



**Division of Behavioral Sciences
and Community Health**

TMD Online

Statement of Informed Consent

Project Title: **Mobile Application Treatment for TMD: Feasibility Trial**
Principal Investigator: **Mark Litt, Ph.D.**
Division/Dept.: **Behavioral Sciences and Community Health/Psychiatry**
Institution: **UConn Health**
Expected Length of Participation: **13-14 months**
Funding Source: **National Institute of Dental and Craniofacial Research**
IRB#: **23-052-1**
Version: **1.1 03/29/2023**
Participant Name: _____

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision to participate in this study.

This research is being done to determine if a treatment for orofacial pain that is delivered using a mobile application can be useful in helping people with their pain problems. The pain problems studied include temporomandibular joint pain (TMJ) or temporomandibular dysfunction pain (TMD), among others.

Your involvement in this treatment research would entail the following:

- This initial diagnostic visit (including a panoramic x-ray and oral examination performed by a dentist) and completion of surveys. Surveys will be completed online, and may be administered via teleconference for your safety.
- Getting dental impressions taken, or having your mouth scanned, for the purpose of fitting you with a dental splint
- 2 weeks of pretreatment monitoring using a smartphone app, 4 times per day, each day. The monitoring periods will be repeated for weeklong periods during treatment at Week 2 and Week 4, and for a week after the posttreatment follow-up is completed
- Delivery and fitting of a dental splint by our Dental Staff at the start of treatment
- Prescription of non-steroidal anti-inflammatory drugs to be used on a schedule for a 2-week period
- 6 weekly 60-90 minute treatment sessions delivered using an online application through your smartphone.
- Online surveys and a teleconferences at posttreatment

This adds up to about 10-12 weeks of involvement with this study, with total possible compensation (for completing monitoring and attending study visits) of \$265 over the entire study.

During the monitoring periods you will be asked to monitor your thoughts, feelings, and behaviors on your cellphone before, during, and after treatment. The treatment will consist of 6 weekly visits using the online application, which is intended to help you analyze your pain problems and find solutions to help reduce your pain and improve your functioning.

The TMD monitoring app procedures and the pain management application procedures in this are considered "experimental," in the sense that they are not part of standard medical/clinical practice.

The most severe risk of this study is clinical deterioration (worsening of your pain problem despite treatment). The most common risks are continuation of the pain problem and loss of confidentiality. Some of the questions on the surveys may seem very personal. Risks are described in more detail later in this document, along with our efforts to minimize those risks.

The treatment provided here may help you manage your pain. While in the study your progress will be followed closely, and we will be available to help you with any problems you might have. This research may also result in information that leads to improved treatments that could help others in the future.

Before making a decision about whether to participate in this research you should know that there are other options available to you. There are other treatment providers in your area.

A more detailed description of this research follows.

Purpose of the Research

The goal of this research is to determine whether a cognitive-behavioral treatment for pain delivered on your cellphone can be a feasible alternative for helping patients manage their orofacial pain problem, by teaching pain management skills. The treatment will involve 6 individual sessions with using the online application, each session taking about one hour (except the first and last sessions, which will take a bit longer), with additional time for weekly assignments. About 20 participants will be recruited for this initial trial. You are being asked to participate because you have indicated that you have a significant orofacial pain problem, such as pain in the area of the temporomandibular joint, and that you wish to seek treatment for that problem.

The treatment being studied is called painTRAINER; a web-based treatment program that is accessed via the patient's smartphone. In addition to the painTRAINER program, patients will receive a standardized conservative treatment for orofacial pain.

The painTRAINER program has been shown to be helpful for persons with a variety of pain problems, including low back pain, but there is less research on its use in TMD-type pain. The standard conservative treatment has been used for many years to help people manage orofacial pain problems.

The Standard Conservative Treatment (STD) will consist of 3 parts: Delivery of a dental splint; prescription of a soft diet; and prescription of oral pain medications. The splint, a plastic mouthpiece that fits snugly over your upper teeth, is used to change the oral habits of patients with respect to clenching and tooth grinding (if present), and to provide a sufficient respite from pain to allow more adaptive oral habits to emerge. Patients will receive the intraoral splint during the first treatment visit, 1-2 weeks after the baseline visit, with instructions to keep it in place continuously (except for eating) if possible for the succeeding 4 weeks. After 4 weeks it will be recommended to patients that they start to taper the splint (e.g., use only as a night guard) in preparation for discontinuing the splint altogether. The purpose of this is to try to prevent the patient from becoming so comfortable with the splint that he/she starts clenching or grinding on the splint itself. (Patients will not have to stop using the splint if they continue to find it useful).

In addition to the splint, patients will also be given a 14-day course of non-steroidal anti-inflammatory medication (NSAIDs) like naproxen (550 mg twice a day) or ibuprofen (400-600 mg 3 to 4 times per day). Extra strength acetaminophen (500 mg three times per day) will be substituted for those patients who have difficulty with NSAIDs or who have gastric ulcer disease.

A soft diet will also be prescribed with special attention paid to avoiding foods that require extreme jaw opening (e.g., large sandwiches) or foods that have caused pain in the past (e.g., steak). Patients will be asked to continue using the splint and the soft diet until the end of the 6-week treatment period, after which they will be informed that they may alter the treatment as they see fit (e.g., discontinuing the splint), but recommending care in their diet.

The PainTRAINER online program is an online cognitive-behavioral treatment program. The painTRAINER program is an interactive, online tool that teaches strategies that patients can use to manage pain. The program was developed by experienced pain clinicians and researchers, led by Christine Rini at Northwestern, and Frank Keefe at Duke, and refined by researchers at University of Melbourne. The painTRAINER program is made up of 8 sessions, each lasting about 45-60 minutes. It was designed so that researchers are able to access the data collected (e.g., session completion data)

allowing tracking of patient progress. For the purposes of this trial, the first 2 and the last 2 components of the painTRAINER program will be combined, creating 6 weekly sessions of about 50-75 minutes each. An outline of the sessions for MobileApp treatment appears below.

| Session Outline for painTRAINER MobileApp treatment | |
|---|---|
| Session 1 | 1. Understanding pain and relaxation 2. Brief relaxation with mini-practices |
| Session 2 | 3. Activity/Rest cycles (Added: Parafunctional Habits; Masseter Massage) |
| Session 3 | 4. Pleasant activity scheduling |
| Session 4 | 5. Coping thoughts and catastrophizing |
| Session 5 | 6. Pleasant imagery and stress management |
| Session 6 | 7. Problem solving 8. Looking back and moving forward: overview and recap |

The overall program has been modified such that patient assignments (skills practice exercises) apply specifically to management of TMD-type pain.

Study Procedures

Intake Evaluation, Determination of Eligibility, and Scanning for Splint Fabrication. As part of the intake evaluation, you will be interviewed and asked to fill out questionnaires concerning many different aspects of your personal history, your pain, and any treatment you may have received. This will require about 1 hour of your time, and may be done online with guidance from a research assistant via teleconference. These questionnaires and instruments will be identified only by a code number previously assigned to you. Part of this interview will be used to determine if you are eligible for treatment in this study. In order to be assigned to a treatment, you need to be 18 or older, have significant jaw pain for at least the last 3 months, with the pain not related to arthritis or nerve problems (neuropathic pain), and not the result of surgery. Participants must also be English-speaking, and must not be using opioid drugs, or be pregnant (or planning on being pregnant), and must not have a serious psychiatric disorder.

As part of this initial evaluation you will receive a panoramic x-ray. This is an x-ray that scans the entire mouth in a single image, including the teeth, and the upper and lower jaws. This will be done to rule out any extensive damage to your temporomandibular joint that we would not be able to treat in this study. You will also be examined by one of our dentists in order to determine what kind of orofacial pain you have (e.g., muscle-related versus nerve related). This will involve pressing against your cheeks and jaw, and having you open and close your mouth.

If you are eligible for the study, you will accepted for treatment. At this point your mouth will be scanned with a wand-like device. This scan will be used to measure your mouth for fabrication of the splint, which should be delivered in about 2 weeks.

You will receive a payment of \$40 for completing the intake measures.

Monitoring with the TMD pain smartphone app. Patients accepted for the study will be asked to monitor pain during this study using a smartphone app (using MetricWire, which is separate from the painTRAINER program), and you will be introduced to the Metric Wire TMD pain monitoring app. After a demonstration, the monitoring system app will be loaded on your phone. The app will make your cell phone signal you four times a day between 8 a.m. and 10 p.m., every day for 14 days. If you incur additional data use charges due to the use of the app we will reimburse you a total of \$25 over the entire study.

