E-TOP - Digital information for parents of very and moderat preterm born infants

Published: 10-05-2022
Last updated: 05-04-2024

The aim of this study is to evaluate the feasibility of the E-TOP module for both VP infants as an addition to the TOP program as well as for MP infants in an adapted TOP program.

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

Summary

ID

NL-OMON54151

Source
ToetsingOnline

Brief title
E-TOP

Condition

- Other condition

Synonym
birth before 34 weeks of gestation, prematurity

Health condition

ontwikkelingsproblemen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: SIA RAAK

Intervention

Keyword: e-health, parental knowledge, prematurity, responsive parenting

Outcome measures

Primary outcome

The process evaluation for the feasibility includes the online use of the E-TOP module and the adapted TOP program for MP infants and parental experiences with the E-TOP module. and the adapted TOP program.

Secondary outcome

Outcomes measures include the questionnaires: Maternal self-efficacy in the Nurturing Role (SENR), Parental Reflective functioning Questionnaire (PRFQ), Massie Cambell scale of Mother-Infants Attachement indicators during Stress (ADS), Ages and Stage Questionnaire: Socio-Emotional, Second Edition (ASQ:SE-2), Distress Thermometer for Parents (DT-P), . Parent-child interaction will be evaluated by the Massie Cambell Scale of Mother-Infants Attachement indicators during Stress (ADS). Motor development will be assessed by the Alberta Infant Motor Scale (AIMS). Parental experiences with the E-TOP and adapted TOP program will be assessed using questionnaires as well as by semi-structured interviews.

Study description

Background summary

Very preterm (VP) and moderate preterm (MP) born infants are vulnerable and at risk for developmental problems. In the Netherlands, the TOP program, a post-discharge responsive parenting program, is part of routine care for VPT infants in the first year. Despite this support, parents still have more

information needs. More parental knowledge of development is associated with better outcomes. Parents of MP infants do not receive the TOP program, and also have information needs.

Study objective

The aim of this study is to evaluate the feasibility of the E-TOP module for both VP infants as an addition to the TOP program as well as for MP infants in an adapted TOP program.

Study design

A pilot feasibility study with a pretest-post test design

Intervention

E-TOP module, families will receive information regadring prematurity, en de consequences for e.g. feeding, sleeping, crying, the behaviour and development of pretermborn infants, and parenthood after preterm birth. Families with an MP infant will receive additionally the adapted TOP program consisting of 6 home visits by a TOP interventionist in the first 6 months.

Study burden and risks

Parents fill in three questionnaires at baseline, and four questionnaires at 6 months follow up. In addition, the TOP paediatric physical therapist will assess at the post-test motor development with the AIMS (already standard for the VPT infants in the TOP program). mother-child interaction will be assessed at pre and posttest using a videotaped observation of a daily situation of approximately 5 minutes, using the ADS.

We hypothesize that the E-TOP module added to the (adapted) TOP program has a positive effect on parental knowledge, parental satisfaction, parental responsiveness and thereby on the development of preterm infants, whereas the risk for children is neglible.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

VP group: participating in the TOP program
MP group: born between 32-34 weeks of gestation

Exclusion criteria

infants with severe congenital abnormalities of parents with severe mental illness

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2022
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	10-05-2022
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
ISRCTN	ISRCTN65709138
CCMO	NL78996.018.21