FULL STUDY PROTOCOL,

STATISTICAL ANALYSIS PLAN (SAP)

& INFORMED CONSENT FORMS (ICF)

Effectiveness of Motion Minder Therapy (MoMT) Among

Children with Spastic Hemiplegic Cerebral Palsy: A Pilot Study

Ethical Approval: 12/32/2024/ISRB/SR/SCPT

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1. Personnel

Principal Investigator	Mr. Jeevarathinam Thirumalai
Investigators	Prof. Dr. Vinodhkumar Ramalingam

2. Introduction

2.1 Background & Aims

Motion Minder Therapy (MoMT) is an innovative intervention, finely tuned to enhance fine motor skills in children facing the complexities of spastic hemiplegic cerebral palsy. MoMT propels forward by seamlessly integrating a unique blend of fine motor exercises and the incorporation of sensory cueing commercial watches. This intricately designed and tailored therapeutic approach holds the potential to reshape the landscape of fine motor skill development, emphasizing coordination and precision within a structured and engaging framework.

MoMT builds upon the successes of "Remind to Move Therapy," a methodology involving 5 to 6 hours of intervention to enhance upper extremity function with the therapist supervision. However, MoMT takes a significant leap forward by streamlining and targeting the intervention to a focused 1-hour duration with the therapist supervision. This strategic refinement aims to optimize the impact on fine motor skills in children with cerebral palsy.

Our futuristic therapy takes a pioneering leap by incorporating advanced sensory cueing mechanisms to augment the rehabilitation process. Leveraging the latest technology, we integrate commercial watches equipped with tactile vibrations and auditory alarms, as outlined in our meticulously crafted protocol.

The incorporation of tactile vibrations from commercial watches serves as a groundbreaking sensory cueing method. These vibrations are strategically designed to provide real-time feedback, enhancing proprioception and facilitating a more profound connection between the individual and their upper extremity functions. The tactile cues act as a guide, promoting a heightened awareness of body positioning and movement execution.

Simultaneously, auditory alarms emitted by the commercial watches introduce an additional layer of sensory stimulation. These alarms are synchronized with specific therapy milestones, creating a

dynamic auditory feedback system. This not only reinforces positive behaviours but also aids in the development of bimanual coordination, and unimanual dexterity. The integration of sound cues into our therapy protocol is a futuristic approach that transforms the rehabilitation experience, making it more engaging, responsive, and tailored to the individual's unique needs.

By merging cutting-edge technology with therapeutic principles, our approach not only addresses motor skills but also explores innovative avenues to enrich the sensory experience, paving the way for a more effective and immersive rehabilitation journey.

2.2 Background Literature Review

In a groundbreaking initiative, **Fong KN et al. (2013)** pioneered the concept of "Remind-to-Move Therapy," presenting the very first article on this innovative approach aimed at enhancing upper extremity motor function. This pioneering pilot study offers compelling proof-of-concept data, demonstrating the potential of a wearable device to serve as a reminder for children with cerebral palsy to engage in a predetermined set of arm exercises. The study's findings suggest that this novel approach holds promise for effectively promoting hemiplegic arm function, marking a significant stride forward in the integration of technology into therapeutic interventions for motor enhancement [(1)].

Various research has looked at the viability and safety of using tactile sensory cueing in a variety of situations, including chronic stroke survivors, with encouraging results. Investigating the effectiveness of combining this tactile cueing method with therapy to improve neurorehabilitation results is a logical next step in the research process [(2)].

In a pivotal study conducted by **Dong AQ et al. in 2016**, a groundbreaking revelation emerged: three weeks of 'Remind-to-Move' treatment proved to be instrumental in enhancing hemiplegic arm

function and increasing the quantity of hand use in children with unilateral cerebral palsy. This temporal intervention demonstrated immediate and tangible benefits, showcasing the potential of this innovative therapeutic approach. However, the study aptly points out that the exploration of long-term carryover effects remains an avenue for further investigation, underscoring the need for continued research to unveil the full scope and sustained impact of this promising intervention in the realm of paediatric rehabilitation [3].

Various convention interventions, such as the Hand-Arm Bimanual Intensive Therapy (HABIT) study by **Gordon AM et al.,** and Constraint-Induced Movement Therapy as studied by **Ramey SL et al.,** have demonstrated noteworthy success in enhancing motor function, surpassing conventional approaches. These therapeutic methods showcase a significant leap forward in improving motor skills, underscoring their potential to rehabilitation practices [4,5]

3. Study Protocol

3.1 Research Design Outline

The study aims to perform a pilot study on spastic hemiplegic cerebral palsy children in Aadhuraa Special School and Saveetha Medical College and Hospital.