If you do not have a smartphone we will provide one to you. If we do lend you a cellphone we will ask you to return it at the end of the study. Phones provided by us will be restricted so that they cannot be used to call friends or family, etc., cannot be used for texting, and cannot be used for internet browsing.

You will be asked to have your phone with you at all times while you are awake. The monitoring calls will be made at random times during the day. When you open the app you will be asked to enter your subject ID number. The system will then ask about any pain you might have had, and any medication or other things (cannabis, alcohol) you have taken to manage pain, along with your thoughts, feelings, behaviors, and current situation. You will be asked to respond to these questions within the cellphone app.

For example, you may receive a signal from your phone at 9:13 AM on a Tuesday. When you open the TMD app the system will ask for your study ID number. Once you enter your ID, the system will show you a sliding scale from 0 (No Pain) to 5 (Worst Possible Pain) so that you may indicate your current level of Jaw Pain – Left Side. Another sliding scale will ask about Jaw Pain – Right side. Other questions presented in the same way will ask about mood states and your current thoughts about your pain problem. A number of questions will be asked in this manner. The total time using the app should be about 2 minutes.

You will be trained how to use the cell phone app to answer these questions. After the 14 days are up treatment will begin. Because answering these questions is so important, we will offer an incentive for doing the cellphone monitoring. You will be paid \$5.00 for every day that at least 3 recordings are completed, and a bonus of \$5.00 a week for each week in which all calls are completed. The possible total incentive will thus be \$40.00 per week, or \$80.00 total in the 2 weeks before treatment begins. These payments will be calculated on the day of your first treatment appointment, and will be paid out by check, made payable to you. The check may take 5 to 10 days to arrive. If you prefer, we will pay you via e-gift card (e.g., Amazon gift card), that would be sent to you in your e-mail.

Treatment. Treatment sessions will be conducted via the painTRAINER online application once per week. The treatment as planned lasts 6 weeks. We know that events in people's lives sometimes interfere with tending to medical issues. Therefore you will have 10 weeks to complete the 6 sessions. Although treatment is delivered online through your phone, you will be asked to schedule a time to pick up written materials at the Health Center, or these materials can be e-mailed to you by the clinical coordinator. These materials include guides, worksheets and other materials used in treatment to help you learn pain management skills.

The treatment program will ask you to try to make changes in your behavior and to work on new skills between treatment sessions ("homework") to help you manage your pain problem. Between-treatment assignments might include practicing relaxation, or keeping track of your teeth grinding and/or clenching.

At the first treatment session, 2 weeks after the intake visit and following the first round of cellphone monitoring, all participants will have their splints delivered and fitted by the dental hygienist and attending dentist. You will receive advice regarding use of the splint, advice on soft diet, and will start your 2-week supply of prescribed pain medication with written instructions. This visit, including delivery of the splint and introduction to the painTRAINER program, may take up to 90 minutes.

At this visit you will be instructed to log in to the painTRAINER program and start the program on that day. The first painTRAINER session may take about 75 minutes at home. Sessions 2 through 6 should each take about 1 hour.

Collection of Treatment Data. As noted above, the painTRAINER program allows researchers to collect data regarding your progress. **These data will not be identified**, and will only be used to find out about how well the program works. Your progress will be known to you (that is, you will have a record of your own progress), but no researcher will contact you about your progress though the program.

If you do not want to consent to this data collection please indicate by placing your initials on the line below.

→ I do not consent to treatment data collection _____(initials)

During-Treatment Smartphone Monitoring. In order to detect changes in habits that might be occurring due to treatment, you will be asked to do the TMD monitoring (MetricWire) again at Week 2 of treatment for 7 days, and at Week 4 of treatment for 7 days. The monitoring will be done the same way as the pretreatment monitoring. As in the pretreatment period, the possible total incentive will be up to \$5 per day for near-complete recording, or \$40 for each week of monitoring.

Post-treatment Interview and Monitoring. At the end of the treatment period you will be asked to meet again with the research assistant via videoconference or telephone and complete post-treatment questionnaires about your pain, any treatments you might have received, and what you have learned in treatment. The session will take about 1 hour, and may be done remotely. You will receive \$25 for completing the post-treatment assessment.

Once again you will be asked to do the TMD MetricWire smartphone monitoring for a period of 7 days. As before, the possible total incentive will be \$40 for the week of monitoring.

In summary, your involvement would consist of the following phases:

Initial evaluation and scanning for splint fabrication, 2 weeks of pretreatment monitoring via smartphone, delivery of your splint, 6 sessions of treatment, a post-treatment follow-ups plus 1 week of posttreatment cellphone monitoring. This adds up to 10-12 weeks of involvement with this study, with total possible compensation of \$265 over the entire study.

It is very important that we be able to find you during this project, so that we may get information, but also so that we can check on your status and provide help if needed. To help us keep track of you we will ask you to provide names of a few people we call Locators (e.g., spouse, adult child, parent, other relative or friend), who will know your whereabouts during the treatment period, to help the research staff locate you if you change your address without notice or become indisposed for some reason (e.g., hospitalization). These people may be contacted if we are unable to locate you. They will not be asked about your pain or medication use. If no one can find you, we are asking you to agree that public information sources, such as telephone directories, motor vehicle records, Social Security Office information, or public locator services, may be used to find you.

We are also asking you to agree to allow us to use social media, through private messages, to contact you if that becomes necessary. (Private messages through social media will alert you that a follow-up interview is due, and that we will compensate you for your time). If you agree, we will also try to contact you through e-mail, text messaging, mail and telephone. If we cannot arrange for you to follow up with us in person or on the telephone, as a last resort we will mail you the relevant questionnaires, along with a paid return envelope, to be completed at home. You will receive a check in the mail (or an e-gift card by e-mail) made payable to you for \$10 for completed packages that are returned to us.

You will be asked to provide information (e.g., telephone number) for use in locating you, if necessary. Because your information is so valuable, we may try to contact you multiple times, through a variety of means, if we lose track of you. Even if you decline or stop treatment we will still want to get information about you. If at any time you wish us to stop trying to reach you, you must explicitly inform us that you wish to withdraw from all aspects of the study, including follow-ups. All information that you provide to us will be handled in a confidential manner.

Reporting alcohol or non-prescribed drug use. Throughout this study you will be asked to tell the research staff about any times you use alcohol or other drugs to help manage your pain while in the study. The staff realizes that people in pain may have to resort to these substances to manage. In order to be helpful to you and to others, they need to know about your alcohol or drug use (including cannabis). Because of the serious risk of opioid dependence and overdose that exists in chronic pain populations, we also need to know about any prescribed or non-prescribed opioid medication you may be using. This includes OxyContin, fentanyl, and heroin. We will not report any such use to the police. We may, however, offer you counseling or additional resources if needed.

Timeline. The overall schedule will be as follows:

| TMD Online: Schedule of Activities | | |
|---|----------|--|
| Visit/session | Week | Participant Activity |
| 1 | -3 to -2 | Potential Participant is initially screened for eligibility via telephone, or in person (e.g., in dental clinic) |
| 2 | -2 | Diagnostic Evaluation (DE) visit (2 – 2.5 hours): <ul style="list-style-type: none"> • Orofacial Examination; Panoramic x-ray, impressions for splint taken • Administration of baseline measures (e.g., SCID, Orofacial pain and function) • Treatment Assignment • Introduction to Experience Sampling - Monitoring X 4 daily via smartphone (X 14 days; completed by treatment start) |
| 3 | 1 – 3* | Splint is delivered NSAIDs started (e.g., naproxen 550mg po BID) Soft diet guidance given to patient painTRAINER website is loaded and bookmarked on patient smartphone Pt. completes tutorial and painTRAINER sessions 1 and 2 (TMD Online Session 1) |
| 4 | 2 – 4* | painTRAINER session 3 (TMD Online Session 2) Start to taper NSAIDs Re-start Experience Sampling - Monitoring X 4 daily via smartphone X 7 days |
| 5 | 3 – 5* | painTRAINER session 4 (TMD Online Session 3) |
| 6 | 4 – 6* | Taper splint (e.g., wear as night guard only) painTRAINER session 5 (TMD Online Session 4) Re-start Experience Sampling - Monitoring X 4 daily via smartphone X 7 days |
| 7 | 5 – 7* | Splint discontinued painTRAINER session 6 (TMD Online Session 5) |
| 8 | 6 – 10* | painTRAINER sessions 7 and 8 (TMD Online Session 6) |
| 9 | 11-14 * | Administration of Posttreatment Self-Report Measures Re-start Experience Sampling - Monitoring X 4 daily via smartphone X 7 days |
| *Recognizing variability in schedules of working adults, flexibility is allowed in completion of study activities. Patients will have 10 weeks to complete the 6 treatment sessions. The Treatment and follow-up sessions will be conducted remotely. | | |

Risks and Safeguards

Clinical Deterioration. As with any treatment for a medical issue, you could experience clinical deterioration (worsening of your pain problem or other life issue) during the course of the study. Such risks are not foreseeable. The research staff will monitor participants for signs of deterioration, and will refer you for more intensive treatment if such a problem arises. If you pursue treatment outside the study, you will be responsible for the costs of that treatment.

Panoramic X-Ray. In order to rule out jaw disorders that we cannot treat in this study we will perform a panoramic x-ray. A dental x-ray will expose you to some radiation. The estimated radiation exposure received by each participant for the panoramic view is 1.5 millirem (15 uSv). This dose equivalent would be less than that received by an individual flying from New York City to San Francisco.

Discomfort with Splint. All participants will be fitted with a splint, or mouth guard, placed on the upper teeth. Some people may find this uncomfortable at first. If discomfort occurs, you may contact the study dental assistant or research assistant, and we will arrange to see you promptly (within a couple of days) to make adjustments to the splint. If the discomfort continues, you may stop using the splint at any time.

Discomfort from use of medication. As part of treatment all participants will be prescribed a non-steroidal anti-inflammatory drug (NSAID), something like Advil (ibuprofen), if there are no contraindications to prescribing those drugs for you. Sometimes these medications can cause discomfort, like upset stomach. Prior to any prescription, one of the study dentists will ask you about your history with these kinds of medications. For those who are sensitive to NSAIDs, another medication such as extra-strength acetaminophen will be prescribed. For those who do receive an NSAID and develop discomfort, that drug will be discontinued and another drug prescribed instead.

Confidentiality. Another potential risk is a possible breach of your confidentiality. Although we cannot guarantee that confidentiality will be maintained, the researchers will make every effort to maintain your confidentiality. Your research record will be labeled with a code number, which will be determined using a random numbers list. A master list that links your name with your code number will be maintained in a

separate and secure location. Consent forms will be stored in electronic form in a secured location (on a secure server) apart from the research record. Your name will not appear in any publication. Only those associated with this study will have access to your research record, or to the master list linking your name with your code number. If your information is used in future research, all identifiers, such as name and date of birth, will be removed. After removal of names and other identifiers, the information you provide could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you, the subject.

You will be instructed in ways to prevent disclosure of sensitive information while participating in TMD app monitoring (e.g., how to keep from being overheard or observed while using the app; how to delay responding to a signal), and while completing paperwork related to treatment assignments. Because someone other than you could pick up your cell phone, the system will not identify itself when it signals a recording. The user will only see: "This is an online survey. Please enter your ID number, and click the 'Submit' box." If there is no response the app will close and repeat the recording attempt 15 minutes later. The monitoring data themselves will be stored on a secure server maintained by our technical partner. Access to these data will be by password only. The data themselves are identified only by code number, and no identifying information will appear in the monitoring records.

A Certificate of Confidentiality has been obtained to further help protect your privacy and the confidentiality of your data. With a Certificate of Confidentiality in place, the investigators cannot be forced to disclose research-related information about you to anyone not connected to the study, except in very limited circumstances. A Certificate of Confidentiality does not stop you from voluntarily disclosing information. It also does not stop the investigators from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The information collected for this research study will be accessible to authorized persons. Authorized persons include study team members, representatives of UConn Health and, as may be applicable, representatives of the Sponsor and/or representatives of Federal agencies when required by law, such as the Department of Health and Human Services when the research is federally funded or supported. Representatives from these areas have access to the information so they may ensure that the study is being done correctly. In addition, because this study uses an online application as a medical device, the FDA may choose to inspect records (including your medical records) identifying you as a subject in this investigation.

