Repetitive Task Practice-based Computer Game-assisted Rehabilitation Platform for Hand and Arm Impairments in Children with Cerebral Palsy

By

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List of Abbreviations

#	Abbreviation	Full Form
1.	ADL	Activities of Daily Living
2.	AHA	Assisting Hand Assessment
3.	BBT	box and blocks test
4.	BOT	Bruininks-Oseretsky Test of Motor Proficiency
5.	BOT-2	Bruininks–Oseretsky Test of Motor Proficiency, Version-2
6.	CG	Control Group
7.	CIMT	Constraint Induced Movement Therapy
8.	COPM	Canadian Occupational Performance Measure
9.	CP	Cerebral palsy
10.	CUE	A Computer Game-Assisted Upper Extremity Assessment Tool
11.	EBS	Emerging Behaviors Scale
12.	FIM	The Functional Independence Measure for Children
13.	GAS	Goal Attainment Scale
14.	GMFCS	Gross Motor Function Classification Scale
15.	GRP	Computer Game-assisted Rehabilitation Platform
16.	HABIT	The Hand Arm Bimanual Intensive Therapy
17.	IB mouse	Inertial Based Mouse
18.	ICC	Intra-Class Coefficient
19.	JTTHF	The Jebson Taylor Test of Hand Function
20.	LIFE-H	Assessment of Life Habits
21.	MACS	Manual Ability Classification Scale

22.	mASH	Modified Ashworth Scale
23.	MAUL	Melbourne Assessment of Upper Limb Function
24.	mCIMT	Modified Constraint Induced Movement Therapy
25.	MDC	Minimal Detectable Change
26.	Mitii	Move it to improve it protocol
27.	MMSE	The Pediatric Version of The Mini-Mental Status Evaluation
28.	PDMS-2	Peabody Developmental Motor Scales, Second Edition
29.	PEDI	The Pediatric Evaluation of Disability Inventory,
30.	PMAL	The Pediatric Motor Activity Log
31.	QUEST	Quality of Upper Extremity Skills Test
32.	RTP	Repetitive Task Practice
33.	SCPE	The Surveillance of cerebral palsy in Europe
34.	TAUT	Toddler Arm Use Test
35.	UE	Upper Extremity
36.	WFMT	The Wolf Fine Motor Test
37.	XG	Experimental Group

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Contribution of authors

Manuscript 1: Reliability and validity of a computer game-based tool of upper extremity assessment for object manipulation tasks in children with Cerebral Palsy.

Authors: Anuprita Kanitkar, Sanjay T Parmar, Tony J Szturm, Gayle Restall, Gina Rempel, Nilashri Naik, Neha Gaonkar, Nariman Sepehri.

Manuscript 2: Evaluation of a computer game-assisted rehabilitation program for manual dexterity of children with cerebral palsy: Feasibility randomized control trial

Authors: Anuprita Kanitkar, Dr. Sanjay Tejraj Parmar, Dr. Tony Joseph Szturm, Dr. Gayle Restall, Dr. Gina Ruth Rempel, Dr. Nariman Sepehri

Manuscript 3: Parents' perspectives on a computer game-assisted rehabilitation program for manual dexterity in children with Cerebral Palsy: Qualitative analysis of expectations, child engagement, and benefits

Authors: Anuprita Kanitkar, Sanjay Tejraj Parmar, Tony J Szturm, Gayle Restall, Gina Rempel, Nariman Sepehri

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Chapter 1: Thesis Abstract

Children with cerebral palsy (CP) often present with upper extremity (UE) function impairments that hamper physical and functional abilities necessary for daily activities of daily living (ADL) and participation at play and leisure activities in various environments. The traditional repetitive task practices (RTP) have proven helpful when therapists provide one-on-one therapy for long duration and with high repetitions. Unfortunately, compliance with such time-intensive therapy interventions is low. We have developed a low-cost computer game-assisted rehabilitation platform (GRP) based on RTP principles to provide fine and gross motor UE exercises for children with CP.

The aim of this thesis was to determine the reliability and validity of the Computer games-assisted Upper Extremity (CUE) assessment tool and feasibility of conducting a full scale, multicenter randomized controlled trial (RCT) to evaluate the treatment effect of the RTP-based computer game-assisted rehabilitation platform (GRP) in improving upper limb function in 4 to 10-year-old children with CP. For understanding the feasibility, a mixed method exploratory randomized controlled trial was conducted.

For assessing the test-retest reliability and convergent validity of the CUE assessment tool, thirty-five children with CP (age 4 to 10 years) were recruited. Assessments were performed two weeks apart. During the first assessment session, participants were assessed using the Quality of Upper Extremity Skills Test (QUEST) and Peabody Developmental Motor Score version-2 (PDMS-2) along with the CUE assessment tool. Data analysis showed moderate to high Intra Class Coefficient (ICC) scores with low to moderate Minimal Detectable Change (MDC) values, with excellent test-retest reliability.

For the RCT, the experimental group received a forty-five minute GRP based therapy session three to five times a week for sixteen weeks. The control group received forty-five minute high repetitions of various task-based activities sessions three to five times a week for sixteen weeks. Pre- and post-intervention assessments were conducted using the QUEST, PDMS-2, and CUE assessment tool scores. Semi-structured interviews of parents were conducted at the end of the 16-week-long therapy protocol. The qualitative and quantitative data analysis results show that the GRP platform effectively improves object manipulation skills in children with hand and arm function impairments due to CP.

Chapter 2: Review of Literature

Epidemiology

Cerebral palsy (CP) is a commonly occurring neurodevelopmental disorder usually diagnosed early in life and persisting throughout the lifespan. In India, where the studies in this thesis were carried out, CP occurs in affects five of every thousand live births. (Mâsse et al., 2013; Odding et al., 2006). Morris et al. (2007) describe CP as “a group of permanent disorders of movement and posture development causing activity limitation, which is attributed to non-progressive disturbances that occurred in the developing, fetal or infant brain” (Morris et al., 2007). CP can be identified by movement disorders and motor disabilities manifested by atypical development of the head and trunk stability, abnormal movement of the extremities, and impaired fine motor function causing difficulty in activities of daily living (*Cerebral Palsy | Ontario Brain Institute*, n.d.). The prenatal causes of CP include toxin or drug exposure, maternal diabetes, and/or hypertension, infection, consanguineous parenthood (Krigger, n.d.). Perinatal injuries to the developing brain can occur due to eclampsia, meconium aspiration, and birth asphyxia (Krigger, n.d.). The first two of years after birth are equally critical for the developing brain, and infections and trauma can be important post-natal causes of CP.

Children with CP are faced with physical impairments such as hypertonicity resulting in deformities and contractures, reduced range of motion, strength, endurance, and speed, along with impairment of coordination in bimanual activities (Morris et al., 2007). These impairments hamper the structural and functional abilities necessary for activities of daily living (ADL) and participation in school, play, and leisure (Arner et al., 2008b).

Almost 50% of children with CP present an arm-hand dysfunction (Arnould et al., 2014). The ability to perform ADL can significantly impact the child’s level of independence.

Impairments in hand and arm function vary according to the underlying pathology and timing of the injury to the developing brain that resulted in the child's CP (Arner et al., 2008a).

The Surveillance of CP in Europe (SCPE) network collected data from 15 countries for defining and classifying CP (CANS et al., 2007; Scpe, 2000). According to this collaborative work, the most widely used, reliable, and valid classification of CP for evaluating interventions is based on the type of motor impairment that causes abnormal movement patterns. In the work of the SCPE, the following types of CP are described:

- Spastic CP typically results in hypertonia and hyperreflexia
- Dyskinetic CP affects involuntary movements with fluctuating tone or dystonic or choreo-athetoid pattern, the latter consisting of manifesting as repetitive, jerky small amplitude movements
- Ataxic CP results in a lack of movement coordination and voluntary tremors

While these topographic classifications of CP have some relevance to the current discussions (for example, unilateral CP is often referred as spastic hemiplegia), these classifications are falling out of favor because these types of classifications are not always exclusive and may coexist as a mixed form of CP (CANS et al., 2007). As a part of the SCPE network, Rosenbaum et al., (2007) further studied the above-mentioned motor impairment classification. The SCPE network suggests that using these descriptive/anatomic classifications of CP can be imprecise. In addition, it does not provide information about the characteristics of the child's impairments based on functional abilities, accompanying impairments, causes, and neuroimaging findings of the CP, which must be taken into consideration (Rosenbaum et al., 2007). They also recommend using various standardized, objective, functional scales such as the Gross Motor Function Classification Scale (GMFCS) and the Manual Ability Classification Scale (MACS) for fine motor classification to further describe the motor impairment in children with CP (Rosenbaum et al., 2007).

The classification in GMFCS stratifies children into five categories based on their level of mobility and their dependence or need for physical assistance (Bodkin et al., 2003a). It is an observation-based scoring system without an objective measurement of function. It focuses only on the gross movements and does not assess or describe the intricate movement patterns or motor control required to perform object manipulation with precision. The MACS categorizes children based on their ability to use daily objects for dressing, feeding, and leisure. This, too, is an observational scale that does not specify the complexity of the objects or functional tasks given to the child (Eliasson et al., 2006a). Thus, both the GMFCS and the MACS are unable to detect gradual improvements in the complex object manipulation movements and functional tasks. Despite these drawbacks, the GMFCS and the MACS are widely used to describe the severity of functional impairments in children with CP due to the simplicity of administering the tests and their high reliability and validity (Bodkin et al., 2003a; Eliasson et al., 2006a; Rosenbaum et al., 2007). However, these assessment tools are too general for the purposes of this study as the focus of this thesis proposal is on the improvements in hand and arm functions in children with spastic CP. More intricate measurement tools are required.

Objective Assessment Tools for Upper Extremity Functioning

When assessing changes in hand and arm function in children with CP, it is important to examine their ability to perform functional object manipulation tasks using a quantifiable objective assessment tool. The Jebson Taylor Test of Hand Function (JTTHF) is used to determine the time taken to complete a given unimanual task. The tasks list includes turning cards, picking up heavy or light objects, writing, etc. The Bruininks–Oseretsky Test of Motor Proficiency, version-2 (BOT-2) assesses bimanual activities such as bouncing a ball with two hands, ball catching and throwing, stringing beads, etc., on a scale of 0 to 9 on four UE function subtests. Several structured, semi-structured interviews and questionnaires such as the Canadian Occupational Performance Measure (COPM), the Pediatric Evaluation of Disability Inventory, the Goal Attainment Scale (GAS), the Pediatric Upper Extremity Motor Activity Log (PMAL), the ABILHAND-kids, and the Functional Independence Measure for Children (FIM) have been used to record the responses of caregivers, children or parents to measure the level of ADL (Arnould et al., 2004; Cup et al., 2003; Kramer et al., 2016; Law et al., 2004; Liu et al., 1998; Uswatte et al., 2012). Therapist observation-based assessments include the Quality of Upper Extremity Skills Test, which examines the range of motion, reflexes, and manipulation of three objects (a cube, a crayon, and a pellet) and the Peabody Developmental Motor Scale version 2, which examines the level of functional activities such as drawing, paper cutting, use of cubes and pellets for play, etc. (Thorley et al., 2012a; H.-H. Wang et al., 2007). Video capture analysis-based assessment tools such as the Assisting Hand Assessment (AHA) and the Melbourne Assessment of Unilateral Upper Limb Function (MAUL) consider the components of every movement, such as range of motion, target accuracy, fluency, grasp quality, release accuracy. However, time constraints allow observation of the manipulation of only two objects (i.e., crayon and pellet) for assessment in the MAUL. Assessment gaps also exist for the AHA, where the details of movement component scoring are missing, and hence the scoring is done subjectively by the assessors (Krumlinde-Sundholm et al., 2007; Randall et al., 2010).

Traditional Repetitive Task Practice (RTP)-based Therapy Approaches

There have been a wide variety of therapy programs proposed for UE rehabilitation. Current fine and gross motor function rehabilitation approaches include RTP of goal-oriented movements and activities, such as constraint-induced movement therapy and hand-arm bimanual intensive therapy (HABIT).

Constraint Induced Movement Therapy (CIMT). The fundamental technique of CIMT requires putting a constraint on the unaffected arm in children with unilateral CP to force more frequent use of the affected arm with the help of therapy to induce active participation of the affected arm.

Originally, CIMT therapy consisted of constraining the unaffected UE with a splint or cast for most or all of the day, for a period of two to four weeks. This was often accompanied by intensive therapy sessions lasting for six or more hours per day. The very first of such studies was a single-blinded, randomized, control study of CIMT in children with unilateral CP (n= 18, 7–96 months old) was by Taub, Ramey, DeLuca, & Echols et al., in 2004 (Taub et al., 2004). This study required participants from the experimental group to keep their unaffected arm and hand in a cast for a one-month period while they received structured practice six hours a day for twenty-one days. The control group received conventional therapy. The details of the control group's intervention are not mentioned. The Pediatric Motor Activity Log and Emerging Behaviors Scale (EBS) were used to maintain the children's log of improvements. The EBS showed a large amount of improvement in the experimental group compared to the control group showing an increased number of motor patterns and classes of behavior exhibited from pre- to post-intervention (change in classes of behavior score, experimental group =9.3 control group = 2.3). They performed a repeated measures Analysis of Co-Variance (ANCOVA) analysis to compare the between-group as well as within-group changes. The results of the analysis showed a significant effect of the intervention. ($p < 0.0001$) Children from the experimental group showed significantly better improvements than children from the control group on the EBS scores. The Pediatric Motor Activity Log subscores for hand use and quality of use for pretreatment and follow-up scores (three weeks post-intervention) were analyzed using a repeated measure, multivariate ANCOVA, which showed a significant effect for the treatment*time interaction ($P<0.0001$). There were significant improvements on both scales for children receiving experimental group therapy compared with the control children. This robust protocol produced excellent results in improving the hand function of the affected arm in children from the experimental group.

Similar results were found in adults with stroke in a large multi-center study by Wolf et al., in 2006 and a subsequent study in 2008 in which 222 participants underwent the “Extremity Constraint Induced Therapy Evaluation (EXCITE) trial. During the EXCITE intervention trial, participants were made to wear a mitt for 90% of their waking hours while undergoing intensive therapy for six hours a day (Wolf et al., 2006, 2008). Like Taub et al., (2004), Wolf et al., demonstrated significant improvements in the experimental group compared to the control group. The use of the protocol was advocated for children and adults. However, it was not a practical, clinical approach because of difficulty maintaining adherence to such intensive forced therapy protocols in children, at least in part related to short attention spans. Hence, clinically feasible and adaptable family-friendly versions of CIMT have been developed.

To improve compliance with the CIMT, the type, duration, and restraint are usually altered in modified CIMT (mCIMT) protocols (Eliasson, Krumlinde-Sundholm, et al., 2005). Eliasson et al., (2005) developed a protocol with decreased hours per day of both the restraint and the RTP in order to achieve the improved motor performance of the affected UE in a selected group of children with unilateral CP (Eliasson, OT, et al., 2005). Forty-one children (aged 1.5 to 4 years) with unilateral CP participated in either an experimental therapy group that constraint induced therapy with a fabric glove for two hours a day for seven days a week for two months or a control group that received regular conventional therapy. The AHA was used to measure the progress made by participants from pre-intervention to 2 months and 4 months post-intervention. The scoring of AHA was based on observation analysis of fifteen-minute video recordings of tasks such as picking up toys of various sizes and dropping them in the bin. The movements made for reaching, moving the upper arm, stabilizing the weight, grasp, and release of the toy, etc., were graded by assessors by viewing the videotaped performances. The experimental group showed a significant increase in assisting hand assessment scores from pre- to follow-up (the 2- and 4-month post-intervention) assessments (Eliasson, Ot, et al., 2005). A significant interaction was found between group and AHA measure on ANOVA analysis (p=0.005). Similar results were seen in a study performed by Wallen et al., (2011).

Table 1 (page 18) presents pilot studies and RCTs that have used the CIMT approach. These trials use a wide range of inclusion criteria based on age, GMFCS, MACS levels. For quantitative data, comparisons were performed using a wide variety of outcome measures and methods. This made it difficult to compare the results of these studies. Overall, these studies reported moderate to large improvements due to CIMT or mCIMT across most UE outcome measures. Comparisons between the experimental and control groups revealed that the CIMT based approaches showed a larger treatment effect compared to the control group receiving conventional protocols.

Table 1: Studies with Constraint Induced Movement Therapy (CIMT) as an experimental group therapy

	Author and title	Article Type	Participants (N)	Experimental Group Protocol	Control Group Protocol	Outcome measures	Results
1.	Taub et al., (2004). Efficacy of constraint-induced movement therapy for children with cerebral palsy with asymmetric motor impairment.	A single-blinded, randomized, control CIMT study	N=18 Children with unilateral CP Age= 7 to 96 months	Structured practice six days a week + Constraining the unaffected upper limb with a splint or cast for most or all of the day, for a period of four to six weeks.	Constraining the unaffected upper limb with a splint or cast for most or all of the day, for a period of four to six weeks. Intensive therapy sessions lasting for six or more hours per day	EBS, PMAL (amount of use subscore and quality of use subscore), TAUT	On the EBS, The ANCOVA analysis showed a significant effect of the treatment in the experimental group (p<0.0001). On the PMAL scores, The RMANOVA showed a significant effect of treatment in the experimental group. Both subscores showed a significantly greater improvement in the experimental group than the controls. The treatment*time interaction effect was significant (p<0.0001). The TAUT scores showed that the experimental group performed significantly

						better than the control group.
2. Wolf et al., (2006) Effect of Constraint-Induced Movement Therapy on Upper Extremity Function 3 to 9 Months After Stroke.	RCT	N= 222 adults with stroke	Participants were made to wear a mitt for 90% of their waking hours while undergoing intensive therapy for six hours a day for a total of fourteen days	Usual protocol ranging from no treatment at all to use of orthotics or regular OT and/or PT sessions	WFMT, PMAL (amount of use subscore and quality of use subscore)	The experimental group showed significant improvements on the Wolf Motor Function Test and the Motor Activity Log
3. Eliasson et al., (2005)	Pilot RCT	N= 41 (aged 1.5 to 4 years) Children with unilateral CP	(n=25) mCIMT. Play-based activities that focused on the use of the unilateral hand. Therapy was provided either at home by parents or by preschool teachers in school for two months, seven days a week, two hours every day. In addition, participants wore a	(n=20) Regular conventional therapy physiotherapy twice per month and occupational therapy was generally once a month, or less often	Video recorded AHA,	The experimental group showed a significant increase in assisting hand assessment scores from pre- to the 2- month and 4-month post-intervention assessments. The control group did not show significant improvement. The treatment*time interaction showed a significant effect of CIMT treatment (*p*=0.005) between group and AHA measure.

				restraining glove two hours a day for two months			
4.	Charles et al., (2006) Efficacy of a child-friendly form of movement therapy in hemiplegic cerebral palsy : a randomized control trial.	A small, single-blinded, RCT	N= 22 (mean age 6 years 8 months)	restraining the unaffected arm for six hours a day for ten days with repetitive task practice (RTP) therapy by focusing on target movements; home therapy for five to seven hours a day during the ten-day intervention period followed by a total of seven hours of home therapy for six months post-intervention	Children in the control group did not receive any treatment	JTTHF Fine motor-subtests of BOT	For JTTHF, both groups improved, but children in the experimental group improved more than the controls (*p*<0.01). For the Fine motor-subtests of the Bruininks–Oseretsky Test of Motor Proficiency, both groups showed improvements in speed and dexterity in the involved hand, but children in the experimental group improved more than the controls (*p*<0.001) There were no significant treatment*time interaction effects seen in these outcome measures

5.	Wallen et al., (2011) Modified constraint-induced therapy for children with hemiplegia Cerebral palsy: a randomized trial	Small RCT	N= 50 Children with unilateral CP (Age range 19mo–7y 10mo)	(n=25) mCIMT with a mitt to constrain the unaffected hand and arm for two hours a day every day for eight weeks	(n=25) eight weeks of occupational therapy-based activities for twenty minutes a day. Therapy was provided by parents	COPM, AHA, GAS, PMAL, Modified Tardieu Scale	There were no clinically or statistically significant differences between groups COPM, AHA, GAS, PMAL, Modified Tardieu Scale at ten weeks or six months.

(EBS: Emerging Behaviors Scale, PMAL: The Pediatric Motor Activity Log-Revised, TAUT: The Toddler Arm Use Test, WFMT: The Wolf Fine Motor Test, AHA: AHA, JTTHF: Jebsen–Taylor Test of Hand Function, COPM: Canadian Occupational Performance Measure, GAS: Goal Attainment Scale).

CIMT has proven most useful in children with unilateral CP, among whom it induces unimanual function improvement of the affected UE. The results of these studies supported the idea of modifying the CIMT protocols by reducing the number of hours of restraint and continuing long term RTP for improving UE function in children with unilateral CP.

The Hand Arm Intensive Bimanual Training (HABIT). Another approach that focuses on RTP based therapy protocols is the Hand-Arm Intensive Bimanual Training, which emphasizes bimanual activity training. In contrast to CIMT, HABIT encourages the affected arm to function as an aid to the unaffected arm.

Initially, Gordon et al., (2007) conducted a small, pilot trial on twenty children with unilateral CP (n=10, aged 3.5 to 14 years). For the intervention group, therapy consisted of play-based functional activities that provided structured bimanual practice six hours per day for ten days, in addition to their regular ongoing therapy. The control group continued with regular, conventional therapy provided by their therapists. Each child was evaluated pre- and post-intervention, and again at 1-month post-intervention. Participants were assessed using the AHA with accelerometers to assess each arm's number of movement repetitions and scoring of activities involving picking up and placing down toys. The BOT-2 was also used for assessment. The Jebson-Taylor Test of Hand Function was used to determine the time taken to complete unimanual activities such as picking up small or light or heavy objects, turning cards, writing a sentence, etc. Finally, the drawer opening task using accelerometers recorded the time taken to complete the task of opening a drawer and clicking a button. The repeated measures ANOVA was performed to observe the within and between-group comparisons. The statistical analysis showed a significant increase ($p< 0.012$) in use of the affected arm during accelerometer recordings by the experimental group but not the control group. The treatment effect measured using AHA in the quality of grasping objects and bimanual task performance was significantly larger in the experimental group than the controls. Based on AHA scores, the affected arm's use improved significantly ($p<0.001$) in the experimental group compared to the control group. Similar results were also seen on the bimanual items subtest of the BOT-2. The BOT- 2 scores showed significant improvements ($p<0.023$) in the experimental group using the affected arm for bimanual activities. Overall, the HABIT approach proved to be more beneficial than the conventional approach (Gordon et al., 2007).

Sakzewski et al., (2011) compared goal-directed, fun, and engaging protocols based on the principles of CIMT and HABIT delivered during circus-themed summer camps for sixty-four children with unilateral CP (average age= 10.2 years)(Sakzewski, Ziviani, Abbott, et al., 2011). Both CIMT and HABIT groups were divided into two subgroups. The low frequency (three hours/day for ten days) subgroups received a total of thirty hours of training, whereas the high frequency (six hours/day for ten days) subgroups received a total of sixty hours of training. Children from the CIMT group were provided with a tailor-made glove during the treatment. The MAUL was used to assess the unimanual capacity of the impaired limb, and AHA was used to assess the bimanual coordination pre-intervention, three weeks post-intervention, and a follow up after twenty-six weeks. The statistical analysis of primary outcome measures showed no significant differences between the low frequency and high-frequency HABIT groups on both, Melbourne Assessment of Unilateral Upper Limb Function and AHA scores.

In contrast, the high-frequency mCIMT group performed significantly better ($p<0.001$) than the low-frequency mCIMT group. The performance scores on the COPM of high-frequency groups of both HABIT and mCIMT showed clinically significant improvements ($p<0.001$) from pre- to post- intervention. The HABIT group showed more improvements on fine motor components on the MAUL (for example, manipulation, grasp, and release items). In contrast, those in the CIMT group showed more improvement on more gross motor items (for example, reach, target accuracy, and transfer) (Sakzewski, Ziviani, & Boyd, 2011).

The principles of HABIT and mCIMT protocols focus on developing engaging, goal-oriented, high-repetition, functional task-based, long-term therapy approaches. Recent studies have used these principles to create more child-friendly combination therapy approaches while complying with these principles.

Table 2 (page 25) presents pilot studies and RCTs that have used the HABIT approach. These trials use a wide range of inclusion criteria based on age, GMFCS and MACS levels. For quantitative data, comparisons were performed using a wide variety of outcome measures and methods. This made it difficult to compare the results of these studies. Overall, these studies reported moderate to large improvements due to HABIT across most UE outcome measures. Comparisons between the experimental and control groups revealed that the HABIT based approaches showed a moderate to large treatment effect compared to the control group receiving conventional protocols.

Table 2: Studies that used HABIT protocol as the experimental group therapy.

	Author and title	Article Type	Participants (N)	Experimental Group Protocol	Control Group Protocol	Outcome measures	Results
1.	Gordon et al., (2007)	a small, randomized controlled trial	N= 20 (aged 3.5 to 14 years)	play-based functional activity practices six hours per day for ten days, in addition to their regular ongoing therapy.	regular, conventional therapy		The intervention group showed greater improvements than the controls in the quality of grasping objects and bimanual task performance measured using AHA (AHA).
2.	Sakzewski et al., (2011) Participation Outcomes in a Randomized Trial of 2 Models of Upper-Limb Rehabilitation for Children with Congenital Hemiplegia	a small, randomized controlled trial	N=64 children with unilateral CP (average age= 10.2 years)	HABIT either three or six hours a day for the ten-day camp	CIMT either three or six hours a day for the ten-day camp	COPM, LIFE-H	There were no between-group differences at Baseline. Both groups made significant changes for COPM Performance at three weeks (*p*=0.001). In the personal care subscore on LIFE_H, significant improvements were seen in both, experimental (*p*=0.01) as well as the control group (*p*=0.006)

3.	Deppe et al., {2013} Modified constraint-induced Movement therapy versus Intensive bimanual training for Children with hemiplegia – a Randomized controlled trial		N=47 children with unilateral cerebral palsy or other non-progressive hemiplegias {aged 3.3–11.4 years}	HABIT eighty hours in total over four weeks	mCIMT sixty hours in total, over a period of four weeks	MAUL, AHA	
4.	Facchin et al., (2011) Multisite Trial Comparing the Efficacy Of Constraint-Induced Movement Therapy with that of Bimanual	RCT	N=105	(n=39) for the CIMT group three hours a day for seven days a week for ten weeks	(n=33) for the HABIT group- three hours a day for seven days a week for ten weeks (n=33) for usual training group-1-hour standard rehabilitation	Videotaped Besta scale of activities of daily living and QUEST	The CIMT group showed significantly greater improvement in the fine grasp abilities of the affected hand, greater than HABIT group on both QUEST and Besta Scales. In comparison to the CIMT and HABITgroups, the usual therapy group showed minimal improvements

Intensive Training in Children With Hemiplegic cerebral palsy Postintervention Results	Sessions once or twice a week for ten weeks

(COPM: Canadian Occupational Performance Measure, LIFE-H: Assessment of Life Habits, MAUL: Melbourne Assessment of Unilateral Upper Limb Function, AHA: AHA, QUEST: Quality of Upper Extremity Skills Test)

The principles of HABIT and mCIMT protocols focus on developing engaging, goal-oriented, high-repetition, functional task-based, long-term therapy approaches. Recent studies have used these principles to create more child-friendly combination therapy approaches while complying with these principles.

Clinical versus Home-based treatment setup. Studies such as Lowing et al., (2009) and Taub et al., (2011) advocate home-based therapy interventions using a mCIMT approach (Löwing et al., 2009; Taub et al., 2004). Other studies such as AL-Oraibi et al., (2011), Wallen et al., (2011), Barzel et al., (2015), and Eliasson et al., (2011) have all used either school, home or community-based, RTP-based protocols such as mCIMT and/or HABIT at home or school setting to observe the effects of home versus clinical setting on the level of improvements (Al-Oraibi & Eliasson, 2011; Barzel et al., 2015; Wallen et al., 2011).

Rostami et al., (2012) compared a clinic-based mCIMT protocol with a home-based mCIMT protocol provided by a therapist in a small group of fourteen children (seven in each group) with unilateral CP (Rostami & Malamiri, 2012). Both groups underwent similar CIMT based programs with activities such as reaching, grasping, and manipulating objects or toys, fine motor skills, dressing, undressing, eating, grooming, etc., based on children's age and level of impairment. Therapy was provided either at a clinical setting or at home by therapists for at least one and a half hours per day, thrice a week for a total of ten sessions. The semi-structured interviews of the PMAL were used to record the parent's views of improvements in the quality of movement and use of the affected arm. The dexterity subtest of the Bruininks–Oseretsky Test of Motor Proficiency was used to measure the performance of fine motor tasks such as copying and tracing shapes cutting paper etc. Based on the results of ANOVA, the pre- to post-intervention assessment scores showed that the UE subtests of the PMAL interviews revealed significant improvements ($p<0.05$) in both groups. The subtests of the BOT that examined dexterity showed a significantly better improvement ($p<0.01$) in the home therapy group as compared to a clinical therapy group. The high scores were retained three months post-intervention in case of home therapy group. Overall, the participants showed better improvements in their upper limb motor function while practicing their natural surroundings than in the clinical setting (Rostami & Malamiri, 2012).

Other studies such as Gordon et al., (2005) also support the efficacy of using children's natural surroundings for developing an intensive, graded repetitive task pracrice (RTP) based therapy program to improve children's performance levels and adherence to therapy (Gordon et al., 2005).

Table 3 (page 29) presents pilot studies and RCTs that have used RTP based approaches. These trials use a wide range of inclusion criteria based on age, GMFCS and MACS levels. For quantitative data, comparisons were performed using a wide variety of outcome measures and methods. This made it difficult to compare the results of these studies. Overall, these studies reported moderate to large improvements due to CIMT, mCIMT, and HABIT across most UE outcome measures. Comparisons between the experimental and control groups revealed that the CIMT based approaches showed a larger treatment effect compared to the control group receiving conventional protocols. There was no significant difference between the groups receiving either HABIT or CIMT; both groups showed improvements with these protocols.

Table 3: Studies that observed the importance of goal-oriented high volume of practice-based treatment protocols and the effect of environment and dose of intervention

#	Author and title	Article Type	Participants (N)	Experimental Group Protocol	Control Group Protocol	Outcome measures	Results
1	Rostami et al., (2012) Effect of treatment environment on modified constraint-induced movement therapy results in children with spastic hemiplegic cerebral palsy: a randomized controlled trial	Small RCT	N=14 children with unilateral CP	Home-based therapy program based on children's daily activities, provided by occupational therapists, for at least one and a half hours per day, thrice a week for a total of ten sessions.	Clinic-based therapy program based on children's daily activities, provided by occupational therapists, for at least one and a half hours per day, thrice a week for a total of ten sessions.	PMAL, BOT	PMAL interviews revealed significant improvements (*p*=0.001). There was a significant treatment *time interaction between the two groups (*p*=0.013). The subtests of the BOT that examined dexterity showed significantly better improvement(*p*=0.025) in the home therapy group as compared to a clinical therapy group
2	Chen et al., (2014) Improvement of Upper	Small RCT	N=45 participants with CP aged 6 to 12 years	a four-week CIMT based therapy at home	Four weeks of conventional clinic-based therapy	PDMS-2 and the FIM	PDMS-2 and the FIM for Children showed greater improvements in the home therapy group

	Extremity Motor Control and Function After Home-Based Constraint Induced Therapy in Children with Unilateral cerebral palsy: Immediate and Long-Term Effects						
3	Ferre et al., (2016) Caregiver-directed home-based intensive bimanual training In young children with unilateral spastic cerebral palsy:	A randomized trial	N=24 children with unilateral spastic cerebral palsy. ages 2y 6mo–10y 1mo	home-based hand-arm bimanual intensive therapy two hours per day, five days per week, for nine weeks	lower limb functional intensive training therapy two hours per day, five days per week, for nine weeks	BBT, AHA, COPM	Based on the levels of AHA scores, the experimental group showed significant improvements (p<0.05) and performed better than the control group in the post-intervention as well as the follow-up scores. Based on the COPM scores, both groups showed significant improvements in levels of parents' satisfaction. Treatment*time interaction

	A randomized trial						indicates children in H-HABIT made greater progress compared to the control group ($p<0.05$).

(PMAL : The Pediatric Motor Activity Log-Revised, BOT : Bruininks-Oseretsky Test of Motor Proficiency, PDMS-2 : Peabody Developmental Motor Scales, Second Edition, FIM : Functional Independence Measure, BBT : Box and Blocks test, AHA : AHA, COPM : Canadian Occupational Performance Measure).

Home-based protocols can be time-consuming and pose difficulties with implementation when high repetitions are required. Compliance with such therapy is often low because it is hard to maintain high levels of motivation in children and parents in such intensive, high RTP. These programs fail to remain engaging over long periods of time (Eugster-Buesch et al., 2012; T. N. Wang et al., 2013). For this reason, there is a need to develop engaging and motivating therapy programs, which can be transferred from a clinical to the home environment and can be monitored and modified by therapists based on children's goals and current needs.

Digital media based repetitive task practice (RTP) for fine motor function impairments

The literature reviewed demonstrates a need to adopt long-term intervention programs to achieve better therapy compliance (L. Miller et al., 2016; Sandlund et al., 2012). Motivational play therapy, not forced-use therapy, is now used in addition to the RTP principles of mCIMT and HABIT. Children's level of participation during the exercise protocols during such long term programs is essential and thus addition of motivational and engaging play activities are helpful

(Majnemer et al., 2010). These adapted therapy programs often use virtual reality (VR) or digital media-based gaming platforms as part of therapy. The idea behind adding such play therapy platforms is to provide an engaging, interactive component to the protocol while ensuring the child is performing a given task or function in a repetitive, trial-and-error based, safe environment. Many commercially available gaming systems are now adapted and experimentally used for rehabilitation.

The Nintendo Wii ™ (Wii™) is a commercially available video game console that uses a hand-held remote controller to detect the movements made by the player while holding the controller. It can detect the movements of the controller in multiple dimensions (Nintendo, 2009). Studies have examined the effectiveness of using this VR system for the rehabilitation of hand function in children with CP (Winkels et al., 2007).

Winkels et al., (2012) studied the effects of Wii™ based UE rehabilitation in a six weeks long protocol in fifteen children with CP in a pilot study (average age= 8.9 years) (Winkels et al., 2007). They received home-based therapy twice a week for six weeks. Each session consisted of thirty minutes of Wii™ training focused on their most affected arm as well as of fifteen minutes of a sport such as boxing or and tennis using Wii™. The quality of movements while performing the tasks such as picking up a pellet and a crayon and bringing the hand to mouth was assessed using a video camera motion analysis-based MAUL. The ABILHAND-kids questionnaire was used to record parents' responses to score the level of activity on tasks such as opening a jar, putting on a shirt or a bag pack, dressing and grooming activities, feeding activities, etc. Although the MAUL did not show any significant improvements in the short treatment protocol, the level of daily activities and their ease showed improvement ($p < 0.05$) on the ABILHAND questionnaire scores. Overall, the addition of VR with the use of Wii™ to improve the quality of upper limb function failed to improve according to MAUL but received good scores on the ABILHAND-Kids questionnaire (Winkels et al., 2007).

The levels of participation in activities of daily living are improved significantly with the use of the Wii™ in children with neurodevelopmental disorders such as CP and developmental delays. The improved levels of participation due to addition of Wii™ games improved arm movements however, no significant hand function improvement or fine motor function improvement was observed in studies performed by Salem et al., (2012) and Kassee et al., (2017). Similar results have been observed in other studies that use Wii™ as a part of UE rehabilitation (Kassee et al., 2017; Salem et al., 2012).

The addition of the Wii™ to UE rehabilitation programs has shown improvements in range of motion exercises in smaller joints in children with CP in case of high frequency, high volume conventional practices (Sajan et al., 2017). The Quality of Upper Extremity Skills Test showed improvement in scores when Wii™ was used as an addition to a goal-directed comprehensive conventional rehabilitation program in case of a study performed by Sajan et al., (2017). The intensive repetitive therapy sessions were provided for forty-five minutes a day, six days a week for three weeks. They consisted of swiss ball exercises, skateboard, pegboard, and ball catching and throwing activities as a part of the program in addition to Wii™ training. In addition to UE intervention, attention was also given to posture and balance rehabilitation. Only the grasp sub-score of Quality of Upper Extremity Skills Test showed significant improvement ($p < 0.027$) in the experimental group children ($n=10$ total $N=20$ age= 8 to 20 years). Although the results showed improvements in the Quality of Upper Extremity Skills Test grasp scores, it is difficult to estimate the amount of influence of the conventional exercises on these scores, as well as, the high volume and high frequency of the protocol provided to these children (Sajan et al., 2017).

Use of motion capture technology such as the Microsoft Xbox Kinect™ (Xbox™) is another novel rehabilitation tool for the treatment of UE function impairments in children with CP. The Xbox™ is a video game console that uses motion sensing input devices as the game controller through players' gestures, movements, and voice commands. Xbox™ uses a depth sensor, an RGB camera (RGB stands for Red Green Blue colour bandwidth) with two-dimensional imaging hardware consisting of an infrared projector, and a special microchip that generates a grid from which the location of a player in multiple dimensions can be recorded.

Using these dimensional tracking features, Luna-Oliva et al., (2013) performed a preliminary study among eleven children with CP undergoing conventional physical therapy (Luna-Oliva et al., 2013). They added video games treatment to their regular therapy for eight weeks. They observed the difference in progress in fine motor skills and manual dexterity along with other gross motor balance and gait improvements. Participants were asked to attend a 30-minute session twice a week for two months. The session consisted of Xbox™ games where a simulated Avatar (a graphical representation of the user’s body that illustrates the movements made by the user) of participants appeared on the screen for visual feedback during task performance. The games involved activities like dancing, shaking hands with virtual characters, and playing sports such as tennis and golf. The Jebsen-Taylor Test of Hand Function was used to measure the progress pre vs. post-intervention in the performance of tasks such as turning cards, placing checkers, feeding activities, etc. BOT measured the levels of quality of activities of daily living by rating the effort, efficiency, safety, and independence of sixteen ADL motor and twenty ADL process skill items in feeding, dressing, and grooming activities and assessment of motor and process skills is a similar assessment tool that measures the quality of activity levels. The Jebsen-Taylor Test of Hand Function test scores showed improvement in daily tasks (p= 0.058), and Assessment of Motor and Process Skills results showed significantly increased (p=0.001) levels of motor performance. Tasks that required endurance, such as lifting heavy objects or manipulation of daily objects, showed none to the low number of improvements. These results demonstrate that fine motor tasks are difficult skills to master and required a large amount of RTP (Luna-Oliva et al., 2013).

A case series study by Chang et al., (2013) showed similar results in gross motor function improvement. The study assessed the effectiveness of using the Xbox™ in a school rehabilitation setup for improving upper limb function (Chang et al., 2013). Similar results were seen in other studies, such as a cross-over randomized controlled trial by Chang et al., 2013 and Ocotillo et al., 2015 (Chang et al., 2013; Zoccolillo et al., 2015). Overall, the addition of Xbox™ in fine motor therapy protocols showed positive results in improving gross motor function, levels of motivation, and activity participation levels but missed the mark on fine motor function and manual dexterity improvement.

Another commonly used form of virtual augmentation of fine motor and gross motor activities is using custom-made gloves attached to a computer to play video games using the virtual images of participants' hands. Custom-made data gloves are embedded with accelerometers and magnetometer for assessment of finger flexion-extension range of motion and multidimensional orientation of the forearm. The recordings of accelerometers and magnetometers help in creating virtual images of participants' hands and arms that mimic the movements made by the participant. They also provide haptic feedback for positive or negative responses using the vibration motors attached on the glove (Gerber et al., 2016b).

Similar protocols using data gloves operated VR games have been used in other studies such as Golomb et al., 2010 and Qiu et al., 2009 (Golomb et al., 2010; Qiu et al., 2009). Gerber et al., (2016) used this protocol in the You-Grabber System (Gerber et al., 2016b). The participants who used the You-Grabber System rated the system as “mediocre” on satisfaction scores but as “high” on therapeutic value. Children needed additional motivation to continue the training as they found the technology complicated, boring, and error prone. The use of gloves with haptic feedback provided a good platform for fine motor function, but this protocol failed to provide sensory feedback of touch, textures, weight, etc., physical properties of various objects, and handling and manipulation practice (Gerber et al., 2016b).

A subsequent protocol using colour tracking cameras and colour markers to play web-based custom-made video games was developed by James et al., (2015) (James et al., 2015a). They conducted a randomized controlled trial of a protocol called “Move It To Improve It” (Mitii™) to improve occupational performance, upper limb function, and visual perception protocol for children with unilateral CP. (James et al., 2015a). The Mitii™ protocol is a web-based multimodal home therapy platform that allows therapists to develop patient individualized programs, telemonitor progress, and adjust exercises to keep the intervention challenging for children. Participants (N=102) in the Mitii™ group (n=51) (mean age 11 years eight months) received twenty weeks of web based Mitii™ therapy program (thirty minutes a day for six days a week). The therapy session was conducted using a web camera and biomarker-based body movement tracking. This helped a team of practitioners to decide individualized therapy programs for each child with activities based on cognition, visual perception, and gross motor function with special attention towards the affected extremity. The age-matched control group (n=51) received conventional forms of therapy with one-on-one clinical consultations.

Assessments were performed pre-intervention and immediately post-intervention using AHA, JTTHF, MAUL, COPM, and test of visual perceptual skills, as well as assessment of motor and process skills. The post-intervention results showed that both the intervention programs were similarly effective and had no significant differences in clinical outcomes (James et al., 2015a).

In 2017, Benham et al. studied the efficacy and feasibility of a motion-capture program for telerehabilitation purposes called "Timocco Gaming Systems™ (Timocco™)." Two children, aged 5 and 7 years, were recruited in this mixed-methods study. The Timocco™ uses a webcam to track the movement of colour markers to interact with a virtual environment displayed on the screen. Participants received 20 sessions of Timocco™ for 30 minutes per session in six weeks period. The pre- vs. post-intervention scores in four domains of the Bruininks-Oseretsky Test of Motor Proficiency namely, fine motor precision and fine motor integration, manual dexterity, and upper limb coordination subscores, were used to assess arm and hand function improvements. Both children showed minor improvements in the fine motor integration scores that include visual-motor tasks such as copying shapes such as a square, a star. Other subscores did not show any major improvements in fine motor function (Benham & Gibbs, 2017). Similar results were seen in other studies that used the timocco system in children with CP, while typically developing children showed higher scores (Gabyzon et al., 2016).

To summarize, digital media-based protocols can provide a fun, engaging, motivating platform for UE rehabilitation in children with CP and can be effective in improving children's therapy compliance. Most of these protocols use commercially available digital media platforms such as the Wii™ and Xbox™. These platforms provide a variety of gross motor exercises for UE movements in the shoulder, elbow, and wrist joints, along with truck control and balance control. Unfortunately, these platforms are unable to detect, record, and assess the precision of fine motor activities and object manipulation tasks.

Various forms of commercially available digital media platforms include the Nintendo Wii™, Microsoft Xbox Kinect™, PlayStation™, custom-made virtual augmentation gloves, and other VR-based platforms such as the “Mitii™” and “Timocco™”. The Wii™-based UE rehabilitation protocol improved the participants' level of participation but did not improve fine and gross motor function in children with CP. The Xbox Kinect™-based Avatar games showed mild to moderate gross motor function improvements, but no significant improvements were seen in fine motor function. The use of custom-made interactive gloves for virtual augmentation using commercial games or custom-made games showed motor improvements in grasping and visual motor activities. Biomarker-based body movement tracking protocols such as Timocco™ did not show any significant improvements in fine motor function but moderately improved the gross motor function.

Therefore, most digital media-based protocols did not show any significant improvements in gross and fine motor function or coordination improvements in bilateral movements and activities in children with CP. However, these studies show the importance of children's active participation during their exercise sessions. The participation levels and therapy compliance increased significantly due to the addition of digital media platforms to the therapy protocols. Table 4 (page 41) summarizes the studies performed to observe the effects of adding digital media to the experimental therapy protocols for children with fine motor function impairments due to CP.

Table 4: the studies performed to observe the effects of adding digital media to the experimental therapy protocols

	Author and title	Article Type	Participants (N)	Experimental Group Protocol	Control Group Protocol	Outcome measures	Results
1.	**Winkels et al., (2012).** Wii™™-habilitation of UE function in children with cerebral palsy. An explorative study	Explorative clinical trial	N= 15 children with CP (average age= 8.9 years)	Home-based therapy twice a week for six weeks + thirty minutes of Wii™ training	No comparison control	MAUL, ABILHAND-Kids	The addition of VR with the use of Wii™ to improve the quality of upper limb function failed to improve according to MAUL but received good scores on the ABILHAND-Kids questionnaire
6.	**Chen et al., (2007).** Use of Virtual Reality to Improve Upper-Extremity Control in Children With cerebral palsy:	A single-subject design	N= 4 children with CP	four-week long intervention program with two hours long, 2 to 3 sessions per week of VR interventions using the Custom-made data gloves and Eye-toy	No comparison control	PDMS2	Improvement in the grasp and visual-motor raw scores of PDMS-2

	A Single-Subject Design			by PlayStation™ systems.			
7.	**Wille et al., (2009).** Virtual reality-based pediatric interactive therapy system (PITS) for improvement of arm and hand function in children with a motor impairment—a pilot study	The pilot study	N=5, children with motor impairment	Therapy sessions using this system were provided for forty-five minutes per session, three sessions per week. The VR was provided as an addition to regular occupational therapy.	No comparison control	The MAUL, Nine-Hole Peg Board Assessment, Box and Block Test	The MAUL and Nine-Hole Peg Board Assessment did not record any significant pre vs. post-intervention changes, but Box and Block Test scores improved significantly in all the participants

MAUL: Melbourne Assessment of Upper Limb Function, PDMS-2: Peabody Developmental Motor Scales, Second Edition)

Summary

Task-specific rehabilitation programs such as CIMT and HABIT have shown positive results when provided by therapists in a one-on-one clinical setting and when provided with high repetitions of engaging task practice in every session. Unfortunately, such protocols are of long durations and often children's level of participation during the exercise sessions is hard to maintain. As these exercise protocols can be repetitive and monotonous, children's therapy compliance is affected. Many studies provide evidence to show that well-designed treatment programs incorporating games based digital media platforms are beneficial in gross motor function improvement in children and adults dealing with neuromuscular impairments. Unfortunately, only a few of those platforms focus on fine motor function and even fewer work on children practicing object manipulation and control during functional tasks. Most VR systems such as the Wii™ or the Xbox™ game-assisted rehabilitation applications fail to work on finger and hand movements or object manipulation tasks.

These activities involve gross arm movements such as grasping a virtual object. These experiences are different from real-world object handling and manipulation. They are required to grasp and manipulate objects with varied physical properties, such as textures, weights, and shapes, etc. Many common and modern commercial video games are fun, motivating, and are a great way to increase the level of compliance. Unfortunately, most digital media-based treatment platforms use one or more proprietary games system with a limited number of games fit for children with CP. Because of their easy accessibility, such game-assisted protocols can be easily monitored when therapy is provided at home. It is also easy to access electronic records of children's performance when using computer games if quantifiable and reliable monitoring and assessment methods are used for tracking children's performance. Such therapy programs have the capacity for smoothly transferring the therapy session from a clinical setting to home therapy sessions.

It is important to develop task-specific repetitive practice-based protocols that are engaging to improve therapy compliance. It is equally important to provide timely feedback, support, and information on progression for therapy. For this reason, computer games-based therapy protocols which are embedded with objective assessment tools need to be studied in detail for the UE rehabilitation in children with CP.

Chapter 3: Statement of purpose

A computer games assisted RTP based (GRP) therapy protocol embedded with computer game assisted upper extremity (CUE) assessment tool has been developed. This thesis focuses on assessing the test-retest reliability and convergent validityof the CUE assessment tool and feasibility of conducting a full scaled randomized controlled trial (RCT) for assessing the effectiveness of the GRP protocol. For these purposes, a reliability validity study as well as a mixed-methods exploratory RCT was conducted with a quantitative component to assess the effect size and the qualitative component to understand parents' perspectives on the usability of the GRP protocol.

Study 1: Reliability and validity of the CUE assessment tool

It is essential to develop quantifiable, objective assessment tools focused on object manipulation skills for children with UE impairments due to CP. While currently available computerized and videographic tests such as AHA and MAUL offer quantifiable objective outcomes. These tests often focus on more than one functional activity however, these activities are not focused on object manipulation tasks. Tests such as the PDMS-2 and QUEST offers a functional evaluation of children's fine motor skills however the scoring is based on therapists' subjective observations therefore, these evaluations lack objective scales. These assessments are extensive however, the time constraints due to the number of things being assessed allow for only two to three objects' manipulation tasks.

Because each of the above-mentioned objective and subjective outcome measures of hand function has limitations, there is a need for an assessment tool that can measure not only the number of successful movements to complete a given task but also the number of errors made and the amount of variance while the participants perform fine or gross motor object manipulation tasks. Such assessment tools can be utilized for assessment in clinical as well as home and community-based settings. The CUE assessment Tool has been developed for these reasons. This assessment tool records the participants' movements and computes measures of movement quality. The CUE includes a custom-designed rehabilitation assessment game, which can monitor a child's performance during therapy.

In this study, the test-retest reliability and convergent validity of the assessment tool embedded in the Game-assisted Rehabilitation Platform (GRP) are discussed, specifically for fine and gross motor skills and psychomotor skills have been established. Since the CUE assessment tool can be easily transferred from a clinical to a home and school setting, the GRP protocol can eventually be transferred to a home or school setting while the therapist can monitor the progress using telerehabilitation methods. With the use of the CUE assessment tool for telemonitoring, the progress of participants during each home exercise session is automatically recorded for monitoring. Electronic performance records derived from the CUE tool can inform a therapist when and how a child is performing, whether they are experiencing any difficulty, and how they are progressing with their exercise program. Parents/children will be able to interact with their therapists through a number of mechanisms: e-mail, telephone, and other methods, and thus obtain timely support, and on a regular basis. The CUE quantifies motor skill parameters as well as produces electronic records for these outcome measures and thus allows tracking of changes over time. It can also provide timely feedback to children and therapists. CUE tool provides the following outcomes: a. Success Rate b. Movement Onset Time c. Movement Error

Study 2 and 3: Mixed-model exploratory randomized controlled trial

There is a need for a more engaging RTP based rehabilitation platform that focuses not only on gross but also fine motor function in children with CP. For this purpose, a low-cost computer game-assisted rehabilitation (GRP) platform with a wide variety of readily available low-cost computer games has been developed. This approach combines fine motor object manipulation and gross movement exercises with computer game activities based on goal-directed task practice appropriate for young children with CP. GRP is consistent with the principles of mCIMT and HABIT. GRP takes advantage of ergonomic properties of common day-to-day objects to amplify limited and small amounts of voluntary movement for manipulation in children with CP and then allows opportunities for an appropriate upgrade to more challenging objects with greater physical and functional demands. GRP allows object properties (size, weight, texture, and surface properties) to be easily manipulated in therapy. This provides graded practice for activities that need to be repeated in daily activities and in play. An important element of the platform is the ability to incorporate movement precision practice. In this regard, GRP targets finger-hand function and not just transfer and/or reaching movements. Different computer games require different levels of movement amplitude, speeds, precision levels, and repetition, as well as appeal to individual preferences. Furthermore, many inexpensive "off the shelf" computer games have a broad range of visuospatial, cognitive content. Knowledge of the therapeutic value (object and games activities) can allow the therapist to prescribe an integrated program to target specific goals (for example, speed, accuracy, endurance, visuospatial functions, and cognitive inhibition), and to exercise 2 or 3 fingers, the whole hand, and bimanual tasks tailored to individual child abilities. In a manner like interval training, 6 to 8 objects selected for specific therapy goals were used to play computer games.

Objects were selected for motor skills training of finger/wrist or elbow and shoulder motions, and bimanual control for the purposes of the present study.

Chapter 4: Study designs and methods for the studies

Participants. For all three studies, initial recruitment was performed by either the consulting pediatrician or physiotherapist working in one of the two centers who informed the parents regarding the ongoing study purpose and participant inclusion criteria. The screening was performed by a physiotherapist. Participants' parents received explanations of all the contents and the protocols of the study personally by a clinician. Parents were asked to give informed consent by signing the consent form after the initial screening process. Parents were responsible for contacting the physiotherapists working in any of the two sites to participate in the study. The participants were asked to sign the assent form if they agreed to participate in the study. The centers for clinical settings were-

1. SDM College of Physiotherapy, Dharwad, India
2. Ushas' School for Exceptional Children, Hubli, India.

Inclusion Criteria. For all three studies, children with a diagnosis of CP who fit the following inclusion criteria were recruited.

1. Gross Motor Function Classification System (GMFCS) from level 1-3 were used to screen and select the participants (Bodkin et al., 2003a). GMFCS was used to include children who have required an amount of postural stability and gross motor function to perform forty-five minutes of a therapy session.
2. Manual Ability Classification System (MACS) from level 1- 3 was used to screen and select the participants (Eliasson et al., 2006a). MACS was used by the assessing physiotherapist to assess participants' level of fine motor function.

3. Modified Ashworth scale (mASH) was used by the assessing physiotherapist to determine the level of spasticity from grade 1 to 1+ in the clients, which was used as a screening tool (Mutlu et al., 2008a).

4. The pediatric version of the Mini-Mental Status Evaluation (MMSE) (level 17 and above) was used to screen the level of cognitive function (Besson & Labbé, 1997). MMSE allows physiotherapists to perform a cognitive screening in children with CP to include participants who can understand the basic working of a computer game and inertial-based motion (IB) mouse.

Exclusion Criteria. The exclusion criteria were as follows.

1. Visual or auditory impairment due to which child cannot see and interact with the video games,
2. Secondary orthopedic complications due to CP or as a result of surgery to the upper limb that may have caused permanent changes in upper limb musculoskeletal structure,
3. Moderate or severe spasticity i.e., a Modified Ashworth score of grade 2 and higher where children would not be able to open hand and handle the everyday objects and toys to play games.
4. Recent Botulinum toxin therapy to the UE (less than six months). History of such therapy was provided by the consulting clinician (Pediatrician or physiotherapist)
5. Uncontrolled seizures with one or more episodes in the last six months. History of such an episode was provided by the consulting clinician (Pediatrician or physiotherapist)
6. Moderate or severe cognitive impairments due to which the child may not understand how to play the game.

Study 1: Reliability and validity of the CUE assessment tool

Objective for study 1: To determine the test-retest reliability and convergent validity of the Computer game-assisted Upper Extremity (CUE) assessment tool. The PDMS-2 and QUEST were used for convergent validity assessment.

Participants. Thirty-five children between the ages of four and ten years were recruited for this study.

Data collection and analysis

Each participant attended two assessment sessions two weeks apart. The first session included the administration of the QUEST, the PDMS-2, and the CUE assessment tool. The performance measures of the CUE assessment tool were quantified offline by an analysis software using MATLAB™ programs.

Statistical analysis

Relative reliability was assessed using a random model Intra-Class Coefficient (ICC)(L. G. Portney & Watkins, 2009; L. Portney & Watkins, 2015). The ICC scores were considered to be high when equal to or greater than 0.70, moderate between 0.5 and 0.69, and low when less than 0.50. Minimal detectable change (MDC) was computed (L. G. Portney & Watkins, 2009; L. Portney & Watkins, 2015). Systematic errors between the test periods were evaluated using a paired t-test. Convergent validity of the CUE outcome measures with the PDMS-2 and QUEST scores was analyzed using Pearson's correlation coefficient (R). The SPSS software for Windows, version 20.0 (SPSS Inc. Chicago) was used for all statistical analysis procedures.

Study 2 And 3: Mixed- model exploratory randomized controlled trial

Objective for study 2: To estimate the treatment effect of the RTP game-assisted exercise programs on UE fine and gross motor skills in children with CP and to determine the variation of the primary outcome measures between groups and overtime periods pre to post-intervention. This information was used to determine the effect size and sample size for a full-scale RCT. In this regard, a power analysis was performed to determine the minimum effect size to calculate the standardized mean difference between the experimental group receiving RTP-based computer game-assisted rehabilitation protocol provided in a clinical setting and a control arm receiving a conventional therapy protocol.

Objective for study 3: To determine the feasibility of conducting a full-scale, multicenter RCT to evaluate the effectiveness of the RTP-based computer game-assisted rehabilitation platform in improving upper limb function to 4 to 10-year-old children with CP. Semi-structured interviews were conducted with participants' parents to explore their experiences with the GRP. Parents' experiences regarding compliance to therapy were reviewed.

Participants. A sample of sixty-three participants (age 4 to 10 years) was recruited.

A total of sixty-three participants (age 4 to 10 years) were randomly assigned to either the experimental GRP group or to the control group. Randomization took place using the sealed envelope method after the participants are included in the study.

Informed consent. The contents and the protocols were explained to participants' parents by a clinician. Parents were asked to consent by signing the consent form after the screening process (performed by a blind assessor and recruiter) if they were interested in participating (please see appendix 2, page 243). The parents were reassured that information would be kept confidential and used only for this study. They could withdraw or drop out of the study if and when they wish. Further, if parents have any queries regarding the study, they could question to the principal investigators. Children were asked to sign the assent form if they agreed to participate in the study. For the informed consent form, see appendix 2 (page 243).

Clinical trial number. Clinicaltrials.gov NCT02728375; http:https://clinicaltrials.gov/ct2/show/NCT02728375 (Archived by WebCite at http://www.webcitation.org/6qDjvszvh)

Method. Two groups of children were examined; one group received the experimental game-assisted program, and the other group received standard conventional therapy. Each child was provided with forty-five minutes of therapy session per day for three to four days a week for sixteen weeks.

Control Group (CG) Intervention. The CG received the comprehensive physical therapy protocol based on the goal-oriented, RTP-based principles of mCIMT and HABIT combination protocols for fine and gross motor skills in children aged 4-10 years diagnosed with CP. Therapy protocols were individualized for every participant according to their level of impairment and pre-set goals, based on the principles of intensive RTP programs such as CIMT and HABIT. Various arm and hand activities were practiced, such as reaching for rings, removing, and putting them back, ball throwing, opening a bottle cap, turning a doorknob, clay activities, picking marbles from sand, and putting pellets, rings, and pegs into sockets. Reach out, ball throw (under and over arm), opening bottle caps (large size bottle), manipulating objects such as water bottle, crumbling paper, clay activities, picking marbles from sand, doorknob, hand-arm bimanual activities such as holding a ball with both hands and transfer, rolling bolster, writing, self-feeding. These tasks chosen for each participant based on their goals and levels of impairment to develop a therapy protocol best suited for their level of activity. The child practiced these tasks in a high number of repetitions with a therapist in a one-on-one therapy session. The protocol was modified as the child progresses throughout the 16-week-long program to keep the tasks challenging.

Experimental Group (XG) Intervention. A typical session for the XG consisted of the RTP-based computer game-assisted exercise program. Participants in this group were asked to use objects instrumented with an inertia- based miniature motion (IB) mouse to play various therapeutic yet entertaining games while handling and moving the therapeutic objects as a part of an experimental therapy protocol. The objects used were everyday items such as a) lifting/rotating a sports ball, small beach ball which requires bimanual handling, b) rolling a cylinder object (diameter 6-10 cm with fingers extended and using elbow and shoulder motion, c) grasping grasp small glass and then a sponge ball with the whole hand and rotating (supination/ pronation motion) d) motion of a small wand (pencil) with 3-finger pinch grip and using hand-wrist motion, and e) turning of a key with 2-finger pinch fine finger control. These objects represent a wide range of physical properties requiring different modes of manipulation and functional demands sufficient to test the assessment tool. The children's and parents' goals were noted down during the first therapy session to create a goal-oriented protocol. The objects used during therapy were taken from participants' day-to-day life to practice movements and activities required to achieve the noted goals. Computer games that best complemented these movements and activities were chosen to practice the object manipulation tasks. Computer games provide a task-based enriching environment for trial-and-error based RTP games. This motivates the children to perform the physical repetitive object manipulation task to achieve the game environment's target. This protocol was constantly updated, and a wide variety of computer games was used for each object manipulation task practice to keep the therapy session interesting and enjoyable to the participants.

Data collection and analysis. A blinded assessor performed pre-intervention and post-intervention (sixteen weeks) assessments in all participants. The primary outcome measures used were-

1. The Peabody Developmental Motor Scales-2 (van Hartingsveldt et al., 2005). a) Grasp raw scores b) Visual-Motor Integration (VMI) subtest raw scores. The Peabody Developmental Motor Scale, Version 2, has high reliability and validity for the composite scores only till the age of 5 years. The raw scores may be considered till the age of ten years (van Hartingsveldt et al., 2005). It was created by considering a typical sequential developing pattern of functional ability until the age of 5 years in typically developing children. Functional abilities of atypically developing children may not follow the same sequential pattern.

2. Computer game-assisted upper extremity assessment tool (CUE) was used (please see appendix 1) to assess the quality and precision of object manipulation by computing-

a. Success Rate- the percentage of the total number of target objects that were caught in one game session,

b. Movement Onset Time- the time is taken to respond to the target appearance by moving the computer cursor,

c. Movement Error- the distance between paddle and target position when the target is missed.

Parents' experiences with the interventions and tools were explored using semi-structured interviews using the qualitative approach (MB Miles, AM Huberman, MA Huberman, n.d.) (Thomas, 2006). The following open-ended questions were asked of the children's parents: (1) when you agreed to participate, how did you hope your child would benefit from the therapy program? (2) Were there things about the game (or exercise therapy program) for your child you liked and things you did not like? (3) What did you think about the computer games your child was asked to play? Did your child enjoy the games? Were there games which your child did not seem to enjoy? (4) Did you feel that this therapy program helped your child? (5) If you were provided with the right setting, would you want your child to continue with these exercises?

Data analysis

Pre-intervention and post-intervention scores of the PDMS-2, the QUEST, and CUE assessment tool of the experimental and control group were compared to calculate the within the group and between-group effects.

The sample size and all statistical procedures were decided after consultation with Brenden Dufault Biostatistician, George & Fay Yee Centre for Healthcare innovations, University of Manitoba.

For the mixed model exploratory study design, the recommendation was a sample size of at least 30 per group. The justifications for this sample size are based on rationale about feasibility, precision about the mean, and variance (Julious, 2005; Moore et al., 2011).

Objective 2. For power calculation and effect size calculation, a biostatistician was consulted. The statistical power and sample size calculation methods were used based on Borm, Fransen, & Lemmens, (2007) and Shieh, (2016). Effect size calculations were performed using the formula (Borm et al., 2007; Shieh, 2016)

Effect size= [(average of experimental group)-(average of control group)]/ [standard deviation] (Coe, n.d.).

The present study observed the differences within and between the experimental and control groups using the Peabody Developmental Motor Scale, Version 2, and CUE outcome measures using analysis of variance (ANOVA), the dependent variable. Residual diagnostics were carried out for the ANOVA model, and if their normality assumption fails to hold, appropriate transformations of the response, such as logarithmic, were explored.

A power analysis was conducted to determine the required sample size to test the difference between the experimental and control groups using the ANOVA model. The present study selected the case that gave the largest sample size with published data from the largest sample. Assuming a correlation of at least 0.6 between baseline and final outcome, a sample size of 128 and a standard deviation of 25 was adequately powered to detect a difference of 10 units with 80% power and 5% alpha post-intervention. We expect an attrition rate of 10% over the study period. Given this, we propose to recruit a sample of 140 children to participate in equal numbers to be randomized to each group for a randomized controlled trial. All calculations were made with PROC GLMPOWER of SAS version 9.3 (SAS Institute, Cary, NC). However, collecting a sample size of 140 for this study is not feasible due to multicenter collaboration time constraints and study staff volunteers' availability. Therefore, for this study, a sample size of sixty as an exploratory trial to assess the feasibility was chosen based on the literature by (Moore et al., 2011).

Objective 3. The parents' responses were analyzed using the interpretive description method (Teodoro et al., 2018; Thorne et al., 1997, 2004). At the end of 16 weeks therapy program, parents' experiences with the intervention protocols were explored using semi-structured interviews with open-ended questions. The data collected during the semi-structured interviews were in the local language.

Responses were transcribed and translated by professional transcribers to organize the data by labeling, structuring, and familiarizing processes. Each participants' data were reviewed and analyzed by two researchers. The transcribed narrative summary of each individual was then sent back to the parents and therapist for review and approval to ensure the transcribed and summarized data's trustworthiness. A second-order analysis took place by creating a coding plan based on the research questions. After the data was coded and sorted, these responses were categorized to identify themes. Care was taken to reduce overlap due to recurrent categories when creating codes. Direct quotes from parents were used to support the data presented from themes.

Chapter 5: STUDY 1

Reliability and Validity of the CUE assessment tool

Reliability and validity of a computer game-assisted tool of UE assessment for object manipulation tasks in children with cerebral palsy.

Abstract

Introduction: A computer game-assisted upper extremity (CUE) assessment tool has been developed to quantify manual dexterity (object manipulation skills) of children with cerebral palsy (CP). The test is guided by standardized computer game-assisted activities and can be used with many different objects having a broad range of physical properties and functional demands. The purpose of this study was to determine the test-retest reliability of the CUE performance measures (success rate, movement onset time, movement error, and movement variation) and convergent validity with the Peabody Developmental Motor Scale version 2 (PDMS-2) and the Quality of Upper Extremity Skills Test (QUEST).

Methods: Thirty-five children with CP aged between four and ten years were tested on two occasions, two weeks apart.

Results: CUE performance measures of five chosen object manipulation tasks exhibited high to moderate intra-class correlation coefficient (ICC) values. There was no significant difference in the CUE performance measures between test periods. With few exceptions, there was no significant correlation between the CUE performance measures and the PDMS-2 or the QUEST test scores.

Conclusions: The moderate to high ICC values and lack of systematic errors indicate that the CUE assessment tool can repeatedly record reliable performance measures of different object manipulation tasks. The lack of a correlation between the CUE and the PDMS-2 or QUEST

scores indicates that performance measures of these assessment tools represent distinct attributes of manual dexterity.

Keywords: Cerebral Palsy, Children, manual dexterity, Computer game-assisted assessment, Telemonitoring, Telerehabilitation

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Background

Cerebral palsy (CP) is one of the most common motor neurodevelopmental disorders, which affects five of every thousand live births in India, where this study was carried out (1, 2). Children with CP often have deficits in the performance of fine and gross motor skills of the upper extremities (Bleyenheuft, Dricot, et al., 2015). Manual dexterity, the ability to perform functional tasks with the hands, is an important predictor of success in daily activities, participation in school, and social activities (Gordon et al., 2013). Children with motor impairments of the upper extremity (UE) benefit from intensive, task-specific therapy programs such as constraint-induced movement therapy (Ramey et al., 2019) and hand-arm bimanual intensive therapy (Ouyang et al., 2020). However, it is difficult to engage children with CP in therapy for long periods and sustain motivation for the intense, repetitive task practices (RTP)s. Thus, there is a need for innovative therapeutic approaches that engage children to participate in long-term exercise programs and provide opportunities to improve neurodevelopmental outcomes.

An emerging approach to engaging children in therapy is to incorporate computer game-aided exercise methods. A range of interactive challenges helps children participate in repetitive motor activities. Studies have provided evidence that well-designed interactive computer games can improve players' motor skills and participation in play as well as other daily activities (Ramey et al., 2019). Ideally, these types of effective therapy programs should be made available in patients' homes, including those in rural communities. With appropriate and reliable telemonitoring tools, remote telerehabilitation programs can be monitored by clinicians. For this purpose, an innovative computer game rehabilitation (GRP) platform was developed (Kanitkar et al., 2017). The GRP includes an embedded game-assisted assessment subsystem that automatically records the player’s performance and computes the outcome measures of object manipulation tasks. It is vital to obtain objective outcome measures and track changes over time to guide and progress individualized home programs. Therefore, exercise programs delivered in the home or within rural communities can be monitored and managed regularly by clinicians or by rural outreach programs.

The computer game-assisted upper extremity (CUE) assessment tool uses a miniature, wireless inertial based (IB) computer mouse, which links physical movements with interactive computer games. When the IB mouse is attached to a test object, the object's natural motion is then used to control the computer cursor's motion or a game paddle. The CUE assessment is guided by standardized computer game-assisted activities. It can be used with many different objects with a broad range of physical properties (e.g., weight, size, shape) and functional demands. The CUE software is configurable, which helps to increase the difficulty level by adjusting a) the target and paddle size (for movement precision), b) movement speed of game objects and c) IB mouse sensitivity (increase/decrease movement amplitude). The CUE software automatically logs the client’s movement response to each game event. It computes various performance-based metrics such as Success Rate, Movement Onset Time, Movement Error, and Movement Variation. These performance metrics are averaged over a number of game events (8, 9). For example, in one minute of gameplay, there were 30 game events and corresponding movement responses. Thus, the CUE assessment tool can provide objective, performance-based outcome measures for many different goal-oriented object manipulation tasks for children with impairments of the upper extremity.

The purpose of this study was to examine the psychometric properties of the CUE assessment tool. This is an essential initial step before the tool can be used routinely in clinical practice and transition to functioning in the home. The first objective of this study was to examine the test-retest reliability of the CUE assessment tool specifically for fine and gross object manipulation skills of children with CP. The second objective was to assess the convergent validity of the CUE with the Peabody Developmental Motor Scale version 2 (PDMS-2) and the Quality of Upper Extremity Skills Test (QUEST). The PDMS-2 and QUEST were chosen for comparison with the cue assessment tool because these assessment tools are most widely used among clinicians for measuring UE function in children with CP. The PDMS-2 is a validated and commonly used assessment tool of hand use in young children that includes tasks such as throwing and catching a ball, stringing beads, and stacking blocks (Elvrum et al., 2016; Folio, 2000; Nijmegen & Nether-, 2005). Another commonly used and validated pediatric assessment of hand use is the QUEST (Thorley et al., 2012a). This assessment evaluates the range of motion and the type of grasp used in the handling and manipulation of three objects: a cube, a crayon, and a pellet (11). The CUE assessment tool focuses on different types and characteristics of hand use than does the PDMS-2 or the QUEST. Therefore, it was speculated that a significant but low correlation (Pearson R-value less than 0.5) was observed.

Methods

Ethical approval for the study was obtained from the Institutional Ethical Committee at both sites; S.D.M. College of Medical Sciences and Hospital Ethics Committee in Dharwad, India, and the Health Research Ethics Board of the University of Manitoba, Canada. Parents of all study participants provided informed consent for the study. Thirty-five children were recruited. All of them were between the ages of four to ten and had a pre-existing diagnosis of CP.

Clinicians working in the Outpatient Physiotherapy Department were requested to recruit participants that fit the following inclusion criteria:

1. Gross Motor Function Classification Scale (GMFCS) level I-III (Bodkin et al., 2003a)

2. Manual Ability Classification System (MACS) level I-III (Eliasson et al., 2006a)

3. Modified Ashworth scale was used to determine the level of spasticity in biceps brachialis, pronators, and finger flexors, from grade 1 to 1+ (Mutlu et al., 2008b)

4. The pediatric version of the Mini-Mental State Exam for children (MMC) score above 17 (Jain & Passi, 2005a)

Exclusion criteria used:

1. Visual or auditory impairment due to which child cannot see and interact with the video games,
2. Secondary orthopedic complications due to CP or as a result of surgery to the upper limb that may have caused permanent changes in upper limb musculoskeletal structure,
3. Moderate or severe spasticity i.e., a Modified Ashworth score of grade 2 and higher where children would not be able to open hand and handle the everyday objects and toys to play games.
4. Recent Botulinum toxin therapy to the UE (less than six months). History of such therapy was provided by the consulting clinician (Pediatrician or physiotherapist)
5. Uncontrolled seizures with one or more episodes in the last six months. History of such an episode was provided by the consulting clinician (Pediatrician or physiotherapist)
6. Moderate or severe cognitive impairments due to which the child may not understand how to play the game.

Tests and Instrumentation

The fine motor quotient (FMQ) raw scores from the PDMS-2 (Folio, 2000) and the grasp score from QUEST (13, 18) were assessed by one clinician on the first day along with the CUE assessment tool. The second CUE assessment was conducted by the same assessor after a two-week time period had elapsed. The grasping and visual-motor integration tasks of the PDMS-2 are scored with three levels: a score of zero if the child is unable to perform the task, a score of one of the tasks is partially performed, or a score of two if the task is completed. There are no time constraints given, so the child may take any amount of time they require to complete or perform the given task. Only the raw scores and not composite scores were considered because the composite scores of the PDMS-2 have only been evaluated in children five years of age and younger and the children in study have a broader age range. The raw scores are recommended for use in older children with impairments (Folio, 2000). The QUEST compares the type of hand grasps used by the child to pick up three objects: a pencil or crayon, a cube, and a pellet. Scoring is based on how typical—or close to typical—the child's grasp of each object is measured on a five-point grading scale (Thorley et al., 2012a).

The CUE assessment tool uses a wireless inertial-based (IB) mouse (Scoop™ Pointer Remote Model: RXR1000-0302E, Hillcrest Labs), which links physical movements with interactive computer games. The IB mouse contains a multi-axis gyroscope and firmware that detects instantaneous angular motion, which causes the movement of a computer cursor or a game paddle. Five test objects with different physical properties and anatomical demands were instrumented with the IB mouse. Figure 5.1 (page 74) describes the five test object manipulation tasks using five test objects: peanut ball, soccer ball, tethered tennis ball, cone, and plastic ring. The CUE assessment software was used to guide several object manipulation tasks. The software presents a target object appearing at random locations at the top of the display screen. The object moves to the bottom of the display screen within two seconds of appearing and then disappears. One game event is defined as the time between the appearance and disappearance of a target. The children use the IB mouse to move the game paddle and catch the moving target objects.

