

# Care pathway with e-consultations for toddlers with low risk for parenting and developmental problems: a randomized controlled trial

Published: 27-06-2018

Last updated: 19-08-2024

To determine the added value of e-consultation compared to a visit to the well baby clinic.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON48803

### Source

ToetsingOnline

### Brief title

Care pathway with e-consultations for toddlers

### Condition

- Other condition

### Synonym

Parenting and developmental problems

### Health condition

Opvoed- en opgroei problemen

### Research involving

Human

## Sponsors and support

**Primary sponsor:** GGD Zeeland

**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** E-consultations, Healthy and safe development, Parenting and developmental problems, Preventive Child Health Care

## Outcome measures

### Primary outcome

- \* time-investment of the preventive child health care professionals.
- \* A safety and healthy development of children in the period of 18-30 months, assessed by the ASQ and ASQ-SE and the judgement of the preventive child health care professional.

### Secondary outcome

- \* reach (percentage children at the age of 24 months living in the participating areas, that participate in e- or physical consultations).
- \* experiences of parents and preventive child health care professionals.

## Study description

### Background summary

Preventive Child Health Care (PCHC) services focus on prevention and early detection of parenting and developmental health problems. PCHC in the Netherlands is organized in pre-defined moments. However, a more flexible schedule would enable PCHC professionals to adequately respond to different needs of parents. Care-pathways have the potential to meet different needs of parents. A care pathway with e-consultations was developed for families with competent parents and low risks for parenting and developmental problems and tested on feasibility. The feasibility study shows this care pathway is feasible and fits the needs of parents. It is unknown whether e-consults contribute in an equally healthy and safe development of children compared with physical

consultations.

## **Study objective**

To determine the added value of e-consultation compared to a visit to the well baby clinic.

## **Study design**

A randomized trial, with an inclusion period of 13 months and 12 months follow-up. Children aged 24 months (N=1365) will be randomized for e-consultation or physical consultation. When the child reached the age of 24 months, an e- or physical consultation will be performed. Six months later, at the age of 30 months, the safety and healthy development of all children will be assessed by a preventive child health care professional.

An e-consultation consists of three questionnaires (ASQ, ASQ-SE and PSS) and questions about changes in family situation. Parents will be invited to fill in the questionnaires when the child is 24 months. A physical consultation consists of a regular consult with a Child Health Care (CHC)-professional. At the age of 30 months, all parents (from intervention- and control group) fill in three questionnaires (ASQ, ASQ-SE and PSS). Changes in the family situation will be discussed during assessment of the safety and healthy development.

## **Study burden and risks**

Parents can miss or misjudge signals of (health) problems. In a physical consultation, professionals might be able to respond to signals of (health) problems. This risk is minimized, by including competent parents with healthy children and low risks for parenting and developmental problems and by the use of valid and reliable instruments during the e-consultation. If parents do not complete the questionnaires, CHC-professionals contact them for a visit to the well baby clinic. An additional visit to the well-baby clinic at 30 months was used for checking safe and healthy development of the child.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

Children who reached the age of 18 months during the study period in the participating areas, who have low risk for parenting and developmental problems according to the SPARK-method performed by the preventive child health nurse during the consultation at 18 months. This includes normal development of the child and competent parents with a healthy lifestyle.

### Exclusion criteria

- Parents do not master digital communication devices.
- Parents do not master the Dutch language.
- Children who have experienced medical issues in the first 18 months, that have to be monitored.
- Children who have a medical family history with high hypermetropia, high myopia, anisometropia, amblyopia, astigmatism, strabismus.

## Study design

### Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	18-09-2018
Enrollment:	1365
Type:	Actual

## Ethics review

Approved WMO	
Date:	27-06-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	10-07-2019
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	NL65369.041.18