

# Norm data for the Infant Motor Profile (IMP) and the Standardized Infant NeuroDevelopmental Assessment (SINDA)

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to generate norm data of the IMP and SINDA.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Congenital and peripartum neurological conditions
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON43209

### Source

ToetsingOnline

### Brief title

Norm data for the IMP and SINDA

### Condition

- Congenital and peripartum neurological conditions

### Synonym

collection of norm data, so mostly typical development is assessed

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Cornelia Stichting en Stichting Ontwikkelingsneurofysiologie Groningen

## Intervention

**Keyword:** infant developmental assessment, Infant Motor Profile, infant neuromotor assessment, norms

## Outcome measures

### Primary outcome

IMP-scores (total score, and five domainscores (variation, adaptability, symmetry, fluency, performance)

### Secondary outcome

SINDA scores (neuromotor and developmental scores)

## Study description

### Background summary

Recently our institute developed two measurement instruments for the detection of developmental disorders in infants, the Infant Motor Profile (IMP) and the Standardized Infant NeuroDevelopmental Assessment (SINDA). Detection of high risk for developmental disorders at early age is a prerequisite for the implementation of early intervention at young age when there is maximum plasticity of the nervous system and chances for improvement are highest. The IMP is a qualitative assessment of motor behaviour of infants aged 3 to 18 months. In addition to being a tool for the detection of infants at high risk for developmental disorders, the IMP may be used to monitor changes in motor development and the effect of early intervention. The SINDA is a tool for paediatricians to assess infant development at 2 to 12 months. SINDA has a neuromotor and a developmental scale. For the implementation of the IMP and SINDA in clinical practise normdata are a prerequisite.

### Study objective

to generate norm data of the IMP and SINDA.

### Study design

In order to generate norm data 1700 infants aged 2 to 18 months will be assessed (100 infants per \*month age\*). The infants will be recruited via

well-baby clinics and day care centres in the three Northern provinces of the Netherlands and via the website of the Kinderacademie ([www.dekinderacademie.com](http://www.dekinderacademie.com)). The sample needs to be representative for the Dutch population in terms of sex, socio-economic and ethnic background. The assessment will consist of an IMP and SINDA assessment and the collection of demographic characteristics. The data will be used to compute developmental curves with cut offs for typical, borderline and atypical development. The infants will be recruited by the Kinderacademie, that has large experience in the generation of norm data for paediatric tests. The infants will be assessed by assessors of the Kinderacademie and assessors of the Institute of Developmental Neurology of the UMCG.

### **Study burden and risks**

The study is not associated with risk for the infant. The assessment of the infant consists of play activities and the performance of routine neurological actions such as the pull-to-sit manoeuvre and the assessment of tendon reflexes. This means that study's burden consists of a time investment of parents and infant. We consider this investment justified as it ultimately will result in norm data for two instruments, that currently are implemented in clinical practise.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

The child lives in one of the three northern provinces of The Netherlands

Age at inclusion between 2 and 18 months

Parents or legal representatives will provide written informed consent

### Exclusion criteria

A potential subject who meets any one of the following criteria will be excluded from participation in this study:

Severe illness precluding the assessment, such as complex congenital heart disorders with insufficient oxygen saturation

Parents have insufficient understanding of the Dutch language to be able to give informed consent

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-01-2017

Enrollment: 1700

Type: Actual

## Ethics review

Approved WMO

Date: 07-11-2016

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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
Other	Aangemeld bij NTR - we wachten nog op een nummer
CCMO	NL58069.042.16