Proposal Title: The Effects of a Specialized Therapy Program on Children with Cerebral Palsy.

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Class/Section: HSC 4730 – 0002

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Abstract

Introduction/Background: Cerebral Palsy (CP) is a non-progressive, neurological disorder caused by brain damage during fetal development and is the most common motor disability in children. Physical activity has shown immense benefits for those with CP and increased activity performance could enhance quality of life.

Purpose statement: This study will evaluate the effectiveness of a Specialized Therapy Program additional to the standard treatment of care for children with CP.

Methods: A quasi-experimental study will be conducted with 100 children ages 5 to 11 with CP, all non-weight bearing (Level V) at baseline. Every 3 months, individual progress will be assessed using the Gross Motor Function Classification System (GMFCS) for 1 year. The Specialized Therapy Program will aim to increase the activity performance of the children with CP by at least one GMFCS level.

Hypothesis: We hypothesize that the children with CP that follow the additional Specialized Therapy Program will have increased activity performance compared to children with CP obtaining the standard treatment of care.

Future Implications: This study could introduce a more direct program to help children with CP increase their weight-bearing ability, and therapists could add the plan to their existing rehabilitation program. To ensure effectiveness, the duration of the study may need to be longer for progress to show. A future study could investigate those with different severities of CP to see the effect of the Specialized Therapy Program on high and low functioning children with CP.

Keywords: cerebral palsy; children; activity performance; GMFCS; therapy

Background/Literature Review

Cerebral Palsy (CP) is the most common motor disability seen in childhood. This disorder affects a child's ability to move, walk, and maintain balance. CP refers to a weakening of muscles having to do with the brain. This disease is caused by abnormal development or damage to the child's brain. It is currently estimated that about 1 in 345 children in the United States suffers from this condition. Although there is no cure for CP, there are many treatments that can help improve the quality of life for the children with this condition. Some common treatments include Physical and Occupational therapy, medication, and surgery.[5] For this study, an additional Specialized Therapy Program will be introduced. The kids that have this program incorporated will have increased activity performance compared to children with CP that obtain the standard treatment of care. The standard treatment of care will be regular Physical and Occupational therapy. We will have a baseline group of non-weight bearing children. According to a study published by the CDC, 33% of children with CP needed special tools to help them move as seen in ***Figure 1.***[5]

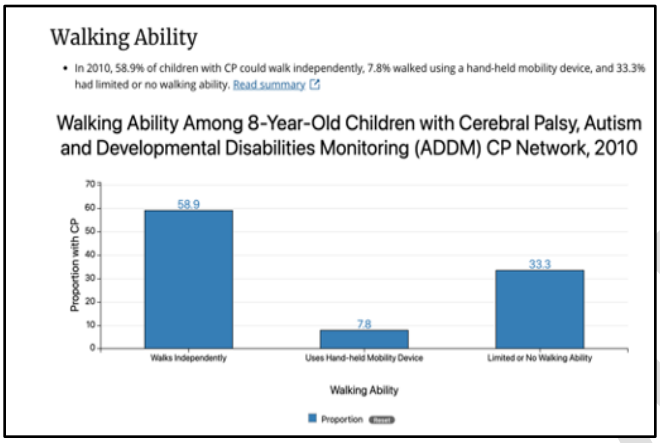

Figure 1: Walking ability among 8-year-old children with Cerebral Palsy and other diseases

Cerebral Palsy has been studied for over more than twenty years. Much is known about this disease such as the causes, risk factors, and what we can do to prevent it. However, there is still much to discover such as new treatment plans and medications that could potentially further help these kids with CP to live longer, healthier lives. Activity performance has an immense benefit for children with CP. This study will increase activity performance in children with CP. It has been seen in many studies that the continuation of treatments is crucial to the development of a better lifestyle for children, however, as the treatment for those with CP has not changed much over the years, it is time to implement a new and more advanced treatment. A study about intensive verse standard care by *Gale Academic OneFile* reported that a high-frequency Physical Therapy regimen could enhance the treatment results.[6] Another study by the *Developmental Medicine & Child Neurology* journal stated that the avoidance of a sedentary lifestyle and continual physical activity play major roles on the health of a child with CP and the development of the disease as well as possible prevention.[11] There are a few studies that have focused on activity performance in children with CP, some of them having weak sample sizes and short intervention periods. This design will have a sufficient sample size and longer intervention periods to showcase the effects of increased activity performance in children with Cerebral Palsy.[12]

