A Randomized Controlled Study of Fish Oil in Obese Patients with Mild Cognitive Impairment

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Subject Informed Consent

You are being invited to participate in a nutrition and health-related research study. This informed consent form provides you with information to help you decide whether or not to participate in this research study, so please read it carefully and ask your doctor or the researchers if you are not sure.

Project description:

1. Basic information of the project

According to the Chinese Guidelines for the Prevention and Control of Overweight and Obesity in Adults, a person with a body mass index (BMI) of 24-27.9 kg/m2 is considered overweight, and ⩾28.0 kg/m2 is considered obese. Numerous studies have shown that human obesity is negatively associated with cognitive performance of the brain, and that obesity increases the risk of mild cognitive impairment (MCI) and dementia with age. The type of dietary fat for obesity and cognitive impairment, increased intake of saturated fatty acid (SFA) and decreased intake of n-3 polyunsaturated fatty acid (n-3 PUFA) may contribute to obesity and thus cognitive decline. Studies have shown that n-3 PUFA may improve obesity status and cognitive function by affecting intestinal anabolic bacteria and their metabolites, modulating inflammatory factor levels, and promoting white fat beige coloration. The present study is a randomized controlled intervention study to investigate the effects of fish oil capsules on intestinal flora, white fat beige coloration index and inflammatory factors in patients with obesity with MCI.

2 Inclusion and exclusion criteria

(1) Inclusion criteria

① Meet the diagnostic criteria of obesity and MCI; ② Age between 35 and 80 years old; ③ Those who have not dieted or stopped dieting in the last 3 months, have not taken fish oil supplements, or are willing to stop self-administration of fish oil 3 months before the intervention; ④ Voluntarily participate in the program with informed consent, and sign the informed consent form.

(2) Exclusion criteria

(1) Suffer from neuropsychiatric diseases such as stroke, epilepsy or schizophrenia; (2) Suffer from depression, thyroid disease, traumatic brain injury, cognitive impairment caused by drugs or alcoholism; (3) Suffer from a history of cerebrovascular disease or cognitive impairment caused by severe cardiac, hepatic, pulmonary or renal impairment; (4) Complete vegetarians who are unable to comply with the balanced dietary pattern; (5) Suffer from severe angina pectoris, wheezing bronchitis, severe infections, systemic lupus erythematosus, and other diseases. , systemic lupus erythematosus, malignant tumors, and other diseases that may affect one's dietary habits and life; ⑥ Celiac disease and lipid malabsorption.

3. Study protocol and procedure

In this study, subjects who met the requirements for inclusion in the study were subjected to a baseline survey of basic information and dietary status, while a fasting blood sample of 8 ml and a fecal sample of 5 g were collected. blood collection was performed aseptically by qualified health care personnel. Subjects were randomly assigned to the intervention

and control groups, with the intervention group receiving fish oil capsules and the control group receiving placebo capsules with the same appearance and odor as the fish oil capsules. During the study period, the subjects' medication intake and health status were recorded regularly, and at the end of the study, cognitive questionnaires and venous blood and feces were collected again for relevant tests.

Subject Rights:

If you decide to participate in this study, you have the right to be informed about the content of this study, the results of the study, the progress of the study, and other relevant information; you may choose not to participate in this study or notify the investigator at any time to request to be withdrawn from the study, and any of your medical treatment and rights and interests will not be affected as a result of this; you have the right to refuse any other requests or tests that are not part of the project's study content; if you have a question related to the study If you have questions about this study, or if you experience any physical discomfort or injury during the study, or if you have questions about your rights as a participant in this study, you may contact us by telephone.

Possible benefits:

You can get indirect or direct benefits by participating in this study.

1. you get a professional dietary status survey and other related health screenings that will help you understand and develop a healthy lifestyle.
2. You receive a 12-month course of fish oil supplements that may improve blood lipid levels, inflammation levels, cognitive and nutritional status to some extent, which may help reduce the impact of disease on health and improve quality of life.

Possible Discomfort and Risks:

Participation in this study will not cause discomfort or pose a health risk to you per se. There may be some delay in the study because you will be required to answer the survey honestly and cooperate with the tester in completing the related tests. Your specimen will be collected in strict accordance with strict aseptic requirements. There are some risks associated with specimen collection, including transient pain, localized bruising, and in a few cases, mild dizziness or, very rarely, needle infection.

There may be some delay in the study because you will be asked to answer the survey honestly and to cooperate with the tester in completing the tests.

This study requires you to take nutritional supplements. If you are truthful with the researchers about your condition, meet the inclusion requirements, and take the supplements as required, your health will not be adversely affected.

Emergency measures:

The blood collection process is carried out in hospitals and units or institutions with medical qualifications, and if the following situations occur, professional physicians will carry out the following emergency measures: if the subject suffers from blood sickness, immediately stop the blood collection process, quickly take the subject away from the scene and take corresponding professional first aid measures in time, and try our best to avoid any possible life-threatening risks and organic injuries to the subject. If necessary, further psychological counseling can be carried out by professional psychologists in consultation with the subject; if the blood sampling site is locally infected, professional physicians of relevant departments will carry out disinfection and clean up the site and

give relevant suggestions.

If the subjects feel uncomfortable during the consumption of the nutrients, please contact the researchers for unblinding and further medical treatment measures.

Confidentiality Commitment:

We are committed to respecting and protecting your privacy and personal information. Information that can be used to identify you during the study will not be disclosed to anyone other than the members of the research team, unless your permission has been obtained; all biological samples such as blood, urine and test results collected during the study will only be used for the scientific research of the project, and will not be used by a third party without your consent; your personal information and test results will be stored in a database established by the researchers for access only; no personal information will be disclosed when the results of this study are published. Your personal information and test results will be kept in the database established by this study and will only be accessible to the researchers; no information about you will be disclosed when the results of this study are published, but your consent must be obtained if necessary; to ensure that the study is carried out in accordance with the regulations, members of the ethical review committee will be able to access your personal data if necessary.

Precautions: None

Compensation in case of damage: according to relevant laws

Whether approved by the Ethics Committee: Yes

Contact person, contact information:

Subject's signature:

Date:

Signature of the researcher:

Contact Tel:

Date: