

Effect of Whole Body Vibration Therapy on Muscle Function, Gross Motor Function and Bone Mineral Density in Children with Spinal Muscular Atrophy - a Feasibility Study

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Abstract

Spinal muscular atrophy (SMA) are one of the common physical disabilities in childhood. For SMA, progressive muscle weakness and early fatigue hamper the mobility of the sufferers. Osteopenia is common for this population group due to poor bone growth and muscle disuse. As a result, non-traumatic related fractures and bone pain are common. Recently, whole body vibration therapy (WBVT) has been proven to improve bone health and muscle function in healthy adults and post-menopausal women. Among the limited studies on the WBVT for children with muscular dystrophies, promising results have been shown on gross motor function, balance, and muscle strength and the WBVT appears to be safe for children with SMA.

The present pilot study is designed to investigate if WBVT is safe and feasible for individuals with SMA and if WBVT can improve muscle function, functional abilities, postural control and bone mineral density in children with SMA. Convenience samples of 10 individuals with SMA type III will be recruited. The participants will receive the WBVT of 25 Hertz and a peak-to-peak amplitude of 4mm for a session of about 18 minutes, 3 days per week for 4 weeks. Assessment will be performed at the baseline and the completion of the intervention to examine the muscle function, functional abilities, postural control and bone mineral density of the participants.

It is anticipated that the outcomes of this pilot study for SMA may show if this intervention is safe, feasible and beneficial for children with SMA type III regarding to muscle function, functional abilities, postural control and bone mineral content and if there may be any related practical issues of this intervention to this population group. The outcomes also provide research evidence to clinicians if this intervention should be recommended to individuals of similar problems.

Objectives

The objective of the present pilot study is to investigate if the WBVT is able to improve the muscle strength, functional abilities, postural control, and bone mineral density in children/adolescents with SMA type III.

Null hypotheses to be tested:

1. That there is no statistically significant difference in gross motor function as measured using the North Star Ambulatory Assessment (NSAA) pre- and post-intervention.
2. That there is no statistically significant difference in functional abilities as measured using Pediatric Evaluation of Disability Inventory (PEDI) pre- and post-intervention.
3. That there is no statistically significant difference in postural control as measured using Segmental Assessment of Trunk Control (SATCo) pre- and post-intervention
4. That there is no statistically significant difference in sub-maximal exercise capacity as measured using the 2-minute walk test (2MWT) pre- and post-intervention.
5. That there is no statistically significant difference in body composition and bone mineral density as measured using dual X-ray absorptiometry (DXA) pre- and post-intervention.

Methodology

This feasibility study aims to examine the safety of the WBVT on children with type III SMA.

Children with type III SMA are targeted as they have adequate independence living in the community but still experience early fatigue during normal level of exercises due to the nature of their condition. They are at high risk of suffering from complications due to compromised mobility such as osteopenia, early loss of ambulation when compared with their healthy peers.

Intervention protocol

The WBVT will be performed on the Galileo™ Med L Plus (Novotech Medical GmbH) with the study participants standing with both knees flexed at least 20 degrees. The vibration frequency and duration will be increased over 5 days to the maximum of 3 minutes of 24 to 25 Hz with a peak to peak amplitude of 4mm. The participants of the intervention group will undergo the WBVT 1 session per day, 3 days per week for 4 weeks. The whole WBVT session will last 18 minutes with 9 minutes of vibration. This intervention regime is based on the recommended dosage to improve bone mineral density in children with physical disabilities in a systematic review on previous relevant literature (Matute-Llorente et al 2014). The intervention regime is as follows:

Day	Vibration 1	Rest 1	Vibration 2	Rest 2	Vibration 3	Rest 3
1st	1 min; 12Hz	3 min	1 min; 12Hz	3 min	1 min; 15Hz	3 min
2nd	1 min; 15Hz	3 min	1 min; 15Hz	3 min	2 min; 15Hz	3 min
3th	2 min; 15Hz	3 min	3 min; 15Hz	3 min	3 min; 15Hz	3 min
4th	2 min; 24-25Hz	3 min	2 min; 24-25Hz	3 min	2 min; 24-25Hz	3 min
>5th	3 min; 24-25Hz	3 min	3 min; 24-25Hz	3 min	3 min; 24-25Hz	3 min

The participants will perform mini-squats (knee flexion from 20 to 40 degrees) during Vibrations 1 and 3 and weight-shifting between right and left legs during Vibration 2 on the vibration platform under the supervision of a research assistant, who will be trained by the PI prior to the commencement of the study. All treatment sessions will be conducted at the Hong Kong Polytechnic University Rehabilitation Clinic as most of children and adolescents with SMA study in main-stream schools in Hong Kong.

