Prospective Longitudinal Cohort Study Children with Vision Impairment

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Our aim is to provide the fPRC with empirical data. With studying questions based on literature and practice, the project aims to provide professionals with necessary knowledge to set up early counselling. Besides, the results of the project can...

Ethical review	Approved WMO
Status	Pending
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55270

Source
ToetsingOnline

Brief title
PLoCC-VI

Condition

- Vision disorders

Synonym
Low vision

Research involving
Human

Sponsors and support

Primary sponsor: Stichting ter Verbetering van het Lot der Blinden
Source(s) of monetary or material Support: Stichting ter Verbetering van het Lot der Blinden.

Intervention

Keyword: Adolescents, Baby, Children, Development, Longitudinal study, Vision impairments

Outcome measures

Primary outcome

The fPCR framework is intended to be filled with empirical data. The outcome measures we use are: sense of self, preferences, activity competences, attendance and environment. These factors are operationalized by various instruments.

Baby cohort:

Preferences

Expectations future Interview expectations for the future

Well-being Cantril ladder

Activity competences

Sensorimotor understanding Reynell-Zinkin scales (RZS)

Response to sound and verbal comprehension RZS

Expressive language structure RZS

Social Adaption RZS

Social and emotional development Developmental Journal Babies Visual Impairment (DJVI)

Communication language and meaning DJVI

Play and learning DJVI

Movement and mobility DJVI

Towards independent self-care DJVI

Mental Health Child Behaviour Checklist (CBCL)

Vision impairment Type/cause vision impairment

Sense of self

Motivation Dimensions of Mastery Questionnaire (DMQ)

Environment

Family function Vragenlijst Gezinsfunctioneren voor Ouders (VGFO)

Well-being parents Cantril ladder

Well-being siblings Cantril ladder

Encouragement PICCOLO

Affection PICCOLO

Responsiveness PICCOLO

Teaching PICCOLO

Parenting Nijmeegse Opvoedingsvragenlijst (NOV: autonomy, responsiveness

Amsterdamse versie van Parental Attitude Research Instrument (APARI:

autonomy, overpretection)

Vragenlijst Toezicht Houden (VTH: supervision)

Parental Dimension Inventory (PDI: consistency)

Parental self-efficacy Self-efficacy in the Nurturing Role

Questionnaire (SENR)

Self-esteem parents The Rosenberg self-esteem scale (RSES)

Important life situations interview (3 questions)

Participation

Attendance Diary activities child with VI

Tiener cohort:

Preferences

Expectations future Interview expectations for the future

Well-being Cantril ladder

Experience of parenting Interview about experiences of the parenting

Activity competences

Cognitive functioning Schooltype

Independence of mobility Interview

Adaptive behaviour Vineland Adaptive Behavior Scales

Mental health CBCL

Vision impairment Type/cause vision impairment

Sense of self

Motivation DMQ

Self-efficacy Self-Efficacy Questionnaire for Children (SEQ-C)

Acceptance of impairment Nottingham Adjustment Scale

Loneliness Dutch Loneliness Scale for Adolescents (De Jong-Giervel &

van Tilburg, 1999)

Self-esteem RSES

Self concept Competentie Belevingsschaal voor Adolescenten (CBSA)

Important life situations interview (3 questions)

Environment

Family function VGFO

Well-being parents Cantril ladder

Well-being siblings Cantril ladder

Encouragement PICCOLO

Affection PICCOLO

Responsiveness PICCOLO

Parenting Nijmeegse Opvoedingsvragenlijst (NOV: autonomy, responsiveness

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Parental Dimension Inventory (PDI: consistency)

Parental self-efficacy PSDQ

Self-esteem parents RSES

Experience of parenting Interview experiences of the parenting

Important life situations interview (3 questions)

Participation

Attendance Journal activities child with VI

Secondary outcome

not applicable.

Study description

Background summary

Various studies indicated that, as a group, children with vision impairments (VI) exhibit delays and sometimes setbacks in their development. For example, they may show delays in social communication, play, language and joint attention. In addition, several researchers report that children with VI regularly exhibit aspects of autism spectrum disorder. These disabilities can make the participation of children more difficult. However, individual

variation and causal relations are largely unknown. Therefore, we propose a new descriptive, longitudinal study: Prospective Longitudinal Cohort Study Children with Vision Impairments (PloCC-VI). For this study the family of Participation Related Constructs (fPRC) is used as a framework to guide the project. The framework focuses on participation, which is influenced by and influences preferences, sense of self, activity competence and environment of the child with VI and its family. We will monitor the development regarding these factors of babies and teenagers with VI in order to gain more insight into their developmental course and important factors within it. fPRC provides the opportunity to examine participation from a broad perspective. In PLoCC-VI we are interested in the individual differences within our specific group.

Study objective

Our aim is to provide the fPRC with empirical data. With studying questions based on literature and practice, the project aims to provide professionals with necessary knowledge to set up early counselling. Besides, the results of the project can provide interventions with a good scientific basis that enables individual alignment of the assistance.

Study design

In this study, we are interested in individual differences, in other words, differences within a population. We did not choose for a comparative approach, looking for group differences, as this approach, *tends to draw our attention away from the variables on which we should be focusing* (Warren, 1994, p3). We agree with Warren that the comparative approach will show that children with VI will certainly differ from sighted children. But this does not bring the understanding of their problems any further. Because the population is small and heterogeneous and our interest is in individual differences, the project is primarily descriptive and exploratory in nature, As much as possible we will make use of triangulation, both quantitative (questionnaires, test instruments) and qualitative (observations) measurements will be used. For this purpose, participants are divided in an extensive cohort and an intensive cohort, inspired by the Bielefeld Longitudinal Study (Brambring, 2007). The baby extensive cohort will be visited every six months at home during 2,5 years, using quantitative measurements. Measurements will take place each half year, this results in six waves in total. Participants of the intensive baby cohort will be visited monthly during the possible setback period (14 - 31 months), using both quantitative and qualitative measurements (12 to 18 waves in total). Beyond this setback period, measurements take place each half year (three or four waves in total). For the whole data collection of the intensive cohort, the total number of waves varies from 16 waves to 21 waves, depending on the participant*s age at onset of the study. Participants of the intensive cohort undergo the same quantitative measurements as the extensive cohort. Both intensive and extensive teenager cohort are visited each half year, resulting

in 5 waves (period of 2 years). Participants of the intensive cohort undergo the same measurements as the extensive cohort, in addition video recordings will be used in the intensive teenager cohort.

Study burden and risks

The chance of physical or mental damage is estimated to be very low. We do not use materials with a social taboo topic. In addition, participants will not be exposed to unpleasant stimuli, such as electric shocks, unpleasant odors or stress-inducing instructions. From the care institutions (Royal Visio/Bartiméus) we know that siblings of visually impaired children can experience strain. They are burdened as little as possible for the research by not giving explicit questionnaires to them. The measurements take place in a familiar environment for the children.

The chance of incidents is estimated to be very low. To reduce the chance of fatigue, video recordings are used instead of 'live' observations, in order to reduce the duration of the home visit.

The research is group-based because we specifically want to investigate the development of children with vision impairments in order to be able to help children within the same condition even better in the future. Carrying out the research with sighted adults would not be able to achieve the same results in any way.

Contacts

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Scientific
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Diependaalsedrift 32
Hilversum 1213CR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

In order to obtain a representative research group, all children between the selected ages who are registered at the regional centres of Bartiméus and Royal Visio are invited to participate. Inclusion criteria are:
o For the baby cohort: Age at the start of participation in the project is between six and 30 months. For the intensive cohort the age is between six and 20 months. For the teenager cohort: Initial age is between 12 and 14 years.
o The participant has to grow up in a family, with care by one or two (foster/step)parents
o Parents and teenager partcipants master the Dutch language
o Registered at one of the regional centers of Bartiméus or Royal Visio. For the teenager cohort, registration for special education or itinerant teacher support also applies.
o The following information must be present: visual functioning (minimum vision both eyes together or best eye, field of vision), type of eye condition, disorder/disease/syndrome, date of birth, term date, status comorbid disorders and sex.

Parents and siblings of the children with VI (if present) will be involved in the study and they are asked to participate in the measurements. Participation of (a) parent(s) is compulsory, that of siblings is not. There is no age limit for the siblings when participating in video recordings (intensive cohort). For the measurements among well-being (extensive cohort), siblings should be at least four years old.

Exclusion criteria

Children with clear multiple disabilities are excluded. This applies to the starting moment of participation in the project. For the baby cohort, children who may turn out to have multiple disabilities at a later age can participate

in the project.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-11-2020
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-02-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	28-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL74630.091.20