



Primary Care Management for TMJD Pain

A. Specific Aims

Overview. The overall goal of this project is to collect data to be used in preparing an application for a Clinical Trial Planning Grant and then in designing a subsequent Phase III clinical trial. The ultimate goal of this series of research projects is to determine the most practical approach to conduct a randomized clinical trial (RCT) to evaluate initial interventions for patients with painful temporomandibular muscle and joint disorders (TMJD) in primary care clinics using NIDCR's Collaboration On Networked Dental and Oral Health Research (CONDOR) group consisting of the three dental Practice-Based Research Networks (PBRNs). A review board for NIDCR's Clinical Trials Program concluded that this goal had programmatic significance and encouraged us to apply for this R21 Clinical Pilot Data Grant. We did this and received a priority score of 211. However, this RFA has since been cancelled. In discussions with NIDCR, it was recommended that we proceed with this project with support from the PBRNs. Regardless, all three PBRNs, Northwest Practice-based REsearch Collaborative in Evidence-based DENTistry (i.e., PRECEDENT), Dental Practice-Based Research Network (i.e., DPBRN), and the Northeast Practitioners Engaged in Applied Research and Learning (i.e., PEARL), support this unprecedented opportunity to assess and establish guidelines for the treatment of patients with painful TMJD in the primary care setting. The proposed project will accomplish the following aim:

Aim 1. Characterize by survey the feasibility of recruiting dentists in primary care dental clinics in the Practice-Based Research Network and document their current initial care for their TMJD pain patients.

- 1.1 Estimate the potential number of CONDOR dentists that provide TMJD pain treatments, the participation rate and their willingness to randomize their TMJD pain patients to different treatment options for an eventual Phase III RCT.
- 1.2 Estimate the potential number of TMJD pain patients per month being seen by the CONDOR dentists.
- 1.3 Determine the CONDOR dentists preferred treatment options to include in the TMJD pain RCT.
- 1.4 Describe the types of treatments of dentists currently providing TMJD care relative to the components of self care, medications recommended or prescribed, and type of splints provided.
- 1.5 Document the economic and business barriers to participation by the CONDOR dentists in an eventual Phase III clinical trial.

B. Background and Significance

It has been estimated that approximately 5-10% of the US population will seek professional dental care for temporomandibular muscle and joint disorders (TMJD) symptoms in their lifetime and more than 5 million people sought care in a 6-12 month time period at an estimated direct cost of \$2 billion dollars.¹⁻³ The 1997 Technology Assessment Conference Statement supported patient education with self-care, pharmacological pain control, physical therapy, splint therapy and occlusal therapies as appropriate initial therapeutic interventions for the management of patients with pain.⁴ This Statement further states: "Although a vast array of therapeutic modalities have been offered for TMD patients, there is a paucity of clinical studies, and especially randomized controlled clinical trials, to guide management of these patients. Given that most patients have a self-limited disorder and that a variety of different therapies appear to result in similar improvements in pain and dysfunction, caution is urged with regard to use of invasive and other irreversible treatments, particularly in the initial management of TMD." The Statement goes on to note that occlusal therapy is irreversible and should only be used to "... identify and eliminate gross occlusal discrepancies such as those that may inadvertently occur as a result of restorative procedures."

Review of randomized clinical trials performed in primary care clinics to assess initial care for TMJD

There are no randomized clinical trials (RCT) that have assessed the comparative effectiveness between any of the above initial treatments in a primary care setting, and only a single RCT has been done in a primary care setting.⁵⁻⁷ This study compared a stabilization splint versus a non-occluding (i.e., placebo) splint in patients with a diagnosis of “muscle disorder or muscle and joint disorder.” No significant differences were found between groups for reducing TMJD pain at the 6-week follow-up.⁵ At 1-year follow-up, 81% of all subjects reported good to excellent reduction in pain with either treatment, and only 14% of the patients were referred to a TMJD specialty clinic.⁶ This suggests that the vast majority of TMJD patients may be able to be treated successfully in the primary care setting by a general dentist.

Short-term Randomized Clinical Trials performed in Tertiary Care Centers

Self-care, medications, splints and jaw exercises have been assessed in tertiary care centers. Self care for TMJD pain traditionally consists of instruction for implementation of a home-based pain-free diet, bilateral chew, use of heat and ice, yawn control, monitoring for and control of oral habits, sleep hygiene, and jaw posture control⁸⁻¹¹ which may be augmented with physical self-regulation including training in breathing and relaxation.¹² The PI on this proposal has been involved in two short-term randomized clinical trials (RCT) assessing self-care versus medications and jaw exercises, respectively.¹⁰⁻¹¹ The results of these 2 short-term RCTs indicated that self care with medication (i.e., flexoril ®) is associated with a 70% reduction in pain intensity compared to 40% for self care with placebo medication.¹⁰ Jaw and postural exercises done with self care did not improve the outcome associated with self care alone.¹¹ Two other RCTs compared self care versus self care with exercises, and one reported a significant difference at reducing pain when exercises were added to self care, and one found no difference, respectively.^{13, 14} When self care and exercises are compared to each other, jaw exercises were superior at decreasing jaw pain.¹⁵ Other RCTs suggest that jaw exercises are superior to sham exercises or a waiting list control at decreasing jaw pain.^{16, 17} RCTs comparing self care and stabilization splints as well as jaw exercises and stabilization splints, reported and no difference between treatments.^{18, 19}

Review articles assessing RCTs comparing different medications suggest that short-term use of benzodiazepine, especially in combination with ibuprofen, and tricyclic antidepressants (i.e., amitriptyline) are efficacious treatments for TMJD pain.²⁰⁻²² Review articles assessing RCTs for physical therapy treatments conclude, “... most of these therapies have not been shown to be more efficacious than placebo.”²³ Review articles assessing RCTs for splint therapy, including “placebo” splints, conclude: “Occlusal splint studies yielded equivocal results. Even in the most studied area, stabilization splints for myofascial pain, the results do not justify definite conclusions about the efficacy of splint therapy.”²⁴⁻²⁶ Overall, these RCTs indicate that most of the commonly used initial treatment options available to dentists can be effective alone or in combination, but no definitive conclusions can be rendered for their relative effectiveness or efficacy. Furthermore, since these trials were done in tertiary care centers, these results may not be applicable to patients in the primary care setting since the patient populations in these two settings may not be comparable for physical diagnoses, psychosocial and behavioral variables, and occurrence of co-morbid conditions.

Long-term Randomized Clinical Trials (RCT) performed in Tertiary Care Centers (1 year or more follow-up)

Long-term follow-up studies for RCTs in the TMJD literature are rare. Simple self care instruction, as described above, has been augmented with cognitive behavioral interventions, including relaxation techniques. The majority of these studies suggest that “augmented” self care is superior long-term to “usual care” (i.e., any combination of initial treatments to be given including simple self care, medications, splints and exercises).²⁷⁻³⁰ However, “augmented” self care requires significant training and typically involves multiple visits with additional telephone follow-ups and, as such, is not suited for testing in the primary care setting. The PI of this proposal recently reported on the 5-year outcome of self care and medical management (i.e., patient education, self care and short-term medications) versus: 1) rehabilitation (i.e., stabilization splints, physical therapy and cognitive behavioral therapy), 2) arthroscopic surgery, or 3) arthroplasty.³¹ This simple self-care protocol was identical to what the PI has previously used in his other studies^{10,11} and is currently being taught in selected dental schools.⁸ This self care protocol is also consistent with the self care instructions used at HealthPartners, one of the regional sites in the DPBRN.

This landmark study performed in patients with severe TMJ pain and limited function showed that 50% of the subjects randomized to medical management never needed more care and had the same outcomes as the other 3 treatment strategies. Retention rate at 5 years was 90% and this study showed no net benefit at any follow-up period associated with rehabilitation with or without either surgery when compared to medical management.

Summary of findings above:

- 1) Simple self care can be an effective treatment for TMJD pain alone or in conjunction with medications, exercises or splints.
- 2) When comparing standard stabilization splints versus non-occluding splints, there is no significant difference between groups for reducing TMJD pain. This suggests that the design of the splint is not a critical factor in reducing TMJD pain.
- 3) The relative effectiveness of exercises or splint therapy compared to self care has not been conclusively determined,
- 4) Adding jaw exercises to self care has not been seen to improve the outcome of self care alone.
- 5) The majority of the TMJD RCTs have short follow-up, and small sample size, thus limited evidentiary value.
- 6) All but one of the TMJD RCTs has been done in tertiary care centers. Thus, it is not clear how these results would apply in the primary care setting. There is a need to conduct a multi-site RCT in the primary care setting with adequate power to establish evidence-based guidelines for the initial management of TMJD patients. The PI and his research team are uniquely experienced to initiate and complete this critical multi-site Phase III clinical trial.

B.1. Significance and Potential Impact on Dental Practice

The proposed study will provide the necessary data to design the most feasible, practical and scientifically valid protocol for a definitive Phase III clinical trial to assess the effectiveness of initial care for TMJD pain patients. The data will identify the initial care methods currently being used in the private dental setting. The clinical relevance of this project is to initiate the process that can ultimately lead to a definitive Phase III clinical trial that will provide initial care guidelines that are practical for the primary care dentist.