Participant Burden. Carrying and answering the smartphone for TMD monitoring can be annoying. This has sometimes been a complaint in others who have monitored pain and other sensations. Most people have not found the phone to be very annoying, however, and have said later that they have learned a lot from doing the monitoring. You will be compensated for successfully completing the MetricWire app surveys.

Discomfort with Personal Questions. Some people may feel uncomfortable about answering personal questions. Unfortunately, we must ask about a lot of personal issues in order to conduct this research. Participants are free to decline to answer any questions, and may withdraw from the study at any time.

Disappointment with Treatment. On occasion someone might be disappointed with the treatment we are providing here. The treatment program used here contains treatment elements that are found in other treatment programs, and all have demonstrated effectiveness. Thus, no participants will be deprived of anything that they might have obtained in a program elsewhere. The only exceptions to this are that no therapist contact will be available, and there will be no prescription of narcotic pain medication. We will not be supplying or prescribing narcotic pain medication in this study. If a subject is dissatisfied with this treatment referral will be made to a treatment setting outside of the study.

Exposure to potentially stressful circumstances. Some people may find the effort to manage pain itself to be stressful, due to lifestyle changes, etc. However, there will be no greater distress in this study than in any other effort to comprehensively manage a chronic pain problem. In addition, the level of support provided by research staff in this project is very high, and will help diminish the stress associated with

treatment. Also, the homework and TMD monitoring activities might be seen as stressful. In order to minimize risk of upset to participants, the patient will be able to schedule homework assignments at their convenience.

Costs of participation. Treatment is provided at no charge to you. There are no additional costs associated with participation in this research above those associated with receiving outpatient treatment for orofacial pain in any other setting (e.g., occasional travel expenses, etc.). You may have to take time from work in order to participate in study visits. You may incur some travel costs to get to study visits. We will schedule follow-up visits at your convenience to minimize costs. If travel to UConn Health is difficult we may provide bus passes, if that would make it easier.

Benefits

There is no guarantee that the treatment you receive will benefit you. However, you may experience benefits such as improving your sleep or functioning, or other improvements in your life. Even if there are no specific benefits for you, this study may provide information that can help others in the future.

Stopping Study Participation

You could be dismissed from the study, or referred for treatment outside the study, if you repeatedly fail to access painTRAINER modules, if you cannot adhere to the TMD monitoring procedures (MetricWire), if you are taking opioid pain medication, or if you are repeatedly under the influence of substances at research visits or interviews. Your obligation to the study is to do your best to work to manage your pain problem, to be honest in responding to questionnaires and online assessments about yourself and your problems, and to be available at the right times for follow-up interviews.

Alternative Treatments

Participants may opt to not pursue treatment in this study. There are pain programs available in other facilities that may offer treatment. If a participant desires a referral we will work to provide that.

Voluntary Participation

Your participation in this research is completely **voluntary**. You are free to choose not to participate. If you do participate, you are free to withdraw at any time. If you choose not to participate, or if you withdraw from the study, it will not harm your relationship with the clinics or doctors at UConn Health. You may discontinue study participation at any time without penalty or loss of benefits to which you would otherwise be entitled. A list of alternative treatment providers is available upon request, and the staff can assist you in selecting among them. Any significant information we discover that might influence your decision to continue participation will be communicated to you in a timely way.

If you do wish to withdraw from study participation, all data collection will be discontinued **only** if you expressly state that you wish to discontinue participation entirely, at which point all communication with you ceases. Your anonymous, de-identified data will remain in the database unless you state that you want that information removed.

If you do wish to discontinue your participation in this study you may contact your research assistant: Kara Dion (860-679-4767), Abi Young (860-679-3718), Diane Wilson, PhD (860-679-3020), or Jane Harrison (860-679-4765). You may also call the Clinical Coordinator, Elise Kabelas-Cormier, PhD (860-679-2657), or call or write to the Principal Investigator, Dr. Mark Litt (860-679-4680) at the Division of Behavioral Sciences, UConn Health, Farmington, CT 06030-3910.

Sharing of Information

We receive money from the National Institutes of Health (NIH) to do this study. NIH requires that we have a plan in place to share information we gain in this study. We anticipate publishing the findings of this research and publishers often require that we have a plan in place to share the information we collect during this study.

