subjects without LTF data. No significant differences were found within the EI Group between subjects with LTF data versus subjects without LTF data, or within the NI group between subjects with LTF data versus subjects without LTF data. Results are summarized in Tables 8 and 9.

Mood and Personality Measures: SCID

Pearson Chi-Square (χ^2) analyses were used to compare LTF EI and NI group subjects on prevalence of DSM-IV-TR diagnoses at three time intervals (intake, one-year follow-up, and LTF). Data were analyzed in three ways: presence or absence of Axis I or II diagnoses; primary groups of Axis I and Axis II diagnoses; and individual diagnoses. Data were examined for 29 subjects (EI, $n = 19$; NI, $n = 10$) at intake, one-year follow-up, and LTF. SCID-I and SCID-II data were not collected from 2 subjects within the LTF group (EI, $n = 2$) at one-year follow-up, and 15 subjects within the LTF group (EI, $n = 10$; NI, $n = 5$) at LTF. Due to limited time availability, 15 subjects who participated by phone were unable to complete a SCID-I or SCID-II.

Assessing absence or presence of Axis I or Axis II diagnoses, no significant differences were found between groups at intake for prevalence of Axis I or Axis II diagnoses. One-year follow-up data analyses revealed that subjects in the EI group had significantly fewer Axis I diagnoses than subjects in the NI group [$\chi^2(1, 29) = 7.64, p = .01$ (OR = 11.20; 95 percent CI, 1.75 to 71.64)]. However, no significant differences were found with one-year follow-up data for Axis II diagnoses. In addition, no significant differences were found between groups at LTF for prevalence of Axis I or Axis II diagnoses.

When examining primary groups of DSM-IV-TR Axis I diagnoses (affective disorders, anxiety disorders, somatoform disorders, substance abuse disorders), intake data analyses yielded significant results for anxiety disorders [$\chi^2(1, 29) = 5.06, p = .03$ (OR = .10; 95 percent CI, .01 to .95)] with EI group subjects having a higher prevalence than NI group subjects. For one-year follow-up data, EI group subjects had significantly fewer somatoform disorders [$\chi^2(1, 29) = 8.52, p < .01$ (OR = 12.44; 95 percent CI, 2.00 to 77.60)] as compared to NI group subjects. LTF data analyses revealed no significant results for primary group diagnoses.

With regard to individual diagnoses analyses, EI group subjects exhibited a higher prevalence of GAD for intake data [$\chi^2(1, 29) = 4.86, p = .03$]. EI group subjects showed significantly less prevalence than NI group subjects on one-year follow-up data for pain disorder [$\chi^2(1, 29) = 8.52, p < .01$]. LTF data analyses yielded no significant results for individual diagnoses. Results are summarized in Tables 10, 11 and 12.

As SCID-I and SCID-II data were not collected for 2 subjects at one-year follow-up and 15 subjects at LTF, an intent-to-treat statistical method to calculate the projected one-year follow-up and LTF results was utilized. This method, last-observation-carried-forward (LOCF), replaces missing values with the last non-missing value. The same analyses were run with LOCF data as described above; however, no additional significant findings resulted.

CHAPTER SEVEN

RESULTS: PARTICIPANT RATINGS SURVEY (PRS)

An informal survey was created by this research team in order to capture additional information that was not covered by study outcome measures. The 7-question PRS was completed by 43 of the 44 subjects who participated in the LTF (Material 1). Means and standard deviations were calculated for Questions 1-6, which were designed as 5-point Likert scales. In addition, the nonparametric Mann-Whitney test was utilized to assess differences between groups on Questions 3-5. Results are summarized in Table 13 and discussed in detail below.

Skills and Techniques

Questions 1 and 2 were related to skills and techniques acquired as part of the intervention, and thus were only applicable to EI participants. In response to Question 1, EI subjects reported that, on average, they used skills and techniques learned in the study to manage their jaw pain *monthly* ($M = 2.61$, $SD = 1.26$). In response to Question 2, EI subjects reported that, on average, they had been *successful* at using the skills and techniques learned in the study ($M = 2.21$, $SD = 1.12$).

Jaw Pain-Related Symptoms

Questions 3-5, which covered jaw pain-related symptoms, were applicable to EI and NI participants. Significant differences were found between groups on all 3 questions (Q3: $U = 108.5$, $z = -2.77$, $p = .01$; Q4: $U = 79.0$, $z = -3.68$, $p < .01$; Q5: $U = 127.5$, $z = -2.23$, $p = .03$). In response to Question 3, both EI and NI subjects reported

that, on average, their jaw pain-related symptoms were *better* (EI: $M = 1.57$; $SD = .79$, NI: $M = 2.40$, $SD = .99$). In response to Question 4, EI subjects reported that, on average, their jaw pain-related symptoms were *much less frequent* ($M = 1.32$, $SD = .55$), while NI subjects reported on average their jaw pain-related symptoms were *less frequent* ($M = 2.40$, $SD = .99$). In response to Question 5, both EI and NI subjects reported that, on average, the duration of their jaw pain-related symptoms was *shorter* (EI: $M = 1.71$, $SD = .81$; NI: $M = 2.33$, $SD = .90$).

Program Evaluation and Feedback

Questions 6 and 7 were related to the study evaluation and thus were only applicable to EI participants. In response to Question 6, 28 out of 29 EI subjects reported they would be *very likely* ($n = 15$) or *likely* ($n = 12$) to recommend the study intervention, while none of the EI subjects reported *not likely* or *definitely not*. Question 7 asked for any other comments or feedback about the intervention. In response to Question 7, subjects perceived the treatment to be beneficial. Below are excerpts from some of their responses.

“I tell all the people I know about this research and how pain and stress go hand in hand.”

