ISRCTN54901093 https://doi.org/10.1186/ISRCTN54901093

A Prospective, Randomised, Double Blind, Placebo Controlled Group Study Of The Benefits Of Omega 3 Fish Oils (Concentrated Fish Oils 500 milligrams) In Children Between the Ages Of 11-16 Years

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/09/2015	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0672184850

Study information

Scientific Title
A Prospective, Randomised, Double Blind, Placebo Controlled Group Study Of The Benefits Of Omega 3 Fish Oils (Concentrated Fish Oils 500 milligrams) In Children Between the Ages Of 11-16 Years

Study objectives
Can Omega 3 Fish Oil (concentrated fish oils 500 milligrams) improve the cognitive function of school age children with moderate to severe learning difficulties in the age range of 11-16 years?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Prospective randomised double-blind placebo-controlled group study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Supplements

Interventions
The potential participants of this study are already under the care of the investigators, whether this is from a Health or Educational perspective. This aspect is of great importance as there is no intervention from anyone who is unfamiliar. It is also routine that any medications the children require are administered by designated teachers at the school. The methodology to be used in this study permits this routine to be maintained.

The parent/s and or guardians of all children in years 6 to 11 (ages 11-16 years) attending Cambridge Park Special School in Grimsby will be invited to attend one of a number of meetings in early September at which the study will be explained to parents / guardians. For those parents / guardians who can not attend any of the school meetings a member of the CPS teaching team will make a home visit to inform them of the study. Home visits to parents / guardians is routine at CPS. Following the meetings parents / guardians will be approached and again with verbal along with written study information being provided to them. Parent/s and or guardians will be given one week to decide whether they wish their child can participate or not. If they decide yes, then they will be asked to sign a consent form. However, they will be reassured that they are free to withdraw their consent at any time without giving a reason. Additionally, they will be informed that the investigators may withdraw their child from the study if that is regarded as in the child's best interests.

If at all possible children will also be asked to agree their participation, although realistically this will probably only be feasible in a few children.
To help raise the awareness of parents that the study is planned, a number of posters will be displayed in the reception area of the school. As a routine part of the schools cycle of testing,

each child is tested at school in June /July of each year. This has already been undertaken at Cambridge Park Special School. Only once consent has been obtained, will these test results will be included as part of this study for those children whose parents / guardians have provided consent. The tests are as follows:
1. Youngs Reading test
2. Youngs Maths Tests
3. Schonell Group Spelling Test
4. Nelson Insight Self Esteem Test.

Following this, children will be match paired. Matched pairing will be carried out by the Educational psychologist. Great care will be taken to ensure that the matching process will consider all aspects and in particular, for age, sex, socio-economic status and ability.

Once the pre-assessments have been completed, children in matched pairs will be randomised to either Fish Oil or Placebo Resulting in one child in the matched pair receiving the fish oil (500 milligrams in two small capsules) and the other receiving the placebo. Randomisation will be computer generated using the Statistical Package for Social Services (SPSS). The randomised intervention will be written on paper and placed in envelopes in numerical order. The envelopes which will be used in numerical order will be kept securely in the office of the Head Teacher at Cambridge Park Special School. Once a randomisation number has been allocated, the participants will only be identified by that number for the duration of the study and will only receive the allocated intervention. For the purpose of code breaking, a master copy of the randomisation will be kept securely by the Northern Lincolnshire & Goole Hospitals NHS Trust (NL&G) Research & Development Department (R&D) and in a sealed envelope by the head teacher at CPS in the event that the R&D Department can not be contacted. This copy will only be opened if there is no other alternative.

The placebo and the fish oil will be offered as two small capsules which will be indistinguishable from each other by external appearances, smell or taste and will be produced and provided free of charge by the manufacturer, Croda Chemicals Europe Ltd. Croda Health Care.

Administration of the fish oils / placebo (two small capsules) will be in school (Monday - Friday) on a daily basis and in term time only. During half term, school holidays and weekends it will not be administered. This is to reduce the element of chance. If parent/s guardians were asked to administer the fish oils / placebo an element of non-compliance may result which has the potential to skew or invalidate the results. If a child has a protracted absence, defined as five consecutive days or longer, from school they will be withdrawn from the study as a protocol violation.
As routine the tests as identified above will be repeated towards the end of the school year.

The total duration of the study will be up to 9 months. Following the second set of testing the two sets of test results will be analysed. The Omega3 / Placebo will be administered by trained members of CPS school staff, who routinely administer medicines. This will be conducted in accordance with the school policy. As routine all medications which are administered at school are recorded on a dedicated medicines chart. The same chart will be used for this study intervention and will be colour co-ordinated with the labels of the containers of Omega 3 / Placebo. All medicine charts will, as routine be kept in a locked filing cabinet in the head teachers office. Only the head teacher and the trained CPS staff will have access to the charts.

Intervention Type
Supplement

Primary outcome(s)
Analysis by significance testing (t-Test) Chi-square test and Mantel-Haenszel Test for a matched pairing, log transformation and McNemar Test. The difference between the response of the 2 units in each matched pair besides the difference of each unit's own individual response are analysed.

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/06/2007

Eligibility

Key inclusion criteria
The sample will be one of convenience. There are approximately 100 children attending the school who may be eligible. Children will be regarded as eligible to participate in the study if all of the following criteria are met:

Assuming that participants will not be Gillick competent:
1. Their parent/s and or guardian agree to their child's participation and will provide a written informed consent
2. Must be attending Cambridge Park Special School in Grimsby
3. Their parent/s and or guardian agree to their child receiving the dietary supplement at school and during school term times
4. If and wherever possible, the child's agreement to participate will be obtained
5. The child is physically able to swallow intact encapsulated fish oil.
6. The child has no known allergies to fish oils
7. The child has no known allergies to the placebo

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Children will be not be regarded as eligible to participate in the study if any of the following criteria are apply:
Assuming that participants will not be Gillick competent
1. Their parent/s and or guardian do not agree to their child's participation and will not provide a written informed consent
2. Children whose parents request them to be given Omega 3 only
3. Not attending Cambridge Park Special School in Grimsby

4. Their parent/s and or guardian do not agree to their child receiving the dietary supplement at school and during school term times
5. The child is not physically able to swallow intact encapsulated fish oil.
6. The child has known allergies to fish oils
7. The child has known allergies to the placebo
8. The child is known to be un-cooperative
9. Children known to be already taking fish oil food supplement

Date of first enrolment
11/09/2006

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Diana Princess of Wales Hospital
Grimsby
United Kingdom
DN33 2BA

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Northern Lincolnshire and Goole Hospitals NHS Trust (UK)

Funder Name
Croda Health Care provides fish oil capsules and the placebo free of charge

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration