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

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

**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**

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 |