“Thanks to [one of the study therapists, L.W.]. I learned many things about myself and jaw pain. It helps on other areas of my life.”

“It has helped me immensely; I always use the techniques whenever I sense my jaw is getting tense.”

“[The intervention] helped with stress management and how to say no to people.”

“[I] got a lot out of the ways to relax, and [to] remind myself not to clench with the sticky notes around the house at stressful times.”

“[You should] open this treatment up to all muscle tension pain such as headaches.”

CHAPTER EIGHT DISCUSSION

The present LTF study further supports and extends the findings of the earlier one-year outcome study by Gatchel and colleagues (2006), indicating an early biopsychosocial intervention is efficacious for patients with acute TMD. By receiving treatment during the acute stage of TMD, patients were less likely to develop chronic TMD. This study was the first to follow TMD subjects past one-year; in fact, between two to six years post intake. As such, it was remarkable that 40% of study subjects participated, and that EI subjects continued to report significantly reduced pain levels, emotional distress, and jaw pain-related health care visits relative to NI subjects. In addition, EI subjects' perceived the intervention as very valuable with 96% *very likely* or *likely* to recommend the study intervention.

Most importantly, the overall statistically significant findings for the CPI, BDI-II, and jaw pain-related health care visits, were quite impressive. There is now a general consensus that a 30% reduction of pain is clinically meaningful (Farrar, Young, LaMoreaux, Werth, & Pool, 2001). This has been further recommended by the IMMPACT group (R. H. Dworkin et al., 2005). This recommendation is primarily based on the results of an analysis of the relationships between changes in pain intensity and patient reports of overall improvement in 10 clinical trials on pain patients with diverse diagnoses (Farrar et al., 2001). Importantly, these relationships were consistent across age, gender, treatment group (different dosages of pregabalin / placebo), five different clinical conditions, and whether the study results demonstrated separation from placebo or not. With the 30% reduction value in mind, for the EI group in the present study, there

was approximately a 100% decrease on the CPI measure of pain from intake ($M = 58.68$) to both one-year follow-up ($M = 23.81$) and LTF ($M = 28.46$). Even though the NI group also showed a decrease on the CPI, the decrease by the EI group was more than 50% greater than the NI group! The results for the BDI-II measure were comparable as EI group subjects once again had a decrease, this time on emotional distress. The EI group decreased by more than 40% from intake ($M = 8.39$) to both one-year follow-up ($M = 5.39$) and LTF ($M = 5.95$), in contrast with the NI group, who increased by more than 30% from intake ($M = 6.21$) to LTF ($M = 8.68$). In addition, analyses of jaw pain-related health care visits showed a decreasing trend for the EI group by 7% from intake ($M = 2.67$) to LTF ($M = 2.50$), while the NI group increased dramatically by 88% from intake ($M = 1.30$) to LTF ($M = 11.30$). As number of jaw pain-related visits directly relates to cost, this finding highlights the financial benefit to EI group subjects over NI group subjects.

Foremost, from the analyses, is the finding of an interaction effect (group-by-time) for CPI, BDI-II, and jaw pain-related health care visits, which provides further evidence of differences between the EI group and the NI group over time. Medium to large magnitude effect sizes suggest that differences between groups can be attributed to the study intervention, and that a larger n (increased power), would have resulted in significant findings on more measures. Thus, the statistical analyses clearly demonstrate the physical, emotional, and cost benefits which resulted from the study intervention. These findings are even more compelling in light of the fact that NI group subjects had considerably more jaw pain-related health care visits as compared to EI group subjects. This brings into question the efficacy of traditional treatments; more visits (treatment)

may not lead to significant improvement; whereas, biopsychosocial treatments, such as the intervention in this study, can lead to significant improvement.

While statistically significant differences were not found for the WOC, EI group subjects benefited from the intervention. EI group subjects improved from intake to LTF on all five subscale coping styles, as compared to NI group subjects who only improved for one of the subscale coping styles. With a larger n (more LTF participants) and more power, differences detectable at one-year follow-up may have been replicated at LTF.

PRS / Subject Feedback

The survey was particularly useful with the EI subjects, as it highlighted that while the EI subjects may not have shown statistically significant improvement on some outcome measures at LTF, many of them perceived that they had benefited greatly from the study intervention. While the study measures captured most aspects of the intervention effect, subject feedback suggests that there may be additional benefits not reflected in study measures. EI subjects were very enthusiastic about the intervention as evidenced by their continued use of the skills and techniques, and willingness to recommend this intervention. Even though NI group subjects had more jaw pain-related health care visits than EI subjects at LTF, many of them still reported TMD symptoms, and over half of them requested to receive the study intervention.

Limitations

While significant results were found in the same areas, several global factors may have contributed to fewer significant findings at LTF than at one-year follow-up. First,

the small sample size of the LTF study ($n = 44$) impacted statistical power and thus the ability to detect differences. With subjects two-six years out from intake, it was a challenge to contact subjects and collect data. Some subjects, elected not to participate due to lack of time or lack of interest. Other subjects had moved, and could not be contacted. Ideally, we would have liked 100% participation. Second, having fewer NI subjects may have made it difficult to find differences. NI subjects may have been less motivated to participate as they had not received the study intervention. Clearly, a more balanced sample groups would have been preferable. Third, statistical phenomena, such as regression towards the mean, and the floor effect, may have increased “noise” or error variance that, in turn, mitigated against finding statistical significance on some measures.

