Power2Walk: The Impact of Functional Power Training on Participation and Activity in Children with Cerebral Palsy - A Randomized Controlled Trial.

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Primary:1. Do twelve weeks of MegaPower training effectively accomplish patient-tailored participation and activity goals in ambulant children with CP, when compared to their usual care? Secondary:1. Do twelve weeks of MegaPower training improve...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON56709

Source
ToetsingOnline

Brief title
Power2Walk

Condition

- Movement disorders (incl parkinsonism)

Synonym
Cerebral Palsy; Brain-Related Movement Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Hersenstichting;KNGF;en Phelps Stichting voor spastici

Intervention

Keyword: Cerebral Palsy, Children, Functional Power Training, Participation

Outcome measures

Primary outcome

The primary research outcome is an improvement in participation and activity, measured through Goal Attainment Scaling (GAS). Using the GAS, patient-tailored goals will be set up and evaluated using a Likert scale with a reach from -3 (decline) to +2 (much more improvement than original goal).

Pre-baseline, the children will undergo the mobility questions of the Canadian Outcome Performance Measure (COPM) together with a therapist. The COPM is especially suited to identify and order personal mobility goals on participation and activity level. After identifying these goals, 1-3 GAS-goals will be written down on both participation and activity level. The child will then have to order their goals and choose a primary goal for both participation and activity. All GAS-goals will be (re-)evaluated at t = 12 weeks (end of intervention), t = 24 weeks (halfway follow-up), and t = 36 weeks (end of follow-up). In case a chosen primary goal cannot be accurately measured or defined using the Likert scale, a secondary goal will become the new primary goal. Only the primary goals will be used for statistical analysis.

Secondary outcome

1. Parent-reported mobility (questionnaires); measured using the Gait Outcomes

Assessment List (GOAL) and Mobility Questionnaire (MobQues28).

2. Physical tests for the following paramaters

a. Walking speed -> 1-minute walk test

b. Aerobic endurance -> 10m shuttle run test

c. Anaerobic capacity -> Muscle Power Sprint Test

3. Body composition; measured using bioelectrical impedance analysis (BIA).

4. Dietary intake at baseline (questionnaire); measured using a 3-day food diary in which parents have to track the nutritional intake of their child during 2 week days and 1 weekend day.

5. Physical activity and sleep, measured over a 7-day period using a wrist-wearable accelerometer.

6. Self-perception of the child (questionnaire); measured using Harter's Self-Perception Profile for Children on the domains of social competence, athletic competence, and global self-worth.

7. General baseline characteristics (questionnaire); including:

o Age, height, weight, BMI, gender, Gross Motor Function Classification System, CP type, Amsterdam Gait Classification, Selective Control Assessment of Lower Extremities, type of education, education level of their parent(s), use of

ankle-foot orthoses.

8. Process evaluation (also see 'aanvullende opmerkingen'). As part of the process evaluation we will also measure parental satisfaction regarding the MegaPower training.

Study description

Background summary

Cerebral palsy (CP) is the most common cause of impaired mobility amongst children. In the Netherlands, approximately 25.000 people are physically impaired as a result of CP. CP is a lifelong disorder that originates from brain-related damage or deviations that occur before, during, or short after child birth. Children that suffer from CP especially struggle with walking. This is in part due to a combination of lowered strength and spasticity in their lower limbs. As a result of their movement disorder, children with CP struggle to participate with typically developing peers during school, sports, and their free time.

Physiotherapy may improve gait, which also improves participation of children with CP. These children with CP require mobility exercises specific to their individual disorder and treatment question(s). Recently, we showed in a small study that Functional Power Training (FPT) according to the so-called 'MegaPower protocol' causes a large increase in walking speed, aerobic enduance, and anaerobic capacity in children with CP after twelve weeks of intensive FPT. Due to the heterogeneity of children with CP, every participant was used as their own control in this study in a so-called double-baseline design. The results of this non-randomised study need to be confirmed in a larger, randomised, multicenter study to implement MegaPower training as regular treatment for ambulant children with CP. Additionally, we want to investigate what factors best identify which ambulant children with CP benefit most from MegaPower training.

The Power2Walk study will provide the framework for whether, and to what extend, MegaPower training has added value in the physiotherapical treatment of children with CP in comparison to their usual care. Additionally, we want to explore what factors best identify which ambulant children with CP benefit most from MegaPower training. Furthermore, we want to investigate whether the effects of the MegaPower training are maintained after 12 and 24 weeks of

follow-up. Lastly, we want to evaluate whether the MegaPower training was implemented as intended at the participating research centers. We expect the MegaPower training to effectively improve participation in children with CP when compared to their usual care.

