Step by step: Functional gait in children with Developmental Coordination Disorder

Published: 17-01-2017
Last updated: 15-04-2024

The main objective of the study is to quantify functional gait abilities in children with DCD. The second goal is to evaluate whether their gait abilities can be improved by training.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON45685

Source
ToetsingOnline

Brief title
Functional gait DCD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Developmental coordination Disorder/clumsy children

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Revalidatiefonds;Johanna Kinderfonds;Adriaanstichting

Intervention

Keyword: Developmental coordination Disorder (DCD), gait, obstacle avoidance

Outcome measures

Primary outcome

Case control study (part 1)

Gait will be measured during overground walking and while walking on the C-mill. The C-mill is a treadmill with embedded force plates. On this treadmill visual stimuli can be projected. During undisturbed walking, gait characteristics, like step length, width and variability, will be determined. An obstacle avoidance (C-mill) task will be performed with and without dual tasks, with failure rate as main outcome measure. For all these measures the scores of the children with DCD will be compared to reference data.

Intervention study (part 2)

The measurements as described in part 1 are the main study parameters in the evaluation of the intervention. These outcomes will be measured directly after the intervention and after 6 months follow up.

Secondary outcome

case control study (part 1)

Secondary outcomes are determined during a motor plan and online correction task (for further description of the tasks see paragraph 6.2 in the protocol). During the motor plan task, step length, width and time (both mean and standard deviation) in the two steps before the target and the lead step that contacts with the target are measured, as well as the approach distance. The main

outcome for the online correction task is the error in foot placement relative to the target position.

To compare the results of the gait measurements on the C-mill, also overground walking and obstacle avoidance performance will be assessed. This will be done by means of a 10 meter walking test (comfortable and fast walking), a standardized obstacle course based on the obstacle subtask of the Emory Functional Ambulation Profile and stepping in a step ladder. For all three measurements time will be assessed and for the latter two also number of failures and losses of balance will be determined (for further description of the tasks see paragraph 6.2 in the protocol).

Furthermore, the Motorische Competentiebelevingsschaal voor Kinderen(CBSK-M) will be used to measure perceived athletic competence.

Intervention study (part 2):
During the intervention study, fall incidence will be measured as secondary outcome measure. The parents will be assessed regarding fall problems of their child. Information regarding the fall frequency and injuries related to falls in the prior 6 months before participating in the study will be collected. During the 6 months follow-up after intervention parents will be asked to register the falls of their children on monthly fall calendars. On this calendar parents can write on each day whether a fall incident has taken place. This way of registering falls is recommended by the Prevention of Falls Network

Europe (ProFaNe) . After a fall has taken place, parents are requested to fill

out a questionnaire regarding the circumstances, causes and consequences of the

fall.

Study description

Background summary

Children with Developmental Coordination Disorder (DCD) are impaired in the coordination of movements, and experience problems with both gross and fine movements. This impairs them in activities of daily life, such as sports, games and school activities. Parents report their children to be very *clumsy* and to trip and/or fall frequently. Until now most studies and measurement instruments in children with DCD focus on fine motor activities, such as writing. However, the reported problems involve also whole body coordination during ambulatory activities. Therefore, it is important to gain insight into the nature of the reported problems in children with DCD during more dynamic tasks, such as walking and avoiding obstacles. Furthermore, it is relevant to investigate whether these problems respond to training, which might lead to improvement in self-experienced skill in ADL tasks and falls reduction.

Study objective

The main objective of the study is to quantify functional gait abilities in children with DCD. The second goal is to evaluate whether their gait abilities can be improved by training.

Study design

The study consists of two parts: a case-control study and an intervention study. In the first part of the study, functional gait abilities of children with DCD will be measured. Functional gait is defined as gait during complex situations, as during the avoidance of obstacles or with dual tasks. Outcomes will be compared to data of a reference group, consisting of typically developing children of comparable age. Data of this reference group has been collected prior to this study.
Children with DCD who perform worse than the reference group will be invited to participate in the intervention part of the study. This intervention consists of 3 weeks gait training on the C-mill (2 times a week, 30 minutes per session). After the intervention and after 6 months follow-up the same measurements as conducted in part 1 of the study will be repeated.

Study burden and risks

The burden and risks associated with participation are minor. The included children will be asked to perform a measurement with tests and equipment that are common in rehabilitation practice. All of them are asked to participate in one test session of maximal 2 hours. Children who show gait problems, as compared to the reference group, are offered an intervention (6x 30 min) and are asked to perform a post and follow up measurement. This will make the total duration of their participation 9 hours during 7-8 months. All tasks are playful and, in our experience, the children enjoy performing both the overground tasks and the measurements on the C-mill. The treatment is aimed at improving functional gait in the children with DCD who show problems in their gait. Therefore, it is hypothesized that they will benefit from participation in this study.
Because there is hardly any evidence regarding gait and fall problems in children with DCD, this study is of importance and it is not possible to perform this with other patient groups, for instance adults, because the results will have no external validity to children with DCD.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

-age 6 to 12 years;In order to be eligible to participate in this study, a subject must meet all of the following criteria (according to the DSM-V criteria for DCD):
- the Movement Assessment Battery for Children (mABC - second edition) assesses the motor abilities of the children. Children can only be diagnosed with DCD group if they have a total mABC-2 score at or below the 16th percentile or the score at the balance component of the mABC-2 is at or below the fifth percentile.
- Motor impairment significantly interferes with daily life and/or academic achievement. This is judged by the medical specialist and can be further assessed by using the Developmental Coordination Disorder Questionnaire (DCD-Q) or Groninger Motoriek Observatieschaal (GMO).
- The motor impairment is not caused by a medical condition. The diagnosis cannot be made if the IQ is 70 or lower. ;If the diagnosis DCD is not made by a medical specialist, the research criteria for DCD are used as inclusion criteria:
- M-ABC-2: total score <= 16 or a score of <= 5 on the balance component of the test.
- Score *indication for DCD* or *suspection of DCD* on the Dutch version of the DCD-Q, filled in by the parents.
- the parents are asked to state whether the symptoms exists from early childhood, that child attends a regular school and did not repeat a class, and that the child has no visual or neurological problems.

Exclusion criteria

- Neurologic, orthopedic or severe visual problems
- Severe behavioral problems
- Temporary physical complaints that might influence walking

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	17-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-11-2017
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	NL59150.091.16