Another potential limitation was that researchers did not initially plan for an LTF, and consequently subjects and personnel assumed study completion at one-year follow-up. If a longer follow-up had been planned from intake, contact would have continued every 3 months, dramatically improving LTF participation. Jaw pain patients have been found to be very cooperative and responsive relative to other pain populations, and as such, with notification of an LTF at intake and on-going follow-up, LTF participation rates would have been better. Also, the death of a key research contact may have limited interest and affected the return call rate. However, by utilizing new research personnel at LTF, interviewer bias was minimized.

An additional limitation was that differences were found in marital status, days of pain, and years of education between LTF EI and NI subjects, and between subjects with LTF data and subjects without LTF data. At intake, subjects were randomized to EI and NI groups by an Urn Randomization Method. Differences were not found with the one-

year follow-up subject pool ($n = 101$), and thus differences found in this subset ($n = 44$) are unexplainable.

Future Research

Future research in acute TMDs would greatly benefit if long-term follow-ups or at least 2-year follow-ups were incorporated into studies. A long-term follow-up was not planned from the onset of this study, and as such, future studies might inform subjects at intake of the possibility of contact for several years and provide incentives for continued participation. When developing future studies, it would also be beneficial to incorporate an attention placebo group in order to control for time and treatment effects.

In addition, future research might focus on a dissemination study, taking this intervention and replicating it outside of a research setting. Feedback from this study suggests that more patients could benefit from biopsychosocial treatments like this one, if offered in a community setting. Future research should also continue to investigate the cost-effectiveness associated with biopsychosocial treatments. In addition to the physical and emotional benefits from this type of treatment, cost benefits can also be realized for both patients and health care providers.

CHAPTER NINE CONCLUSION

The present LTF study further supports and extends the findings of the earlier one-year outcome study by Gatchel and colleagues (2006), indicating an early biopsychosocial intervention is efficacious for patients with acute TMD. By receiving treatment during the acute stage of TMD, patients are less likely to develop chronic TMD. This study was the first to follow TMD subjects past one-year; in fact, between two to six years post intake. As such, it was remarkable that 40% of study subjects participated, and that EI subjects continued to report significantly reduced pain levels, emotional distress, and jaw pain-related health care visits relative to NI subjects.

Significant differences were found on several measures, and responses to the informal survey (PRS) were very positive. EI subject's perceived the intervention as beneficial with 96% *very likely* or *likely* to recommend this intervention. Future research should include long-term follow-up and should continue to investigate the cost benefits associated with biopsychosocial treatments. Disseminating this type of treatment into a community setting is also essential as it will allow more acute TMD patients to benefit physically, emotionally, and financially from efficacious biopsychosocial treatments.

APPENDIX A

FIGURES

Figure 1

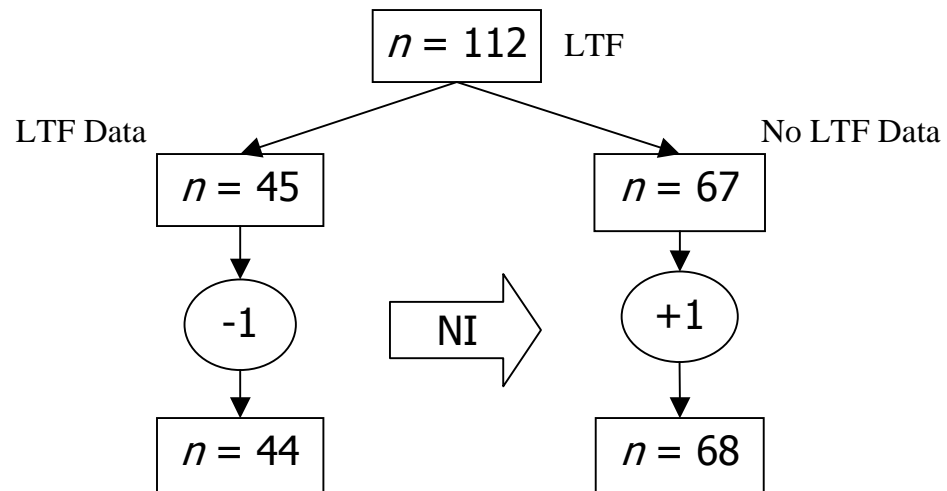
LTF Subjects

Figure 2

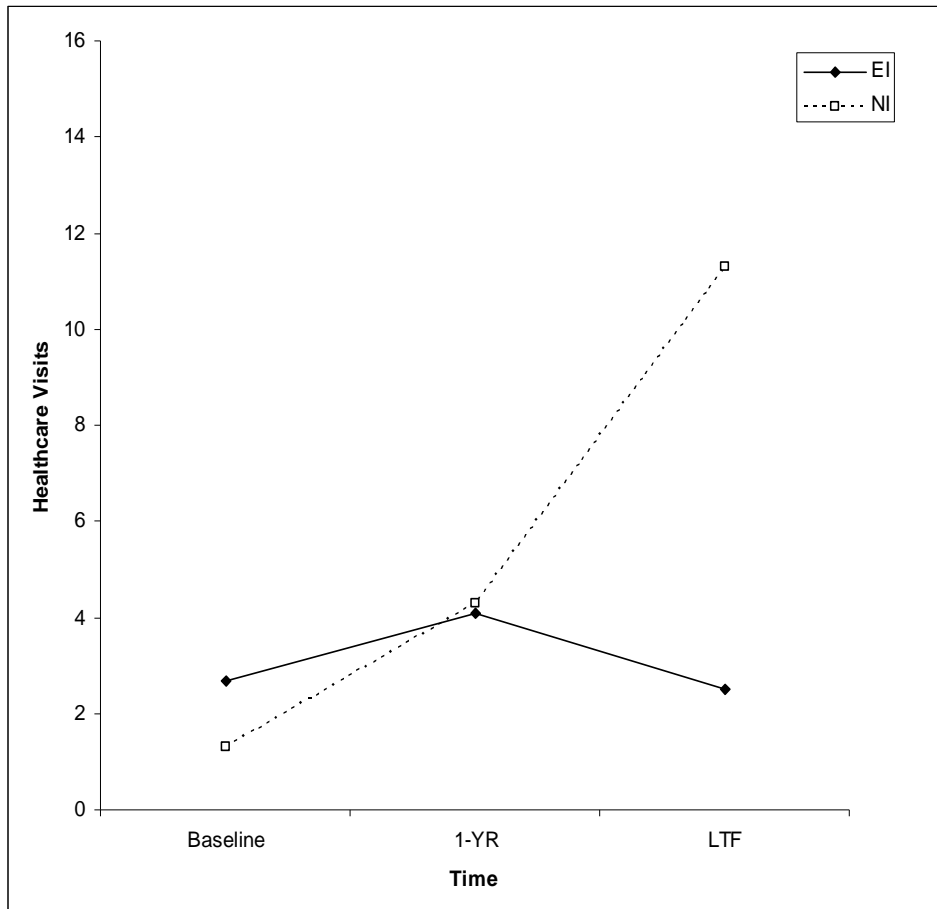
Jaw Pain-Related Health Care Visits Linear Trend

