Motor development and physical fitness after preterm birth in children at school age.

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To explore motor development, the level of physical activity and participation in daily (school) life in preterm born children at the age of 10-12, who were seen earlier at the follow-up outpatient clinic in Maxima MC at the age of 5.5 and 8.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51324

Source
ToetsingOnline

Brief title
Physical fitness in preterm born children at school age.

Condition

- Other condition

Synonym
physical fitness; developmental coordination disorder

Health condition

motorische ontwikkeling en fitheid na vroeggeboorte

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Eigen subsidie vanuit Maxima MC

Intervention

Keyword: developmental coordination disorder, follow-up after preterm birth, physical fitness at school age

Outcome measures

Primary outcome

1. Longitudinal motor development: comparison of the total score and subscale scores of the m-ABC with previous m-ABC results at 5.5 and 8 years of age.

2. Fitness has no composite outcome measure. However, reference values **do exist for the individual components relating to fitness (endurance, muscle strength, aerobic and anaerobic capacity).

Secondary outcome

1. Can we predict physical fitness at the age of 10-12 years based on previous follow-up assessments. Are there neonatal predictors (gestational age; birth weight; gender, etc.)?

2. Approximately 25% of preterm infants have a total m-ABC score <= 5 at ages 5 and 8 and are at risk for a developmental coordination disorder (DCD). How many children aged 10-12 with a total score <= 5 on the M-ABC experience difficulties in daily life or physical participation?

Study description

Background summary

Máxima MC has a neonatal intensive care unit where premature babies are treated. In accordance with the guideline of the National Neonatal Follow-up working group, children born prematurely <30 weeks or <1000 g at the age of 0.5, 1, 2, 5.5 and 8 years are seen at the follow-up outpatient clinic. This outpatient check-up is multidisciplinary, whereby each child is seen by a paediatrician, neonatologist, psychologist and paediatric physiotherapist. In this context, a questionnaire is completed by the parents (CBCL behavioural questionnaire) and the children are tested with psychometric measuring instruments (Bayley at two years, WPPSI or WISC at 5.5 and 8 years) and motor measuring instruments (Bayley at two years or movement ABC at 5.5 and 8 years). All this research is part of regular care. Although follow-up research often focuses on the child's cognitive abilities, in this study we want to look at the physical skills and fitness of the child. Previous Máxima MC research has shown that approximately a quarter of preterm children score moderately on certain motor skills (such as balance) at the age of 5.5 and 8 years. What we don't know is the extent to which this affects their physical fitness and whether it affects their (extra)curricular activities.

Study objective

To explore motor development, the level of physical activity and participation in daily (school) life in preterm born children at the age of 10-12, who were seen earlier at the follow-up outpatient clinic in Maxima MC at the age of 5.5 and 8.

Study design

1. Retrospective data of the motor function (movement-ABC, CBCL behavioural checklist) tested at 5.5 and 8 years of age (standard follow-up)
2. Prospective data, obtained at the age of 10-10 years. The children will be tested (duration 1h) twice at an interval of two weeks. The testing location is at home or in a local practice of physiotherapy in the direct neighbourhood of the children and performed by paediatric physiotherapist in training, under supervision of AVANS+ Breda. Between the two visits the children wear an activity tracker. At the first day motor performance, aerobe and anaerobe capacity will be tested. At the second day strength and mobility will be tested.

Study burden and risks

Testing takes place in a play form (short sprint, squeeze force measurement or pedometer). The exercise fitness is measured with valid non-invasive measures of validated questionnaires (behaviour questionnaire, quality of life) that do not infringe the integrity of the child or parent. They are familiar with the testing and questionnaires because of previous standard care after preterm

birth.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Preterm birth < 30 weeks' gestation with a previously completed standard follow-up at 5.5 and 8 years at the out-patient (follow-up) clinic of Máxima MC;

Exclusion criteria

Children with cerebral palsy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-02-2023
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2022
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-09-2023
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL82166.015.22