Development and evaluation of the feasibility of an ageappropriate additional, preventive intervention for very preterm children at 18 months.

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Primary Objective: To develop and evaluate the feasibility of an additional, preventive intervention at 18 months CA for very preterm children and their parents who received the ToP programme.Secondary Objective(s): 1. To evaluate the parental…

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

Summary

ID

NL-OMON37610

Source
ToetsingOnline

Brief title
additional preventive intervention for preterm children

Condition

- Other condition

Synonym
preterm born children, very low birth weight children

Health condition

prematuur geboren kinderen

Research involving

Human

Sponsors and support

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

Intervention

Keyword: child development, early intervention, premature infants, sensitive period

Outcome measures

Primary outcome

For this pilot study, the process evaluation for the feasibility of the additional intervention includes the number of parents and children that participate in the study and in the intervention, the reasons for not complying with the intervention, the number of home visits per child, the duration and content of the home visits and parental satisfaction with the intervention. In addition, the feasibility of the assessments that we want to include in a RCT includes the number of completed assessments and returned questionnaires, missing data and reasons for not participating in the assessments or not returning questionnaires.

Secondary outcome

Secondary study parameter, used to obtain information on the effect size of the additional intervention: the Lexilist for receptive language, the Ages and Stages Questionnaire (ASQ), the Infant Toddler Social and Emotional Assessment (ITSEA), the motor and cognitive scales of the Bayley Scales of Infant and Toddler Development, third edition (BSID-III), and the Emotional Availability Scales (EAS).

Study description

Background summary

Very preterm born children are vulnerable and have a significantly higher risk for developmental problems. The Infant Behavioral Assessment and Intervention Program (IBAIP), an early preventive intervention, given at home until 6 months of corrected age (CA), had a positive effect on the motor, mental, and behavioural development of very preterm children at 6 months CA. At 24 and 44 months, we still found a positive effect on motor development, but not on behavioural and mental development anymore. Recent literature suggests that the behavioural and mental development of children might improve optimally if the intervention coincides with the sensitive periods for these developmental domains. Taking advantage of this sensitive period, by facilitating developmental-appropriate learning situations, is a unique opportunity to stimulate development, and thus prevent developmental problems at a later age.

Study objective

Primary Objective:
To develop and evaluate the feasibility of an additional, preventive intervention at 18 months CA for very preterm children and their parents who received the ToP programme.

Secondary Objective(s):
1. To evaluate the parental satisfaction of the additional intervention.
2. To obtain information on the effect size of the additional intervention on mental, language, and behavioural development in very preterm children compared to very preterm children who received only the ToP programme.

Endpoints of the study are (1) there is an additional, preventive intervention to support parents in the development of their very preterm child at 18 months CA, and the intervention can be applied to parents from diverse cultural backgrounds, (2) parents are satisfied with the additional intervention, (3) information is available for power calculations to evaluate the effect of the additional intervention in a randomized controlled trial.

Study design

Design: The pilot study design is a non-randomized controlled trial, with a pre-post test design.

Intervention

The additional intervention will follow the same steps and approaches of the

ToP rogramme, but will be implemented during play and daily activities suitable for children from approximately 18 to 22 months CA. Parents will be encouraged to positively engage in practical activities with their child, comprising free play, shared book reading, and daily activities as eating and dressing. In line with the ToP programme, the behaviour of the child is analysed and interpreted as follows: 1) When the child shows stabile, information seeking behaviour, parents are encouraged to enjoy their child*s autonomy or positively engage in practical activities with their child, adding associating language or small developmental steps; 2) When the child shows self-regulatory efforts to concentrate, cope, or console, parents are encouraged to give verbal, visual, or physical support to their child*s own self-regulating strategies; or parents may adapt the environment when their child*s efforts are at the cost of their energy and protect their child from interference when engaged in a focused activity; 3) When the child shows signs of disorganization or non-engagement, parents are encouraged to adapt the timing, intensity or complexity of the environmental information to protect their child from stress, or to provide the child*s internal needs to recover from disbalance (e.g. sleep or food).
An evidence-based intervention program that, similar to the IBAIP, involves a responsive parenting style, specifically targeting communication, is the Hanen programme (www.hanen.org). The Hanen programme, based on the transactional model of development, assumes that increased parental responsiveness in communication interactions leads to children who are more active in interactions and in turn increase the diversity of their vocabulary (22). The (pre)speech therapist from the EOP, certified in both the IBAIP and the Hanen programme, will incorporate elements of these programmes in the training for the paediatric physical therapists who implement the additional intervention. The additional intervention will also take place at home, and will be carried out by the same interventionist who provided the ToP programme, which will enhance the feasibility of the programme. Similar to the ToP programme, after each session a written report will be made for the parents, including a summary of the findings, strength-based recommendations, and photo*s. The amount of home visits will depend on the individual needs of the child and parent, and vary between 4-6 sessions.

Study burden and risks

Burden: All parents of the children fill in three questionnaires at 18 and 24 months CA. During the regular appointment at the Couveuze Nazorg Poli, the BSID-III will be administered (this is already standard care in the VUMC for all very preterm born children and in the AMC for children with a birth weight < 1000 g or gestational age < 30 weeks). In addition, a videotaped observation of a parent-child interaction will be performed, of approximately 10 minutes.
Benefits: we hypothesize that the additional intervention has a positive effect on the cognitive, language and behavioural development of the very preterm children.
Risks: the risk for children in this study is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Very preterm born childeren: GA < 32 weeks and/or birth weight < 1500 gr, and participated in the early intervention ToP programme

Exclusion criteria

No sufficient knowledge of Dutch language and no interpretator available.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2012
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
CCMO	NL40208.018.12