Protocol for: The DHA (Docosahexaenoic acid) Oxford Learning And Behaviour (DOLAB) II Study

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Abstract

PROTOCOL SUMMARY

Title:

The DHA(docosahexaenoic acid) Oxford Learning and Behaviour (DOLAB) II Study.

Type of Study:

The study is a randomized, placebo controlled trial (RCT), double blind, fixed dose, parallel groups.

Population:

Four hundred children from academic year groups 3, 4 and 5 (who are generally aged 7 to 9 years) attending mainstream schools who are currently underperforming in reading (lowest quintile on nationally standardized achievement tests).

Number of Sites:

Up to two hundred schools from up to eight local authorities as required.

Intervention:

The active compound (DHA Omega-3), 600mg per day) and corn/soy placebo (matching in package, taste and appearance) will be administered in an oral supplement.

Study Duration and process:

The parents/guardians of children who are underperforming in reading (according to national tests or school records) will be invited to consent to their child participating in a short school-

based session, involving brief assessments of reading and working memory, an optional pinprick blood sample, and behaviour ratings from their teachers and parents. Our previous study (DOLAB) indicated that we should anticipate that 1300 children will need to be screened at the Local Authority stage. Of those approximately half are likely to consent to participate in these brief assessments at school. Those children whose parents consent, and whose reading assessment scores place them in the lowest quintile (on a standardized reading test), will be invited to join the study provided they meet the other inclusion/exclusion criteria (n = 400). Baseline measures will be collected after which children will be randomly allocated to DHA Omega-3 or placebo conditions and followed up after 16 weeks. Recruitment will be carried out over two years.

Research Questions:

Primary:

- Can supplementation with DHA Omega-3 improve child behaviour and learning in underperforming children in year groups 3, 4 and 5 (who are generally aged 7-9 years)?

Outcomes assessed will include reading performance, working memory and ADHD-type symptoms (inattention, hyperactivity, impulsivity) as rated by parents.

Secondary:

- Can supplementation with DHA Omega-3 improve child ADHD-type symptoms (inattention, hyperactivity, impulsivity) as rated by teachers?

- Do children's levels of DHA Omega-3 or related fatty acids (assessed objectively via a pinprick blood sample) predict their learning or behaviour?

- Are any observed changes in behaviour or cognitive performance associated with changes in blood fatty acid status?

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Materials

- 600mg docosahexaenoic acid (DHA), 22:6, n-3 by Contributed by users

Protocol

Step 1.