Protocol

Each participant attended two assessment sessions two weeks apart. The first session included the administration of the QUEST, the PDMS-2, and the CUE assessment tool. The participants were allowed to play the CUE assessment game with the IB mouse until they became familiar with the game activities. During the assessment, participants were comfortably seated at a table with adjustable height. Each of the five test objects was placed on the table at a comfortable reaching distance within arm's length of the participants. The order in which the different objects were assessed was kept constant between the first and second assessment sessions. The same clinician conducted both assessments. The CUE assessment tool is computer-controlled, and the coordinate data of the movements are automatically logged by the computer (see figure 5.2, page 75). The performance measures were quantified offline by an analysis software using MATLAB™ programs.

Data Processing and Outcome Measures

Figure 5.2 describes the CUE assessment tool in detail. The duration of each game event lasted 2 seconds, and the game was played for 60 seconds. Thus, 30 contextual movement responses are recorded for analysis, 15 in one direction and 15 in the other. For a comprehensive description of the game movement indexing and segmentation, see (Lockery et al., 2011). Appendix 5.1 (page 76) describes the four outcome measures: Success Rate, Movement Onset Time, Movement Error, and Movement Variation.

Statistical Analysis

The sample size for this study was computed using Table 1 from Zou et al. (2012)(Zou, 2012). Thirty-five participants were required for an intra-class correlation coefficient (ICC) value of 0.8, assurance of 70%, and class interval half-width of 0.15. Relative reliability was assessed using a random model ICC. The ICC scores were considered to be high when equal to or greater than 0.70, moderate between 0.5 and 0.69, and low when less than 0.50. Minimal detectable change (MDC) was computed (Fitzpatrick et al., 1998; Haley & Fragala-pinkham, 2017; Messick, 2005). Systematic errors between the test periods were evaluated using a paired t-test. Convergent validity of the CUE outcome measures with the PDMS-2 and QUEST scores was analyzed using Pearson's correlation coefficient (R)(Messick, 2005). The SPSS software for Windows, version 20.0 (SPSS Inc. Chicago) was used for all statistical analysis procedures.

Results

Children with CP (n=35) between the ages of four to ten with UE impairments (GMFCS I to III) and fine motor control abnormalities (MACS I to III) were recruited. Table 5.1 (page 66) shows the average demographic data of the 35 participants.

Tables 5.2-5.5 (page 76 -79) present the results of the test-retest reliability analysis of the four CUE performance measures for the five object manipulation tasks.

The following summarizes the test-retest reliability results for success rate:

1. Test-retest reliability was high ($ICC>0.7$, $p\leq0.05$) for manipulation of the peanut ball for both directions, roll backward direction of the soccer ball, concentric supination of cone and ring, and concentric ulnar deviation of the tethered tennis ball.
2. Test-retest reliability was moderate ($ICC=0.5$ to 0.7, $p\leq0.05$) for roll forward direction of the soccer ball, eccentric pronation of cone and ring, and eccentric radial deviation of the tethered tennis ball.

The following summarizes the findings for the movement onset time outcome measure:

1. Test-retest reliability was moderate (ICC=0.5 to 0.7, $p \leq 0.05$) for manipulation of the peanut ball, soccer ball, cone, ring, and tethered ball in both directions except for the roll backward direction of the soccer ball, for which the test-retest reliability was high (ICC>0.7, $p \leq 0.05$).

The following summarizes the test-retest reliability results for movement error:

1. Test-retest reliability was high (ICC>0.7, $p \leq 0.05$) for the roll backward direction of the soccer ball, eccentric pronation of cone and ring, and eccentric radial deviation of the tethered tennis ball.
2. Test-retest reliability was moderate (ICC=0.5 to 0.7, $p \leq 0.05$) for manipulation of the peanut ball for both directions, roll forward direction of the soccer ball, concentric supination of cone and ring, and concentric ulnar deviation of the tethered tennis ball.

The following summarizes the test-retest reliability results for movement variation:

1. Test-retest reliability was high (ICC>0.7, $p \leq 0.05$) for the roll backward direction of a soccer ball and concentric ulnar deviation of a tethered tennis ball.
2. Test-retest reliability was moderate (ICC= 0.5 to 0.7, $p \leq 0.05$) for the peanut ball, roll forward direction of the soccer ball, the cone manipulation for both directions, concentric supination of ring manipulation task, and eccentric radial deviation of a tethered tennis ball.

Results of the paired student's t-tests showed no significant difference in any of the CUE assessment outcome measures between the first and second tests. This was the case for all object-manipulation tasks.

For most cases, the MDC as a percentage of the group means (%MDC) was less than 30% for average movement onset time of the peanut ball and soccer ball roll backward task cone concentric supination and ring eccentric supination. The %MDC was more than 60% for a) success rate of cone eccentric pronation, ring eccentric pronation, tethered tennis ball eccentric radial deviation, and b) movement error of peanut ball in both directions, soccer ball roll forward task, cone concentric supination, ring manipulation in both directions, and tethered tennis ball concentric ulnar deviation.

Convergent Validity

Results of the correlation analysis of the object manipulation test scores with QUEST or PDMS-2 scores revealed that the majority of the correlations were not significant (16 of 20 possible comparisons between the manipulation test scores and PDMS-2 and the QUEST, 19 of 20 possible comparisons between the manipulation test scores and PDMS-2).

Discussion

With few exceptions, the CUE assessment tool showed moderate to high test-retest reliability for all the object manipulation tasks and performance measures with no significant difference between the first and second test's mean scores. A variance of the performance measures among the subjects and MDC values were notably large for most object manipulation tasks.

Hundreds of objects can be instrumented with the IB mouse and used to assess the manual dexterity skills of the object manipulation tasks required in daily life and in play. The five manipulation tasks tested in the present study were chosen to span a broad range of functional properties and anatomical requirements. Rolling the peanut and soccer ball forward and backward were similar to each other and involved a combination of shoulder and elbow flexions and extensions while keeping the hand in contact with the surface and the fingers extended. As the soccer ball was manipulated forward and backward, the participants were required to prevent the ball from rolling left and right. Rolling the ball in one direction while minimizing its motion in other directions required more control—and thereby degrees of freedom—than the rolling of the peanut ball, i.e., a cylinder moves only about a single axis. Irrespective of the increased degrees of freedom, ICC values were similar for the peanut ball and soccer ball rolling task. The tethered tennis ball rotation task also could only rotate about a single fixed axis, and mass and torque were eliminated. Fine rotation of the tennis ball was produced by radio-ulnar deviation while maintaining the wrist in extension. Performance measures of this task also had high to moderate ICC values.

Four performance-based outcome measures were quantified in the present study: the success rate of each game event, movement onset time, movement error, and movement variation. These performance metrics represent different features of the signals recorded and different aspects of the processing involved, i.e., goal attainment, information processing and motor planning time, spatial aspects of movement precision, and movement consistency as measured over multiple responses. In the present study, the duration of each game event lasted 2 seconds, and the game was played for 60 seconds; thus, 30 contextual movement responses are recorded for analysis, 15 in one direction and 15 in the other. In this case, Success Rate is based on 30 game movement responses, and Movement Onset, Movement Error, as well as Movement Variation are the averages of 5 movement responses in each direction.

When evaluating the effectiveness of treatment programs, performance measures having high MDC values of greater than 20% would require a greater amount of change from pre- to post-intervention for them to be significant (26). Minimal detectible change is dependent on both the level of correlation between the first and second tests (ICC value) and on the variation among subjects, i.e., group standard deviation. In the present study, the standard deviation for most CUE variables was quite high and ranged from 20%- 60% as a percentage of the group average. To reduce the variation among subjects and to see if %MDC decreased, a subgroup analysis was performed on the cone and ring performance measures for children in MACS level I (n=12) and MACS level II (n=14). The results for the ring and cone object manipulation task showed that for all outcome measures, the standard deviation and the %MDC for MACS level I and II subgroups either increased or stayed the same as compared to the whole group analysis. For example, the standard deviation as a percentage of the group average for Success Rate was 34% for a cone for MACS I.

It was unexpected that the standard deviation in performance measures for the manipulation tasks among the children in MACS level I did not decrease from the variance observed for the whole group MACS levels I to III. By definition, MACS level I includes children who can handle objects with minimal difficulty. However, for the object manipulation tasks tested in the present study, goal attainment (Success Rate) was low with a range of 29-59 with a relatively large variation among the children in MACS level I. These findings were also true for the children in the MACS level II subgroup.

With few exceptions, there were no significant correlations found between the CUE assessment tool performance measures and the PDMS-2 or QUEST scores. This would signify that the CUE assessment tool assesses different attributes of object manipulation skills than QUEST and PDMS-2, or that the skills required to manipulate the test objects of the present study are different than the ones tested in the QUEST or PDMS-2. During the PDMS-2 assessment, children are given credit for partial completion of the respective items, but the criteria provided contain limited information or descriptors of the quality of the performance expected. For example, performance metrics, such as the movement onset time as well as the number and magnitude of movement errors, are not determined by the scoring method of the

PDMS-2. In the QUEST assessment, participants are not required to manipulate the object. The game activities of the CUE assessment tool have specific goals and time constraints that can be adjusted. The speed of the game objects, paddle size, and movement amplitude can be varied depending on the task requirements and level of impairment. In addition, the tasks are repeated multiple times, and averages are obtained across the total data.

Limitations

One main limitation of the CUE is that it requires an IB mouse, a computer, and basic knowledge of computer operation. Several fine motor skills cannot be assessed using the CUE assessment tool, such as buttoning and unbuttoning, tying shoelaces, and cutting food. Another limitation is that the IB mouse detects angular motion; therefore, it is not possible to practice tasks that require only linear motion. Although participants were shown how best to perform the various task with the desired arm segment motions and were made aware of the importance of minimizing compensatory associative movements, it was difficult to ensure this was accomplished each time given the age and level of understanding of each participant.

Conclusion

The moderate to high ICC values and lack of systematic errors in the outcome measures indicate that the CUE assessment tool has the ability to repeatedly record reliable performance measures of many different object manipulation tasks that have a broad range of physical properties and functional demands. Due to the high variation in CUE outcome measures among the participants, most MDC values were in the range of 30-60% of the group average. The lack of a significant correlation between CUE performance measures and the QUEST or PDMS-2 indicates that the two assessment tools represent distinct attributes or features of object handling and manipulation skills.

Table 5.1: Demographic and Clinical Characteristics of Participants with Cerebral Palsy

Participant	**Age In years (Average)**	**Gender**	**GMFCS Level (Average)**	**mASH Level (Average)**			**MMSE Score (Average)**	**MACS Level (Average)**		
				Elbow	Forearm	hand				
N=35	7.5 (2.32)	F=12, M=23	III	1	1	1	30/37	I=12	II=14	III=9

Table 5.2: Presents values of the test-retest reliability analysis for Success Rate outcome measure.

Object	Object and direction	Average (CI)	Average (CI)	ICC (95% CI)	MDC (% of mean)	F-value (Sig)
Peanut Ball	(Roll Forward)	43.95 (21.96-65.95)	46.37(24.2-68.48)	0.8(0.8-1.0)	25.66 (58.4)	13.1(0.0001)
	(Roll Backward)	44.63 (22.92-66.34)	39.51(21.44-57.58)	0.9(0.7-0.9)	16.16 (40.9)	6.8 (0.0001)
Soccer Ball	(Roll Forward)	42.07 (24.00-60.13)	49.01 (31.33-66.68)	0.6(0.2-0.8)	29.39(59.9)	2.8 (0.004)
	(Roll Backward)	43.63 (24.30-62.96)	44.01 (28.43-59.59)	0.8(0.5-0.9)	18.03(40.9)	4.1(0.0001)
Cone	(Eccentric Pronation)	47.66(26.98-68.35)	45.70(21.02-70.37)	0.7(0.4-0.9)	32.01(67.2)	3.3 (0.001)
	(Concentric Supination)	50.88(25.67-76.08)	52.17(27.67-76.67)	0.8(0.6-0.9)	25.97(51.0)	5.1(0.0001)
Ring	(Eccentric Pronation)	47.28(20.87-73.68)	53.80(30.02-77.57)	0.7 (0.3-0.9)	37.04(68.8)	3.2 (0.001)
	(Concentric Supination)	53.64 (33.28-74.00)	52.64(32.66-72.61)	0.8 (0.6-0.9)	24.39(46.3)	5.2(0.0001)
Tethered Tennis Ball	(Concentric Ulnar Deviation)	36.67(16.67-56.66)	41.18(19.11-63.24)	0.8 (0.7-0.9)	24.07(58.4)	6.5 (0.0001)
	(Eccentric Radial Deviation)	34.88(14.63-55.13)	34.51(12.92-56.10)	0.6 (0.2-0.8)	31.82(92.2)	2.5(0.008)

Table 5.3: Presents values of the test-retest reliability analysis for Average Movement Onset Time

Object	Object and direction	Average (CI)	Average (CI)	ICC (95% CI)	MDC (% of mean)	F-value (Sig)
Peanut Ball	(Roll Forward)	0.89 (0.67-1.11)	0.92(0.73-1.12)	0.6 (0.2-0.8)	0.41(46.7)	2.5(0.007)
	(Roll Backward)	0.95 (0.76-1.14)	0.86(0.70-1.02)	0.6(0.2-0.8)	0.23(26.8)	2.6(0.006)
Soccer Ball	(Roll Forward)	1.25 (0.23-2.73)	0.95 (0.72-1.19)	0.7(0.5-0.9)	0.33(35.3)	3.8(0.0001)
	(Roll Backward)	0.85 (0.72-0.98)	0.91 (0.75-1.06)	0.8(0.5-0.9)	0.18(20.1)	4.0 (0.0001)
Cone	(Eccentric Pronation)	0.86(0.59-1.12)	0.90(0.68-1.13)	0.6(-0.4-0.7)	0.46(54.2)	1.4(0.2)
	(Concentric Supination)	0.90(0.75-1.04)	0.86(0.73-0.99)	0.6(-0.2-0.8)	0.21(23.4)	2.1 (0.03)
Ring	(Eccentric Pronation)	0.92(0.34-1.51)	0.82(0.68-0.96-)	0.7(0.3-0.8)	0.22(27.3)	3.1(0.001)
	(Concentric Supination)	0.86(0.71-1.02)	0.91(0.76-1.05)	0.5(0.4-0.8)	0.27(30.6)	2.2(0.02)
Tethered Tennis Ball	(Concentric Ulnar Deviation)	0.89(0.70-1.09)	0.87(0.69-1.04)	0.7(0.3-0.8)	0.27(32.1)	3.0(0.002)
	(Eccentric Radial Deviation)	0.82(0.56-1.09)	0.84(0.61-1.08)	0.7(0.4-0.9)	0.30(35.6)	3.3(0.001)

Table 5.4: Presents values of the test-retest reliability analysis for Movement Error outcome measure.

Object	**Object and direction**	**Average (CI)**	**Average (CI)**	**ICC (95% CI)**	**MDC (% of mean)**	**F-value (Sig)**
Peanut Ball	(Roll Forward)	0.24 (0.14-0.34)	0.22(0.11-0.32)	0.5 (0.3-0.9)	0.2 (82.6)	3.1 (0.002)
	(Roll Backward)	0.25 (0.10-0.39)	0.22(0.11-0.34)	0.7 (0.4-0.9)	0.14 (62.9)	3.4(0.001)
Soccer Ball	(Roll Forward)	0.24 (0.11-0.36)	0.23 (0.12-0.34)	0.5 (0.7-0.9)	0.21 (93.4)	8.6(0.0001)
	(Roll Backward)	0.26(0.13-0.39)	0.24 (0.12-0.37)	0.8 (0.5-0.9)	0.13 (54.9)	4.5(0.0001)
Cone	(Eccentric Pronation)	0.22(0.08-0.35)	0.20(0.09-0.31)	0.9 (0.8-1.0)	0.12 (55.6)	9.6 (0.0001)
	(Concentric Supination)	0.22(0.09-0.34)	0.23(0.08-0.38)	0.7 (0.4-0.9)	0.15 (68.3)	3.7(0.001)
Ring	(Eccentric Pronation)	0.64(0.47-1.75)	0.21(0.08-0.35)	0.8 (0.5-0.9)	0.18 (84.7)	4.2(0.0001)
	(Concentric Supination)	0.19(0.09-0.29)	0.20(0.09-0.32)	0.7 (0.3-0.9)	0.17 (86.5)	3.2 (0.002)
Tethered Tennis Ball	(Concentric Ulnar Deviation)	0.28(0.13-0.42)	0.28(0.13-0.42)	0.7 (0.4-0.9)	0.2 (71.9)	3.9(0.0001)
	(Eccentric Radial Deviation)	0.29(0.18-0.40)	0.27(0.15-0.39)	0.8 (0.6-0.9)	0.11(43.9)	5.4(0.0001)

Table 5.5: Presents values of the test-retest reliability analysis for Movement Variance outcome measure.

Object	Object and direction	Average (CI)	Average (CI)	ICC (95% CI)	MDC (% of mean)	F-value (Sig)
Peanut Ball	(Roll Forward)	0.28 (0.18-0.38)	0.27(0.17-0.38)	0.6 (0.5-0.9)	0.17 (61.4)	4.1(0.0001)
	(Roll Backward)	0.28 (0.19-0.37)	0.25(0.15-0.35)	0.7 (0.4-0.9)	0.12 (49.0)	3.4 (0.001)
Soccer Ball	(Roll Forward)	0.82(2.10-3.74)	0.32 (0.22-0.41)	0.7 (0.4-0.9)	0.14 (44.7)	3.4 (0.001)
	(Roll Backward)	0.28 (0.18-0.39)	0.32 (0.22-0.41)	0.8 (0.6-0.9)	0.1 (31.1)	5.1(0.0001)
Cone	(Eccentric Pronation)	0.24(0.14-0.34)	0.26(0.17-0.36)	0.7 (0.4-0.9)	0.14 (60.9)	3.4 (0.001)
	(Concentric Supination)	0.26 (0.16-0.35)	0.26 (0.17-0.35)	0.7 (0.3-0.9)	0.12 (47.9)	3.0(0.002)
Ring	(Eccentric Pronation)	0.45(0.27-1.18)	0.30(0.22-0.38)	0.3 (0.3-0.8)	0.17 (58.9)	2.8 (0.003)
	(Concentric Supination)	0.26(0.17-0.35)	0.29(0.20-0.39)	0.7 (0.3-0.9)	0.13 (44.5)	3.7(0.0001)
Tethered Tennis Ball	(Concentric Ulnar Deviation)	0.27(0.18-0.36)	0.27(0.18-0.35)	0.8 (0.6-0.9)	0.1 (38.7)	4.9 (0.0001)
	(Eccentric Radial Deviation)	0.30(0.22-0.37)	0.26(0.17-0.36)	0.6 (0.05-0.8)	0.14 (54.0)	2.2 (0.02)

Figure 5.1 Describes the five-test object manipulation tasks; peanut ball, soccer ball, tethered tennis ball, cone, and plastic ring.

Test object manipulation tasks

The Peanut Ball

Peanut

A sixty centimeters diameter peanut-shaped cylinder. The child was instructed to place their hand on top of the peanut ball and to roll it backward and forward using a combination of shoulder and elbow motion, and while maintaining an open hand and slightly extended.

The cone-shaped plastic toy.

Cone

The child was asked to grasp the cone shaped toy with their whole hand and opposed thumb. The toy was rotated using pronation and supination while maintaining the grasp.

The Soccer Ball

Soccer Ball

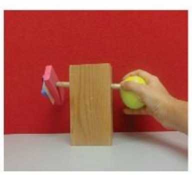
The soccer ball was rolled backward and forward using a combination of shoulder and elbow motion, and while maintaining an open hand and slight wrist extension.

A donut-shaped plastic ring.

Ring

The child was asked to grasp the donut shaped ring between their thumb and index-middle fingers and to rotate it using pronation and supination.

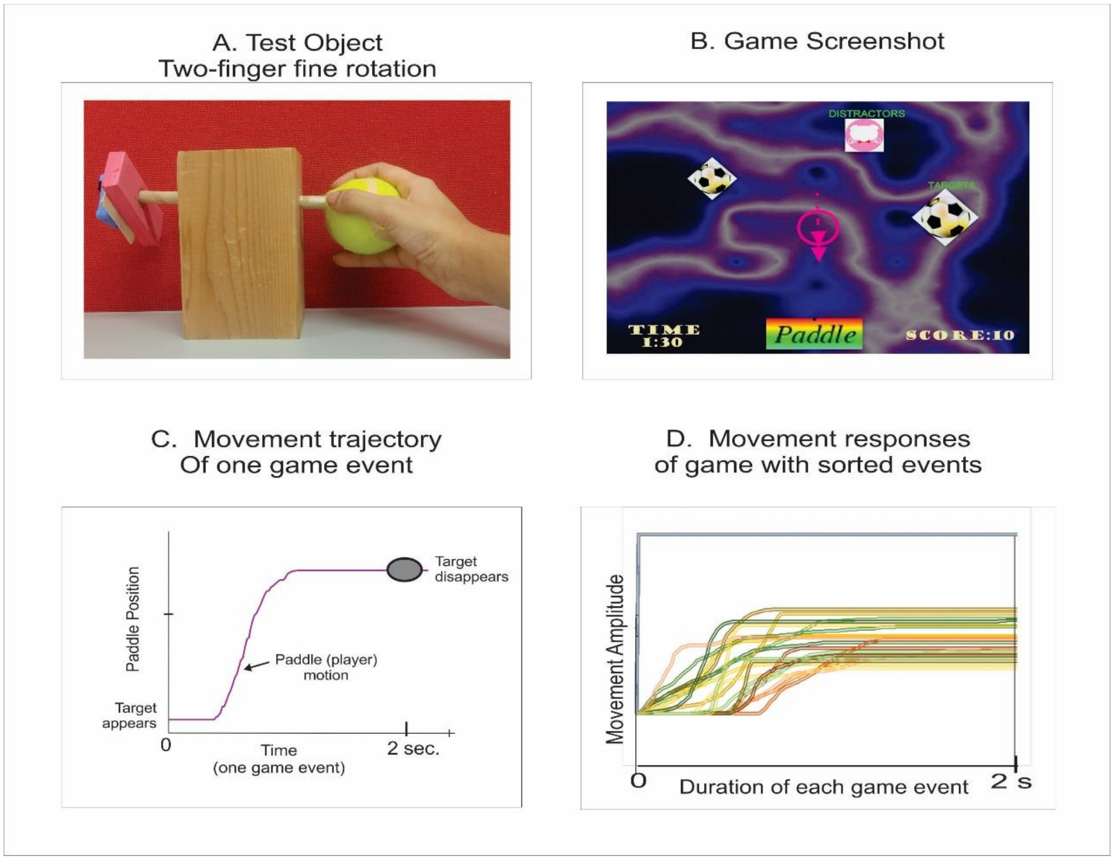
The Tennis Ball



Tennis Ball

The fifth crafted object consisted of a 12 cm square wooden block. A 11.5 cm hole was drilled through the wooden block where a 15 cm long wooden dowel was inserted. The IB mouse was attached to one end of the wooden dowel, and a tennis balled was secured to the other end. Thus rotation of the tennis ball would rotate the IB mouse. This simple crafted object eliminated gravity and torque during fine rotation movements of the IB mouse. The child was asked to grasp the ball with the tips of their fingers and thumb and to rotate the ball using radial and ulnar deviation.

Figure 5.2A presents a screenshot of the CUE game and a plot of the trajectory of a typical paddle movement (motion of the test object) of one game event. Figure 5.2B presents the trajectory of a single game movement response. Figure 5.2C presents a single game trajectory of one game event. Figure 5.2D presents overlay plots of all game movement responses for each direction obtained from one game session.



Appendix 5.1: CUE outcome measures

1. Success Rate: the percentage of the total number of target objects that were caught in one game session.

2. Average Movement Onset Time: the time from target appearance to the start of the game paddle movement. Values for average movement onset time are determined for each game movement response, and the average is computed over the group of game movement responses for each direction.

3. Absolute Movement Error: the magnitude of the error is recorded as movement error (distance between paddle and target position) when a target is missed. The average value for all misses is then computed as the movement error. Units are percentages of screen width.

4. Movement Variance: There were 15 game movement responses in each direction for each game trial. For each game movement trajectory, there are 200 sample data points of paddle position. The mean paddle position and standard deviation over the 15 game movement responses were computed for each sample period. The standard deviation of the paddle positions for the 200 samples was summed to obtain a measure of the variance of the 15 repeated game movement responses with units defined as a percentage of screen width/height.

MATLAB™ (The Math Works, Natick, MA, version 2010a) was used to compute all outcome measures described above.

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Chapter 6: Connecting text 1

The computer game based upper extremity (CUE) assessment tool was developed specifically to quantify object manipulation skills. This game-assisted assessment software application is a critical feature embedded in the computer games-based rehabilitation protocol (GRP). It produces standardized computer-generated tasks with choices to guide and elicit goal-directed movement responses. The electronic outcome measures derived from the automated CUE assessment tool can inform a therapist when and how a child is performing, whether they are experiencing any difficulty, and how they progress in their home exercise program. Based on this information, the GRP platform can be individualized.

A mixed model exploratory RCT was conducted using the innovative GRP protocol for manual dexterity impairments in children with mild to moderate motor impairment of the UE to provide evidence of the feasibility of conducting a full-scale randomized controlled trial (RCT). The objective of the present study was to evaluate the therapeutic value and treatment effect size using a mixed model exploratory RCT using GRP based exercise program for children with mild to moderate motor impairment of the UE. The first hypothesis was that an engaging, game-assisted UE exercise regime using the GRP would result in greater improvements in hand-arm function as compared to the usual outpatient physical therapy program. This emerging approach incorporates computer game-assisted exercise methods to engage children in therapy. The GRP protocol was individualized based on children's level of impairments, abilities, and functional demands.

Chapter 7: Quantitative study

Evaluation of a computer games-assisted rehabilitation platform for manual dexterity impairments in children with cerebral palsy: an exploratory randomized control trial

Abstract

Introduction: There is a need for innovation to improve engagement and compliance of rehabilitation programs for children with upper extremity (UE) motor impairments due to cerebral palsy (CP). A computer game-assisted rehabilitation platform (GRP) was developed to address this need. With the novel application of a miniature inertial-based computer (IB) mouse and taking advantage of the wide variety of commercial computer games, the GRP can provide engaging task-specific exercises for rehabilitation of manual dexterity.

Objective: A feasibility randomized clinical trial was conducted to evaluate the therapeutic value and treatment effect size of an exercise program using the GRP in children with CP.

Methods: A total of sixty-three children with CP (age 4 to 10 years) were recruited. The Peabody Developmental Motor Scale-2 (PDMS-2), a) Grasp, b) Visual-Motor Integration (VMI) subtest, and a computer game-assisted upper extremity (CUE) assessment tool were used to assess participants prior to and following a 16-week intervention program delivered thrice per week. The Experimental group (XG) received a computer game-assisted exercise program targeting object manipulation tasks. The active control arm consisted of task-specific training similar to the tasks used in constrained induced movement therapy.

Results: Both the XG and control group (CG) groups showed significant improvements pre- to post-intervention with large effect sizes. Improvements in the PDMS-2 Grasp and VMI scores observed in the XG group were significantly greater than that in the CG group. The CUE

assessment tool performance measure showed mixed time* group interaction effects. Improved Movement Onset Times were significantly greater in XG compared to CG.

Limitation: One limitation of the GRP is that it requires an IB mouse, a computer, and a source of common/modern computer games. The IB mouse detects angular motion; therefore, it is not possible to practice tasks that require only linear motion. Additional outcome measures, such as health-related quality of life and participation, will also be required to validate the findings.

Conclusion: This study demonstrates the utility of the GRP to practice a broad range of object manipulation tasks in children with CP. Clinical meaningful changes in manual dexterity were observed with moderate to large effect sizes. These findings and the theoretical evidence direct the next phase of a full-scale randomized controlled trial (RCT).

Introduction

Many children with cerebral palsy (CP) have deficits in fine motor skills of the upper extremity (UE) (CANS et al., 2007; Scpe, 2000). Manual dexterity involving handling and manipulating objects is essential for many activities of daily living (ADL), social activities, and participation in play (James et al., 2015b). These activities require manipulation of objects with a wide range of physical properties and functional demands, i.e., often require a high degree of precision. Therapy programs designed to improve manual dexterity, eye-hand coordination, and other related visual-spatial processing skills must strive to maximize neurodevelopmental capacities and prevent secondary disabilities. Constraint-induced movement therapy (CIMT) (Gordon et al., 2005; Hoare et al., 2007; Klingels et al., 2013) and Hand Arm Bimanual Intensive Therapy (HABIT) (Bleyenheuft, Arnould, et al., 2015; Gelkop et al., 2015) are promising rehabilitation programs for hand-arm function impairments (Maier et al., 2019a). These treatment approaches stress that functional improvements reflects learning achieved through generating real experiences, applying focused attention, simulating close-to-normal movements, and repetition (Maier et al., 2019b). However, it is difficult to engage children with CP in therapy for long periods of time and sustain motivation for the intense, RTPs(L. Miller et al., 2016). Parents and clinicians rate motivation as the most influential personal characteristic for adherence to therapy (Majnemer et al., 2010). A promising approach to engaging children in therapy is the use of video games in which a range of interactive challenges help children to participate in exercise (Howcroft et al., 2012). Studies have provided evidence of the benefits of incorporating video games in the rehabilitation of motor skills and visual-spatial processing skills. For this purpose, we have developed a low-cost computer game-assisted rehabilitation platform (GRP) that combines fine manipulation and gross movement exercises with attention and planning game activities appropriate for young children with CP (Hickman et al., 2017; Lopes et al., 2018). This approach focuses on the goal-oriented, task-specific practice of object handling and manipulation to address difficulties in manual dexterity (Szturm et al., 2014). The GRP uses a commercial, miniature, wireless inertial based computer (IB) mouse which links physical movements with interactive computer games. The precision and responsiveness of the IB mouse are equivalent to that of a standard optical computer mouse. Multiple objects with varied sizes, shapes, weight, and surface properties can easily be instrumented with the IB mouse. Therefore, the natural motion of these IB mouse-equipped objects can be used to control the motion of a computer cursor or game paddle. Because the GRP allows handling and manipulation of many objects in game-assisted practice (i.e., ones commonly used in daily activities), activity goals can be embedded in the therapy program. Another important feature of the platform is the ability to incorporate movement precision. Not only do the object and task have specific therapeutic value, but so does the choice of computer game. There is a large variety of inexpensive and readily available commercial computer games that require different levels of movement amplitude, speeds, accuracy, as well as appeal to individual preferences. Performing goal-directed manipulation tasks through engaging and guided repetition is crucial to improving the brain's ability to learn. The GRP combines object manipulation exercises with computer game-assisted activities based on goal directed RTP appropriate for young children with CP.

The purpose of this study was to provide evidence of the feasibility of conducting a full-scale randomized controlled trial (RCT) using the GRP for the rehabilitation of manual dexterity in children with mild to moderate motor impairment of the UE. The objective of the present study was to evaluate the therapeutic value and treatment effect size using a mixed model exploratory RCT using GRP based exercise program for children with mild to moderate motor impairment of the UE. The first hypothesis was that an engaging, game-assisted UE exercise regime using the GRP would result in greater improvements in hand-arm function as compared to the usual outpatient physical therapy program. The second hypothesis was that the UE exercise program, which uses computer games having a variety of visual-spatial activities, would result in greater improvements in visuospatial cognitive functions as compared to the usual outpatient physical therapy program. In addition, a qualitative analysis was conducted, which is presented in a different paper. This study was conducted to explore children's parents' experiences and investigate; a) difficulties with the exercises and using the technologies, and b) engagement and motivational value of the computer games.

Methods

A total of sixty-three children with CP (age 4 to 10 years) that fit the following inclusion criteria were recruited. For this single-blind randomized clinical trial with an active control arm. See appendix 1 (page 152) for the CONSORT diagram.

1. Gross Motor Function Classification System (GMFCS) from level 1-3 (Bodkin et al., 2003b)

2. Manual Ability Classification System (MACS) from level 1- 3 (Eliasson et al., 2006b)

3. Modified Ashworth scale (mASH) the level of spasticity from grade 1 to 1+ (Mutlu et al., 2008a)

4. The pediatric version of the Mini Mental Status Evaluation (MMSE) (Jain & Passi, 2005b) (level 17 and above was set as the inclusion criteria to ensure the children's ability to follow computer games instructions)

Exclusion criteria include the following:

1. Visual or auditory impairment or with a communication disorder that would prevent a child from being able to follow instructions or comprehend the computer games

2. Recent orthopedic surgery or botulinum toxin injection to the UE within the last six months

3. History of seizures within the last six months

After the initial screening process, parents were asked to give written informed consent. The Clinical trial number. Clinicaltrials.gov NCT02728375; http:https://clinicaltrials.gov/ct2/show/NCT02728375 (Archived by WebCite at http://ww.webcitation.org/6qDjvszvh)

Procedures and Interventions

The initial two sessions included the following assessments

1. The following subtests of the Peabody Developmental Motor Scale-2, a) Grasping, a 26-item subtest measures a child's ability to use his or her hands, b) Visual-Motor Integration (VMI) subtest. This 72-item subtest measures a child's ability to use visual perceptual skills. Both the PDMS-2 grasp score and visual-motor integration subtest score have shown high test-retest reliability and have good construct validity (Nijmegen & Nether-, 2005).

2. Computer Game-assisted Upper Extremity assessment (CUE): The IB mouse was secured using Velcro ™ to five test objects chosen for assessment of manual dexterity. When the IB mouse is attached to a "test" object, the manipulation of the object is then used to control the motion of a computer cursor or game paddle. Importantly, the IB mouse can be attached to a broad range of objects with different physical properties and functional demands. A computer application was used to guide the object manipulation tasks. A custom computer application with the following assessment module was used Computer game-assisted Upper Extremity assessment (CUE). Figure 7.1 (page 178) illustrates the gaming setup as well as the CUE game tasks and plots of game movement responses. The following performance measures for the CUE were quantified: a) Success Rate, b) Movement Onset Time (MOT), and c) Movement Error (ME) for

details of the analysis procedures used to quantify CUE performance measures, refer to previously published researches (Lockery et al., 2011).

These assessments were repeated after completion of a 16-week intervention (three 45-minute exercise sessions per week) to determine the treatment effect (i.e., quantitative analysis) completed. Upon completing the 16-week exercise program, all parents were invited to participate in an interview to explore children's parents' experiences with their respective exercise programs.

Experimental group intervention: The initial exercise protocol for each participant was established based on the child and parents' goals, the level of impairment, and functional status. A typical session for the experimental group consisted of the RTP-based computer game-assisted exercise program. Children were provided six to eight objects for exercise and play several computer games (see Appendix 7.2, page 147). The objects used were everyday items such as balls of various sizes, daily objects like spoons, glasses, cups, school activities related objects such as markers, pens, and play-based objects such as toys and instruments. These objects represented a wide range of physical properties requiring different modes of manipulation and functional demands. This protocol takes advantage of ergonomic properties of common objects to amplify limited and small amounts of voluntary movement for manipulation in children with CP and then allows opportunities for progression to more challenging objects with greater physical and functional demands. Appendix 2 (Page 147) presents several object manipulation tasks used in the present study for game-assisted RTP.

Children were instructed on how to perform the various tasks with the desired hand and arm segment motions and not to substitute them with associated movements. Computer games that best suited the object manipulation tasks were chosen for the exercise program. The computer games were chosen based on the following game properties: a) movement amplitude required to move the game paddle, b) game speed, and c) game precision requirement. Many inexpensive arcade-style computer games are readily available online and can be downloaded from websites such as www.bigfishgames.com (see appendix 3, page 148). This protocol was updated every four weeks based on the child's improvements, current goals, and functional demands. When the computer games became familiar and repetitive, they were changed to increase the level of precision, speed, or movement amplitude.

Control group intervention: The control group received the comprehensive physical therapy protocol based on the goal-oriented, RTP-based principles of mCIMT and HABIT. Therapy protocols were individualized for every participant according to their level of impairment and pre-set goals. A variety of arm and hand activities were practiced, such as reaching for rings, ball throwing, clay activities, picking marbles from sand, and putting pellets and pegs into sockets. These tasks were practiced by the child with the guidance and assistance of a therapist. New tasks and challenges were added as the child progressed.

Data Analysis

The assessments were performed pre-intervention and post-intervention at the end of sixteen weeks. The grasp and VMI subscores of PDMS-2 were used as the primary outcome measures, along with the CUE outcome measures. MATLAB^{TM} (The Math Works, Natick, MA, version 2010a) was used to compute the CUE outcome measures.

Statistical Analysis

The normality of the data was checked using the Shapiro-Wilk test (SS & MB, 1965). Results determined the data was normally distributed. The effects of Time (pre- to post-intervention), Group (experimental and control), and Time*Group interaction on the PDMS-2 and CUE outcome measures were evaluated using a mixed model ANOVA with repeated measures. The significance level was set at 0.05, and the statistical analysis was conducted using SPSS (Version 24) (SPSS Science, Chicago).

A custom computer simulation was used to calculate statistical power for the repeated measures models, with the present study data providing estimates of the treatment effect sizes. A random-intercepts linear mixed-effects model was used and 256 datasets with randomly generated observations were generated for each combination of sample size, number of visits, and effect size. For all simulations, the treatment allocation for experimental intervention and active control arm was assumed to be 1:1 (balanced design). Each data set was analyzed by a linear mixed model with a group, time, and Time*Group interaction. Power was calculated as the fraction of models with a significant ($p < 0.05$) Time*Group interaction term which quantifies the difference in slopes between the two groups over time. SAS PROX MIXED version 9.4 was used to perform the simulations. Significant results are adequately powered at 80% for the observed Time*Group effect sizes.

Results

Table 7.1 (page 143) presents the demographic and clinical data by group (XG n=33, mean age 7.2, CG n=30, mean age 7.8). Three participants from the CG withdrew from the study after attending 6 to 8 sessions of therapy due to a change of school, commute, and transportation-related issues (see appendix 7.1 CONSORT diagram, page 146).

Group means and standard deviation (SD) for PDMS-2 test scores are presented in Figure 2 (page 156). Table 7.2 (page 143) presents ANOVA results for Time, group, and Interaction effects for PDMS-2 test scores. A significant improvement in Grasp and VMI test scores from pre to post-intervention were seen for both groups.

As can be seen in Figure 7.2 (page 152), improvements in PDMS-2 test scores were significantly greater (Time*Group interaction) for the XG group compared to the CG group. There was also a significant group effect, with the XG group having higher test scores than the CG group. Effect sizes were large, ranging from 0.69 to 0.8. On average, the Grasp scores improved by 0.19 for the XG and 0.12 for CG, VMI scores improved by 0.14 for XG and 0.09 for CG.

Group means and standard deviation (SD) for Success Rate, Movement Onset Time, and Movement Error are presented in Figures 7.3 to 7.5 (page 153-155). Tables 7.3 to 7.5 (page 143-145) presents ANOVA results of Time, group, and Interaction effects for Success Rate, Movement Onset Time, and Movement Error.

With few exceptions, there was a significant improvement pre- to post-intervention in Success Rate, Movement Onset Time, and Movement Error in both XG as well as CG. For the CUE assessment tool, the effect sizes were (a)small to moderate for Movement Onset (range 0.04-0.4), (b) small to moderate for Success Rate (range 0.08-0.29), and (c) small to moderate for Movement Error Rate (range 0.07-0.22).

As can be seen in Figures 7.3 to 7.5 (page 153-155), improvements in Movement Onset Time were significantly greater (Time*Group interaction) for the XG group compared to the CG group. With few exceptions, there was no significant Time*Group Interaction seen for Success Rate or Movement Error. In the majority of cases (objects and movement direction), there was a significant group effect for Success Rate, Movement Onset Time, and Movement Error. The

Success Rate was higher in the XG group compared to the CG group. Movement Onset Time and Movement Error were lower in the XG than the CG group.

In the majority of cases (object and movement direction), there was a significant group effect for Success Rate, Movement Onset Time, and Movement Error. The Success Rate was higher in the XG group compared to the CG group. Movement Onset Time and Movement Error were lower in the XG than the CG group. The effect sizes were (a)small to moderate for Movement Onset Time (range 0.04-0.40), (b) small to moderate for Success Rate (range 0.08-0.29), and (c) small to moderate for Movement Error Rate (range 0.07-0.22).

The QUEST scores did not have any significant improvements withing and between group. The sample size calculations were done using the means and sigma values with alpha (**α**) set at 0.05, and the value for the desired power set at 80%. The sample sizes based on PDMS-2 VMI subscore were N=22, based on Movement Onset Time of the cone manipulation task were N=49, and based on the Success Rate of the cone manipulation task were N=72. Results of the computer simulation for statistical power (SAS PROX MIXED revealed that the present study was adequately powered at 80%, (significance level 0.05) based on the observed Time*Group effect sizes of: a) the primary outcome measures, PDMS-2 Grasp and VMI test scores, and b) the CUE Movement Onset Time.

Discussion

The objective of the present study was to evaluate the therapeutic value and treatment effect size of an exercise program using the GRP in children with mild to moderate motor impairment of the UE. Both the XG and CG groups showed significant improvements pre- to post-intervention with large effect sizes. Improvements in the PDMS-2 Grasp and VMI scores observed in the XG group were significantly greater than that in the CG group. The CUE assessment tool performance measure showed mixed time* group interaction effects. Improved Movement Onset Times were significantly greater in XG compared to CG.

The present findings are consistent with previous studies that demonstrate high repetition and task-specific training are effective in promoting recovery of UE function(Imran Z, Szturm TJ; Pooyania S, Kanitkar A, Mahana, 2020; Szturm et al., 2020a). One main feature of the game-assisted exercise program was to increase the number of repetitions. Typically, each game was played for 5-7 minutes, and the duration of each game event lasted an average of two seconds. Therefore, the object was manipulated at least 100 times, which is a high number of repetitions of goal-directed movements. For most games, the game targets appear at random locations and move in unpredictable trajectories or directions; this would represent variable practice. In addition, visual feedback of the game paddle was used to initiate and guide the movement responses; the child views the game events and not the object being manipulated. This type of practice would promote implicit learning of eye-hand coordination(Ayed et al., 2019).

The significant substantial improvements observed in the fine motor tasks of the PDMS-2 occurred even though these tasks were not practiced during the GRP intervention, for example, tasks such as buttoning, unbuttoning, and drawing/coloring. On average, the PDMS-2 Grasp scores improved by 20% for the XG and 12% for CG from pre to post-intervention and with a large effect size within-group (aἠ2= 0.75). The VMI scores improved by 15% for XG and 9% for CG from pre to post-intervention and with a large effect size within-group (aἠ2=0.79). Other studies that used PDMS-2 as the primary outcome measure have shown low to moderate effect sizes. A study by El-Shamy et al. (2020)(El-Shamy, 2018) examined the effects of Wii™ training on hand function in children with CP. They reported a 16% improvement in the Grasp subscore. Lin et al., 2011(Lin et al., 2011) examined the effects of CIMT on PDMS-2. They report a 25% improvement in the Grasp subscore. In the present study, the GRP game tasks required goal-directed movements based on visual feedback of moving game objects. This is reflected by the substantial improvement in the performance of the visuomotor tasks of the PDMS-2. These types of training components are not often a focus of conventional therapy programs.

Improvements in Movement Onset Times for several object manipulation tasks were also significantly greater in the XG group compared to the CG group. This is likely due to the time constraints of XG game tasks, i.e., Constraints of less than 2 seconds to rotate the exercise objects and catch the game target objects before they disappeared. However, the significant improvements pre-post intervention in success rate (goal attainment) and the amount of movement errors where similar in both the XG and CG groups.

A number of gaming systems have been used as rehabilitation tools. These include commercial entertainment gaming systems like the Wii™ (H.-C. Chiu et al., 2014) and Kinect (Chang et al., 2013), as well as the Leaps 3D depth camera(Daoud et al., 2020) and sensor-equipped gloves(Gerber et al., 2016c). These gaming systems detect arm segment motions or finger motions. The corresponding segment motion signals are used to interact with virtual Avatars/objects or control a game paddle for play. However, these systems have limitations; in particular, they do not target object handling and manipulation. Therefore, there is no sensorimotor processing of skin tactile sensory information regarding stability and slip of the moving objects (Callier et al., 2019; Miall et al., 2019; Sundaram et al., 2019). In this regard, most parents expressed their willingness to participate in the trial because therapy would focus on manual dexterity and concerns over the lack of eye-hand coordination of their children.

The GRP provides interactive and engaging computer game-assisted practice of a broad range of tasks that need to be performed by the UE in daily life. Hundreds of objects of different mass, shape, and size, surface friction can be changed to function exactly as the IB mouse simply by attaching the IB mouse using Velcro ™. Exercise objects can be chosen to be handled with a 2-finger grip, 3-finger grip, whole hand, and both hands, as well as to incorporate a combination of the wrist, elbow, and shoulder motion. The GRP takes advantage of ergonomic properties of common objects to amplify limited and small amounts of voluntary movement and then allows opportunities for an appropriate switch to objects having more demanding movement requirements or functional demands. For example, the weight of the arm is supported during rolling a cylinder and a soccer ball forward and backward. These tasks involved a combination of shoulder and elbow flexions and extensions while keeping the hand in contact with the surface and the fingers extended. While the cylinder could only rotate about one axis, the soccer ball can move in multiple directions. Thus, when rolling the ball forward and backward, any off-axis rotation or slipping of the hand sideways off the object would need to be prevented, i.e., additional degrees of control and coordination by internal-external rotators and abductors-adductors. Fine precision rotation tasks while handling the different size and shaped objects involved voluntary movements of the thumb, fingers, and wrist segments. A thorough knowledge about objects and their geometrical properties, functional and anatomical demands will help set specific treatment goals tailored to each child and obtain objective outcome measures and monitor progression.

The inclusion of a gaming element was intended to provide extra motivation for the children in the form of a challenge and a more enjoyable means of encouraging them to follow tedious, repetitive movements that are often a part of the rehabilitation process. In the qualitative component conducted as an addition to this RCT, parents' perspectives about the use of computer games were recorded. Most parents from the XG reported that their child had never interacted with computers before and reported that the exercises were challenging yet engaging, and their children enjoyed playing the games. They felt that this gratification was important and improved children's compliance with the therapy program. This finding was similar to previous studies that have used commercial entertainment gaming platforms for therapy (Ayed et al., 2019; El-Shamy, 2018; Imran Z, Szturm TJ; Pooyania S, Kanitkar A, Mahana, 2020; Szturm et al., 2020b). Parents from the CG provided a mixed review regarding the child's interest and compliance in their supervised exercise programs over the sixteen weeks. Previous studies reported caregivers and children's increased levels of frustration and discomfort due to the restraint used for CIMT protocols(Eliasson, Ot, et al., 2005; Gilmore et al., 2010). To note, there were no dropouts in the XG group, whereas there were three dropouts in the CG group.

Not only do the types of object manipulation task have specific therapeutic value, but so does the choice of computer game. Different commercial video games require different levels of movement amplitude, speeds, accuracy, repetition as well as appeal to individual preferences. Updating and progressing the games and difficulty levels regularly to maintain the level of difficulty and providing a new set of games to play is an important aspect of maintaining interest and participation. There are a large number of inexpensive and readily available common and modern commercial games that are engaging, and that can be played with a computer mouse or equivalent like the IB mouse. Examples of games can be found in Appendix 3. Initially, children having severe impairments could only play games that involved slow movements and low precision (i.e., large paddle size and large game target objects). On the other hand, children with moderate to mild impairment could play a larger variety of games with increased movement speeds, precision levels, and added cognitive content.

To determine the minimum effect size and to determine the sample size for a fully powered RCT, a power analysis was performed to calculate the standardized mean difference between the experimental group receiving RTP based GRP protocol provided in a clinical setting and a control arm receiving a conventional therapy protocol. The results of the power calculations showed that it is reasonable to justify the current sample size (N=63) based on the CUE assessment tool variables' confidence interval width.

Limitations

One limitation of the GRP is that it requires an IB mouse, a computer, and a source of common/modern computer games. Several fine motor skills cannot be performed with the game-assisted RTP approach using the IB mouse, such as writing, doing up buttons, tying shoelaces, cutting food. Another limitation is that the IB mouse detects angular motion; therefore, it is not possible to practice tasks that require only linear motion. The long-term effects of GRP training on manual dexterity in children with CP will need to be confirmed in larger, adequately powered studies. Additional outcome measures, such as health-related quality of life and participation, will also be required to validate the findings.

Conclusion

This study demonstrates the utility of the GRP to exercise a broad range of object manipulation tasks in children with CP. Clinical meaningful changes in manual dexterity were observed with moderate to large effect sizes. These effects were larger in the group receiving the GRP as compared to conventional task-specific therapy. These findings and the theoretical evidence direct the next phase of an RCT. Results of the computer simulation for statistical power (SAS PROX MIXED revealed that the present study was adequately powered.

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Table 7.1: Demographic data

	Age (years) Mean (SD)	MMSE Mean SD)	GMFCS	MACS	PDMS-2 Grasp Mean (SD)	PDMS-2 VMI Mean (SD)
Control group (CG)	7.8 (1.9)	27.7 (1.4)	I=6 II =14, III =7	I =6 II =16, III = 11	38.8 (4.2)	110.4 (10.1)
Experimental group (XG)	7.3 (2.1)	29.0 (0.3)	I=8, II=15, III=10	I =4 II = 15, III = 8	38.5 (3.1)	107.6 (8)
T-TEST p-value	0.2	0.4			0.8	0.5

Table 7.2 Results of ANOVA for the PDMS-2 test scores

Outcome	Time of the assessment (Within-group) F, p, η^2	Experimental vs. control group (Between-group) F, p, η^2	Time*Group F, p, η^2
Grasp	175.979 .000 .755	12.342 .001 .178	10.365 .002 .154
VMI	121.503 .000 .688	10.957 .002 .166	6.669 .013 .108

Table 7.3 Results of ANOVA for Success Rate

Outcome	Time of the assessment (Within-group)	Experimental vs. control group (Between-group) F, p, η^2	Time*Group F, p, η^2

	F, p, $\dot{\eta}^2$								
CN_LM	22.9	0.000	0.294	0.001	0.181	12.158	.010	.921	.000
CN_RM	.000	.228	17.973	6.148	.016	.092	.969	.000	.001
PB_LM	5.935	.018	.091	1.696	.198	.028	4.710	.034	.074
PB_RM	.000	.266	21.371	5.186	.026	.081	.010	.106	6.999
SB_LM	5.643	.021	.083	1.962	.166	.031	1.432	.236	.023
SB_RM	10.801	.002	.148	4.441	.039	.067	3.727	.058	.057
SD_LM	8.341	.005	.117	.836	.364	.013	1.017	.317	.016
SD_RM	8.017	.006	.113	3.332	.073	.050	.057	.811	.001

Table 7.4 Results of ANOVA for MOVEMENT ONSET:

Outcome	Time of the assessment (Within-group) F, p, $\dot{\eta}^2$			Experimental vs. control group (Between-group) F, p, $\dot{\eta}^2$			Time*Group F, p, $\dot{\eta}^2$		
CN_LM	26.291	.000	.312	8.789	.004	.132	8.297	.006	.125
CN_RM	10.306	.002	.145	9.386	.003	.133	.001	.972	.000
PB_LM	30.050	.000	.334	16.380	.000	.214	30.537	.000	.337
PB_RM	39.873	.000	.399	17.192	.000	.223	34.012	.000	.362
SB_LM	3.179	.080	.049	5.795	.019	.085	5.232	.026	.078
SB_RM	13.937	.000	.184	15.972	.000	.205	19.051	.000	.235
SD_LM	31.184	.000	.331	1.435	.235	.022	6.411	.014	.092
SD_RM	22.050	.000	.259	14.366	.000	.186	.000	.259	22.050

Table 7.5 Results of ANOVA for MOVEMENT ERROR:

Outcome	Time of the assessment (Within-group) F, p, $\dot{\eta}^2$			Experimental vs. control group (Between-group) F, p, $\dot{\eta}^2$			Time*Group F, p, $\dot{\eta}^2$		
CN_LM	7.042	.010	.103	41.916	.000	.407	3.064	.085	.048
CN_RM	16.815	.000	.216	4.634	.035	.071	.398	.531	.006
PB_LM	4.565	.037	.072	4.968	.030	.078	.313	.578	.005
PB_RM	9.071	.004	.133	9.200	.004	.135	.334	.566	.006
SB_LM	12.486	.001	.168	.580	.449	.009	.824	.368	.013
SB_RM	8.915	.004	.126	.046	.832	.001	.226	.636	.004
SD_LM	12.307	.001	.163	.254	.616	.004	1.133	.291	.018
SD_RM	4.648	.035	.069	3.791	.056	.057	.000	.995	.000

Appendix 7.1: CONSORT Flow Diagram

ENROLLMENT

Children with CP (4-10 years) (n= 63) with moderate UE impairments and fine motor control abnormalities along with mild-moderate cognitive impairment
GMFCS Level 1-3
MACS Level 1-3
Modified Ashworth's scale level 0- 1+
Pediatric version of MMSE score level 17-23

Excluded
- Not meeting inclusion criteria
- Declined to participate
- Other reasons

Excluded
- Severe cognitive impairments
- Secondary Orthopedic, Auditory, and severe visual impairments
- Unwilling patients or parents
- Recent Surgical intervention

Randomized (n= 33 in XG and n=30 in CG) Single blind clinical trial with active control arm. A permuted block randomization scheme with random block size, stratified by age and level of impairment

ALLOCATION

Allocated to Experimental therapy intervention (n=33)
- Receive computer game-assisted therapy intervention (n= 33) for sixteen weeks, three therapy sessions per week forty-five minutes per session
- Do not receive allocated intervention (give reasons)

Allocated to control therapy intervention (n= 30)
- Receive allocated conventional therapy intervention using principles of CIMT, HABIT and repetitive task practices (n= 27) for sixteen weeks, three therapy sessions per week forty-five minutes per session
- Do not receive allocated intervention

FOLLOW-UP

Lost to follow-up (n=0)
Discontinued intervention (n=0)

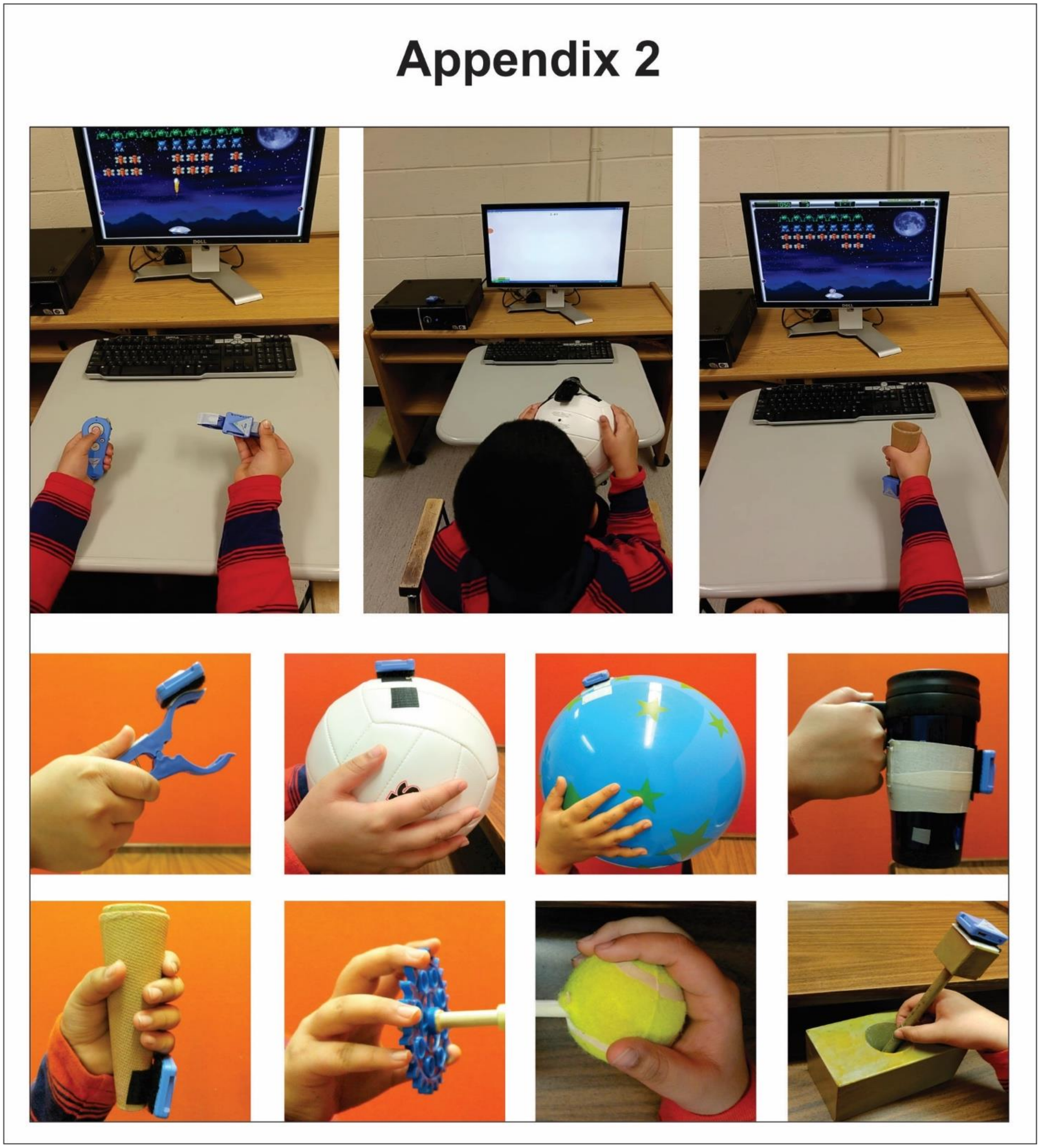
Lost to follow-up (n= 3)
Discontinued intervention (n=3)

ANALYSIS

Analysed (n=33)
- Excluded from analysis (give reasons) (n=0)

Analysed (n=27)
- Excluded from analysis (give reasons) (n=3)

Appendix 7.2 Example object manipulation tasks



Appendix 7.3: Big Fish Games™ Details.

Note matching and shooting games require participants to use the IB mouse with a left-mouse button to press when needed or small hand-held clickers with a left mouse button to press when needed.

Big Fish Game™	Axis Play	Start Difficulty	Type	Clicker	Precision	Background	Distractor	Executive Function
Abundante	Horizontal	Difficult	Match 3	Yes	Moderate	Low Optokinetic	No	Matching and Puzzle Solving
action ball	Horizontal	Moderate	Brick Buster	No	Moderate	High Optokinetic	Yes	Visual Tracking & Spatial
Aqua Ball	Horizontal	Easy	Brick Buster	No	Low	Medium optokinetic	Yes	Visual Tracking & Spatial
Astrobugs Revenge	Horizontal	Difficult	Match 3	Yes	High	Medium optokinetic	No	Matching
Birds Town	Horizontal	Moderate	Match 3	Yes	High	Low Optokinetic	No	Matching
Brave Piglet	Vertical	Moderate	Shooting	Yes	High	Low Optokinetic	Yes	Visual Tracking & Spatial
Bricks of Egypt	Horizontal	Easy	Brick Buster	No	Variable	Low Optokinetic	Yes	Visual Tracking & Spatial
Butterfly Escape	Horizontal	Moderate	Match 3	Yes	High	Low Optokinetic	Yes	Visual Tracking & Spatial
Bubble Town	Horizontal	High	Match 3	Yes	High	Moderate Optokinetic	No	Matching, Pairing
Bubble Nauts	Horizontal	Low	Match 3	Yes	Moderate	Moderate Optokinetic	Yes	Visual Tracking & Spatial

Chicken Invaders	Variable	High	Shooting	Yes	Moderate	High Optokinetic	Yes	Search and Select
Clear It 2	Variable	High	Match 3	Yes	High	Moderate Optokinetic	No	Visual Tracking & Spatial
Egyptian Ball	Horizontal	Difficult	Brick Buster	No	Moderate	High Optokinetic	No	Search and Select
Feeding Frenzy	Variable	Difficult	Aim and Move	No	High	Low Optokinetic	Yes	Visual Tracking & Spatial
Hyperballoid 2	Horizontal	Difficult	Brick Buster	No	Moderate	High Optokinetic	No	Visual Tracking & Spatial
Invadazoid	Horizontal	Difficult	Brick Buster	No	High	Moderate Optokinetic	Yes	Visual Tracking & Spatial
Jar of Marbles	Horizontal	Easy	Match 3	Yes	Medium	Low Optokinetic	No	Matching Three, aligning
Jet Jumper	Variable	Difficult	Driving Game	Yes	High	High Optokinetic	Yes	Visual Tracking and Driving
Luxor 3	Horizontal	Moderate	Match 3	Yes	High	Moderate Optokinetic	Yes	Match 3, Aligning
Luxor HD	Horizontal	Moderate	Match 3	Yes	High	Moderate Optokinetic	Yes	Match 3, Aligning
Luxor 5th Passage	Horizontal	Moderate	Match 3	Yes	High	Moderate Optokinetic	Yes	Match 3, Aligning
Ozzy bubbles	Horizontal	Difficult	Aim and Move	Yes	Low	Low Optokinetic	Yes	Driving game
Ricochet Recharge	Horizontal	Moderate	Brick Buster	No	High	Moderate Optokinetic	No	Visual Tracking & Spatial

Figure 7.1A presents a test object manipulation task. Figure 7.1B presents a screenshot of the CUE game and a plot of the trajectory of a typical paddle movement (motion of the test object) of one game event. Figure 7.1C presents a single game trajectory of one game event. Figure 7.1D presents overlay plots of all game movement responses for each direction obtained from one game session.

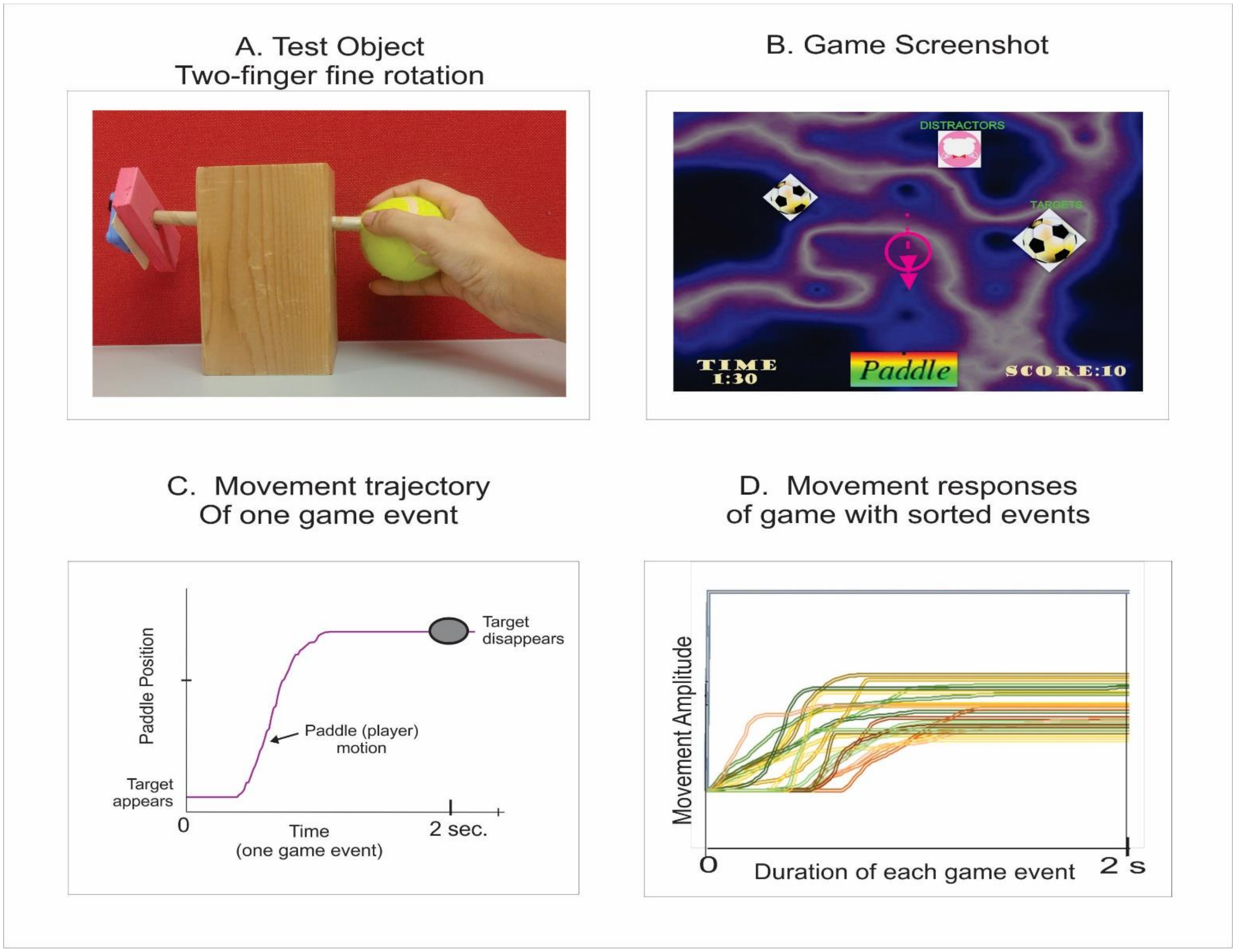


Figure 7.2: Results of pre to post-intervention scores of PDMS-2 in XG and CG

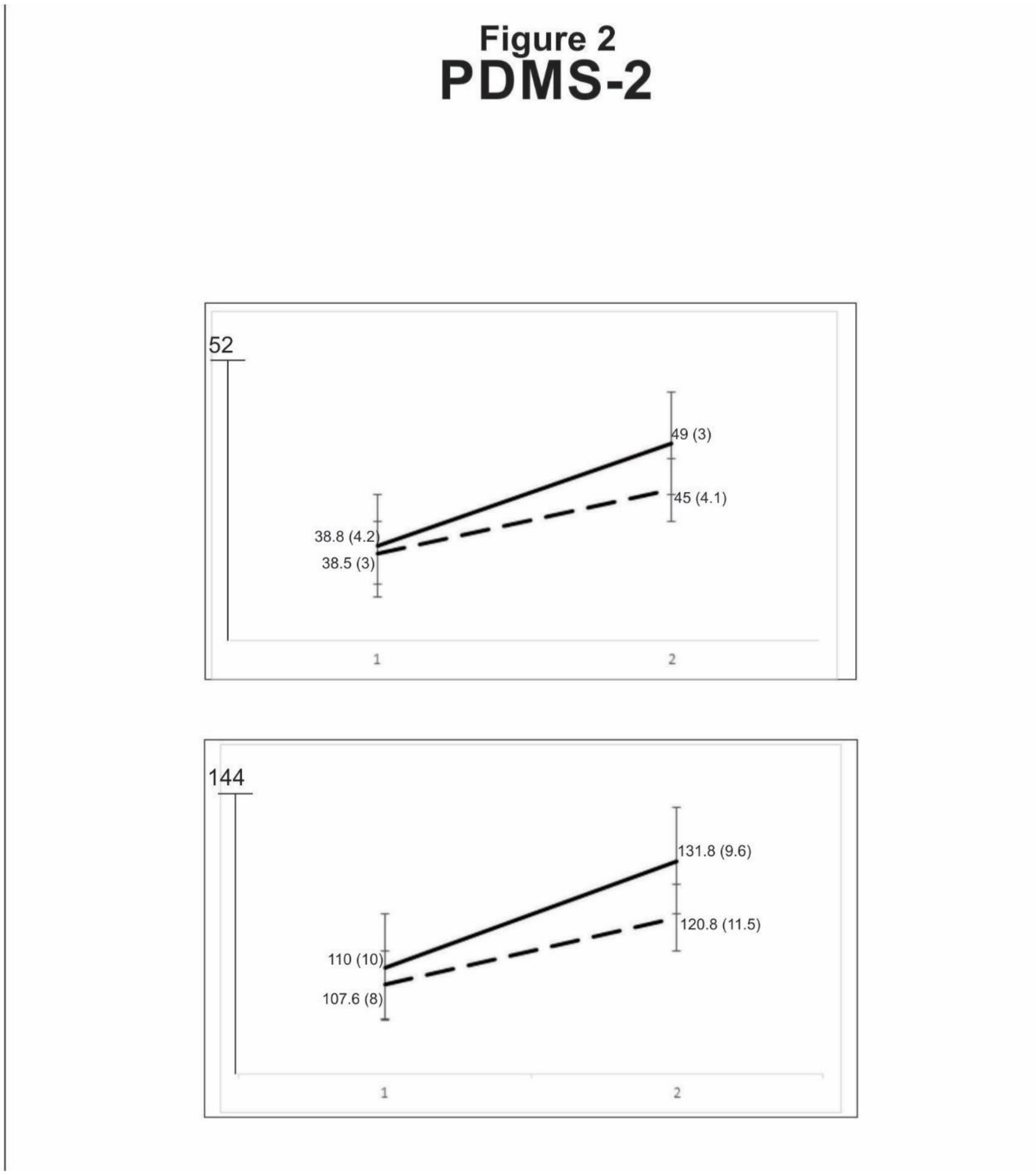


Figure 7.3: Results of pre to post-intervention scores of Success Rate in XG and CG

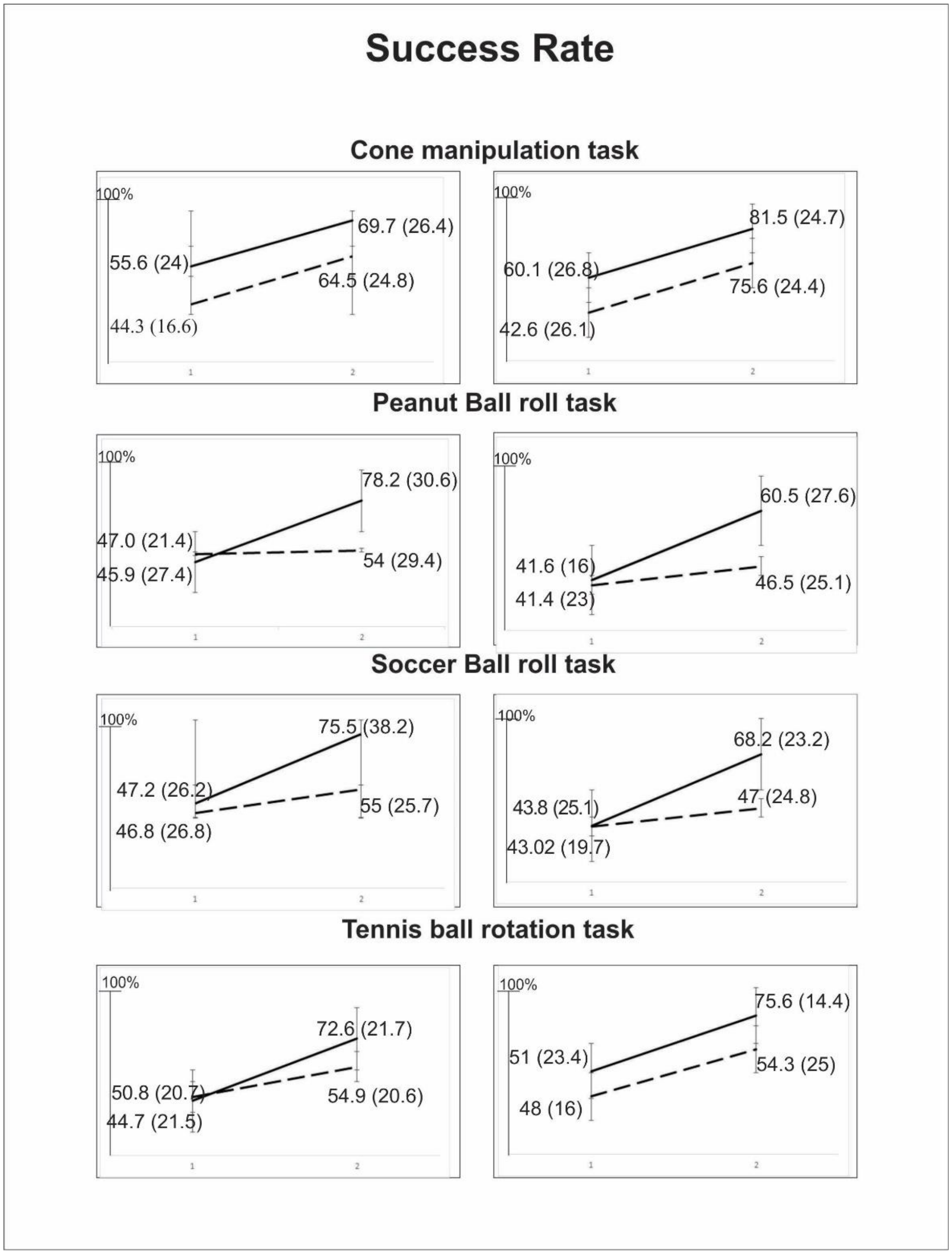

Success Rate
Cone manipulation task
100%
55.6 (24)
69.7 (26.4)
64.5 (24.8)
44.3 (16.6)
100%
81.5 (24.7)
60.1 (26.8)
75.6 (24.4)
42.6 (26.1)
Peanut Ball roll task
100%
78.2 (30.6)
47.0 (21.4)
45.9 (27.4)
54 (29.4)
100%
60.5 (27.6)
41.6 (16)
41.4 (23)
46.5 (25.1)
Soccer Ball roll task
100%
75.5 (38.2)
47.2 (26.2)
46.8 (26.8)
55 (25.7)
100%
68.2 (23.2)
47 (24.8)
43.8 (25.1)
43.02 (19.7)
Tennis ball rotation task
100%
72.6 (21.7)
50.8 (20.7)
44.7 (21.5)
54.9 (20.6)
100%
75.6 (14.4)
51 (23.4)
54.3 (25)
48 (16)

