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Effectiveness of Functional Power Training on Walking Ability in Young Children With Cerebral Palsy: Study Protocol of a Double-Baseline Trial

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Purpose: To evaluate the effect of functional high-velocity resistance (power) training to improve walking ability of young children with cerebral palsy.

Methods: Twenty-two children with bi- or unilateral spastic cerebral palsy, Gross Motor Function Classification System levels I and II, aged 4 to 10 years will be recruited. A double-baseline design will be used to compare a 14-week functional power training (3 times a week) program with a 14-week usual care period and a 14-week follow-up period. The power exercises will be loaded and performed at 50% to 70% of the maximum unloaded speed. Load will be increased when exercises are performed faster than 70% of the unloaded speed. Primary outcomes will be sprinting capacity (15-m Muscle Power Sprint Test) and goal attainment scaling score of walking-related treatment goals. Secondary outcomes will be walking speed (1-min walk test), endurance (10-m shuttle run test), gross motor function, lower-limb strength, and parent-reported mobility. (Pediatr Phys Ther 2017;29:275–282)

Key words: cerebral palsy, gait, high-velocity training, muscle strength, plantar flexor muscles, power training, walking

INTRODUCTION AND PURPOSE

Cerebral palsy (CP) comprises a group of disorders in the development of movement and posture, attributed to nonprogressive disturbances that have occurred in the developing fetal or infant brain.¹ Prevalence rates of CP are about 2 per 1000 births in Europe, of which 82% are spastic CP.² Motor impairment in CP is multifactorial and includes problems such as spas-

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At the time this article was written, Liesbeth van Vulpen was a PhD student at Amsterdam Rehabilitation Research Center, Reade, Amsterdam, the Netherlands, in collaboration with the Department of Rehabilitation Medicine, VU University Medical Center, Amsterdam, the Netherlands. She was also working as a pediatric physical therapist at Reade, Center for Rehabilitation and Rheumatology, Amsterdam, the Netherlands.

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ticity, coordination problems, loss of selective motor control, and muscle weakness.² In the group of children with spastic CP, 60% to 70% have achieved walking ability with or without assistive mobility devices between 6 and 12 years, which is levels I to III according to the Gross Motor Function Classification System (GMFCS).^{1,3} Children who ambulate and with CP are often integrated in community schools and recreational facilities, and thus are required to perform the same activities alongside their peers developing typically, like playing in the schoolyard and walking from class to the gym or at school outings.⁴ As a result of their motor impairments, children with CP may have problems in daily life with keeping up with peers in their walking ability.⁴

Muscle strength is an important impairment that is closely related to walking ability in children with CP.⁵ Plantar flexor strength seems to be particularly important for walking because of its contribution to generate power at push-off, which is necessary for step length and walking speed. Muscle power production of plantar flexors is more reduced than the proximal muscle groups in children with CP in comparison with children who are developing typically.⁶

Several studies have examined methods to improve the walking ability of children with CP by muscle strengthening.⁷ Progressive Resistance Exercise (PRE) training has therefore been applied to improve gross motor function and walking ability through increases in muscle strength. However, despite increases in strength in most lower-limb muscles, there were

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only limited or no improvements of walking ability after PRE training.⁷ The improvement in muscle strength after PRE is apparently not transferred to walking activity. Moreau et al⁸ suggested that training at higher, more functional movement velocities than generally used in PRE training might lead to functional improvements. This suggestion was based on their findings that children with CP have a reduced ability to rapidly generate forces.⁸ This is likely to affect daily life and playing activities, such as playground games or sports such as football, as in almost all of these activities the child is more involved in high-intensity physical activities of short duration. These high-intensity physical activities may be limited in children with CP due to the aforementioned reduced ability to rapidly generate forces.⁸ Children with CP have lower sprint capacity than their peers who are developing typically.9 Training of high-velocity movement may be especially important during the growing years when neural plasticity and motor coordination are most sensitive to change.10

Another possible reason for limited effects of PRE training on walking ability is that most previous studies did not train the plantar flexor muscles whereas, as previously mentioned, plantar flexor strength is strongly related to the generated power at push-off in walking.¹¹ Plantar flexor muscles in children who are ambulant and with CP produce as little as 48% of the force of those in matched children who are developing typically.⁶ This is already seen in young children with CP from the age of 6 years.⁶ Yet several common treatments are likely to weaken the plantar flexors such as botulinum toxin injections and casting periods to increase muscle length. However, training of the plantar flexor muscles seems particularly important for improving walking ability in this population.

Therefore, we developed a functional power training program, called MegaPower training, consisting of loaded functional exercises, such as walking, running, and climbing stairs, performed at high velocities. Training duration, frequency, and intensity are based on strength training guidelines for youth from the National Strength and Conditioning Association.^{10,12} In this functional power training program, the children will train on high-movement velocities to promote neuromuscular adaptations and maximize the training effects on walking ability.10,13 To our knowledge, combining high-movement velocities with external loads and a controlled progression in load during the training period, embedded in functional exercises, have not been investigated in children with CP. The children will be guided carefully during the exercises by the trainer and a story about superheroes will keep the children motivated to give their best effort during the training.

The aim of this study is to evaluate the effect of resistance training at high-movement velocities in functional exercises (functional power training) on walking ability in young children with CP. This article describes the design and training protocol of a double-baseline trial to assess the effectiveness of functional power training on walking ability (sprinting ability, walking speed, and endurance) and plantar flexor strength in young children with cerebral palsy compared with a period of usual care.

METHODS

Participants

We will include 22 children (GMFCS levels I and II) with predominantly spastic CP aged 4 to 10 years. Parents and/or the children have a treatment question related to walking ability (such as being able to walk longer or faster). The children have to be able to understand and follow instructions. Exclusion criteria will be (1) treatment with botulinum toxin A in lower limb and/or serial casting of lower limb less than 6 months before the start of the functional power training, (2) selective dorsal rhizotomy treatment less than a year before the functional power training, and (3) walking is not (yet) the preferred mobility.

Design and Procedure

This research protocol has a "double-baseline" design (see Figure 1). The participants act as their own controls by comparing the changes in outcome measures in a 14-weeks usual care period with the changes in a 14-week training intervention (functional power training) that follows immediately after the usual care period. Measurements will be done before the usual care period (pretest 1), after the 14-week usual care period, which is also the start of the training period (pretest 2), after the 14-week training period (posttest), and a follow-up test will be scheduled 14 weeks after the posttest to assess whether the potential improvement remains (follow-up test).

Primary outcomes are sprinting capacity measured with the 15-m Muscle Power Sprint Test (MPST) and evaluation of treatment goals with a focus on walking reported by parents and participants measured with goal attainment scaling (Figure 2). Secondary outcomes are walking capacity measured with 1-minute walk test (walking speed), 10-m shuttle run test (endurance), gross motor function, and lower-limb strength. Parent-reported mobility performance will be measured with the Mobility Questionnaire (MobQues) and the Functional Mobility Scale (FMS). For each participant, body mass and body height will be measured. GMFCS level and type of CP will be determined by a pediatric physical therapist together with the physician.

The Medical Ethics Committee of the Slotervaart medical center and Reade rehabilitation research center in Amsterdam, the Netherlands, approved this study, and written informed consent forms will be obtained from the parents of each participant.



Fig. 1. Double-baseline research protocol with follow-up measurement.

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Fig. 2. Study outcomes in ICF levels (*primary outcomes, †secondary outcomes, §adverse outcomes, and ‡control outcomes). CP indicates cerebral palsy; FMS, Functional Mobility Scale; GAS, Goal Attainment Scaling; GMFCS, Gross Motor Function Classification System; GMFM, Gross Motor Function Measure; HHD, hand-held dynamometer; MobQues, Mobility Questionnaire; MPST, Muscle Power Sprint Test; 1MWT, 1-minute walk test.

Setting

Participants will be recruited from a rehabilitation center, 2 schools for children with physical disabilities and an outpatient clinic of a university medical center. The training and assessments will take place in 2 special schools for children who are physically disabled and in a rehabilitation center in the Netherlands.

