Effect of whole body vibration therapy on functional abilities in children and young adults with moderate severity of cerebral palsy- a pilot study

The following pages include:

1. Intervention protocol of the whole body vibration therapy to the study participants; and
2. Statistical methods to analyze the results
3. Ethics approval

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Study proposal	
Project Title :	Effect of whole body vibration therapy on functional abilities in children and young adults with moderate severity of cerebral palsy- a pilot study.
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Project Objectives :

Osteopenia is common in children with cerebral palsy (CP) due to poor bone growth and muscle disuse and the problem extends to their adulthood. These children and young adults with CP, especially those with moderate physical disabilities, are unable to perform the required amount of exercise to improve their bone health as their typically developing counterparts. It has been demonstrated that strong bones or good bone health are related to muscle contractions during normal movements and regular exercises. As a result, non-traumatic fractures and bone pain are common in individuals with moderate severity of CP. Whole body vibration therapy (WBVT) has been recently proven to improve bone health and muscle function in healthy adults and post-menopausal women. It has been postulated that the vibration can stimulate the muscle spindles and elicit consistent muscle contractions. This would be a great advantage to the individuals with physical disabilities, who have limited movements and control in their body and prevent them to perform regular exercises as the normal individuals. Among the research of the WBVT for children with CP, promising results have been shown on gross motor function, balance and muscle strength for children with mild disability. Among these published studies, the vibration protocols required the study participants to perform simple exercises on the vibration platform. Very limited studies have been conducted on children and young adults with moderate CP. At present, we do not know if the effect of WBVT on this population group would be similar to those with mild CP in terms of their gross motor function and balance, because the moderate group is greatly compromised in their mobility and extent of regular exercises when compared with the normal population and those with mild CP. In addition, we do not know if static standing on the vibration platform would have similar effects on the gross motor function as doing simple exercises on the vibration platform.

This pilot study aims to examine the effect of WBVT on children and young adults with moderate severity of CP. A convenience sample of 5 pre-puberty children aged between 6 to 14 years and 5 young adults aged between 18 to 40 years with moderate CP, i.e. Gross Motor Function Classification System, GMFCS level III or IV, will be recruited to systematically investigate the effects of WBVT on their functional abilities. Individuals with GMFCS level III mobilise with hand-held mobility devices such as crutches or walking frames. Individuals of levels IV have very limited functional mobility and are mostly limited to an indoor environment.

Inclusion criteria:

1. Aged 6 to 14 years or 18 to 40 years
2. Have a diagnosis of cerebral palsy with GMFCS levels III or IV
3. Be able to stand for 3 minutes independently or with own hand support on rails
4. Be able to follow simple instructions
5. Be able to undertake clinical examination; and
6. 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. Women during pregnancy
3. Metal implants in their spine or lower limbs

The children and young adults will receive the WBVT when standing still on a vibration platform of 20 Hertz and a peak-to-peak amplitude of 2 mm: sessions will be 18 minutes in length, 4 days per week for 4 weeks. Assessments will be performed at baseline and at completion of the intervention to examine the

functional abilities of these children and young adults. The vibration frequency, duration and amplitude will be progressively increased over 2 weeks to the maximum of 3 minutes of 20 Hz with a peak-to-peak amplitude of 2mm. The intervention regime is as follows:

Day	**Vibration 1**	**Rest 1**	**Vibration 2**	**Rest 2**	**Vibration 3**	**Rest 3**
1st	1 min; 12Hz, 1mm	3 min	1 min; 12Hz, 1mm	3 min	1 min; 15Hz, 1mm	3 min
2nd	1 min; 15Hz, 1mm	3 min	1 min; 15Hz, 1mm	3 min	2 min; 15Hz, 1mm	3 min
3th	2 min; 15Hz, 1mm	3 min	3 min; 15Hz, 1mm	3 min	3 min; 15Hz, 1mm	3 min
4th	2 min; 18Hz, 1mm	3 min	2 min; 18Hz, 1mm	3 min	2 min; 18Hz, 1mm	3 min
5th	3 min; 20Hz, 1mm	3 min	3 min; 20Hz, 1mm	3 min	3 min; 20Hz, 1mm	3 min
6th	3 min; 20Hz, 1mm	3 min	3 min; 20Hz, 2mm	3 min	3 min; 20Hz, 2mm	3 min
>7th	3 min; 20Hz, 2mm	3 min	3 min; 20Hz, 2mm	3 min	3 min; 20Hz, 2mm	3 min

The outcome measures comprise:
1. Gross Motor Function Measure (GMFM-66) item set to assess the gross motor function of study participants. Raw scores will be reported.
2. 2-minute walk test (2MWT) to assess submaximal exercise capacity of the study participants by measuring the distance covered in 2 minutes using a distance-measuring trundle wheel.
3. A validated Chinese version of the Pediatric Evaluation of Disability Inventory (PEDI) to assess functional capacities in the domains of daily activities, mobility and social/cognitive function.
4. Timed up and go test to assess balance and functional mobility of the study participants
5. Parental/ participant questionnaire to record satisfaction or comments on the intervention regime by children/ young adults/ parents of the intervention group.
6. Visual analogue scale of 0 to 10, in which 0 means no discomfort and 10 as extreme discomfort to assess discomfort, if any, associated with the intervention as reported by the study participants and/or by their carers' proxy

Analysis of data/ statistics:
Results will be presented as means, standard deviations and standard errors of measurement. Due to the present small sample size, non-parametric analyses would be conducted. Wilcoxon Sign test will be used to compare the outcome measures before and after the intervention for outcome measures #1 to #4 mentioned above. The feedback from the participants and/or their parents would be summarized, if any.

Significance of present proposal:
If the WBVT is found to be effective in improving BMD and functional abilities at the conclusion of the present study, the participants in the control group would be offered the same intervention regime as the intervention group upon study completion.The outcomes of this pilot study will show if this intervention is beneficial for children and young adults with moderate CP with respect to their functional abilities, and if there may be any related practical issues of this intervention to this population group. The outcomes also provide preliminary evidence to clinicians if this intervention is effective to improve functional abilities of children and young adults with moderate severity of CP and provide preliminary data to calculate sample sizes for future studies.