Informed Consent

Evaluating the Effects of Omega-3 Polyunsaturated Fatty Acids in Pediatric

Migraine Patients

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University of North Carolina at Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study

Consent Form Version Date: 3/24/2025
IRB Study # 24-2715
Title of Study: Evaluating the Effects of Omega-3 Polyunsaturated Fatty Acids in Pediatric Migraine Patients
Principal Investigator: Caroline Sawicki
Principal Investigator Department: Pediatric Dentistry and Dental Public Health, Adams School of Dentistry
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Principal Investigator Email Address: caroline_sawicki@unc.edu

Funding Source and/or Sponsor: University of North Carolina Nutrition and Obesity Research Center

CONCISE SUMMARY

This is a research study to understand the clinical and biochemical effects of omega-3 fatty acid supplementation in children and adolescents suffering from migraine, including its effects on migraine disability, psychological distress, and overall quality of life. If enrolled, your child will be randomized to receive either an omega-3 PUFA dietary supplement or placebo daily for 12 weeks, with assessments conducted at baseline (i.e., pre-intervention) and at 12 weeks (i.e., post-intervention). At both baseline and week 12, we will conduct a 24-hour dietary recall with your child over the phone to gather detailed information about their food and beverage intake during the previous day and weekend. We will collect a finger prick blood sample from your child at baseline and at week 12. Additionally, your child will be asked to fill out three online surveys, consisting of approximately 10-15 questions each, at baseline and at week 12. We will conduct two study phone calls (week 4, week 8) to determine study adherence. During these phone calls, we will ask you to verbally confirm that your child has been taking their assigned supplement daily. There is no follow up regarding the study, and your child is only eligible to participate once.

There are minimal risks to participating in the study. There is a potential risk regarding breach of confidentiality of your child's personal health information. At UNC, we operate on a secure network to ensure that your child's data is protected. Potential side effects of the omega-3 supplement and placebo are uncommon but might include minor stomach distress or belching. Additionally, the omega-3 supplement might cause body odor and/or bad breath. The fingerprick blood sample may cause transient pain/discomfort.

At the completion of all study procedures (*i.e.,* completion of week 12 study visit), you as the parent participant will receive a $100 Amazon e-gift card.

There is no additional follow up regarding the study, and your child is only eligible to participate in the study once. If you are interested in learning more about this study, please continue reading below.

What are some general things you and you child should know about research studies?
You are being asked to allow your child to take part in a research study. To join the study is voluntary.
You may decide to not allow your child to participate, or you may withdraw your permission for your child to be in the study, for any reason, without penalty. Even if you give your permission, your child can decide not to be in the study or to leave the study early.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child 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 or your child's relationship with the researcher, the health care provider, or the University of North Carolina-Chapel Hill. If your child is a patient with an illness, your child does 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 and your child understand this information so that you and your child can make an informed choice about being in this research study.
You will be given a copy of this consent form. You and your child 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 research study is to learn about the clinical and biochemical effects of omega-3 PUFA supplementation in children and adolescents suffering from migraine. Your child is being asked to be in the study because he/she has a diagnosis of migraine.

Are there any reasons your child should not be in this study?
Your child should not be in this study if he/she is not able to read the English language, is below the age of 10, or is above the age of 17.

How many people will take part in this study?
Approximately 80 youth at the University of North Carolina at Chapel Hill will take part in this study.

How long will your child's part in this study last?
Your child's part in the study will last 12 weeks. Two in-person study visits (each lasting approximately 15 minutes) will include a finger prick blood sample and completion of three surveys (10-15 questions each). At both baseline and week 12, we will conduct a 24-hour dietary recall with your child over the phone to gather detailed information about their food and beverage intake during the previous day and weekend (each phone call will last about 10 minutes).

What will happen if your child takes part in the study?
Your child will be randomized to receive either an omega-3 PUFA dietary supplement or placebo daily for 12 weeks, with assessments conducted at baseline (i.e., pre-intervention) and at

12 weeks (i.e., post-intervention). At both baseline and week 12, we will conduct a 24-hour dietary recall with your child over the phone to gather detailed information about their food and beverage intake during the previous day and weekend. We will collect a finger prick blood sample from your child at baseline and at week 12. Additionally, your child will be asked to fill out three online surveys, consisting of approximately 10-15 questions each, at baseline and at week 12. We will conduct two study phone calls (week 4, week 8) to determine study adherence. During these phone calls, we will ask you to verbally confirm that your child has been taking their assigned supplement daily. The surveys ask about the pain he/she is experiencing due to migraine, in addition to possible indicators or anxiety and/or depression. You will be asked to complete a short demographic survey about your child. The survey will take less than a minute to complete.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. If your child is assigned to the intervention group (i.e., omega-3 supplement), they may experience a reduction in pain intensity and interference, migraine disability, and psychological distress.

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

There may be uncommon or previously unknown risks. A possible risk that you should be aware of is a possible breach of confidentiality, meaning that someone could access your child's personal information. This risk is minimal as we have systems in place for your safety and to protect your child and his or her information. For example, survey responses will be collected in CDART, a secure online platform, and any downloaded data will be stored on a secure local server. You should report any problems to the researcher. Potential side effects of the omega-3 supplement include unpleasant taste, bad breath, bad-smelling sweat, headache, gastrointestinal symptoms such as heartburn, nausea, and diarrhea. The coconut oil placebo might cause increased cholesterol levels, increased blood pressure, hormonal imbalances, and gastrointestinal symptoms such as diarrhea, nausea, abdominal pain, and bloating. The fingerprick blood sample may cause transient pain/discomfort.

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

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

How will information about your child be protected?

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent. 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-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your child's 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.

What will happen if your child is injured by this research?

All research involves a chance that something bad might happen to your child. If your child is hurt from something that was done as part of this study, the researcher will help your child get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you or your child for any such injuries or for the related medical care. Any costs for medical expenses will be billed to your child, you, or your insurance company. You/your child may be responsible for any co-payments and your child's insurance may not cover the costs of study related injuries.

If you think your child has been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you and your child should do.

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

What if you or your child wants to stop before your child's part in the study is complete?
You can withdraw your child from this study at any time, without penalty. The investigators also have the right to stop your child's participation at any time. This could be because your child has had an unexpected reaction, or has failed to follow instructions, or because the entire study has been stopped. If you withdraw your child or your child is withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your child's withdrawal.

Will your child receive anything for being in this study?
As a parent participant, you will receive a $100 Amazon e-gift card if you and your child complete all study procedures. Since your child's participation is essential to the study, we encourage you to share the compensation with them as a token of appreciation for their involvement. 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 and contact information, 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.

Will it cost you anything for your child to be in this study?
It will not cost anything extra to be in this study.

Who is sponsoring this study?
This research is funded by the Nutrition and Obesity Research Center at the University of North Carolina at Chapel Hill. This means that the research team is receiving funding from the sponsor to conduct the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you or your child has questions about this study?
You and your child have the right to ask, and have answered, any questions you may have about

this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form**.**

What if there are questions about your child's rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your child's rights and welfare. If there are questions or concerns about your child's 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.

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Principal Investigator: Caroline Sawicki

Parent's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

_____
Name of Research Participant (child) (Type First and Last Name)

_____
eSignature of Parent (Typed Signature)

_____
Date

_____
Name of Parent (Type First and Last Name)

_____
eSignature of Research Team Member Obtaining Permission (Typed Signature)

_____
Date

_____
Name of Research Team Member Obtaining Permission (Type First and Last Name)

_____
eSignature 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) (Type First and Last Name)

_____
Date

_____
Name of Witness (Type First and Last Name)