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Memory Intervention with Nutrition for Dementia (re-MIND)

Submission date
19/06/2018

Recruitment status
No longer recruiting

Registration date
20/06/2018

Overall study status
Completed

Last Edited
06/01/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Studies show that nutrients in our food are important for brain health and can also reduce the risk of developing Alzheimer's disease (AD). AD is a disease that impacts memory and language and is associated with emotional and behavioral problems. Omega-3 fatty acids, which are found in high concentrations in fish oil and in fatty fish such salmon and herring, are thought to improve brain function. Other food items (nutrients) of interest include carotenoids, which are powerful antioxidants (substances that prevent harmful oxygen reactions) found in many fruits and vegetables. Studies suggest that vitamin E may provide protection against a loss of brain function. This study aims to test a unique nutritional strategy, combining three carotenoids (lutein, zeaxanthin and meso-zeaxanthin), omega-3 fatty acids and vitamin E to potentially slow the worsening of AD and aid in the management of this disease.

Who can participate?
120 males and females with mild to moderate Alzheimer's disease can participate in the study.

What does the study involve?
80 subjects will swallow 3 capsules a day, containing: 22 mg macular carotenoids, 1 gram fish oil and 15 mg Vitamin E, this is called an active ingredients capsule. 40 subjects will similarly swallow 3 capsules a day but containing sunflower oil, this is known as a placebo capsule. The researchers and the participants will not know who is receiving the active or placebo capsules for the duration of the study, since both capsules are identical in appearance. Participants will take the capsules every day (3 soft gel capsules with a meal) and will be followed for 24 months. Study visits are performed in the participant's home study at baseline, month 12 and month 24 (final visit). At each study visit, the participant and their carer will be interviewed or will fill out questionnaires, the participant will take a vision test, the participant's intake of certain foods will be recorded, the participant's skin concentration of carotenoids will be measured using a test where they hold their hand onto a scanner, and blood samples will be taken.

What are the potential benefits and risks of participating?
We expect no risks to individuals participating in this study. All the nutritional supplements have

been studied and are considered safe to consume. We hope that society will benefit from the research. In the absence of a cure for Alzheimer's disease, we hope to potentially slow the progression of Alzheimer's disease.

Where is the study run from?
The Nutrition Research Centre Ireland, Waterford Institute of Technology (Ireland)

When is the study starting and how long is it expected to run for?
May 2018 to June 2021

Who is funding the study?
The Howard Foundation

Who is the main contact?
Rebecca Power
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Contact information

Type(s)
Scientific

Contact name
Prof John Nolan

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
re-MIND version 1

Study information

Scientific Title
Memory Intervention with Nutrition for Dementia (re-MIND): to investigate the impact of dietary nutrient supplements on the natural progression of individuals with Alzheimer's disease

Acronym
re-MIND

Study objectives
The aim of the study is to provide dietary nutrient supplements to a group of individuals with mild to moderate Alzheimer's disease (AD) and investigate the supplement's impact on the natural progression of the individuals' AD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Waterford Institute of Technology Research Ethics Committee, 17/05/2018, 18/HS-NRCI/01

Study design
Single-centre randomised double-blind placebo-controlled intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Alzheimer's disease

Interventions
Block randomisation will be performed using a trial management system “Trial Controller” designed by our research group. 120 patients will be randomised in a 2:1 (Active:Placebo) masked fashion.
80 AD subjects will consume 3 active capsules a day, combined the soft gels contain: 10 mg L, 10 mg MZ, 2 mg Z, 1 g fish oil and 15 mg alpha-tocopherol.
40 AD subjects will consume 3 placebo capsules (sunflower oil) a day.
Subjects will consume the intervention every day (3 soft gels with a meal) and will be followed for 24 months. Study visits are at baseline, month 12 and month 24 (final visit).

Intervention Type
Supplement

Primary outcome measure

AD progression assessed using using mini mental state examination (MMSE) at baseline (visit 1), 12 months (visit 2) and 24 months (final visit). MMSE is a 30-point questionnaire that can be used to systematically and thoroughly assess mental status. It is an 11-question measure that tests five areas of cognitive function: orientation, registration, attention and calculation, recall, and language. Mild to moderate AD is defined as score of 10 to 25.

Secondary outcome measures

1.Quality of life, assessed using using Quality of life in Alzheimer's Disease family and Participant version (QOL-AD). QOL-AD is a 13-item scale (total score range 13–52; higher scores indicate better QOL). The QOL-AD scale uses a scale of 1–4 (poor, fair, good, or excellent) to rate a variety of life domains, including the patient's physical health, mood, relationships, activities, and ability to complete tasks. The researcher will interview the patient and patient's carer separately.
2. Functional ability assessed using Dementia Severity Rating Scale (DSRS) and Clinical frailty score.
2.1. The DSRS is an informant-based, multiple-choice questionnaire that assesses severity from the mildest to the most severe stages in the major functional and cognitive domains affected in AD. Sections include: memory, speech and language, recognition of family members, orientation to time, orientation to place, ability to make decisions, social and community activity, home activities and responsibilities, personal care/cleanliness, eating, control of urination and bowels, and ability to get from place to place. Results are interpreted by adding up the points for all sections. Score of 0-18: mild, score of 19-36: moderate, and score of 37-54: severe.
2.2. Clinical frailty score (0-9) is recorded by the research nurse using a visual analogue scale. It is expected that mild to moderate AD patients will have a high score (i.e. 7). Functional ability will be evaluated by assessing the scores of each test over time (i.e. improvements, no changes and /or decline over 24 months).
3. Clinical collateral: a descriptive "story" of each subject will be recorded by the researcher including an interview of the patient's carer (the primary person responsible for caring for the patient with Alzheimer's disease) to assess the patient's health status and medical observations. Structured questions include:
3.1. Have you noticed any change in the patient's memory (same, worse, better)?
3.2. What are the main memory concerns?
3.3. How are they managing every activities – specifically getting dressed, making a cup of tea, cooking, grocery shopping?
3.4. Has there been a change in personality – specifically agitation, wandering, low mood, sleep disturbance?
4. Near acuity and contrast sensitivity measured using the M&S Technologies system. The test is carried out in the patient's home and controlled by the researcher using a smart system tablet (Android). The research nurse can customize the layout (e.g. distance and symbols) to each patient's preference.
5. Dietary intake of lutein (L), zeaxanthin (Z), and omega. L and Z levels in the diet are assessed by inputting the patient's weekly intake of carotenoid-rich foods (eggs, broccoli, corn, dark leafy vegetables) into the 'L/Z screener' to give a carotenoid-based diet score. Values are weighted for frequency of intake of the food and for bioavailability of L and Z within these foods. A ranking score reflecting the relative intakes (representing arbitrary units) will be generated and used in analysis. Similarly, a subject's weekly intake of fish (e.g. herring, sardines, salmon) and seeds (linseed oil and flaxseeds) will be inputted into the 'Omega screener' to give a gram per day omega consumption. AD subject's dietary habits will be confirmed by a family member or carer.
6. Measurement of serum concentrations of L, Z, meso-zeaxanthin (MZ), and vitamin E assessed using non-fasting blood samples.

7. Skin carotenoid concentration scores assessed using the Pharmanex® BioPhotonic S3 Scanner. This scanner measures carotenoid levels in human tissue at the skin surface (palm of the hand) using optical signals (resonant Raman spectroscopy). These signals identify the unique molecular structure of carotenoids, allowing their measurement without interference by other molecular substances. The individual is asked to place a specific point (between the maximal and distal palmar creases, directly below the fifth finger) of their right hand in front of the scanner's low-energy blue light for 30 seconds. From this, a skin carotenoid score (SCS) will be generated, which provided an indication of the individual's overall antioxidant levels. This was repeated twice more and an average score was calculated. This technology is safe and has been previously validated against serum carotenoid concentrations.
8. Gas chromatography analysis of DHA and EPA assessed using non-fasting blood samples.

All secondary outcome measures will be measured at baseline (visit 1), 12 months (visit 2) and 24 months (final visit).

Overall study start date
30/05/2018

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Diagnosis of mild to moderate Alzheimer's disease
2. Aged >65 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Total final enrolment
77

Key exclusion criteria
1. Consumption of carotenoids and/or omega supplements within the last 3 months
2. Inability to swallow capsules
3. Depression (under active review and medication change)
4. Previously confirmed stroke disease and/or infarct on brain scan
5. Mini-Mental State Evaluation (MMSE) >24
6. Intact clock drawing test and semantic fluency test (i.e. naming more than 11 objects starting with the letter F in 1 minute)

Date of first enrolment
05/11/2018

Date of final enrolment
03/03/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Now-Science Consultancy Limited
Waterford
Ireland
X91 K236

Sponsor information

Organisation
Now-Science Consultancy Limited

Sponsor details
C/O Carriganore House, WIT West Campus, Carriganore
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Sponsor type
Industry

Funder(s)

Funder type
Not defined

Funder Name
The Howard Foundation

Results and Publications

Publication and dissemination plan
Planned publications in a high-impact peer-reviewed journal expected to be published.

Intention to publish date
30/04/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. John Nolan (jmnolan@wit.ie). Type of data: quantitative (SPSS). When the data will become available: December 2022 (estimate only). For how long: no minimum period has been set. The decision to share data will be at the discretion of the Principal Investigator (Prof. John Nolan), all data entered into SPSS is pseudo-anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/10/2022	06/01/2023	Yes	No