Formerly titled "Effectiveness of Motion Minder Therapy (MoMT) Among Children with Spastic Hemiplegic Cerebral Palsy: A Pilot Study" involves children with spastic hemiplegic cerebral palsy children by using the Shriners Hospital Upper Extremity Evaluation 10. The outcome is the total score of the spontaneous functional analysis, dynamic positional analysis, and grasp/release analysis. Total scores of 45 for spontaneous functional analysis, 72 for dynamic positional analysis and 6 for grasp/release. Higher scores mean a better outcome.

3.2 Participants

Special school students from Aadhuraa Special School and Outpatient children from Saveetha Medical College and Hospital with spastic hemiplegic cerebral palsy will be eligible to participate in this study.

3.3 Recruitment

All children with spastic hemiplegic cerebral palsy attending Aadhuraa Special School and Saveetha Medical College and Hospital will be enrolled in the pilot stud. The participation information and consent sheet will be distributed to parents' which details including inclusion and exclusion criteria. Parents who agree to the investigation will be invited to undergo baseline assessments (Upper Limb Function - Shriners Hospital Upper Extremity Evaluation (SHUEE), Dexterity - Nine Hole Peg Test, Behavior - Strengths and difficulties questionnaire) All parents will have to return a signed consent form to the site principal investigator.

3.4 Administration

Time (Min)	Activity	Time (Min)	Sensory Cueing Timing
0.00 To 05.00	**Sticker Sorting**	**5 min**	0.00
5.00 To 6.00	Rest & Reflection	1 min	-
6.00 To 14.00	**Beads On Parade**	**8 min**	06.00
14.00 To 16.00	Rest & Reflection	2 min	-
16.00 To 24.00	**Pegboard Activities**	**8 min**	16.00
24.00 To 26.00	Rest & Reflection	2 min	-
26.00 To 32.00	**Sensory Bins**	**5 min**	26.00

32.00 To 33.00	Rest & Reflection	1 min	-
33.00 To 41.00	**Sculpture Building**	**8 min**	33.00
41.00 To 46.00	Rest	5 min	-
46.00 To 54.00	**Finger Painting & Drawing with different tools**	**8 min**	46.00
54.00 To 55.00	Rest & Reflection	2 min	-
55.00 To 60.00	**Musical Instrument Play**	**5 min**	55.00

*Min – Minutes

1. Sticker Sorting:

Sticker sorting involves using a variety of colourful stickers that differ in size, shape, and texture. The child is encouraged to sort and place stickers onto corresponding shapes or categories. This activity enhances fine motor skills, hand-eye coordination, and cognitive abilities through visual discrimination.

2. Beads on Parade:

Beads On Parade involves threading colourful beads onto strings or wires to create vibrant patterns or jewellery. This activity targets fine motor coordination, bilateral hand use, and visual-motor integration. It fosters improved dexterity and hand strength while encouraging creativity.

3. Pegboard Activities:

Pegboard activities consist of arranging and securing pegs into a board with corresponding holes. Children can create various designs or replicate given patterns, promoting precision, hand strength, and spatial awareness. This activity enhances both fine motor skills.

4. Sensory Bins:

Sensory bins are containers filled with materials that engage different senses, such as touch and sight. Children explore and manipulate items like rice, beans, or textured objects, stimulating sensory perception and improving tactile sensitivity. This activity also encourages hand exploration for fine motor skills and sensory integration.

5. Sculpture Building:

Sculpture building involves using materials like clay or playdough or clay to create three-dimensional shapes and structures. This activity enhances fine motor skills, hand strength, coordination and creativity. Children with hemiplegic cerebral palsy can benefit from practicing bilateral hand use and refining their grasp patterns.

6. Finger Painting & Drawing with Different Tools:

Finger painting and drawing involve creating art using various tools like paintbrushes, sponges, or even fingers. This activity enhances fine motor skills, hand control, and creativity. Offering a range of tools accommodates different grip strengths and preferences, allowing children to explore their artistic abilities.

7. Musical Instrument Play:

Musical instrument play involves using instruments such as Mini Guitar, Maracas and Xylophone. Children are encouraged to use both hands to produce different sounds and rhythms. This activity promotes bilateral coordination, fine motor control, and sensory integration through auditory and tactile experiences.

3.5 Assessment & Outcomes Measures

3.5.1 Primary outcomes

- Shriners Hospital Upper Extremity Evaluation (SHUEE)
    - The Shriners Hospital Upper Extremity Evaluation is a video-based tool for the assessment of upper extremity function. The outcome is the total score of the spontaneous functional analysis, dynamic positional analysis, and grasp/release analysis.
    - Total scores of 45 for spontaneous functional analysis, 72 for dynamic positional analysis and 6 for grasp/release. Higher scores mean a better outcome.
    - [Time Frame: Baseline, 4th week, 8th week, 12th week]
- Nine Hole Peg Test
    - Nine Hole Peg Test is used to measure the dexterity. Scores on nine-hole peg test are measured in seconds, indicating time taken to complete task.
    - Higher scores indicate worse outcome, as they show slower completion times and reduced dexterity.
    - [Time Frame: Baseline, 4th week, 8th week, 12th week]

3.5.2 Secondary outcomes

- Strengths and difficulties questionnaire
    - The 25 item Strengths and Difficulties Questionnaire (SDQ) measures behavioral and emotional function. These 25 items are divided into 5 subscales: emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship

problems, and prosocial behavior.

