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Municipal Transition and Intervention Program for Premature infants and their parents.

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/01/2014	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title

Acronym
STIPP

Study objectives
The hypothesis is that infants who receive the Infant Behavioural Assessment and Intervention Program (IBAIP) will be able to regulate themselves better and that disabilities will therefore be prevented or develop to a less serious degree.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, single blind, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Behavioural self-regulation and/or psychomotor problems

Interventions
For the intervention the IBA Intervention Program (IBAIP) will be used. The theoretical framework underlying the IBAIP is the "Synactive Model of Newborn Behavioural Organisation and Development".

The intervention aims at improving the developmental outcome of the child by assisting the parents as early as possible to support their childs self regulation at a stage where changes are still reversible. The intervention method does not only support the child, but the parents as well, by offering them emotional, practical and individual support, so that excessive stress can be prevented.

By means of standardised IBA observations the childs self regulating skills are examined.
All the childs behavioural expressions and the inter-relationship are observed systematically and are interpreted by means of 4 systems:

1. The autonomic system
2. The motor system
3. The state system
4. The attention-interaction system

With the help of this neurological behaviour assessment one judges how a child can play with its various systems and is able to use them to achieve its goal. Consequently the measure of self-regulation determines the amount of support/intervention that should be offered.

The parental support consists of an increased awareness of their babys behavioural expressions and the interpretation of these expressions, so that the parents learn to intermediate between their childs regulatory skills and the environment. The support they give may affect the environment (e.g. light, sounds, social interaction), functional positioning and ways of handling and the childs specific self-regulatory strategies (e.g. sucking, holding something, seeking support).

As the child grows older it is to be expected that there will be an increase in the childs self regulatory skills and consequently a decrease in the need for support/intervention. The family composition, the cultural diversity and the social/cultural safety network of the (often immigrant) parents will explicitly be taken into account during the project. After each home visit a report will be sent to the parents. This report will especially stress the competencies of the child and its parents. The interventions will be given by specially trained paediatric physical therapists that have the IBAIP certificate.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The Bayley Scales of Infant Development-II (BSID-II) at the corrected age of 24 months
2. The Still Face procedure at 6 months
3. The Working Model of Child Interview at 18 months

Secondary outcome measures
1. The Infant Behavioural Assessment at 6 months
2. The BSID-II at 6 and 12 months
3. The Infant Toddler Symptom Checklist at 6, 12 and 24 months
4. The General Health Questionnaire at 6, 12 and 24 months

Overall study start date
01/01/2004

Completion date
31/12/2008

Eligibility

Key inclusion criteria

1. Gestation of less than 32 weeks and/or birth weight less than 1500 grams
2. Born in one of the Amsterdam hospitals
3. The infant's parents live in the Amsterdam area

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Chromosome or syndrome disease
2. Children of addicted mothers (hard drugs or alcohol)
3. Parents unable to communicate in Dutch or English and who have no interpreter
4. Mothers with severe psychiatric illness

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Rehabilitation, A01
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Government

Funder Name
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

Funder Name
Reserve Voormalige Vrijwillige Ziekenfondsen (RVVZ) (Netherlands) - a governmental non-profit health organisation

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	pilot study results	01/02/2005		Yes	No

Results article	results	01/03/2010	Yes	No
Results article	results	01/12/2011	Yes	No
Results article	results	01/03/2012	Yes	No
Results article	results	01/08/2012	Yes	No
Results article	results	01/11/2013	Yes	No