

The BeeBOFT Study.

No registrations found.

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

Summary

ID

NL-OMON26981

Source

Nationaal Trial Register

Brief title

BeeBOFT (Breastfeeding, Breakfast daily, Outside playing, Few sugar sweetened drinks, less Tv viewing)

Health condition

Overweight, Obesity, Prevention, Youth Health Care, Preschool Children, tailored advice, E-health, Parenting style. Child rearing issues.

Sponsors and support

Primary sponsor: Erasmus MC - University Medical Center Rotterdam-, Department of Public Health, Rotterdam, The Netherlands.

TNO, Quality of Life, Leiden, The Netherlands.

Source(s) of monetary or material Support: ZONMw, The Netherlands Organization for Health Research and Development (Project number: 120610018)

Intervention

Outcome measures

Primary outcome

1. BMI (weight/height²) according to standardized procedures during scheduled YHC visits; waist circumference;

2. Energy balance-related behaviors: Exercise and outdoor playing, having an appropriate family breakfast daily, sugar sweetened drinks consumption, and TV viewing, measured by parental questionnaires;
3. Additionally: Proportion of overweight children based on internationally accepted gender and age-specific cut-off values.

Secondary outcome

1. Attitudes, motivation and perceived control of parents regarding the four energy balance-related ('BOFT') behaviors;
2. General parenting styles and parental practices and rules. These will be measured by Child rearing questionnaire for parents; Parenting style (PS) ; Parenting practices and rules (PP);
3. Child's health and well-being: Infant Toddler Quality of Life questionnaire (ITQOL), brief-Infant-Toddler Social and Emotional Assessment (ITSEA).

Study description

Background summary

This study aims to evaluate the effects on the prevention of overweight of three approaches that are currently being applied in Dutch preventive Youth Health Care (YHC) to parents of infants and toddlers:

1. 'Usual care', i.e. common advices regarding nutrition and playing of the infant and toddler;
2. 'BOFT+', i.e. a training of YHC-nurses regarding their skills to advice parents regarding parenting;
3. The 'Healthy toddler', i.e. a specific advice to parents of toddlers at age 18 months and 24 months regarding nutritional habits, playing habits and watching TV, supported by a written advice generated by Internet.

Forty-five Youth Health Care (YHC) teams of circa 10 regional YHC providers will participate in this study with net 1.500 children. The 45 teams will be assigned at random to:

1. Continue 'Usual care' (15 teams), or;
2. To participate in the training for nurses regarding parenting skills (i.e. 15 'BOFT+' teams), or;

3. To YHC-teams that will apply the 'Healthy toddler' face-to-face consultation at age 18-months regarding nutritional habits, playing habits and watching TV, supported by an Internet generated, tailored written advice (15 teams).

Informed consent to participate in this study will be obtained from the parents during a regular home visit by member of the YHC-team circa 2 weeks after birth; follow-up of the parents and their children is till the child is 36 months old.

According to the current YHC Overweight prevention protocol ('Overbruggingsplan') YHC-teams, in order to contribute to the prevention of overweight in childhood should promote:

1. Breastfeeding;
2. Outdoor exercise, activity and play;
3. Having breakfast daily;
4. Few soft drinks;
5. Less TV time (in Dutch: 'B-BOFT'-behaviors).

'Care as usual' consists of common advices regarding nutrition and playing of the infant and toddler, and the above-mentioned 'B-BOFT' behaviors are part of such advices that are given according to the Product Description YHC, i.e. the regular scheme of YHC visits, e.g. through oral information and generic information leaflets.

The 'BOFT+' intervention is also based on this approach. However, the YHC-nurses in the 'BOFT+' teams will be trained how to provide parents with parenting skills necessary to act according to the recommended behaviors (e.g. only few TV time). In 'BOFT+', the YHC-nurses will have more knowledge and skills to augment usual care with explicit guidelines on childrearing. These guidelines are simple and encompass principles of stimulus control and modeling. YHC-workers will therefore be able to educate parents in how to set concrete boundaries for their children and how to create preconditions to make the child behave positively. The YHC-nurses will know how to advice parents regarding structuring time and space, how to implement rules and habits, how to be unambiguous and consistent and how to set clear boundaries. The nurses will be trained how to help parents controlling stimuli, and how unwanted behavior can be avoided. Parenting skills based on operant conditioning will be incorporated in the training of professionals. Enlarging parenting skills is thought to be a precondition in order to change child-rearing styles.

The 'Healthy toddler' intervention is also based on the YHC-Overweight prevention protocol and has a focus on the promotion of parenting competence by face-to-face counseling, using a counseling style called 'motivational interviewing', strengthened by a dedicated E-health module. The 4 recommended behaviors, daily exercise/outdoor playing, family breakfast daily, few sugar sweetened drinks, minimal TV time ('BOFT'), and associated parenting skills/attitudes will be assessed by the E-health module, prior to face-to-face counseling and result in a tailored advice, subsequently discussed during face-to-face counseling by a trained YHC-professional using motivational interviewing techniques. The E-health module includes a written reminder of useful information at approximately 1 month after the YHC-visit. The 'Healthy toddler' intervention will be provided twice to the parents/toddlers: at the age of 18 months and 24 months.

The study questions are:

1. Effect evaluation:

What are the effects of the 'BOFT+' intervention, applied from birth onwards and the 'Healthy toddler' intervention, applied when the child becomes a toddler, in terms of:

A. Improvement of energy balance-related behaviors, i.e. daily outdoor playing, daily family breakfast, few sugar sweetened drinks per day, and limited TV time per day;

B. In terms of optimal parenting practices/style;

C. In terms of measures of body fatness at the population level, at follow-up at age circa 36 months?

2. Process evaluation:

What is the adherence of parents and YHC professionals to the distinct elements of the 'BOFT+' intervention and the 'Healthy toddler' intervention, how do they appreciate these elements, how often and to whom are these elements applied?

3. Cost-effectiveness evaluation:

What is the ratio between costs and effects in terms of improvement of the four behaviors and potential future reduction in the prevalence of overweight of the 'BOFT+' and the 'Healthy toddler' intervention compared to a control group receiving usual care?

We will explore differences in effects and process characteristics for subgroups of socially disadvantaged and non-Dutch children.

Study objective

The prevention protocol (intervention BBOFT+ and the healthy toddler intervention) applied to parents and their new born children results in a better lifestyle at age 3 and results in a relatively lower BMI and waist circumference compared to children in the control group who receive usual care.

Study design

Time points measurements:

1. At Baseline (child circa 1 month);
2. At child age 6 months (questionnaire);
3. At child age 15 months (questionnaire);
4. At child age 24 months (weight / length and waist circumference at YHC centers);
5. At child age 36 months (weight/length and waist circumference at YHC centers and questionnaire).

Intervention

In this study we will evaluate the effects of 2 distinct primary prevention strategies regarding overweight in preventive Youth Health Care (YHC) for preschool children (Jeugdgezondheidszorg 0-4 jarigen):

1. The 'BOFT+' intervention with - as primary starting point - a focus on child rearing issues that are relevant for the development of behaviors related to overweight, starting at birth and using elements of learning theory, stimulus control and modeling;

2. The 'Healthy toddler' intervention with - as primary starting point - a focus on behaviors related to overweight using E-health in combination with face-to-face counseling and motivational interviewing for parents of young toddlers (18-24 months).

Both are based on the broadly accepted YHC-Overweight-prevention-protocol, saying that five behaviors should be promoted: breast feeding, daily exercise/outdoor playing, family breakfast daily, few sugar sweetened drinks, minimal TV time (so-called 'B-BOFT' behaviors). The control condition in the study implies 'usual care' according to the Product Description YHC with general information regarding nutrition, playing and exercise, e.g. through oral information and generic information leaflets.

Contacts

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Eligibility criteria

Inclusion criteria

The study population consists of all newborn children and their parents who will be visited in the first weeks after birth by one of the nurses of the 45 participating YHC-teams of the 10 participating Youth Health Care centers in the Netherlands (year 2009/2010).

Exclusion criteria

For the questionnaires used in this study the parents should have basic Dutch language skills.

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):	01-05-2008
Enrollment:	3000

Type: Anticipated

Ethics review

Positive opinion

Date: 25-05-2009

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	NL1721
NTR-old	NTR1831
Other	ZonMw project number : 120610018
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A