Informed Consent

Title of Research: Dietary counselling plus omega-3 supplementation in the treatment of generalized anxiety disorder: A randomized wait-list controlled pilot trial (the "EASe-GAD trial")

Introduction

You have been invited to take part in a research study. Please read this consent form carefully before signing. It explains what this research study is about, how the study will take place, and what you will need to do during the study. If you have any questions, please ask someone from the research team. Do not sign this consent form until you understand everything. You will be given a copy of this form to keep. We will tell you about any new information that may affect whether or not you would like to continue participating in this study. Signing this consent form does not take away any of your rights or release the researchers from responsibility for negligence.

Purpose of the Study

The food that we eat impacts the health of our bodies and our mental health. Researchers do not know how diet changes might impact levels of anxiety in people with anxiety disorders. In this study we will provide diet counselling (recommendations on how to improve your food choices) and omega-3 (fish oil) and vitamin D supplements to people with generalized anxiety disorder. We want to know if this treatment is acceptable and helpful for people with anxiety. We will be measuring changes in your diet habits, levels of certain nutrients (such as vitamins and fats in blood), and any changes in your anxiety symptoms.

Study Procedure

If you decide to participate, you will be put into one of two groups. The odds of being in each group are the same. Selections are made in a manner similar to drawing numbers from a hat. Both groups will complete the program. Half of the participants in the study will start the program right away. The other half of participants will wait 12 weeks before starting the program. We expect that a total of 50 participants will take part in the study. See Diagram 1.

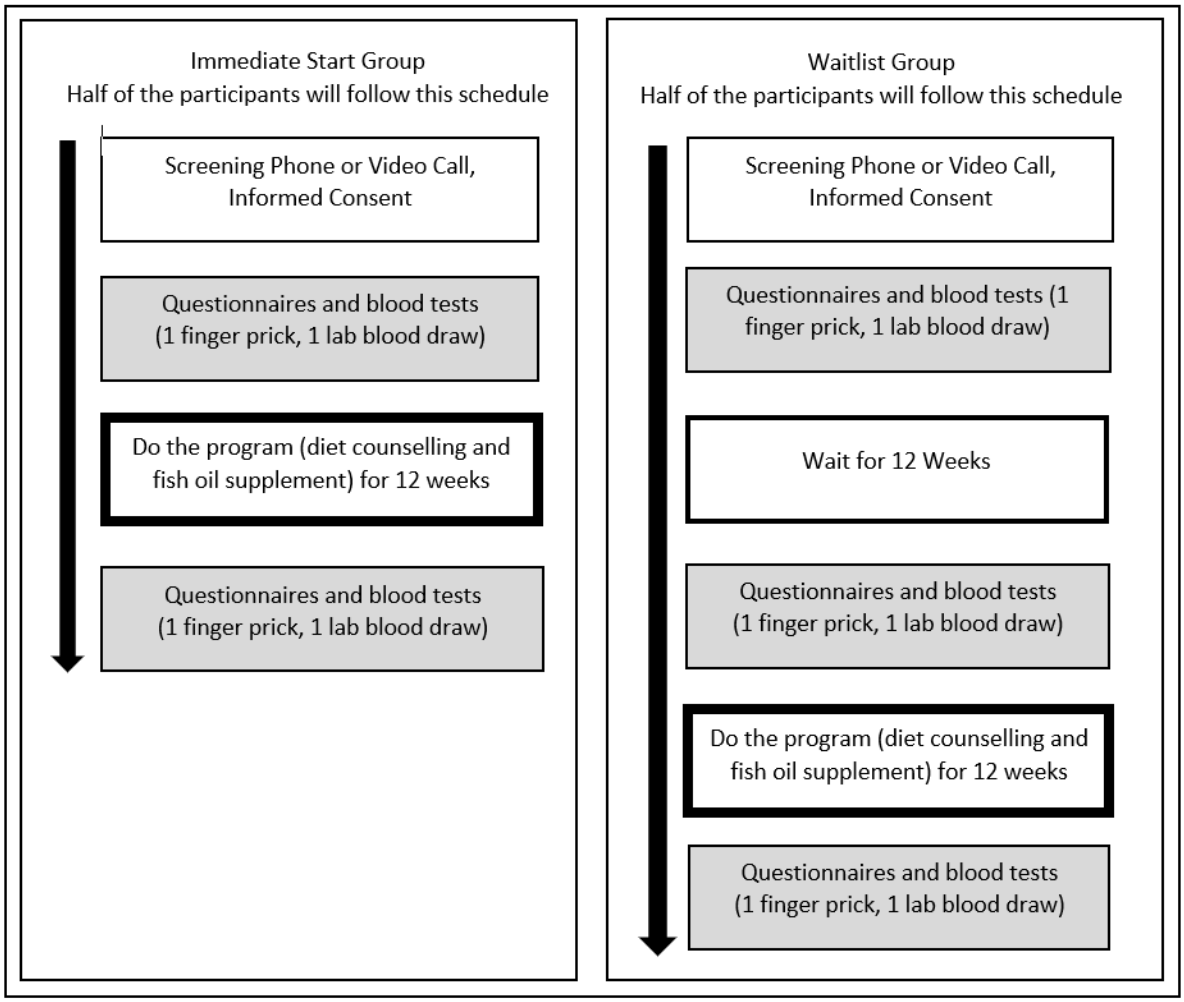

Diagram 1: Research Study Schedule.

Before starting the program

Both groups will start by completing questionnaires. You may complete the questionnaires using your own computer or electronic device and internet connection. Completing the questionnaires will take 30 to 60 minutes. The questionnaires will include questions about the foods you eat and your eating patterns, your anxiety symptoms, your quality of life, your exercise habits, medications that you take, use of alcohol and cigarette smoking, and information about your marital status, employment, education, income, and ethnic background. If you do not have access to a computer or the internet, we will mail the questionnaires to your home, and you can mail them back. We will give you an envelope with postage prepaid. You will also provide two blood samples to measure levels of vitamins, sugar, and fats in your blood. One will be a finger prick where you will provide one or two drops of blood. You will collect this sample at home with the help of instructions and materials we provide you with, and then mail it to us. The other is a venipuncture blood sample. You will go to a lab and a needle will be put in your vein near your elbow. A few tablespoons of blood will be collected in tubes. At the first in person session, we will measure your height and weight.

The Program

The treatment program is 12 weeks long. You will have 7 individual, dietary counselling sessions with a nutritional professional (one session every 2 weeks). Each session will be 45 to 60 minutes in length. Three sessions will take place in person (the first, fourth, and seventh) and the other sessions will take place by secure video call. If you do not have access to a computer and internet, you can complete all sessions in person. If changes need to be made because of COVID-19 restrictions, we will tell you right away. In these sessions, you will be asked about your current diet habits. You will be given suggestions on how to improve your diet habits based on the Mediterranean diet. The Mediterranean diet includes plenty of vegetables and fruit, fish, lentils and beans, whole grains, nuts and seeds, and water. It contains lower amounts of foods that are high in sugar. You may receive information like handouts, recipes, videos, and grocery lists to help with cooking skills, behaviour change, and goal setting. You will also receive some food items at the first and fourth visits.

During the 12 weeks, you will also be asked to take an omega-3 (fish oil) supplement. The supplement is called ”High EPA Omega-3” and it is made by AquaOmega. The total daily dose contains 3450mg of omega-3 fatty acids, including Eicosapentaenoic acid (EPA) 2659mg, Docosahexaenoic acid (DHA) 532mg, and 800 IU Vitamin D. You will need to take four capsules, once per day, with food.

After the program

After completing the treatment program, you will be asked to complete the questionnaires again (30 to 60 minutes in length) and provide another 2 blood samples (one finger prick and one lab blood draw). If you wish to receive a copy of your lab results, you may request this from the study coordinator after you have completed the study.

WaitList Group

If you are in the waitlist group, you will wait 12 weeks before starting the program. You will come to the clinic once before you start the waiting period. Your weight and height will be measured at this time. You will complete the questionnaires and blood tests (both the finger prick and the lab blood draw) 3 times: as soon as you start the study, after the 12 week wait and after you finish the treatment program (see Diagram 1).

Other Treatments

During the study (including the waitlist time), we ask that you not start a new treatment for mental health symptoms. This includes medication, psychotherapy or natural health products (such as vitamins, herbs, or homeopathics). We ask that you keep your dose of medications and natural health products that you are already taking the same, if possible. However, if you feel that your anxiety or depression levels are too high, you may start new treatment or change your medication dose, as recommended by your mental healthcare provider (such as your psychiatrist, family doctor or psychologist). At each study visit you will be asked about changes in your other treatments. Please tell us about any changes. If you add a new medication in the last 3 weeks of the waiting period you may need to wait longer to start the nutrition counselling program. We will ask you to wait until 4 weeks have passed since you started the new treatment.

If you are currently taking between 1701 and 4000IU of vitamin D, you can choose to take part in this study if you decrease your vitamin D supplementation to 1700IU per day while taking the study product. The study product includes 800IU of vitamin D which means that your total dose would be 2500IU. The purpose of this is to ensure that participants do not experience negative effects of having too much vitamin D while taking part in the study. If you do not wish to change your current vitamin D supplement dose, you may choose not to take part in this study. If high dose vitamin D was recommended to you by your health care provider, please speak with them before changing your dose.

Potential Harms

Some possible side effects of omega-3 supplements include fishy aftertaste, bad breath, heartburn, nausea, or loose stools. There is a chance that high dose fish oil supplements may increase the risk of atrial fibrillation (a kind of rapid heartbeat). There is also a chance that taking fish oil and blood thinning medication at the same time could increase the risk of bleeding. There may be unknown risks from taking this product.

It is possible that your anxiety levels may remain the same or get worse during the study. If your anxiety levels are too high, please contact your mental healthcare provider for recommendations about other treatments that you can begin. We encourage you to keep your medication and supplements the same during the study. However, if your symptoms get worse, you may begin new treatments that your healthcare provider recommends. You must tell us at your next research study visit if you change your medication or add new ones.

You are required to fast (avoid eating or drinking anything other than water for 12 hours) before each of the blood tests (either 2 or 3 times depending on which group you are in). The risks associated with having blood drawn include pain, bruising and/or rarely, infection at the site where the needle is inserted; however alcohol will be used to minimize this risk. Some people may feel faint or lightheaded when having blood drawn. If you experience a feeling of light-headedness, you should lie down right away to avoid possible injuries caused by falling and notify the lab staff right away to help you. If you have had previous bad experiences with blood draws, please let the lab staff know so that they can help minimize any risks or discomforts.

Potential Benefits and Compensation

Research has shown that eating the Mediterranean diet can improve your health. However, you may not experience any personal health benefit from participating in this study. The results of the study may help to improve our understanding of how to help people with anxiety disorders in the future.

You will receive $50 each time you complete questionnaires and blood work to thank you for your time. If you are in the group that starts the treatment program right away, this will happen 2 times (before and after the program). If you are in the group that completes the waiting time before the program, you will complete the questionnaires and blood work 3 times (before the wait, after the wait and after the program). People in this group will receive the $50 thank-you 3 times.

You will also be provided with some food items at two of the in person visits so that you can try the foods and recipes that are part of the program. These foods will not require refrigeration.

Participant Responsibilities

Participants are responsible for completing the study questionnaires and blood tests and attending the treatment program appointments (7 sessions over 12 weeks). At the final visit participants are required to return the supplement bottles including any capsules that were not consumed during the study. Participants are expected to report any negative effects that they experience and to report any changes in medications, psychotherapy/counseling, or supplements during the study period. You will report these changes during your treatment sessions. If you experience changes in your health during the waitlist period, please email the study coordinator at EASeGAD@ccnm.edu. If you experience a serious side effect or a serious worsening of your health, please contact us immediately using this email address: EASeGAD@ccnm.edu or phone number: 647-361-4022. Or, contact your nearest emergency department and/or your health care provider. If you require medical visit or medication that is not covered by the Ontario Health Insurance Plan (OHIP), these costs will be reimbursed by the study sponsor, the Canadian College of Naturopathic Medicine. If you experience an allergic reaction to the fish oil supplement or any of the new foods that you try, please take the diphenhydramine (Benadryl) that was provided to you, following the instructions on the label. You are required to tell us if you used this medication for an allergic reaction and return any that was not used at the final visit.

Privacy and Confidentiality

Your identity and participation in this study is kept confidential – your personal information will not be shared with anyone. In other words, we will not tell anyone you took part in this study. When we share the results, we will not use your name or any information that would allow you to be identified. All information that you provide will be kept in a locked cabinet or on a password protected computer and destroyed (deleted or shredded) after 15 years. If needed, monitors, auditors, research ethics board, Health Canada and other regulatory authority will be granted direct access to the study participants original medical records for verification of clinical trial procedures and/or data.

Participation and Withdrawal

It is your choice to take part. If you decide to be part of the study you can decide to stop at any time, even after signing this form. If you decide to stop, there will be no negative effects to you and no effect on your medical care. If you stop part way through, we will keep the results that have already been collected. The researcher may withdraw you from the study at any time if you have an allergic reaction or other serious negative reaction to the omega-3 supplement. You may be withdrawn if your mental health worsens so much that it is not safe for you to continue to participate. If your blood work suggests that you have a medical condition that requires treatment right away, we will advise you to schedule an appointment with your health care provider. With your permission, we will send the blood work results to them. You will be allowed to continue to participate in the study.

Cost

There is no cost for participating in this study.

Research Ethics Board Contact:

This study has been reviewed by the Research Ethics Board at the Canadian College of Naturopathic Medicine. If you wish to speak with someone who is not a member of the research team about your rights as a participant, or if you wish to make a complaint about a project, please contact:

Nicole Henry, CCNM Research Ethics Board Chair
Email: REBchair@ccnm.edu

Study Location: Canadian College of Naturopathic Medicine

1255 Sheppard Ave E, Toronto ON, M2K 1E2

Study Team:

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Study Sponsor: Canadian College of Naturopathic Medicine

Funding for this study has been provided by: Ekhagastiftelsen, AquaOmega, Mitacs Accelerate, and Sobeys Inc.

Study Contact: If you have any questions or need more information about the study, please contact the study coordinator: EASeGAD@ccnm.edu, 647-361-4022

I agree to participate in this research study called "Dietary counselling plus omega-3 supplementation in the treatment of generalized anxiety disorder: A randomized wait-list controlled pilot trial (the "EASe-GAD trial")."

_____	_____	_____
Participant Signature	Printed Name	Date
_____	_____	_____
Signature of Person Receiving Informed Consent	Printed Name	Date