

The What and How in Weaning

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lifestyle issues
Study type	Interventional

Summary

ID

NL-OMON42681

Source

ToetsingOnline

Brief title

Baby's first bites

Condition

- Lifestyle issues

Synonym

niet van toepassing

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: NWO,Nutricia

Intervention

Keyword: Responsive feeding, Vegetables, Weaning

Outcome measures

Primary outcome

The main study parameters are the infant's vegetable consumption, the mothers' perceived liking, maternal feeding behaviour and maternal sensitivity.

Secondary outcome

/

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. Many food preferences, also for vegetables, are learned early in life and settled by the age of two years.

A high vegetable intake is associated with a lower prevalence of overweight and obesity. Evidence shows 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. Investigation of these principles will ultimately contribute to optimizing advice given to parents concerning the health and development of their child and prevent overweight in later in life.

Study objective

The aim of this study is firstly to investigate the effect of repeated exposure to vegetables or fruit at the start of weaning on short and long term vegetable intake. A second objective is , to investigate the effect of a responsive feeding intervention on short and long term vegetable intake and on parental responsive feeding practices. And finally to investigate the combined effect of these principles on short and long term vegetable intake.

Study design

The present study is a randomized controlled trial to assess the effects of vegetable exposure and responsive feeding on vegetable acceptance in infants and toddlers.

Intervention

Participants are randomly assigned to receive one of three behavioural interventions aimed at enhancing vegetable intake of infants in the first three years of life or to the control group.

Study burden and risks

The risks for the participants are negligible, the study procedures are non-invasive. Food products used in the study are commercially available and specifically produced for infants. Furthermore, all other aspects of the interventions are behavioural. Parents will follow a weaning schedule of 19 days consisting of 1 meal per day. Follow-up measurements will be carried out when children are 12, 18, 24, 30 and 36 months old during a home-visit. In addition parents will be asked to complete several questionnaires throughout the study period. This can be considered time consuming and burdensome. However, the time investment is divided over the measurement moments in the 2,5 year study period.

The involvement of infants is needed because the first introduction to solid food is key to our research questions and objectives. Adults have extensive experience with eating all kinds of foods, and therefore findings in adults cannot be extrapolated to infants.

Contacts

Public

Wageningen Universiteit

Bomenweg 2
Wageningen 6703HD
NL

Scientific

Wageningen Universiteit

Bomenweg 2
Wageningen 6703HD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

- Child of first time mothers
- Healthy term
- Not being weaned yet
- Mother of the child participates in the study

Exclusion criteria

The infant has:

- Medical problems that influence the ability to eat e.g swallowing or digestion problems
- Medical drug use
- Food allergies
- Blindness and or deafness
- Had more than one week of tube feeding
- A twin

The parent has:

- A major psychiatric disorder (e.g., personality disorders, major depression, schizophrenia)
- A problem with weaning exclusively with commercially available vegetable/fruit purées.
- A problem to with being video-taped.

Study design

Design

Study type: Interventional

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2016
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO	
Date:	15-12-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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
CCMO	NL54422.081.15