Alzheimer Europe

Making dementia a priority:
changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

LO-MAPT STUDY

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LO-MAPT study

1. Study Information	
Name of the study	Prevention of cognitive decline in older adults with low Dha/Epa index in red blood cells
Study sponsor	University Hospital, Toulouse
Disease	At risk of developing Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Omega-3
Administration	Three capsules taken orally per day
Is the drug already on the market for another medical condition?	Omega-3 is a dietary supplement. The omega-3 long-chain polyunsaturated fatty acids, eicosapentaenoic (EPA) and docosahexaenoic (DHA), are described as being essential components of a healthy and balanced diet and playing an important role in human physiology.
Will all participants receive the same drug?	Participants will be selected at random to either receive one of the following options during the first 18 months: • A capsule of Omega-3 • A placebo capsule (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested). Neither the participant nor their doctor will know if the person is receiving the investigational drug or the placebo. After 18 months, all participants will receive the drug for another 12-month open-label extension period.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the efficacy of omega-3 supplementation on cognitive decline in older adults with low DHA/EPA status and subjective memory complaints or family history of Alzheimer's disease.

How long will the treatment last?	• 36 months • During the first 18 months, participants will need to attend regular study appointments (enrolment visit and 4 follow-up visits) with the study doctor and research staff.
What your involvement will entail?	• Participants will be asked to complete tests and questionnaires that will assess cognitive performance and memory. Further information on the procedures, tests and visits can be obtained from the study team.

4. Who can participate in this study?	
Who can participate in the study?	To take part in the study, participants must: • Have 70 years old or older • Have a low DHA/EPA status (≤ 4.83%) and subjective memory complaint or family history of Alzheimer's disease • Have a score ≥ 24 points in the MMSE test (a memory test to assess cognitive function). This would suggest that the person has a normal cognition • Be willing to have a study partner who has a sufficient contact with the participant (at least weekly contact) is willing to accompany the participant to the study visits and provides the necessary information about the participant's symptoms and behaviour • Have sufficient vision and hearing to complete tests • Be covered by a health insurance system.
Who cannot participate in the study?	Exclusion criteria include: • Dementia and Alzheimer's disease • Presence of serious diseases, which could be life-threatening in the short term

	• Treatment with omega-3 (apart from food) within the past 6 months • Visual or hearing impairments incompatible with performance and/or interpretation of the tests • A disease or a medical condition that may interfere with the safety or study assessments • Participation in another clinical study in the previous month or participation scheduled during the study • Food allergy. The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.

5. Where and when will the study be conducted?	
European country involved in the trial	• France
Estimated start date of recruitment	April 2018

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT03691519
Study contact information	Bruno Vellas 0033 5 61 77 70 41 vellas.b@chu-toulouse.fr Arnaud Lendriey 0033 5 61 77 83 50 lendrieux.a@chu-toulouse.fr
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03691519

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on August 2019.

✓ This document has not been reviewed by the pharmaceutical company running this trial.

✓ This document has been reviewed by a member of the European Working Group of People with Dementia.