FEASIBILITY AND SHORT-TERM OUTCOMES OF A SHAMANIC TREATMENT FOR TEMPOROMANDIBULAR JOINT DISORDERS

Nancy H. Vuckovic, PhD; Christina M. Gullion, PhD; Louise A. Williams, PhD; Michelle Ramirez, PhD; Jennifer Schneider, MPH

Context • Temporomandibular joint disorders (TMDs) are chronic, recurrent, non-progressive pain conditions affecting the jaw and face. Patients least likely to respond to allopathic treatment are those with the most marked biological responsiveness to external stressors and concomitant emotional and psychosocial difficulties. These characteristics describe individuals who are "dispirited" and may benefit from shamanic healing, an ancient form of spiritual healing.

Objective • This phase 1 study tested feasibility and safety of shamanic healing for TMDs.

Design • Participants were randomized to 1 of 4 shamanic practitioners and attended 5 shamanic healing sessions. Self-reported pain and disability were recorded at baseline and each treatment visit and at 1, 3, 6, and 9-month follow-ups. Participants also were clinically evaluated at baseline and end of treatment. In-depth interviews, part of our mixed methods design, were conducted at baseline and end of treatment to evaluate acceptability and nonclinical changes associated with treatment.

Setting • Portland, Oregon

Patients or Other Participants • Twenty-three women with diagnosed TMDs.

Intervention • Shamanic treatment carried out during 5 treatment visits.

Main Outcome Measures • Change from baseline to posttreatment in diagnosis of TMDs by Research Diagnostic Criteria (RDC) exam and participant self-ratings on the "usual" pain, "worst" pain, and functional impact of TMDs subscales of the RDC Axis II Pain Related Disability and Psychological Status Scale. This paper reports on outcomes at end of treatment.

Results • This study demonstrated the feasibility and acceptability of clinical trials of shamanic healing. The mean of usual pain went from 4.96 to 2.70, $P<.0001$; worst pain from 7.48 to 3.60, $P<.0001$, and functional impact of TMDs from 3.74 to 1.15, $P<.0052$. Only 4 women were clinically diagnosed with TMDs at the end of treatment. (*Altern Ther Health Med*. 2007;13(6):18-29.)

Nancy H. Vuckovic, PhD, is an afflilate investigator, Christina M. Gullion, PhD, is a senior investigator, and Jennifer Schneider, MPH, is a senior research associate, all at Kaiser Permanente Center for Health Research, Portland, Oregon. Louise A. Williams, PhD, is an investigator at the Center for Advancement of Innovated Health Practices, Portland. Michelle Ramirez, PhD, is an assistant professor of Anthropology at the University of the Sciences in Philadelphia, Pennsylvania.

Temporomandibular disorders (TMDs) are chronic, recurrent, non-progressive pain conditions affecting the temporomandibular joint (TMJ) and surrounding tissues.[1-4] Individuals with TMDs may experience a range of symptoms: facial pain, jaw-joint pain, headaches, earaches, dizziness, masticatory musculature hypertrophy, limited mouth opening, closed or open lock on the TM joint, abnormal occlusal wear, and clicking or popping sounds in the jaw joint.

TMDs are found primarily in young and middle-aged adults, and are nearly twice as common in women as in men.[5,6] Approximately one third of adults will be affected at some time during their life span[7]; about 5% of them will seek care for these conditions. Similar to other chronic pain conditions, people with TMDs suffer from adverse psychological, behavioral, and social factors in addition to physical pathology. Stress, depression, disability, and dysfunctional illness behaviors are characteristic of many patients with TMDs.[8,9] The lifetime prevalence of depression among individuals with TMDs is more than twice that of the general population.[10] Some people with TMDs also appear to be particularly sensitive to stress and pain.[11,12] Healthcare costs are 1.6 times higher in TMDs patients than in matched controls.[13]

Allopathic management of these patients often includes emphasis on behavioral and symptomatic components of the chronic pain.[14] Splint therapy to decrease muscle hypertonicity, decrease bruxing, and decrease loading of the TMJ are often prescribed, along with posture information, diet advice, and pain medication. Treatment outcomes for TMDs have been more successfully predicted by psychosocial factors than by clinical or demographic factors.[9,14] In particular, evidence indicates that

psychosocial stressors play a role in the clinical course of TMDs.[15] The 20%-30% of patients who are non-responsive to standard allopathic treatment appear to have more complex psychosocial problems, including more severe depression.[8,9,11,16-18] These findings suggest that patients least likely to respond to conservative allopathic treatment are those with the most marked biological responsiveness to external stressors as well as those with more concomitant emotional and psychosocial difficulties. They also highlight the potential value of complementary and alternative medicine (CAM) therapies that treat holistically, seek to provide a continuity of care, and therefore are able to address multiple complaints, such as those that are common in people with chronic TMDs pain.

SHAMANIC TREATMENT

Shamanism is an ancient and widespread form of spiritual healing.[19,20] Shamanic practitioners (SPs) view health and healing from the perspective of the whole person in a larger system: body/mind/spirit is connected to community/earth/universe—all are one. In the shamanic worldview, poor health and illnesses usually are due to both spiritual and non-spiritual factors. In contrast to allopathic medicine, which concentrates on curing disease (ie, biological disorders), shamanic healing focuses on healing illness (ie, the patients' experience of their disorder), which can be influenced by both biology and the socio-cultural context of the disorder.[20-22]

The task of SP is to deal with the spiritual factors associated with illness. Shamans believe all living beings have a soul—the spiritual essence required for life.[19,20,23,24] Two principal types of spiritual factors can contribute to or bring about illness: (1) loss of a spiritual energy that is important to the patient's well-being (personal soul loss and guardian spirit loss are chief among these) and (2) presence of a spirit or energetic force that is detrimental to the patient's well-being (eg, spirit intrusions, involuntary possessions).[25] In shamanic healing, practitioners use their connection with the spirits to retrieve lost soul essences, remove spiritual intrusions, and engage in spiritual healing.

Shamans recognize 2 realities that depend on one's state of consciousness. People in the "ordinary state of consciousness" perceive only "ordinary reality" (OR); those in the "shamanic state of consciousness" (SSC) enter into and perceive "non-ordinary reality" (NOR). Shamanic practitioners in contemporary Western practice typically enter the SSC only through use of sonic driving (drumming or rattle) in a frequency range of 4 to 7 Hz, which corresponds to that of theta EEG waves.[26-31] Entering into NOR and the experiences in this state comprise a shamanic "journey." Shamans, by definition, are individuals who journey with discipline in NOR with the specific intent of helping others.[20,25] In NOR, the shaman accesses a knowledge that is not bound by the time or space constraints of ordinary reality, including encounters with spirits or soul essences.

Shamanic healing is interactive. It enables individuals to regain their "power" and participate in their own healing if they choose to do so. Thus, treatment may involve helping the patient to integrate the effects of shamanic healing through changes in behavior, diet, or lifestyle, engaging in counseling, or incorporating ritual or spiritual practice (eg, learning to journey for themselves) into their life.

OBJECTIVE

Individuals who are "dispirited," who have chronic illness or pain, or who have experienced trauma of various kinds in their lives may particularly benefit from shamanic healing. Based on information gathered during focus groups conducted at the Oregon Center for Complementary and Alternative Medicine (OCCAM), women with TMDs pain and multiple health complaints appear to fit this profile.[24,32] Because emotional and spiritual factors have been shown to be connected to physical and biological effects, healing emotional and spiritual distress may indeed affect physical symptoms, such as pain or immune response.[33-35]

This article describes outcomes of a phase 1 study to assess the feasibility and safety of shamanic healing, an ancient form of alternative medicine, on TMDs. We also report changes from baseline in this uncontrolled trial.

DESIGN

Overview

Participants completed 5 visits to a randomly assigned shamanic practitioner (SP). They provided self-ratings of pain and related functioning before, during, and in an extended follow-up (about 9 months) after treatment by the SPs. They also participated in 2 in-depth interviews, pre- and post-treatment, and a research clinical diagnostic TMDs examination conducted by a calibrated dental examiner at the beginning and end of treatment. The primary outcomes are self-reported pain as measured by questionnaires and clinical evaluation. Table 1 summarizes the flow of participants through treatment and measurement events. This article describes outcomes from baseline to 1 month after treatment.

This study was approved by the institutional review board (IRB) of Kaiser Permanente Northwest, the institutional home of the Center for Health Research. The investigators and SPs all received formal human subjects protection and training on the Health Insurance Portability and Accountability Act before beginning work on the project. The SPs also were trained in procedures and use of study forms before any participants were enrolled. The protocol and measures were pre-tested with 4 participants (1 to each primary SP). We made some minor revisions to streamline study procedures after the pre-test, and these were approved by the IRB.

Participants

Eligible women were between 25 and 55 years of age, had an existing diagnosis of TMDs that was confirmed by a trained and calibrated dental examiner at initial screening, and scored a pain level of 3 or higher on a 0-10–point item measuring current facial pain (see "Measures"). To be eligible, women also had to self-report

TABLE 1 Study Flow*

Week	Event	Activities, data collection
	Screening call	Inclusion/exclusion criteria screening Axis II pain and disability scales Demographics
0	Screening visit	TMD RDC exam Axis II depression and symptom scales Hope Scale (Pathways subscale) Q-LES-Q-SF NEO-FFI Life events MYMOP Overall health Medication use CAM attitudes Past treatment experience (CAM, allopathic)
1	Treatment visit 1	Introduction to shaman and shamanic treatment Diagnostic journey Axis II pain and disability scales Journey text Chart notes
2	Pre-treatment interview	Salience of diagnostic journey Expectations of treatment HAQ-II-P
3-7	Treatment visits 2-5	Shamanic treatment, chart notes Axis II pain and disability scales
8	Post-treatment visit	TMD RDC exam Axis II depression and symptom scales Hope Scale (Pathways subscale) Q-LES-Q-SF MYMOP Treatment experience (CAM, allopathic) during study Medication use Overall health
	Post-treatment interview	Treatment experience Change resulting from treatment HAQ-II-P
1, 3, 6, 9 mos	Telephone assessment	Axis II pain and disability scales

*TMD indicates temporomandibular joint disorder; RDC, Research Diagnostic Criteria; Q-LES-Q-SF, Quality of Life and Enjoyment Scale-short form; NEO-FFI, NEO Five Factor Inventory; MYMOP, Measure Yourself Medical Outcome Profile; CAM, complementary and alternative medicine; HAQ-II-P, Helping Alliance Questionnaire, Version 2, patient form.

2 or more of the following additional chronic conditions in the past 2 years: fibromyalgia; chronic fatigue syndrome; depression; stomach or intestinal problems (ulcers, irritable bowel, Crohn's disease); reproductive problems (endometriosis, fibroids, menstrual problems); upper respiratory problems (asthma, chronic bronchitis); or chronic headaches or migraines. Women were excluded if they had previous shamanic treatment, were pregnant or trying to become pregnant, or if they self- reported any of the following: diagnosed schizophrenia or bipolar disorder (depression was allowed), a neurological diagnosis (epilepsy or Parkinson's disease), or current treatment for cancer.

Providers

The SPs were all women who have an active contemporary Western shamanic healing practice in the Portland metropolitan area. They were trained in soul retrieval by Sandra Ingerman, author of *Soul Retrieval, Mending the Fragmented Self* (New York, NY: Harper Collins; 1991), and received extensive training from the Foundation for Shamanic Studies and other experienced shamans and were recommended by Ingerman because of their years of experience and their reputation in the community. Four shamans served as primary providers, and a fifth agreed to serve as an alternate. None of the SPs previously had participated as providers in a clinical trial. The alternate was never needed.

Measures

The study flow and measurement schedule is summarized in Table 1. We used standardized, validated, questionnaires to determine eligibility, to evaluate the primary and secondary outcomes, and to assess other psychological characteristics of participants before and after treatment. As noted in Table 1, data collection consisted of self-administered questionnaires at baseline and end of treatment, and via orally administered surveys during treatment and at 1, 3, 6, and 9 months post-treatment follow-up.

Diagnosis

Eligibility and clinical outcome were measured via the Research Diagnostic Criteria (RDC) instrument.[36] The RDC is a series of standardized Western biomedical clinical examinations (Axis I) and self-reported questions (Axis II) that are used to determine whether a participant has TMDs and to measure associated features. The validity and reliability of the RDC is well established,[37-39] and it has been used by other funded TMDS studies.[40] It is now in use in more than 30 countries and has been translated into 10 languages.

The Axis I RDC examination was used to evaluate the eligibility of all potential participants during their initial clinical examination. This examination includes ratings of pain (0, no pain, to 3, severe pain) on palpation at 10 sites (each side); the sum of ratings must exceed 3 to meet criteria for TMDs. The RDC examination was performed by the same dental examiner at baseline and at end of treatment, to provide an objective, clinical measure of change in TMDs-related pain and function. The dental examiner was not involved in the trial otherwise and had no contact with the SPs

until after all post-treatment measures were complete.

Before patients were recruited, Kimberly H. Huggins, RDH, BS (GSE), University of Washington, trained the study examiner in TMDs examination procedures and criteria for measurement and diagnosis. Huggins served as the "gold standard," and the examiner's procedures were calibrated to Huggins' clinical examination and research diagnosis.

Primary Outcome Measures

The primary measures of treatment effect were change from baseline (randomization visit) to end of treatment in the diagnosis of TMDs by RDC (Axis I), and participant self-ratings on the usual pain, worst pain, and functional impact of TMDs subscales of the RDC Axis II Pain Related Disability and Psychological Status Scale.[36] The secondary outcomes were change from baseline to end of treatment in self-ratings of depression, nonspecific symptoms (subscores for pain and non-pain), and quality of life (Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form [Q-LES-Q-SF]). All of these measures are described below.

