

ORIGINAL ARTICLE

The use of serial casting in the treatment of children with cerebral palsy: a study protocol

Raísa Marques de Sousa^{a,b,c}, Marisa de Paula Paro^{a,b,c}, Amanda Orasmo Simcsik^d, Marina Junqueira Airoidi^c, Beatriz Vieira dos Santos^c, Íbis Ariana Peña de Moraes^{d,e}, Helen Dawes^f, Carlos Bandeira de Mello Monteiro^{b,d}, Talita Dias da Silva^{a,d,f}



^aDepartamento de Medicina (Cardiologia), Universidade Federal de São Paulo (UNIFESP), São Paulo, Brazil;

^bGrupo de Pesquisa e Aplicações Tecnológicas em Reabilitação (PATER), Escola de Artes, Ciências e Humanidades, Universidade de São Paulo (EACH-USP), São Paulo, Brazil;

^cTherapies Centro de Reabilitação Intensiva, Campinas, São Paulo, Brazil;

^dPrograma de Pós-Graduação em Ciências da Reabilitação, Faculdade de Medicina da Universidade de São Paulo (FMUSP), São Paulo, Brazil;

^eMedical School, College of Medicine and Health, St Lukes Campus, University of Exeter;

^fFaculdade de Medicina, Universidade Cidade de São Paulo (UNICID), São Paulo, Brazil.

Corresponding author
amanda.simcsik@usp.br

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Abstract

Introduction: Cerebral Palsy (CP) is characterized by a disorder of posture and movement, commonly leading to disabling orthopedic alterations, including muscle shortening, especially in the lower limbs. Stretching methods, performed gradually, are necessary to delay the impairment in function from muscle shortening. The use of serial casting aims to promote proper alignment, and an ideal and stable support base, in addition to better bone and joint health, leading to better posture, mobility, muscle function, and, subsequently, increased fitness and health.

Objective: evaluate range of motion, postural control, and motor performance in children with CP, using serial casting, as well as to measure its effect on fitness through the autonomic nervous system (ANS).

Methods: Sixty children and adolescents with CP, of both sexes, 3 to 12 years of age, will be divided into three groups: Groups A, B, and C, with 20 individuals each. Group A will use serial casting, Group B will use the orthosis continuously (with removal only allowed for bathing), and Group C will use the orthosis in their daily routine. Range of motion of the ankle of first and second resistance levels (R1 and R2), gross motor function measure (GMFM), and balance (measured by BERG scale) will be used in the initial and final assessments, and after 6 months and one year of follow-up. Timed-up-and-go (TUG), load distribution (baropodometry), motor performance measured through a real basketball game and the virtual MoveHero game, analysis of body angulation with “mydartfish”, and cardiac autonomic modulation through heart rate variability will be assessed in three different situations: barefoot, with orthosis, and with casting.

Conclusion: Serial casting demonstrates the potential to produce positive results in the treatment of individuals with CP regarding better alignment, with consequent motor and autonomic improvement.

Keywords: Cerebral palsy, plaster casts, fiberglass casts, virtual reality exposure therapy, autonomic nervous system, muscle stretching exercises.

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Authors summary

Why was this study done?

The present study aims to evaluate the range of motion through the intervention with serial cast and its impacts on static and dynamic balance, functional activities and relate it to heart rate variability, thus evaluating the impacts that the intervention can cause by promoting a base ideal and stable support for children with CP.

What did the researchers do and find?

Analysis of children with CP divided into three groups. The groups were compared, and the effects of the serial cast intervention were analyzed, as well as its impact on postural control and repercussions on heart rate variability.

What do these findings mean?

Considering the serial casting, this technique has a potential to produce positive results in the treatment of individuals with CP regarding better alignment, with consequent motor and autonomic improvement.

Highlights

- Serial casting aims to promote proper alignment, an ideal and stable support base.
- Casting is a method used to reduce contracture due to spasticity.
- Serial casting involves the removal and reapplication of a cast at intervals.
- Protocol to analyze benefits with serial casting in individuals with cerebral palsy.
- We hypothesis children with plaster will improve performance and have benefits.

INTRODUCTION

Cerebral Palsy (CP) is defined as a group of movement and posture disorders causing activity limitation¹. Considering lower limb difficulty in CP, a systematic review of techniques aimed at lower limb function in children with CP concluded that the discharge of adequate weight in the lower limbs leads to improvement in bone mineral density^{1,2}. With better ankle positioning, people with CP can perform different tasks in daily life, such as standing and walking short and long distances, which can contribute to their activity and participation³. This leads to better cardiovascular functioning, preventing metabolic syndromes, which are a large concern when children with CP reach adulthood⁴.

According to Nordmark *et al.*⁵ one problem in the lower limbs that causes activity limitations and participation restrictions in individuals with CP is reduced range of motion, with values that tend to decrease with advancing age. Thus, an important target in rehabilitation programs to provide lower limb function is the inclusion of treatments to assist in maintaining range of motion.

Considering the insufficient evidence available on whether gradual and gentle stretching can contribute to changing the rehabilitation scenario about the prevention and treatment of lower limb muscle-tendon shortening and the importance of the quality of prolonged muscle alignment, serial casting has emerged in clinical practice, presenting promising results⁵. This method is based on the theory that muscles adapt to an imposed increase in length⁶. Some authors found a significant increase in passive ankle dorsiflexion following serial casting in groups of children and adults with and without neurological conditions⁷⁻⁹.

Serial casting is referred to as the application of two or more successive fiberglass or plaster casts to a particular joint, with efforts to increase passive range of motion (PROM) around a joint, by maintaining prolonged passive stretching in the submaximal or maximal range¹⁰⁻¹² which allows more opportunity for active ROM (AROM). Serial casting is effective for increasing the amplitude of passive ankle dorsiflexion and decreasing hypertonia in the lower limbs¹³.

A recent systematic review conducted by Novak *et al.*¹⁴ summarized the evidence from various interventions for children with CP. Although evidence was found to support the use of plastering the lower limbs to alter body structures, only low-quality evidence was reported showing a positive effect on reducing activity limitations according to the International Classification of Functionality model, Disability and Health (ICF)¹⁵. This highlights the importance of clinical trials with better methodological quality to improve the evidence on serial casting for improvement of skills to perform activities and increase participation.

Although some studies with serial casting have shown benefits in CP¹⁶ most studies used a combination of serial casting and botulinum toxin-A (BTX-A) injections¹⁷⁻¹⁹ with the objective of achieving benefits aided by the contribution of BTX-A. Therefore, it is important to investigate the effect of serial casting on the lower limbs alone with studies of good methodological quality¹³ since studies with treatments with botulinum toxin in animals found that these injections caused dramatic reductions in target muscle size and strength and were associated with greater intramuscular fat infiltration²⁰, in addition to which, there is a high cost for the treatment and need for hospital admission in children.

Considering the above, we designed a protocol of a randomized longitudinal clinical trial to analyze the benefits of the use of serial casting in individuals with cerebral palsy. Individuals with CP will be divided into three groups, with 20 children in each: Group A will participate in an intervention using serial casting; Group B will participate in an intervention using their own lower limb orthoses 24h per day; and Group C will participate in their usual rehabilitation intervention in daily life (with their orthoses with no specific time of use required). All individuals will be analyzed before and after the intervention using range of motion, distribution of weight unloading, posture, and performance in motor activities of static and dynamic balance, spasticity, standing tasks, and upper limb function in a standing position. In addition, the effects of the intervention on the autonomic nervous system will be

assessed (ANS), as some studies point to an alteration in the ANS, with a reduction in HRV in individuals with CP²¹.

We hypothesize that only individuals from groups A and B will present improvement in performance and other benefits after the protocol. However, the group with serial casting (A) will present greater improvement in increased ankle dorsiflexion PROM and reduced hypertonicity, as well as improved functional skills and ANS balance.

This, this is objective is evaluate range of motion, postural control, and motor performance in children with CP, using serial casting, as well as to measure its effect on fitness through the autonomic nervous system (ANS).

METHODS

Study Design

This is a protocol of a randomized longitudinal clinical trial, registered on Rebec – Registro Brasileiro de Ensaio Clínicos, RBR-5ynppq, Registration Date: September 23rd, 2020. This paper has been reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials – see table 1 and figure 1 (SPIRIT)²². This project was approved by the research ethics committee of the Federal University of São Paulo - UNIFESP; opinion number 4,013,566. CAAE: 30117820.5.0000.5505.

Sixty individuals with Cerebral Palsy (CP) will participate in this study. Researchers will contact the patients who attend the Therapies Centro de Reabilitação Intensiva - Campinas SP - Brazil. All participants will be required to present a free and informed consent form signed by their legal guardian, in addition to the term of free and informed assent signed by the child.

The sample size was calculated using statistical software (GPower 3.1.5) on the main outcome measure (*i.e.*, motor performance). Considering a power of 0.80; alpha of 0.05; and effect size of 0.65 (Cohen's *d*), the sample estimation indicated that 60 participants would be necessary (*i.e.*, 20 per group).

This study is in its first stage of recruitment. Participant recruitment started in September 2020 and is expected to end in December 2021. Study completion is estimated by March 2022.

Study Population and Eligibility Criteria

Inclusion Criteria

As inclusion criteria we considered children from 3 to 12 years of age, diagnosed with Cerebral Palsy, with Gross Motor Function Classification System (GMFCS) levels I, II, and III, who are able to understand simple commands and the previously presented tasks. Children will be required not to have undergone bone surgery and / or arthrodesis, applied botulinum toxin, or serial plaster in the previous six months, undergone muscle-tendon surgeries in the previous year, and undergone intensive treatment during the application of serial casting.

Exclusion Criteria

As exclusion criteria we will consider children who present pain with the use of serial casting, allergy to the material, medical complications, or abandonment of the protocol.

Withdrawal Criteria

Participants will be withdrawn from the study if they are not willing to continue or cannot be present on the day of the experiment. If they miss one session, they will be excluded. Our expectation is that very few patients will be lost during the process.

Randomization

Participants will be randomly allocated to one of the Groups A, B, or C with a 1:1:1 allocation defined by a website (randomization.com). After collecting the participant characteristics, immediately after randomization the age and motor function (GMFCS) will be compared between groups, and if the groups are not homogeneous, a new randomization will be performed. This protocol will be repeated until there is no difference between age and GMFCS between groups (we have always achieved homogeneous groups within a maximum of three randomization attempts).

