

# Baby's first bites

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25947

### Source

Nationaal Trial Register

### Brief title

Baby's Eerste Hapjes

### Health condition

Child eating behaviour (eating of vegetables; picky eating); childhood overweight

Eetgedrag van kinderen (eten van groenten, kieskeurige eters); overgewicht bij kinderen

## Sponsors and support

**Primary sponsor:** Leiden University, Wageningen University, Danone Nutricia Research and Nutricia Nederland BV

**Source(s) of monetary or material Support:** NWO and Nutricia Nederland BV

## Intervention

## Outcome measures

### Primary outcome

Infants' and toddlers':

- Vegetable consumption
- Vegetable liking
- Self-regulation of energy intake

### **Secondary outcome**

- Maternal feeding style
- General child eating behavior
- BMI/child overweight

## **Study description**

### **Background summary**

The weaning period in infancy is an important time for introducing healthy eating patterns that include vegetables to protect children against the development of overweight. There is evidence that it is important what weaning infants are offered: starting exclusively with vegetables is more successful for the promotion of vegetable acceptance than starting with fruits. There is also evidence that it is important how infants are weaned: responsive feeding characterised by sensitive responses to infant cues during feeding fosters healthy eating. However, the what and the how of infant weaning have never been experimentally tested in the same study to determine their relative importance for fostering vegetable acceptance, nor have they been combined to test whether a focus on both may be superior to each approach separately. The proposed study employs a randomised controlled design testing the effectiveness of (a) a focus on the what in weaning, i.e., a vegetable-exposure intervention; (b) a focus on the how in weaning, i.e., an intervention to enhance responsive feeding; (c) a combined focus on what and how in weaning in an integrated intervention; (d) an attention-control group. Vegetable acceptance will be measured before, during and directly after the interventions, and at the child's age of 24 and 36 months. The proposed study is based on a unique integration of expert knowledge from the field of nutrition and the field of parenting, which will provide new insights into the mechanisms underlying the development of vegetable acceptance in infants, and ultimately the prevention of overweight.

### **Study objective**

1. A vegetable exposure intervention consisting of a 19 day feeding schedule during the first weeks of complimentary feeding in infants and continued information on the importance of providing children vegetables every day up until the age of 16 months will lead to a) higher vegetable consumption; b) better liking of vegetables; and c) healthier weight in children up

to the age of 3 years compared to a control condition without information on the importance of eating vegetables.

2) An intervention promoting responsive feeding will be more effective than the control condition in promoting a) vegetable consumption; b) vegetable liking; c) self-regulation of energy-intake and d) healthy child weight, up until the age of 36 months

3) A combined vegetable-exposure and responsive feeding intervention will be more effective than any of the two interventions alone in influencing the above mentioned outcome measures.

2)

## **Study design**

Outcomes are assessed at child's age:

- 4-6 months (start of weaning schedule)
- 4-6 months (end of weaning schedule)
- 12 months
- 18 months
- 24 months
- 36 months

## **Intervention**

Intervention A: What to Feed Weaning Babies

Intervention condition A aims to promote vegetable acceptance by repeatedly exposing infants and toddlers to vegetables. It is based on the intervention described by Barends and colleagues and will follow the same procedure for the first 19 days of weaning, i.e. 2 days of pre-test, a 15-day feeding schedule and 2 days of post-test [2-3]. During 15 consecutive days, children are exposed to one of two target vegetables according to a set scheme, which mothers will receive in print. In this scheme, one target vegetable is offered to the infant every other day. On the days in between, infants receive other vegetables to bring variety in the diet.

During the feeding-schedule on day 5 and 12 (in line with the first two sessions of Intervention-group B and C), mothers will receive a phone call by a trained student using motivational interviewing techniques to motivate mothers to continue exposing their infant to vegetables. After the feeding schedule, when the children are 8, 13 and 16 months of age,

mothers will receive a booster phone call during which daily vegetable intake is reinforced again.

In addition, following the detailed weaning instruction for the first 19 days, mothers are asked to keep serving their infant vegetables on a daily basis, although they can of course decide for themselves whether or not to comply. In addition, they will receive a folder in which the importance of repeated exposure to vegetables is explained and emphasized once again. Moreover, mothers in this condition will receive 20 vegetable purées a month, until 5 months after the feeding schedule, in order to reinforce the exposure to vegetables even more. However, mothers can decide for themselves whether or not to use the purées.

#### Intervention B: How to Feed Weaning Babies

Mothers in condition B receive an intervention on how to feed their infant, in addition to a 15-day feeding schedule consisting of mostly fruit. Thus, the infants will not be repeatedly exposed to vegetables (although they do receive some carrots), and the intervention they receive purely focuses on the promotion of responsive feeding practices of the mother. The intervention mothers will receive is based on the Video-feedback Intervention to promote Positive Parenting and Sensitive Discipline protocol (VIPP-SD). For the present project, the VIPP-SD was adapted to specifically target the situation of weaning an infant - VIPP-Feeding Infants (VIPP-FI). VIPP-FI focuses on improving responsive feeding and sensitive ways of dealing with unwilling infants during the feeding process. To reach this goal, mothers are shown videotapes of their own feeding-interaction with their infant, and receive feedback on these tapes by a trained intervener. The VIPP-FI is delivered in the same way as the original VIPP-sessions, by conducting home visits.

#### Intervention C: What and How to Feed Weaning Babies

Mothers who have been randomly assigned to Intervention C will receive a combination of Intervention A and Intervention B. Mothers will be asked to feed the infant according to the schedule for the vegetable-exposure intervention and will also receive feedback on how they should go about the feeding of their infant according to the VIPP-FI intervention.

#### Attention-Control Condition D

Mothers who have been randomly assigned to the attention-control condition D receive the same feeding schedule as Intervention B consisting of mostly fruits. In addition, they will receive phone calls at the same time-points as the intervention groups in which they will not receive any specific advice, but will be asked about topics such as the general development of the child. If mothers have questions about weaning or feeding, they are referred to “Het Voedingscentrum” or their infant welfare centre (consultatiebureau).

## Contacts

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## Eligibility criteria

### Inclusion criteria

- First-time mothers of healthy term infants who report to have good reading and writing skills in the Dutch language

### Exclusion criteria

- Medical problems in the infant that influence the ability to eat
- Major psychiatric problems in the mother, like depression
- Mothers who are not willing to start weaning exclusively with prepared vegetable/fruit purées from the Nutricia brand
- Mothers who are not willing for themselves and/or their infants to be video-taped

## Study design

### Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2016
Enrollment:	240
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	17-07-2017
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	NL6397
NTR-old	NTR6572
Other	NWO : 057-14-002

# Study results

## Summary results

None