Patient self-report of pain is the "gold standard" for assessment of pain syndromes.[41] The participants rated aspects of their pain that we adapted from the six 11-point scales and an item measuring days of disability that are used to score the 4-level RDC Axis II Graded Chronic Pain Scale[36] (Table 2). These ratings were obtained at screening, at each visit, and at follow-up telephone surveys at 1, 3, 6, and 9 months post-treatment. For the screening questions, we changed the order of phrases but used the same 7 questions about "facial pain" that were validated by Dworkin et al.[36] However, at subsequent occasions, we asked only 3 of the 7 scales in the RDC Axis II (plus 2 we devised), and we substituted the term "TMDs-related" for "facial." We used the questions about worst pain, usual or average pain, and interference with daily activities as primary outcomes.

Secondary Outcome Measures

The Axis II distress scale of the RDC TMDs assessment consists of 32 symptom items rated on how distressing each is, from 0 ("not at all") to 4 ("extremely"). The 3 subscales are depression with vegetative symptoms (20 items) and 2 non-specific symptom scores: pain symptoms (5 items) and non-pain symptoms (7 items). The items are from the depression, somatization, and "additional" scales of the SCL-90-R (Symptom Checklist 90-R),[42] a widely used self-rating instrument. The RDC developers explicitly rejected use of the term *somatization* when referring to the TMDs pain syndrome, in favor of *non-specific symptoms*. All 3 subscales were secondary outcomes. They are scored by taking the mean of the non-missing items; if more than one third of the responses are missing for a scale, it is set to missing. For the depression subscale, a score of <0.535 indicates an absence of depression.[42]

The Q-LES-Q-SF consists of the 14 items in the "General Activities" section of the long form, which showed good internal consistency and validity.[43] The items ask for ratings, on a 5-level scale of "very poor" (1) to "very good" (5), of a broad range of aspects of daily life including health, relationships, and activities.

TABLE 2 Items Rating Pain and Functional Impact

Questions Asked During the Screening Call	
Pain Intensity Items	
1	On a scale of 0 to 10 where 0 is "no pain" and 10 is "the worst pain you can imagine," how would you rate your facial pain in the last week?
2	On a scale of 0 to 10 where 0 is "no pain" and 10 is "the worst pain you can imagine," how intense was your worst pain in the past 6 months?
3	On a scale of 0 to 10 where 0 is "no pain" and 10 is "the worst pain you can imagine," on the average how intense was your pain in the past 6 months? (That is, your usual pain at times you were experiencing pain.)
Functional Impact Items	
4	About how many days in the last 6 months have you been kept from your usual activities (work, school, or housework) because of facial pain?
5	On a scale of 0 to 10 where 0 is "no interference" and 10 is "unable to carry on any activities," how much has facial pain interfered with your daily activities in the past 6 months?
6	On a scale of 0 to 10, where 0 is "no change" and 10 is "extreme change," how much has facial pain changed your ability to take part in recreational, social, and family activities in the past 6 months?
7	On a scale of 0 to 10, where 0 is "no change" and 10 is "extreme change," how much has facial pain changed your ability to work (including housework) in the past 6 months?
Questions Asked at Each Treatment Visit and During Follow-up	
1	In the last week, how intense was your worst TMDs-related pain, rated on a 0 to 10 scale where 0 is "no pain" and 10 is "pain as bad as it could be"?
2	In the last week, on average, how intense was your TMDs-related pain, rated on a 0 to 10 scale where 0 is "no pain" and 10 is "pain as bad as it could be"?
3	In the last week, how improved was your TMDs-related pain rated on a 0 to 10 scale where 0 is "much worse," 10 is "much improved, " and 5 is "no change"?
4	In the last week, how much has TMDs-related pain interfered with your daily activities rated on a 0 to 10 scale where 0 is "no interference" and 10 is "unable to carry on activities"?

The sum of these items (possible range, 14-70) is converted to percent of maximum, (range 0-100). This was the fourth secondary outcome measure.

Other Self-report Measures

We piloted the acceptability and potential usefulness of several measures of psychological state and traits as potential mediating variables for a planned larger trial. These are described below. We also measured factors hypothesized to moderate receptivity toward CAM treatment[44,45] in pre- and post-treatment questionnaires. Other items were used to measure beliefs about CAM, expectations of treatment, and the effect of intervention treatment on use of other healthcare (allopathic, CAM, self-care). In addition to those listed below but not reported on here, we collected baseline and follow-up responses to the Measure Yourself Medical Outcome Profile (MYMOP).[46,47] Results of the MYMOP, along with other qualitative results, are the subject of another paper.

Scales used in the questionnaires included the following.

NEO Five-Factor Inventory (NEO-FFI).[48] The full NEO-FFI is a 60-item self-report measure of 5 personality domains. We used two 12-item subscales: neuroticism and openness. The items are statements about typical behavior and thoughts (eg, "I often try new and foreign foods") to which the participant responds by marking a choice from "strongly disagree" (0) to "strongly agree" (4). The scores are a sum of the item ratings, with a range of 0-48 on each scale.

The *Hope Scale*[49] Pathways subscale consists of 4 items from the longer Hope Scale questionnaire. Participants rate statements about handling difficulties in one's life on a 4-point scale from "definitely false" (1) to "definitely true" (4). The total score is the sum of these items, with a range of 4-16.

Helping Alliance Questionnaire, Version 2 Patient form(HAQ-II-P).[50] The HAQ-II-P measures practitioner-client affective attachments and willingness to invest in the therapy process (ie, therapeutic alliance). It consists of 19 statements rated on a 6-level scale from "strongly disagree" (1) to "strongly agree" (6). The score is the mean of these ratings, with a range of 1-6. The HAQ-II-P has been used extensively and has acceptable reliability and validity.[51]

Modified Life Events. We obtained 2 scores from this instrument.[52-54] "Number of events in past year" is a count of events marked, with scores >3 grouped into a single value and missing if no boxes are marked. ("No" is an available option.) "Impact of life events" is a count of items rated "very upsetting," grouped into 1, 2, 3, 4-5, and >5. It is missing if no life events or impact ratings are marked.

Items assessing CAM use and attitudes used in this study developed by the authors for the OCCAM measured use of CAM for TMDs and non-TMDs conditions through yes/no responses about 14 CAM treatments. Attitude toward CAM was measured by "helpfulness" rating on the 14 CAM modalities for treatment of TMDs. Items were considered missing if none of the options was marked.

Recruitment

We recruited participants from the general population in Portland, Oregon, via brief descriptive flyers and newspaper ads. The flyers were posted in bookstores; health food groceries; yoga studios; and the offices of physicians, psychologists, and CAM providers. Ads for the study were placed in an alternative health newspaper, a Portland-area independent newspaper, and in newspapers targeted to the African American and Latino communities. Women interested in the study contacted the project recruiter by phone and underwent a brief phone screening, which included self-ratings on the RDC Axis II pain and functional impact scales (described above). Potential participants had to have at least a 3 on the rating of facial pain in the last week to be eligible. Recruiters answered participant questions about the study and confirmed eligibility.

