

# GigaGaaf!

Gepubliceerd: 01-12-2015 Laatste bijgewerkt: 13-12-2022

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...

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Niet van toepassing   |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20892

### Bron

Nationaal Trial Register

### Verkorte titel

HTAA

### Aandoening

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

## Ondersteuning

**Primaire sponsor:** University Medical Center Groningen, TNO, Erasmus University

**Overige ondersteuning:** ZonMw

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

- 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.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

## **Doel van het onderzoek**

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.

## **Onderzoeksopzet**

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).

## **Onderzoeksproduct en/of interventie**

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.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

# Onderzoeksopzet

## Opzet

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Parallel                |
| Toewijzing:      | Niet-gerandomiseerd     |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | Placebo                 |

## Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 15-06-2015           |
| Aantal proefpersonen:   | 1000                 |
| Type:                   | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

|                     |                     |
|---------------------|---------------------|
| Niet van toepassing |                     |
| Soort:              | Niet van toepassing |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

### Register

NTR-new

NTR-old

Ander register

### ID

NL4174

NTR5587

- : 200199501

## Resultaten

### Samenvatting resultaten

None