University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: August 03, 2026
IRB Study # 25-0878
Title of Study: Safety and analgesic efficacy of marine lipid precursors of specialized pro-resolving mediators in adults with chronic temporomandibular pain.
Principal Investigator: Anne Sanders
Principal Investigator Department: Pediatric Dentistry and Dental Public Health
Principal Investigator Phone number: 919-537-3275
Principal Investigator Email Address: anne_sanders@unc.edu
Funding Source and/or Sponsor: National Institutes of Health (NIH)

You are being asked to take part in a study to see if a dietary supplement made from marine oils can help reduce face and jaw pain from temporomandibular disorder (TMD).

If you join, you are asked to take either the supplement or a placebo (a pill with no active ingredient) twice a day for 8 weeks. You are asked to complete daily pain ratings and attend four clinic visits for exams, blood samples, and pressure-sensitivity tests. You will also be asked to complete a few questionnaires.

Your regular medical care will not change. If you take daily TMD pain medicine, you must continue it during the study. The study supplement may or may not help you, but your participation may help others in the future. Blood draws may cause brief discomfort or bruising. Your information will be kept private, though there is a small risk it could be shared by accident.

What are some general things you should know about research studies?

You are being asked to take part in a research study. Joining the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or UNC at Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this study is to learn whether a dietary supplement made from marine lipids (fish oils) can help reduce facial pain in adults with long-lasting temporomandibular disorder (TMD). The supplement contains special fats from fish oils that may help the body calm inflammation, ease pain, and reduce anxiety. This type of supplement has been used safely by people before, but we need more research to better understand its safety and how it works in people with chronic TMD pain. The Food and Drug Administration (FDA) is allowing this study to move forward without an Investigational New Drug application, all rules that protect the safety and rights of study participants still apply to this study.

Are there any reasons you should not be in this study?

You are being asked to be in the study because you are an adult with a chronic pain condition called temporomandibular disorder. You will not be able to take part in this study if any of the following apply to you:

- You are pregnant or planning to become pregnant, as participants randomized to placebo would not receive a potential benefit of fish oil supplementation during pregnancy.
- You have serious medical conditions, such as heart disease, kidney failure, immune disorders, or severe obesity.
- You have serious mental health issues or have recently received treatment for substance abuse.
- You are currently receiving chemotherapy or radiation therapy.
- You take blood thinners (other than low-dose aspirin), opioid pain medicines, or recently started a new pain medication.
- You recently had facial surgery or a facial injury.
- You are allergic to fish or seafood.
- You recently had treatments for facial pain, such as injections, Botox, or acupuncture.
- The study doctor believes you have any condition that could make participation unsafe or interfere with the study.

How many people will take part in this study?

Approximately 100 people at UNC Chapel Hill will take part in this study.

How long will your part in this study last?

Your participation in this study will last about 10-12 weeks. During 8 weeks of this time, you will take the active supplement or placebo daily and rate your pain intensity on a paper form every day. You will attend four clinic visits, each lasting up to 2½ hours. After the study, there will be a brief follow-up phone call to check on your health and any changes since the study ended.

What will happen if you take part in the study?

Participation in the research study is voluntary. Prior to the first study visit, you will answer brief screening questions by phone or online to see if you meet key inclusion criteria. People who meet initial screening criteria will be invited to attend a study visit at the Adams School of Dentistry at the University of North Carolina at Chapel Hill. As explained below, there are four study visits in

total. At each study visit, you will be asked to self-report whether you are pregnant. Some procedures, like signing the consent form and attending study visits, are required to stay in the study. For other procedures, you can choose not to answer any questions or skip any procedures if you feel uncomfortable, without affecting your participation. At the end of the study, you will complete a brief phone call with the study coordinator, who will review any side effects (also called adverse events) since your last visit.

Pregnancy testing is not required. At each visit, you will be asked to self-report whether you are pregnant. If you become pregnant during the study, you may remain in the study and choose to stop taking the study product or withdraw entirely. If you stop the study product, the study team will ask your permission to continue collecting study information.