Blinding

It is not possible to have blinding of either researchers or patients in this study, because group A (plaster) will receive the intervention through the construction of plastered boots, and therefore, it is necessary to evaluate the muscle shortening and range of motion of the ankle joint. The data will be archived in a computer without the access of principal researchers, only the researcher responsible for the analysis will have access to the data.

Procedures/Instruments/Assessments

Participants will be divided into three groups, A, B, and C, with 20 individuals in each: Group A will use serial plaster casting for one month (with changes every 10 days), Group B will use the orthosis full-time for one month, being only allowed to take it off to bathe, and Group C will be evaluated at the beginning and end of the month, without any specific guidance or intervention, using their orthosis freely as in their daily life. Assessments will be carried out before and after this one-month intervention (explained in the following sessions). Six months and one year after the end of the intervention, reassessments will be carried out, considered the follow-up period (table 1 and figure 1). An adverse event will be defined as any untoward occurrence in a subject (such as pain, any kind of damage to the plaster, and any allergies that are pre-existing or come from the plaster). Any modifications to the protocol which could impact on the conduct of the study or potential benefits to the patient, or that may affect patient safety, including changes in study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol.

Data category	Trial information
Primary registry and trial identifying number	ReBec - Registro Brasileiro de Ensaios Clinicos, ID: RBR-5ynppq
Date of registration in primary registry	September 23rd, 2020
Secondary identifying numbers	Ethical Committee of the Federal University of São Paulo, under the number CAAE: 30117820.5.0000.5505
Source(s) of monetary or material support	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior–Brasil (CAPES)
Primary sponsor	Federal University of Sao Paulo – UNIFESP
Secondary sponsor(s)	NA
Contact for public queries	TDS, CBMM
Contact for scientific queries	TDS, CBMM

Figure 1: SPIRIT: Description of the study protocol, schedule of enrolment, interventions, and assessments. *List of specific timepoints in this row.

Table 1: Trial characteristics based on WHO Trial Registration Data Set

Data category	Trial information
Primary registry and trial identifying number	ReBec - Registro Brasileiro de Ensaios Clinicos, ID: RBR-5ynppq
Date of registration in primary registry	September 23rd, 2020
Secondary identifying numbers	Ethical Committee of the Federal University of São Paulo, under the number CAAE: 30117820.5.0000.5505
Source(s) of monetary or material support	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior–Brasil (CAPES)
Primary sponsor	Federal University of Sao Paulo – UNIFESP
Secondary sponsor(s)	NA
Contact for public queries	TDS, CBMM
Contact for scientific queries	TDS, CBMM
Public title	The use of serial casting in the treatment of children with cerebral palsy: A study Protocol
Scientific title	The use of serial casting in the treatment of children with cerebral palsy: A study Protocol
Country of recruitment	Brazil
Health condition(s) or problem(s) studied	Cerebral Palsy, Spasticity
Interventions	Group A will use serial plaster casting for one month (with changes every 10 days), Group B will use the orthosis full-time for one month, being only allowed to take it off to bathe, and Group C will be evaluated at the beginning and end of the month, without any specific guidance or intervention, using their orthosis freely as in their daily life.
Key inclusion and exclusion criteria	As inclusion criteria we considered children from 3 to 12 years of age, diagnosed with Cerebral Palsy, with Gross Motor Function Classification System (GMFCS) levels I, II, and III, who are able to understand simple commands and the previously presented tasks. Children will be required not to have undergone bone surgery and / or arthrodesis, applied botulinum toxin, or serial plaster in the previous six months, undergone muscle-tendon surgeries in the previous year, and undergone intensive treatment during the application of serial casting. As exclusion criteria we will consider children who present pain with the use of serial casting, allergy to the material, medical complications, or abandonment of the protocol.
Study type	Interventional
Allocation:	randomized
Masking:	randomization and data analyst
Assignment:	NA
Primary purpose:	treatment
Date of first enrolment	May 2022
Target sample size	60
Recruitment status	Recruiting
Primary outcome(s)	Functional capacity improvement
Key secondary outcome(s)	HRV improvement

For all participants, the evaluation protocol will have the following sequence: parents will fill out a questionnaire with epidemiological characteristics, GMFCS level, main form of mobility, and medical history of the children, after which the rating scales (GMFM, BERG, TUG) will be applied, as well as the image of the child standing in a lateral view, timed static balance time with bipedal support, and the measures of range of motion of the ankles. For group C the parents will be asked about the amount of time each child uses the orthosis per day.

Additionally, for the virtual reality assessment, the coincident timing task will be performed with a short-term motor learning protocol. After 15 minutes without contact with the task, during which the real basketball game is performed (with a total of 10 shots) and the graphic analysis of weight distribution is collected, the participants will play the virtual game. HRV will be recorded during 10 minutes of rest sitting in a comfortable chair or their own wheelchair, for a further 10 minutes during the real task, for 10 minutes during the virtual task, and for 10 more minutes during recovery. The evaluation part of the protocol will take around 1 hour and 30 minutes in total. The entire protocol will be applied with the child barefoot and wearing their orthosis. For the children in group A (plaster), the application of the plastered boot after completion of the protocol will also be analyzed. Plaster application is described in the Methods - item 11. The participant's files and personal data will be stored in numerical order in a secure and accessible place in the location of the study. Participant's files will be maintained in storage for a period of 3 years after completion of the study and study information will not be released outside the study without the written permission of the participant. The patients enrolled in the study will be covered by indemnity for any possible negligent harm by the researchers.

