ISRCTN48803273 https://doi.org/10.1186/ISRCTN48803273

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

Registration date
26/02/2013

Overall study status
Completed

Last Edited
05/03/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
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 docosahexaneoic 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

Study type(s)
Other

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(s)
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)

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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 years

Upper age limit
9 years

Sex
All

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
United Kingdom

England

Study participating centre
University of Oxford
Oxford
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Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
DSM Nutritional Products (USA)

Results and Publications

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
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