2024

A MASTERS THESIS

The Effects of Perturbation-Based Training (PBT) on Functional Balance in Children with Cerebral Palsy: Pre-Post Clinical Trial

SUPERVISORS:
PROF. PRASHANT JAMWAL
DR. YELTAY RAKHMANOV

THESIS BY:
DILNOZA KARIBZHANOVA

NAZARBAYEV UNIVERSITY
SCHOOL OF MEDICINE

CONTENTS

ABSTRACT

This study investigates the efficacy of a combined perturbation therapy, delivered simultaneously from the ground and in the transverse plane, to enhance gait stability and functional balance in children diagnosed with cerebral palsy at Gross Motor Function Classification System (GMFCS) levels I–II. With a minimum expectation of three participants aged between 14 to 18 years old, our research hypothesizes that combining perturbations will lead to greater improvements in functional balance, endurance, power and Muscle Activation Index. We anticipate that participants receiving combined perturbations will exhibit superior functional balance outcomes. The study employs standard equipment alongside an indigenous autonomous system developed to administer random perturbations to participants. Through this investigation, we aim to determine the effects of perturbations given from the ground and in the transverse plane on postural and functional balance of children with CP to enhance their overall quality of life.

ACKNOWLEDGEMENTS

I would specifically like to thank Prof. Prashant Jamwal and Dr. Yeltay Rakhmanov for supervising my research on this project and providing resources for

I extend my heartfelt gratitude to the dedicated team from the engineering department, particularly Shyngys Dauletbayev, Daulet Sagidoldin, and Darkhan Keikibayev, for their remarkable efforts in realizing our idea and creating the perturbation system essential for this project. Their expertise, innovation, and commitment have been instrumental in the success of our study.

I also express my sincere appreciation to my groupmates Mereke Tukayev and Amna Riaz Khawaja, pursuing Masters in Sports Medicine and Rehabilitation at the Nazarbayev University, for their invaluable assistance during the assessments conducted as part of this research. Their collaboration and support have significantly contributed to the smooth execution of the study protocols and data collection process.

Furthermore, I extend my deepest gratitude to the parents and children who participated in this study. Their trust, willingness, and contributions to advancing scientific knowledge are truly commendable. Without their involvement and dedication, this research would not have been possible.

This project was made possible through the collective efforts and collaboration of all involved, and we are immensely grateful for the support and contributions of each individual and team. the experiments.

LIST OF ABBREVIATIONS

CP	Cerebral Palsy
CPT	Conventional physical therapy
A-TPAD	Active-Tethered Pelvic Assist Device
PBT	Perturbation-Based Training
WHODAS 2.0	WHO disability assessment schedule 2.0
BBS	Berg Balance Scale
10 MWT	10 Meters Walking Test
6 MWT	6 Minute Walking Test
TUGT	Timed Up and Go test
EMG	Electromyography
IMU	Inertial measurement units

CHAPTER ONE: INTRODUCTION

Cerebral Palsy (CP) encompasses a range of disorders attributed to abnormalities or injuries in the brain during early development, predominantly characterized by motor and postural impairments that hinder daily activities and self-care. It is the predominant cause of physical disabilities in children, affecting approximately 17 million individuals globally, resulting in significant socio-economic implications (Cortés-Pérez et al., 2022). McIntyre et al., (2022) noted a current overall CP birth prevalence of 1.6 per 1000 live births, including post-neonatal cases. This is a 25% decrease from the birth prevalence reported in 2013, which was 2.1 per 1000.

Reduced balance and abnormal gait patterns linked to anatomical abnormalities are common in patients with cerebral palsy, which have an immediate effect on locomotor functioning (Krasowicz, 2019). Additionally, a higher risk of falling is linked to decreased gait stability (Hamacher et al., 2019). Therefore, the focus of therapeutic treatments for children with cerebral palsy is frequently on the development of independent walking and gait efficiency in order to ensure their independence in daily life (Llamas-Ramos et al., 2022). Improved balance and walking ability has a positive impact on achievement of daily activities and motivating social engagement (Booth et al., 2018).

The most accessible technique for teaching balance in CP is conventional physical therapy (CPT). Exercises for balance, strengthening, stretching, and flexibility are also a part of CPT. Despite the fact that, the CPT therapies have been successful in helping CP children with balance and other motor impairments, in recent years, virtual reality and balancing boards are two examples of innovative technologies with therapeutic applications that have received significant attention from research and clinical practice in balance gait training.

The utilization of balancing boards in therapeutic and training contexts is predicated on the principle of enhancing postural control and stability, primarily through the mechanism of proprioceptive feedback enhancement and muscular strengthening. This approach specifically aims to augment the capacity of individuals to maintain or regain stability in situations that potentially lead to falls. According to Montoro-Cárdenas et al. the Nintendo Wii treatment (NWT) system seems to be the most widely used one. NWT needs more active engagement and movement than other traditional video game systems, such as the PlayStation or Xbox, and is one of the most popular non-immersive virtual reality devices in the neurorehabilitation of children with CP (Montoro-Cárdenas et al., 2021). However, unlike SensoPro, NWT does not actually engage the vestibular system and muscles during rehabilitation. The instability of the SensoPro bands on which the user stands forces the body to engage entire muscle groups throughout the workout, providing maximum muscle activation. The literature preceding before it primarily focused on responses to balance perturbations given while standing, even though the majority of falls in CP are reported while walking.

The Perturbation-Based Training (PBT) has emerged as a valuable tool for assessing and enhancing balance in various patient populations, including the elderly (Rieger et al., 2023; Gerards et al., 2021), individuals with Parkinson’s disease (Martelli et al., 2017; Coelho et al., 2022), and stroke survivors (van Duijnhoven et al., 2018; Handelzalts et al., 2019). Berg et al. (1989) delineated three fundamental aspects of balance crucial for functional autonomy: static balance control, or the ability to maintain various postures; proactive balance control, which involves postural adjustments in anticipation of voluntary movements; and reactive balance control, the capacity to respond to unforeseen external perturbations(Berg, 1989). This multifaceted conceptualization of balance underscores the complexity of achieving functional stability across different conditions and populations. The efficacy of perturbation-based balance training in enhancing balance and gait has been a subject of considerable research interest. One innovative approach to this form of training is the Active-Tethered Pelvic Assist Device (A-TPAD), developed at Columbia University (Martelli et al., 2017). The A-TPAD system employs a lightweight belt fitted around the pelvis, connected to wires whose tension is dynamically adjusted by motors. This setup facilitates the application of continuous forces at the waist, simulating perturbations that challenge and thereby improve the user's balance control mechanisms (Kang et al., 2017). The use of the A-TPAD has demonstrated promising results in improving gait dynamics among individuals with Parkinson’s disease and children with cerebral palsy, showcasing the potential of perturbation-based interventions in rehabilitative practices. In this work, an innovative cable-driven mechanism conceived for balance rehabilitation was used to investigate the effects of balance training in the presence of externally applied forces on the SENSOPRO during functional balance and gait stability in children with cerebral palsy.

HYPOTHESES

Balance training in the presence of externally applied forces will improve functional balance in children with cerebral palsy.

RESEARCH QUESTION

Do the balance training given in the form of externally applied forces improve functional balance in children with cerebral palsy?

OBJECTIVE

Investigate the effects of balance training in the presence of externally applied forces on functional balance in children with cerebral palsy.

CHAPTER TWO: MATERIAL AND METHODS

2.1 Study design and participants

This study is pre-post clinical trial. The study will be conducted at the Rehabilitation center inside the Athletics Center of Nazarbayev University Astana, Kazakhstan.

Three subjects with spastic CP aged between 14-18 years old and GMFCS level I & II will be participating in the study. Inclusion criteria for the participants of this study is as follows: 1) cognitively intact, 2) shoe size 37 and more, 3) good general wellness, without unconsolidated fractures. The total trial duration will be 5 weeks including pre-post assessments. All experiments will be performed in accordance with relevant guidelines and regulations. Before signing a written consent form, each participant will be given the opportunity to ask any questions and familiarize themselves with the protocol before the experiment started.

2.2 Ethical considerations

The experimental protocol was reviewed and approved by the Nazarbayev University Institutional Research Ethics Committee (NU IREC) on 11.03.2024 the approval number is 858/19022024. Before taking part, all subjects will be told about the research protocol and need to sign a written consent form that has been authorized by the NU IREC.

2.3 Data collection

After getting informed consent from the children’s parents and children. Pre- and post-assessment will be performed. Subjects’ disability scores would be established using WHO disability assessment schedule 2.0 (WHODAS 2.0) (Potcovaru et al., 2024, Pizzighello et al., 2023). The ability of individuals to safely maintain their balance will be measured using the Berg Balance Scale (BBS) and Timed Up and Go test (Wang et al., 2023, Alonso et al., 2014). The distance traveled during a 6-minute period (6-minute Walking Test) will be used as an indicator to compare shifts in performance capability (Niiler, 2018). Furthermore, the 10 Meters

Walking Test (10MWT) will be utilized to determine the speed at which a child could cover a short distance, quantified in meters per second (Graser et al., 2016, Moll et al., 2023).

Electromyography (EMG) data will be collected via the multi-modal Ultium® EMG sensor system, both prior to and following the main training sessions, facilitating the analysis of muscular coordination and strength (Kang et al., 2017). Moreover, inertial measurement units (IMUs) will be used to measure anatomical joint angles, torque, linear acceleration and COM (Martelli et al., 2017, Park & Yoon, 2021). To further evaluate gait stability, balance, and pressure distribution, data from Smart Insoles developed by Ultium® will be utilized (Hamacher et al., 2019, Huang et al., 2021). This comprehensive approach allows for a detailed assessment of the participants' biomechanical, physiological and neuromuscular responses to the training regimen (Moreau et al., 2016).

2.4 Experimental Protocol

SENSOPRO is a coordination training device (Figure 1-2). Device has two tapes, 24 tubes with 3 different strengths (Aquamarine = weak; Azure blue = medium; Coral red = strong), side rails and Sensopro Video Kit touchscreen. Video Kit provides a variety of videos with instruction to help patients with their training program (Figure 3). The videos offer thorough instructions on the exercises from two angles, are content-categorized, and can be seen on a large screen on the device. Maximum muscular activation is achieved during the training session due to the instability of the tapes on which the patients stands.

Figure 1. *Illustrates the Sensopro device.*

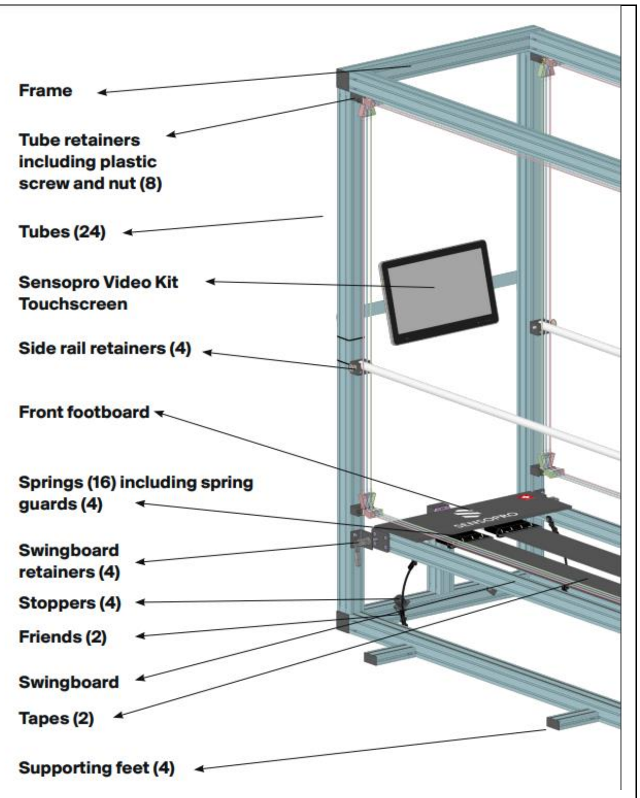


Figure 2. *Components of the Sensopro device.*

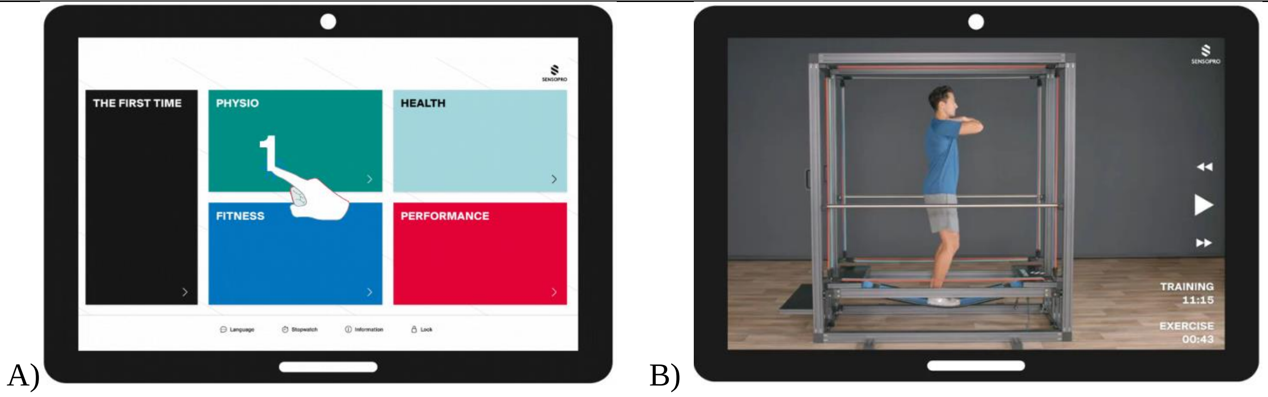


Figure 3. *The Sensopro Video Kit. A) Illustrates 4 types of protocols: Physio, Health, Fitness and Performance. Protocols help select the best type of training and then the right program within the category. B) Example of a video instruction. Individuals should repeat the exercises from the video to finish each one at a time.*

Four motors will be used and mounted on an inertial rigid frame, and combined to the subject's hip belt by low-stretch nylon-coated stainless steel cables and pulleys. Pulleys that will be directed diagonally will be used to route cables. By placing a transient pulse on two of the four wires, waist-pull perturbations with peak force of a chosen amplitude proportional to the subject's body weight (BW) will be produced.

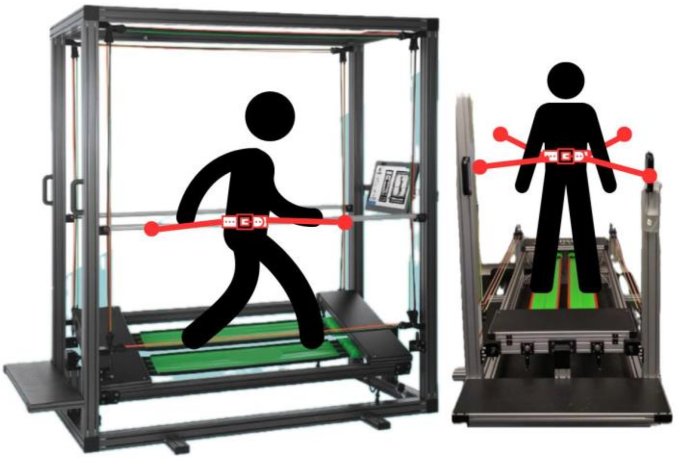


Figure 4. *Experimental Setup. Schematic of the coordination training device with perturbation system. Red lines indicates the perturbation cables and red dots indicates motors.*

2.5 Intervention

After baseline measurements, a 4-week training program consisting of three appointments per week will be conducted (Figure 5). Each appointment will last for 60 minutes, including preparation time.

Participants will receive introductory training on the Sensopro on the first day (FIRST DAY) to become familiar with the equipment. On subsequent days, participants will begin with ten minutes of exercises using the coordination training device (BALANCE 1). Cables will be connected to the belt, and participants will undergo 10 anterior and posterior diagonal perturbations with a peak amplitude of 15% of body weight (TEST 1) initially.

Following the initial perturbations, participants will undergo training involving five blocks of progressively more intense back-left (BL), back-right (BR), front-left (FL), and front-right (FR) perturbations (TRAINING). Initially, the maximum force for all four perturbations will be set at 5% of body weight. With each subsequent block, the force will increase by 2% of body weight.

The perturbations within each block will be arranged in a random order, and the time between perturbations will be randomly set between 2 and 10 seconds. Each block will take approximately two minutes to complete. All subjects will experience the same set of diagonal perturbations before the cables are removed (TEST 2). After the cables are removed, all subjects will continue training for another ten minutes (BALANCE 2) (Martelli et al., 2017).

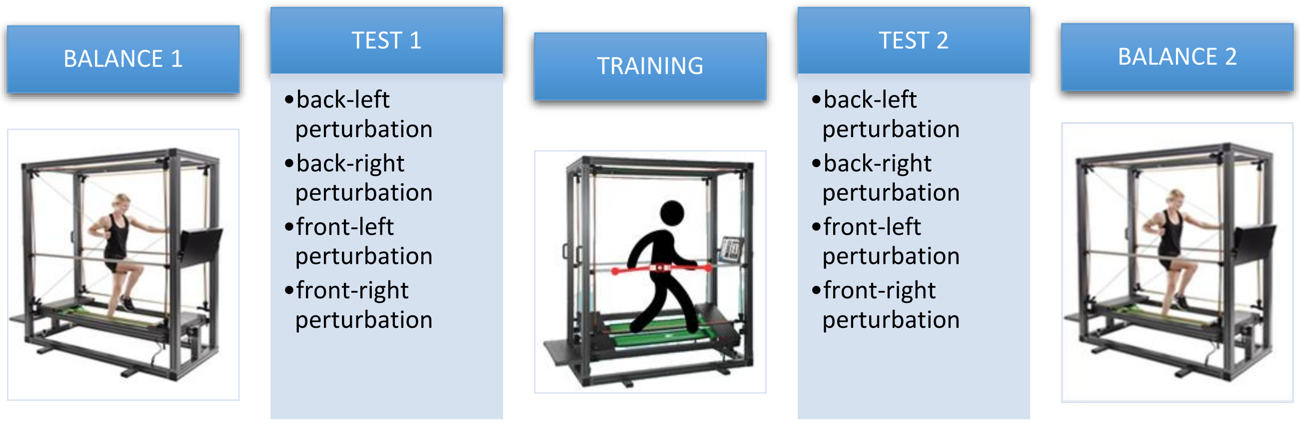


Figure 5. *Experimental Protocol. The study involves a four-week training program with three weekly appointments. Participants undergo an introduction to the Sensopro equipment on the first day, followed by eleven sessions on a coordination training device with perturbations. The training incorporates progressively more intense perturbations, with the force increasing by 2% of body weight, and varying force levels and time between perturbations. Subsequently, after removing the cables, participants will continue training for another ten minutes on Balance 2.*

2.6 Data analysis

Data will be analyzed using descriptive statistics (mean value and standard deviation). Differences in pre and post assessments, including muscle activity, functional balance, endurance, power and COM will be analyzed using One way ANOVA test adjusting for the pre- and post- measurements. These analyses will be conducted separately for each GMFCS level to account for potential differences in baseline characteristics.

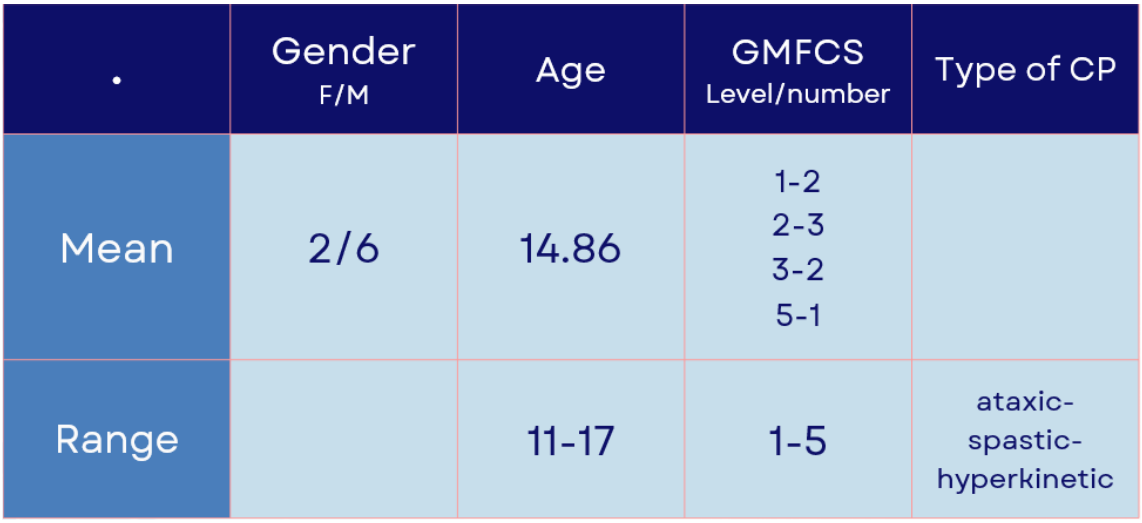
CHAPTER THREE: RESULTS

3.1 Pre-intervention assessment results

The results consist solely of pre-intervention assessments conducted during the recruitment of patients. At the time of writing the thesis, a total of 8 children with CP had participated in the recruitment process. The assessments encompassed the following measures: WHODAS, BBS, 6MWT, 10MWT, TUGT, EMG, IMU, and Smart Insoles.

Table 1 describes the baseline demographics and clinical characteristics of recruiters. Every participant showed a high level of subjective health and well-being. The median age was 14.86 years, with 75% being males and 25% females. The children ranged from levels 1 to 5 according to the Gross Motor Function Classification System and presented with ataxic, spastic, and hyperkinetic types of cerebral palsy.

Table 1. *Descriptive statistics of recruiters. GMFCS = Gross Motor Function Classification Scale.*



.	Gender F/M	Age	GMFCS Level/number	Type of CP
Mean	2/6	14.86	1-2 2-3 3-2 5-1	
Range		11-17	1-5	ataxic-spastic-hyperkinetic

The 6 Minute Walk Test was conducted on a hard-surfaced track measuring 30 meters in length to measure endurance (Thompson et al., 2008). Each patient was allocated 6 minutes to complete the walk, during which they were free to pause and relax as needed. The length of the walk was measured after the 6-minute duration (An et al., 2024). A 10-meter-long straight walkway was used to conduct the 10-Meter Walk Test as a measure of gait speed. The patients were told to move from one end of the path to the other at a comfortable speed. To

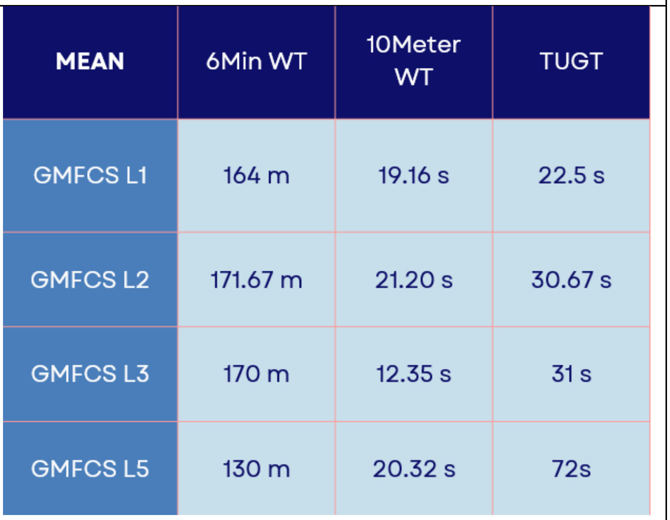
guarantee a consistent measurement of walking speed, timing began as soon as the patient began to walk and ended when they arrived at the predetermined end point (Thompson et al., 2008). Timed Up and Go test is used to measure the dynamic balance and functional mobility in the neurological population. During the TUGT the task assigned to the participants was to get up, move three meters, turn at a mark on the floor, move back to the chair, and then sit down. The TUG test started when the participants moved to stand in response to the cue "ready, go," and it ended when they sat down in the chair and stopped moving (Carey et al., 2016).

Table 2 presents the mean, standard deviation, and range of the assessments. Each of these measurements has a very large standard deviation (6MWT=65.92 m; 10MWT=6.55 sec; TUGT=17.22 sec). This suggests that although the cohort performs moderately on average in terms of walking endurance, speed and functional mobility, there is a significant amount of variation in every participant of the group's walking capacity. Some people have endurance that is noticeably higher or lower than mean. Table 3 compares the means of the assessments across various Gross Motor Function Classification System (GMFCS) levels. For the 6 Minute Walk Test, individuals in GMFCS Level II display the highest variability in walking endurance. Conversely, in the 10 Meter Walk Test, GMFCS Level III individuals exhibit the highest parameter in walking speed. During the Time Up and Go Test, GMFCS Level II individuals demonstrate the highest variability in functional mobility and dynamic balance. However, GMFCS Level V individuals show the lowest variability in functional mobility and dynamic balance.

Table 2. *The mean, standard deviation and range of the three assessments: the 6 minute walk test, the 10-meter walk test and the timed up and go test.*

	6Min WT	10Meter WT	TUGT
Mean	167.44	17.03	30.22
SD	65.92 m	6.55 sec	17.22sec
Range	99-290	11-30.2	19-72

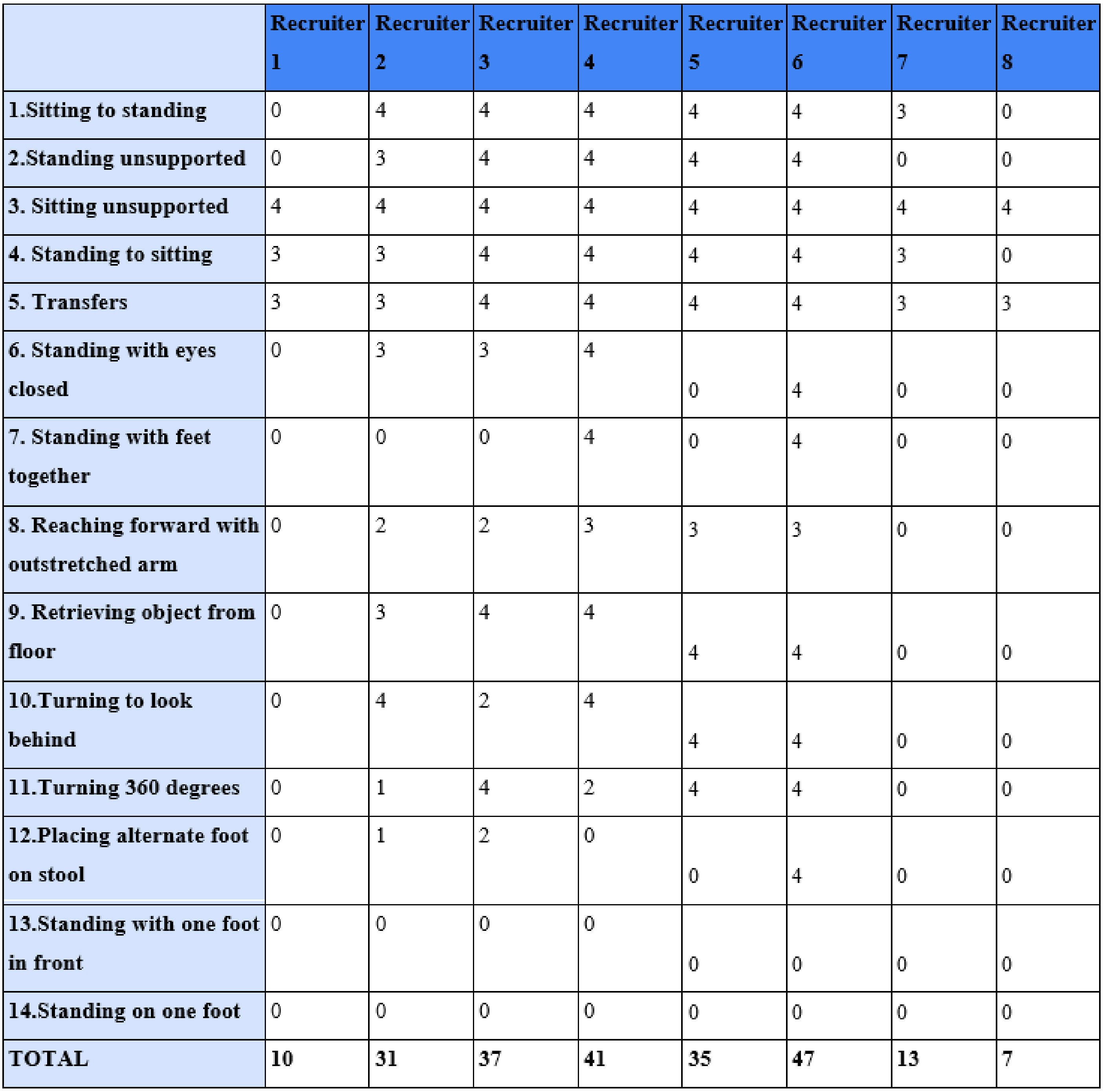
Tables 3*. Comparison of the means of the assessments across different the GMFCS level.*



MEAN	6Min WT	10Meter WT	TUGT
GMFCS L1	164 m	19.16 s	22.5 s
GMFCS L2	171.67 m	21.20 s	30.67 s
GMFCS L3	170 m	12.35 s	31 s
GMFCS L5	130 m	20.32 s	72s

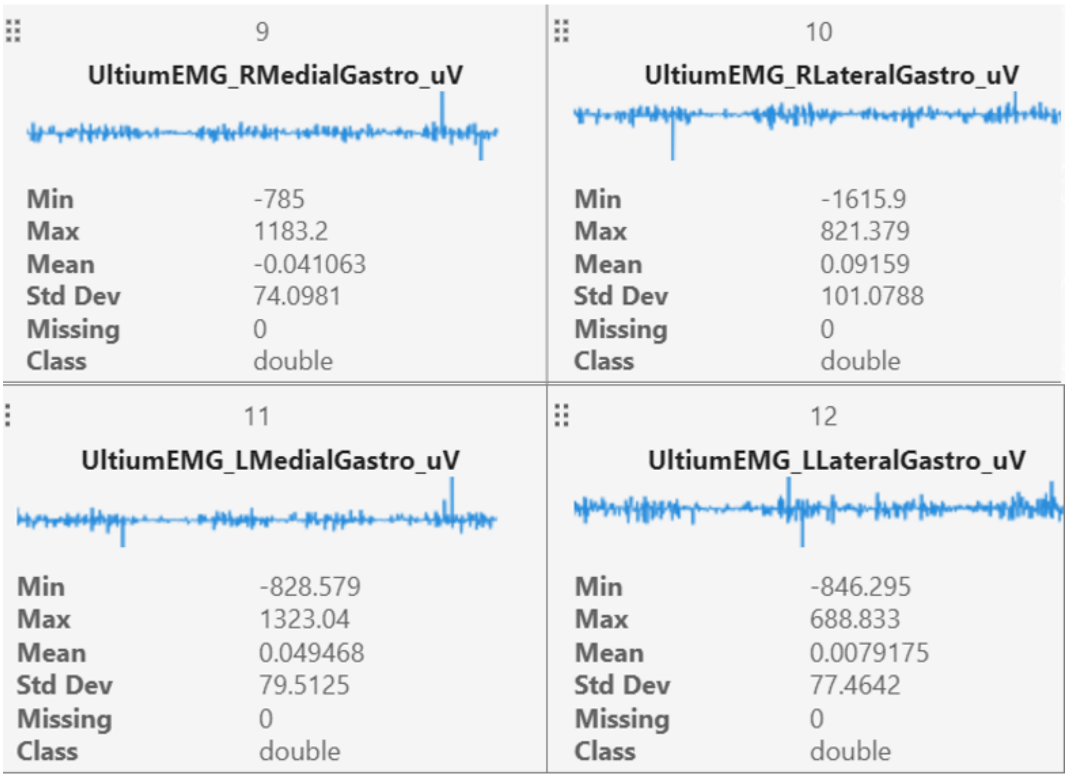
Using the BBS, functional balance was evaluated. Fourteen fundamental balance exercises, including standing on one foot and getting up from a seated position, formed the assessment. A score of 0 (unable to execute) to 4 (able to complete independently) was assigned to each task, and the sum of the sub-scores indicated the level of success (An et al., 2024). The mean score of the Berg Balance Scale Test for this cohort is approximately 28 out of a maximum possible score of 56 (Table 4). This indicates a moderate level of balance ability on average among the individuals in the cohort. However, the results show a wide variety of balancing abilities across the cohort, ranging from a low of 7 to a high of 47. Some participant's scores were significantly below the mean, indicating difficulties or impairments with their ability to maintain balance.

Table 4. *Berg Balance Scale data for 14 tasks are summarized as follows: Mean = 27.62, Variance = 129.4, Standard Deviation = 11.37.*



	Recruiter 1	**Recruiter 2**	**Recruiter 3**	**Recruiter 4**	**Recruiter 5**	**Recruiter 6**	**Recruiter 7**	**Recruiter 8**
1.Sitting to standing	0	4	4	4	4	4	3	0
2.Standing unsupported	0	3	4	4	4	4	0	0
3. Sitting unsupported	4	4	4	4	4	4	4	4
4. Standing to sitting	3	3	4	4	4	4	3	0
5. Transfers	3	3	4	4	4	4	3	3
6. Standing with eyes closed	0	3	3	4	0	4	0	0
7. Standing with feet together	0	0	0	4	0	4	0	0
8. Reaching forward with outstretched arm	0	2	2	3	3	3	0	0
9. Retrieving object from floor	0	3	4	4	4	4	0	0
10.Turning to look behind	0	4	2	4	4	4	0	0
11.Turning 360 degrees	0	1	4	2	4	4	0	0
12.Placing alternate foot on stool	0	1	2	0	0	4	0	0
13.Standing with one foot in front	0	0	0	0	0	0	0	0
14.Standing on one foot	0	0	0	0	0	0	0	0
TOTAL	**10**	**31**	**37**	**41**	**35**	**47**	**13**	**7**

A metric for measuring the degree of muscular activity is the muscle activation index. Electromyography (EMG), which captures the electrical activity of muscles throughout a variety of activities like standing, walking, and training, is used to evaluate it. The results will be analyzed using Matlab and an appropriate statistical analysis comparing results before and after the intervention. As an example, Figure 6 illustrates the minimum and maximum values of muscle activation in microvolts (uV) for four muscles: the left and right medial gastrocnemius (MG), and the left and right lateral gastrocnemius (LG) muscles of one of the recruiters with GMFCS 1. Additionally, the figure presents the mean and standard deviation of these muscles, calculated using Matlab. There seems to be a bigger variation between the right and left LG muscles and show different activation levels at various points, which could suggest different levels of engagement, strength, or potential compensatory movements.



9

UltiumEMG_RMedialGastro_uV

Min	-785
Max	1183.2
Mean	-0.041063
Std Dev	74.0981
Missing	0
Class	double

10

UltiumEMG_RLateralGastro_uV

Min	-1615.9
Max	821.379
Mean	0.09159
Std Dev	101.0788
Missing	0
Class	double

11

UltiumEMG_LMedialGastro_uV

Min	-828.579
Max	1323.04
Mean	0.049468
Std Dev	79.5125
Missing	0
Class	double

12

UltiumEMG_LLateralGastro_uV

Min	-846.295
Max	688.833
Mean	0.0079175
Std Dev	77.4642
Missing	0
Class	double

Figure 6. *Mean, standard deviation, the minimum and maximum values of muscle activation in microvolts (uV) for four muscles: the left and right medial gastrocnemius, and the left and right lateral gastrocnemius muscles.*

Inertial measurement units will be utilized to measure anatomical joint angles, torque, linear acceleration, and COM. The results comparing before and after the intervention will be analyzed using Matlab and an appropriate statistical analysis. The Smart Insole dataset was created using information obtained from pressure sensor insoles (Figure 7). Participants were asked to start from standing position and walk 10 meters in a straight line. They made a 180-degree turn and went back to the starting point after completing the 10-meter distance. Figure 7, where the peaks represent heel strikes, shows example when the subject did not always apply enough force to the heels while walking (A). This was most evident when the subject was making 180-degree turns and mostly used their toes (B).

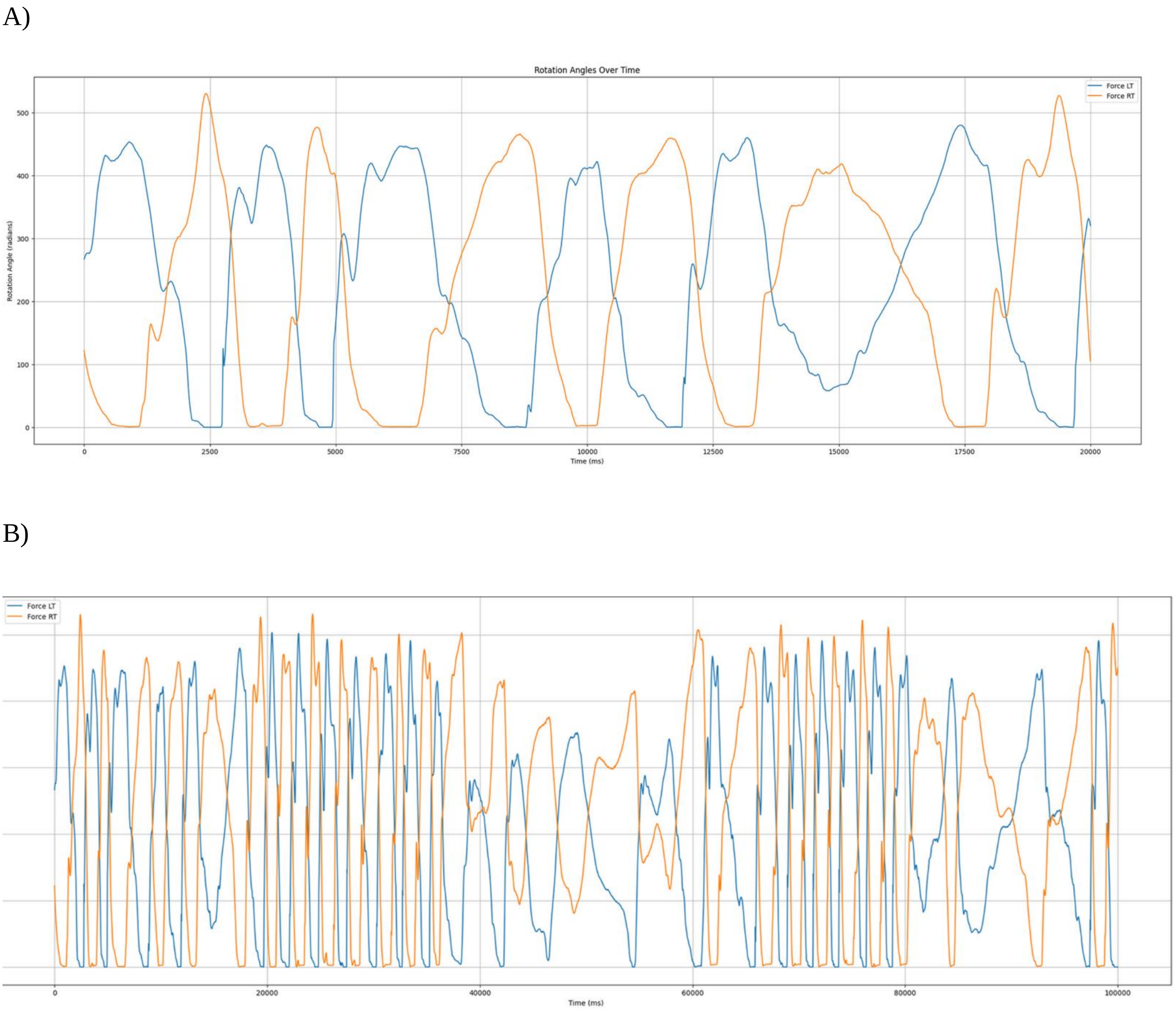


Figure 7. *Gate analysis using Smart Insoles. Blue is for left foot and orange for right foot. A) 20 seconds gate analysis B) gate data collected over a duration of 100 seconds.*

3.2 Anticipated results

This section delves into the expected outcomes, emphasizing on four assessments (6MWT, 10MWT, TUGT, BBS) carried out as a component of our research methodology. We estimate a suitable sample and effect sizes using accepted formulae and assumptions in order to guarantee the statistical power required to identify significant differences and connections (Santamaria et al., 2023).

Table 5. *Pre-intervention results and anticipated post-intervention data for 4 assessment: 6 MWT, 10MWT, TUGT, BBS*

6MWT in meters		**10 MWT in seconds**		**TUGT in seconds**		**BBS total score**	
Pre- Actual data	Post- Anticipated	Pre- Actual data	Post- Anticipated	Pre- Actual data	Post- Anticipated	Pre- Actual data	Post- Anticipated
130	145	20.32	14,20	72	65	10	15
200	218	20	14,00	26	21	31	36
290	315	11	7,70	26	20	37	40
99	123	22.4	15,60	23	18	41	47
128	145	18.31	12,80	19	15	35	41
160	172	11.4	8,00	27	23	47	51
126	150	30.2	21,00	43	37	13	15

Calculating Effect Size

The magnitude of the association between variables is measured by effect size or the difference between groups, offering valuable insights into the real-world implications of our research outcomes.

To calculate the effect size for our study, we used Cohen's d, which measures the size of the difference between two groups. In our case, we will compute Cohen's d to quantify the magnitude of change between pre and post-intervention assessments within the same group. Cohen's d formula is as follows:

$$d = \frac{x_1 - x_2}{s}$$

Where:

- (x_1) is the mean of the pre-intervention assessments.
- (x_2) is the mean of the post-intervention assessments.
- *(S)* is the standard deviation of the assessments.

Interpreting results:

Small effect size (around 0.2): Indicates a small but perhaps significant change.

Medium effect size (around 0.5): Indicates a moderate shift with applicability.

Large effect size (above 0.8): Indicates a big shift with important real-world ramifications..

We use the standard deviation of the pre-intervention assessments in our calculations.

Table 6. *Based on the provided data from the pre-intervention and anticipated post-intervention assessments of the 10 Meter Walk Test (10MWT), the Effect Size was performed using the formula.*

10MWT (sec)	**Actual data pre**	**Anticipated post**
	20,32	14,20
	20,00	14,00
	11,00	7,70
	22,41	15,60
	18,31	12,80
	11,40	8,00
	30,20	21,00
Mean	19,09	13,33
SD	6,607925616	4,574827605
pooled SD		5,683033018
d_values Effect size		-1,014046043

The effect size, calculated using Cohen's d, yielded a value of -1.014, indicating a large effect size (Table 6). This substantial effect size suggests that the observed change in performance between the pre and anticipated post-intervention assessments is not only statistically significant but also practically significant.

General Considerations for Sample Size Estimation:

For the calculation of an appropriate sample size, we use the formula for sample size (n) is given by:

$$n = \frac{2\sigma^2(z_{crit}+z_{pow})^2}{D^2}$$ (Wang & Ji, 2020)

where:

- (σ^2) is the variance of either group,

- (D^2) is the smallest observable difference between the two means, Effect Size

- (z_{crit}) is the standard normal deviate at the level of significance (e.g., 1.96 for a 5% level of significance for two-sided tests),

- (z_{pow}) is the standard normal deviate at the desired power (e.g., 0.84 for 80% power or 1.28 for 90% power).

We calculated the required sample size using the formula, taking into account the variance and the smallest detectable difference (Table 7). This calculation takes into consideration variables like the necessary statistical power and significance level (Wang & Ji, 2020).

Table 7. *Based on the provided data from the pre-intervention and anticipated post-intervention assessments of the 10 Meter Walk Test (10MWT), the sample size estimation was performed using the formula.*

10MWT (sec)	**Actual data pre**	**Anticipated post**
	20,32	14,20
	20,00	14,00
	11,00	7,70
	22,41	15,60
	18,31	12,80
	11,40	8,00
	30,20	21,00
Mean	19,09	13,33
SD	6,607925616	4,574827605
pooled SD		5,683033018
d_values Effect size		-1,014046043
Sample Size		492,4828005

- Mean pre-intervention score (μ_1) = 19.09 seconds
- Mean post-intervention score (μ_2) = 13.33 seconds
  - The pre-interventions' standard deviation (s) = 6.60
  - The post-interventions' standard deviation (s) = 4.57
- Pooled standard deviation (pooled SD) = 5.68
- Effect size (d_values) = -1.01

The minimal detectable difference (D) between pre- and post-intervention means is calculated as the absolute difference between the means, which is 19.09−13.33 =5.76

Substituting the values into the formula, the estimated sample size for the 10MWT is calculated as approximately 492 participants. The sample size will decrease as the post-assessment results improve. All things considered, the sample size calculation offers a strong foundation for the planning and execution of our research, guaranteeing that we have sufficient statistical power to identify any significant effects of the intervention.

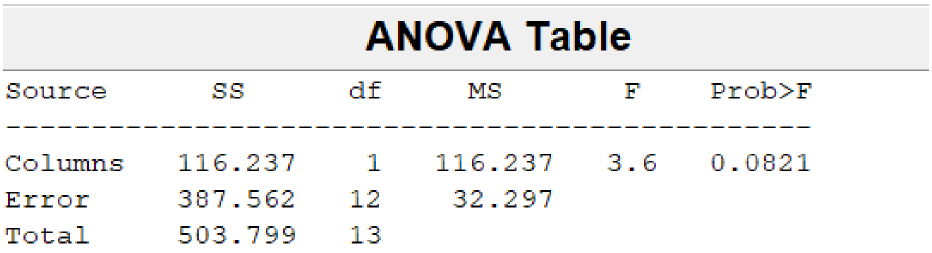
Data Analysis Using One-Way Analysis of Variance Test:

To compare the means within the group, we will use the one-way ANOVA (Analysis of Variance) test after gathering the pre- and post-intervention data (Mishra et al., 2019). We selected a significance level (α), typically set at 0.05, to determine the threshold for statistical significance and formulated hypothesis, which is:

- Null Hypothesis (H0): There is no significant difference between the means of pre and post intervention assessments in the group.
- Alternative Hypothesis (H1): There is a significant difference between the means of pre and post intervention assessments in the group.

The overall variance in the data is broken down into two components in the ANOVA table (table 8): variation within groups (error) and variation across groups (columns). Given that the p-value (0.0821) is higher than the significance criterion of 0.05, it may be concluded that there is no statistically significant difference between the group's pre- and post-intervention measures on the 10MWT. The comparatively low p-value, however, points to a possible trend toward significance and calls for more research using a bigger sample size or additional studies.

Table 8. *The statistical analysis conducted to compare the pre and post-intervention results on the 10-Meter Walk Test (10MWT) within the same group.*



```
ANOVA Table
Source        SS       df      MS        F     Prob>F
---------------------------------------------------
Columns    116.237     1    116.237    3.6    0.0821
Error      387.562    12     32.297
Total      503.799    13
```

The sum of squares (SS) associated with the "Columns" factor is 116.237, indicating the magnitude of variation between the pre and post-intervention measurements, while the SS for "Error" is 387.562, reflecting the overall variability within the group. Degrees of freedom (df) reveal that there is 1 df linked to the "Columns" factor and 12 df associated with the "Error" term. Mean squares (MS) provide additional insight, with the MS for "Columns" being 116.237 and for "Error" being 32.297. The F-statistic, calculated as the ratio of MS for "Columns" to MS for "Error," is 3.6. Lastly, the p-value (0.0821) associated with the F-statistic signifies the likelihood of observing an F-value as extreme as the calculated one under the assumption of no significant difference between the pre and post-intervention measurements.

CHAPTER FOUR: DISCUSSION

The purpose of this research is to determine if balance therapy, such as ground perturbation training with training using transverse plane perturbation are beneficial in helping adolescents with ataxic and spastic cerebral palsy to improve their functional balance. It is anticipated that, upon completion, the research will offer insightful information about the effectiveness of various balance therapy methods for children with CP.

Since the mid-2000s, there has been a growing interest in using mechanical perturbations to prevent falls (McCrum et al., 2022). Several important works on perturbation-based training were noted by McCrum et al. in their work. Grabiner et al. (2008) and Oddsson et al. (2007) have explored task-specific training to reduce fall risk, while Mansfield et al. (2007) published the first protocol for a randomized controlled trial of PBT in older adults. The results of this study demonstrate the potential benefits of PBT therapies for both clinical viability and the incidence of falls in daily life. Understanding these mechanisms might help in the creation of specialized therapies that target specific problems and encourage neuroplasticity in children with cerebral palsy.

This study's findings could significantly impact clinical practice in rehabilitation for individuals with cerebral palsy. The proposed balance therapy interventions could improve functional outcomes, mobility, and independence. The study's methodology could guide future research in pediatric rehabilitation, and its structured training protocol could inspire innovative multimodal interventions targeting balance control mechanisms. Furthermore, for wide-spread adoption and scalability, cost-effectiveness of integrating perturbation-based balance training in clinical practice is crucial.

As a result, this study establishes the foundation for further investigation into balance training therapies for children with cerebral palsy and the development of treatment plans that maximize motor function and enhance quality of life for this population. We can further improve the effectiveness and accessibility of rehabilitation programs for people with CP by addressing these future directions.

Strengths and limitations of this study

- **Small sample size:** The study might not have enough statistical power to identify significant differences or correlations between variables if the sample size is limited.

- **Limited Generalizability:** Only children with spastic CP who are categorized as GMFCS levels I and II are eligible to participate in the study. The results might not apply to a larger group of kids with cerebral palsy because of this specific demographic.

- **Innovative Intervention Strategy:** The study presents an innovative approach that combines perturbation given simultaneously from the ground and in the transverse plane. Several aspects of balance control in children with cerebral palsy may be addressed by this novel technique, which could result in more positive outcomes.

- **Multifaceted Outcome Measures:** The study uses a wide range of outcome measures, including Timed Up and Go Tests, 6MWT, 10MWT, and the Berg Balance Scale. Additionally, a thorough assessment of the biomechanical, physiological, and neuromuscular responses is made possible by the application of cutting-edge technologies such as Electromyography, Smart Insoles and Inertial Measuring Units.

CHAPTER FIVE: CONCLUSION

By using externally applied forces during balance training, this study seeks to close a significant knowledge gap on the impact on functional balance and gait stability in children with cerebral palsy. We can increase our knowledge of and efficacy in balance training interventions for children with cerebral palsy by utilizing the body of current research and implementing a thorough approach to intervention design and evaluation. This will ultimately improve the functional outcomes and quality of life for these children. To further understand the long-term effects of balance training with externally applied forces on motor function and quality of life in children with cerebral palsy, longer-term research with bigger sample sizes are necessary. A thorough grasp of the factors influencing treatment results and the sustainability of treatment effects could be achieved by longitudinal studies.

REFERENCES

1. Cortés-Pérez, I., González-González, N., Peinado-Rubia, A. B., Nieto-Escamez, F. A., Obrero-Gaitán, E., & García-López, H. (2022, December 16). Efficacy of Robot-Assisted Gait Therapy Compared to Conventional Therapy or Treadmill Training in Children with Cerebral Palsy: A Systematic Review with Meta-Analysis. Sensors, 22(24), 9910. https://doi.org/10.3390/s22249910

2. McIntyre, S., Goldsmith, S., Webb, A., Ehlinger, V., Hollung, S. J., McConnell, K., Arnaud, C., Smithers-Sheedy, H., Oskoui, M., Khandaker, G., & Himmelmann, K. (2022, August 11). Global prevalence of cerebral palsy: A systematic analysis. Developmental Medicine & Child Neurology, 64(12), 1494–1506. https://doi.org/10.1111/dmcn.15346

3. Krasowicz, K. (2019, October 31). The Influence of Orthotics on Lower Limbs Biomechanics in CP. Ortopedia Traumatologia Rehabilitacja, 21(5), 389–398. https://doi.org/10.5604/01.3001.0013.5791

4. Hamacher, D., Liebl, D., Hödl, C., Heßler, V., Kniewasser, C. K., Thönnessen, T., & Zech, A. (2019, January 24). Gait Stability and Its Influencing Factors in Older Adults. Frontiers in Physiology, 9. https://doi.org/10.3389/fphys.2018.01955

5. Llamas-Ramos, R., Sánchez-González, J. L., & Llamas-Ramos, I. (2022, April 22). Robotic Systems for the Physiotherapy Treatment of Children with Cerebral Palsy: A Systematic Review. International Journal of Environmental Research and Public Health, 19(9), 5116. https://doi.org/10.3390/ijerph19095116

6. Booth, A. T. C., Buizer, A. I., Meyns, P., Oude Lansink, I. L. B., Steenbrink, F., & van der Krogt, M. M. (2018, March 7). The efficacy of functional gait training in children and young adults with cerebral palsy: a systematic review and meta-analysis. Developmental Medicine & Child Neurology, 60(9), 866–883. https://doi.org/10.1111/dmcn.13708

7. Montoro-Cárdenas, D., Cortés-Pérez, I., Zagalaz-Anula, N., Osuna-Pérez, M. C., Obrero-Gaitán, E., & Lomas-Vega, R. (2021, June 8). Nintendo Wii Balance Board therapy for postural control in children with cerebral palsy: a systematic review and meta-analysis. Developmental Medicine & Child Neurology, 63(11), 1262–1275. https://doi.org/10.1111/dmcn.14947

8. Rieger, M. M., Papegaaij, S., Steenbrink, F., van Dieën, J. H., & Pijnappels, M. (2023, October 9). Effects of Perturbation-Based Treadmill Training on Balance Performance, Daily Life Gait, and Falls in Older Adults: REACT Randomized Controlled Trial. Physical Therapy, 104(1). https://doi.org/10.1093/ptj/pzad136

9. Gerards, M. H. G., Marcellis, R. G. J., Poeze, M., Lenssen, A. F., Meijer, K., & de Bie, R. A. (2021, January 6). Perturbation-based balance training to improve balance control and reduce falls in older adults – study protocol for a randomized controlled trial. BMC Geriatrics, 21(1). https://doi.org/10.1186/s12877-020-01944-7

10. Martelli, D., Luo, L., Kang, J., Kang, U. J., Fahn, S., & Agrawal, S. K. (2017, December 19). Adaptation of Stability during Perturbed Walking in Parkinson's Disease. Scientific Reports, 7(1). https://doi.org/10.1038/s41598-017-18075-6

11. Coelho, D. B., de Oliveira, C. E. N., Guimarães, M. V. C., Ribeiro de Souza, C., dos Santos, M. L., & de Lima-Pardini, A. C. (2022, September). A systematic review on the effectiveness of perturbation-based balance training in postural control and gait in Parkinson's disease. Physiotherapy, 116, 58–71. https://doi.org/10.1016/j.physio.2022.02.005

12. van Duijnhoven, H. J. R., Roelofs, J. M. B., den Boer, J. J., Lem, F. C., Hofman, R., van Bon, G. E. A., Geurts, A. C. H., & Weerdesteyn, V. (2018, November 22). Perturbation-Based Balance Training to Improve Step Quality in the Chronic Phase After Stroke: A Proof-of-Concept Study. Frontiers in Neurology, 9. https://doi.org/10.3389/fneur.2018.00980

