

The DHA (docosahexaenoic acid) Oxford Learning and Behaviour (DOLAB II) Study: does taking an Omega 3 food supplement help children's learning and behaviour?

| | | |
|--|---|--|
| Submission date 25/01/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 26/02/2013 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 05/03/2018 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

UK children's diets are low in the long-chain omega-3 fatty acid DHA (docosahexaenoic acid), essential for mental and physical health. Small trials involving children with conditions like Attention deficit-hyperactivity disorder (ADHD), dyslexia or other behaviour and/or learning difficulties have indicated that increased intakes of long-chain omega-3 (found naturally in fish, seafood and some algae) can improve their behaviour and learning, raising the possibility that similar benefits might extend to children from the general school population. A trial involving children aged 7-9 years from mainstream schools (known as the DHA Oxford Learning and Behaviour (DOLAB) study) was recently completed by this research team at Oxford University. Results showed that dietary supplementation with 600mg/day of DHA for 16 weeks led to significant benefits for reading progress in poorer readers when compared with a placebo (dummy), with no negative side-effects. Significant improvements were also reported by parents in the children's behaviour (attention, concentration and hyperactivity-impulsivity). Additional findings revealed that blood concentrations of DHA in these healthy children were low by comparison with recommendations for general health in adults, and were also directly related to their performance in reading, working memory and behaviour. This new study is designed to see if these results can be replicated. If so, the implications would be profound since there is an urgent need for safe, effective ways to help children with learning and behaviour problems, which create substantial costs for society as well as for the individuals concerned.

Who can participate?

Children aged 7-9 years will be recruited from mainstream schools in counties proximate to Oxfordshire, UK. We will specifically focus on those pupils who fall within the lowest 20th centile on age-standardised tests of reading achievement.

What does the study involve?

Children aged 7 to 9 years (initially screened via data on literacy attainments held by Local Authorities and schools) will be invited to participate in a short school-based session, involving

brief assessments of reading and working memory, an optional pinprick blood sample, and child behaviour ratings from their teachers and parents.

What are the possible benefits and risks of participating?

Increased intakes of DHA should result in improvements in participants reading and behaviour. We are happy to report that as expected, no serious adverse events were reported from the recent DOLAB study using the same supplement, nor were there any unfavourable side-effects. Given this experience risks for participants are thought to be minimal.

Where is the study run from?

The study will be undertaken by researchers from the Centre for Evidence Based Intervention at University of Oxford, UK.

When is the study starting and how long is it expected to run for?

The study started in January 2013 and expected to be finished in August 2015.

Who is funding the study?

DSM Nutritional Products (USA).

Who is the main contact?

Mrs Jenny Burton

jennifer.burton@spi.ox.ac.uk

Study website

<http://tinyurl.com/Dolab-Studies>

Contact information

Type(s)

Scientific

Contact name

Prof Paul Montgomery

Contact details

University of Oxford

Centre for Evidence Based Intervention

Barnett House

32 Wellington Square

Oxford

United Kingdom

OX1 2ER

-

paul.montgomery@spi.ox.ac.uk

Type(s)

Scientific

Contact name

Ms Jenny Burton

Contact details

Centre for Evidence Based Intervention
Barnett House
32 Wellington Square
Oxford
United Kingdom
OX1 2ER
+44 (0)1865 270320
jennifer.burton@spi.oxac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

12/SC/0465

Study information**Scientific Title**

The DHA (docosahexaenoic acid) Oxford Learning and Behaviour Study (DOLAB II): a randomised double-blind controlled study measuring the effect of DHA on children's reading ability, cognition and behaviour

Acronym

DOLAB II

Study objectives

We hypothesise that docosahexaenoic acid (DHA) (in a daily dose of 600 mg) will improve the behaviour and learning of normal children aged 7 - 9 years in mainstream state schools who are under performing in reading according to nationally standardised tests.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford B NHS Ethics Board, 15/10/2012, ref:12/SC/0465

Study design

Randomised double-blind placebo-controlled trial (fixed dose, parallel groups)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Other

Participant information sheet

Not available in web format, please contact Jenny Burton, jennifer.burton@spi.ox.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied

Learning and Behaviour in Children

Interventions

Current Intervention as of 01/09/2014:

The active intervention will consist of 3 x 500 mg capsules per day, each capsule providing 200 mg of DHA Omega-3 as a triglyceride. The liquid fill contains DHA-S oil derived from the microalgae, *Schizochytrium* sp., high-oleic sunflower oil, natural mixed tocopherols, ascorbyl palmitate, rosemary extract, natural orange flavouring and natural masker. The vegetarian gelatine shell contains carrageenan, non-GMO modified cornstarch, glycerine, sorbitol, water, betacarotene and caramel powder.

The placebo will consist of 3 x 500 mg capsules per day containing corn/soy oil. The dimensions, taste, appearance and colour will be identical to those of the DHA Omega-3 capsules. The shell of the capsule will be the same as the DHA Omega-3 capsule. The liquid fill contains corn/soy oil, natural orange flavouring, natural masker, tocoblend L70 IP, rosemary oil and ascorbyl palmitate.

Previous interventions from 12/03/2014 to 01/09/2014:

The active intervention will consist of 3 x 500 mg capsules per day, each capsule providing 200 mg of DHA Omega-3 as a triglyceride. The liquid fill contains DHA-S oil, derived from the microalgae, *Schizochytrium* sp., high-oleic sunflower oil, natural mixed tocopherols, ascorbyl palmitate, and rosemary extract, and orange extract (flavouring). The animal gelatin shell contains glycerin, water, and colouring (sunset yellow [E110]) [details of colouring amended on 10/01/2014].

The placebo will consist of 3 x 500 mg capsules per day containing corn/soy oil. The dimensions, taste, appearance and colour will be identical to those of the DHA Omega-3 capsules. The shell of the capsule will be the same as the DHA Omega-3 capsule. The liquid fill contains corn/soy oil and orange extract (flavouring).

Original interventions:

The active intervention will consist of 3 x 500 mg capsules per day (to be taken orally with food and drink), each capsule providing 200 mg of DHA as a triglyceride. The liquid fill contains DHASCO®-S oil derived from the microalgae *Schizochytrium* sp., high-oleic sunflower oil, natural mixed tocopherols, ascorbyl palmitate, and rosemary extract (flavouring). The gelatin shell contains glycerin, water, and colouring (carmel, carmine, turmeric).

The placebo will consist of 3 x 500 mg capsules per day (again, to be taken orally with food and drink) containing soya/corn oil. The dimensions, taste, appearance and colour will be identical to those of the DHA capsules. The shell of the capsule will be the same as the DHA capsule.

Duration of interventions: 16 weeks

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Omega 3 supplements [docosahexaenoic acid]

Primary outcome measure

Current primary outcome measures as of 19/06/2013:

Children's age-standardised scores for learning (reading performance and working memory) and behaviour (parent ratings of attention deficit hyperactivity disorder [ADHD]-type symptoms) assessed both at baseline and post-intervention. The following validated measures will be used:

1. British Ability Scale (BAS II): Word reading
2. British Ability Scale (BAS II): Recall of Digits
3. Conners Parent Ratings (CPRS-L)
4. British Ability Scale (BAS3): Word reading.

Previous primary outcome measures until 19/06/2013:

Children's age-standardised scores for learning (reading performance and working memory) and behaviour (parent ratings of attention deficit hyperactivity disorder [ADHD]-type symptoms) assessed both at baseline and post-intervention. The following validated measures will be used:

1. British Ability Scale (BAS II): Word reading
2. British Ability Scale (BAS II): Recall of Digits
3. Conners Parent Ratings (CPRS-L)

Secondary outcome measures

Behaviour (teacher ratings of attention deficit hyperactivity disorder [ADHD]-type symptoms) assessed both at baseline and post-intervention using Conners Teacher Ratings (CTRS-L)

Overall study start date

01/01/2013

Completion date

31/07/2015

Eligibility

Key inclusion criteria

1. Children (both males and females) aged 7 - 9 years from mainstream state schools who are under performing in literacy skills according to nationally standardised assessments of scholastic achievement at age 7 years (Key Stage 1). To be eligible, children must score below the 20th centile for reading but have no other significant learning difficulty.
2. English as a first language

Participant type(s)

Patient

Age group

Child

Lower age limit

7 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

400 participant (200 per treatment group)

Key exclusion criteria

1. Major learning disabilities or medical disorders
2. Taking medications expected to affect behaviour and learning
3. Taking fish oils already, or eating fish two times or more a week

Date of first enrolment

01/01/2013

Date of final enrolment

31/07/2015

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University of Oxford

Oxford

United Kingdom

OX1 2ER

Sponsor information**Organisation**

University of Oxford (UK)

Sponsor details

Joint Research Office
Block 60
Churchill Hospital
Headington
Oxford
England
United Kingdom
OX3 7LE

-
heather.house@admin.ox.ac.uk

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Industry

Funder Name

DSM Nutritional Products (USA)

Results and Publications

Publication and dissemination plan**Intention to publish date****Individual participant data (IPD) sharing plan**

The datasets generated during and analysed during the current study is stored in a publically available repository (<https://osf.io/9ynjf/>).

Type of data: Deidentified individual participant data is provided. The data is shared as .csv and .dta (Stata) file.

Data access: Data is shared under Creative Commons Attribution 4.0 International Public License, and thus freely available to anyone who wishes to access the data for all type purpose when copyright notice and references are given.

Anonymization: No demographic information is provided to ensure anonymity.

Data availability: Data has been made available following the publication of the main trial results (see publication). Data is available indefinitely at <https://osf.io/9ynjf/>

IPD sharing plan summary

Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 20/02/2018 | | Yes | No |