Adaptive functioning and quality of life in children and adolescents with mild intellectual disabilities to borderline intellectual functioning

Published: 17-10-2017
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON44608

Source
ToetsingOnline

Brief title
Adaptive functioning and quality of life in children with MID-BIF

Condition

- Developmental disorders NEC

Synonym
intellectual disability, mild to borderline intellectual functioning

Research involving
Human

Sponsors and support

Primary sponsor: Karakter Kinder en Jeugdpsychiatrie

Source(s) of monetary or material Support: eigen financiering instelling

Intervention

Keyword: adaptive functioning, intellectual disability, quality of life

Outcome measures

Primary outcome

The main study parameter is the level of quality of life pre * and post-treatment, rated by both parents.

Secondary outcome

Secondary study parameters include subtest (domain) scores on the ABAS-3 (social, conceptual and practical adaptive functioning), intellectual functioning as measured by a Wechsler scale of intellectual functioning (either the WISC-III, WISC-V), academic achievement (results provided by schools on *leerlingvolgsysteem * CITO-testing*), several neuropsychological variables such as social cognition and working memory and experienced parenting stress as measured by the OBVL-k.

Study description

Background summary

In accordance with the 2002 AAIDD-definition of intellectual disabilities, the DSM-5 has shifted its focus away from full-scale IQ-scores to a more clinically relevant focus on impairments in adaptive functioning (Greenspan & Woods, 2014). An impairment in at least one of three domains (social, conceptual and practical) is required in order to receive a DSM-5 classification of Intellectual Developmental Disorder (IDD). Adaptive functioning, however, is a broad construct (Tassé et al., 2012) and how this construct should be translated to the process of test diagnostics, is currently unclear (Greenspan & Woods, 2014; Uzieblo, Habets & Jeandarme, 2015). Furthermore, adaptive functioning is susceptible to the influence of several differing factors

(Papazoglou et al., 2013) and the influence of impairments in adaptive functioning on actual success in daily life or quality of life in children with IDD is, at present, unclear.

Study objective

The main objective of our study is to disentangle the factors that determine the quality of life in children and adolescents with intellectual developmental disorders and psychiatric disorders, and in the process, develop a more systematic and multidimensional approach to diagnosing these children according to the most recent guidelines and current empirical evidence.

Study design

Longitudinal observational study

Study burden and risks

The risk and burden for participants is minimal since the majority of the study protocol is part of care as usual (standard process of diagnostic assessment) at Karakter. Parents and children are asked to participate in one extra assessment. To facilitate parents and children in participation, it will be possible to conduct the additional assessment either at Karakter, in the child*s school or at home.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Children and adolescents between the ages of 7 years, 0 months and 16 years, 11 months
Below average intellectual functioning, measured with a standardized intelligence test, full scale IQ-scores between 50 and 85
The presence of a psychiatric disorder, as classified by the DSM-5

Exclusion criteria

* Unwilling or unable to participate
* Children with full scale IQ scores below 50 or above 85
* Children older than 16 years 11 months and children younger than 7 years of age.

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):	11-07-2019
Enrollment:	61
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-05-2019
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	NL61686.091.17