Figure 7.4: Results of pre to post-intervention scores of Movement Onset Time in XG and CG

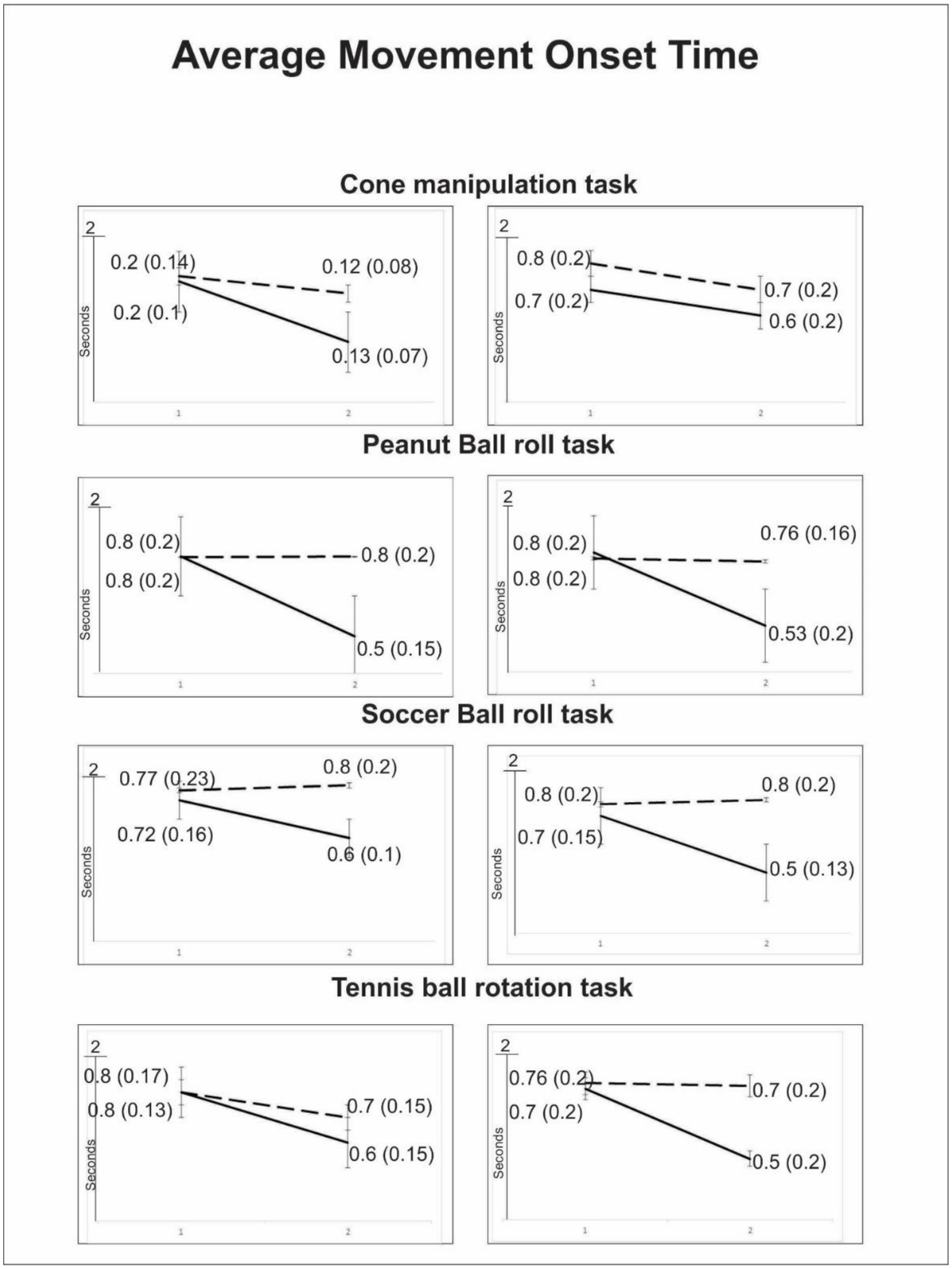
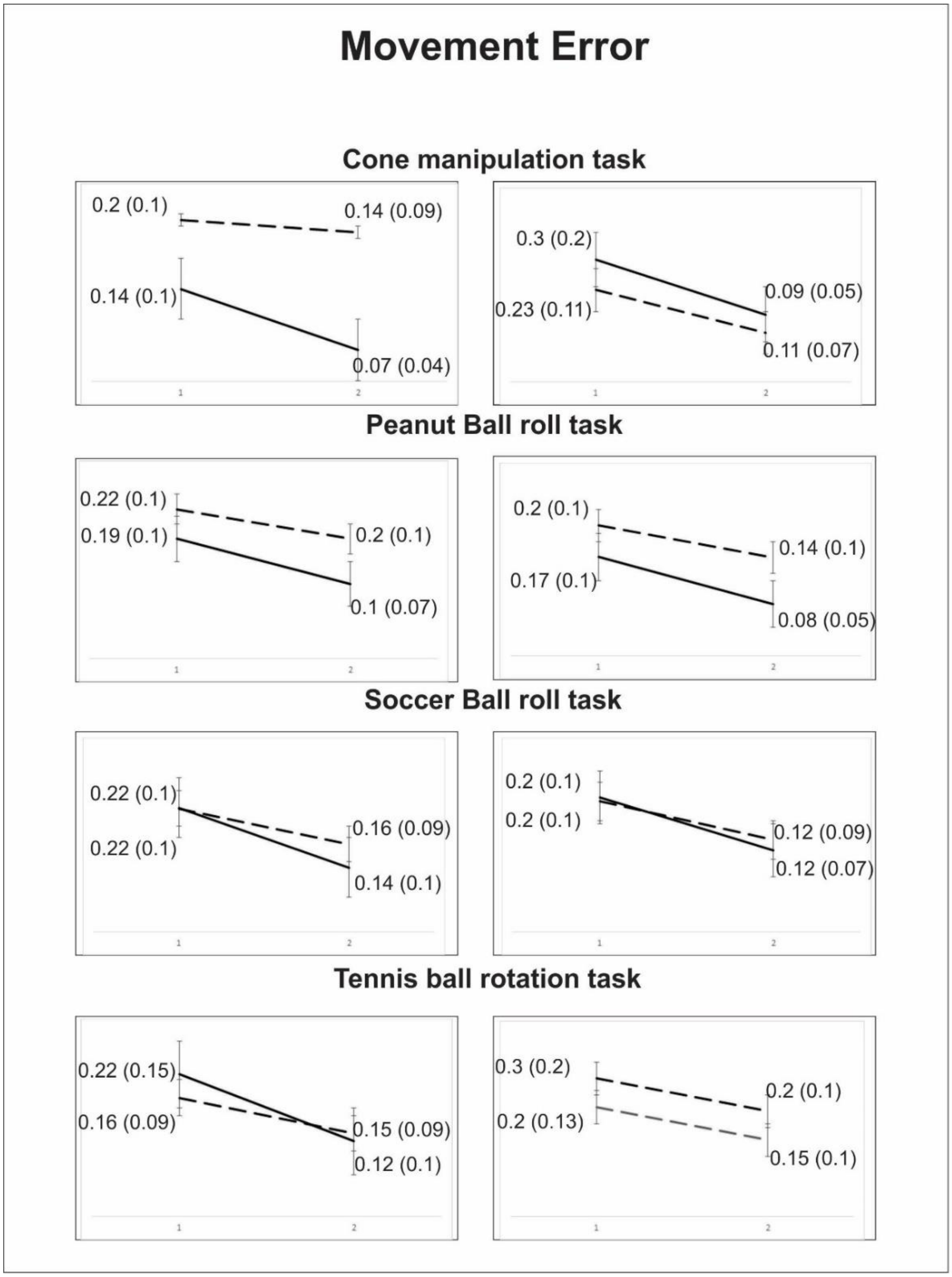


Figure 7.5: Results of pre to post-intervention scores of Movement Error in XG and CG



Chapter 8: Connecting Text 2

Game-assisted rehabilitation technologies are still a relatively young discipline, and therefore it is essential to study the feasibility and acceptability of newer computer games-based protocols such as the GRP. For this reason, the qualitative component of the mixed model exploratory RCT was to understand parents' perspectives on using the GRP protocol for UE impairments in children with CP. The second hypothesis for this RCT was that the UE exercise program, which uses computer games having a variety of visual-spatial activities, would result in greater improvements in visuospatial cognitive functions as compared to the usual outpatient physical therapy program. For this reason, the qualitative component of this RCT was conducted to explore parents' lived experiences with their respective exercise programs. The qualitative analysis was important for gaining knowledge from parents' experiences with the GRP program and reinforcing and strengthening the evidence obtained from a quantitative analysis of treatment effects.

Chapter 9: Qualitative Study

Parents’ perspectives on a computer game-assisted rehabilitation program for manual dexterity in children with cerebral palsy: Qualitative analysis of expectations, child engagement, and benefits

Abstract

Introduction: A computer game-assisted rehabilitation (GRP) platform was developed that combines fine manipulation and gross movement exercises with engaging game activities appropriate for young children with cerebral palsy (CP). A mixed-method and randomized controlled trial (RCT) was conducted to examine the feasibility and to estimate the effect size of two exercise programs for rehabilitation of manual dexterity of children with CP: one using the GRP or the conventional therapy

The objectives of the present qualitative analysis were to investigate parents’ perspectives and opinions about expectations, challenges, and benefits between the two interventions.

Methods: Parents of twenty-six of the children who completed the GRP program (n=33) and parents of fifteen of the children who completed the conventional therapy program (n=27) participated in the interviews. A general conductive approach was used to analyze the data recorded during parents’ interviews.

Results: Five themes captured the range of parent’s experiences, viewpoints, and ideas. They were 1. Parents’ expectations, 2. Child’s Engagement with Therapy, 3. Positive Effects of Interventions, 4. Challenges, and 5. Improving the Protocol.

Interpretation: Parents from both groups recognized that their expectations related to improving children’s object handling and manipulation skills, including participation in activities of daily

living (ADL), were addressed during the 16-week therapy program. Parents perceived a change in the children's level of independence in their daily tasks at home, school, and leisure activities.

Keywords: Cerebral Palsy, parents' expectations, fine motor function, object manipulation, computer games-based treatment protocol.

Introduction

Children with motor impairments of the upper extremity (UE) due to cerebral palsy (CP) face numerous difficulties in their activities of daily living, participation in school, and during play. Task-specific rehabilitation programs such as Constraint Induced Movement Therapy (CIMT) (Ramey et al., 2019) and Hand-Arm Bimanual Intensive Training (HABIT) (Ouyang et al., 2020) have shown positive results when provided by therapists in a one-on-one clinical setting with high repetitions of task practice (Jamali & Amini, 2018).

Recent studies have introduced digital media to enhance the play-based therapy protocols for children with CP (Rohrbach et al., 2019). Based on this information, a computer game-assisted rehabilitation (GRP) platform was developed (Sanjay et al., 2020; Szturm et al., 2014, 2020b) to focus on object handling and manipulation tasks. The GRP uses a miniature commercial wireless inertial based (IB) computer mouse, which links physical movements with engaging, interactive computer games. The precision and responsiveness of the IB mouse are equivalent to that of a standard optical computer mouse. When the IB mouse is attached to an "exercise" object, the manipulation of the object is used to control the motion of a computer cursor or game paddle. Importantly, the IB mouse can be attached to a broad range of objects with different physical properties and functional demands. Therefore, many objects of varied size, shape, weight, and surface properties can be used in the game-assisted exercise program. Several principles of motor learning are incorporated in the GRP (Geerdink et al., 2013; Maier et al., 2019a; Muratori et al., 2013), which includes task-specific training of object handling and manipulation, multisensory stimulation, and feedback/knowledge of performance.

Using game-assisted rehabilitation technologies is still a relatively new discipline. There is a need to develop study designs to explore the implementation, acceptability, and appropriateness of these technology-based interventions (Proctor et al., 2011; Rohrbach et al., 2019). For this reason, a mixed-method exploratory randomized controlled trial (RCT) to assess the feasibility of conducting a full scale RCT to understand the effectiveness of the GRP was conducted to provide an estimate of the treatment effect size and implement any modifications to the protocol that would direct a future full-scale RCT as well as to explore children's parents' experiences with their respective exercise programs.

The quantitative component of the exploratory RCT has shown promise as a therapeutic intervention. Hence it is important to understand consumer experience with the GRP. Thus, the qualitative analysis is important for gaining knowledge from parents' experiences with the GRP program and to reinforce and strengthen the evidence obtained from a quantitative analysis of treatment effects (Berkwits & Inui, 1998). The results of the qualitative analysis are presented in this paper.

The objectives of the present study were to investigate parents' perspectives about:

a. Their expectations and benefits of the GRP game-assisted exercise programs targeting hand and arm function of young children with CP,
b. Their expectations and benefits of the conventional therapy programs targeting hand and arm function of young children with CP
c. Their children's engagement with therapy
d. Positive effects of interventions
e. Challenges implementing the exercise program

Methods

Children with CP, aged 4 -10 years, and who met the following inclusion criteria were recruited from SDM college of Physiotherapy and hospital, Dharwad, India and Usha's school for exceptional children, Hubli, India:

a. Gross Motor Function Classification System (GMFCS) from level 1-3 (Bodkin et al., 2003b)
b. Manual Ability Classification System (MACS) from level 1- 3 (Eliasson et al., 2006a)
c. Modified Ashworth Scale (mASH) the level of spasticity from grade 1 to 1+ (Mutlu et al., 2008a)

Paediatric version of the Mini-Mental Status Evaluation (MMSE) (Jain & Passi, 2005b) (level 17 and above was set as the inclusion criteria to ensure the children's ability to follow computer games instructions)

After the initial screening process, parents provided written informed consent. The Clinical Trials number. Clinicaltrials.gov NCT02728375; http:https://clinicaltrials.gov/ct2/show/NCT02728375 (Archived by Web Site at http://www.webcitation.org/6qDjvszvh)

The initial session included the following assessments

a. The Grasp and Visual-Motor Integration (VMI) subtests for Fine Motor Quotient (FMQ) of the Peabody Developmental Motor Scale-2 (PDMS-2) (van Hartingsveldt et al., 2005)
b. Computer game-assisted assessment. A miniature wireless IB mouse (Scoop Pointer Remote Model: RXR1000-0302E, Hillcrest lab) was secured using Velcro™ to five test objects chosen for assessment of manual dexterity. Performance measures for the five object manipulation tasks included Success Rate, Movement Onset Time, and Movement Error developed (Sanjay et al., 2020; Szturm et al., 2014, 2020b).

Experimental Group (XG) intervention: The initial exercise protocol for each participant was established based on the child and parents' goals, the level of impairment, and functional status. A typical session for the XG consisted of a computer game-assisted exercise program.

Children were provided between 6-8 IB mouse-equipped objects for exercise, which were used to play several computer games. The objects were everyday items such as balls of various sizes, daily objects like spoons, glasses, cups, school-related objects such as markers, and play-based objects such as toys.

These objects represented a wide range of physical properties requiring different modes of manipulation and functional demands. The GRP can take advantage of ergonomic properties of common objects to amplify limited and small voluntary movements during gameplay and then allows opportunities to use exercise objects with more challenging demands. Figure 1 (page 178) presents a description of several object manipulation tasks used in the present study for game-assisted RTP.

Treating physiotherapists instructed children on how to perform the various tasks with the desired hand and arm segment motions and to avoid substitution with associated movements. Computer games that best suited the object manipulation tasks were chosen for the exercise program. The games were chosen based on the following game properties: a) movement amplitude required to move the game paddle, b) game speed, and c) game precision requirement. Many inexpensive arcade-style computer games are readily available online and can be downloaded from websites such as www.bigfishgames.com. Appendix 9.1 presents a list of computer games used and a description of movement and cognitive requirements. This protocol was updated every four weeks based on the child's improvements, current goals, and functional demands.

Control Group (CG) intervention: The CG received a comprehensive physical therapy protocol based on the goal-oriented, RTP-based principles of mCIMT and HABIT. Therapy protocols were individualized for every participant according to their level of impairment and pre-set goals. A variety of arm and hand activities were practiced, such as reaching for rings, ball throwing, clay activities, picking marbles from sand, and putting pellets and pegs into sockets. These tasks were practiced by the child with the guidance and assistance of a therapist.

Qualitative Data Collection

Parents of children in the XG and CGs were invited to participate in interviews conducted at the end of the intervention. The purpose of the interviews was to understand parents' opinions about and experiences with the intervention. An interviewer who was blinded to the intervention received by the parent's child conducted all the interviews using a semi-structured interview guide (Table 1). Interviews were conducted in local languages or parents' preferred language. Parents were encouraged to describe and explain their ideas, thoughts, opinions, and personal experiences. The interviewer noted any non-verbal communications and other observations in field notes. The interviews audio recorded. Audio recordings were both professionally transcribed and translated to English.

The analytical framework of interpretive description was used for thematic interpretation (Thorne et al., 1997). Translated transcripts and field notes were initially read by one researcher who developed the coding system by paraphrasing, generalizing, and abstracting the written transcripts of each interview. A second researcher scrutinized the coded data and identified any additional unique responses and codes. The two researchers then met via video calls to compare their analyses and resolve disagreements in a final code system. This was done to ensure trustworthiness of the data.

These coded responses and direct quotes from the interviews were back-translated to parent’s preferred languages. Parents were asked to review this material and to provide feedback about the accuracy of the researcher’s interpretations. This was done as a member checking procedure to promote trustworthiness and fidelity (Sandelowski, 1986). After receiving parent feedback, the data and coding were again reviewed by both researchers and organized into final themes and subthemes described below.

Results

Table 9.2 presents the demographic and clinical data by group (XG n=33, mean age 7.2, CG n=30, mean age 7.8). Three participants from the CG withdrew from the study due to a change of school, commute, and transportation-related issues (see appendix 9.1 CONSORT diagram). Parents of twenty-six of the children from the XG and parents of fifteen of the children from the CG agreed to participate in the interviews. However, after the member checking procedure, only twenty-four parents from the XG and fourteen from the CG responded back in person or via phone in addition to their written feedback.

The following five themes and subthemes captured and interpreted the range of parent’s experiences, viewpoints, and ideas. Tables 9.3-9.8 present examples of parents' direct quotes for each theme.

Parents’ Expectations

All participants had been undergoing conventional therapy for at least two years, and their expressed reasons for joining the study were varied. Most parents expressed their willingness to participate in the trial because therapy would focus on manual dexterity (Table 9.3, quotes 1 and 2). Many parents from both groups (XG n=22, CG n = 11) expressed concerns regarding a gap in current therapy services that often focus on arm movements rather than manual dexterity (Table 9.3, quote 1). Many parents from both groups (XG= 13, CG= 5) expressed their concerns regarding their child's inability to participate in both play and school activities due to lack of eye-hand coordination (Table 9.3, quotes 3-6). Considering that the protocol required children to focus on the computer screen while performing fine motor tasks, some parents assigned to the GRP program believed that this therapy might improve their children's eye-hand coordination as well as their attention span (Table 9.3, quote 4). Eight parents made the decision to participate in the study with hopes the intervention would improve their child's handwriting (Table 9.3, quote 4).

Use of computers: Many parents joined the GRP protocol with the goal of getting their child acquainted with computers (Table 9.4, quotes 1, 2, and 3). In addition, many parents expressed that technology would play a major role in helping children achieve future goals, such as employment and university level education (Table 9.4, quote 1). Most parents from the XG reported that their child had never interacted with computers before (Table 9.4, quote 1 and 2). Most parents presented an overall positive attitude towards using computer games and allowing their children to play computer games as a part of therapy (Table 9.4, quote 1).

Many parents believed that introducing their children to computers while performing play-based therapy would create positive learning experiences (Table 9.4, quote 3). Parents expressed their intentions to participate in the study and later continue the therapy so that their child's communication skills could improve by a boost of confidence while also improving their social interactions in schools and later in (Table 9.4, quotes 3 and 4).

Child's Engagement with Therapy

Many parents expressed the view that conventional therapy becomes repetitive and boring as the children get older. Nineteen parents in the XG commented that it was easier to convince children to perform exercises using the GRP than conventional exercises (i.e., based on prior therapy, Table 9.5, quotes 1 and 2). Many parents perceived that their child found most of the chosen computer games engaging and viewed the exercises as play (Table 9.5, quotes 3-5). Seven parents from the CG commented on a lack of interest in their child in participation during the therapy session (Table 9.5, quotes 6-9). Often, parents observed improvements in their children during the initial sessions, but the children lost interest with time (Table 9.5, quotes 6-8).

Positive Effects of Interventions

Twenty-two parents from the XG reported that they perceived improvements in their children's manual dexterity, object manipulation skills, and eye-hand coordination (Table 9.6, quotes 1-4). Some parents reported that their children not only improved in their "ability to pick up and hold objects" but also to "manipulate objects with more precision," and "stability" in unimanual as well as bimanual activities (Table 9.6, quotes 1 and 2). Parents also observed improvements from XG in using technology-based gadgets like phones and laptops due to improved confidence levels (Table 9.6, quotes 3 and 4).

Some parents commented that they observed improvements in the quality of arm movements as well as posture and balance while sitting and playing computer games (Table 9.6, quotes 5 and 6). Many parents commented about their perception that the use of chosen computer games had a positive on their child's cognitive abilities (Table 9.6, quote 5), hyperactivity (Table 9.6, quote 5), reduced attention span (Table 9.6, quote 6), and anger (Table 9.6, quote 8). One set of parents mentioned that their four-year-old child developed better colour and pattern recognition in addition to spatial orientation (Table 9.6, quote 6).

Most parents in the CG also provided positive feedback. Parents appreciated the one-on-one therapy sessions (Table 9.6, quotes 7 and 8). Parents gave positive feedback using words such as “improved independence,” “good results,” “happy,” and “thankful for therapy” (Table 9.6, quote 7). Many parents in the CG reported improvements in the child’s UE function and increased level of independence (Table 9.6, quote 8). Parents from CG observed that the children were actively performing daily tasks such as self-feeding and dressing activities since their participation in the conventional protocol.

Challenges

The experimental GRP protocol was updated every four weeks. Four parents felt that the four weeks was too long a period between exercise/game updates and commented that their child lost interest with their exercise when a game was used over the four-week time-period (Table 9.7, quotes1 and 2). Parents expressed that it was challenging to understand the protocol during the first couple of sessions, and 2-4 sessions were required for the child to learn how to use the gaming system (Table 9.7, quote 5).

The most common challenges reported by parents from the CG were about their child’s compliance with therapy and engagement or interest with the exercise program (Table 9.7, quotes 3 and 4).

Improving the Protocol

Many parents suggested adding educational games such as math and language games as well as computer games with a broader range of cognitive content (Table 9.8, quote 1). One parent from the CG suggested that the activities should be changed more regularly and to incorporate play-based child-parent activities in the protocol (Table 9.8, quote 2). Most parents in the XG expressed their interest in continuing to use GRP instead of conventional therapy for their child's exercise program (Table 9.8, quote 3). Many parents from the XG suggested providing the GRP platform as a home-based protocol and, therefore, to avoid costly and time-consuming travel to the rehabilitation center (Table 9.8, quote 4).

Discussion

The present study findings establish that the parents recognized that their expectations related to improving children's object handling and manipulation skills, including participation in ADL activities, were addressed during the 16-week therapy program. Parents perceived a change in the children's level of independence in their daily tasks at home, school, and leisure activities. Parents also shared the challenges they faced regarding children's participation in therapy and the game-assisted exercise program experiences.

Therapies, such as CIMT and HABIT, have established the importance of task-specific training (AM et al., 2007). Most parents identified the focus on handling and manipulating objects as an important feature of the GRP exercise program and that it included many different objects used in day-to-day life. Parents from the XG commented on several benefits of coupling object manipulation exercises with common computer games. Interaction with the game activities required children to manipulate each object using precise movements of varying speed and amplitudes. Different games were chosen to increase the precision level of the task (i.e., small game paddles and game targets). Several studies also support the principles of goal-directed therapy for improved motor learning outcomes in children with CP (Löwing et al., 2009; Morgan et al., 2014; Sandlund et al., 2012).

The main focus of the game-assisted exercise program was to increase the number of repetitions. Typically, each game was played for 5-7 minutes, and the duration of each game event lasted an average of two seconds apiece. Therefore, the object was moved at least 100 times, which is a high number of repetitions of goal-directed movements. For most games, the game targets appear at random locations or move in unpredictable trajectories or directions, i.e., variable practice. In addition, visual feedback of the game paddle was used to initiate and guide the movement responses; the child views the game events and not the object being manipulated. This type of practice would promote implicit learning of eye-hand coordination (Maier et al., 2019a).

