

The WinFood Intervention Study: the effects of improved complementary foods on nutrition and health among Cambodian infants and children

Submission date 24/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/06/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

The WinFood Intervention Study: the effects of improved complementary foods on nutrition and health among Cambodian infants and children, a randomised, single-blind study

Acronym

WinFood

Study objectives

Improved complementary foods based on locally available traditional ingredients will improve the nutritional and health status of Cambodian infants and children

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Ethics Committee for Health Research (NECHR), Cambodia, 22/10/2010, ref: Version No 1 dated 28-05-2010

Primary study design

Interventional

Study design

Randomised single-blind study

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Infants at risk of undernutrition

Interventions

Four different pre-cooked complementary food supplements given as a porridge daily from 6-15 months of age (6-8 months: 50 g, 9-12 months: 75 g, 13-15 months: 125 g)

1. WinFood CF: rice and two highly-nutritious fish and one spider species
2. WinFood Light: rice and a common fish species plus vitamin-mineral premix
3. Corn-Soy-Blend Plus (CSB+)
4. Corn-Soy-Blend Plus Plus (CSB++).

Food class (1 & 2) are the experimental and food class (3 & 4) are the control interventions

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Changes in fat-free body mass (deuterium dilution) and iron status (serum ferritin and transferrin receptors) from baseline (age 6 months) until the end of the 9 month intervention

Key secondary outcome(s)

Changes in:

1. Ponderal and linear growth
2. Physical activity (using an accelerometer, actigraph)
3. Motor milestones (questionnaire, clinic visits)

4. Morbidity
5. Haemoglobin concentration (using Haemocue)
6. Serum concentrations of acute phase proteins [C-reactive protein (CRP) and a-acid glycoprotein(AGP)], insulin-like growth factor (IGF)-1 and zinc
7. Whole blood fatty acid composition

Measured from baseline (age 6 months) until the end of the 9 month intervention

Completion date

10/02/2012

Eligibility

Key inclusion criteria

Children who are 6 months old and have a weight-for-height z-score > -3

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Months

Sex

All

Key exclusion criteria

1. Weight-for-height z-score < -3
2. Bilateral pitting oedema
3. Haemoglobin (Hb) < 80 g/L
4. Clinical signs of vitamin A deficiency (xerosis or Bitot spots). These children will be referred for treatment.

Date of first enrolment

07/03/2011

Date of final enrolment

10/02/2012

Locations

Countries of recruitment

Cambodia

Denmark

Study participating centre
Rolighedvej 30
Frederiksberg
Denmark
1958

Sponsor information

Organisation
University of Copenhagen (Denmark)

ROR
<https://ror.org/035b05819>

Funder(s)

Funder type
Government

Funder Name
Danish Ministry of Foreign Affairs (Denmark) - Danish International Development Agency (Danida) (ref: 57-08-LIFE)

Results and Publications

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	01/01/2014		Yes	No
Results article	results	01/04/2015		Yes	No