Dutch norms for the Bayley III

Published: 16-02-2010
Last updated: 04-05-2024

The aim of the study is to provide Dutch norms for the Bayley Scales of Infant and Toddler Development, 3rd edition (Bayley III; Bayley 2006), including a reliability and validation study.

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

Summary

ID

NL-OMON35131

Source
ToetsingOnline

Brief title
Dutch norms for the Bayley III

Condition

- Other condition
- Developmental disorders NEC

Synonym
Infant and toddler development

Health condition

Normale ontwikkeling

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,ZONMW,Pearson

Assessment and Information

Intervention

Keyword: baby's, developmental problems, measurements

Outcome measures

Primary outcome

The primary study outcome are the Dutch norms for the Bayley III including validation and reliability studies done in subgroups of the healthy children.

The validation study concerns the following developmental assessments: the Ages and Stages Questionnaires (ASQ; Squires, Potter & Bricker, 1999; ASQ-SE; Squires et al., 2002) for children between 2 and 60 months old; de Wechsler Preschool and Primary Scale of Intelligence (WPPSI, Wechsler, 2002) for children between 30 and 42 months old; the Reynell test for language comprehension (Van Eldik, Schlichting, Lutje Spelberg, B.F. van der Meulen & Sj. van der Meulen, 1995) and the Schlichting test for language expression (Schlichting, van Eldik, Lutje Spelberg, Sj. van der Meulen & B.F. van der Meulen, 1995) for children between 15 and 27 months old; as wel as the old version of the Dutch Bayley scales, BSID-II-NL (Van der Meulen, Ruiter, Lutje Spelberg & Smrkovsky, 2002).

Secondary outcome

Parent questionnaires inform on parenting, personality, and family background characteristics that may affect child development. This information is needed for descriptive purposes and may be used in relation to evaluate children with extreme scores.

Study description

Background summary

Standardized diagnostic instruments for infants and toddlers with appropriate Dutch norms are necessary for research as well as clinical practice in The Netherlands, in order to identify developmental problems and to evaluate intervention programs. In the western world, as well as in The Netherlands the Bayley Scales of Infant Development (BSID II, Bayley 1993; BSID-II-NL ((Van der Meulen, Ruiter, Lutje Spelberg & Smrkovsky, 2000) are frequently used for these purposes. In 2006 a new version was published, the Bayley III. This version is an adaptation of the earlier editions, that results in a better and more differentiated assessment of the developmental level of infants and toddlers. In stead of two scales (concerning mental and motor development), the Bayley III now consists of five subscales, regarding cognitive development, language comprehension and - expression, and fine and gross motor development. A parent questionnaire was added that regards socio-emotional development and adaptive functioning. This has increased the diagnostic potential of the scales. However, Dutch norms for the Bayley III are lacking.

Study objective

The aim of the study is to provide Dutch norms for the Bayley Scales of Infant and Toddler Development, 3rd edition (Bayley III; Bayley 2006), including a reliability and validation study.

Study design

This is an observational and crossectional study that is designed in analogy to the American norm studies for the original Bayley III.

Study burden and risks

Parents' participation is voluntary and they are free to withdraw from the study at all times without consequences. The study does not burden the children. Usually the infants and toddlers enjoy the games and play materials very much. If they don't want to cooperate with a game another game is selected. If the children repeatedly do not want to cooperate, or if the parents like to stop, the assessment is broken off. Time investment depends on the age of the child and varies from * to 1* hours per test. Two appointments are made for children in the test-retest reliability subgroup, resulting in in 1 to 3 hours in total. For the children in the validation subgroup also two appointemnets are made, needing a total of 2 to 2* hours. The parents answer questionnaires that takes 1* to 2 hours, They also escort their children to the appointements, which needs another * to 3 hours, making a total of 2 to 5 hours

for the parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

90% Of the normgroup consists of healthy children, representative for the Dutch population regarding parental education, geografic location, and etnic origin. Concerning age, 17 agegroups will be used: these vary from 16 days to 1 months and 15 days gradually to 39 months and 0 days to 43 months and 15 days. The normgroups consists of 50% boys and 50% girls.
However, 10% Of the data come from assessments of children with risk factors (e.g. premature birth, delayed language development, symtoms within the autistic spectrum) or a special condition (e.g. Down syndrome or Cerebral Palsy), in order to improve representativeness of the normgroup.

Exclusion criteria

90% (N=1530) of the normgroup consists of healthy children without risk factors or specific conditions, such as, prematurity; low birthweight; hospital admittance during the study; severe sensory impairments; respiratory disorder; intraventricular hemorrhage; inborn errors of metabolism; one of the following diagnoses: attention deficit hyperactivity disorder, chromosomal abnormality, congenital infections, disorder due to prenatal exposure to toxic substances, disorders repflecting disturbance of the development of the nervous system, genetic or congenital disorder, mental retardation.
However for 10% (N=170) of the sample one of these risk factors or special conditions explicitly forms a selection criterium.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	1800
Type:	Actual

Ethics review

Approved WMO

Date:	16-02-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL29428.041.09