Figure 3

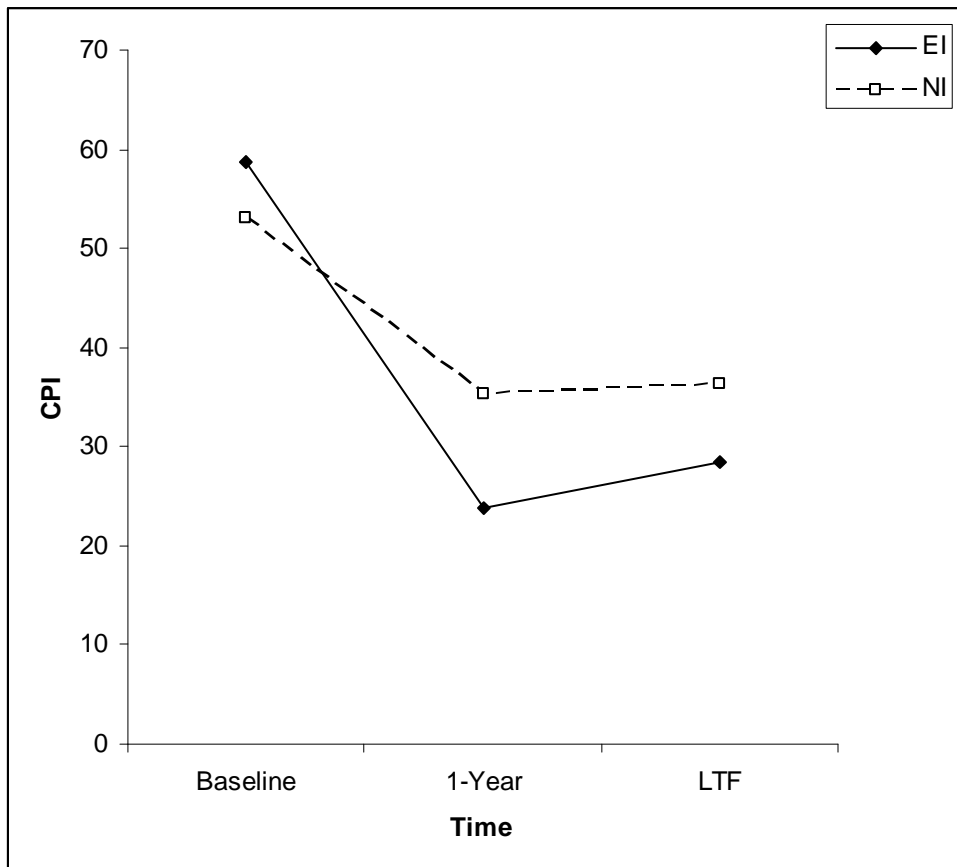
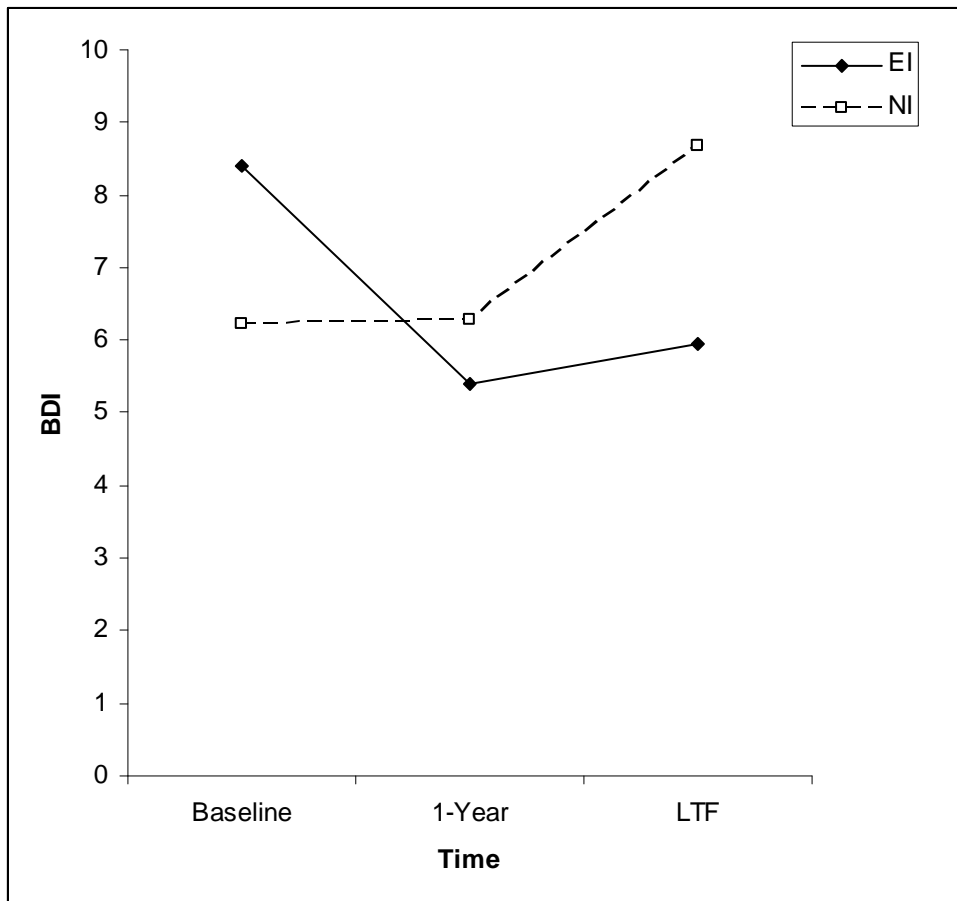
CPI Linear Trend