Intervention

In the intervention period, participants will follow the functional power training for a period of 14 weeks, 3 times a week. Each training session lasts 60 minutes. The training consists of the following phases: warm-up (10 minutes), 3 to 4 different power exercises (35 minutes), and end game (15 minutes). The training sessions will be in small groups (3-6 children) and will be supervised by the same number of therapists. During each training session, participants will wear regular sport shoes without their splints, and sport outfit. Each training session starts with a warm-up with walking and running exercises and dynamic calf muscle-stretching exercises. Power exercises and the end game will be chosen in line with the treatment goals of the parents and children. A story about superheroes and secret missions is made to keep the children motivated and to give their best effort during the training sessions. They will receive a T-shirt with their superhero to stimulate group morale and training motivation.

Power Exercises

For all participants, 4 to 6 different power exercises will be selected that are relevant for the treatment goals set by the parents and participants for improving daily life activities. In each training session, participants will perform 3 or 4 of the power exercises (Table 1). The power exercises are specifically designed to strengthen the plantar flexor muscles while performing functional exercises (Figure 3). Characteristics of the power exercises are described in Table 1. Key elements of the power exercises are (a) functional loaded multijoint exercises such as running and walking, with a focus on the ankle pushoff, (b) high-movement velocity (similar to the velocity used in daily/playing activities), and (c) progressive load. The following exercises will be used: (1) running, (2) walking, (3) pushing chair, (4) stair climbing, (5) propelling scooter, and (6) sideways walking. Training volume is determined by load, movement velocity, and number of repetitions (Table 1). The exercise load will be adjusted to a level that allows participants to perform at 70% of their maximum unloaded speed. Each exercise will be performed at maximal effort for 25 seconds, with a resting period of 30 to 50 seconds, and with 6 to 8 repetitions each exercise. For each power exercise, velocity and distance will be calculated at baseline (Table 2). When participants become faster (ie, performs the exercise in less than 25 seconds at maximal effort), load will be increased (by steps of approximately 10% of the current load) to maintain the target velocity. To motivate the participants and to control the movements during the exercises, every participant will be supervised individually during the power exercises (one on one).

Primary Outcome Measures

Sprint Performance. Sprint performance will be measured with the MPST. The MPST is an intermittent sprint test, in which the participant stops and starts at standardized intervals. The MPST measures the sprint capacity of the participant expressed in mean power and peak power.¹⁴ Participants sprint at maximum speed over 15 m with 6 repetitions. Between the 6 sprints is a 10-second break in which the participant can turn and be ready for the next sprint. The time used for each sprint is

TABLE 1						
Characteristics and I	Fraining Volume	of the 6	Different	Functional	Power	Exercises

Exercise	Load	Method of Loading	Sets	Duration, s	Rest, s	Intensity
Running	Load level that allows child to perform at 50%-70% of maximal unloaded running speed	Dragging a loaded box over ground with belt around the hips (Figure 3A)	6-8 repetitions	25	30-50	Maximal effort
Walking	Load level that allows child to perform at 50%-70% of maximal unloaded walking speed	Dragging a loaded box over ground with belt around the hips (Figure 3A)	6-8 repetitions	25	30-50	Maximal effort
Pushing chair	Load level that allows child to perform at 50%-70% of maximal unloaded running speed	Chair, with a loaded box underneath (Figure 3B)	6-8 repetitions	25	30-50	Maximal effort
Stair climbing	Load level that allows child to perform at 50%-70% of maximal speed for unloaded stair climbing	Loaded vest (Figure 3C)	6-8 repetitions	25	30-50	Maximal effort
Propelling a 3-wheel scooter	Load level that allows child to perform at 50%-70% of maximal speed for unloaded scooter propelling, for each leg separately	Loaded box attached to scooter (Figure 3D)	6-8 repetitions	25	30-50	Maximal effort
Sideways walking	Load level that allows child to perform at 50%-70% of maximal unloaded sideways walking speed	Dragging a loaded box over ground with belt around the hips	6-8 repetitions	25	30-50	Maximal effort



Fig. 3. Examples of MegaPower exercises: (A) running while dragging a loaded box, (B) pushing a loaded chair, (C) running up the stairs with loaded vest, and (D) propelling a 3-wheel scooter while dragging a loaded box.

