The effect of growing up milk with a specific night composition on sleep efficiency, onset, and quality, as well as on memory consolidation and alertness.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22683

Source
NTR

Health condition

Sleep quality, sleep efficiency, memory consolidation, allertness

Slaap kwaliteit, slaap efficientie, geheugen opslag, waakzaamheid

Sponsors and support

Primary sponsor: Fakultas Kedokteran Universitas Indonesia
Source(s) of monetary or material Support: FrieslandCampina

Intervention

Outcome measures

Primary outcome

Sleep efficiency as measured by Actiwatch

Alertness the next morning during the first 3 hours after consumption of growing up milk.

Secondary outcome

1. Memory consolidation;

2. Nocturnal acidosis;

3. Cortisol concentrations in saliva.

Study description

Background summary

It is well known that a good night sleep supports performance the next day. It is also known from literature that a relevant percent of children cope with sleep disturbances. This study aims to improve sleep efficiency in Indonesian children 5-6 years of age by adding specific nutrients to a growing up milk that will be consumed in the evening. At day time in the morning they all will receive a standard growing up milk. An improved sleep efficiency is thought to increase alertness and memory consolidation.

Study objective

The addition of milk protein hydrolysate and tryptophan rich proteins and/or decreasing stomach emptying rate in combination with increased satiety, will improve sleep onset and efficiency significantly as compared with the current available growing up milk.

Study design

Measurements of sleep efficiency, alertness, and memory will take place at the start of the study and after 6 weeks of intervention.

Urine samples will be collected at the start and at the end of the study (after 6 weeks) for the measurement of pH and potassium.

Saliva samples will be collected at the end of the study at 0 and 120 minutes post-consumption of the growing up milk.

Methods of measurement:

1. Sleep efficiency: Measured by 3-days Actiwatch monitoring in combination with a sleep diary;

2. Allertness: Measured by cognitive performance test using the Amsterdam Neuropsychological Tasks (ANT) method, testing at baseline (before consumption) and after 90 and 180 minutes post consumption of the growing up formula;

3. Memory consolidation: Word-pair recall percentage; training (4 times) the evening before the test day. Recall early in the morning just before baseline ANT testing.

Intervention

A. Standard growing up milk;

B. A + protein hydrolysate + alfa-lactalbumin;

C. A + satiety increasing ingredients.

During 6 weeks the children will receive two servings of growing up milk per day. In the morning this will be the standard growing up milk for all children and in the evening the standard growing up milk (A), or one of the special formulations (B or C). Morning sachets have a white color, evening sachets silver. Measurements will be done at the start of the study and after 6 weeks of consumption.

Contacts

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Eligibility criteria

Inclusion criteria

1. Drinking milk (2 portions per day of 200 ml each);

2. Normal weight-for- height percentile (between 5th and 95th percentile);

3. Normal mental status (based on Wechsler test);

4. No medications that may effect digestion or absorption of food;

5. No medications that may effect alertness or sleep or mental performance;

5. Normal Hb level (by fingerprick);

6. No vitamin supplements during the last 14 days before the start of the study;

7. Sub-normal sleep pattern based on Brief Infant Sleep Questionnaire (BISQ) or Child Sleep Habits Questionnaire.

Exclusion criteria

Lactose intolerance, malaria, and a family history of impaired iron metabolism (haptoglobin Hp2-2, hemochromatosis, sickelcell anemia, thalassemia).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2012

Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion Date:	29-03-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3220
NTR-old	NTR3372
Other	FrieslandCampina : Nutr-AS-005-2012
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A