Participants:

10 children with type III SMA aged from 6 to 18 years will be recruited. The age range is extended aiming to increase the number of recruitment due to the rarity of the condition. All participants will continue their usual intervention regime, if any, during the study period. They are strongly encouraged not to participate any activities that may involve any total body vibration during the study period.

Inclusion criteria:

To be included in the study, children must:

1. Be able to stand on the vibration platform without support;
2. Be able to undertake clinical examination and DXA evaluation; and
3. Informed consent by the participant’s parent/ guardian.

Exclusion criteria:

1. There is a history of fracture within 8 weeks of enrolment of the present study and acute thrombosis, muscle or tendon inflammation, renal stones, discopathy or arthritis as reported by

their parent/ guardian.

2. There is a history of using any of the following medications, regardless of dose, for at least 1 month, within 3 months of enrolment into the present study: anabolic agents or growth hormone.

Outcome measures:

Assessments will be performed at baseline and after 4 weeks of the intervention. All outcome measures will be conducted on all study children, unless specified to children with specific diagnoses. They include:

1. Muscle strength

a) hand-held dynamometer will be used to measure muscle strength in hip flexors, hip extensors, hip abductors, knee extensors, knee flexors, ankle plantarflexors and dorsiflexors in standardised muscle testing positions (Clarkson and Gilewich 2000). Muscle strength will be reported in kilograms.

2. Functional abilities

a) North Star Ambulatory Assessment (NSAA) will be used to examine the gross motor function of the participants (Mayhew et al 2011, Scott et al 2012).

b) 2-minute walk test (2MWT) will be used to assess submaximal exercise capacity (Pin 2014, Pin and Choi 2016). Distance covered in 2MWT will be measured by a distance-measuring trundle wheel in metres.

c) Range of movements in hip flexion, extension and abduction, knee flexion and extensions and ankle dorsiflexion and plantarflexion will be measured in standardised positions (Clarkson and Gilewich 2000).

d) Segmental Assessment of Trunk Control (SATCo) to assess the segment trunk control (Butler et al 2010).

e) Pediatric Evaluation of Disability Inventory (PEDI) (Haley et al 1992) to assess functional capacities in the domains of daily activities, mobility and social/cognitive function. A validated Chinese version will be used (Chen et al 2009).

3. Bone mineral density

a) Dual Energy X-ray Absorptiometry (DXA)- bone mineral content (BMC) and areal bone mineral density (aBMD) of the distal femur and total body will be measured. *Only if* it is not feasible to obtain the BMC and aBMD of the femur, BMD of the lumbar spine will be used. The effective radiation dose for these DXA studies will be <2 microSv, which is a very minimal dose of radiation (Houlihan and Stevenson 2009). All participants will have DXA done in a private service as bone density examination is not routine for the children with motor disabilities in Hong Kong.

b) Anthropometry at baseline and 4 weeks including standing height and weight. Body mass index (BMI) will be calculated and converted into a z-score.

4. Parental satisfaction

a) Parental/ participant questionnaire to record present medications of their children, satisfaction or comments on the intervention regime by children/ parents of the intervention group.

b) Visual analogue scale of 0 to 10, in which 0 means no pain and 10 as extreme pain to assess pain or discomfort at rest and if any, pain or discomfort associated with the intervention as reported by the children and/or parents.

c) A log of compliance and comments during the intervention.

Statistical analysis plan

Due to the small sample size, non-parametric tests will be used to analyse the results. All results will be reported in means and standard deviations. Wilcoxon Signed test will be used to

compare all the outcome measures listed above (no. 1 to 3) before and after the intervention. Results of outcome measure no. 4 listed above will be reported in descriptive terms for the comments from the parents and/or from the participants and compliance/ comments during the intervention and Wilcoxon Signed test will also be used to compared the visual analogue score of discomfort before and after the intervention.