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# The OPAL Study: Older People And n-3 Long-chain polyunsaturated fatty acids

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 27/05/2004 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 14/07/2004 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 27/04/2010 | Eye Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Alan Dangour

**Contact details**
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7958 8133
Alan.Dangour@lshtm.ac.uk

## Additional identifiers

**Protocol serial number**
N/A

## Study information

**Scientific Title**

**Acronym**

OPAL

## Study objectives
There is considerable interest in the hypothesis that improving the diet of older people, specifically increasing the dietary intake of n-3 long-chain polyunsaturated fatty acids (n-3 LCPs) may be able to delay the initiation, or slow the progression, of cognitive decline. To date, there has been little attention given to the possible protective role of n-3 LCPs in age-related loss of cognitive or retinal function. OPAL is a double-blind randomised placebo-controlled trial carried out among adults aged 70-79 years in the UK. The intervention arm will receive a daily capsule containing 700 mg n-3 LCP (both decosahexaenoic acid DHA and eicosapentaenoic acid EPA) while the placebo arm will receive a daily capsule containing olive oil. The main outcome variable assessed at 24 months will be cognitive performance and a second major outcome variable will be retinal function. Retinal function tests are included as the retina is a specifically differentiated neural tissue and therefore represents an accessible window into the functioning of the brain. The overall purpose of this public-health research is to help define a simple and effective dietary intervention aimed at maintaining cognitive and retinal function in later life. This is the first trial of its kind aiming to slow the decline of cognitive and retinal function in older people by increasing daily dietary intake of n-3 LCPs. The link between cognitive ability, visual function and quality of life among older people suggests that this novel line of research may have considerable public health importance.

Study hypotheses:
1. For healthy, cognitively normal adults aged 70-79 years of age, daily supplementation with n-3 LCPs (500 mg DHA and 200 mg EPA) will slow the rate, or delay the onset, of cognitive decline.
2. For healthy, cognitively normal adults aged 70-79 years of age, daily supplementation with n-3 LCPs (500 mg DHA and 200 mg EPA) will improve visual function by enhancing rod photoreceptor response to light and visual-cortical integration.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Not Specified

## Health condition(s) or problem(s) studied
Cognitive and retinal function

## Interventions
Daily nutritional supplement of 0.7 g of n-3 long chain polyunsaturated fatty acids (fish oil) versus placebo.

The main outcome variable assessed at 24 months will be cognitive performance and a second major outcome variable will be retinal function (Moorfields Eye Hospital will undertake retinal testing in a sub group).

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
1. Change in cognitive function at 24 months determined by the California Verbal Learning Test
2. Change in rod sensitivity over 24 months of intervention as measured by electroretinogram

### Key secondary outcome(s))
1. Cognitive performance as measured by immediate and delayed recall of a short story, tests of prospective memory, timed letter search/cancellation task, verbal fluency, digit span backwards, symbol digit modalities test, simple and choice reaction time, dual-task performance and spatial memory
2. Blood pressure
3. Measure of depression
4. Change in Body Mass Index
5. Compliance determined by counting the number of tablets remaining every 3 months, and by measuring the change in n-3 LCP concentration in buccal epithelial cells over 24 months
6. Number of hospital admissions for cardiovascular events over 24 months
7. Death
8. Colour vision measured by detecting sensitivity to colour contrast which is a good marker of central retinal function
9. Eye health assessed by carrying out a full ophthalmic examination

### Completion date
31/03/2007

## Eligibility

### Key inclusion criteria
Healthy volunteers aged between 70-79 years of age, who have no previous history of diabetes or dementia. Participants will be selected from 20 GP practices.

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
Not Specified

### Key exclusion criteria
1. Pre-existing type I or type II diabetes at baseline
2. Pre-existing dementia at baseline
3. Reported daily use of fish-oil supplements (in liquid or capsule form) at baseline
4. Mini-mental state examination (MMSE) score <24 at baseline screen

### Date of first enrolment
01/03/2004

### Date of final enrolment
31/03/2007

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**London School of Hygiene and Tropical Medicine**
London
United Kingdom
WC1E 7HT

## Sponsor information

### Organisation
Medical Research Council (UK)

### ROR
https://ror.org/03x94j517

## Funder(s)

### Funder type
Government

### Funder Name
UK Food Standards Agency

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2010 | | Yes | No |
| Protocol article | protocol | 31/08/2006 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |