Gezonde Peutermonden

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25790

Source
Nationaal Trial Register

Brief title
GPM

Health condition

Dental caries

Sponsors and support

Primary sponsor: Utrecht University of Applied Science (HU); Academic Centre for Dentistry Amsterdam (ACTA).
Source(s) of monetary or material Support: SIA Raak and NWO

Intervention

Outcome measures

Primary outcome

The study primary study outcome at the age of 48 (± 3) months is caries experience expressed as the proportion of children with one or more caries lesions and the average number of tooth surfaces affected by caries (ECC-index/modified ICDAS).

Secondary outcome

Other outcome measures for this study at the age of 48 (± 3) months are:
- Proportion of children with one or more caries-related inflammations (pufa-index);
- Behavioral determinants of the parent: knowledge, risk perception, action self-efficacy, intention, action planning, coping
planning and coping self-efficacy (HAPA model);
- Parental behavior regarding oral health of the child and themselves;
- Time to first caries lesion (caries free survival time);
- Plaque score (Simplified Oral Hygiene - index;
- Oral health related quality of life (ECOHIS).

Study description

Background summary

Background: Early childhood caries (ECC) can be prevented by adopting healthy oral hygiene and dietary habits. Nevertheless, 30% of Dutch 5-year olds still have ECC and 10% have severe-ECC (dmfs ≥6). Many infants are first seen in dental practices around the age of 4 years. In the Netherlands, conventional oral health education for infants is provided at health-baby clinics (HBCs), with little success. Therefore, a ChildSmile like preventive oral health programme has been developed and has started to be implemented at HBCs, where oral-health coaches (OHCs) are specifically dedicated to this task.

Aim: The aim of this project is to optimize preventive oral health care for infants and provide evidence for (cost)effectiveness and feasibility of the programme.

Methods: After ethics approval from the UMC Utrecht's research ethics committee, parents/caregivers with babies of 8(±3) months, who visited selected HBCs, are invited to participate in this multicentre pragmatic RCT with concealed allocation of intervention. 400 parent-child dyads (effect size 0.33 at T2) are assigned, using a 1:1 ratio and stratified by SES (3 groups), into control or intervention groups. The control group receive conventional oral health education at HBCs. The intervention group receive conventional oral health education plus tailored preventive oral health care from an OHC, during regular HBC visits, between the ages of 8-48 months. Data will be collected at baseline T0, at 24 months (T1) and 48 months (T2). Primary study-outcomes are the (cost)effectiveness measured by proportion caries-free children at 48 months, caries-free survival time and parental oral health behaviour-changes.

Study objective

The hypothesis is that children in the intervention group have better oral health (expressed in terms of caries) than children in the control group at the age of 48 (± 3) months.

Study design

Measurement of behavior and psychosocial determinants at baseline (T0) when the child is 8 (± 3) months old, at 24 (± 3) months (T1) and at 48 (± 3) months old (T2).
Clinical examination at T1 and T2.

Intervention

At all health-baby clinics both an intervention- and a control group are present.
At the age of 8 (± 3) months, preferably with the eruption of the first primary teeth, all parent-child dyads in the intervention group receive a call from the Oral Health Coach, who is located in or near the health-baby clinic. The Oral Health Coach provide preventive oral health care based on the NOCTP or Nexø method, which means that caries-risk assessment is leading during appointments and determines the recall interval.

Combined with the schedule of the health-baby clinic, a first appointment will be made when the child is at 8 (± 3) months of age. All subsequent appointments will initially follow the schedule of the health baby clinic at the ages of: 15, 18, 24, 36 and 48 months. Based on the individual caries risk assessment, the appointment interval can be shorted.

During appointments with the OHC (10-20 minutes) all the following aspect will be addressed and the findings will be documented in a predefined patient chart developed for this research:
- Health promotion: a briefing on the need of appropriate dietary and oral health behaviors, oral hygiene maintenance and
oral health self-care with regard to age related aspects;
- Oral health risk-assessment to evaluate the previous period and to determine recall interval;
- Assessing parents' phase of behavioral change with respect to oral health self-care, analyzing barriers for healthy behavior
using psychosocial determinants from the HAPA model;
- Make an health plan for the next period;
- Upon detection of incipient caries, fluoride is applied to the lesion;
- When caries progress and require treatment, referral to a dental office.

The oral risk assessment will be based on: Nexø en HAPA:
1. Visible amount of plaque on the front teeth of the children after lifting the lip or using a toothpick to show cervical plaque
at the molars;
2. The presence of active caries lesions;
3. Motivation of parent caregiver.

All appointments with the Oral Health Coach will take place at or near the health baby clinic when combined with scheduled appointments for the health baby clinic. If extra appointments are necessary, it depend on health baby clinic settings like available consultation rooms, preferences of the parents and OHC whether they decide to do the extra appointment at the health baby clinic, at the dental of office where the OHC is working or a home visit.

The parent-child dyads allocated to the control group receive care as usual. Which means,

brief oral health information from physicians and nurses during the scheduled visits at the health baby clinic and a the advice to visit a dental care professional around the age of two. For this parent-child dyads no additional measures and activities will be undertaken.

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Eligibility criteria

Inclusion criteria

- Children aged 8 (± 3) months;
- Both parents (or person with legal parental authority) has signed the informed consent form.

Exclusion criteria

- Children with any medically compromised condition, physical- or mental handicap in need of specialty health care;
- Parents who insufficiently speak and understand the Dutch language.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2017
Enrollment:	400
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL8737
Other	METC University Medical Centre Utrecht : 17-133/D

Study results