The development of the Dutch ICF Activity Inventory for children and adolescents with a visual impairment (D-AI KIDS)

Published: 19-03-2013
Last updated: 24-04-2024

Development and validation of the D-AI KIDS and the D-AI YA:Currently there is no standardized instrument that measures visually impaired children*s and young adults' participation based on the nine ICF-CY domains. The primary objective of this...

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

Summary

ID

NL-OMON41493

Source
ToetsingOnline

Brief title
The D-AI KIDS

Condition

- Vision disorders

Synonym
vision loss, visual impairment

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Koninklijke Visio

Intervention

Keyword: ICF, Measurement instrument, Minors, Visual impairment

Outcome measures

Primary outcome

Development of the D-AI KIDS and the D-AI YA and assessment of the psychometric properties by analyzing data obtained from the target population and their parents. Psychometric properties such as content validity, construct validity, reliability and feasibility of the instrument will be investigated, and are important endpoints in this study.

Secondary outcome

Secundary study parameters: not applicable

Other study parameters:

- Disabled children*s participation: Child and adolescent scale of participation (CASP).
- Data on the feasibility and psychometric properties of the Dutch translation of the CASP.
- Health related quality-of-life in children aged 8-18 years: KIDSCREEN - 52
- Sociodemographic data will be collected, i.e. age, gender, diagnosis, age when diagnosed.

- Process evaluation: in order to optimize the D-AI KIDS and the D-AI YA

assessors administering

the instrument and participating parents, children and adolescents will be

asked to

fill-out an evaluation form.

Study description

Background summary

In the Participation round 2007-2010 of ZonMw InZicht, the research project *Development of the Dutch Activity Inventory to measure rehabilitation needs of visually impaired elderly and rehabilitation outcome* was financed. This resulted in the development of the Dutch Activity Inventory (D-AI) which allows one to structurally identify rehabilitation needs, using the nine ICF domains of the Participation and Activity scale. The D-AI also enables one to determine the effects of rehabilitation interventions, both on goal-level (e.g. cooking) and task-level (e.g. reading recipes, cutting vegetables). The D-AI is aimed at adults aged eighteen years and older with a visual disability. In 2010 Royal Dutch Visio and Bartiméus have implemented the D-AI as a new and structured intake assessment instrument. Immediate advantages are increased transparency, improvement of client-perspective when defining their area(s) of difficulty and the possibility of measuring the effects of the rehabilitation process. Royal Dutch Visio and Bartiméus have now commissioned the VU University Medical Centre to increase the applicability of the D-AI to children and adolescents aged <18 years.

Since Visio and Bartiméus have reported that the rehabilitation goals of young adults (18-25 years) are not covered by the DAI for adults (the goals of the young adults have a different emphasis), the develpment of a specific questionnaire for young adults was requested. For the development of this questionnaire the perspectives of young adults and professionals will be central to the study. Evaluation of the rehabilitation goals will also be possible with the D-AI YA.

Study objective

Development and validation of the D-AI KIDS and the D-AI YA:
Currently there is no standardized instrument that measures visually impaired children*s and young adults' participation based on the nine ICF-CY domains.

The primary objective of this study is to develop the D-AI KIDS and the D-AI YA: assessment instruments - to be used during the intake procedure at MRCs - for visually impaired children and young adults aged 0- 25 years old, which measures activity and participation needs. It can also be used to evaluate the rehabilitation process. The study can be divided into a qualitative and a quantitative stage in order to develop and assess the instruments' psychometric properties, respectively. Practical implementation of the D-AI KIDS and the D-AI YA will lead to a more standardized way of diagnosing rehabilitation needs (restrictions in participation). This is likely to result in more streamlined referrals to available rehabilitation programs, and ultimately, to better participation.

Study design

The study design is an observational cohort study, developing the D-AI KIDS and the D-AI YA and assessing the psychometric properties. The study consists out of a qualitative and a quantitative stage.
The qualitative stage consists out of a patient file study, a psychometric review of available acticity and participation instruments and focus groups/interviews and concept mapping workshops with the target population, parents and professionals. Based on this a first draft of the D-AI KIDS and the D-AI YA will be developed and pilot tested. The pilot study will result in a second draft of the D-AI KIDS and the D-AI YA.
The quantitative stage consists out of a large field study with two points of measurement; a baseline measurement and a measurement after six months. Analysis and evaluation will lead to the third draft of the D-AI KIDS and the D-AI YA which will be implemented by Royal Dutch Visio and Bartiméus.

Study burden and risks

This study can be characterized as a study without risk. At all times the children will be carefully monitored, for example for signs of *objection*. As the participants are minors who will not always be able to verbalise their objection; the researchers and assessors will look closely for signs of objection (or *verzet* in Dutch). What constitutes objection is different for every child. Each child has its own unique pattern of behaviour. Behaviour can be influenced by the mood of the child, the parent-child relationship, the researcher-child relationship, the environment etc. Before assessment the researcher and the parents will discuss how the child generally behaves. Behavioural patterns that might indicate objection will be identified. During the assessment the child will be closely monitored for any signs of discomfort, or behaviour that falls outside normal parameters for the child. When this occurs, it will be seen as a sign of objection from the child and participation in the study will be terminated. During all phases of the research-process the parents are allowed to retract their consent. As both researchers are psychologists, it is believed that the children*s behaviour can be adequately

monitored and judged.
Participation is entirely voluntary and participants can withdraw from the study at any given time without an explanation and without it having any consequence for future treatment. Children aged 0 to 7 years old will only be indirectly involved in the study through parent report. Children aged seven years and over will experience minimal burden and negligible risk. The assessments are non-invasive. The minimal burden lies in the time the child and parents have to spend either during the focus groups/interviews or concept mapping workshop, the pilot study or the field study. All participants will be clearly informed about the expected duration of their input before consent.
The PhD candidate has a master*s degree in developmental psychology and some experience working as a professional in the field. She therefore has good knowledge of child development/behaviour and good child-interpersonal skills.
The child and parents benefit from participating in the study by obtaining an extensive and complete overview of the child*s rehabilitation needs on the basis of which a personalized rehabilitation plan can be designed. This plan can then be reviewed to see whether the intended progress is made or whether the plan needs to be modified. Current intake procedures are not standardized and can therefore not be reviewed systematically.
Systematically reviewing participation scores will lead to a more effective rehabilitation process and ultimately to better participartion.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Visual disability according to Dutch guidelines (van Rens et. al., 2011)
- Aged between 0 and 18 years old for D-AI KIDS
- aged between 18-25 years old for D-AI YA
- Informed consent is given
- Sufficient understanding of the Dutch language (both parents and children when age-appropriate)
- Children with (severe) cognitive impairment will be included, however data will only be obtained from the parents.

Exclusion criteria

- Parents with severe cognitive impairment
- Parents with insufficient knowledge and understanding of the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2014

Enrollment:	1495
Type:	Actual

Ethics review

Approved WMO Date:	19-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL42657.029.12