Your information will only be shared in an anonymous way. Sharing research data helps to translate research results into knowledge, products, and procedures that improve human health. If you provide permission now to share your anonymized (unidentified) information with the database noted below, you may withdraw your permission later without any penalty or loss of benefit. The information will be withdrawn from the database. However, if the information has already been shared with other researchers that information will not be able to be deleted.

The anonymized information from this study will be placed in a Data Coordination Center maintained by the National Institutes of Health. The information will be freely available in a public, unrestricted database that anyone can use for future research. The public database will include information on the pain, medical symptoms and questionnaire findings of thousands of people in studies like this one. The only health information included will be whether you had TMD/orofacial pain or not. This public information will not be labeled with your name or other information that could be used to easily identify you. Please indicate whether we may share your anonymized information by initialing your preference:

Yes, my anonymized information may be shared for future research _____(initials)

No, do not include my anonymized information in the data that is shared _____(initials)

Participant Injury/Adverse Events

Every effort to prevent injury as a result of your participation in this study will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. If at any time during treatment, or during the follow-up period, you experience a serious problem, you may contact the study staff (860-679-2657) to request referrals for additional treatment. UConn Health does not offer free care. However, treatment for a research-related injury can be obtained at UConn Health for the usual fee. UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UConn Health Institutional Review Board at 860-679-4849 or 860-679-8729.

Questions/Comments

Your assigned research assistant will be available by calling that person directly or by calling the Clinical Coordinator, Dr. Elise Kabela-Cormier, at 860-679-2657, or the Principal Investigator, Dr. Mark Litt, at 860-679-4680. You will be encouraged to call if you have any questions or problems. Drs. Litt and Kabela-Cormier are available during business hours, Monday through Friday. For problems that occur after business hours patients should contact 911, their local emergency room, or Infoline for non-emergency services. You will be given a list of emergency and non-emergency services and their phone numbers to be used if needed.

You are encouraged to ask about anything you don't understand, and to consider this research and the consent form carefully before you agree to participate. You may take as much time as necessary to think it over.

You may also call a coordinator at the Institutional Review Board (860-679-4849 or 860-679-8729) if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies. Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Other Information

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. If you wish, you may request that a

summary of the results be sent to you once the study is completed. We will not be able to provide you with information specific to you personally.

You may also request that your records be released to your personal physician. If we release study records for clinical care purposes, then we will remove all identifying information from your records prior to releasing them.

This project provides compensation to participants. Our general practice is to issue checks payable to a participant by name, or by issuing an e-gift card. In the case of issuing checks, you must either bring identification to pick the check up in person or have it mailed to you. You can also choose not to receive any compensation. If you do choose reimbursement by check no reference to this study will appear on the check ledger line.

We are required to advise you that if you receive over \$600 from participating in research studies over the course of a calendar year, that money must be reported to the IRS as income, and a signed W-9 form may be required in that circumstance. (The total compensation from this study will be less than \$600).

Please indicate your preference by initialing below (You may change this at any time by informing the study team):

If possible, I would prefer an e-gift card to be sent to my e-mail _____

I prefer not to receive compensation for this study _____

I would like to be reimbursed by check, and I will pick the check(s) up in person _____

I would like to be reimbursed by check, and I would prefer the check(s) be mailed to me _____

We would also like your permission to contact you in the future regarding this or other research. At this time we have no plans to contact you further, but we are asking your permission in case it might be useful to reach you again. You are not required to agree to this additional contact, and we will not attempt to contact you more than 24 months after your last meeting with us in any case. If we do contact you in the future we will not refer to any previous study participation. Would you agree to be contacted in the future?

☐ **Yes, I agree to be contacted in the future**

☐ **No, I do not agree to be contacted in the future**

Consent to Participate

By signing this form you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study and been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

You will also be given a Participant Feedback Form that you may complete and submit to Institutional Review Board to provide information about your general experience as a study volunteer for purposes of quality improvement. You may use this form to offer suggestions, express concerns, complaints or compliments about your involvement in a research study, or to ask general questions or obtain information about participation in other clinical research studies.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of the signed document will be provided to the subject.

Role

Date

Participant

Printed Name

PI or authorized research
personnel

Signature

Printed Name

Signature