C. Preliminary Results

The Principal Investigator (PI), Eric Schiffman, has co-authored three publications^{10, 11, 31} reporting on RCT that assessed the splint therapy and self-care protocols, or similar protocols, that could be used in the proposed Phase III clinical trial if the current R21 proposal is funded (see below). The first RCT assessed the effectiveness of self care with exercises; the second RCT compared the effectiveness of different medications in combination with self care. The third RCT compared the effectiveness of rehabilitation that includes self-care with medical management, rehabilitation, arthroscopic surgery with post-operative rehabilitation, or arthroplasty with post-operative rehabilitation. Thus the PI has experience for successfully designing, managing and completing this planning project and the eventual Phase III multi-site clinical trial. Furthermore, Dr. Schiffman's ongoing U01 DE0 13331 project demonstrates his experience with directing a multi-site study and his research team's expertise with developing diagnostic criteria for TMJD pain. Detailed descriptions of the PI research projects are in the Appendix 1.

C.1. Prevalence of TMJD pain and occlusal splint use in the Northwest PRECEDENT.

The presence and type of orofacial pain during the previous year were abstracted from dental charts in a survey with a systematic random sample of adult patients (n=1272, 18-93 years old, 43% female) visiting Northwest PRECEDENT general dentists (n=75). Among different types of pain, the prevalence of temporomandibular muscle and joint pain, including arthralgia and myalgia, was 5.9% (95%CI=3.6%-8.2%). In addition, the preliminary results of this survey revealed that 6.3% (95%CI=4.2%-8.3%) of the patients had used an occlusal splint/mouth guard.

C.2. Current practice for the treatment of TMJD pain in the DPBRN.

In a cross-sectional study, 50 general dentists at HealthPartners of Central Minnesota, a regional center for the Dental Practice-Based Research Network (DPBRN), were invited by Dr. Brad Rindal, the DPBRN's Minnesota site investigator and member of the DPBRN's executive committee, to complete a questionnaire assessing: the current number of DPBRN dentists that provide TMJD pain treatments, the type of treatment currently provided by DPBRN dentists for the initial care of TMJD pain, and the barriers for providing any TMJD pain treatment. Thirty-four DPBRN dentists agreed to participate (68%). The results of this questionnaire show that among 82% (n=28) of the dentists that treat TMJD pain, the most common, non-exclusive practices are self-care (100%), over the counter analgesic medication (82%) and splint/mouth guard (61%) (Table 1).

Table 1. Distribution of the TMJD pain treatment currently provided by 28 DPBRN dentists

Type of treatment:	N (%)
self-care	28 (100)
over the counter analgesic medication	23 (82)
splint/mouth guard	17 (61)
prescriptions medications	14 (50)
Other	3 (11)
<i>Combinations of the treatments used:</i>	
self-care and splint	8 (29)
self-care and medication	3 (11)
splint and medication	8 (29)

Thirteen of 28 (46%) dentists that treat TMJD pain reported facing barriers for TMJD treatment, and from these, the most common was the treatment cost associated with the splint (Table 2).

Table 2. Proportion of the TMJD treatment with barriers for providing TMJD pain treatment among 13 DPBRN dentists

Types of Treatment	Results N (%)
self care	2 (15)
medication	1 (8)
splint/mouth guard	6 (46)
Other	4 (31)
Reported barriers:	
cost associated with splint	10 (77)
patient compliance	2 (15)

In addition, 24 (86%) of the dentists that treat TMJD pain answered that they have a preference for the type of initial treatment. Most of them preferred self-care (96%), medication (33%) or splint/mouth guard (33%).

D. Research Design and Methods

D.1. Study design, sample size and practice selection

This project consists of a survey of diagnosis and treatments of TMJD pain among primary care dentists selected from three PBRNs: DPBRNs, PRECEDENT and PEARL.

The CONDOR directors from three PBRNs (DPBRN, PRECEDENT, and PEARL) have agreed to participate in this project. The development of the project will be coordinated by the PI of this study (Dr. Schiffman), with the help of an epidemiologist (Dr. Velly). All three PBRNs will be involved on the design and management of

this study. One individual from each PBRN was identified as key personnel to interact with Drs Schiffman and Velly: Drs Joana Cunha-Cruz from PRECEDENT, Van Thompson from PEARL and Dale Williams from DPBRN (see Appendix 2).

Each PBRN accepted responsibility for a portion of the project:

- a. PRECEDENT – Development and completion of the survey;
- b. PEARL – Curation of the survey;
- c. DPBRN – Data management between the 3 PBRNs and providing the combined data, with initial analyses completed, to Drs Schiffman and Velly. For more details see Appendix 2.

Initially, weekly teleconferences will take place between the CONDOR coordinators, or designated individuals, and Dr. Schiffman and Dr. Velly. This schedule of meeting will be adjusted as indicated and will involve the CONDOR directors only as needed. In Dr. Schiffman’s previous multi-site project, Validation of the Research Diagnostic Criteria for TMD (U01 DE13331), weekly teleconferences had been held, with minimal exceptions, with the site PI and their coordinators, at a specific time each week for the duration of the study. Teleconferences are critical to the success of the project, and for future planning of proposals. Members of the PBRNs that were on the teleconference will send edits of the survey to Drs. Schiffman and Velly.

D.1.1. Sample size

Table 3 presents the current number of dentists in each PBRN. Based on a CONDOR dentist participation rate of 50%, it may be possible to recruit an estimated 150, 50, 62 from each, respectively, PBRN. These estimates are based on a participation rate that is more conservative than those observed in the HealthPartners of Central Minnesota DPBRN study (see section C.2 Current practice for the treatment of TMJD pain on DPBRN).

Table 3. Current CONDOR dentists participants* at each of the three PBRN sites

PBRN Network	Number of PBRN dentists
DPBRN	300
PRECEDENT	100
PEARL	125

* Participating dentists are those who have enrolled in one of the CONDOR networks and have participated in at least one study.

D.1.2. Selection of Practices

Participants are those dentists who have enrolled in one of the PBRNs and have taken part in at least one PBRN-based study. All eligible dentist-investigators of the network will be invited to participate in the study. The goal is to include all active dentist members. An effort will be made to ensure that the number of participating active practices will comprise at least 80% of the active members. Participation is voluntary.

D.2. Participant Enrollment

All primary care dentists in the three PBRNs: DPBRNs, PRECEDENT and PEARL will be invited to participate in this survey.

D.2.1. Inclusion Criteria

The inclusion criterion is to be an active member of one of the three PBRNs.

D.2.2. Screening, Enrollment and Informed Consent

Dentists will be invited to participate in this study by mail and/or e-mail with a brief explanation of the study. Each PBRN data coordinating center will send the invitations for their dentist members. An opportunity will be provided to have any questions answered by the PBRN Research Coordinators by phone or e-mail. PBRN dentists who fail to respond to this invitation will receive a reminder letter, by mail or e-mail, four weeks after the questionnaire is initially sent. Two weeks later, those dentists who fail to respond to the questionnaire sent by mail or e-mail will receive a telephone call asking them to schedule a time to respond to the questionnaire. Depending on the Institutional Review Board at their institution PBRN dentists may be required to complete a consent form for participation. All PBRN dentists will be informed that participation is voluntary and that their responses will be kept confidential. The dentist will have the right to opt out at any time during data collection, and no information will be collected after that point. Participants will receive \$50.00 U.S as a monetary incentive for participation in the study.

D.3. Data Collection

All PBRNs will disseminate and collect the completed surveys using their already established protocol. Data collection will be performed through paper or online questionnaire depending of the preference of each PBRN. The pre-tested questionnaire (see Appendix 3: TMJD Questionnaire) will be formulated by Drs. Schiffman and Velly as well as Joana Cunha-Cruz at PRECEDENT, to assess:

1. The current number of dentists in CONDOR (DPBRNs, PRECEDENT and PEARL) that provide TMJD pain treatments, the participation rate in this survey, and their willingness to randomize their TMJD pain patients to different treatment options in an eventual Phase III RCT.
2. The number of patients with TMJD pain that the dentist treats per month.
3. The dentist's preferred method(s) for treating TMJD pain.
4. Types of treatment currently provide by CONDOR dentists for the initial care of TMJD pain.
5. Documentation of the economic and business barriers to participation by the CONDOR dentists in the subsequent Phase III RCT.

The aim of these questions is to organize a feasible future Phase III RCT that will respond to the relevant questions of the CONDOR dentists and that improve TMD pain management.

D.4. Training

We anticipate that no training will be necessary because the dentists have been trained on the methods to complete online or paper surveys. If necessary, Research Coordinators can arrange a teleconference with the practices to go over procedures of the study.

D.5. Quality Assurance

The Regional Coordinators and Data Coordinators will monitor the progress of the dentists. Three mailings will be performed to maximize the number of dentists participating in the study. An enrollment log will be maintained by each PBRN coordinator to monitor and document the data collection process. A copy of the enrollment logs from each PBRN coordinator will be sent to the University of Minnesota to validate data completion.

Monthly teleconferences with the PBRN coordinators, the PI for this project (Dr. Schiffman) and the epidemiologist (Dr. Velly) will also be held to monitor recruitment, to evaluate progress toward the completion of the questionnaire and to discuss methods to maximize the questionnaire return rate, if necessary. Reports for each reporting period will be submitted by the PI (Dr. Schiffman) to the individual PBRN directors. The reports will include a description of the activities during the reporting period, interim results, and the activities planned for the ensuing reporting period.

D.5.1. Pilot Study

Drs. Joana Cunha-Cruz from PRECEDENT, Van Thompson from PEARL and Dale Williams from DPBRN, the **key personnel** from the 3 PBRNs, will disseminate the revised survey within their PBRN and provide Drs Schiffman and Velly with edits and suggestions. The questionnaire will be piloted with a vanguard wave of five to ten dentists from each of PBRNs to assess the adequacy of the study procedures, the clarity and completeness of the questionnaire and the time involved in answering the questions. Targeted reviewers are members of the executive committee and selected dentist within the PBRN (5 to 10 at each PBRN). A convenient sample of dentists will be selected using the selection method already in place in the three PBRNs. The dentists will be interviewed by the Research Coordinators and if they report problems or suggestions, changes will be made to the protocol or questionnaire before initiating the other waves. Given our previous experience at HealthPartners DPBRN-Minnesota's site, this pre-test survey should not take longer than one month to complete. In this previous experience with HealthPartners DPBRN-Minnesota site, four items of the questionnaire were evaluated by survey, in a cohort of general dentists (see section C Preliminary Results).

D.5.2. Anticipated problems and solutions

Low participation rate among CONDOR dentists: The solution is to organize the study in a manner that CONDOR dentists will want to participate. We will assess the CONDOR dentists preferred treatment options, since it is critical that they determine the treatments that will be assessed in the Phase III RCT. If the response rate is lower than expected, Regional Coordinators will communicate with the dentists via e-mail and telephone to encourage participation and to understand the reasons for not participating. An effort will be made to remove the barriers for participation such as mailing the paper questionnaires instead of using a web survey. Finally, we will compensate monetarily the CONDOR dentists for their participation.

Missing data: Data will be regularly monitored to decrease the amount of missing data. When missing data is identified, the designated PBRN coordinator will contact the participant to assist in the completion of the data collection. The University of Minnesota study team is also experienced in data recovery and error correction.

D.6. Data Management

The practitioner survey will be completed using a paper questionnaire or directly on an online system. The data from each PBRN will be combined by the DPBRN under the direction of Dr. Dale Williams. He will coordinate this activity (see Appendix 2). Data from paper questionnaires will be entered twice. The first batch will be re-entered by the original data entry technician to determine intra-rater reliability. A different technician will also re-enter the data to assess the inter-rater reliability. If the discrepancy rate is above 0.5%, then the full batch will be re-entered. Re-training may be needed if error rates persist.

The Web-based data acquisition system and the paper questionnaire data entry system will be programmed to make sure that all required fields are completed. Most fields will require a categorical response and those that ask for a numeric response will have programmed allowable ranges to screen out most data entry errors. Logical consistency checks will be programmed to further prevent data errors. Data Coordinators will monitor data as it is being entered to look for patterns in the unanswered Data Clarification Forms (DCFs) generated by the system. Forms with missing data or data outside of the range will be identified and revised for correct data input. In addition, recording procedures will be routinely evaluated on data quality at monthly intervals via monthly teleconferences. Reports that summarize the completion of the data collection and completeness of data will be reviewed at the Data Coordinating regular meetings.

All paper records will be stored in an easily retrievable and fire-protected locked filing cabinet in secured rooms. Electronic data will be located on a secure network drive with restricted access. The data will be stored using the current database software packages. The database programming staff will work with the coordinating center investigators and Network Chair to certify that the necessary systems are accessible on time and function efficiently.

D.7. Statistical Analysis

The initial analysis of the survey results will be done by the DPBRN. The raw data and the initial results will be provided to Drs. Schiffman and Velly (see Appendix 2).

Descriptive analyses will be performed to estimate the following variables:

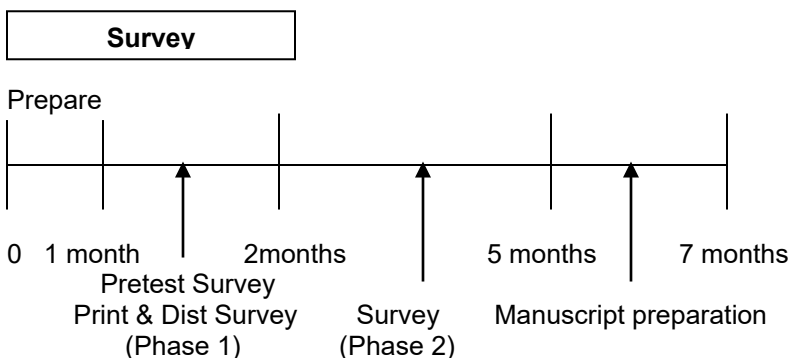
1. *Participation rate*: dentist participation will be expressed as a percentage of the total number of CONDOR dentists invited to participate in the survey.
2. *TMJD dentists' ratio*: The frequency of participant CONDOR dentists that treat TMJD pain will be expressed as a percentage of the total number of participant CONDOR dentists.
3. *TMJD pain patients' monthly ratio*: The frequency of TMJD pain patients reported by participant CONDOR dentists per month will be expressed as a percentage of the total number of participant CONDOR dentists' patients per month.
4. *Phase III dentists' ratio*: The frequency of participant CONDOR dentists who indicated willingness to participate in an eventual Phase III RCT will be expressed as a percentage of the total number of participant CONDOR dentists that treat TMJD pain patients.
5. *TMJD pain care type*: The type of each treatment for TMJD pain will be described. The distribution of each treatment will be presented as percentages of the total number of treatments for TMJD pain. The distribution of initial treatments will be presented as percentages of the total number of initial treatments.
6. *Economic/business barriers ratio*: The economic and business barriers to participation in the eventual Phase III RCT will be presented in a narrative format. In addition, the frequency of each economic/business barrier will be estimated as a percentage of the total number of economic/business barriers reported by participant CONDOR dentists.

The statistics above will be estimated for the whole sample taking into account the clustering of participants within CONDOR. Stratified analysis by PDRN will also be presented. In the secondary analyses, we will describe CONDOR participant dentists with respect to sociodemographic characteristics (age, gender, ethnicity, years of education and years of practice). Count, mean, median, standard deviation (SD), and inter-quartile ranges will be estimated, as applicable, for the variables above by CONDOR or participant dentist. The proportions of each categorical variable will also be estimated. Statistical analysis will be performed using SAS 9.1 software.

D.8. Timeline

The total duration of the study is estimated to be 7 months. In the first months, a pre-test phase will be used to assess the adequacy of the study procedures and questionnaire. After mail and e-mail invitations are sent to all CONDOR member dentists, it is expected that the duration of the study will be 3 months, including the time for two follow-up mailings. The remaining study time will be devoted for data analysis and manuscript preparation.

Figure 1: Study timeline and sequence of events



D.9. Dissemination of Results

At the conclusion of the study the network members will receive a final report of the study results. In addition, the outcomes of the study will be disseminated to the Network as well as to the dental profession as a whole in a number of ways: 1) articles in the Network newsletter, 2) news articles placed on the Network website, 3) presentations at the network annual meetings and scientific conferences, and 4) articles in scientific journals.

Drs. Schiffman and Velly will write a manuscript for publication. The directors of the 3 PBRNs will review the manuscript and provide feedback to Drs, Schiffman and Velly (see Appendix 2).

E. Human Subjects

This Human Subjects Research meets the definition of Clinical Research. All dentists from the networks will be considered potential participants.

E.1. Protection of Human Subjects

The risk to participants in this research is possible breach of confidentiality. This risk is considered minimal because the information being collected is not of a sensitive nature. The risk is small relative to the benefits from the information to be gained which will benefit the general population of the networks and possibly other dental practices in the country. The risk of breach of confidentiality will be minimized by assigning unique identifiers to each participant and by transmitting the information to the coordinating center with the unique identifier. Information will be transmitted to the coordinating center in encrypted form and all data will be maintained on password protected computers.

E.2. Inclusion of Women and Minorities

Participant selection will be done without regard to gender or minority status. Both females and males will be included and all minority groups will be included in proportion to their frequency in the population of dentists.

E.3. Inclusion of Children

Children will not be included in this study because the objective of the study is to understand the dentist practice in relation to TMJD diagnosis and treatment.

E.4. Data and Safety Monitoring Plan

The data will be monitored by the Executive Committee of three networks. The Committee will receive a report from the PI that includes information on numbers of dentists sampled, consented, and enrolled in the study. Descriptive information on the data and the data quality will also be presented.

F. Literature cited

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G. Appendices:

G.1. Appendix 1. Preliminary Data

1. A Randomized Clinical Trial Assessing the Efficacy of Adding 6x6 Exercises to Self-care for the Treatment of Masticatory Myofascial Pain. Mariona Mulet, DDS, MS, Karen L. Decker, PT, John O. Look, DDS, MPH, PhD, Patricia A. Lenton, GDH, MA and Eric L. Schiffman, DDS, MS ¹¹

This was a double-blind randomized clinical trial with a four-week follow-up. It included forty-five subjects (43 female and 2 male, mean age 24) who were randomly assigned to self-care or self-care + 6x6 exercises (self-care + 6x6). The primary outcome measure was intensity of jaw pain on a Numerical Graphic Rating Scale (NGRS). Secondary outcome measures were jaw pain on a verbal rating scale (VRS), neck pain (NGRS and VRS) and change in head posture. Both treatment groups showed statistically significant ($p=0.001$) and clinical (>2 on NGRS) improvement in jaw pain intensity (NGRS). Jaw pain (VRS) and neck pain improved significantly ($p<0.01$) in both groups. It was concluded that the 6x6 exercises did not add an observable improvement in the intensity of jaw and neck pain over self-care alone, nor were they beneficial in improving head posture within the 4-week duration of this study. Data from this study are used in the preliminary sample size estimates shown below.

2. The Effectiveness of Adding Pharmacologic Treatment with Clonazepam or Cyclobenzaprine to Patient Education and Self-Care for the Treatment of Jaw Pain upon Awakening: A Randomized Clinical Trial Cory R. Herman, DDS, MS; Eric L. Schiffman, DDS, MS; John O. Look, DDS, MPH, PhD; D. Brad Rindal, DDS¹⁰.

This was a double-blind randomized clinical trial with a three-week follow-up to compare the relative effectiveness of a benzodiazepine (clonazepam), a muscle relaxant (cyclobenzaprine), and a placebo for the treatment of jaw pain upon awakening, when each is combined with the recommended self-care for initial medical management. Forty-one subjects were recruited with a diagnosis of myofascial pain and were given education about TMD and a self-care program. Subjects were randomized into 1 of 3 groups: clonazepam (0.5 mg/night), cyclobenzaprine (10 mg/night), or placebo. The primary outcome measure was the subjects' average intensity of jaw pain upon awakening over the prior week. This was recorded with a visual analog scale at pretreatment and at the completion of the 3-week trial. Within-group changes showed a statistically significant ($P < .001$) decrease in jaw pain upon awakening for all treatment groups including a 40% decrease in pain for the self-care plus placebo group.

3. Randomized Effectiveness Study of Four Therapeutic Strategies for TMJ Closed Lock. Schiffman EL, Look JO, Hodges JS, Swift JQ, Decker KL, Hathaway KM, Templeton RB, Friction JR ³¹

For individuals with temporomandibular joint (TMJ) disc displacement without reduction with limited mouth opening (closed lock), interventions vary from minimal treatment to surgery. In a single-blind trial, 106 individuals with TMJ closed lock were randomized among medical management, rehabilitation, arthroscopic surgery with post-operative rehabilitation, or arthroplasty with post-operative rehabilitation. Evaluations at baseline, 3, 6, 12, 18, 24, and 60 months used the Craniomandibular Index (CMI) and Symptom Severity Index (SSI) for jaw function and TMJ pain respectively. Using an intention-to-treat analysis, we observed no between-group difference at any follow-up for CMI ($p \geq 0.33$) or SSI ($p = 0.08$). Both outcomes showed within-group improvement ($p < 0.0001$) for all groups. The findings of this study suggest that primary treatment for individuals with TMJ closed lock should consist of medical management or rehabilitation. The use of this approach will avoid unnecessary surgical procedures.

4. Revised Research Diagnostic Criteria for Temporomandibular Disorders (TMJD): Reliability and Validity. Eric Schiffman is the Principal Investigator (PI) for this multi-site project (U01 DE0 13331) that includes assessing the reliability and validity of Research Diagnostic Criteria for Temporomandibular Disorders (RDC for TMD) including the current diagnostic criteria for TMJD pain (i.e., arthralgia and myofascial pain). The sites in this project are the University of Minnesota, University at Buffalo and University of Washington.

Briefly, the validity of the current diagnostic criteria for arthralgia (i.e., jaw joint pain) and myofascial pain* (i.e., jaw muscle pain), is acceptable for myofascial pain but is not acceptable for arthralgia. Specifically, for myofascial pain, the sensitivity is 0.87 and specificity is 0.98. For arthralgia, the sensitivity is 0.54 and specificity is 0.86. The validity of the revised diagnostic criteria for these diagnoses is as follows: myofascial pain, the sensitivity is 0.93 (and specificity is 0.97, and for arthralgia the sensitivity is 0.71 and specificity is 0.88. The revised algorithms for arthralgia require a positive response to the question “Have you had pain in the face, jaw, temple, in front of the ear, or in the ear in the last month?” The required exam items for arthralgia are a positive report of pain with 1) Lateral joint palpation, bilaterally, or joint pain with range of motion of the jaw. The revised algorithms for myofascial pain are identical to those for arthralgia except that the palpation component only includes palpation of the masseter and temporalis muscles, bilaterally.

