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Supporting parents of preterm infants with digital information

Submission date
04/11/2022

Recruitment status
No longer recruiting

Registration date
07/11/2022

Overall study status
Completed

Last Edited
07/11/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims:
Very preterm born infants are infants born after a pregnancy of fewer than 32 weeks. Moderate preterm born infants are born after a pregnancy of 32-34 weeks. Both very and moderate preterm-born infants are at risk for developmental problems. In the Netherlands, the TOP program is part of routine care for very preterm-born infants in the first year. (TOP: Transmurale Ontwikkelingsondersteuning Prematuurgeboren kinderen en hun ouders. In English: Transmural Developmental Support for preterm born infants and their parents.) The aim of the TOP program is to improve development. There is no routine intervention program for moderate preterm-born infants and their parents. Both parents of very and moderate preterm-born infants seek information about their infant's health and development, sleeping or feeding. Parents report that finding and understanding the information is difficult. Therefore, an information app (e-TOP) was developed specifically with relevant information for parents of preterm-born infants. Also, the TOP program was shortened for moderate preterm-born infants. In the study, 80 families will use the e-TOP app during the first 6 months of the TOP program or during the adapted TOP program. The study aims to evaluate how parents use the e-TOP information app and what their experiences with the app are, and the experiences of the adapted TOP program for parents of moderate preterm-born infants.

Who can participate?
Families with a very preterm infant who are supported in the TOP program.
Families with a moderate preterm infant (gestational age 32-34 weeks) who is discharged home.

What does the study involve?
All families who participate will have access to the e-TOP app. Families with a moderate preterm infant will also receive 6 home visits in the first 6 months. At the start and after 6 months parents will fill in online questionnaires, and parent-infant interaction is assessed. At 6 months, motor development is assessed and semi-structured interviews with parents and TOP interventionists regarding their experiences are performed.

What are the possible benefits and risks of participating?
The e-TOP app added to the (adapted) TOP program provides parents with reliable and relevant information. This may have a positive effect on parental knowledge, parental satisfaction,

parental responsiveness and thereby on the development of preterm infants. The risks are negligible.

Where is the study run from?
AmsterdamUMC (Netherlands)

When is the study starting and how long is it expected to run for?
November 2021 to September 2023

Who is funding the study?
The study is funded by Nationaal Regieorgaan Praktijkgericht Onderzoek SIA (Netherlands)

Who is the main contact?
Monique Flierman, m.flierman@amsterdamumc.nl

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ABR 78986

Study information

Scientific Title

eTOP digital information for parents of very and moderate preterm-born infants

Acronym
eTOP

Study objectives
The aim of this study is to evaluate the feasibility of the E-TOP module for both very preterm (VP) infants as an addition to the routine TOP program as well as for moderately preterm (MP) infants in an adapted TOP program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/05/2022, Medical Ethics Review Committee AMC (Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands; +31 (0)20 566 9111; mecamc@amsterdamumc.nl), ref: 2021_245 - NL78996.018.21

Study design
Single center interventional pilot feasibility study with a pretest-posttest design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Preterm-born infants and their parents

Interventions
A mobile app with digital information for parents of preterm infants. Families receive the E-TOP module in addition to either the routine TOP program (very preterm infants) or the adapted TOP program (moderately preterm infants).
The interventions have a duration of 6 months. The post-assessment is immediately after the end of the intervention.

Intervention Type
Behavioural

Primary outcome measure

1. The use of the E-TOP module, the frequency and duration, will be quantified by online user-data during 6 months. Parental and interventionists experiences will be assessed using questionnaire and semi-structured interviews with parents and TOP interventionists at 6 months. The questionnaire will be composed for the E-TOP module, based on questionnaires measuring parental experiences with app use.
2. For moderate preterm infants, the number of home visits per infant, the duration and content of the home visits will be assessed using a checklist filled in by the interventionist after each home visit. Parental and interventionists experiences will be assessed using questionnaire and semi-structured interviews with parents and TOP interventionists at 6 months. The questionnaire will be composed for this intervention, based on questionnaires measuring parental experiences with intervention.

Secondary outcome measures
1. Parenting self-efficacy measured using the questionnaire Maternal Self-Efficacy in the Nurturing Role (SENR) at baseline and 6 months.
2. Parental mentalizing measured using the questionnaire Parental Reflective Functioning Questionnaire (PRFQ) at baseline and 6 months.
3. Parent-infant interaction using a videotaped observation, scored with The Massie-Campbell Scale of Mother-infant Attachment indicators During Stress (ADS) at baseline and 6 months.
4. Socio-emotional development of the infants measured using the questionnaire the Ages and Stages Questionnaire: Socio-Emotional, Second Edition (ASQ:SE-2) at 6 months.
5. Motor development measured using the Alberta Infant Motor Scale (AIMS) is an observational motor assessment administered by a pediatric physical therapist at 6 months.

Overall study start date
01/11/2021

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. VP infant, with a gestational age <32 weeks and/or birthweight <1500 grams who is enrolled in the TOP program.
2. MP infant with a gestational age between 32 and 34 weeks and a birthweight >1500 grams, within two weeks post-discharge.
3. In each group, at least 15 infants from families with low health literacy will be included. Low health literacy is defined as level of education MBO-2 or less or less than 10 years of education in another country.

Participant type(s)
Mixed

Age group
Neonate

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Severe congenital malformations or syndromes
2. Recent surgical intervention
3. Severe psychiatric maternal problems
4.. Support by a paediatric physical therapist in the post-discharge period

Date of first enrolment
11/11/2022

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC, location AMC
Meibergdreef 9
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Netherlands
1105 AZ

Sponsor information

Organisation
Amsterdam UMC Location VUmc

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Sponsor type
University/education

Website
https://www.amc.nl

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name
Nationaal Regieorgaan Praktijkgericht Onderzoek SIA

Alternative Name(s)
Nationaal Regieorgaan Praktijkgericht Onderzoek, National Board of Practice-Oriented Research SIA, National Board of Practice-Oriented Research, Regieorgaan SIA, NRPO-SIA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/11/2024

Individual participant data (IPD) sharing plan
The quantitative datasets generated during and/or analysed during the current study will be available upon request from Raoul Engelbert (r.h.engelbert@amsterdamumc.nl).

IPD sharing plan summary
Available on request