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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21583

Source
NTR

Brief title
STIPP

Health condition

Very Low Birth Weight Infants
(< 32 weeks of gestation and / or birth weight < 1500 grams)

Sponsors and support

Source(s) of monetary or material Support: RVVZ
ZonMw

Intervention

Outcome measures

Primary outcome

1. The Bayley Scales of Infant Development-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

1. The Infant Behavioral 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.

Study description

Background summary

Longitudinal studies of VLBW infants (gestation < 32 weeks and/or < 1500 grams) show that 2/3 of these children have functional limitations (POPS) at the age of 14. Each year ± 2200 VLBW infants are born in The Netherlands.

Although the prospects for the VLBW infants are better than they used to be, the long-term prevalence of serious handicaps and/or disabilities will still be 5-10%. This serious, mainly neurological morbidity is usually recognized before discharge from hospital and these children are given the necessary, specialized (follow-up) care. However, pediatricians/neonatologists discharge the vast majority (90%) of the VLBW infants from treatment and further follow-up care as sufficiently healthy. They receive the standard follow-up care according to the protocol of the National Neonatal Follow-up program. However, in more than 50% of the cases the children develop one or more problems later in life, especially in the field of behavioural self-regulation and/or psychomotor problems.

There are indications that these ‘late onset’ problems in VLBW infants that appeared to be healthy when discharged, are the consequence of a mismatch between biological factors in the child and unfavorable environmental factors, especially during the child’s first years. Results of neuroscientific research support this hypothesis. During the fetal development and during the early childhood stage the growth of the brain is regulated mainly genetically, but it is also influenced by sensorial information and experiences from the environment. The fact is that at this stage neuronal connections are still being formed and modified.

The analyzed intervention is based on the hypothesis that neurophysiologic stability and a positive sensory approach stimulate the development of the child. The intervention consists of a combination of activities which, together, are called the ‘Infant Behavioral Assessment and Intervention Program’ (IBAIP). It can be applied to infants of 0 to 6 months and is based

on H. Als' 'neuro-behavioral approach. Unlike the more traditional interventions that start from the idea that the premature child is 'under stimulated' and therefore needs extra stimulation, de 'neuro-behavioral approach' assumes that the child needs to be supported in its individual neurophysiologic abilities.
Studies in which interventions stemming from this 'neuro-behavioral approach' took place on NICUs ('Newborn Individualized Developmental Care and Assesment Program' (NIDCAP) showed a positive effect on the developmental results of VLBW infants, both at term-age and at the ages of 9 months and 3 years.
In 2 earlier pilot studies (1999-2002) we investigated the feasibility of the IBAIP ('proof of principle in practice'). These studies showed that VLBW infants that appeared to be healthy do show development problems at a very early age and that IBAIP intervention is feasible, with indications of effect.

The proposed randomized, single-blinded study of 180 VLBW infants compares the effect of IBAIP with standard follow-up care for behavior regulation and psychomotor development of children and the well-being of the parents. The result of the BSID-2 at 24 months was chosen as outcome measure on account of the generally accepted assumption that it is a proxy for long-term development disorders.

The hypothesis is that infants who receive the IBA intervention will be able to regulate themselves better and that disabilities will therefore be prevented or develop to a less serious degree.

Study objective

The hypothesis is that infants who receive the Infant Behavioral 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.

Intervention

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

The intervention aims at improving the developmental outcome of the child by assisting the parents as early as possible to support their child's 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 standardized IBA observations the child's self regulating skills are examined. All the child's behavioral expressions and the interrelationship are observed systematically and are interpreted by means of 4 systems:
- the autonomic system,
- the motor system,

- the state system and the attention-interaction system.
With the help of this neurological behavior 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 baby’s behavioral expressions and the interpretation of these expressions, so that the parents learn to intermediate between their child’s 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 child’s 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 child’s 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 pediatric physical therapists that have the IBAIP certificate.

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Eligibility criteria

Inclusion criteria

1. Gestation of < 32 weeks and/or birth weight < 1500 grams;

2. Born in one of the Amsterdam hospitals;
3. The infant's parents live in the Amsterdam area

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2004
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-08-2005
Application type:	First submission

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
NTR-new	NL131
NTR-old	NTR165
Other	: 1
ISRCTN	ISRCTN65503576

Study results

Summary results
The ‘Infant Behavioral Assessment and Intervention Program’ to support preterm infants and their parents after discharge from hospital, a pilot study. Koldewijn K, Wolf MJ et al. Dev Med Child Neurol. 2005:47:105-112
Early Intervention in Preterm Infants after Discharge from Hospital. Wolf MJ et al. Pediatrics (Letter) 2004;114:1738-1739
Neurobehavioral and Developmental Profile of Very Low Birth Weight Infants in early Infancy. Wolf MJ et al. Acta Paediatrica 2002; 91:930-938.
Behavioural problems in children with low birth weight. Wolf MJ et al. Lancet (Letter) 2001;358:843