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The Middlesbrough study: a randomised, controlled trial of dietary supplements with omega-3/omega-6 fatty acids in mainstream school children

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 01/11/2013	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

DCC-RCT-MIDD-00001

Study information

Scientific Title

Study objectives
Omega-3 consumption in children in western Countries has been declining. At the same time there has been concerns about the increased levels of poor concentration, hyperactivity and learning difficulties evidenced in the UK school population. Of these children a proportion (30%) do not appear to respond to standard interventions and a large proportion were found to have eczema, asthma, lactose intolerance and other allergies that may be related to dietary deficiencies. The focus of this study is to determine the effect of dietary intervention on learning and behavioural conditions.

Previous Randomised Controlled Trials (RCTs) have indicated a positive effect on reducing hyperactivity and improved educational attainment in children with specific learning difficulties (Dyslexia/Developmental Coordination Disorder [Dyspraxia] and Attention Deficit Hyperactivity Disorder [ADHD]) following dietary supplementation with omega-3/omega-6 fatty acids. This trial will test the hypothesis that similar effects are evident with dietary omega-3/omega-6 supplementation in a cross-section of mainstream schoolchildren, who do not have diagnosed learning difficulties/behavioural problems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval was sought in March 2005 from South Tees Local Research Ethics Committee. At that time, the committee stated "This study does not fall within Section 3 of Governance Arrangements for Research Ethics Committees (GAfREC), which identifies that ethical advice from the appropriate NHS REC is required for any research involving activities within Section 3.1 a-g".

The committee were asked to review their decision and their response has been:

"In accordance with Section 1.88 of the Standard Operating Procedures for Research Ethics Committees (SOPs), I have been asked to review the file and to comment. I have been asked for my opinion as Chair of County Durham and Tees Valley 1 REC. I was Chair of South Tees LREC in April 2005.

"If submitted for full review by the LREC, it must be judged by the standard and requirements at the time, that is Spring 2005. This project is an extension of previous work, but in this case specifically looking to recruit a different child population, including children that were educationally underachieving.

"The research team and facilities were appropriate. The only identified risk was a minimal risk of mild digestive upset with a reported rate of 3%. Standard psychometric assessments were proposed. Children were randomly allocated to the active or a placebo supplement and the researchers were 'blinded' to the allocation.

"The welfare of all the participants was appropriately safeguarded and the exclusion criteria sensible.

"The provision of information to the school staff, general practitioners, parents and children were satisfactory and consent dealt with appropriately. In my view, the Committee at that time would have given a 'favourable' opinion."

Study design
Interventional, multi-centre, randomised double-blind, placebo controlled, one-way crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Poor concentration, hyperactivity, learning abilities and working memory

Interventions
Active treatment: dietary supplement (Eye q):
Omega-3/omega-6 dietary supplement in capsule form, six times/day providing 558 mg Eicosapentaenoic Acid (EPA), 174 mg Docosahexaenoic Acid (DHA), 60 mg Gamma Linolenic Acid for duration of trial.

Control group: dietary supplement (placebo):
Placebo containing medium-chain triglycerides derived from olive oil, 4% of the capsule comprised EPA and DHA to ensure a fishy taste and carrot oil macerate for colouring. After three months this group crossed over to the active treatment.

The duration of the treatment was six months (one-way crossover from placebo to active after three months) with staggered entry over two months. Assessments for primary/secondary outcome measures were completed at baseline, three and six months. A random sample of 50 participants will be tracked until they leave school, aged 16/18. Follow up will involve monitoring participants' attainments in National Tests (KS 1, 2 and 3 results and performance at KS4 via GCSE/Vocational qualifications).

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omega-3/omega-6 supplements (including Eicosapentaenoic Acid, Docosahexaenoic Acid, Gamma Linolenic Acid)

Primary outcome measure
1. Measurement of change in working memory, confirmed by results from Wechsler Intelligence Scale for Children (WISC-III UK) digit span assessment; time frame: 6 months
2. Measurement of change in reading ability, using the Wechsler Objective Reading Dimensions (WORD) assessment; time frame: 6 months

Secondary outcome measures
1. Measuring a range of behavioural parameters including cognitive problems, hyperactivity, social problems, ADHD and emotional lability as identified by parents using the Conners' Parent Rating Scales-Long Version (CPRS-L); time frame: 6 months
2. Measuring a range of behavioural parameters including cognitive problems, hyperactivity, social problems, ADHD and emotional lability as identified by teachers using the Conners' Teacher Rating Scales-Long Version (CTRS-L); time frame: 6 months

Overall study start date
01/04/2005

Completion date
31/01/2006

Eligibility

Key inclusion criteria
Participants attend mainstream school.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
250

Key exclusion criteria
Children with:
1. Significant neurological problems
2. Psychiatric conditions
3. Any of the following medical problems:
3.1. Epilepsy
3.2. Cerebral palsy
3.3. Multiple sclerosis
3.4. Myalgic encephalopathy

3.5. Pervasive developmental disorder
3.6. Autism
4. Diagnosed ADHD
5. Consumption of essential fatty-acid supplementation within previous three months

Date of first enrolment
01/04/2005

Date of final enrolment
31/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Education Development Centre
Spennymoor
United Kingdom
DL16 6JE

Sponsor information

Organisation
Durham County Council (UK)

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Sponsor type
Government

Website
http://www.durham.gov.uk/

ROR
https://ror.org/05btx4z39

Funder(s)

Funder type
Government

Funder Name
Middlesbrough Council (UK) - funding

Funder Name
Durham County Council (UK) - funding

Funder Name
Equazen Ltd (UK) - provided active and placebo treatments

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration