

GigaGaaf!

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20892

Source

NTR

Brief title

HTAA

Health condition

caries, tooth brushing, socioeconomic status, diet, bottle feeding, sugar intake.

Sponsors and support

Primary sponsor: University Medical Center Groningen, TNO, Erasmus University

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

a) Caries experience measured based on the International Caries Detection and Assessment System (ICDAS) and Nyvad criteria.

b) Parental knowledge and behavior regarding oral health of the child.

Secondary outcome

- a) Parental attitude regarding oral health of the child
- b) Costs
- c) Impact of Covid-19 period on parental oral health behavior regarding oral health of the child

Study description

Background summary

The purpose of the study is to evaluate the effect of a community-based intervention named “GigaGaaf!”. The intervention aims to promote oral health of children aged 4 to 11 months to 4-6 years. Participants are children aged 4 to 11 months and their parents in two regions, i.e. the province of Groningen (mainly low socioeconomic status, Dutch origin) and the city of The Hague (mainly low socioeconomic status, varying ethnic background). In both regions, both intervention- and control-group will be composed. Children in the intervention-group receive the GigaGaaf! Intervention and children in the control-group receive care as usual. The follow-up is until ages 4 to 6 years.

The GigaGaaf! intervention consists of 1); A referral from the well-baby clinic physician to a dental clinic for the first preventive dental appointment between ages 4-12 months and education about the importance of this first appointment and 2) Providing supervision from an oral health professional who works according to the Non Operative Caries Treatment Programme (NOCTP). NOCTP is an individualized caries prevention program.

Care as usual is dental care starting at varying ages (but usually not before the age of 2 years), with next mostly visits of the dental

clinic once every half year.

The evaluation consists of:

1) an effect evaluation relating to caries experience of children measured by ICDAS and Nyvad criteria at the age of 4 to 6 years and parental knowledge and behavior regarding oral health measured by a questionnaire at the ages of 6 months, 2 years, and 4 to 6 years to explore if there is a difference between the intervention and control group;

2) a cost-effectiveness analysis.

Study objective

Children aged 4 to 6 years in the intervention group who have received the GigaGaaf! intervention have a different oral health than children aged 4 to 6 years from the control group who have received care as usual. Parents of the children aged 4 to 6 years who have received the GigaGaaf! intervention have different knowledge and behavior regarding oral health of their child than parents of children aged 4 to 6 years who have received care as usual group.

Study design

Measurements (of knowledge/behavior) at child ages 6 months (T1: 2015-2016), 2 years (T2: 2017-2018) and 4 to 6 years (T3: 2020).

Caries experience measurements at 4 to 6 years (T3: 2020).

Intervention

The GigaGaaf! intervention consists of 1); A referral from the well-baby clinic physician to a dental clinic for the first preventive dental appointment between ages 4-12 months and education about the importance of this first appointment and 2) Providing supervision from an oral health professional who works according to the Non Operative Caries Treatment Programme (NOCTP). NOCTP is an individualized caries prevention program wherein the recall interval is individually assessed based on the risk criteria: 1) caries progression; and 2)

parents' motivation and compliance to favorable behavior regarding oral health regarding brushing teeth with fluoride toothpaste, brushing/additional brushing by parents, and limiting the frequency of eating and drinking and healthy child nutrition.

Control condition: The control condition consists of care as usual, which is dental care starting at varying ages (but usually not before the age of 2 years), with next mostly visits of the dental clinic once every half year.

Contacts

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Eligibility criteria

Inclusion criteria

Children aged 4 to 11 months who routinely visit the well-baby clinics in specific deprived areas in the Province of Groningen and specific deprived areas in the city of The Hague.

Exclusion criteria

Parents who do not have sufficient mastery of the Dutch or English language to fill out the questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-06-2015
Enrollment:	1000
Type:	Anticipated

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

NTR-new

NTR-old

Other

ID

NL4174

NTR5587

- : 200199501

Study results

Summary results

None