For initially eligible women, the recruiter set up an in-person screening visit and sent a confirmation letter, a baseline questionnaire to complete and bring to the screening visit, and a copy of the study's informed consent to review before the visit.

At the screening visit, potential enrollees were examined by a trained, calibrated dental examiner using the Research Diagnostic Criteria Exam (RDC)[36] to confirm the diagnosis of current TMDs.

Safety

Because the safety of shamanic healing had not yet been demonstrated in a clinical trial and because of the prevalence of depression among individuals with TMDS, we developed a psychiatric critical incident response protocol. The protocol defined procedures for practitioners and study staff members to assess suicidality and appropriate response. A psychiatric nurse practitioner was on call throughout the duration of the study to provide consultation and intervene if necessary.

Randomization

Before participants were enrolled, the study statistician (CG) prepared the randomization list using permuted blocks with masked block size. Eligible participants were randomly assigned to 1 of 4 SPs. Assignment was masked until after the eligibility and consent processes were complete.

Intervention

During the first visit, the SP explained shamanic healing, did a diagnostic journey, and answered participant questions. Shamanic treatments were carried out during visits 2 through 5. SPs scheduled the visits with the participants. The SP's recounting of her journey to the participant was audio recorded (for subsequent transcription and qualitative analysis). The SP also maintained a chart for each participant with notes of treatment and patient condition and the participant's self-ratings of pain. The goal was to complete all visits within a 6-week period (42 days).

The shamanic healing protocol was developed through collaboration between the authors (led by LW) and the SPs. We paid particular attention to building consensus among the SPs

regarding the content, number, and timing of visits by participants to an SP's office. For example, the SPs anticipated that most of the participants would need soul retrieval but agreed that soul retrieval was not a required treatment. The protocol therefore consisted of guidelines for acceptable treatments but did not prescribe which treatments needed to be used or in what order. SPs agreed to schedule weekly appointments with allowance for 2 weeks after soul retrieval because of the need for participants to integrate the soul retrieval experience. This protocol accommodated the individualized treatment typical of shamanic healing and allowed the SPs to follow the indications of her spiritual guides for each participant's treatment.

Study staff members shared information on the illness and psychologically complex profile of the likely participants, based on study staff members' experience interviewing these patients in past studies. The SPs agreed that these participants would likely be suffering the following spiritual illnesses.

Soul loss, indicating a fracture of a person's sense of wholeness, is often characterized as not feeling in one's body. Soul retrieval brings back those soul essences that dissociated, often during trauma, restoring the individual's sense of wholeness or well-being.

Power loss is characterized by feelings of helplessness and loss of power or energy. Power animal retrieval restores the individual's connection with a spirit animal or teacher to help restore a sense of personal power.

Spiritual intrusion is characterized by pain, feelings that parts of the body are numb, and a sense of blackness or heaviness. Extraction removes the heavy, negative energy from the individual.

Dispirited or low energy is characterized by an occasional awareness of other voices or negative energies felt in the spirit/body. Influence of ancestors or presence of non-living suffering beings may be interfering with the energy in an individual and are removed by depossession or psychopomp (helping a suffering being to go into the light).

Over the course of 5 sessions, SPs usually teach the client to journey so she can become empowered for her own healing and integrate the information brought back to her from treatment. Staff members and SPs felt that some participants might not wish to learn to journey. SPs agreed to use guided visualizations and meditations to help participants integrate their healing. SPs also agreed to use soul remembering, which helps the client to become more aware of her life purpose, during the fifth visit if SPs spirit guides indicated that participants were ready for that ceremony.

SPs were also trained in how to use the psychiatric critical response protocol. A psychiatric nurse practitioner was on call throughout the duration of the study to provide consultation and intervene if necessary.

Statistical Analysis

Feasibility is reported as number of participants completing each phase. Acceptability of treatment is assessed through post-treatment interviews with participants. Safety is reported as adverse events by time point during treatment and follow-up. In addition, we report on psychological crises, which were closely monitored.

Efficacy is evaluated on change in the RDC diagnosis and change in self-reported symptoms relevant to TMDs from baseline to end of treatment. The primary test of the other outcomes is a paired t test comparing the baseline value of each primary outcome measure to the corresponding end of treatment measure. The effect size measure is Cohen's d,[55] which is the ratio of the difference score over the standard error of the difference. Since this study is a pilot, we set 2-sided α at .05 to determine significance and did not adjust for multiple comparisons.

We did not attempt to impute missing data in this small sample. Instead, we evaluated the sensitivity of the results to sample definition by examining how changing the sample definition affected the effect size estimates. The 2 sample definitions are (1) eligible participants who completed treatment ("eligible completers") and (2) all eligible participants, with the last observation carried forward to impute end of treatment values for the participants who dropped out. (We expected this result would show a bias toward less change.)

In secondary, exploratory analyses, we evaluated the impact of an *a priori* list of baseline measures on the change scores. Since we did not know what to expect, we used a stepwise regression to select predictors. Because we were concerned about making type I errors, we used the relatively stringent method of forward stepwise with significance level to enter set at .05. We analyzed only preselected predictors. The preselected predictors of primary outcomes are HAQ-II-P, Q-LES-Q-SF, NEO-FFI Neuroticism, NEO-FFI Openness, Hope Pathways, Modified Life Events (4 scores: 1-year events, 1-year impact, 5-year events, 5-year impact), SCL-90 Depression Scale, Axis II Non-Specific Symptoms-non-pain, and Axis II Non-Specific Symptoms-pain scales. The last 4 predictors served as both covariates in analysis of primary outcomes and as secondary outcomes. We also evaluated whether the assigned shaman had any impact on the primary and secondary outcomes, using 1-way analysis of variance.

Before proceeding with the quantitative analysis, we investigated missing and out-of-range data and corrected as needed. We verified the distributional assumptions of the planned analyses and took suitable statistical transformations as needed. We also evaluated the correlations between planned covariates to identify any potential collinearities. Finally, we tested for baseline differences between SPs to evaluate whether the randomized assignment resulted in equivalent participant groups. For these tests we used 1-way analysis of variance (continuous normally distributed), Kruskal-Wallis (continuous, not normally distributed), or Mantel-Haenszel χ^2 (ordinal) tests as appropriate for the type of variable (indicated in parentheses).

RESULTS

Feasibility: Recruiting and Retention

Recruiting experience is documented in the CONSORT flow diagram (Figure).[56] We recruited 47 people by newspaper, 18 by flyer, 4 through healthcare providers, 4 through word of mouth, and 10 by other means.