- The Strengths and Difficulties Questionnaire is scored on a 3-point Likert-type scale, with total scores (excluding the prosocial scale) ranging from 0 to 40. Higher scores reflect greater behavioral and emotional difficulties.
- [Time Frame: Baseline, 4th week, 8th week, 12th week]

4. Statistical Analysis Plan (SAP)

Descriptive and inferential statistics will be used. Normally distributed data will be presented by mean and standard deviation (SD) and non-normally distributed data will be presented by median and interquartile range. Categorical data will be presented using percentages. SPSS (version 22.0) will be used for all statistical analyses.

4.1 Primary Outcomes

The primary analyses will find effect i) pilot group guidelines on their mean and standard deviation: (i) Shriners Hospital Upper Extremity Evaluation (SHUEE), (ii) Nine Hole Peg Test. P-values <0.05 will be considered statistically significant.

1*4-Repeated measures analysis of variance (ANOVA) will be performed to test the effectiveness in the intervention between the time intervals (baseline, mid-intervention, post-intervention, and follow-up).

The post–hoc analysis will be conducted to investigate significant effect within the time intervals. Condition on if the sphericity violated (p-value < 0.05), the Greenhouse- Geisser estimated correction will be applied.

4.2 Secondary Outcomes

The primary analyses will find effect i) pilot group guidelines on their mean and standard deviation: (i) Strength and Difficulties Questionnaire (SDQ). P-values <0.05 will be considered statistically significant.

1*4-Repeated measures analysis of variance (ANOVA) will be performed to test the effectiveness in the intervention between the time intervals (baseline, mid-intervention, post-intervention, and follow-up).

The post–hoc analysis will be conducted to investigate significant effect within the time intervals. Condition on if the sphericity violated (p-value < 0.05), the Greenhouse- Geisser estimated correction will be applied.

4.3 Missing Data

For children who do not attend the assessment, the mean imputation of the assessment scores from their allocation group will be used.

5. Informed Consent Forms (ICF)

Written consent will be gained from the parents of children with spastic hemiplegic cerebral palsy using the consent forms attached to the application.

5.1 Rights and Risks to participants

Rights

The parents may decide to stop being a part of this research study at any time without explanation. The parents have the right to omit or refuse to answer or respond to any

question that is asked about their children. In addition, they have the right to ask any questions about the procedures practiced in children (unless answering these questions would interfere with the study outcome). If they having any questions on this information sheet/test/training, they may ask the investigator or research in-charge person before the study begins or during the course of assessment and interventions. Participation in this study is voluntary and it doesnot carry any remuneration or reimbursement.

Risks

Researcher does not anticipate any risk from this research study.

5.2 Privacy and Confidentiality

All children will be de-identified and assigned a unique ID number at the time of enrollment, which will be recorded by the administration officer at the study site. The videos of the Shriners Hospital Upper Extremity Evaluation will not be shared in any way due to the ethical policies of the study sites.

6. References

1. Fong KN, Jim ES, Dong VA, Cheung HK. 'Remind to move': a pilot study on the effects of sensory cueing treatment on hemiplegic upper limb functions in children with unilateral cerebral palsy. Clinical Rehabilitation. 2013 Jan;27(1):82-9.
2. Seo NJ, Enders LR, Fortune A, Cain S, Vatinno AA, Schuster E, Ramakrishnan V, Feng W. Phase I safety trial: Extended daily peripheral sensory stimulation using a wrist-worn vibrator in stroke survivors. Translational stroke research. 2020 Apr;11:204-13.
3. Dong AQ, Fong NK. Remind to move–A novel treatment on hemiplegic arm functions in children with unilateral cerebral palsy: A randomized cross-over study. Developmental neurorehabilitation. 2016 Sep 2;19(5):275-83.

4. Gordon AM, Schneider JA, Chinnan A, Charles JR. Efficacy of a hand–arm bimanual intensive therapy (HABIT) in children with hemiplegic cerebral palsy: a randomized control trial. Developmental Medicine & Child Neurology. 2007 Nov;49(11):830-8.9
5. Ramey SL, DeLuca SC, Stevenson RD, Conaway M, Darragh AR, Lo W. Constraint-induced movement therapy for cerebral palsy: A randomized trial. Pediatrics. 2021 Nov 1;148(5).