WeFit! - Improving physical fitness in 7-12-year-old children with developmental coordination disorder: Protocol of a multicenter single-arm mixed-method study

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We12BFit!- Improving physical fitness in 7-12-year-old children with developmental coordination disorder: Protocol of a multicenter single-arm mixed-method study

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Abstract

**Background:** Children with developmental coordination disorder (DCD) are less physically fit than their typically developing peers. No substantiated treatments are available for children with DCD to address this issue.

**Aims:** This study aims to describe 1) the design and rationale of We12BFit!-PF, a training to increase cardiorespiratory fitness, muscle strength and anaerobic power in 7-12-year-old children with DCD and 2) the methods to examine its preliminary effectiveness and feasibility.

**Methods:** We12BFit!-PF was developed using the steps of defining a treatment theory as proposed by Whyte et al. This includes the definition of targets, mechanisms of action, and essential ingredients. We12BFit!-PF will be evaluated in children diagnosed with DCD according to the criteria of the Diagnostic and Statistical Manual of mental disorders (DSM-5) aged 7-12, recruited from rehabilitation centres and physical therapy clinics. Indication for participation will be a need related to enhancing PF, for example tiring quickly, being quickly out of breath or being unable to keep up with peers during PA. During the treatment the participants will be engaged in a group training (2 × 60 min/week, 10 weeks) targeting cardiorespiratory fitness using high intensity interval training, muscle strength using exercises without weights and anaerobic power using plyometrics. Training intensity during high intensity interval training will be monitored with heart rate monitors, if necessary the intensity will be adjusted. Using a single-arm mixed-method design, the preliminary effectiveness will be determined using the 20 meter Shuttle Run Test, hand held dynamometry (JAMAR and MicroFET) and the Muscle Power Sprint Test, which will be assessed in week 0, 11, and 23. Feasibility will be assessed by interviewing parents and children and by organising a focus group session with the trainers at the end of We12BFit!-PF. Based on a 5% improvement in VO2peak the minimum sample size is 19 children.

**Ethics and dissemination:** The University of Groningen, University Medical Centre Groningen medical ethics committee approved the study (METC 2015.216). Final results will be disseminated via scientific publications, presentations and congress proceedings. Funding organisations will receive a final study report.

**Trial Registration:** This study was registered with Netherlands Trial Registry (NTR6334, www.trialregister.nl).
1. Introduction

Children with developmental coordination disorder (DCD) have difficulties with coordinated motor skills, “manifested as clumsiness (e.g., dropping or bumping into objects) as well as slowness and inaccuracy of performance of motor skills (e.g., catching an object, using scissors or cutlery, handwriting, riding a bike, or participating in sports)”\(^1\). DCD interferes significantly with daily activities and often persists into adulthood. Approximately 5 to 8% of all school children have DCD.

Likely as a consequence of their motor problems,\(^2\) children with DCD are at risk of low levels of physical fitness (PF).\(^3\) Children with DCD have problems with all five health-related PF components: cardiorespiratory fitness (CRF),\(^3,4\) muscle strength,\(^3,6\) muscle endurance,\(^3\) flexibility,\(^7,9\) and body composition.\(^3,5\) This deprived PF can have serious consequences on short and long term aspects of functioning and health. In the short-term, psychological and cognitive functioning may be negatively affected, whereas long-term effects may include cardiovascular disease.\(^10\) The seriousness of these consequences stresses the need for treatment of impaired PF next to treating the problems in motor coordination of children with DCD.

To our knowledge, no treatments directly targeting multiple components of health-related PF have been developed for children with DCD. However, a number of studies targeted a single component of PF. One intervention focused on endurance training for 16 weeks, three times 50 minutes per week, and found that children with DCD improved their CRF.\(^11\) Others have shown that it is possible to induce strength gains in children with DCD.\(^12,14\) In one study, children with DCD participated in weekly Taekwondo training aimed at improving muscle strength combined with exercises to practice at home.\(^12\) After 12 weeks children with DCD had significantly improved their muscle strength, to a level comparable to typically developing (TD) children. In two case studies, improvements in muscle strength were found after strength training programmes of approximately 12 weeks.\(^13,14\) From these studies it can be concluded that children with DCD are able to exercise and improve components of PF, despite their motor coordination problems.

In the current study, a treatment will be developed targeting multiple components of PF in children with DCD. Intervention development requires a systematic method to ensure adequate design and evaluation of the treatment. Treatment theory can be used to carefully define three subsequent domains of treatment development: treatment targets and participants, mechanism of action and treatment ingredients.\(^15\) Treatment targets are the main aspects of functioning that are expected to be improved by the treatment and are changed directly by the mechanism of action of the treatment. This mechanism of action offers a theoretical account of how essential ingredients induce changes in the treatment target. Treatment ingredients are “observable (and, therefore, in principle, measurable) actions (…) that are selected or delivered by the clinician” (p. S32.e2).\(^15\) This includes essential ingredients, hypothesised to be necessary to induce an effect on the treatment target, and
other active ingredients that moderate the treatment effects. Treatment ingredients can be specified by reporting dosing parameters, progression and type of activity. Defining a treatment theory compels one to explicate the underlying theory of the treatment which leads to critical and possibly more comprehensive choices in the treatment development and evaluation. In turn this allows for more detailed insight in mechanisms and effective components of treatments.

The aim of this study is to describe 1) the design and rationale of a training called We12BFit!-PF targeting cardiorespiratory fitness, muscle strength and anaerobic power in 7 to 12-year-old children with DCD and 2) the methods to examine its preliminary effectiveness and feasibility. We hypothesise that CRF, muscle strength and anaerobic power will improve and that the treatment will be feasible. We12BFit!-PF is the first part of a multidisciplinary treatment called We12BFit!. The second part, We12BFit!-Lifestyle physical activity, aims to improve the children’s lifestyle physical activity (PA) using parent coaching, provision of information and self-monitoring of activity [described elsewhere].

2. Methods

2.1 Design and Rationale of We12BFit!-PF

2.1.1 Method of treatment development

The development of We12BFit!-PF is based on a literature search and a focus group with professionals, which will be discussed using the three consecutive steps of defining a treatment theory: targets, mechanism of action, and ingredients.

A scoping literature search was performed in PubMed, WebOfScience and PsychInfo, including background information on DCD, theories on exercise physiology, PF treatments and reference values for PF parameters (to ascertain inclusion criteria and targets). Due to the lack of research on these topics in children with DCD, the scope was broadened to populations matching the target group as closely as possible with regard to age or impairment. This included children suspected of DCD, children with cerebral palsy, chronic diseases, typically developing children and adolescents. As the development of a treatment is a comprehensive process, we provided a narrative synthesis.

A two hour focus group was organised to establish a process of co-creation between professionals with different professional background and expertise in the field of DCD and/or training of PF. In order to stimulate the discussion and to be comprehensive we aimed to compose a heterogeneous focus group. Participants were selected to have overlapping expertise on the full range of subtopics for the development of the treatment and different levels of experience. Moreover, they were selected to include all disciplines that might be involved in the treatment. Fifteen participants were purposely selected and invited by email, and by telephone if necessary, to take part in the focus group. Eight invited professionals participated, seven professionals declined the invitation because of work-re-
lated obligations. The group consisted of two (paediatric) physical therapists, a paediatric rehabilitation physician, a motor remedial teacher, a human movement scientist with expertise in exercise physiology, two researchers in (paediatric) rehabilitation and a physical education teacher working in special education. The focus group was conducted at University Medical Centre Groningen, Centre for Rehabilitation and was led by a researcher (Ph.D.) with ample experience in conducting qualitative research and a background in physical therapy. The focus group leader was not involved in the design of the research and had no specific experience in treating children with DCD. Five participants were (distantly) acquainted to the focus group leader. One other researcher who was involved in the development of the treatment, took field notes during the focus group. The focus group guide (Appendix A) was developed by the authors. The focus group discussion was audio-taped and transcribed verbatim afterwards. Subsequently a thematic content analysis was performed. Two researchers independently performed initial coding, placed the codes in the framework of dysfunction and treatment theory and searched for subthemes among codes using Atlas-Ti 5.2 software. Subsequently, the researchers discussed their coding until they reached consensus on the coding tree (Appendix B). For the topics targets, participants and essential ingredients information from both literature search and focus group were combined. Mechanism of action and dosing parameters were not covered in the focus group as this is mainly a theoretical topic for which literature suffices. Two parents of a child with DCD were interviewed on their preferences for the treatment (frequency, location, activities) and two children with DCD pilot tested the training activities for at least 8 weeks.

2.1.2 Intervention: Treatment definition
Step 1: Targets
Information on the five health-related PF components was gathered. According to the literature CRF, measured as VO\textsubscript{2max} was 7 to 22% lower in children with DCD compared with TD children.\textsuperscript{3,6} Muscle strength was about 15% lower in children with DCD compared with TD children.\textsuperscript{6} However, flexibility profiles in children with DCD were heterogeneous: some children showed high levels of flexibility whereas others showed low levels of flexibility.\textsuperscript{3} Although body composition was found to be worse in the majority of articles on children with motor problems,\textsuperscript{3} this was not found in a Dutch sample of children with DCD.\textsuperscript{6} Anaerobic power is not a health-related PF component, but is an important factor to consider, since children’s daily activity patterns predominantly consist of short intermittent activities with both high intensity and low to moderate intensity activities.\textsuperscript{17,18} Children with DCD or motor learning difficulties scored 10 to 30% lower than TD peers on this skill-related component of PF.\textsuperscript{3}

The focus group identified CRF, muscle strength and anaerobic power as the main components of PF that should be targeted in children with DCD. They considered these three components of PF to be impaired and argued that anaerobic power is important in
the ability to keep up with the intermittent play activities that children often engage in. Their concerns seemed to be related to direct functional problems rather than to health-risk associated with low CRF and muscle strength. Moreover, the focus group considered participation, quality of life and social-emotional wellbeing, as the ultimate goal of the treatment. Furthermore, they considered a request for help related to PF as a prerequisite for participation in the treatment, rendering a quantification of low PF unnecessary.

Consequently, based on the literature and focus group, the targets selected for We12B-Fit!-PF are CRF, muscle strength and anaerobic power. Flexibility was found to be too heterogeneous and evidence on body composition was inconsistent. Broader goals related to participation and quality of life cannot be targeted directly and should therefore be considered as distal treatment aims that may improve indirectly by training PF.

**Step 2: Mechanism of action**
The literature indicates that changes in CRF, muscle strength and anaerobic power rely on the principles of overload and specificity. The principle of overload holds that “for a training effect to occur, a system or tissue must be challenged with an intensity, duration, or frequency of exercise to which it is unaccustomed” [p. 262–263]. The adaptations that occur over time abide by the principle of specificity: “the training effect is specific to the fiber types recruited, the principal energy system involved (aerobic vs. anaerobic), the velocity of contraction and the type of muscle contraction (eccentric, concentric, or isometric)” [p.262–263].

**Step 3.a: Essential ingredients and dosing parameters**
Aiming to closely follow the principle of specificity of training, the high intensity interval training (HIIT) running protocol of Baquet et al. will be used to target CRF. HIIT matches the intermittent character of children’s activities and allows for more variation than continuous training. In order to elicit overload, the intensity of the HIIT will be based on each individuals’ maximal aerobic speed (MAS) attained on the 20 meter Shuttle Run Test (20 mSRT). As the participants are likely unaccustomed to training at (near) maximal intensity, the 7 week protocol of Baquet et al. will be extended to 10 weeks (session 1 of the original protocol will be performed four times, session 2-4 will be performed twice). Training intensity should be at least 80% of maximal heart rate. If this is not met during two consecutive sessions, running distances will be adjusted in the next training session. The protocol is expected to be feasible for groups since time intervals are the same for all participants. Distances will depend on the participants’ starting levels.

Strength exercises will be performed with body weight only (no external weights) since the participants likely have low muscle strength and problems with motor coordination. The plank exercise will be used as it involves large muscle groups in the whole body. Exercises of increasing difficulty will be used as the level of muscle strength may vary among children with DCD. Initially the participants will perform static exercises which
will be systematically extended in duration. When a variation can be sustained for a sufficient duration, the participant will continue with a more difficult variation. Eventually this includes a dynamic strength exercise: the push up. The participants will perform three sets of 15 repetitions of this exercise at the most.24

Plyometric exercises start with a rapid stretch of a muscle followed by rapid shortening such as jumps and will be incorporated to improve anaerobic power. As the participants likely have low anaerobic power, they will start with two sets of 10 to 12 jumps. This progresses systematically into higher jumps that are performed in three sets of 10 to 12 jumps.25 Variations of jumps on steps and over cardboards will be used. The HIIT, strength and plyometric exercises will be offered concurrently in 60 minute sessions, twice a week on non-consecutive days for 10 weeks.20,25,26 No negative interference effects of aerobic training to strength gains are expected in children.27 Each session will start with a warming up with low intensity exercises, after the session the participants perform a cooling down.

The focus group provided further suggestions, such as a circuit of exercises, the wheelbarrow walk and games. In addition they identified a number of concerns that need to be addressed: fatigue, pain, low muscle tone, and the heterogeneity of motor problems experienced among children with DCD. Therefore, some training recommendations from the literature were adjusted: extended duration, slower progression of training intensity and exercise complexity throughout the treatment. The training protocol will include decision rules for adjusting training intensity if a child is unable to follow the planned intensity progression. Parents indicated that they thought that training two times a week for 60 minutes would be feasible. Although they expressed preference for one training at the rehabilitation centre/school combined with one training session at home, they were hesitant whether they would manage to provide the training themselves. Moreover, they indicated that their child also had to perform a few exercises at home during previous physical therapy and that adherence to that was low. Therefore, training will be two times a week at the rehabilitation centre/school. Parents suggested the wheelbarrow walk, sack races, running and ball games. Pilot testing of the training showed that the training is feasible and that more games are needed to make the activities more enjoyable. Table 1 summarises the essential ingredients and dosing parameters for targets CRF, muscle strength and anaerobic power.

Table 1. Targets, ingredients and corresponding dosing parameters of We12BFit!-PF.

<table>
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<tr>
<th>Overall</th>
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<td>Frequency</td>
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| Warming up                    | 10 Min: dynamic, low intensity aerobic activities  
|                               | (speed ladder, bench jumps over hands, core stability exercises) |
Table 1 (Continued)

Target: cardiorespiratory fitness

Ingredient: HIIT based on running, with active rest between sets

Dosing parameters:

| Intensity                           | - Progressive: increasing duration and MAS
|                                    | - Relative to participant’s maximal exercise capacity (110-130% MAS), distance will be extended when HIIT mean heart rate (rest included) is below 80% of maximal heart rate during two consecutive sessions |
| Time                                | 25 Min |
| Type                                | Running |
| Sets*repetitions*duration, intensity | - Start: 4*(10*10 s) at 110% MAS
|                                    | - End: 1*(5*20 s) at 110% MAS + 1*(5*20 s) at 120% MAS + 2*(5*20 s) at 130% MAS |
| Rest intervals                      | - Start: rest between runs: 10 s; rest between sets 3 min
|                                    | - End: rest between runs: 20 s; rest between sets 3 min |

Target: muscle strength and anaerobic power

Ingredients: strength and plyometric exercises

Dosing parameters:

| Intensity                           | - Progressive: exercises of increasing difficulty
|                                    | - Relative: difficulty level of the exercise depends on individual participant’s starting level |
| Time                                | 10 Min |
| Type                                | Training with own body weight (variations of push up, jumps) |
| Repetitions*duration; sets*repetitions | Strength and plyometric exercises of increasing difficulty:
|                                    | - Start: strength 1*10 s; plyometric 2*(10 to 12)
|                                    | - End: strength 3*15 s; plyometric 3*(10 to 12) |
| Rest interval sets                 | During rest of the strength exercises participants perform plyometric exercises and vice versa |

Cooling down 10 Min: low intensity game

Abbreviations: MAS = maximal aerobic speed attained at 20 mSRT.
Step 3.b: Other active ingredients
In order to increase compliance, the following other active ingredients will be part of the treatment. At the start of the treatment all children and parents will receive an information letter. During an intake, personal preferences, specific participant needs, eligibility criteria, and participant questions will be addressed.

We12BFit!-PF will be provided in small groups (two to six participants). Each training session will start with a short group conversation: the trainers will check how the participants felt after the previous training and how they recovered. Furthermore, the plans for the upcoming session will be discussed using a planning board. The training components will be offered in the same order each session. Exercises will focus on maximizing success and enjoyment and avoid cognitive-motor dual tasks. The exercises will be alternated by low intensity games, a variety of sports, and activities suggested by participants.

If parents are present they will be invited to watch their child during the first and last 5 minutes of the session and occasionally they will be invited to join the final activity during the cooling down. Paediatric physical therapists in collaboration with people with a background in psychomotor therapy or physical education will train the participants.

2.1.3 Materials and equipment for We12BFit!-PF
During the first training all children will receive a t-shirt with the logo of We12BFit!. Materials used during the training sessions are at least: one speed ladder, one bench and an unstable surface such as Bosu Ball for warming up; ten playground cones or similar materials to demarcate the individual distances for the HIIT; two steps and two gymnastics mats for the plyometric exercises. Each study site will receive a box with a stopwatch, game materials, and game instructions that can be used during the HIIT.

2.2 Methods for evaluation of effectiveness and feasibility
2.2.1 Study Design
In this multicenter single-arm study preliminary effectiveness and feasibility will be evaluated using mixed-methods.

2.2.2 Stepwise Procedure
Figure 1 provides an overview of the procedure that will be followed in this study.

2.2.3 Recruitment of study sites
All rehabilitation centres in the Netherlands and all paediatric physical therapy clinics in the province of Groningen will receive an invitation to participate in the study. Study site eligibility depends on willingness to participate, availability of coaches, trainers, and appropriate facilities.
Figure 1. Stepwise procedure of We12BFit! and its evaluation.
2.2.4 Recruitment of participants
Physical therapists and rehabilitation physicians will be responsible for recruiting participants. Participant eligibility criteria are listed in Table 2. Participants will not partake in other physical therapy or treatments focusing on PF during their participation in We12BFit!-PF. If participants decide to withdraw their participation they will be asked for their reason to do so.

The minimum required sample size is 19 participants. The calculation of sample size was based on the primary outcome measure VO$_{2\text{peak}}$ (ml/ kg/ min), as attained on the 20 mSRT. First, effect size $d$, $d = \frac{|x_1 - x_2|}{(s^* (1 - r)^{0.5})}$, was calculated using mean VO$_{2\text{peak}}$ from preliminary research ($x_1$), mean VO$_{2\text{peak}}$ after 5% improvement ($x_2$), standard deviation ($s$) and at least moderate Pearson correlation ($r > 0.3$). Next, sample size was calculated based on a two-tailed t-test with a power of 80% and alpha of 0.05, resulting in a required sample size of 19 participants.

Table 2. In- and exclusion criteria for participation of children with DCD in the treatment.

**Inclusion criteria**

1. Previously diagnosed with DCD by a physician according to DSM-5 criteria$^1$ or DSM-5 criteria A, B and C are met and criterion D is checked in school record (pDCD)
2. Ages 7 to 12
3. Needs related to enhancing PF, for example tiring quickly, quickly out of breath or unable to keep up with peers during PA
4. Motivated to participate in the treatment
5. Parents/ care takers are willing to invest their time and effort

**Exclusion criteria**

1. Medical history that contra-indicates exercising or maximal exercise testing
2. Inability to function in a group (assessed by care provider, e.g.: the child is unable to participate in PE classes or sports activities, the child disturbs activities of other children)*
3. Inability to follow instructions (assessed by care provider, e.g.: easily distracted, refuses to execute instructions, does not understand basic instructions)*
4. Insufficient understanding of Dutch or English language that prevents the child to participate successfully

* Comorbidities such as autism spectrum disorder and attention deficit hyperactivity disorder are no reason for exclusion.

2.2.5 Intake
When potential participants or their parents have expressed interest they will be invited for an intake with a trainer or coach of We12BFit! During the intake the trainer or
coach will assess the eligibility of the child, inform the parents and their child about the intervention. If the child is eligible, the trainer or coach will provide an information letter and an informed consent. The parents and their child will be given the opportunity to ask questions, and the information letter contains the contact information of the developers of We12BFit! and of an independent physician.

2.2.6 Measurements
If parents and their child decide to participate and hand in a signed informed consent, they will be scheduled for the measurements and the intervention. The first measurement will be one week before the first training session, the second measurement will be one week after the last training session and the third measurement will be 13 weeks after the last training session.

2.2.7 Outcome measures
The intensity of HIIT will be monitored with heart rate monitors (Polar RS300X) every training session. Preliminary effectiveness will be assessed at measurement 0, 1 and 2. The primary outcome will be the score on the 20 mSRT expressed as VO$_{2\text{peak}}$ (ml/ kg/ min) and number of runs, indicative of CRF. VO$_{2\text{peak}}$ obtained from the 20 mSRT shows moderate to good correlation with the cycle ergometer test in children scoring at the 15th percentile of the Movement Assessment Battery for Children. The 20 mSRT will be conducted in small groups and a therapist will join the participants for pacing and motivation. Heart rate (Polar RS300x) and the Children’s OMNI Scale of Perceived Exertion will be assessed right before and after the test. OMNI Rating of Perceived Exertion ranges from 0 to 10 with a higher score indicating more fatigue.

Secondary measures will include handgrip strength assessed with the Jamar (Jamar-Sammons Preston, Bolingbroke, GA) hand-held dynamometer (HHD), strength of elbow and knee flexion and extension assessed with the MicroFET 2 (HOGGAN Health Industries Inc, Salt Lake City, UT) HHD, and mean power will be assessed with the Muscle Power Sprint Test (MPST). Strength measures were selected to minimally include motor coordination. The Jamar showed high reproducibility in children with myopathy, and is considered the gold standard for measuring hand grip strength. The MicroFET showed good to high reliability in children with cerebral palsy, and will be executed using the break method. Three measures will be taken for each muscle group of the dominant and non-dominant side. If two measures differ by more than 20%, a fourth measure will be taken. The MPST has been shown to be reliable and practical for assessing anaerobic performance in children. Six individual 15m runs at maximal speed will be timed. Between runs the participants will rest for 10 seconds. A therapist will join the participant.