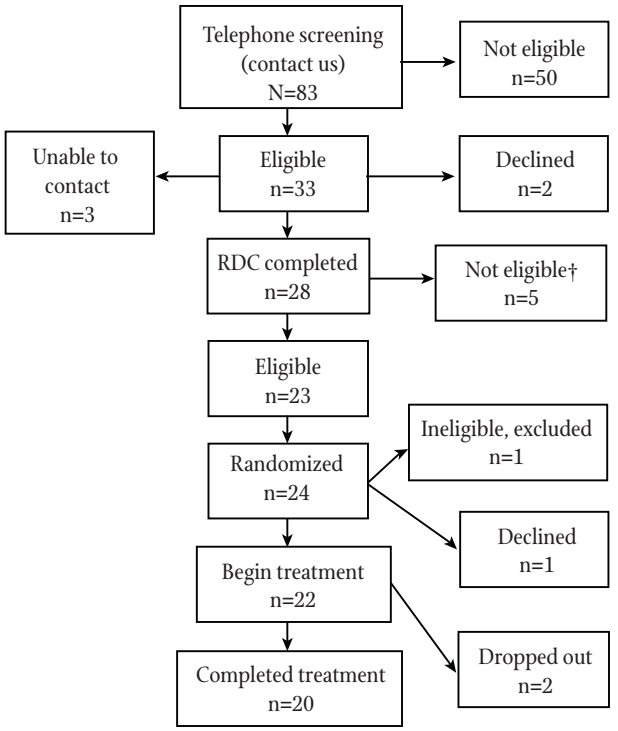

FIGURE CONSORT Diagram*

*RDC indicates Research Diagnostic Criteria.
†1 randomized in error.

As the figure shows, of 83 women who contacted us about the study, 23 were eligible; all agreed to be randomized. One additional woman was randomized in error. She was found to be ineligible upon audit of her RDC examination shortly after randomization; she did not receive any treatments and was not followed further. Of 23 eligible randomizations, 20 went on to complete treatment. Of the 3 women who dropped out, 1 failed to appear for first appointment (passive refusal), 1 moved out of the area, and 1 dropped out after 1 treatment. This individual declined further treatment but agreed to be followed and will be included in long-term follow-up analyses (to be reported in a separate article).

To evaluate the SP visit scheduling, we excluded the 2 subjects who dropped out within 1 week of randomization. Visits 1 and 2 were supposed to be 2 weeks apart to allow time for the pretreatment interview; the mean interval was 15.2 days (SD 10.0, median 14). The mean interval between later visits was 10.6 (SD 8.2), with a median of 7 days. On average, the visits were completed within 47.5 days (SD 12.2, median 47), with a range of 31-77 days. In 3 instances, there was a gap of more than a month between a pair of visits. The mean interval from last treatment visit to posttreatment RDC exam was 11.2 days (SD 6.6, median 8.5).

Intervention

Table 3 summarizes the treatments. Twenty-two participants received a diagnostic journey at the first treatment visit. Two participants dropped out after the first visit. Of the 20 participants who completed treatment, all received a soul retrieval; 3 received 2 soul retrievals each. Several participants received more than 1 extraction. Integration of the SP's journey information brought back to the participants was a significant component of the shamanic intervention; SPs did 30 guided meditations and visualizations with the participants. Nine participants received a depossession and 7 received psychopomp. Nine participants received a soul remembering ceremony during their last visit to the SP.

SPs showed consistency in treatment of participants: all SPs used the diagnostic journey, soul retrieval, extraction, power animal retrieval, and soul remembering.

TABLE 3 Summary of Shamanic Treatments Used in This Study

	Total number of treatments	Number of shamanic practitioners using the treatment at least once	Number of participants who received treatment at least once*
Soul retrieval	23	4	20
Extraction	23	4	19
Depossession	9	3	9
Power animal retrieval	16	4	14
Psychopomp	7	3	7
Guided meditation	30	3	17
Ritual or ceremony	9	3	9
Soul remembering	9	4	9
Body part retrieval	2	1	2
Energy work/energy retrieval	6	2	6
Curse unravel/cord cutting	3	2	3
Spirit helper retrieval	1	1	1

*Counts include the 20 who completed visits.

Sample Characteristics

The characteristics of the eligible, randomized sample are shown in Table 4. The group was all white, with 1 woman reporting Hispanic ethnicity. Only 1 of the 23 enrolled participants had never sought allopathic treatment for TMDs; 52% had sought such treatment in the previous 6 months.

Twenty of the 23 participants had tried at least 1 of 13 CAM modalities as treatment for TMDs before entering this study; the median was 4. The most frequently tried were massage therapy (59%), chiropractic care (50%), meditation or progressive relaxation

TABLE 4 Demographics (N=23)

Variable	Mean or %	SD
Age (years)	38.3	8.3
Education		
Less than college degree	39.1%	
College graduate or higher	60.9%	
Income		
$0-$14,999	39.4%	
$15,000-$49,999	34.8%	
$50,000 or more	26.1%	
Marital status (% single)*	45.4%	
No of CAM therapies		
for TMD	4.3	2.8
for other conditions	8.7	4.1
No. of allopathic treatments for TMD	1.8	1.3
Overall health		
Excellent/very good	17.4%	
Good/fair	82.6%	

*1 missing.

(47%), yoga (44%), and acupuncture (41%). The first 3 were rated as "helpful" by a majority of those who had tried them. Other modalities were tried by 25% or less of the group; most were judged helpful by less than 50%.

The most frequently reported co-morbid conditions (Table 5) were depression (74%) and headaches (69%). Gastrointestinal and reproductive problems were reported by 48% and 43%, respectively; no other condition was reported by more than 25% of the participants. About 43% reported 2 conditions (the minimum for entry), and the balance reported 3-6 conditions.

Out of 26 tests (Kruskal-Wallis or Mantel-Haenszel) for differences between SPs on baseline characteristics of the participants, none reached significance. There also were no differences between SPs in the effects of treatment.

Table 5 shows the means for outcomes and planned covariates at baseline and after treatment. Compared to norms for women on the NEO-FFI, the sample is at the 87th percentile on the neuroticism scale and at the 95th percentile on the openness scale. The score of 54.22 on the Q-LES-Q-SF indicates an average quality of life rating of about "fair" on this 14-item scale. Their mean at baseline on the Hope Pathways was moderate. The HAQ II-P shows good alliance, with a mean of 5.24 out of a possible 6.

TABLE 5 Outcomes and Covariates, Pre- and Post-treatment*

	Baseline			Post-treatment		
Variable	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
Primary outcomes						
Usual pain	23	4.96	1.33	20	2.70	2.20
Worst pain	23	7.48	1.41	20	3.60	2.52
Functional impact of TMD	23	3.74	3.15	20	1.15	2.25
Secondary outcomes						
SCL 90-R (depression)	23	1.50	0.76	20	0.87	0.62
Non-specific symptoms-pain	23	0.89	0.73	20	0.63	0.68
Non-specific symptoms-nonpain	23	1.24	0.61	20	0.98	0.65
Pre-specified covariates						
HAQ II-P	21	5.24	0.80	20	5.47	0.53
Q-LES-Q-SF	23	54.22	16.28	20	64.45	15.15
Hope Pathways subscale	23	11.70	1.89	20	12.90	1.74
NEO-FFI neuroticism†	23	27.87	7.98			
NEO-FFI openness†	23	36.04	6.77			
Number of life events: past yr†	23	3.57	2.43			
Impact of life events: past yr†	23	2.39	2.54			
Number of life events: past 5 yrs†	23	4.57	2.27			
Impact of life events: past 5 yrs†	23	2.87	2.24			

*TMD indicates temporomandibular joint disorder; SCL 90-R, Symptom Checklist 90-R; HAQ-II-P, Helping Alliance Questionnaire, Version 2, patient form; Q-LES-Q-SF, Quality of Life and Enjoyment Scale-short form; NEO-FFI, NEO Five Factor Inventory.
†Not administered/asked at follow-up.