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TABLE 2

Calculation of Training Velocity, Distance, and Load for Each Functional Power Exercise

Exercise	Velocity	Target Distance	Starting Load	Progression
Running	Maximal unloaded running speed is calculated as the average speed over the 6 trials of the MPST ^a	Target distance (m) is calculated as maximal running speed (m/s) × 25 s × 0.7 (ie, 70% of maximal unloaded speed)	Starting load is determined by asking maximal effort of the child when running the target distance while dragging a loaded box. If the child completes the target distance in less than 25 s, load is added to the box. If the child cannot complete the target distance within 25 s, load is removed from the box. <i>Indication for starting load</i> is 25% of the child's body mass	Load is increased with approximately 10% of the current load (0.5 kg is the lowest amount of load to increase) when the child becomes faster during the training period, ie, reaches the target distance of the exercise in less than 25 s (ie, $>70\%$ max speed)
Pushing chair	Maximal unloaded running speed is calculated as the average speed over the 6 trials of the MPST ^a	Target distance (m) is calculated as maximal running speed (m/s) × 25 s × 0.7 (ie, 70% of maximal unloaded speed)	Starting load is determined by asking maximal effort of the child when running the target distance while pushing a loaded chair. If the child completes the target distance in less than 25 s, load is added to the chair. If the child cannot complete the target distance within 25 s, load is removed from the chair. <i>Indication for</i> <i>starting load</i> is 15% of the child's body mass	Load is increased with approximately 10% of the current load (0.5 kg is the lowest amount of load to increase) when the child becomes faster during the training period, ie, reaches the target distance of the exercise in less than 25 s (ie, >70% max speed)
Walking	Maximal unloaded walking speed is calculated as the average walking speed of the 1-min walk test	Target distance (m) is calculated as maximal walking speed (m/s) × 25 s × 0.7	Starting load is determined by asking maximal effort of the child when walking the target distance while dragging a loaded box. If the child completes the target distance in less than 25 s, load is added to the box. If the child cannot complete the distance within 25 s, load is removed from the box. <i>Indication for</i> <i>starting load</i> is around 45% of the child's body mass	Load is increased with approximately 10% when the child becomes faster during the training period, ie, reaches the target distance in less than 25 s (ie, >70% max speed)
Stair climbing	Maximal number of stair steps is determined as the number of steps when climbing the stairs as fast as possible in 25 s with unloaded vest	Maximal number of steps in 25 s × 0.7	Starting load is determined by asking maximal effort of the child when climbing stairs with a loaded vest. If the child completes the target number of steps in less than 25 s, load is added to the vest. If the child cannot complete the target number of steps within 25 s, load is removed from the vest. <i>Indication for starting</i> <i>load</i> is around 15% of the child's body mass	Load is increased with approximately 10% when the child becomes faster during the training period, ie, reaches the target distance in less than 25 s (ie, >70% max speed)
Propelling a 3-wheel scooter	Maximal speed is determined (for each leg separately) by asking the child to propel the scooter with an unloaded box as fast as possible for 25 s	Target distance (m) is calculated as distance propelling the scooter unloaded in 25 s × 0.7	Starting load is determined by asking maximal effort of the child when propelling the scooter over the target distance while dragging a loaded box attached to the scooter. If the child completes the target distance in less than 25 s, load is added to the box. If the child cannot complete the distance within 25 s, load is removed from the box. <i>Indication for starting</i> <i>load</i> is around 15% of the child's body mass	Load is increased with approximately 10% when the child becomes faster during the training period, ie, reaches the target distance in less than 25 s (ie, >70% max speed)
Sideways walking	Maximal unloaded sideways walking speed is determined by asking the child to walk sideways as fast as possible while dragging an unloaded box over 25 s	Target distance (m) is calculated as distance sideways walking unloaded in 25 s × 0.7	Starting load is determined by asking maximal effort of the child when sideways walking the calculated target distance while dragging a loaded box. If the child completes the target distance in less than 25 s, load is added to the box. If the child cannot complete the distance within 25 s, load is removed from the box. <i>Indication for starting load</i> is around 35% of the child's body mass	Load is increased with approximately 10% when the child becomes faster during the training period, ie, reaches the target distance in less than 25 s (ie, >70% max speed)

^aMuscle Power Sprint Test 6 times 15-m sprint.