Outcomes

Primary

To assess the effect of serial casting on the postural control of children with CP we will evaluate the range of motion.

Assessment of Primary outcome

To verify the effect of the serial casting, we will evaluate the range of motion, which provides information on muscle shortening.

Secondary

The weight distribution in the bipedal posture, time in the standing posture, and functional abilities will be measured in order to verify possible improvements in structure, capacity to perform activities, gross motor functions, and balance.

We will observe changes in ANS through Heart Rate Variability after serial casting application at rest and its adaptation during real and virtual tasks in children with CP, as well as their recovery from these tasks.

Assessment of Secondary outcome

The distribution of weight in the bipedal posture and time in the standing posture can reveal whether there

is an improvement in posture due to the possible gain obtained through the use of serial casting. Gross motor function and balance assessments will provide data on the motor capacity of these individuals after the intervention, pointing to possible improvements in their motor performance. These improvements can impact functional capacity, which will also be assessed by the static balance time, basketball game, and gait speed in the TUG test.

ANS will be verified during the intervention through the analysis of Heart Rate Variability (HRV). Some studies point to ANS alteration, with reduced HRV in individuals with CP^{21,23}. HRV represents autonomic function, and short-term HRV measurement has been used to assess the sympathetic system and parasympathetic modulation of heart rate. Low HRV is often an indicator of abnormal and insufficient ANS adaptation, which may indicate the presence of physiological malfunction in the individual²⁴ and is associated with an increased risk of cardiac events²⁵.

All children will participate in an initial assessment, including completion of a form with personal characteristics such as age, height, and weight, GMFCS level classification, and the use of a walking aid device, followed by the assessments detailed below in this specific order:

1) Range of Motion: One way to measure range of motion in the joints is through measurements of Resistance-1 (R1) and Resistance-2 (R2), where R1 is considered the first resistance to passive ankle dorsiflexion movement, performed with the joint in congruence, and R2 is the maximum possible range of motion performed passively. These measures can be reapplied at different times, and will be used in this study to determine the range of motion of the ankle joint at the beginning of the protocol with serial plaster casting²⁶.

2) Standardized photos in the orthostatic position: We will use a checkered background, with a distance mark of the feet on the floor. The child will be photographed in the front right side and back views. The cell phone used to take the photos will be placed 1.60 m away from the checkered background and 50 cm from the ground; if support is needed, it can be supported in exactly the same place (numbered support) before and after the placement of the plaster. The photos will be analyzed through the application "My dartfish", where it is possible to mark the angle between trunk and lower limbs in the orthostatic position. The right-side view of all participants will be used.

3) Dimensions D and E of the Gross Motor Function Measurement (GMFM);

4) Graphical analysis of the weight-bearing distribution and bipedal support with the child on an electronic baropodometer;

5) Timed static balance time with bipedal support on marks on the floor;

6) Motor performance in a real task (associated with the use of the heart rate variability monitor), through a basketball game, where 10 attempts will be allowed and hits and falls will be analyzed. The basketball backboard will be placed at the child's height at a distance of 1.5 meters from the child.

7) Activities in a virtual environment (associated

with the heart rate variability analysis, better explained in item 10), using MoveHero software, developed at the School of Arts, Sciences and Humanities, University of São Paulo²⁷. The game features spheres that fall, in four imaginary columns on the computer screen, to the rhythm of a song chosen by the researcher, for 5 minutes. The task is not to let the spheres fall to the bottom of the screen. However, the spheres can only be touched when they reach four circles placed in parallel (at two height levels), two on the left and two on the right of the participant. The game captures the participant's movements through a webcam. No physical contact is required to perform the task, as the participant moves their upper limbs at a distance of 0.5 - 1

meter from the computer screen. The participant must wait for the balls to fall until they start to overlap one of the target circles (moment when they change color to green). Therefore, the game requires the participant to have a strategy of anticipating the movement to reach the spheres within the circles. The game offers hit feedback through a number (+1) that appears next to the sphere that has been successfully hit within the target. In addition, the total score is visible in the upper left corner of the screen, with 10 points for each hit. Figure 2 represents a participant playing the virtual game barefoot, with the orthosis, and with the plaster casting.

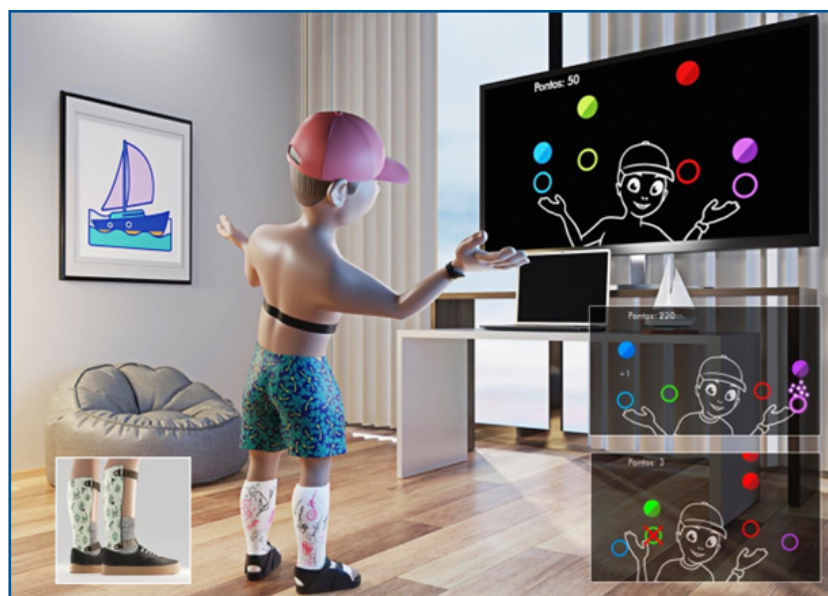


Figure 2: Graphic representation of MoveHero

8) Application of the Timed Up and Go (TUG), which is a quick and practical test that has been widely used in clinical practice as an outcome measure to assess basic ambulatory or functional mobility, or dynamic balance in adults²⁸⁻³³ with adaptation for its use in children³⁴. In this test, children are asked to touch a target on a wall, and the instructions are repeated during the test. An armless stool will be selected from the children's environment with the height of the seat such that the child's knee angle is at 90° flexion with feet flat on the floor. The child will be asked to walk naturally without providing qualitative guidance (for example, "walk as normally as possible") to ensure normal performance³⁵. The stopwatch will be started when the child leaves the seat and turned off when the child touches the seat, in order to measure only the travel time. The TUG (modified version) can be used reliably in children as young as 3 years without any motor impairment, and is also valid for children and young people with motor disabilities. This test integrates transitions and walking skills, and provides a measure of capacity that is meaningful to most people³⁶. The test will be stopped if the children show any changes in motor behavior, such as jumping or falling.

9) Application of the BERG balance scale - pediatric version: To assess the functional balance of the children, the Pediatric Balance scale (PBS) will be used³⁷. This is a validated assessment instrument able to evaluate functional balance in children with motor disorders, adapted from the

Berg Balance Scale (BBS). The PBS can be used to assess balance in children with CP or other motor disabilities³⁷ through simple materials and practical activities that outline the important points to be worked on in rehabilitation and to monitor progress within a therapeutic program³⁸. The scale is composed of 14 activities ordered in an increasing level of difficulty, when compared to that applied to adults and older adults, and with adaptation in the time spent in different postures. The total score of the scale is the sum of all scores obtained during the 14 exercises and can vary from 0 to 56, with the highest scores indicating better skills in controlling balance³⁷.

10) Analysis of heart rate variability: HRV is a simple, reliable, inexpensive and non-invasive measure to capture autonomic impulses. The widespread use and cost-effectiveness of the technique and the ease of data acquisition make HRV an appropriate choice for the interpretation of autonomic functioning and a promising clinical tool to assess and identify physiological changes. Fluctuations in HRV patterns provide an early and sensitive diagnosis of the human body's physiological behavior and the individual's health status³⁹. Thus, we will evaluate HRV as a control variable, in resting conditions, during the real and virtual tasks, and during recovery after the tasks. All heart rate records will be performed using a cardiofrequencymeter (Polar H10 chest strip and Elite HRV application). HRV will be recorded with the

individual seated at rest for 10 minutes, during the real task for 10 minutes, during the MoveHero task for 10 minutes, and for 10 minutes during recovery. For analysis of HRV data, at least 256 consecutive RR intervals will be used. Kubios HRV software will be used to assess HRV.

11) Application of plaster (only if the individual is included in Group A).

This evaluation will be performed under normal conditions, that is, without the use of orthoses or any assisted technology. After this evaluation, the plaster cast will be made individually, consisting of:

- First a layer of protection of bony prominences, with the child seated, where we will use a foam sheet 0.5 cm thick, density 23, to make the necessary cutouts for each child;

- At each end a layer of synthetic cotton will be placed for the plaster;

- Tubular mesh will cover the entire area to be cast;

- The child will be laid in a prone position on a stretcher, comfortably, with one of the lower limbs in knee flexion at 90 degrees and with the foot in a neutral position, respecting the R1 of each child;

- The placement of powder plaster will begin, covering the child's entire foot up to the calf, molding the medial arch of the child's feet at this stage;

- The second layer of plaster will be made with "fiberglass", or synthetic plaster, covering the entire plastered end, from the toes to two fingers below the popliteal fossa;

- When the plaster is dry, and with the child seated, the necessary adjustments will be made with shims and chocks to reach the best and most stable support base for that child;

At the end of making and adjusting the plaster, all evaluation tests will be repeated for further comparisons of the data.

Data Analysis

The clinical analysis of each individual will be collected under three conditions; condition 1: barefoot child; condition 2: using orthosis; and condition 3: using plaster cast (this third condition only for group A).

As dependent variables we will consider the scores from the scales, performance data from the real and virtual tasks, and Heart Rate Variability indices. If the data meet the assumptions for the use of parametric analysis, ANOVA will be performed to identify intra and inter-group differences. These, if any, will be detected using the post hoc Tukey-HSD test. If the normality assumptions are not met, non-parametric analyses will be undertaken to identify and locate the differences; a Friedman and post hoc Wilcoxon test (for within groups) and a Kruskal-Wallis and post hoc Mann-Whitney U-test (between groups). For the between-groups analysis of HRV indices, MANOVA will be used, with repeated measures for within groups analyses (for evaluations and follow-up) or Mann-Whitney for intergroup analyses and Friedman for intragroup analyses. A significance level of 0.05 (5%) will be defined; all intervals constructed throughout the work will have 95% statistical confidence. The statistical

program SPSS (Statistical Package for Social Sciences), version 26.0 will be used.

No interim-analysis will be performed. While the trial is ongoing, only the researchers that collect the data will have access to the data. The principal investigator will have the ultimate authority to stop and modify the trial. Every attempt will be made to reduce to an absolute minimum the interval between the completion of data collection and the release of the study results. The study results will be released to the participating researchers, patients, and the general health community.

Ethical and Legal Aspects of the Research

The studies involving human participants were reviewed and approved by the research ethics committee of the Federal University of São Paulo - UNIFESP; opinion number 4,013,566. CAAE: 30117820.5.0000.5505. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin. It is planned that any important protocol modifications will be communicated to relevant parties. A researcher will be responsible to protect personal information about potential and enrolled participants that will be collected, this researcher will have access to the data only in his computer to protect confidentiality before, during, and after the trial. A researcher will be responsible to obtain informed consent or assent from potential trial participants or authorised surrogates through a term of consent with his signature, one copy to the patient or his responsible and one to the researcher.

DISCUSSION

Considering the management of contracture in patients with CP, serial casting and injection with botulinum toxin have been used as effective treatment techniques to reduce ankle contractures⁴⁰.

According to Booth *et al.*⁴⁰, casting is an efficient method used to reduce contracture due to spasticity. Compared to a single fixed cast, serial casting involves the removal and reapplication of a cast at certain intervals. Each time the cast is changed, the ankle is positioned in greater dorsiflexion. Currently most of the available research associates serial casting with Botox, which led us to think about the effect of the isolated use of serial casting, aiming at the prolonged stretching of posterior chain muscles of lower limbs, considering that this would reduce costs for families and invasive procedures for children with CP.

Therefore, the current work aims to investigate the promising isolated action of serial casting in children with CP.

If the hypothesis of this study is accepted, the results could positively influence rehabilitation programs and provide answers to five important topics:

- 1) The possibility of obtaining satisfactory results in gain in range of motion from serial plaster casting performed without being associated with the application of botulinum toxin;

- 2) Post-serial casting effects on the gross motor function of these individuals;

- 3) Effects of the use of serial casting on weight distribution and static and dynamic postural control;

4) Improvement in functional abilities, such as gait speed in children undergoing intervention with serial casting; and

5) Changes in the ANS in children using serial casting, as well as in the recovery from these tasks.

Thus, in addition to aiming at improvements in body structure and function, such as gains in range of motion and better load distribution in the orthostatic posture, the results of this study could impact the activity and participation of CP individuals, reaching personal goals that can be met through better postural control, greater gait speed, and increased balance strategies. It will also be possible to assess the duration of the serial casting effect through the evaluations that will be performed 6 months and 1 year after the intervention.

Author Contributions

All authors contributed to the manuscript. Raísa Marques de Sousa: Participated in data collection, in the definition of the study design, revising and writing of the text; Marisa de Paula Paro: Participated in data collection, in the definition of the study design, revising and writing of the text/ Amanda Orasmo Simcsik: Participated in revising and writing of the text; Marina Junqueira Aioldi: Participated data collection phase and revision of the text; Beatriz Vieira dos Santos: Participated data collection phase and revision of the text; Íbis Ariana Peña de Moraes: Participated in the general orientation of the research, definition of the study design and final revision of the text;

Helen Dawes: Participated in the general orientation of the research, definition of the study design and final revision of the text; Carlos Bandeira de Mello Monteiro: Participated in the general orientation of the research, definition of the study design and final revision of the text; Talita Dias da Silva: Participated in the general orientation of the research, definition of the study design and final revision of the text.

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Conflicts of Interest

The authors report no conflict of interest.

REFERENCES

- Rosenbaum, P., Paneth, N., Leviton, A., Goldstein, M., Bax, M., Damiano, D., et al. A report: the definition and classification of cerebral palsy April 2006. *Dev Med Child Neurol Suppl.* 2007; 109(suppl 109), 8-14.
- Franki, I., Desloovere, K., De Cat, J., Feys, H., Molenaers, G., Calders, P, et al. The evidence-base for basic physical therapy techniques targeting lower limb function in children with cerebral palsy—a systematic review using the ICF as a conceptual framework. *Journal of rehabilitation medicine.* 2012;44(5), 385-395.
- Desloovere, K., Molenaers, G., Jonkers, I., De Cat, J., De Borre, L., Nijs, J, et al. A randomized study of combined botulinum toxin type A and casting in the ambulant child with cerebral palsy using objective outcome measures. *European Journal of Neurology.* 2001;8, 75-87.
- Silva, T. D. D., Silva, P. L. D., Valenzuela, E. D. J., Dias, E. D., Simcsik, A. O., de Carvalho, M. et al. Serious game platform as a possibility for home-based telerehabilitation for individuals with Cerebral Palsy during COVID-19 quarantine—a cross-sectional pilot study. *Frontiers in psychology.* 2021;12, 622678.
- Nordmark, E., Hägglund, G., Lauge-Pedersen, H., Wagner, P., & Westbom, L. Development of lower limb range of motion from early childhood to adolescence in cerebral palsy: a population-based study. *BMC medicine.* 2009;7(1), 1-11.
- Gajdosik, R. L. Passive extensibility of skeletal muscle: review of the literature with clinical implications. *Clinical biomechanics.* 2001;16(2), 87-101.
- Tardieu, G., Tardieu, C., Colbeau-Justin, P., & Bret, M. D. Effects of muscle length on an increased stretch reflex in children with cerebral palsy. *Journal of Neurology, Neurosurgery & Psychiatry.* 1982;45(4), 348-352.
- Westin, G. W., & Dye, S. Conservative management of cerebral palsy in the growing child. *Foot & Ankle.* 1983;4(3), 160-163.
- Glanzman, A. M., Kim, H., Swaminathan, K., & Beck, T. Efficacy of botulinum toxin A, serial casting, and combined treatment for spastic equinus: a retrospective analysis. *Developmental medicine and child neurology.* 2004;46(12), 807-811.

10. Flett PJ, Stern LM, Waddy H, Connell TM, Seeger JD, Gibson SK. Botulinum toxin a versus fixed cast stretching for dynamic calf tightness in cerebral palsy. *J Paediatr Child Health*. 1999;35(1):71–7.
11. Kelly B, MacKay Lyons M, Ruggles T, Woodward J. Botulinum toxin type A and serial casting versus botulinum toxin type A or serial casting in treating equinus gait of children with cerebral palsy. *Cochrane Database of Systematic Reviews*. 2008(3).
12. Teplicky R, Law M, Russell D. The effectiveness of casts, orthoses, and splints for children with neurological disorders. *Infants Young Child*. 2002;15(1):42–50.
13. Milne, N., Miao, M., & Beattie, E. The effects of serial casting on lower limb function for children with Cerebral Palsy: a systematic review with meta-analysis. *BMC pediatrics*.2020; 20(1), 1-23.
14. Novak I, McIntyre S, Morgan C, Campbell L, Dark L, Morton N, et al. A systematic review of interventions for children with cerebral palsy: state of the evidence [with consumer summary]. *Develop Med Child Neurol*. 2013; 55(10):885–910 2013.
15. Organization. WH. International classification of functioning, disability and health: ICF. Geneva: World Health Organization; 2001.
16. Blackmore AM, Boettcher-Hunt E, Jordan M, Chan MDY. A systematic review of the effects of casting on equinus in children with cerebral palsy: an evidence reports of the AACPD. *Dev Med Child Neurol*. 2007;49(10):781–90.
17. Shweta Jain, M. B. B. S., Navnendra Mathur MS, D. N. B., Mrinal Joshi MD, D. N. B., Jindal, R., & Goenka, S. Problems in management of cerebral palsy in a developing country. *Developmental Medicine and Child Neurology*. 2008;50(3), 239.
18. Mathevon L, Bonan I, Barnais JL, Boyer F, Dinomais M. Adjunct therapies to improve outcomes after botulinum toxin injection in children: A systematic review. *Annals of physical and rehabilitation medicine*. 2019;62(4):283–90.
19. Picelli A, Santamato A, Chemello E, Cinone N, Cisari C, Gandolfi M, et al. Adjuvant treatments associated with botulinum toxin injection for managing spasticity: an overview of the literature. *Ann Phys Rehab Med*. 2018.
20. Yaraskavitch M, Leonard T, Herzog W. Botox produces functional weakness in non-injected muscles adjacent to the target muscle. *J Biomech*. 2008;41:897–902.
21. Verschuren, O., & Takken, T. Aerobic capacity in children and adolescents with cerebral palsy. *Research in developmental disabilities*. 2010;31(6), 1352-1357.
22. Chan, A. W., Tetzlaff, J. M., Altman, D. G., Laupacis, A., Gøtzsche, P. C., Krleža-Jerić, K et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Annals of internal medicine*. 2013;158(3), 200–207.
23. Amichai T, Eylon S, Dor-Haim H, Berger I, Katz-Leurer M. Cardiac autonomic system response to submaximal test in children with cerebral palsy. *Pediatric Physical Therapy*. 2017;29:125–8. doi:
24. Vanderlei LCM, Pastre CM, Hoshi RA, Carvalho TD, Godoy MF. Basic notions of heart rate variability and its clinical applicability. *Rev Bras Cir Cardiovasc*. 2009;24:205–17.
25. Katz-Leurer M, Amichai T. Heart rate variability in children with cerebral palsy. *Dev Med Child Neurol*. 2019;61:730–1.
26. Cusick BD. Serial casting and other equinus deformity management strategies for children and adults with central nervous system dysfunction. *Telluride: Progressive gaitways*; 2010.
27. Martins, F., Massetti, T., Crocetta, T. B., Lopes, P. B., da Silva, A. A., Figueiredo, et al. Analysis of motor performance in individuals with cerebral palsy using a non-immersive virtual reality task - a pilot study. *Neuropsychiatric disease and treatment*. 2019;15, 417–428.
28. Shumway-Cook A, Brauer S, Woollacott M. Predicting the probability for falls in community-dwelling older adults using the timed up and go test. *Phys Ther*. 2000;80:896–903.
29. Creel GL, Light KE, Thigpen MT. Concurrent and construct validity of scores on the timed movement battery (TMB). *Phys Ther*. 2001;81:789–798.
30. Gray C, Wall JC, Farris J, Rich A, van Camp J. Balance and the post-polio syndrome. *Phys Ther*. 2001;81:64.
31. Morris S, Morris ME, Iansek R. Reliability of measurements obtained with the timed 'up & go' test in people with Parkinson disease. *Phys Ther*. 2001;81:810–818.
32. Steffen TM, Hacker TA, Mollinger L. Age- and gender-related test performance in community-dwelling elderly people: sixminute walk test, Berg balance scale, timed up & go test, and gait speeds. *Phys Ther*. 2002;82:128–137.

33. Andersson C, Grooten W, Hellsten M, Kaping K, Mattson E. Adults with cerebral palsy: walking ability after progressive strength training. *Dev Med Child Neurol.* 2003;45:220–228.
34. Podsiadlo D, Richardson S. The timed 'up and go': a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc.* 1991;39:142–148.
35. Bronfenbrenner U. Towards an experimental ecology of human development. *Am Psychol.* 1977;32:513–521.
36. Williams EN, et al. The Timed 'Up & Go' Test in Children *Developmental Medicine & Child Neurology.* 2005; 47:518–524
37. Franjoine, M.R.; Gunther, J. S. & Taylor, M.J.. Pediatric Balance Scale: A Modified Version of the Berg Balance Scale for the School-Age Child with Mild to Moderate Motor Impairment. Research Report. Physical Therapy Program, Daemen College, Amherst, New York. *Pediatric Physical Therapy.* 2003;114-128.
38. Miyamoto, S. T., Lombardi Júnior, I., Berg, K. O., Ramos, L. R., & Natour, J. Brazilian version of the Berg balance scale. *Brazilian journal of medical and biological research.* 2004;37:1411-1421.
39. Alvarez, M. P. B., Silva, T. D. D., Favero, F. M., Valenti, V. E., Raimundo, R. D., Vanderlei, L et al. Autonomic modulation in duchenne muscular dystrophy during a computer task: a prospective control trial. *PLoS One.* 2017;12:1, e0169633.
40. Booth M., Yates C., Edgar T. and Bandy W., Serial Casting vs Combined Intervention with Botulinum Toxin A and Serial Casting in the Treatment of Spastic Equinus in Children, *Pediatric Physical Therapy,* 2003.

Resumo

Introdução: a Paralisia Cerebral (PC) é caracterizada por um distúrbio da postura e do movimento, comumente levando a alterações ortopédicas incapacitantes, incluindo encurtamento muscular, principalmente nos membros inferiores. Métodos de alongamento, realizados gradualmente, são necessários para retardar o comprometimento da função pelo encurtamento muscular. O uso da fundição seriada visa promover o alinhamento adequado e uma base de sustentação ideal e estável, além de melhorar a saúde óssea e articular, levando a uma melhor postura, mobilidade, função muscular e, conseqüentemente, aumento do condicionamento físico e da saúde.

Objetivo: avaliar a amplitude de movimento, o controle postural e o desempenho motor em crianças com PC, usando gesso seriado, bem como medir seu efeito no condicionamento físico por meio do sistema nervoso autônomo (SNA).

Método: Sessenta crianças e adolescentes com PC, de ambos os sexos, de 3 a 12 anos de idade, serão divididos em três grupos: Grupos A, B e C, com 20 indivíduos cada. O Grupo A usará gesso seriado, o Grupo B usará a órtese continuamente (com a retirada permitida apenas para o banho) e o Grupo C usará a órtese em sua rotina diária. A amplitude de movimento do tornozelo do primeiro e segundo níveis de resistência (R1 e R2), medida da função motora grossa (GMFM) e equilíbrio (medido pela escala de BERG) serão utilizados nas avaliações inicial e final, e após 6 meses e um ano de acompanhamento. Timed-up-and-go (TUG), distribuição de carga (baropodometria), desempenho motor medido através de um jogo de basquete real e do jogo virtual MoveHero, análise da angulação corporal com "mydartfish" e modulação autonômica cardíaca através da variabilidade da frequência cardíaca serão avaliados em três situações diferentes: descalço, com órtese e com gesso.

Conclusão: O gesso seriado demonstra potencial para produzir resultados positivos no tratamento de indivíduos com PC quanto ao melhor alinhamento, com conseqüente melhora motora e autonômica.

Palavras-chave: Paralisia cerebral, gesso, fibra de vidro, terapia de exposição à realidade virtual, sistema nervoso autônomo, exercícios de alongamento muscular.

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