Brushing children's teeth by parents of high caries risk children. An intervention based on the Health Action Process Approach

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49576

Source
ToetsingOnline

Brief title
HINK HAPA-based oral health prevention in kids

Condition

- Other condition

Synonym
cavities, dental cariës

Health condition

cariës, mondgezondheid

Research involving

Human

Sponsors and support

Primary sponsor: ACTA, fuculteit tandheelkunde van de Vrije Universiteit en de Universiteit van Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Nederlandse Vereniging voor Kindertandheelkunde (NVvK)

Intervention

Keyword: Health Action Process Approach, paediatric dentistry, prevention, tandenpoetsen

Outcome measures

Primary outcome

1. the level of dental plaque in children

2. the HAPA score per construct

Secondary outcome

1.caries incidence in deciduous and permanent dentition

2. the cost-effectiveness

3. the acceptance and experiences of parents

4. the applicability and experiences of the dental team

5.. Action Planning, Coping Planning, Action Control

Study description

Background summary

Caries is the most common non-communicable disease with high prevalence. It seems that the parents of high caries risk children to not benefit from conventional prevention programmes. A prevention programme that is based on theory from health behavioural science could be beneficial for the oral health of children. The Health Action Process Approach (HAPA) is a model from health

behavioural sciences that emphasizes bridging the intention behaviour gap.

Hypotheses:
It is expected that HAPA-based prevention programme will result in lower level of dental plaque, higher scores on the HAPA constructs, higher brushing frequency, less caries, better quality of life and more cost-effectiveness than a conventional prevention programme in young high caries risk children, after 12 months, and in less caries after 24 months.

Study objective

The primary aim of the study is to improve the oral cleanliness of young high caries active children by a HAPA-based intervention to improve the brushing behaviour of parents in their children. Therefore, the effect of the HAPA-based intervention is compared with conventional prevention after one, three, six and twelve months on the following variables:
* the level of dental plaque in the children
* the mean scores of the parents on the social cognitive constructs from the HAPA model, being *action self-efficacy*, *risk perceptions*,* outcomes expectancies*, *intention*, *action planning*, *coping planning*, *coping self-efficacy* en *action control*.

The secondary aim is to compare the control group with the interventiongroup on:
1. caries incidence in primary and permanent dentition after 12 and 24 months.
2. the cost-effectiveness during the study period
3. the acceptance and experience of the dental staff, practitioners, parents and children during the study period
4. the quality of life of the children after 12 months.

Study design

This is a multicenter patient randomised clinical intervention study with two parallel arms: one intervention group and one control group. Besides the usual restorative dental care both groups receive conventional prevention as usual care, based on the Ivoren Kruis. Additionally in the intervention group the HAPA-based-model is applied the improve the preventive oral health behavioral change, by using action planning, coping planning and action control (mobile website).
The study is partially blind (examiner). The primary end point is one year after start intervention. A secondary end point for caries incidence is two year after start intervention. Parents, investigators are not blind for the intervention as they receive and give the intervention. Only desk clerk, examiners of the dental and caries, data processors and primary investigator are blind for the allocation.

Intervention

Parents in both groups receive five conventional prevention interviews per year. Parents in the intervention group will focus on action planning, coping planning and action control during each prevention interview. In addition, parents in the intervention group receive a reminder of their brushing goals and register their brushing behavior on the mobile website (action control) every day.

Study burden and risks

Parents in both groups are expected to benefit from conventional prevention and parents in the intervention group are expected to benefit more from prevention. There are no known risks associated with conventional prevention or HAPA prevention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

Parents/caregivers
*of children 4 to 8 years old with ASA 1 of 2
*who have signed the informed consent
who have a proper understanding of the Dutch language to fill out the questionnaire
* who have a proper understand fo the Dutch language to receive the intervention

Exclusion criteria

Parents/caretakers
of children with syndromes
of children who are not treatable because of behaviour managment problems
of children with enamal abnormalities other than caries

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	154
Type:	Anticipated

Ethics review

Approved WMO Date:	01-04-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL72154.029.20