Study objective

Primary:
1. Do twelve weeks of MegaPower training effectively accomplish patient-tailored participation and activity goals in ambulant children with CP, when compared to their usual care?

Secondary:
1. Do twelve weeks of MegaPower training improve walking ability, aerobic endurance, and anaerobic capacity in ambulant children with CP, when compared to their usual care?
2. What factors best identify which ambulant children with CP benefit most from twelve weeks of MegaPower training?
3. To what extend was MegaPower training implemented as intended in the participating research centers?
4. Are the effects of MegaPower training maintained after 12 and 24 weeks of follow-up?

Study design

This study is a single-blind randomized controlled parallel trial with a 24 week follow-up. Half of the children will follow the MegaPower training three times a week for twelve weeks (intervention group). The other half will receive their usual care during the same time period, which consists for example of physiotheraphy (control group). During the follow-up, the intervention group will receive 24 weeks of usual care. Simultaneously, the control group will do twelve weeks of MegaPower training during the follow-up, followed by twelve weeks of usual care. This is because we believe it is important that the control group also receives the MegaPower training.

Intervention

Intervention group:

The MegaPower training is a 12 week long functional power training program in which children will perform functional power training 3 times a week together with a personal trainer. During the intervention, training volume will be influenced by training weight, velocity of movement, and amount of repetitions. The training program has the following characteristics:
1. (Weighted) functional exercises like walking, running, and walking stairs.
2. High velocity movements.

3. Progressive overload.

Prior to and during the training, a sports consultant makes a plan together with parent and child to find a fitting place where the child can stay physically active after the training (for example a sports club or group). We do this because we want to implement the results of the study in day-to-day life. Both at 12 and 24 weeks during the follow-up, parent and child will visit again to measure whether the effects on participation are durable.

Control group:

The control group will receive their usual care for 12 weeks (non-intervention group). This usual care consists of physiotherapy appointments for example. Important to mention is that the control group will also follow MegaPower training during the first 12 weeks of the follow-up, because we believe it is important to also provide the training to this group.

Study burden and risks

1. Burden:

The burden consists of three components:

- Participation in MegaPower training: Total burden of 36 hours spread over 12 weeks of training with 3 moments of training per week that each last 1 hour.
- Measurement days: Total burden of 5 hours spread over 4 measurement days in total. The first measurement day takes 2 hours. The other measurement days each take 1 hour. After every 12 weeks of the study, a week is planned to take these measurements. This adds up to 3 x 12 + 4 = 40 weeks.
- Parent questionnaires: Total burden of 2.5 hours spread over 40 weeks. Questionnaires can be filled out at home.

The total burden for the children is 41 hours over 40 weeks. The total burden for the parents is 2.5 hours over 40 weeks.

Important to mention is that MegaPower training is part of the usual care that these children receive. The added burden that children will experience as a result of the training is exactly the same for children that do not participate in the study, since they would follow the training regardless. Solely the measurement days and parent questionnaires are an added burden as a result of participating in the study.

2. Risks:

The risks are very low. The risks of the MegaPower training are not larger than those of usual care, although participants may experience some muscle ache and fatigue during the beginning of the training program. These go away after a

short amount of time. Additionally, it should be mentioned that the BIA sends an unnoticable electric pulse through the body. The BIA then measures impedance accross the body. BIA has a small risk for participants that wear an electronic medical implant, like for example a pacemaker. Parent and child will be asked if the child has an electronic medical implant before the measurements take place. Participants that wear an electronic medical implant, will not undergo any measurements using the BIA. The BIA is completely safe for all other participants. Important to mention is that these children would participate in the MegaPower training, even when they would not participate in the study. This is why participation in this study specifically does not introduce any added risks for these children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Children with cerebral palsy or a related non-progressive disorder between the ages of 4 and 12.
- Gross Motor Function Classification System (GMFCS) level I - III.
- Parents and/or children have a treatment question related to either walking ability and/or participation of their child.

Exclusion criteria

- Participants that suffer from a progressive neurological disorder.
- Treatment with botulinum toxin and/or serial casting in lower extremities planned during the study.
- Treatment with botulinum toxin in the 12 weeks prior to the study.
- Treatment with serial casting in the 3 weeks prior to the study.
- Children that underwent a selective dorsal rhizotomy in the 12 months before participation in the study.
- Children that underwent orthopedic surgery on their lower extremities in the 12 months before participation in the study.
- Children that have already received MegaPower training in the last 4 months before participation in the study
- Children for whom walking is not their preferred method of locomotion (yet).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-07-2024
Enrollment:	66

Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	25-03-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2024
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	NL85905.018.23