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The impact of micronutrients and docosahexaenoic acid (DHA) on cognitive development of school-aged children: the NEMO studies

Submission date 19/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/12/2005	**Overall study status** Completed	
Last Edited 03/11/2008	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jan Willem van Klinken

Contact details
Unilever Food and Health Research Institute (UFHRI)
P.O. Box 114
Vlaardingen
Netherlands
3130 AC
Jan-Willem-van.Klinken@Unilever.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR362

Study information

Scientific Title
The impact of micronutrients with or without docosahexaenoic acid (DHA) on cognitive development of school-aged children in Indonesia and South Australia: a randomised controlled trial

Acronym
NEMO

Study objectives
An intervention with a fortified drink containing iron, zinc, vitamin A, vitamin C, folate, vitamin B-12 and B-6 and/or omega-3 polyunsaturated fatty acids over one year can improve cognitive performance in Australian well-nourished children and Indonesian marginally-nourished children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised, double blind, placebo controlled, factorial trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cognitive development

Interventions
Children receiving fortified drink containing either:
1. Micronutrient mix (iron, vitamin A, vitamin C, vitamin B12, vitamin B6 at one recommended daily allowance [RDA], zinc at half RDA)
2. 88 mg DHA and 22 mg EPA
3. Both
4. Placebo

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Iron, zinc, vitamin A, vitamin C, folate, vitamin B-12 and B-6 and/or omega-3 polyunsaturated fatty acids

Primary outcome measure
Cognitive performance (working memory, attention and concentration, perceptual speed, problem solving, executive function, learning and memory, school performance)

Secondary outcome measures
1. Biochemical indicators (blood iron status, zinc status, folate, vitamin B12)
2. Fatty acids status (plasma EPA, DPA, DHA, ALA and total n-3 plasma mass)
3. Growth (weight, height, body mass index)

Overall study start date
01/08/2003

Completion date
01/04/2005

Eligibility

Key inclusion criteria
1. Children aged 6-9 years of age from six selected schools in urban Jakarta and 42 public schools in Southern Australia
2. Parents or carers provided informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
780

Key exclusion criteria
In the two study sites:
1. Children with severe physical and neurological health problems
2. No (intended) use of micronutrient/mineral and/or fatty acid supplements

In addition in Indonesia:
3. Children who are severely malnourished (weight/height Z-score less than or equal to -3 standard deviation [SD]) or severely anaemic (haemoglobin less than 8 g/l)

Date of first enrolment
01/08/2003

Date of final enrolment
01/04/2005

Locations

Countries of recruitment
Australia

Indonesia

Netherlands

Study participating centre
Unilever Food and Health Research Institute (UFHRI)
Vlaardingen
Netherlands
3130 AC

Sponsor information

Organisation
Unilever Nederlands BV (The Netherlands)

Sponsor details
P.O. Box 160
Rotterdam
Netherlands
3000 AD

Sponsor type
Industry

Website

http://www.unilever.nl/

ROR
https://ror.org/02436cs38

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/10/2007		Yes	No