Feasibility and indirect effects of the treatment will be assessed by student observations of the training sessions. Second, parents and children will be interviewed about the treatment (Appendix C), their answers will be written down during the interview. In addition, trainers will discuss their experiences and make suggestions for improvement of the
training during a two hour focus group (Appendix D). The focus group will be audio-taped and transcribed verbatim afterwards.

Potential adverse effects will be monitored both during and after the treatment. Training sessions will be observed by students using an observation scheme which includes the report of any adverse effects. In addition, the trainers will also write a report about the training sessions and during the parent interviews parents will be asked for any changes since their child’s participation in We12BFit!

2.2.8 Data management
The data will be collected by researchers, who will be assisted by students. The students will enter and de-identify the data and the researchers will conduct the data analysis. Access to data will be granted only to the research team. The data will be stored securely in locked cabinets and password-protected computer files.

2.2.9 Data analysis
\[ \text{VO}_{2\text{peak}} \text{ (ml/ kg/ min)} = 31.025 + 3.28 \times \text{speed} - 3.248 \times \text{age} + 0.1536 \times \text{speed} \times \text{age}, \]  
with speed being determined as \(8 + 0.5 \times \text{final stage.}^{28}\) Speed is expressed in km/ h and age in years. Strength for each muscle group will be calculated as the mean of the three closest scores. Power (Watt) will be calculated using: \(\text{(body mass} \times 15^2) / \text{time}^3\), with body mass expressed in kg and time in seconds.\(^{36}\) Mean power of the six runs will be included in the analysis. Normally distributed data will be analysed using a dependent t-test. Not normally distributed data will be analysed using a Wilcoxon test.

The focus group and interview data will be analysed in a thematic content analysis using Atlas.ti version 8 software. Two researchers will independently code the transcript using the terminology of treatment theory and search for subthemes.

3. Discussion

Although it is known that children with DCD often have lower PF than typically developing peers, no substantiated and systematically developed treatment directly targeting multiple components of PF is available for children with DCD. This study describes both the development of We12BFit!-PF, a group treatment for 7 to 12 year old children with DCD to improve CRF, muscle strength and anaerobic power, and the methods to evaluate the preliminary effectiveness and feasibility of this treatment.

Not every training effort automatically results in improved fitness.\(^{22}\) Treatment theory, as laid out in this study, may help researchers to develop viable treatments: a treatment theory compels researchers to design their treatments systematically and ensures careful selection of targets and ingredients based on the expected mechanism of action. Over
time this systematic approach for developing treatments may contribute to revealing how treatments work and for whom. When applied consistently by researchers in the field this will improve study comparability, with the potential to extend our understanding of what constitutes an effective treatment.

In addition, the development of a treatment theory helps researchers to distinguish targets from aims. Aims are “aspect(s) of the (...) participant’s functioning or personal factors that are predicted to change indirectly (...) as a result of the treatment induced change in the treatment target.”  

Professionals in the focus group were very clear that the ultimate goal of We12BFit!-PF should be participation, quality of life and social-emotional wellbeing. These aspects are considered to be aims and not targets of the treatment. They will not be targeted directly but may improve by increased PF, or by improved social skills gained from the interactions with other children and by experiencing success during the training sessions. Moreover, training of muscle strength through strength and plyometric exercises may also improve motor skills such as running, jumping, and throwing as well and thus indirectly may improve their participation in sports.

The aims specified by the focus group seem to reflect a durable focus on lifelong PF and participation in PA. Although we expect that PF may act as a prerequisite for engaging in PA, we expect that more factors are involved and that a more behaviourally oriented treatment is needed. Therefore we developed the complementary treatment We12BFit!-Lifestyle PA, where motivation for PA is targeted through application of behaviour change strategies. It should be noted that although the designs are described separately, the effects of these treatments may not just be complementary but may also reinforce each other.

The development of this treatment was based on evidence-based findings from literature as well as experience-based and practical considerations offered by the focus group. These sources of information mainly complemented each other, but were sometimes conflicting. For instance, the focus group advocated a client-centred approach resulting in different individual treatment targets and highly tailored ingredients to enable optimal participation in PA. Although the focus group considered the group aspect to be valuable, the group aspect limited the extent to which the treatment can be adjusted to individual requests during the treatment. Moreover, the treatment theory as well as research technical considerations require predefined targets and predefined ingredients. To solve this conflict, we selected children with similar requests for help for each group and we systematically adjusted the training intensity to each child’s starting level. In addition, the second part of We12BFit!, We12BFit!-Lifestyle PA, allows for a more individual approach.