13. Handelzalts, S., Kenner-Furman, M., Gray, G., Soroker, N., Shani, G., & Melzer, I. (2019, February 15). Effects of Perturbation-Based Balance Training in Subacute Persons With Stroke: A Randomized Controlled Trial. Neurorehabilitation and Neural Repair, 33(3), 213–224. https://doi.org/10.1177/1545968319829453

14. Berg, K. (1989, November). Measuring balance in the elderly: preliminary development of an instrument. Physiotherapy Canada, 41(6), 304–311. https://doi.org/10.3138/ptc.41.6.304

15. Kang, J., Martelli, D., Vashista, V., Martinez-Hernandez, I., Kim, H., & Agrawal, S. K. (2017, July 19). Robot-driven downward pelvic pull to improve crouch gait in children with cerebral palsy. Science Robotics, 2(8). https://doi.org/10.1126/scirobotics.aan2634

16. Chan, A. W., Tetzlaff, J. M., Gotzsche, P. C., Altman, D. G., Mann, H., Berlin, J. A., Dickersin, K., Hrobjartsson, A., Schulz, K. F., Parulekar, W. R., Krleza-Jeric, K., Laupacis, A., & Moher, D. (2013, January 9). SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ, 346(jan08 15), e7586–e7586. https://doi.org/10.1136/bmj.e7586

17. Potcovaru, C. G., Salmen, T., Bîgu, D., Săndulescu, M. I., Filip, P. V., Diaconu, L. S., Pop, C., Ciobanu, I., Cinteză, D., & Berteanu, M. (2024, February 22). Assessing the Effectiveness of Rehabilitation Interventions through the World Health Organization Disability Assessment Schedule 2.0 on Disability—A Systematic Review. Journal of Clinical Medicine, 13(5), 1252. https://doi.org/10.3390/jcm13051252

18. Pizzighello, S., Raggi, A., Vavla, M., Uliana, M., Pellegri, A., Martinuzzi, M., & Martinuzzi, A. (2023, July 4). The perception of disability in cerebral palsy: a cross-sectional study using the WHODAS 2.0. Developmental Neurorehabilitation, 26(5), 302–308. https://doi.org/10.1080/17518423.2023.2232002

19. Wang, Y., Zhang, P., & Li, C. (2023, July 26). Systematic review and network meta-analysis of robot-assisted gait training on lower limb function in patients with cerebral palsy. Neurological Sciences, 44(11), 3863–3875. https://doi.org/10.1007/s10072-023-06964-w

20. Alonso, A. C., Luna, N. M., Dionísio, F. N., Speciali, D. S., Leme, L. E. G., & Greve, J. M. D. (2014). Functional Balance Assessment: review. Medical Express, 1(6). https://doi.org/10.5935/medicalexpress.2014.06.03

21. Niiler, T. A. (2018). Assessing Dynamic Balance in Children with Cerebral Palsy. Cerebral Palsy, 1–32. https://doi.org/10.1007/978-3-319-50592-3_49-1

22. Graser, J. V., Letsch, C., & van Hedel, H. J. A. (2016, January 31). Reliability of timed walking tests and temporo-spatial gait parameters in youths with neurological gait disorders. BMC Neurology, 16(1). https://doi.org/10.1186/s12883-016-0538-y

23. Moll, F., Kessel, A., Bonetto, A., Stresow, J., Herten, M., Dudda, M., & Adermann, J. (2023, February 11). Safety and Feasibility of Robot-assisted Gait Training in Adults with Cerebral Palsy in an Inpatient Setting – an Observational Study. Journal of Developmental and Physical Disabilities, 35(6), 1091–1106. https://doi.org/10.1007/s10882-023-09895-8

24. Park, S., & Yoon, S. (2021, May 25). Validity Evaluation of an Inertial Measurement Unit (IMU) in Gait Analysis Using Statistical Parametric Mapping (SPM). Sensors, 21(11), 3667. https://doi.org/10.3390/s21113667

25. Huang, H. P., Hsu, C. F., Mao, Y. C., Hsu, L., & Chi, S. (2021, March 31). Gait Stability Measurement by Using Average Entropy. Entropy, 23(4), 412. https://doi.org/10.3390/e23040412

26. Moreau, N. G., Bodkin, A. W., Bjornson, K., Hobbs, A., Soileau, M., & Lahasky, K. (2016, December 1). Effectiveness of Rehabilitation Interventions to Improve Gait Speed in Children With Cerebral Palsy: Systematic Review and Meta-analysis. Physical Therapy, 96(12), 1938–1954. https://doi.org/10.2522/ptj.20150401

27. McCrum, C., Bhatt, T. S., Gerards, M. H. G., Karamanidis, K., Rogers, M. W., Lord, S. R., & Okubo, Y. (2022, October 6). Perturbation-based balance training: Principles, mechanisms and implementation in clinical practice. Frontiers in Sports and Active Living, 4. https://doi.org/10.3389/fspor.2022.1015394

28. Grabiner, M. D., Donovan, S., Bareither, M. L., Marone, J. R., Hamstra-Wright, K., Gatts, S., & Troy, K. L. (2008, April). Trunk kinematics and fall risk of older adults: Translating biomechanical results to the clinic. Journal of Electromyography and Kinesiology, 18(2), 197–204. https://doi.org/10.1016/j.jelekin.2007.06.009

29. Oddsson, L. I. E., Boissy, P., & Melzer, I. (2007, February 27). How to improve gait and balance function in elderly individuals—compliance with principles of training. European Review of Aging and Physical Activity, 4(1), 15–23. https://doi.org/10.1007/s11556-007-0019-9

30. Mansfield, A., Peters, A. L., Liu, B. A., & Maki, B. E. (2007, May 31). A perturbation-based balance training program for older adults: study protocol for a randomised controlled trial. BMC Geriatrics, 7(1). https://doi.org/10.1186/1471-2318-7-12

31. An, Y., Min, S., & Park, C. (2024, March 8). Clinical effects of a novel deep learning-based rehabilitation application on cardiopulmonary function, dynamic and static balance, gait function, and activities of daily living in adolescents with hemiplegic cerebral palsy. Medicine, 103(10), e37528. https://doi.org/10.1097/md.0000000000037528

32. Thompson, P., Beath, T., Bell, J., Jacobson, G., Phair, T., Salbach, N. M., & Wright, F. V. (2008, March 18). Test–retest reliability of the 10-metre fast walk test and 6-minute walk test in ambulatory school-aged children with cerebral palsy. Developmental Medicine & Child Neurology, 50(5), 370–376. https://doi.org/10.1111/j.1469-8749.2008.02048.x

33. Carey, H., Martin, K., Combs-Miller, S., & Heathcock, J. C. (2016, December). Reliability and Responsiveness of the Timed Up and Go Test in Children With Cerebral Palsy. Pediatric Physical Therapy, 28(4), 401–408. https://doi.org/10.1097/pep.0000000000000301

34. Chatzaki, C., Skaramagkas, V., Tachos, N., Christodoulakis, G., Maniadi, E., Kefalopoulou, Z., Fotiadis, D. I., & Tsiknakis, M. (2021, April 16). The Smart-Insole Dataset: Gait Analysis Using Wearable Sensors with a Focus on Elderly and Parkinson's Patients. Sensors, 21(8), 2821. https://doi.org/10.3390/s21082821

35. Mishra, P., Singh, U., Pandey, C., Mishra, P., & Pandey, G. (2019). Application of student's t-test, analysis of variance, and covariance. Annals of Cardiac Anaesthesia, 22(4), 407. https://doi.org/10.4103/aca.aca_94_19

36. Wang, X., & Ji, X. (2020, July). Sample Size Estimation in Clinical Research. Chest, 158(1), S12–S20. https://doi.org/10.1016/j.chest.2020.03.010

37. Santamaria, V., Ai, X., Chin, K., Dutkowsky, J. P., Gordon, A. M., & Agrawal, S. K. (2023, August). Study protocol for a randomised controlled trial to determine the efficacy of an intensive seated postural intervention delivered with robotic and rigid trunk support systems. BMJ Open, 13(8), e073166. https://doi.org/10.1136/bmjopen-2023-073166