We are currently testing a simple screening instrument for TMJD pain for use by the general dentist from our recently completed project (i.e., U01 DE0 13331 Administrative Supplement). Preliminary data suggests that the current RDC for TMD³² history item: “Have you had pain in the face, jaw, temple, in front of the ear, or in the ear in the last month?” can be modified with data we collected to include only “jaw pain”. In addition, the sensitivity and specificity is improved by adding 1 additional question that assesses jaw pain associated with jaw movement, function or parafunction. This question is: “In the past month, did any of the following activities CHANGE your jaw pain?” The possible responses for this question are:

1. Opening your mouth or moving your jaw forward or to the side,
2. Biting into food with your front teeth,
3. Chewing hard or tough food,
4. Jaw habits such as holding teeth together, clenching/grinding teeth or chewing gum,
5. Resting the jaw,
6. Awakenings from sleep, and
7. Other jaw activities such as talking, kissing or yawning.

We are also modifying the revised algorithm for myofascial pain to include only palpation of the masseter muscles. Currently, all derived algorithms have sensitivities and specificities greater than 0.70 and 0.90, respectively. Also, when we combine these two pain diagnoses into “TMJD pain”, the sensitivity is improved with minimal decrease in specificity. Finally, a similar TMJD screening questionnaire was developed to assess for the presence of TMJD pain in adolescents (sensitivity 0.96, specificity 0.83).³³ This questionnaire also consists of two questions pertaining to 1. the presence of TMJD pain, in the past week, and 2. if this pain is affected by opening of the mouth opening or chewing foods. This study’s results suggest that we will be able to develop a valid screening instrument for use in adults. Therefore, we believe that both the screening instrument and the algorithms for diagnosing TMJD pain, from our ongoing project, will be available to be used by the CONDOR dentists, and will result in valid TMJD pain diagnoses.

Dr. Schiffman’s ongoing U01 DE0 13331 project demonstrates his experience with directing a multi-site study and his research team’s expertise with developing diagnostic criteria for TMJD pain.

G.2. Appendix 2. Summary of 11-20-08 TMJD survey teleconference

TO: CONDOR members

From: Drs. Eric Schiffman and Ana Velly

Date: 11-21-08

1. **One individual from each PBRN was identified as key personnel to interact with Drs Schiffman and Velly.**
 - a. Joana Cunha-Cruz – PRECEDENT
 - b. Van Thompson – PEARL
 - c. Dale Williams – DPBRN

2. **Each PBRN accepted responsibility for a portion of the project.**
 - a. PRECEDENT – Development and completion of the survey.
 - b. PEARL – Curation of the survey.
 - c. DPBRN – Data management between the 3 PBRNs and providing the combined data, with initial analyze completed, to Drs Schiffman and Velly.

3. **Flow of activity**
 - a. Members of the PBRNs that were on the teleconference will send edits of the survey to Drs. Schiffman and Velly.
 - b. Drs. Schiffman and Velly as well as Joana Cunha-Cruz at **PRECEDENT** will develop a revised survey. Concurrently, Drs. Schiffman and Velly will pilot the survey with general dentists in Mpls area.
 - c. Pilot revised survey: The **key personnel** from the 3 PBRNs will disseminate the revised survey within their PBRN and provide Drs Schiffman Velly and Cunha-Cruz with edits and suggestions. Targeted reviewers are members of the executive committee and selected dentist within each PBRN (5 to 10 at each PBRN).
 - d. Dr. Schiffman will provide Dr. DeNucci/NIDCR with the final TMJD Survey proposal and survey so that it can be reviewed at the next Condor Protocol Review Committee meeting.
 - e. After the study is approved by the Condor Protocol Review Committee, each PBRN will be responsible for addressing the IRB issue in their network. Drs. Schiffman and Velly will be involved as needed.
 - f. Drs Schiffman and Velly will finalize the survey with Joana Cunha-Cruz (Precedent). The other 3 key personnel will get final approval for the survey from each of their PBRNs.
 - g. The survey will be curated by **PEARL**.
 - h. All PBRNs will disseminate and collect the completed surveys using their already established protocol. The data from each PBRN will be combined by the **DPBRN** under the direction of Dale Williams. He will coordinate this activity. The initial analysis of the survey results will be done by the **DPBRN**. The raw data and the initials results will be provided to Drs. Schiffman and Velly.
 - i. Drs. Schiffman and Velly will write a manuscript for publication. The directors of the 3 PBRNs will review the manuscript and provide feedback to Drs, Schiffman and Velly.
 - j. Drs. Schiffman and Velly will discuss the feasibility of doing a Phase III clinical trial for the initial treatment of TMJD pain in the 3 PBRNs. If appropriate, Drs, Schifman and Velly will write a R01 to obtain funding for the phase III clinical trial.

4. **Authorship:** Drs. Schiffman and Velly will be first and second authors on publications from this survey. Each PBRN can identify at least one individual for authorship on the paper. Acknowledgement in manuscripts will be given to each PBRN.
5. **Outstanding issue:** Does PIRG want to add a question to the survey to assess the impact of the outcomes of the survey on any change in the dentist's practice relative to initial treatment of patients with TMJD pain.