There are several strengths to this study. First, an innovative aspect of this study is the use of the treatment theory allowing for thorough development of the treatment. Second, we combined information from the literature and a focus group. This resulted in both comprehensive and complementary information which informed the design of the treatment. Moreover, it allowed for the development of a treatment tailored to the needs.
of children with DCD, limiting the likelihood of any adverse effects such as injuries. Third, the focus group consisted of professionals with different backgrounds, ensuring that the perspectives and expertise of different professions on training of PF were included. Most experts had ample experience working with children with DCD which allowed us to direct the treatment to the specific needs of this target group. Despite these strengths a number of shortcomings should be taken into account as well. First, although we hypothesised that children with DCD are comparable to TD children, the information on training from the literature was on TD children and not specific to children with DCD. Testing of the treatment should reveal whether the choices made are appropriate. Second, we conducted a focus group with eight participants. In order to reach data saturation more focus groups may be required. Moreover, although parents were involved in the development of the treatment their role was limited. By means of the evaluative parent interviews after the treatment, their input in the further development of the intervention will become stronger. Finally, including a control group would improve the interpretability of the results. However, as this concerns a newly developed treatment we will not include a control group. To minimise the amount of testing for the participants no extended baseline measurements will be included in the evaluation.

To our knowledge this is the first study to describe a treatment directly targeting multiple components of PF in children with DCD. The selected treatment ingredients offer a functionally meaningful, varied and potentially enjoyable combination of activities that bear the potential of enhancing the PF of children with DCD. Evaluation of the treatment may provide insight in the trainability of PF in children with DCD. If successful, the treatment may extend the effectiveness of rehabilitation of children with DCD.

**Ethics and dissemination**
Written informed consent will obtained from parents, and children aged 12 years (Appendices E, F). The local medical ethics committee approved the study (METC 2015.216). Final results will be disseminated via scientific publications, presentations and congress proceedings.
### References


13. Kaufman LB, Schilling DL. Implementation of a strength training program for a 5-year-


Appendix A

Focus group topics and questions to inform the development of We12BFit!-PF

Opening question
Please briefly introduce yourself by telling who you are, where you work and what you do.

1. Treatment targets
1.1 Please write down the most important reason why it may be worthwhile to have children with DCD train their PF and the most important reason why it may not be worthwhile to have children with DCD train their PF.
1.2 What are important components of PF that children with DCD should improve?
1.3 What are feasible goals for children with DCD in a PF treatment conducted by physical therapists?

2. Recipient characteristics: in- and exclusion criteria
2.1 Please respond to the following stand: Not just children with DCD with low PF, but also children with DCD with a healthy fitness level should be invited to participate in the treatment.
2.2 How to define low PF?

3. Treatment ingredients and parameters
3.1 How do components like CRF and muscle strength relate to each other?
   - Are they of equal importance?
   - Would you train them simultaneously?
   - Why?
3.2 How would you train the CRF of children with DCD, what activities or exercises would you recommend?
   - What considerations should be taken into account when selecting these activities?
3.3 How would you train muscle strength in children with DCD, what activities or exercises would you recommend?
   - What considerations should be taken into account when selecting these activities?
3.4 Is it necessary to adjust treatments for adults to children?
   - If so, what adjustments would you make to a PF training when implementing it in children?
   - Why?
3.5 Is it necessary to adjust CRF training for typically developing children to children with DCD?
   - If so, how would you do this with regard to frequency, duration and intensity?
3.6 Is it necessary to adjust muscle strength training for typically developing children to children with DCD?
   - If so, how would you do this with regard to frequency, duration and intensity?

Closing questions
Did we miss anything important?
Of all adjustments we discussed, which one is most important according to you?
Appendix C

Questions for parents and children to evaluate We12BFit!-PF

Questions for parents
1. How did you experience the past ten weeks during which your child participated in the training?
2. To what extent did your participation meet your expectations?
3. What did you experience as positive?
4. What did you experience as negative?
5. What would you have liked to have been done differently?
6. Do you have any suggestions for improvement?
7. How do you think your child experienced the training sessions?
8. To what extent does your child understand why he/she participates in We12BFit!-PF?
9. What does your child tell you about We12BFit!-PF?
10. What does your child tell others about We12BFit!-PF?
11. What struck you about what your child told about We12BFit!-PF?
12. Have you noticed any changes since your child started We12BFit!-PF? If so, what did you notice?
13. Would you recommend other parents of a child with a similar need to participate in We12BFit!-PF? Why so or why not?

Questions for children
1. Have you noticed any changes since you participated in the training sessions? If so, what did you notice?
2. What would you tell your friends about We12BFit!-PF if they were curious about it?
3. Why did you participate in We12BFit!-PF?
4. What did you like about We12BFit!-PF?
5. What didn’t you like about We12BFit!-PF?
6. How would you change the training sessions to be more fun?
Appendix D

Focus group topics and questions to evaluate We12BFit!-PF with the trainers

<table>
<thead>
<tr>
<th>Opening question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Please briefly introduce yourself by telling who you are and why you decided to be a trainer for We12BFit!-PF.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Main questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Please indicate what the participants of your training group gained from the training or what they should have improved on more according to you.</td>
</tr>
<tr>
<td>&gt; How did you notice this?</td>
</tr>
<tr>
<td>&gt; What did the participants and parents say about this?</td>
</tr>
<tr>
<td>3 What did you learn by providing the training?</td>
</tr>
<tr>
<td>&gt; In what aspects did the training differ from your usual working method?</td>
</tr>
<tr>
<td>&gt; What would you take from this training if you were to start a comparable training?</td>
</tr>
<tr>
<td>&gt; What aspects of the training did you need to get used to?</td>
</tr>
<tr>
<td>4 What should be the main target of the training according to you?</td>
</tr>
<tr>
<td>5 Which bottlenecks did you come across?</td>
</tr>
<tr>
<td>&gt; How to solve this?</td>
</tr>
<tr>
<td>6 What did you think of the group composition?</td>
</tr>
<tr>
<td>&gt; What in- and exclusion criteria would you suggest to be adapted?</td>
</tr>
<tr>
<td>7 Which children may benefit from the training according to you?</td>
</tr>
<tr>
<td>&gt; Could it be used for children with other diagnoses?</td>
</tr>
<tr>
<td>&gt; How would you compose the groups if you were to include other children as well?</td>
</tr>
<tr>
<td>8 How can we accommodate the training for children with DCD with more severe behavioural problems?</td>
</tr>
<tr>
<td>9 In this set up We12BFit!-Lifestyle PA is provided by separate coaches, how do you feel about that?</td>
</tr>
<tr>
<td>&gt; Would you like to contribute to We12BFit!-Lifestyle PA? If so, what would you like to do and why? If not, why not?</td>
</tr>
<tr>
<td>&gt; Would you like to be a coach? If so, what do you need to able to do that? If not, why not?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Closing questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 Did we miss anything important?</td>
</tr>
<tr>
<td>11 Of all adjustments we discussed, which one is most important according to you?</td>
</tr>
</tbody>
</table>
Appendix E

Informed consent parent/guardian

Informed consent for participation in scientific research on: ‘We12BFit!’

Statement parent/guardian:

By signing this form I declare the following:

- I read the information letter. I could ask any question I had. My questions have been answered satisfactory. I had sufficient time to decide whether I want to let my son or daughter participate in We12BFit!.

- I am aware that participation is voluntary. I am aware that I can decide to revoke my participation at any time. I am not obligated to provide an explanation for this.

- I know that the coaches and the research team of We12BFit! have access to my data that is filed for We12BFit!. I know that my data will be processed anonymously.

- I give permission to use my data for the aims listed in the information letter.

I hereby declare that I agree with the participation of my child in the abovementioned scientific research We12BFit!, on which I have been informed by an information letter.

Name parent/guardian:

Name participating child:

Signature parent/guardian: Date:

-----------------------------------------------------------------------------------------------------------------

Statement researcher:
I hereby declare that I informed the abovementioned parent/guardian sufficiently about We12BFit!.

Name researcher:

Signature: Date:
Appendix F

Informed consent child

Informed consent for participation in scientific research on: ‘We12BFit!’

Statement child:

By signing this form I declare the following:

- I read the information letter. I could ask any question I had. My questions have been answered satisfactory. I had enough time to decide whether I want to participate in We12BFit!.

- I am aware that participation is voluntary. I am aware that I can decide to not participate anymore at any time. I am not obligated to provide an explanation for this.

- I know that the coaches and the research team of We12BFit! have access to my data that is filed for We12BFit!. I know that my data will be processed anonymously.

- I give permission to use my data for the aims listed in the information letter.

I hereby declare that I agree with the participation of my child in abovementioned scientific research We12BFit! on which I have been informed by an information letter.

Name parent/guardian:

Name participating child:

Signature participating child:    Date:

------------------------------------------------------------------------------------------------------------------

Statement researcher:

I hereby declare that I informed the abovementioned participating child sufficiently about We12BFit!.

Name researcher:

Signature:       Date: