Toddler Oral Health Project - Oral health coach imbedded in youth health chain

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

Summary

ID

NL-OMON55949

Source
ToetsingOnline

Brief title
Toddler Oral Health Project

Condition

- Other condition

Synonym
dental cavities, early childhood caries

Health condition

cariës

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Early childhood caries, Oral health, Preschool children, Preventive dentistry

Outcome measures

Primary outcome

Primary study outcome is the oral health of children in terms of cariouslesions (dmfs/dmft)) at 72 months

Secondary outcome

Secondary outcome measures are: number of inflammations related to caries-related in the mouth (pufa); change in oral health behavior; cariesfree survival time; plaque scores and oral health related quality of life at 72 months.

Other outcome measures are process outcomes: caries risk score for each consultation, duration of consultations, number of visits per child, cost of care (hours and materials (fluoride, restorations, etc.), time (indirect) costs that the parent is lost through visits to oral health coach or visit dental care professionals in practice.

When the child is 24 and 45 months an interim measure will be conducted with all the above mentioned primary and secondary outcomes.

Study description

Background summary

A healthy mouth at young age translates into better overall health. Severe early childhood caries reduces the overall health, quality of life and hinders the overall development. The past 25 years no improvement in children's oral health has occurred. Although dental caries is relatively easy to prevent, still nearly 50% of Dutch five-year olds suffer from dental caries. The gap in health between lower and higher socio-economic classes has increased and problems with oral health are mainly concentrated in lower socio-economic classes. Primary dental care for children is insured, though, most children visit a dental care professional too late. Many children already developed caries before their first dental visit and in case of severe dental caries, treatment under general anesthesia is often required. At present, treatment of dental caries is the largest expense of the insured care for children. Despite the task to promote oral health and refer to dental practices at well-baby clinics, focus on this topic is missing. There is a lack of effectstudies on preventive dental care for preschool children, resulting in the fact that insurers still clinging to curative fees.

Based on the successful Scotisch Chilsmile program, an oral health coach will be detached at well-baby clinics in order to improve the task of oral health promotion. The oral health coach will work according to the NOCTP methodology which has been proven effective to prevent dental caries in schoolchildren.

The central question in this study: Does the implementation of an oral health coach at well-baby clinics, working according to the NOCTP methodology and using the Health Action Process Aproach behavior model, lead to behavior change in parents, better oral health in preschoolchildren and is it feasible and cost-effective?

Study objective

The objective of this study is to contribute to evidence based intervention to optimize dental care for preschool children, and deliver evidence of feasibility and (cost-)effectiveness of this innovative intervention in which an oral health coach is integrated in primary health care.

Study design

A randomized controlled trial with blinded outcome measures will be performed, in which the interventiongroup receive oral health care at well-baby clinics offered by an oral health coach started from the age of six months (eruption first primary tooth) up to 72 months (last visit well-baby clinic). The control

group will receive usual care. The research is conducted at five well-baby clinics in Utrecht, Amsterdam, Culemborg, Den Bosch and Tilburg. Well-baby clinics selected for this study are located in focus districts which are populated by predominantly lower socio economic classes.

Intervention

At all well-baby clinics both an intervention as a control group is present. Children in the control group receive usual care, which consist of limited oral health promotion by health professional at well-baby clinic and referral to dental clinic from the age of two year. The intervention group receive oral health care according to the NOCTP method with a tailored risk based interval combined with usual visits to the well-baby clinic.

Study burden and risks

There are no risks associated with participation in this study. In the Netherlands oral health care is insured for al children under 18 years of age. Care provided by the oral health coach as well as the clinical examinations are comparable with usual care. Children in the interventiongroup may benefit from participation due to improvement of oral health. The burden for participating parents and children is minimal. Visits to the oral health coach are combined with regular well-baby centre visits. Only when a child is at high risk for developing dental caries, parents are advised to visit the oral health coach more often. All children included in this study will have two clinical examinations at 24 months and 45 months (10-20 minutes per examination). All parents are asked to complete a questionnaire, baseline, 24 and 45 months (10-15 minutes per questionnaire). At 72 months, parents will be asked for another questionnaire and clinical examination.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

first tooth eruption

Exclusion criteria

Parents/caregivers must be able to perform oral health care in their children

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2018
Enrollment:	400

Type:	Actual

Ethics review

Approved WMO Date:	10-05-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-07-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-09-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-10-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL60021.041.17