The Gross Motor Function Classification System (GMFCS) will be used to help visualize and categorize the children with CP at the beginning of the study as a baseline and throughout the study to track progress as seen in ***Figure 2.***

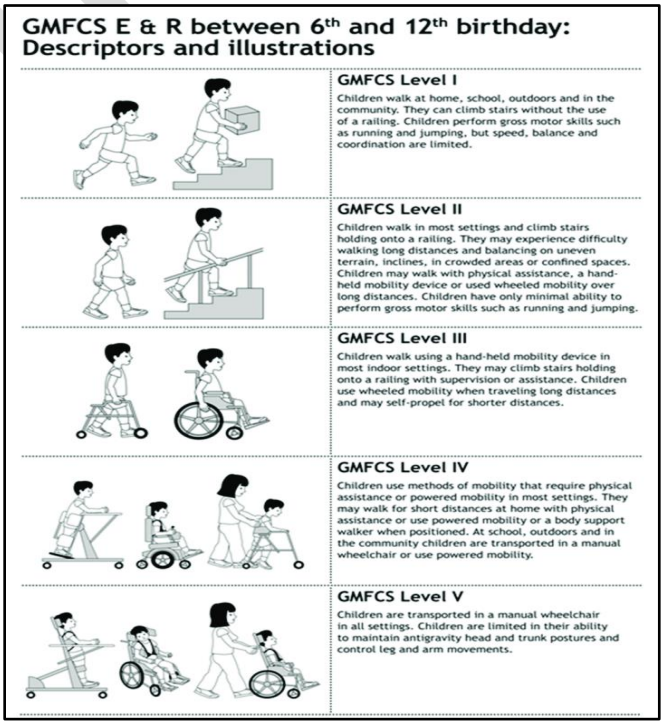

Figure 2: Gross Motor Function Classification System (GMFCS)

Methods

Overview

The study design will be a quasi-experimental design that would take place in an Occupational Therapy office. This method was chosen, as best, to replay the cause-and-effect relationship between being in a standard physical therapy program or a specialized physical therapy program. In total, 100 children with Cerebral Palsy between the ages of 5 and 11 years old will be recruited from a pediatric therapy center. This range of children would be best to recruit because starting therapy at a younger age would be most beneficial for the children and would highlight the amount of progression or no change to their GMFCS. Since children grow and adapt at higher rates than teens and adults, their progression is easier to account and record for. The children recruited to participate in the study will be non-weight bearing at baseline (Level V). This scale is most favorable because one could see how well the therapies could be affecting the kids that would need the most help. Our recruitment method to encourage families to allow their children to participate includes informing them of the exponential progress the children could potentially experience regarding activity performance, such as walking. They would also be informed that the therapy sessions are free and every therapy protocol they follow can be written down and taken home for continued practice.

Protocol

From the 100 children chosen, 50 will be picked at random for the experimental group with completed consent forms and will be asked to attend a specialized standing/walking program. The other 50 children will be used as a control group to compare to the children attending the specialized program, however, those in the control group will only attend the baseline amount of physical therapy recommended for children with CP. The experimental group will be asked to go to the therapy center for an hour, three times a week for an entire year and complete the specialized program that heavily focuses on activities and exercises that will aid in the progression of walking while the control group will attend and perform their therapy on their own account and time that they wish to attend.

A few examples of exercises that the specialized program would include are standing unassisted against a wall, playing in a free-standing position, asymmetrical standing, and walking with different aids for as long as they can each time. Over time, these example exercises, along with other exercises, will not only increase in length of the exercise but also by intensity to increase their activity performance in terms of walking. Every three months, both groups of children will be reassessed in terms of progress and ability to walk.

Figure 3 shows a few examples of exercises that the specialized program would include: standing unassisted, playing in a free-standing position, asymmetrical standing, and walking with different kinds of aids.

Figure 3: Exercises from the specialized program

Groups

The intervention group will be the children with Cerebral Palsy who complete the Specialized Therapy Program and will have 150 sessions at the therapy center (3 sessions every week for 1 year). Each session will be in-person with a licensed Occupational Therapist and last one hour, which can be seen in ***Figure 4.***

The control group includes the children with Cerebral Palsy who are also non-weight bearing at baseline but will be receiving standard care and not the specialized therapy program. They will attend therapy in-person, which is standard care for those with CP, but will not participate in the program that focuses on specific exercises to increase walking performance. They will also not be given any guidelines on how many times a week or how long they chose to be in standard therapy for.

Timeline of Procedure											
Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Experimental group: Children attend therapy with OT 3 days a week, every week, for a year											
Day 1: Initial assessment & add additional therapy program (for duration of study)		Month 3: 3 month assessment			Month 6: 3 month assessment			Month 9: 3 month assessment			Final Day: final assessment

Figure 4: Timeline of experimental study

Measures

Activity Performance. The Occupational Therapist administering the therapy will use the Gross Motor Function Classification System (GMFCS) to observe the progress in activity performance of the children. The scale has five levels, Level I indicating no restrictions walking while Level V indicating non-weight bearing, wheelchair bound, and limited ability in control of arms and leg movements. The children, both in the experimental group and control group, will be measured pre-intervention, every 3 months, and post-intervention using the system over the period of a year. Progress will be defined as a single increase in level, for example, a child starts at Level V on the system and ends treatment at a Level IV. In a 2009 prospective study *Activity focused and goal directed therapy for children with cerebral palsy – Do goals make a difference?*" the GMFCS was used as one of the tools to evaluate the change in gross motor function and recording the children's performance. The system is reliable and reflects accurately on the status of the person by scaling the ability of movement they can achieve.

Data Handling Procedures

The main outcome of interest for our study is assessing what would hope to be the increase in activity performance for children with Cerebral Palsy in a Specialized Therapy Program, more specifically, the increase from non-weight bearing to weight bearing and walking. Making sure that the participants that are in the specialized program are keeping up with their therapy sessions and continuing to keep up their part, over the year, is the best way to receive accurate results. We plan to dichotomize our outcome variable into (1) those who move from a lower level on the GMFCS to a higher level versus (2) those who do not move up by any level.

Analytic Plan

The main independent variable of this study is the specialized therapy program that the selected group of children with CP will follow over a year in hopes to increase activity performance. The dependent variable is the level of activity performance or level of walking (independently, with aid, or non-weight bearing). A covariate of this study is age, in that the children must be within 5-11 years old to partake. The type of analysis used to answer the research question will be a T-test. This test will determine if there is a significant difference between the two groups, experimental and control.

Expected Results

After reading through various peer-reviewed articles, the hypothesis for this study is that if children with Cerebral Palsy follow the additional Specialized Therapy Program implemented, then they will have increased activity performance compared to the children with CP that obtain the standard treatment of care. We discovered one study that focused on two different training therapies to improve gait, balance, and muscle strength in children with CP. This study focused on treadmill training with virtual reality versus treadmill training without, leading to the conclusion that gross motor function increased significantly from 63.1 to 72.2 in the Virtual Reality Treadmill Training group and from 62.0 to 65.2 in the Treadmill Training group after training.[3] Similarly to this study, it is expected that the CP children that participate in the additional Specialized Therapy Program (experimental group) will have a greater increase in growth motor performance compared to those who do not participate in the additional Specialized Therapy Program (control group), as pictured in ***Figure 5***.

Figure 5: Expected results based on hypothesis

Limitations

A limitation of our study may be the accountability and upkeep responsibility of the participants. Being that the participants would have to attend our additional specialized therapy sessions a few days a week as well as their pre-existing therapy program, there is a possibility they may not be attending all sessions. Another limitation of our study is that the participants can be of different severities of Cerebral Palsy. The participants' severity (high functioning verses low functioning) could pre-determine the success of the child's program. In addition, the intervention period of 1 year may not show extensive progress of walking in the children with CP.

Ethical Principles

We will ensure the research will be conducted in a safe, harmless, and confidential manner through informed consent. Informed consent ensures participants understand they are taking part in research and what is required of them. Researchers will also be available for any questions or concerns the caretaker of the child may have to make certain they stay committed to the study.

Future Implication

A future implication for this study would be to have a longer intervention period as the results may not demonstrate potential long-term therapeutic efficacy, due to the intervention period only being one year. This future research study could also focus on mitigating the adverse effect of motor disability which is essential to improve the performance of physical activities in children with Cerebral Palsy. Severity of fine motor impairment is the most common determinant shared by both performance of physical activities and cognitive and behavioral activities. Thus, a future study could compare progress between children of different severities of CP to see the effect of the Specialized Therapy Program on high and low functioning children with CP. Another ideal future implication would be to work closely with the current therapists of the children with Cerebral Palsy to incorporate this Specialized Therapy Program into their current therapy sessions.

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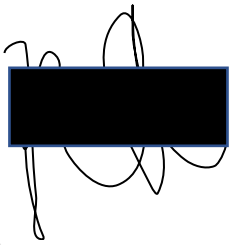
[redacted]	20%	
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