



Effectiveness of a Nintendo Wii balance board exercise programme on standing balance of children with cerebral palsy: A randomised clinical trial protocol



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ABSTRACT

Background: Patients with cerebral palsy (CP) typically receive limited physical therapy services. However, the Nintendo Wii system offers a simple and affordable mode of virtual reality therapy. There are no clinical trials assessing the Nintendo Wii balance board for improving standing balance in CP.

Methods: This randomised clinical trial will evaluate the effectiveness of an 18-session/six-week protocol using Wii therapy (W-t) compared with conventional therapy (C-t) in Chilean CP patients. The C-t group will perform the typical exercises prescribed by physical therapists for 40 min each session. W-t will consist of a virtual reality training session using the Nintendo Wii balance board console for 30 min each session. The primary outcome variable is the area of centre-of-pressure (CoP) sway (CoP_{Sway}). The secondary outcomes are the standard deviation (SD_{ML}; SD_{AP}) and velocity (V_{ML}; V_{AP}) of CoP in the ML and AP directions. For a mean difference of 21.5 cm² (CoP_{Sway}) between the groups, we required a minimum of 16 participants in each group. Data will be collected at baseline (week 0), during the study (weeks 2 and 4), at the end of the study (week 6), and during the follow-up (weeks 8 and 10). Measurements of postural control during quiet standing for both groups will be assessed on a force platform AMTI OR67.

Discussion: This is the first trial that measures and compares the effects of a Nintendo Wii Balance Board exercise programme on standing balance in children with cerebral palsy compared to conventional therapy.

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1. Introduction

Cerebral palsy (CP) is the most common condition treated by therapists and rehabilitators in infant neurological units, and is the most common cause of motor disability in children and adolescents [1,2]. In the last years, CP has shown signs of increasing in developed countries, with a prevalence of 2.11 per 1000 live births [3]. Many forms of CP have been defined, but spastic hemiplegia (SHE) and diplegia (SDI) are the most prevalent [1,4]. Both forms of CP present motor alterations, such as deficient postural control during

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standing balance, which directly impacts day-to-day functional activities [5,6].

Patients with SDI have a higher sway and area of centre-of-pressure (CoP_{Sway}), indicating that these individuals have a poorer standing postural balance than do hemiplegics [5,6]. In addition, patients with SDI show impairment of postural balance in the M-L axis of movement while SHE in the A-P axis [5,6]. Postural control during standing balance depends on sensory input (visual, vestibular and proprioceptive) and can be disrupted by perturbations, pathology, medications, alcohol consumption, and the ageing process [7,8].

Children and adolescents with CP typically receive limited physical therapy services. Repetition, sensory feedback, and high-intensity physical therapy programmes are necessary to optimise motor learning [9]. The main reason for providing postural balance rehabilitation programmes during childhood and adolescence is the high plasticity against multisensory stimulation environments of the central nervous system. It is important to note that neural maturity of sensory systems responsible for control of postural balance is sequential and dependent on age, reaching fully maturing at 15 and 16 years of age [10,11].

Virtual environments created by software are characterised as artificial functional spaces of multi-sensory interaction, with a motivational purpose, and are easy to manipulate [12]. A virtual reality interface device of low economic cost generates greater accessibility and transferability to patients with CP at neurological care centres. The Nintendo Wii system offers a simple and affordable mode of virtual reality therapy [13,14].

The Nintendo Wii and its peripheral balance board have been proposed as a training tool to improve standing balance in the elderly, adults with total knee replacements, post-stroke patients, and patients with Parkinson's disease [15–19]. Evidence in the field of CP regarding the effectiveness of a systemic exercise programme (intensity, frequency, and duration) for standing balance training and guidance (physiotherapists) with the Nintendo Wii system is limited. Three weeks of interactive video gaming with the Nintendo Wii system improved balanced control in 14 children with spastic hemiplegic CP [19], and 12 weeks of training using the Nintendo Wii and balance board improved balance functions in 14 patients with CP: seven diplegic, five hemiplegic, and two dyskinetic [20]. Despite the above, research about the effects of the Nintendo Wii on postural balance in children with CP using a force platform is scarce [21]. Currently, there are no reports of clinical trials that used the Nintendo Wii balance board to improve standing balance in CP, which is directly associated with functional skills that impact the daily lives of children and adolescents with CP.

2. Objective and hypotheses

The objective of this study is to examine the effectiveness of two therapy programmes, the Wii therapy (W-t) with Nintendo Wii balance board and conventional physical therapy (C-t), on the performance of standing balance in children according to the type of CP (SHE or SDI), and the programme effects over time.

The primary hypothesis is that W-t would increase the performance of standing balance compared with C-t, at the end of week 6. Secondly, it is hypothesised that W-t would improve standing balance, depending on the type of CP.

3. Method

3.1. Ethical considerations

The trial adheres to the Declaration of Helsinki and the Chilean laws of rights and duties of the patient and research in humans.

Ethical approval was obtained from the Bioethics Committee of the University of Talca (Ref. No. 00068). This study was registered with the Brazilian Registry of Clinical Trials (RBR-3sc9zc). Written informed consent (Appendix A) will be obtained from parents and participants over 10-years-old and verbal assent will be obtained from younger children.

3.2. Trial design

A two-arm, matched-pairs (type of CP and age), parallel-groups, randomised, controlled clinical trial will be carried out to assess the effectiveness of a virtual reality-based exercise protocol using W-t compared with C-t for six weeks of training and four weeks of follow-up in participants with diplegic and spastic hemiplegic CP (Fig. 1). Therapies will be performed in the rehabilitation centre, and patients will be evaluated at the Human Motor Control Laboratory, Universidad de Talca, Talca, Chile.

3.3. Participants

Children and adolescents with congenital hemiplegic and spastic diplegic CP will be recruited from a rehabilitation centre in Talca that receives outpatients with neurological disorders from various locations in central Chile.

3.3.1. Eligibility criteria

The study's inclusion criteria are as follows: (1) levels I or II on the Gross Motor Function Classification System (GMFCS) [22] and on the Expanded and Revised Gross Motor Function Classification System (GMFCS-ER) [23]; (2) aged 7–14 years (both sexes); and (3) having mild cognitive impairment or no impairment. Patients with other neurological disorders, epilepsy, and associated impairments (visual and hearing, uncorrected) will be excluded. Participants with access to a Nintendo Wii at home will be also excluded. Generally, the patients from the rehabilitation centre will have little or no experience using the Nintendo Wii balance board. An experienced staff of health professionals, comprised of a physician and two physical therapists, will recruit participants according to the inclusion/exclusion criteria.

The participants will be randomised using SPSS 20.00 software (SPSS Inc., Armonk, NY, USA) and will be allocated to one of the branches of the study. The ID and randomised allocation will be concealed until the therapies and evaluations conclude. Personnel not directly involved in the study will perform the randomised assignment to the groups.

3.4. Sample size

The sample size was calculated in order to detect clinically relevant changes in the effects of postural balance of W-t and C-t at six weeks. Based on data from earlier studies [11,15], we propose a mean difference of 21.5 cm^2 (CoP_{Sway}) as the minimum difference required for substantial clinical relevance. We also considered a standard deviation of 20.68 cm^2 , a significance alpha level of 0.05, 80% statistical power, and with an allowance for 8% attrition, we required a minimum of 16 participants in each group (total sample of 32).

3.5. Procedure

This study will collect baseline data (week 0), as well as data during the study period (weeks 2 and 4), at the end of the study period (week 6) and during the follow-up phase (weeks 8 and 10). Week 0 data will correspond to evaluations made during the week prior to training.

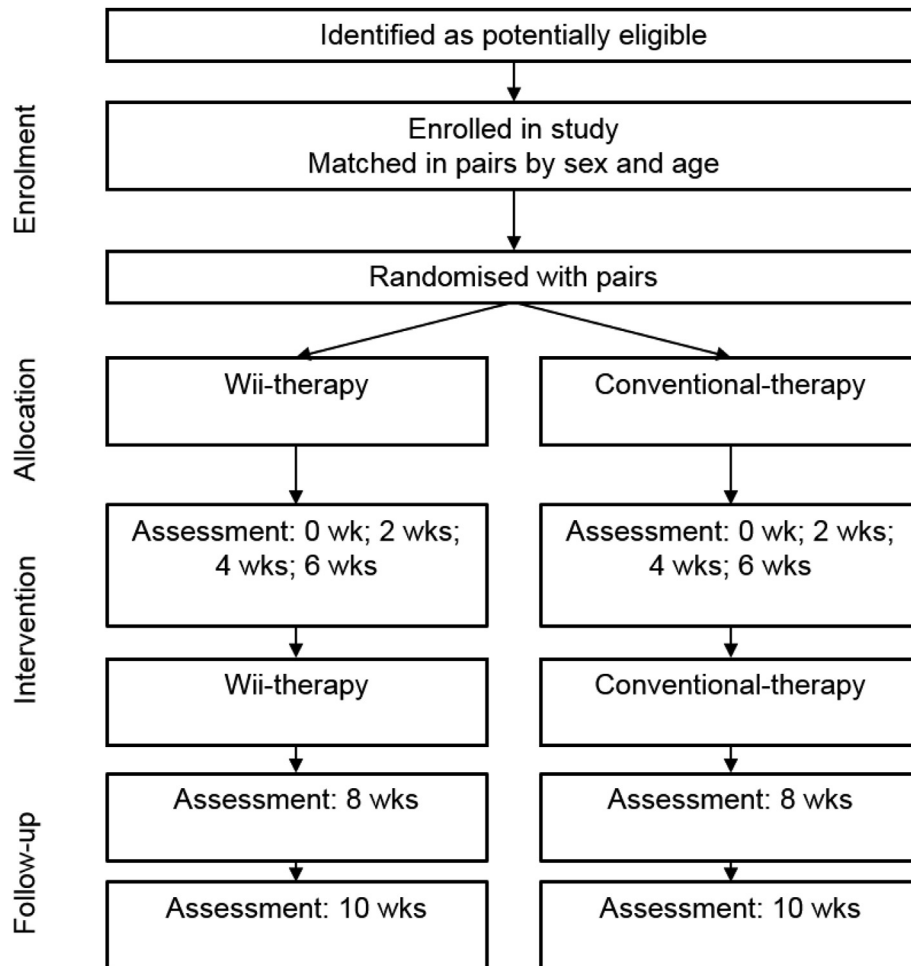


Fig. 1. Trial's flowchart.

All measurements will be performed at the same time under the same conditions and by the same evaluator. Measurements of postural control during quiet standing for both groups will be assessed on a force platform AMTI OR67 (Watertown, MA, USA). Each participant will be standing in a relaxed position with their arms at the sides of their body [24]. All participants will be assessed at zero weeks, two weeks, four weeks, six weeks, eight weeks and 10 weeks, and in two conditions: eyes open and eyes closed, for 30 s each. For the closed-eyes phase, participants will be provided with a mask to cover their eyes. Each condition will be repeated three times, randomly selecting only one record per condition.

3.6. Acquisition and processing

The AMTI NetForce software (Watertown, MA, USA) will be used for the acquisition of moments and forces in the X, Y and Z axes. These physical variables will then be used to obtain the CoP, which describes postural balance. A low-pass filter will be used with a cut-off frequency of 40 Hz and a sampling rate of 200 Hz. Data will be stored and recorded on a personal computer. CoP variables will be processed using Matlab r2012 (Mathworks Inc., Natick, MA, USA).

3.7. Intervention

Each therapy modality will include 18 total sessions, which will be provided at a frequency of three times per week for six weeks.

Each group will attend the respective exercise programme in separate rooms at the neurological centre [9:00–1:00pm and 3:00–6:00pm].

The C-t group will perform the typical exercises prescribed by physical therapists at the neurological centre for 40 min each session. These include stretching, flexibility, strengthening and balance exercises. W-t will consist of a virtual reality training session using the Nintendo Wii balance board console for 30 min each session. This programme is based on previous studies [15], that demonstrate the training of balance is in all three planes of motion [25].

The exercises will be guided by two physical therapists that are not employed by the neurological centre, and will be trained for three weeks. A physical therapist will work in the morning and another will work in the afternoon. The protocol has three series of exercises and activates postural balance in the three planes of motion: sagittal, frontal and transversal. The games – Snowboard, Penguin Slide and Super Hula Hoop – will be used for the first two series of exercises, and the yoga game will be used for the third series. In the first series of exercises, the children with CP stand with their arms and hands at their sides in a relaxed manner. In the second series of exercises, each game will be repeated in a standing position with their hands on their waists. Between the first and the second series of exercises, there will be a one to two minute break, where the children will sit on a chair until they had recovered. The third series of exercises will consist of keeping their posture as

relaxed as possible during the yoga game with their eyes open and then repeating it with their eyes closed. The children who have great difficulty accomplishing the snowboard game in three or four continuous sessions will use a more basic game, such as Run Plus or Heading Football, according to the patient's own adaptation.

3.8. Outcome measures

Postural balance is quantitatively represented by the displacement of the CoP, which is measured standing on force plate [24,26]. CoP variables have been shown to be sensitive in determining the performance of balance in young adults [27], patients with post-stroke hemiparesis [28], patients with Parkinson's disease [28,29] and children with CP [30–33].

3.8.1. Primary outcome

The primary outcome variable is the CoP_{Sway} , which is defined as the total trajectory that CoP makes in the mediolateral (ML) and anteroposterior (AP) directions. A high reliability for the CoP_{Sway} has been reported in young adults [27]. Bauer et al. [34] reported intraclass correlation reliability coefficients (ICC) > 0.9 for the oscillation CoP_{Sway} variable during narrow standing in a population of 30 elderly individuals. Our previous studies have suggested that the CoP_{Sway} variable best perceives differences in standing postural balance in people with CP [6,11].

3.8.2. Secondary outcomes

The secondary outcomes of CoP for this research will be standard deviation (SD_{ML} ; SD_{AP}) and velocity (V_{ML} ; V_{AP}) of CoP in the ML and AP directions. Standard deviation corresponds to the distribution of CoP displacement from the middle position during a time interval and velocity determines the speed of displacement of the CoP. Lin et al. [27] reported a reliability of 0.79 in young adults for the velocity of CoP during standing balance on a force platform.

3.9. Statistical analyses

Statistical analyses will be performed using SPSS 20.00 for Windows (SPSS Inc., Armonk, NY, USA). Descriptive statistics will be used to calculate the demographic and clinical characteristics of participants in the intervention and comparison groups (unpaired t-tests and χ^2 tests).

The Shapiro-Wilk and Levene tests will be used to measure the normality and homogeneity of the variance of all of the outcome measures. The Mann–Whitney test will be used to determine differences between the therapies. Friedman's one-way ANOVA with post-hoc pairwise comparisons (Wilcoxon signed ranks test) will be used to determine the effect over time for each type of therapy and subtypes of CP.

For all analyses, a p value of ≤ 0.05 will be considered statistically significant.

4. Discussion

The plausible mechanism that would explain improvements and changes in postural balance in CP is the sensory feedback provided by virtual reality interface devices, in this case by the Nintendo Wii Balance Board. Sensory feedback occurs via the multi-sensory environments generated during W-t. By using the balance board games, VR therapy trains the postural balance in a sequence of exercises in three planes of motion: sagittal, frontal and transverse. The repetition (that is the basis of plasticity) of movements during games requires patients to demonstrate continuous weight-shifting between feet and from the heel to toes, producing a sufficient mechanical stimulation to trigger the proprioceptors at this

level. Additionally, visual feedback has been postulated to improve balance in participants. The video game creates the perception that they can perform more complex activities, generating kinaesthetic movements, thus the proprioceptors in the lower limbs, upper limbs and the trunk are activated [35]. Such information ascends to the CNS (sensorimotor cortex) and descends through spinal cord, performing postural adjustments necessary to meet the demands of each individual [15].

A limitation of this project is the inclusion of children with and without mild levels intellectual disability, because will limit the generalisability of these results to other CP populations. Another limitation is the use of an open-label approach, but we have to consider that the measures are based on CoP, so the chance that patient will be biased is unlikely. Although each group of CP patients will be trained in different rooms to avoid contact between the groups, given the amount of time (months, years) that these children were enrolled at the neurological centre, they knew each other and could exchange information related to the type of therapy that they received.

For future research, exercise programmes with the Nintendo Wii that improve standing balance should also consider children with CP who have greater motor disabilities, such as GMFCS/GMFCS-ER levels III, IV and V.

In summary, this will be the first study assessing the effects of a six-week exercise programme using the Nintendo Wii balance board to improve standing balance in children and adolescents with CP compared to the effects of C-t. This trial will provide evidence on the effectiveness of the Nintendo Wii for improving standing balance in CP.

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Conflicts of interest

There are no conflicts of interest to disclose.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.conctc.2017.02.008>.

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