Acceptability

During the post-treatment interviews, participants were queried about the acceptability of treatment, including their reaction to the location and ambience of the treatment setting, scheduling of visits, the duration and number of visits, and their overall general experience of treatment. All of the participants reported the location and ambience of their treatment setting as "easy" and acceptable. Most of the participants reported scheduling to be flexible and convenient. A majority of the participants found the length and number of visits (5) acceptable, and about half of the participants indicated they would have been willing to participate in more shamanic treatments. Also, about half of the participants indicated the spacing of the visits (1 per week) to be too frequent at times. Participants recommended that future studies of this nature allow for more flexibility in the spacing of visits so that participants have time to integrate the experiences between visits. Overall, all participants reported the experience of participating in the study and receiving shamanic treatments as positive.

Safety

No adverse events, including critical mental health incidents, were reported.

Efficacy

All of the women met research diagnostic criteria for TMDs at baseline, but only 4 continued to meet RDC after treatment. All of the *t* tests of changes from baseline in the primary and secondary outcomes are significant (Table 6), with improvements in all measured symptoms. The mean of usual pain went from 4.96 to 2.70, $P<.0001$; worst pain from 7.48 to 3.60, $P<.0001$; and functional impact of TMDs from 3.74 to 1.15, $P<.0052$. These changes remained significant even when we carried forward the baseline values of the 3 participants who dropped out. There were no differences between SPs in either primary or secondary outcome measures.

The stepwise regression analysis on baseline predictors was sensitive to small changes in the dataset (eg, whether the HAQ-II-P with 1 missing value was included in the model or not). We

TABLE 6 *t*-test Results for Primary and Secondary Outcomes (Post-treatment-Pretreatment)

Dependent variable	Mean	SD	95% Confidence limits	*t*	*P*	Cohen's *d*
Primary analysis: completers (N=20)						
Primary outcomes						
Usual pain	-2.25	2.07	-3.22, -1.28	-4.85	.0001	1.09
Worst pain	-3.90	2.38	-5.02, -2.78	-7.32	<.0001	1.64
Functional impact of TMDs	-2.30	3.26	-3.83, -0.77	-3.15	.0052	0.71
Secondary outcome						
SCL 90-R (depression)	-0.71	0.66	-1.02, -0.41	-4.85	.0001	1.08
Quality of life	-11.80	14.17	-18.43, -5.17	-3.72	.0014	0.83
Non-specific symptoms-pain	-0.28	0.54	-0.02, -0.53	-2.26	.0356	0.52
Non-specific symptoms-nonpain	-0.29	0.45	-0.08, -0.50	-2.91	.0090	0.65
Sensitivity analysis: last observation carried forward (N=23)						
Primary outcomes						
Usual pain	-1.96	2.08	-2.85, -1.06	-4.52	.0002	0.94
Worst pain	-3.39	2.59	-4.51, -2.27	-6.28	<.0001	1.31
Functional impact of TMDs	-2.00	3.13	-3.36, -0.64	-3.06	.0057	0.64
Secondary outcomes						
SCL 90-R (depression)	-0.62	0.66	-0.90, -0.34	-4.52	.0002	0.94
Quality of life	-10.26	13.78	-16.22, -4.30	-0.357	.0017	0.74
Non-specific symptoms-pain	-0.24	0.51	-0.02, -0.46	-2.23	.0361	0.47
Non-specific symptoms-nonpain	-0.25	0.43	-0.07, -0.44	-2.84	.0096	0.59

concluded that the sample is too small to obtain reliable regression results.

DISCUSSION

In this first-ever clinical trial of shamanic healing for TMDs, we found that a study of shamanic healing was feasible and acceptable to patients. The question of whether participants would enroll and remain in a study of shamanic healing was answered favorably. We were able to complete recruitment in a much shorter amount of time than expected due to the overwhelming response to our recruitment ads. Our dropout rate was low (and early in the study for those who did so), which indicates that the protocol was not overly burdensome.

Safety was demonstrated by lack of adverse events. Although individuals showed indications of depression at baseline, none had these symptoms exacerbated by the treatment. In fact, participants showed marked improvement in depression from baseline to end of treatment. Depression is responsive to attention; however, short-term depression outcomes should be viewed with some caution. Analysis of longer-term outcomes will reveal whether these changes are persistent or an artifact of study participation.

The impressive efficacy results suggest that this form of healing may be a viable treatment for this chronic pain disorder. It is intriguing that although the shamanic healing protocol did not include any physical treatment of TMDs (as in other CAM studies involving acupuncture, massage, or chiropractic), the treatment appears to have had a significant impact on participants' pain levels. CAM practitioners and mind-body researchers theorize that healing happens through correcting imbalances in energy meridians or neuropeptides.[33,34] However, CAM therapies may not only change physiological and biological processes but also reframe the patient's mental representation of the symptoms.[23] For example, a patient may shift from viewing symptoms as dysfunction to viewing them as a cue to his or her physical and mental status, such as muscle tension or mental stress. If treatment effect is confirmed in a larger, controlled study, it would be useful to explore the mechanisms underlying these effects.

One challenge of conducting CAM clinical trials is to develop protocols that respect the individualistic and holistic nature of CAM, yet meet the replicability demands of a rigorous clinical trial. An aim of this phase 1 study was to develop and test a "whole systems" protocol for shamanic healing. As we developed the study protocol, it became necessary to create a best practices model that incorporated commonalities in shamanic practice and navigated through the idiosyncratic practices of individual SPs. For example, all practitioners agreed that accepted practice includes treatments such as soul retrieval and power animal retrieval. The practitioners further agreed to use guided visualizations and meditations as a substitute for teaching participants to journey in order to maintain consistency among participants. Part of the usual shamanic healing "protocol" is for the SP to encourage the client to learn to journey so they can become empowered to communicate with their own spirits and begin to heal themselves. Other features of practices—especially the number of visits that constitute adequate treatment—varied across practitioners, influenced by their personal style or the financial and time constraints of their clients.

Working with a community SP in a participatory research model,[57] we developed a protocol that reflected what all practitioners felt to be a model of good practice. The compromise made to the external constraints of the study was the weekly pace of the visits. This seemed to be an acceptable schedule of treatment, although it is a less flexible approach to scheduling than is typical in practice. In post-treatment debriefing interviews, both participants and practitioners recommended more time between treatments to allow for integration of changes initiated by the treatments.

Another challenge of this trial is the nature of this chronic condition and how it affects all aspects of these women's lives. In addition to experiencing pain and depression, a number of these women were living very stressful lives. Several lost family members or jobs, ended relationships, and/or became homeless or moved during the study. The SPs accommodated the needs of participants who often canceled appointments. The stressful lives of people with chronic pain is a significant challenge to their healing and their ability to participate in clinical studies.

Limitations

The results of this study should be considered in light of some limitations of the study. First, we had no control group. Shamanic healing had never been evaluated in a clinical trial; therefore, we integrated qualitative interviews into the study design to determine how participants defined and assessed healing and characterized the experience and acceptability of shamanic healing. Information from this study will guide selection of an appropriate control group in future studies. This model is appropriate for a phase 1 trial to develop and test a previously unstudied healing method, but our use of it did not provide an opportunity to compare outcomes of shamanic healing to a more standard form of treatment.

A second limitation is the small sample size. Although appropriate for a phase 1 trial, the limited sample size permitted only limited examination of provider effects and ruled out multivariable analyses. By deliberately designing a study that is both a clinical trial and an ethnography of shamanic healing, we were able to document the process of developing whole systems protocols and the effects of study participation on both participants and providers. These results are beyond the scope of this article and will be reported elsewhere.

The third limitation is the fact that items used at baseline to measure pain intensity were not identical to those used during and after treatment. In addition to the reference time frame being different (ie, "in the past 6 months" at baseline and "in the past week" at other points), the wording of the items was different (Table 2). At baseline, the item asked about "facial pain," whereas subsequent surveys asked about "TMDs-related pain." In addition, although all pain questions were administered as

oral survey items, the study practitioners, rather than study administrative staff members, asked the questions during treatment. It is possible that the internal validity of assessments collected at treatment visits was compromised as a result. Nevertheless, the consistency of self-report at all follow-ups, as well as in qualitative interviews, leads us to believe that the variation in wording and data collection methods did not affect the validity of our findings.

Third, all of our SPs were white, female, and trained in a Western-adapted form of shamanism. We decided to use a Western-adapted form of shamanism to ensure consistency of treatment and to provide the least cultural dissonance for participants. We elected to use only female providers because we felt this would be most comfortable for female participants, who were in direct, if limited, physical contact with the provider during treatment. Our providers are representative of the majority of individuals who seek Harner/Ingerman training.

Although all of our participants were female and Caucasian, these characteristics are consistent with TMDs prevalence data[5,6] and do not adversely affect generalizability of results.

CONCLUSION

This study of shamanic healing for women with TMDs is, to our knowledge, the first clinical trial of shamanic healing and the first to test the feasibility, acceptability, and safety of a shamanic healing protocol for chronic pain (TMDs). We found the clinical trial to be feasible, and the shamanic healing was acceptable to participants and providers. Further, the highly significant efficacy results warrant further research into this form of healing as a viable treatment for TMDs.

Traditional systems of healing, such as shamanism, may not readily lend themselves to conventional research methods, yet studying their effectiveness is especially germane in the case of chronic conditions (such as TMDs) that involve an emotional component that eludes allopathic treatment regimes.

Acknowledgments

Funding for this study was provided by the National Center for Complementary and Alternative Medicine Grant R21 AT000951. The authors wish to express their appreciation to the shamanic practitioners, Karyn Armstrong, Michelle Catalani-Stringham, Michelle Christiansen, and Stephanie Turner, who consulted with us and provided care in this study. We could not have completed this study without their dedication and willingness to engage in clinical research. We also wish to acknowledge Lynn Debar, Vicki Axford, Kelly Reis, Donna Clark, Jen Coury, Jeanne Reinhardt, and Paul Cheek for their valuable assistance with this study. We are also grateful to our participants for their time and commitment.