Overview of your Activities at Study Visits

Visit 0. Baseline and Screening Visit

- Complete a short interview to see if you are eligible for the study
- Review and sign consent forms
- Provide demographic information and contact details
- Answer questions about medical history, medications, and therapies
- Learn how to complete the Daily Symptom Diary
- Receive new Daily Symptom Diary to complete at home
- Have your height and weight measured
- Participate in a clinical examination of your face and jaw area
- Complete simple pressure sensitivity tests

Visit 1. Randomization Visit

- Review your medical history, medications and treatments
- Provide your completed Daily Symptom Diary
- Receive new Daily Symptom Diary
- Be randomly assigned to a study group
- Receive the study product to take at home
- Have blood drawn
- Complete questionnaires

Visit 2. Mid-Study Visit

- Review your medical history, medications and treatments
- Answer questions about side effects (adverse events) since your last visit
- Provide your completed Daily Symptom Diary
- Receive new Daily Symptom Diary
- Provide your study product container for a pill count
- Receive more study product to take at home
- Complete simple pressure sensitivity tests
- Complete questionnaires

Visit 3. Final Study Visit

- Review your medical history, medications and treatments
- Answer questions about side effects (adverse events) since your last visit
- Provide your completed Daily Symptom Diary
- Provide your study product container for a pill count
- Participate in a clinical examination of your face and jaw area

- Complete simple pressure sensitivity tests
- Have blood drawn
- Complete questionnaires

Post-Study Phone Interview

- Answer questions about any side effects or problems you experienced while taking the study product.

If you meet all eligibility criteria, you will be assigned by chance—like flipping a coin—to one of two groups. One group will receive an active supplement made from marine lipids, and the other group will receive a placebo made from medium chain triglycerides, which looks the same but does not contain the active ingredients. This process helps ensure the study fairly compares the effects of the supplement with placebo.

In this study, neither you nor the staff working with you will know if you are receiving the active supplement or the placebo. This "masking" helps ensure the study results are reliable. However, in a medical emergency, the principal investigator (PI) can find out your treatment to provide proper care. This is called "unmasking" and will only happen if necessary for your safety**.**

Two blood samples will be collected from you during the study at Visits 1 and 3. Each blood draw will take about 10 milliliters (approximately 2 teaspoons) of blood. Fasting is not required before these blood draws. The samples will be used to measure markers related to the biochemical effects of the supplement. The blood samples will be analyzed only for this study. After testing is complete, any remaining blood or biological material will be securely destroyed according to UNC policies. The samples will **not** be used for whole genome sequencing and will **not** be stored for future research

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. Participants may or may not benefit from receiving the investigational product by experiencing decreased pain and improved functionality.

What are the possible risks or discomforts involved from being in this study?

During the study, we will examine your jaw muscles and joints using finger pressure and a device that measures pressure sensitivity. These tests may cause brief discomfort or pain, but you can stop at any time and no test will continue if you ask. These tests are not expected to cause lasting pain or harm. If you feel more than mild pain, the Study Coordinator will inform the study doctor.

Blood draws may cause mild pain or bruising. Trained staff will follow standard procedures to collect blood safely.

You may be asked personal questions about your health, symptoms, or emotions. Answering is voluntary, and you can skip any question that makes you uncomfortable.

If you disclose illegal drug use, this information will only be used to determine eligibility and will be kept separate from information that identifies you.

As with all research, there is a chance that your information may be seen by people outside of the research team. We take steps to make sure all of the study information is stored securely. More information about how we secure your information is described in a later section.
There may be uncommon or previously unknown risks. You should report any problems to the researcher.

If you choose not to be in the study, what other treatment options do you have?

You do not have to be in this research study in order to receive treatment. You may also choose to receive clinical care from Dr. Pei Feng Lim, an orofacial pain specialist, or another provider at the UNC Adams School of Dentistry without participating in this study. The other procedures or treatments for TMD pain that are available outside of this study include physical therapy, medications (e.g., non-steroidal anti-inflammatory drugs, muscle relaxants), behavioral strategies, and oral appliances.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

Only members of the study staff will have access to potentially identifiable information. Participant survey data, interview data, and biospecimens will be collected solely by trained study staff members. All paper forms will be stored in a locked file cabinet in a secure area.

All electronic data will be stored on encrypted, password-protected computers on an IRB-approved secure network at the UNC Adams School of Dentistry. Each member of the research team will access the data directly. Data sent through email will be encrypted and sent securely.

To protect your privacy, we will use anonymous ID numbers instead of names whenever possible. The linkage between names and ID numbers will be stored in a separate, secure file that is accessible only to authorized study personnel. Biospecimens will be labeled with anonymous ID numbers and stored in a secure laboratory facility; no names will be included on specimen labels. Participants will **not** be identified in any report or publication about this study. No data provided by study participants will be used for future research. Likewise, no biospecimens donated by study participants will be used for future research.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC at Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. If any of these groups need your records, they may also need your entire medical record.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide

healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

The study team will message you by email or text, however you may say "no" to receiving these messages and still participate in this study. These messages may include appointment reminders, requests to contact the study team, or reminders to complete study activities. The study team will ask you to provide your preferred email address or cell phone number. These messages will be sent from a Google Voice account created for the study. If you respond to the message, your message will be received in the Google Voice account. This means there is the risk your information could be shared beyond you and the study team.

If you wish to stop receiving unencrypted communication from the study team or have lost access to your device or email account, please notify the study team using the study contact information on the first page of this consent form.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.
The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911.

The National Institutes of Health and the UNC at Chapel Hill have not set aside funds to pay you for any such injuries, illnesses, or reactions, or for the related medical care. Any costs for medical expenses will be billed to you and your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries.

By signing this form, you do not give up your right to seek payment or other risks if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time without penalty or loss of benefits. The study team also has the right to stop your participation if you experience an unexpected reaction, do not follow study instructions, or if the study itself is stopped. You may be withdrawn for any of the following reasons: you choose to withdraw, you no longer meet eligibility requirements, noncompliance as determined by the principal investigator, or if continuing is not in your best interest.

If you withdraw or are withdrawn, all information and sample collected up to that point will be kept and used in the study analysis and cannot be removed. No further information or samples will be collected unless you give additional written permission to continue.

Will you receive anything for being in this study?

Participants who are randomized and who complete all study visits will receive $320 in total compensation. Compensation has been budgeted at approximately $30 per hour of clinic attendance, prorated up to a total of $320 for each randomized participant. All compensation, including reimbursement for parking costs, will be provided through a ClinCard (a prepaid debit card used for research participant payments). You will be compensated at each study visit as follows:

- Visit 0: $60
- Visit 1: $75
- Visit 2: $60
- Visit 3: $75
- $50 bonus for completion of all study visits

Payment of those who withdraw will be prorated according to the number of attended visits. Reimbursement for parking costs incurred during clinic visits will also be loaded onto your ClinCard.

Any payment provided for participation in this study may be subject to applicable tax withholding obligations. In order to process payments, the University may share certain identifiable information about you, such as name, contact information, and Social Security Number where required with third parties that the University retains to process payments on its behalf. If you do not want to agree with sharing your information with these third parties, then you will be unable to receive payment/compensation for participating in the study. Your name, address, and U.S. tax payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS.

U.S. participants must complete Form W-9 if payment by UNC equals or exceeds $600 per calendar year. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents. This information will not be linked to any of the study data and will only be used for payment purposes.

If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation. However, you may still choose to participate in this study.

Will it cost you anything to be in this study?

There are no study related costs to you for being in this study. All study-related procedures and materials will be provided at no charge.

Who is sponsoring this study?

This research is funded by the National Institute of Dental and Craniofacial Research (NIDCR). This means that the research team's university is being paid by NIDCR for doing the study. The researchers do not, however, have a direct financial interest with NIDCR or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Consent to Provide Social Security Number for Reimbursement

If you choose to participate in this study, you may receive up to $320 as reimbursement for your time and effort. Payments will be made through a ClinCard (a reloadable prepaid card). The University requires us to collect your Social Security Number (SSN) to process these payments for tax reporting purposes. Your SSN will be kept secure and used only for this purpose.

Please check one box below to indicate your choice regarding reimbursement:

☐ Yes, I agree to provide my Social Security Number so I can receive reimbursement.
☐ No, I do not agree to provide my Social Security Number and understand I will not be reimbursed.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time.
I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____

Printed Name of Witness