Figure 4

BDI-II Linear Trend

APPENDIX B

TABLES

Table 1

Duration in Years from Intake to Present for EI and NI Groups

Duration in Years	EI (<i>n</i> =62)	NI (<i>n</i> =50)
1	2	2
2	10	3
3	16	12
4	12	8
5	10	12
6	12	13

Table 2

Demographic Characteristics for LTF Subjects (EI versus NI)

Variables	EI (n=29)	NI (n=15)	χ^2
Gender (%) at Intake			n.s.
Male	17.2	13.3	
Female	82.8	86.7	
Race (%) at Intake			n.s.
Caucasian	69.0	93.3	
Latino	3.4	0.0	
African American	10.3	0.0	
Asian	10.3	6.7	
Other	6.9	0.0	
Marital Status (%) at Intake			$\chi^2(2,44) = 10.77, p = .01^*$
Single	27.6	40.0	
Married / Living Together as Married	72.4	33.3	
Divorced or separated	0.0	26.7	
Employment Status (%) at Intake			n.s.
Full-Time	58.6	73.3	
Part-Time	10.3	6.7	
Not working b/c of jaw problems	0.0	0.0	
Not working b/c of injury	6.9	0.0	
Self-employed	3.4	6.7	
NW non-income producing activities	10.3	6.7	
NW before jaw pain and still not working	10.3	6.7	
Health Insurance (%) at Intake			n.s.
No Insurance	20.7	6.7	
Insurance	79.3	93.3	
Dental Ins. (%) at Intake			n.s.
No Insurance	34.5	20.0	
Insurance	65.5	80.0	

Table 2 (cont.)

Variables	EI (<i>n</i> =29)	NI (<i>n</i> =15)	<i>F</i>
Mean Education in Years (<i>SD</i>) at Intake	15.90 (1.97)	16.40 (2.06)	n.s.
Mean Age in Years (<i>SD</i>) at Intake	38.48 (11.85)	42.09 (11.75)	n.s.
Mean Monthly Income Before Taxes (<i>SD</i>) at Intake	\$6,219 (6,397)	\$5,267 (3,920)	n.s.
Length of Jaw Pain in Days (<i>SD</i>) at Intake	92.51 (47.08)	77.87 (34.38)	n.s.
Referral Type (%) at Intake			n.s.
Dentist Referred	44.8	40.0	
Non-Dentist Referred	55.2	60.0	

* significant, $p < .05$

Table 3

Demographic Characteristics (Subjects with LTF data versus Subjects without LTF data)

Variables	LTF DATA (n=44)	NO LTF DATA (n=68)	χ^2
Gender (%) at Intake			n.s.
Male	15.9	23.5	
Female	84.1	76.5	
Race (%) at Intake			n.s.
Caucasian	77.3	76.5	
Latino	2.3	8.8	
African American	6.8	10.3	
Asian	9.1	1.5	
Other	4.5	2.9	
Marital Status (%) at Intake			n.s.
Single	31.8	20.6	
Married / Living Together as Married	59.1	66.2	
Divorced or separated	9.1	13.2	
Employment Status (%) at Intake			n.s.
Full-Time	63.6	54.4	
Part-Time	9.1	8.8	
Not working b/c of jaw problems	0.0	1.6	
Not working b/c of injury	4.5	0.0	
Self-employed	4.5	7.4	
NW non-income producing activities	9.1	19.1	
NW before jaw pain and still not working	9.1	8.8	
Health Insurance (%) at Intake			n.s.
No Insurance	15.9	7.5	
Insurance	84.1	92.5	
Dental Ins. (%) at Intake			n.s.
No Insurance	29.5	19.4	
Insurance	70.5	80.6	

Table 3 (cont.)

Variables	LTF DATA (<i>n</i> =44)	NO LTF DATA (<i>n</i> =68)	<i>F</i>
Mean Education in Years (<i>SD</i>) at Intake	16.07 (1.99)	14.97 (2.07)	$F(1,110) = 7.72, p = .01^*$
Mean Age in Years (<i>SD</i>) at Intake	39.72 (11.81)	37.04 (11.24)	n.s.
Mean Monthly Income Before Taxes (<i>SD</i>) at Intake	\$5,895 (5,645)	\$8,537 (15,441)	n.s.
Length of Jaw Pain in Days (<i>SD</i>) at Intake	87.52 (43.33)	105.59 (50.23)	$F(1,110) = 3.84, p = .05$
Referral Type (%) at Intake			n.s.
Dentist Referred	43.2	55.9	
Non-Dentist Referred	56.8	44.1	

* significant, $p < .05$

Table 4

Demographic Characteristics for EI Group (Subjects with LTF data versus Subjects without LTF data)

Variables	LTF DATA (n=29)	NO LTF DATA (n=33)	χ^2
Gender (%) at Intake			n.s.
Male	17.2	24.2	
Female	82.8	75.8	
Race (%) at Intake			n.s.
Caucasian	69.0	75.8	
Latino	3.4	9.1	
African American	10.3	9.1	
Asian	10.3	3.0	
Other	6.9	3.0	
Marital Status (%) at Intake			n.s.
Single	27.6	24.2	
Married / Living Together as Married	72.4	60.6	
Divorced or separated	0.0	15.2	
Employment Status (%) at Intake			n.s.
Full-Time	58.6	51.5	
Part-Time	10.3	12.1	
Not working b/c of injury	6.9	0.0	
Self-employed	3.4	6.1	
NW non-income producing activities	10.3	24.2	
NW before jaw pain and still not working	10.3	6.1	
Health Insurance (%) at Intake			n.s.
No Insurance	20.7	9.1	
Insurance	79.3	90.9	
Dental Ins. (%) at Intake			n.s.
No Insurance	34.5	24.2	
Insurance	65.5	75.8	

Table 4 (cont.)

Variables	LTF DATA (<i>n</i> =29)	NO LTF DATA (<i>n</i> =33)	<i>F</i>
Mean Education in Years (<i>SD</i>) at Intake	15.90 (1.97)	14.55 (1.86)	$F(1,60) = 7.72, p = .01^*$
Mean Age in Years (<i>SD</i>) at Intake	38.49 (11.85)	35.27 (11.15)	n.s.
Mean Monthly Income Before Taxes (<i>SD</i>) at Intake	\$6,219 (6,397)	\$6,001 (6,374)	n.s.
Length of Jaw Pain in Days (<i>SD</i>) at Intake	92.52 (47.08)	101.33 (50.16)	n.s.
Referral Type (%) at Intake			n.s.
Dentist Referred	44.8	54.5	
Non-Dentist Referred	55.2	45.5	

* significant, $p < .05$

Table 5

Demographic Characteristics for NI Group (Subjects with LTF data versus Subjects without LTF data)

Variables	LTF DATA (n=15)	NO LTF DATA (n=35)	χ^2
Gender (%) at Intake			n.s.
Male	13.3	22.9	
Female	86.7	77.1	
Race (%) at Intake			n.s.
Caucasian	93.3	77.1	
Latino	0.0	8.6	
African American	0.0	11.4	
Asian	6.7	0.0	
Other	0.0	2.9	
Marital Status (%) at Intake			$\chi^2(2,50) = 6.35, p < .04^*$
Single	40.0	17.1	
Married / Living Together as Married	33.3	71.4	
Divorced or separated	26.7	11.4	
Employment Status (%) at Intake			n.s.
Full-Time	73.3	57.1	
Part-Time	6.7	5.7	
Not working b/c of jaw problems	0.0	2.9	
Not working b/c of injury	-	-	
Self-employed	6.7	8.6	
NW non-income producing activities	6.7	14.3	
NW before jaw pain and still not working	6.7	11.4	
Health Insurance (%) at Intake			n.s.
No Insurance	6.7	5.9	
Insurance	93.3	94.1	
Dental Ins. (%) at Intake			n.s.
No Insurance	20.0	14.7	
Insurance	80.0	85.3	

Table 5 (cont.)

Variables	LTF DATA (<i>n</i> =15)	NO LTF DATA (<i>n</i> =35)	<i>U</i>
Mean Education in Years (<i>SD</i>) at Intake	16.40 (2.06)	15.39 (2.26)	n.s.
Mean Age in Years (<i>SD</i>) at Intake	42.09 (11.75)	38.09 (11.12)	n.s.
Mean Monthly Income Before Taxes (<i>SD</i>) at Intake	\$5,267 (3,920)	\$10,919 (20,476)	n.s.
Length of Jaw Pain in Days (<i>SD</i>) at Intake	77.87 (34.38)	108.03 (51.67)	$U = 155, z = -2.28, p = .05$
Referral Type (%) at Intake			n.s.
Dentist Referred	40.0	57.1	
Non-Dentist Referred	60.0	42.9	

* significant, $p < .05$

Table 6

Jaw Pain-Related Health Care Visits by Subject

Subjects	No. of Health Care Visits						
	Intake	1-Year	2-Year	3-Year	4-Year	5-Year	6-Year
EI (n=12)*							
S ₁	0	0					1
S ₂	0	2					0
S ₃	2	0					10
S ₄	4	27				2	
S ₅	8	1			0		
S ₆	2	0		1			
S ₇	1	0			2		
S ₈	4	10		0			
S ₉	8	9		2			
S ₁₀	2	0	1				
S ₁₁	0	0	8				
S ₁₂	1	0	3				
NI (n=10)**							
S ₁₃	0	3					0
S ₁₄	1	0				2	
S ₁₅	1	1				0	
S ₁₆	1	24				0	
S ₁₇	5	2			35		
S ₁₈	2	1			4		
S ₁₉	2	10		40			
S ₂₀	0	1		2			
S ₂₁	0	0		30			
S ₂₂	1	1	0				

* Within the EI group, data was collected at one-year follow-up and/or LTF for 12 of the 29 subjects.