REFERENCES

1. NIH. Conference Statement. Management of Temporomandibular Disorders. Paper presented at: NIH Technology Assessment Conference on Management of Temporomandibular Disorders Conference; April 29, 1996; Bethesda, MD.
2. Von Korff M, Ormel J, Keefe F, Dworkin SF. Grading the severity of chronic pain. *Pain.* 1992;50(2):133-149.
3. Dworkin SF. Perspectives on the interaction of biological, psychological and social factors in TMDS. *J Am Dent Assoc.* 1994;125(7):856-863.
4. Carlsson GE, LeResche L. Epidemiology of temporomandibular disorders. In: Sessle BJ, Bryant PS, Dionne RA, eds. *Temporomadibular Disorders and Related Pain Conditions: Progress in Pain Research and Management.* Vol. 4. Seattle, WA: IASP Press, 1995:211-226.
5. LeResche L. Epidemiology of temporomandibular disorders: implications for the investigation of etiologic factors. *Crit Rev Oral Biol Med.* 1997;8(3):291-305. Review.
6. Shimshak DG, Kent RL, DeFuria M. Medical claims profiles of subjects with temporomandibular joint disorders. *Cranio.* 1997;15(2):150-158.
7. Von Korff MR, Howard JA, Truelove EL, Sommers E, Wagner EH, Dworkin S. Temporomandibular disorders. Variation in clinical practice. *Med Care.* 1988;26(3):307-314.
8. Schwartz RA, Greene CS, Laskin DM. Personality characteristics of patients with myofascial pain-dysfunction (MPD) syndrome unresponsive to conventional therapy. *J Dent Res.* 1979;58(5):1435-1439.
9. Turk DC, Zaki HS, Rudy TE. Effects of intraoral appliance and biofeedback/stress management alone and in combination in treating pain and depression in patients with temporomandibular disorders. *J Prosthet Dent.* 1993;70(2):158-164.
10. Korszun A, Hinderstein B, Wong M. Comorbidity of depression with chronic facial pain and temporomandibular disorders. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* 1996;82(5):496-500.
11. Jones DA, Rollman GB, Brooke RI. The cortisol response to psychological stress in temporomandibular dysfunction. *Pain.* 1997;72(1-2):171-182.
12. Fillingim RB, Maixner W, Kincaid S, Sigurdsson A, Harris MB. Pain sensitivity in patients with temporomandibular disorders: relationship to clinical and psychosocial factors. *Clin J Pain.* 1996;12(4):260-269.
13. White BA, Williams LA, Leben JR. Health care utilization and cost among health maintenance organization members with temporomandibular disorders. *J Orofac Pain*. 2001;15(2):158-167.
14. Gale EN, Funch DP. Factors associated with successful outcome from behavioral therapy for chronic temporomandibular joint (TMJ) pain. *J Psychosom Res.* 1984;28(6):441-448.
15. Turk DC, Rudy TE, Zaki HS. Multiaxial assessment and classification of temporomandibular disorder pain patients: implications for treatment. In: Fricton JR, Dubner R, eds. *Orofacial Pain and Temporomandibular Disorders.* New York: Raven Press, Ltd.; 1995:145-163.
16. Gessel AH. Electromygraphic biofeedback and tricyclic antidepressants in myofascial pain-dysfunction syndrome: psychological predictors of outcome. *J Am Dent Assoc.* 1975;91(5):1048-1052.
17. McCreary CP, Clark GT, Oakley ME, Flack V. Predicting response to treatment for temporomandibular disorders. *J Craniomandib Disord.* 1992;6(3):161-169.
18. Dworkin SF, Von Korff M, LeResche L. Multiple pains and psychiatric disturbance. An epidemiologic investigation. *Arch Gen Psychiatry.* 1990;47:239-244.
19. Eliade M. Trask WR, trans. *Shamanism: Archaic Techniques of Ecstasy*. Princeton University Press; 1964.
20. Harner M. *The Way of the Shaman*. NY: HarperCollins; 1980.
21. Kleinman AM. Medicine's symbolic reality: On a central problem in the philosophy of medicine. *Inquiry.* 1973;16:206-213.
22. McGuire MB, Kantor D. *Ritual Healing in Suburban America*. New Brunswick, NJ: Rutgers University Press; 1988.
23. Achterberg J. *Imagery in Healing: Shamanism and Modern Medicine*. Boston, MA: New Science Library; 1985.
24. Ingerman S. *Soul Retrieval: Mending the Fragmented Self Through Shamanic Practice*. NY: HarperCollins; 1991.
25. Harner M, Harner S. Core practices in the shamanic treatment of illness. *Shamanism.* 2000;13(1 and 2):19-30.
26. Neher A. Auditory driving observed with scalp electrodes in normal subjects. *Electroencephalogr Clin Neurophysiol.* 1961;13:449-451.
27. Neher A. A physiological explanation of unusual behavior in ceremonies involving drums. *Hum Biol.* 1962;34:151-160.
28. Maxfield M. *Effects of Rhythmic Drumming on EEG and Subjective Experience* [master's thesis]. Ann Arbor, MI: University of Michigan; 1990.
29. Maxfield M. The journey of the drum. *ReVision.* 1994;16:148-156.
30. Harner S, Tyron W. Psychoimmunological effects of shamanic drumming. In: Hoppal M, Pentikainen J, eds. *Northern Religions and Shamanism.* Budapest: Akademiai Kiado, Helsinki Finnish Literature Society; 1992:196-204.
31. Harner S. *Immune and Affect Response to Shamanic Drumming* [dissertation]. New York, NY: Fordham University; 1994.
32. Schneider J, Vuckovic N, DeBar L. Willingness to participate in complementary and alternative medicine clinical trials among patients with craniofacial disorders. *J Altern Complement Med.* 2003;9(3):389-401.
33. Pert CB, Dreher HE, Ruff MR. The psychosomatic network: foundations of mind-body medicine. *Altern Ther Health Med.* 1998;4(4):30-41.
34. Borysenko J. Psychoneuroimmunology: behavioral factors and the immune response. *ReVision* 1984;7(1):56-65.
35. Pert CB. Emotions in the body, not just in the brain. *Brain/Mind Bull.* 1986;11(4):1-2.
36. Dworkin SF, LeResche L. Research diagnostic criteria for temporomandibular disorders: review, criteria, examinations and specifications, critique. *J Craniomandib Disord.* 1992;6(4):301-355.
37. John MT, Dworkin SF, Mancl LA. Reliability of clinical temporomandibular disorder diagnoses. *Pain.* 2005;118(1-2):61-69.
38. Schmitter M, Ohlmann B, John MT, Hirsch C, Rammelsberg P. Research diagnostic criteria for temporomandibular disorders: a calibration and reliability study. *Cranio.* 2005;23(3):212-218.
39. Widmer CG. Examination and history data collection. *J Craniomandib Disord Facial Oral Pain.* 1992;6(4):335-345.
40. LeResche L, Sherman JJ, Huggins K, et al. Musculoskeletal orofacial pain and other signs and symptoms of temporomandibular disorders during pregnancy: a prospective study. *J Orofac Pain.* 2005;19(3):193-201.
41. Bruera E, Watanabe S. New developments in the assessment of pain in cancer patients. *Support Care Cancer.* 1994;2(5):312-318. Review.

42. Derogatis L. The SCL90R: *Administration, Scoring and Procedures Manual II*. Towson, MD: Clinic Psychometric Research; 1983. *Clinical Psychometric Research*. 1983.
43. Endicott JF, Nee JF, Harrison WF, Blumenthal R. Quality of Life Enjoyment and Satisfaction Questionnaire: a new measure. *Psychopharmacol Bull.* 1993;29:321-326.
44. Tellegen A, Atkinson G. Openness to absorbing and self-altering experiences ("absorption"), a trait related to hypnotic susceptibility. *J Abnorm Psychol.* 1974;83(3):268-277.
45. Owens JE, Taylor AG, Degood D. Complementary and alternative medicine and psychologic factors: toward an individual differences model of complementary and alternative medicine use and outcomes. *J Altern Complement Med.* 1999;5(6):529-541.
46. Paterson C, Britten N. In pursuit of patient-centred outcomes: a qualitative evaluation of the 'Measure Yourself Medical Outcome Profile.' *J Health Serv Res Policy*. 2000;5(1):27-36.
47. Paterson C. Measuring outcomes in primary care: a patient generated measure, MYMOP, compared with the SF-36 health survey. *BMJ*. 1996;312(7037):1016-1020.
48. Costa PT, McCrae RR. *Revised NEO Personality Inventory (NEO PI-R) and NEO Five-Factor Inventory (NEO-FFI)*. Odessa, FL: Psychological Assessment Resources; 1992.
49. Snyder C, Harris C, Anderson J, et al. The will and the ways: development and validation of an individual-differences measure of hope. *J Pers Soc Psychol.* 1991;60(4):570-585.
50. Luborsky L, Barber JP, Siqueland L, et al. The revised Helping Alliance questionnaire (HAq-II): Psychometric properties. *J Psychother Pract Res*. 1996; 5(3):260-271.
51. Martin DJ, Garske JP, Davis MK. Relation of the therapeutic alliance with outcome and other variables: a meta-alalytic review. *J Consult Clin Psychol.* 2000;68(3):438-450.
52. Berkman LF, Syme SL. Social networks, host resistance, and mortality: a nine-year follow-up study of Alameda County residents. *Am J Epidemiol.* 1979;109(2):186-204.
53. Ruberman W, Weinblatt E, Goldberg JD, Chaudhary BS. Psychosocial influences on mortality after myocardial infarction. *N Engl J Med.* 1984;311(9):552-559.
54. Brugha TS, Cragg D. The List of Threatening Experiences: the reliability and validity of a brief life events questionnaire. *Acta Psychiatr Scand*. 1990;82(1):77-81.
55. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. Hillsdale NJ: Lawrence Erlbaum Associates; 1988.
56. Moher D, Jones A, Lepage L. Use of the CONSORT statement and quality of reports of randomized trials: A comparative before and after evaluation. *JAMA*. 2001;285(15):1992-1995.
57. Cornwall A, Jewkes R. What is participatory research? *Soc Sci Med.* 1995;41(12):1667-1676.