measured with a stopwatch. Power output for each sprint will be estimated from the collected data using the following equations:

velocity (m/s) = 15 m/time acceleration (m/s²) = velocity/time force (kg·m/s²) = body mass × acceleration power (W) = force × velocity¹⁴

For each of the six 15-m runs, the power will be calculated. Peak power will be defined as the highest power output of those 6 runs. Mean power will be defined as average power output of the 6 runs. The reliability of the MPST, with an intraclass

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correlation coefficient (ICC) of 0.97, as well as the feasibility and construct validity, is reported as good.^{14,15}

Treatment Goals Reported by Parents and/or Participants. Treatment goals will be measured by the Goal Attainment Scaling (GAS), an individualized measurement to evaluate parents' and participants' progress towards activity and participation goals.¹⁶ The GAS is a sensitive evaluative measurement that describes the change of individuals or groups after treatment (ICC = 0.86).¹⁷ It is a 6-point scale measurement, with the score -2 representing the level equal to start, score -1less progress than expected, score 0 for the expected level of functioning, score +1 and score +2 for achievement of more and much more than was expected, respectively, and score -3for deterioration. We will adhere to the following criteria for scale development: (a) goals will be set by experienced pediatric physical therapists in consultation with parents and participants, based on their main aim of therapy in terms of activity and participation domains of the International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY), (b) the 6 levels of the GAS scales will be specific, measurable, achievable, realistic/relevant, and time-related (SMART), and (c) scales will be constructed ordinal with incremental steps of equal intervals.17

Secondary Outcome Measures

Walking Ability. The secondary outcome measures on the activity level of the ICF-CY on walking capacity will be the 1-minute walk test (1MWT) and the 10-m shuttle run test (SRT), as shown in Figure 2.

The 1MWT measures walking speed as the distance walked in 1 minute. The participants will be asked to walk as fast as possible without running around an oval track. The reliability (ICC = 0.94) and the validity of the 1MWT are reported as good.^{18,19}

The SRT is developed for children with CP GMFCS levels I and II and measures endurance.²⁰ Participants walk or run between 2 markers delineating the respective course of 10-m, at a set incremental speed determined by a signal. Experienced pediatric physical therapists will accompany the participants to help keep pace with the audio signal. The test is finished when, on 2 consecutive paced signals, the participants do not reach the marker. participants with GMFCS level I will perform the SRT-II with starting speed 5 km/h. Participants with GMFCS level II will perform the SRT-II with starting speed 2 km/h. Both SRT tests increase 0.25 km/h in speed every minute. Reliability and validity of the SRT-II and SRT-II are reported as good (SRT-I, ICC = 0.87-0.97; and SRT-II, ICC = 0.94-0.99).²⁰

Gross Motor Function

Gross motor function will be measured with the 66-item version of the Gross Motor Function Measure (GMFM-66). The GMFM-66 is a standardized tool designed to evaluate changes in gross motor function in children with CP.^{21,22} Items that will be tested are, for instance, activities in walking, running, and jumping skills. There is a 4-point scoring system for each item. Good reliability, validity, and responsiveness of the GMFM-66 have been demonstrated.^{21,22}

Mobility Performance Reported by Parents

Mobility performance will be measured with the FMS and the MobQues. The FMS is a questionnaire to classify functional mobility in children with CP in the age of 4 till 18 years.²³ Functional mobility is scored over 3 distances, chosen to represent mobility in the home (5 m), at school (50 m), and in the wider community (500 m). Parents will be asked to rate participants' usual walking performance of the 3 distances according to the need for assistive devices, such as walking frame, crutches, or wheelchair. Test-retest reliability of the FMS is reported as good ($\kappa = 0.86$ -0.92) as well as the construct, content, and concurrent validity.²³

The MobQues is a Dutch questionnaire for parents with children in the ages of 2 to 13 years to determine the extent of difficulty the child has with his mobility. The questionnaire addresses 28 mobility activities in everyday life and includes indoor activities, such as "how difficult is it for your child to go upstairs?" as well as outdoor activities, such as "how difficult is it for your child to walk on sand?". The response options, given on a 5-point scale, are not difficult at all, slightly difficult, somewhat difficult, very difficult, and impossible without help. The test has a good intrarater reliability (ICC = 0.96) and content and construct validity.^{24,25}

Muscle Strength

Secondary outcome measures in terms of body function and structures will be isometric muscle strength of the plantar flexors, quadriceps, hip abductors, and dynamic muscle strength of the plantar flexors. The make method will be used, where the participant gradually builds force against a hand-held dynamometer (microFET Hand-held Dynamometer, Biometrics BV, Almere, the Netherlands) for approximately 5 seconds. The participant will be allowed 1 or 2 practice trials for each test until the investigator is confident that the participant understands the task. Each participant will perform subsequently 3 repetitions for each muscle group and the maximum force (peak force) for each repetition will be registered. When the concentration and/or motivation of the participant is not optimal, a fourth or fifth repetition will be performed. Strong verbal encouragement during the measurement will be given to produce maximal effort. A standardized protocol will be used for positioning of the participant, joint fixation, joint positioning, and dynamometer resistance.²⁶ Lever arm will be measured between standardized landmarks with a hard tape measure, according to test procedures of van Vulpen et al.²⁶ Torque (Nm) will be calculated by multiplying force (newton) by the length (meter) of the lever arm. To improve reliability, isometric muscle strength will be measured at 2 different test occasions (different days, with a maximum of 7 days within measurements) on each measurement moment (Figure 1). The mean of the six measurements (2 test occasions with 3 repetitions each) will be used in the analysis. Isometric strength measurements have good reliability in children with CP when measured with 3 repetitions in 2 different test occasions (ICC = 0.88-0.98).²⁶

Dynamic muscle strength of the plantar flexors will be measured with the standing heel-rise test on 1 limb. Both limbs will be tested. The number of repetitions for standing heel rise on 1 limb will be measured on the basis of a standardized protocol. Participants are allowed to touch the examiner only with a single finger for balance. The test is terminated when the participant leans or pushes down on the examiner, the participant's knees flexes, or when the participant gives up or asks to stop despite encouragement. Moderate to good reliability is reported for the heel-rise test in young children with CP (ICC = 0.86-0.98).²⁶

Adverse Outcomes

Range of Motion. Range of motion of the ankle (dorsiflexion) will be measured as joint angle, with a goniometer with knees flexed and with the knees extended while the participant is lying in supine position.¹¹

Spasticity

Spasticity in the hamstrings, soleus, and gastrocnemius muscles will be assessed by the joint angle at which a "catch" (defined as a sudden increase in muscle tone, blocking further movement) will occur in a fast passive stretch (<1 second) with the participant supine.²⁷

Statistical Analysis

Sample Size. A power calculation was performed for the primary outcome measure (ie, the mean power [W] of the MPST). A pilot study (n = 10) showed an increase of 85% (mean \pm standard deviation: 13.1 \pm 12.2 W) in mean power after functional power training. Calculations were based on a within-subject design with a dependent *t* test, a power of 0.8, an α level of 0.05, and an effect size of 0.7. According to the power calculation, a sample size of at least 19 participants is needed. Twenty-two participants will be recruited to allow a dropout of 10%.

Changes in the usual care period (Δ t0-t1), training period (Δ t1-t2), and follow-up period (Δ t2-t3) will be calculated. Paired sample *t* tests (if normally distributed) and Wilcoxon signed rank tests (if not normally distributed) will be used to determine whether the changes within these periods differ significantly between periods. All statistical analyses will be performed using Statistical Package for the Social Sciences (SPSS) version 22.0 software (IBM Corporation, New York).

DISCUSSION

The "double-baseline" design will be used instead of a randomized controlled trial to increase the feasibility of the study in a heterogeneous group of participants with CP. Using this design, participants serve as their own controls by comparing the changes during a usual care period to the changes during an intervention period, in which the participants follow the functional power training. The advantage of this design is that statistical power can be reached with smaller subject groups. Previous randomized-controlled intervention studies in children with CP suffered from low statistical power because of small sample sizes and heterogeneous groups, emphasizing the need for alternative statistical approaches.²⁸ Apart from this higher feasibility and increased statistical power, another advantage of this design is that all of the children will receive the intervention.

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