** Within the NI group, data was collected at one-year follow-up and/or LTF for 10 of the 15 subjects.

Table 7

Jaw Pain-Related Health Care Visits at Intake, One-Year Follow-Up, and LTF by Group

Health Care Visits*	EI (<i>n</i> = 12)			NI (<i>n</i> = 10)		
	Intake	1-Year	LTF	Intake	1-Year	LTF
<i>M</i>	2.67	4.08	2.50	1.30	4.30	11.30
(<i>SD</i>)	(2.84)	(8.06)	(3.21)	(1.50)	(7.51)	(16.57)

* Significant group-by-time interaction, $F(1, 20) = 4.49$, $p = .05$, $\eta^2 = .18$.

Table 8

Measures at Intake, One-Year Follow-Up, and LTF by Group

Measure	EI (<i>n</i> = 29) <i>M</i> (<i>SD</i>)			NI (<i>n</i> = 15) <i>M</i> (<i>SD</i>)		
	Intake	1-Year	LTF	Intake	1-Year	LTF
CPI*	58.68 (10.05)	23.81 (19.65)	28.46 (20.09)	53.00 (10.70)	35.29 (25.56)	36.22 (25.10)
BDI†	8.39 (9.22)	5.39 (6.78)	5.95 (7.19)	6.21 (3.66)	6.29 (4.91)	8.68 (7.67)
WOC						
<i>Blamed Self</i>	17.54 (3.64)	15.12 (4.26)	15.94 (4.69)	14.63 (5.19)	16.18 (4.74)	15.49 (6.40)
<i>Wishful Thinking</i>	19.56 (3.94)	19.04 (3.96)	19.13 (3.89)	17.62 (2.90)	17.85 (3.34)	17.58 (2.73)
<i>Avoidance</i>	16.52 (2.85)	15.83 (2.88)	16.49 (2.58)	15.22 (2.67)	15.67 (2.48)	15.82 (3.16)
<i>Problem-Focused</i>	23.52 (3.98)	24.30 (3.46)	24.01 (3.40)	25.10 (4.13)	24.59 (3.63)	24.93 (3.94)
<i>Seeks Social Support</i>	22.87 (3.51)	25.71 (5.19)	24.44 (3.81)	27.43 (3.64)	25.71 (3.55)	26.16 (4.82)

* Significant main effect of time, $F(1, 41) = 58.35, p < .01, \eta^2 = .59$, significant group-by-time interaction, $F(2, 82) = 4.02, p = .02, \eta^2 = .09$.

† Significant group-by-time interaction, $F(1.82, 72.88) = 3.33, p = .05, \eta^2 = .08$.

Table 9

Measures at Intake and One-Year Follow-Up for EI and NI Groups (Subjects with LTF data versus Subjects without LTF data)

Measure	Intake <i>M</i> (<i>SD</i>)				1-Year <i>M</i> (<i>SD</i>)			
	EI		NI		EI		NI	
	LTF (<i>n</i> =29)	No LTF (<i>n</i> =33)	LTF (<i>n</i> =15)	No LTF (<i>n</i> =35)	LTF (<i>n</i> =28)	No LTF (<i>n</i> =34)	LTF (<i>n</i> =15)	No LTF (<i>n</i> =35)
CPI	57.93 (10.66)	58.12 (12.60)	53.00 (10.70)	58.77 (12.95)	23.81 (19.65)	19.37 (13.46)	35.29 (25.56)	31.00 (25.77)
BDI	8.31 (9.06)	9.70 (10.38)	6.40 (12.97)	9.63 (7.68)	5.39 (6.78)	4.96 (7.49)	6.07 (4.80)	8.53 (107.91)

Table 10

DSM-IV Axis I (Clinical) Primary Groupings of Diagnoses*

Variables (categorical)	EI† <i>n</i> = 19			NI † <i>n</i> = 10			χ^2
%	Intake	1-Year	LTF	Intake	1-Year	LTF	
Total Axis I	94.7	26.3	42.1	70.0	80.0	10.0	Intake: 3.37, <i>p</i> = .07 1 yr: 7.64, <i>p</i> = .01‡ LTF: 3.16, <i>p</i> = .08
Affective Disorders	15.8	5.3	10.5	0.0	10.0	0.0	Intake: 1.76, <i>p</i> = .18 1 yr: .23, <i>p</i> = .63 LTF: 1.13, <i>p</i> = .29
Anxiety Disorders	52.6	5.3	36.8	10.0	20.0	10.0	Intake: 5.06, <i>p</i> = .03¶ 1 yr: 1.53, <i>p</i> = .22 LTF: 2.36, <i>p</i> = .12
Somatoform Disorders	89.5	15.8	5.3	70.0	70.0	0.0	Intake: 1.74, <i>p</i> = .19 1 yr: 8.52, <i>p</i> < .01# LTF: .55, <i>p</i> = .46
Substance Abuse	10.5	5.3	0.0	0.0	0.0	0.0	Intake: 1.13, <i>p</i> = .29 1 yr: .55, <i>p</i> = .46 LTF: n.s.

* DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (American Psychiatric Association, 1994).

† Values are presented as percentages of the total number of subjects in the early intervention and non-intervention groups, respectively. All values are based on the presence or absence of a current or lifetime Structured Clinical Interview, or SCID, Axis I diagnosis. (First, Spitzer, Gibbon et al., 1995; First et al., 1994).

‡ Significant difference between EI and NI group subjects at one-year follow-up [χ^2 (1,29) = 7.64, *p* = .01 (OR = 11.20; 95 percent CI, 1.75 to 71.64)].

¶ Significant difference between EI and NI group subjects at intake [χ^2 (1,29) = 5.06, *p* = .03 (OR = .10; 95 percent CI, .01 to .95)].

Significant difference between EI and NI group subjects at one-year follow-up [χ^2 (1,29) = 8.52, *p* < .01 (OR = 12.44; 95 percent CI, 2.00 to 77.60)].

Table 11

DSM-IV Axis II (Clinical) Primary Groupings of Diagnoses*

Variables (categorical)	EI † <i>n</i> = 19			NI † <i>n</i> = 10			χ^2
%	Intake	1-Year	LTF	Intake	1-Year	LTF	
Total Axis II	84.3	89.5	63.2	70.0	70.0	30.0	Intake: .81, <i>p</i> = .37 1 yr: 1.74, <i>p</i> = .19 LTF: 2.89, <i>p</i> = .09
Cluster A	10.5	10.5	10.5	0.0	0.0	0.0	Intake: 1.13, <i>p</i> = .29 1 yr: 1.13, <i>p</i> = .29 LTF: 1.13, <i>p</i> = .29
Cluster B	21.1	15.8	5.3	20.0	10.0	0.0	Intake: .00, <i>p</i> = .95 1 yr: .19, <i>p</i> = .67 LTF: .55, <i>p</i> = .46
Cluster C	84.2	89.5	63.2	70.0	70.0	30.0	Intake: .81, <i>p</i> = .37 1 yr: 1.74, <i>p</i> = .19 LTF: 2.89, <i>p</i> = .09

* DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (American Psychiatric Association, 1994).

† Values are presented as percentages of the total number of subjects in the early intervention and non-intervention groups, respectively.

Table 12

DSM-IV Axis I Clinical Diagnoses (Significant Findings)*

Variables (categorical)	EI† <i>n</i> = 19			NI † <i>n</i> = 10			χ^2
	Intake	1-Year	LTF	Intake	1-Year	LTF	
Generalized Anxiety Disorder (GAD)	36.8	5.3	5.3	0.0	0.0	0.0	Intake: 4.86, $p = .03^\ddagger$ 1 yr: .55, $p = .46$ LTF: .55, $p = .46$
Pain Disorders	89.5	15.8	5.3	70.0	70.0	0.0	Intake: 1.74, $p = .19$ 1 yr: 8.52, $p < .01^\P$ LTF: .55, $p = .46$

* DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (American Psychiatric Association, 1994).

† Values are presented as percentages of the total number of subjects in the early intervention and non-intervention groups, respectively.

‡ Significant difference between EI and NI group subjects at intake [$\chi^2(1,29) = 4.86, p = .03$].

¶ Significant difference between EI and NI group subjects at one-year follow-up [$\chi^2(1,29) = 8.52, p < .01$].

Table 13

Participant Ratings Survey (PRS)

	EI (<i>n</i> =28) <i>M</i> (<i>SD</i>)	NI (<i>n</i> =15) <i>M</i> (<i>SD</i>)
#1 How often do you use the skills and techniques...? daily...never	2.61 (1.26)	NA
#2 How successful have you been in using the skills and techniques...? very successful...not successful	2.21 (1.20)	NA
#3 Are your jaw pain-related symptoms, much better... much worse? *	1.57 (0.79)	2.40 (0.99)
#4 Are your jaw pain-related symptoms, much less frequent...much more frequent? †	1.32 (0.55)	2.40 (0.99)
#5 When you have jaw pain-related symptoms is the duration, much shorter...much longer? ‡	1.71 (0.81)	2.33 (0.90)
#6 How likely are you to recommend...? very likely...definitely not	1.50 (0.58)	NA

* Significant differences were found between EI group subjects and NI group subjects on Question 3, $U = 108.5$, $z = -2.77$, $p = .01$.

† Significant differences were found between EI group subjects and NI group subjects on Question 4, $U = 79.0$, $z = -3.68$, $p < .01$.

‡ Significant differences were found between EI group subjects and NI group subjects on Question 5, $U = 127.5$, $z = -2.23$, $p = .03$.

APPENDIX C

MATERIALS

Material 1

Participant Ratings Survey (PRS)

1. How often do you use the skills and techniques learned in this program to manage your jaw pain?
 - ☐ Daily
 - ☐ Weekly
 - ☐ Monthly
 - ☐ A few times
 - ☐ Never
2. How successful have you been in using the skills and techniques you learned in this program to manage your jaw pain? _____ (I did not receive the program intervention.)
 - ☐ Very successful
 - ☐ Successful
 - ☐ Some success
 - ☐ Not much success
 - ☐ Not successful
3. Since program participation, are your jaw pain-related symptoms...?
 - ☐ Much better
 - ☐ Better
 - ☐ Same
 - ☐ Worse
 - ☐ Much worse
4. Since program participation, are your jaw pain-related symptoms...?
 - ☐ Much less frequent
 - ☐ Less frequent
 - ☐ Same
 - ☐ More frequent
 - ☐ Much more frequent

5. Since program participation, when you have jaw pain-related symptoms is the duration...?
- ☐ Much shorter
 - ☐ Shorter
 - ☐ Same
 - ☐ Longer
 - ☐ Much longer
6. How likely are you to recommend participation in a program such as this one? _____
(I did not receive the program intervention.)
- ☐ Very likely
 - ☐ Likely
 - ☐ Maybe
 - ☐ Not likely
 - ☐ Definitely not
7. Any other comments/feedback about this program?

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VITAE

Kelly Robinson was born in New York, on June 2, the daughter of James and Ann Robinson. After graduating valedictorian from North Smithfield High School, Rhode Island in 1984, she entered Northwestern University. She received the degree of Bachelor of Science with a major in Industrial Engineering from Northwestern University in June, 1988. She worked in technology marketing before deciding to pursue an MBA. In May, 1995 she was awarded the degree of Master of Business Administration from the University of Texas at Austin, Graduate School of Business. After working for Fortune 500 companies in Japan and California, she entered the University of Texas Southwestern Medical Center at Dallas, Graduate School of Biomedical Sciences in September 2003. Currently, she lives in Texas with her husband and son.