Parents from the XG reported that the exercises were challenging yet engaging, and their children enjoyed playing the games. They felt that this gratification was important and improved children's compliance with the therapy program. The motivation to do better at the computer games influenced children's therapy compliance and level of skill. Other studies that focused on motivation in children in CP have found similar results. A study performed by Monomer et al (2010), showed that children with CP are motivated to master skills or activities, which they find enjoyable or engaging. They established that mastering an enjoyable task can be used as motivation to improve children's motor performance. They recommended that when goal-setting and choosing activities for rehabilitation interventions, therapists should consider choosing activities that are the most motivating (Majnemer et al., 2010). It can be interpreted form parents' perceptions that the GRP protocol followed these recommendations. Jennings et al, (1988) suggested that lack of motivation to perform repetitive motor tasks must be addressed to improve children's involvement in therapy and practice skills that are important for their ADL (Jennings et al., 1988). Bartlett et al, (2002) suggest that children with cp experience pleasure in mastering challenging tasks if they find it engaging and have set goals and are more motivated to persist with challenging tasks. Motivation is important for treatment compliance and development of skills and functional achievements (Bartlett et al, 2002). The XG group had no dropouts and showed significant improvements as they completed the GRP protocol.

Several studies have compared the results of the use of computer games versus conventional therapy in terms of patient acceptability have observed improved engagement in children who received computer games based therapy. (S. Miller & Reid, 2003). Previous studies that have used various game-assisted platforms to improve engagement and participation in the therapy of children with CP include commercial entertainment gaming systems like the Wii™ (H. C. Chiu et al., 2014) or Kinect (Jannink et al., 2008), and some require robotic manipulandums (Preston, Weightman, Gallagher, Holt, et al., 2016), or sensor-equipped gloves (Gerber et al., 2016d). These gaming systems can detect arm segment motions or finger motions in the case of the instrumented glove. These sensor motion signals are used to interact with virtual objects or to control a game paddle for play; however, these cannot be used to couple goal-directed object handling and manipulation exercises with computer games. In addition, these gaming systems come with a limited number of games suitable for young children with motor impairments, whereas there is many inexpensive and readily available common and modern commercial games that are engaging and that can be played with a computer mouse or equivalent like the IB mouse, i.e., a sensor detects instantaneous position. Examples of games can be found in Appendix 9.1.

Many parents from the XG asked about where they could obtain other low-cost or free computer games suitable for use with the IB mouse. Understandably, updating and progressing the protocol regularly to maintain the level of difficulty and providing a new set of games to play was noted by the parents as an important aspect to maintain interest and participation. Parents commented that this would likely require a large pool of different computer games. Practically, this can be difficult to achieve because although there are a number of commercial games readily available online, not all games are suitable for each object manipulation task or for young children who have substantial motor impairments of the UE.

Initially, children with severe impairments could only play games involving slow movements and low precision (i.e., large paddle size and large game target objects). On the other hand, children with mild to moderate impairment could play a larger variety of games with increased movement speeds, precision levels, and added cognitive content.

Parents from the CG provided a mixed review regarding the child's interest and compliance in their exercise programs over the sixteen weeks. Previous studies reported caregivers' and children's increased levels of frustration and discomfort due to the restraint used for mCIMT and CIMT protocols (Gilmore et al., 2010; Mancini et al., 2013). Parents perceived that the cognitive activities of the GRP did contribute to improvements in their child's manual dexterity, handwriting, eye-hand coordination, cognition, as well as notable improvement in some ADL (i.e., feeding, dressing, and participation in play activities). For example, the games selected included activities for logic, problem-solving, visual search and attention, cognitive inhibition, set-shifting, verbal and non-verbal memory, colour and shape recognition, and others. Previous studies have reported that computer games and educational computer programs can benefit academically relevant content and other cognitive skills (Blumberg et al., 2019). Parents from the CG also reported that their children had improved fine motor skills following the supervised therapy program. They identified one-to-one supervision provided by the therapist to get the children to practice their respective exercises.

The results of the quantitative analysis allowed us to determine the treatment effect size and whether an exercise program using the GRP is superior to the conventional therapy program.

Limitations

The number of interviews in the XG is higher than the number of interviews in the CG. It is not known why more parents in the CG declined to consent to be interviewed as compared to parents in the XG.

Conclusion

This study demonstrated the feasibility and acceptability of the GRP platform for hand and arm function rehabilitation in children with CP. Parents who participated in the interview responded positively towards the use of the GRP and requested to continue with this therapy program after completing the 16-week intervention. Parents from the XG expressed that children were more engaged during the GRP protocol as compared to the conventional protocols from the past. The challenges faced by parents regarding children’s engagement in the protocol can be easily resolved by updating the protocol more often or by changing the difficulty levels of the tasks. Other challenges were mainly due to the difficulties due to commute and time.

Figure legends

Figure 9.1: Example Object Manipulation Tasks illustrated by a therapist used in GRP.

a. Handling a plastic cup with wrist radioulnar deviation while midprone forearm is maintained with the elbow resting on a surface

b. Handling a sponge ball (12 cm diameter) using wrist flexion-extension while maintaining a palmar grasp while midprone forearm is maintained with the elbow resting on a surface

c. Rotation of a jar lid (open and closing) using five-finger grasp over the lid and wrist radio-ulnar deviation and five finger flexion-extension with the elbow resting on an elevated surface

d. The rolling movement of a toy wheel, manipulated using the index and middle fingertips and moved using shoulder flexion-extension

e. Bimanual beach ball manipulation using open hands using elbow flexion-extension for movement while forearms maintained in midprone and shoulders maintained in mild flexion.

f. Rolling a stick using the index and middle fingertips and thumb opposition, wrist maintained in neutral, while midprone forearm is maintained with the elbow resting on an elevated surface.

g. Manipulating a pen with index and middle fingers and thumb opposition using a tripod grip, wrist resting on the table maintained in neutral.

h. Bimanual roll of a pool noodle using thumbs and finger flexion-extension using fingertips for manipulation while midprone forearm is maintained with the elbow resting on a surface

Fork manipulation using the tip to pad grip using the index, middle finger, and thumb opposition, forearm supination-pronation with the elbow resting on an elevated surface

Figure 1: Object Manipulation Tasks

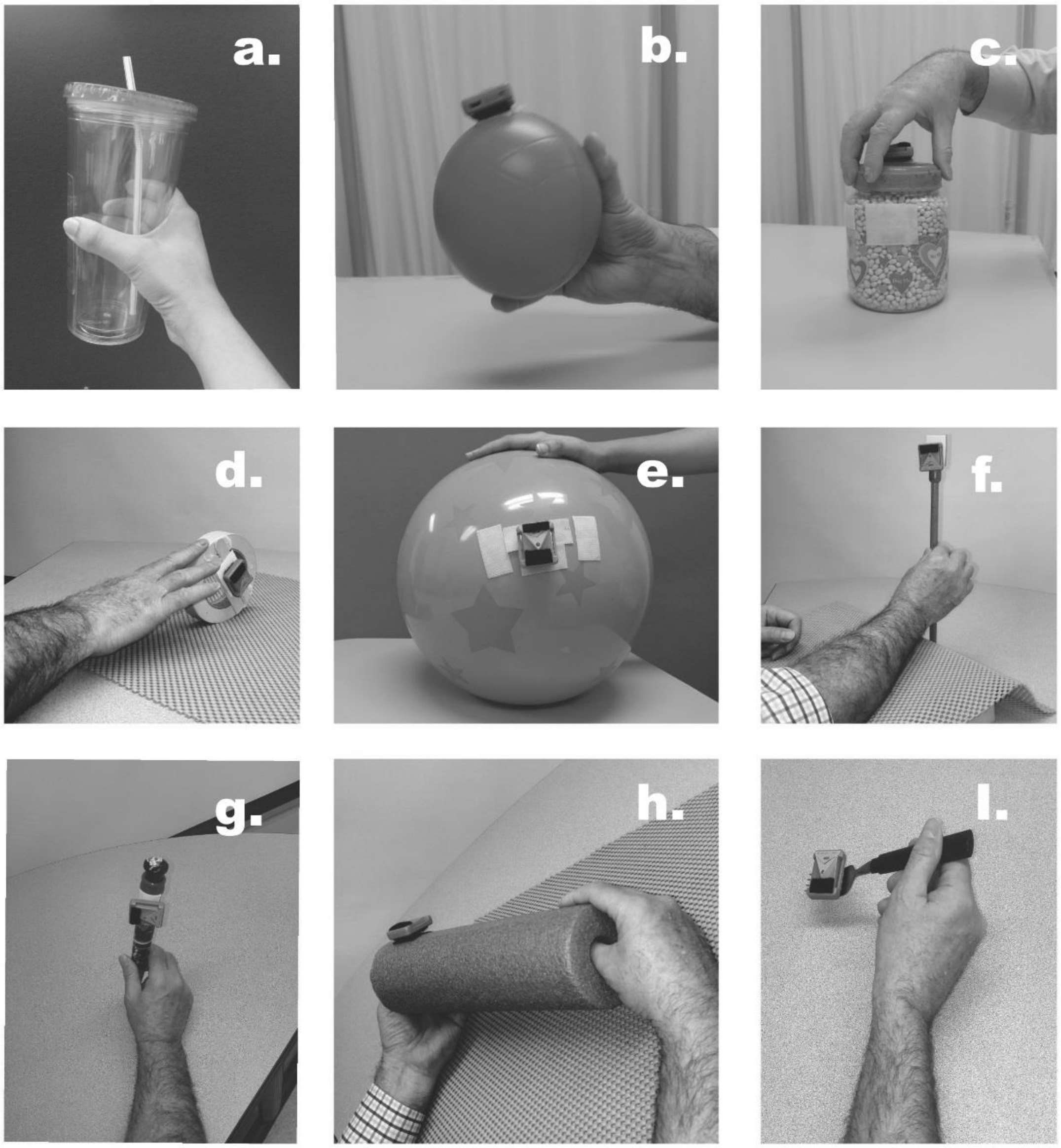


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Table 9.1: the interview guide

1. When you agreed to participate, how did you hope your child would benefit from the therapy program?
2. What did you like about the therapy program?
3. What was difficult or challenging about implementing the therapy program for your child and you?
4. What did you think about the computer games/exercises your child was asked to play?
5. How did your child respond to the games/exercises? Were there games/exercises which your child did not seem to enjoy?
6. How did technology integrate into your daily life?
7. Would you want your child to continue with the same type of therapy program? Why or why not?
8. Any other suggestion?

Table 9.2: Demographic data

	Age (years) Mean (SD)	**MMSE Mean SD)**	**GMFCS**	**MACS**	**PDMS-2 Grasp Mean (SD)**	**PDMS-2 VMI Mean (SD)**
Control group (CG)	7.8 (1.9)	27.7 (1.4)	I=6 II =14, III =7	I =6 II =16, III = 11	38.8 (4.2)	110.4 (10.1)
Experimental group (XG)	7.3 (2.1)	29.0 (0.3)	I=8, II=15, III=10	I =4	38.5 (3.1)	107.6 (8)

				II = 15, III = 8		
T-TEST p-value	0.2	0.4			0.8	0.5

Table 9.3: Parents' expectations when joining the program

1. "My daughter had and hand and leg weakness for a few years. We have tried many places; they have worked with her hand for picking up toys and playing with putty and elastics, but she is still not able to use her hand independently and normally. The therapy is just not working so far so we decided to come here to SDM. Then (the therapist) told us about this new study."- Mother 12

   I approached this treatment because I hoped she will practice activities using different objects with her hands, and with time and practice those actions will improve." -Mother 12
2. "My child had problems with fine finger movements. Our consultant physician had told us that he was never going to use his fingers. When we heard about this program, we thought that this program might help." -Mother 4
3. "My daughter had difficulty in moving her right hand, that was the main thing, but we are hoping that this (GRP protocol) will also help her in analyzing things and improve her concentration " -Mother 5
4. "We joined this therapy with the hopes that it will improve her handwriting along with eye-hand coordination" -Father 23

5.	"When we started this therapy, we hoped this therapy with computers would increase his interest and attention in studying." –Mother 15
6.	"Knowledge of Technology is always helpful as today's life is full of Technology, it would help him in concentration, Overall development using Technology, hand movement and motivate him to play and learn."- Mother 18
7.	"It is very useful to communicate and relate to the world. In this way, it helps my child to learn and use a computer through this therapy."-Mother 22

	Table 9.4: Use of Computers
1.	"When we started this therapy, we hoped this therapy with computers would increase his interest and attention in studying. It will help him in his future when he goes to college or work." -Mother 15
2.	"Computers seem so attractive, and he wants to learn how to use them. Knowledge of Technology is always helpful as today's life is full of Technology; it would help him in concentration. Overall development using Technology, we hope he improves his hand movement and motivates him to play and learn along with his classmates." -Mother 18
3.	"It (Technology) is very useful to communicate and relate to the world. In this way, it helps my child to learn and use a computer through this therapy. I think it will be more fun also, which means less complaints." -Mother 22

4. From this treatment she acquires the knowledge of computer and also gets to know other information in technology –Father 23

Table 9.5: Child's Engagement with Therapy
1. "Kids nowadays do not like traditional therapy. My child gets annoyed and bored easily there." -Parent 1
2. "Earlier during (conventional) therapy sessions, my child used to get frustrated and annoyed quite easily. Then, we started the computer games therapy and now my child feels relaxed and enjoys these therapy tasks while playing computer games. Because of this, we have observed a lot of progress in her behaviour; it's positive." -Mother 12
3. "She does really well in the game. She likes to play the fish game because varieties of fishes are there in that game where one fish attacks and eats all the other fishes. So, by this, the memory power is increased." -Mother 24
4. "In this treatment, my son liked all the therapy games. He learned to play games using various objects. His grip has become stronger now, and the main thing is that he likes therapy now." 5. -Mother 57
6. "Maybe the kids would enjoy this more than conventional therapy. He was bored with conventional therapy, now he is coming easily for computer games (for GRP based therapy) than conventional therapy." -Mother 47
7. "She is a bit tired after all this time, but she was giving good response at first, she has improved a lot" -Mother 26

8. "We have been doing therapy for almost ten years now, he is very bored with therapy, and he gets angry and cranky now." -Father 10
9. "Well, as she is growing up, she is certainly developing moods, so the therapy needs to be made more interesting for her" -Mother 34
10. "Uhh, (child's name) is still small, I hope that when she grows up, she gets a little bit more motivated to do this. This is for her own good." -Mother 2
11. "She is doing well. She likes to play with the ball and other fun things" -Mother 56

Table 9.6: Positive effects of interventions
1. "I'm happy to see my daughter using both hands to hold toys (objects) and playing games. I also assume that she tries to catch the game toy (practice object for therapy) and play the (computer) game. So, I think now she knows how to move her hands (using therapy objects) while playing the (computer) game." -Mother 25
2. "He learned playing games holding various objects. I can see him using his hands more now when eating and playing" -Mother 42
3. "With this game therapy, he is able to play and understand other game concepts even when he is playing in the apartment with friends." -Mother 38
4. "In our day-to-day life, we hardly have any need for technology-based things. Since this therapy program has started, we have observed drastic changes in my child's day to day life. My child's handwriting is improved." -Father 33

5.	"Yes, He seems smarter, he knows about colours, he knows about shape and directions, He sits back properly, His hand fingers are more active, and he also gets some exercise for the eyes." -Mother 22
6.	"Dr. (therapist's name) is simply the best! We can already see that he is using his right hand for more activities, he pays more attention." -Mother 7
7.	"He has done well so far; he is more independent. This therapy program helped him with that." -Mother 4
8.	"I like that the sessions are one on one and that the therapists look after her alone for the whole time. You can see the difference in her. She is not irritated and angry like she used to be all the time "-Mother 26

Table 9.7: Challenges faced by parents	
1.	"We didn't have any difficulties during computer therapy, but I would have liked to see him do more games. Once he has achieved one game, see to it that you please give him other challenging games which will help him to improve more." -Mother 57
2.	"Sometimes my child doesn't like the objects because he finds little difficult to hold and move the object." -Mother 1
	When we started this therapy, our hope was that this will help our son in learning computers, and his hand and arm will get stronger, more skillful.

3.	We hoped this therapy with computers will increase his interest and attention in studying, and he will speak fluently. My problem is, on a day-to-day basis, I have no need for such high technology other than my phone, so I get a bit tensed to use these devices, so I don't have such costly things at home. I get scared, what if someone breaks it? -Mother 4
4.	"Well, the session takes really long, its time consuming, I wish we could reduce the duration of the activities. He is starting to get tired of the things to do on the table." -Mother 10
5.	First three-four sessions, he struggled. It took time to realize what he was supposed to do, but now after so many sessions, he enjoys it. –Mother 18

Table 9.8: Improving the Protocol	
1.	"Yes, this technology-based program is helping a lot in children's daily life. Integrating educational games, quiz games, puzzle games, would be a lot more helpful." -Mother 22
2.	"My suggestion would be to add more variety of activities to his therapy. In one session he does a lot of activities, but it's the same every time we come. He needs something more fun and games, something more age-appropriate." -Mother 7.
3.	"We noticed a lot of changes during and after computer (based) therapy program. Compared to his previous reports, we saw a lot of positive changes in his object handling

	and behaviour. Wholeheartedly, I would request the treatment to be continued." -Mother 47
4.	"My suggestion is that we should make these kids play these games more often, or if I could get her to do it at home, she will have more practice." -Mother 24

Appendix 9.1: CONSORT Flow Diagram

ENROLLMENT

Children with CP (4-10 years) (n= 63) with moderate UE impairments and fine motor control abnormalities along with mild-moderate cognitive impairment
GMFCS Level 1-3
MACS Level 1-3
Modified Ashworth's scale level 1- 1+
Pediatric version of MMSE score level 17-23

Excluded (n=13)
Not meeting inclusion criteria (n=6)
Declined to participate (n= 7)
Other reasons (n=0)

Excluded (n=5)
- Severe cognitive impairments
- Secondary orthopedic, auditory, and severe visual impairments
- Unwilling patients or parents
- Recent surgical intervention

Randomized (n= 33 in XG and n=30 in CG) Single blind clinical trial with active control arm. A permuted block randomization scheme with random block size, stratified by age and level of impairment

ALLOCATION

Allocated to Experimental therapy intervention (n=33)
- Receive computer game-assisted therapy intervention (n= 33) for sixteen weeks, three therapy sessions per week forty-five minutes per session

Allocated to control therapy intervention (n= 30)
- Receive allocated conventional therapy intervention using principles of CIMT, HABIT and RTP (n= 27) for sixteen weeks, three therapy sessions per week forty-five minutes per session
- Do not receive allocated intervention (n=3) Dropped out due to commute problems, change of school and transportation-related issues.

FOLLOW-UP

Lost to follow-up (n=0)
Discontinued intervention (n=0)

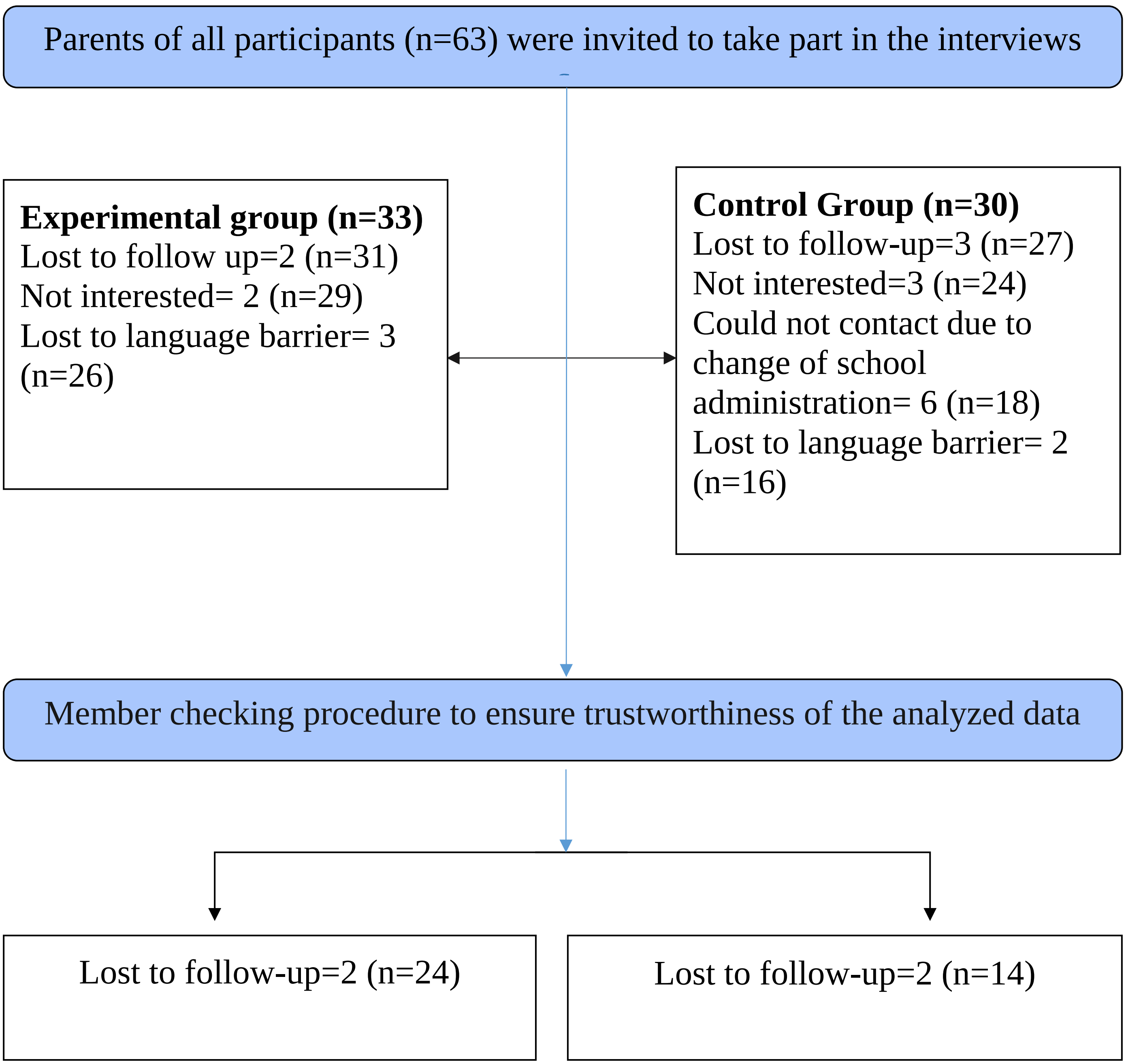
Lost to follow-up (n= 3)
Discontinued intervention (n=0)

ANALYSIS

Interviewed (n=26)
Declined to participate in interviews (n=6)
Responded back after member checking procedure **(n=24)**

Interviewed (n=15)
Declined to participate in interviews (n=12)
Responded back after member checking procedure **(n=14)**

Appendix 9.2: CONSORT diagram: Participation of Parents in post intervention interviews



Appendix 9.3: Big Fish Games™ Details.

Note matching and shooting games require participants to use a small wireless optical computer mouse with a left-mouse button to press when needed or small hand-held clickers with a left mouse button to press when needed.

Big Fish Game™	Axis Play	Start Difficulty	Type	Clicker	Precision	Background	Distractor	Executive Function
Abundante	Horizontal	Difficult	Match 3	Yes	Moderate	Low Optokinetic	No	Matching and Puzzle Solving
Action ball	Horizontal	Moderate	Brick Buster	No	Moderate	High Optokinetic	Yes	Visual Tracking & Spatial
Aqua Ball	Horizontal	Easy	Brick Buster	No	Low	Medium optokinetic	Yes	Visual Tracking & Spatial
Astrobugs Revenge	Horizontal	Difficult	Match 3	Yes	High	Medium optokinetic	No	Matching
Birds Town	Horizontal	Moderate	Match 3	Yes	High	Low Optokinetic	No	Matching
Brave Piglet	Vertical	Moderate	Shooting	Yes	High	Low Optokinetic	Yes	Visual Tracking & Spatial
Bricks of Egypt	Horizontal	Easy	Brick Buster	No	Variable	Low Optokinetic	Yes	Visual Tracking & Spatial
Butterfly Escape	Horizontal	Moderate	Match 3	Yes	High	Low Optokinetic	Yes	Visual Tracking & Spatial
Bubble Town	Horizontal	High	Match 3	Yes	High	Moderate Optokinetic	No	Matching, Pairing
Bubble Nauts	Horizontal	Low	Match 3	Yes	Moderate	Moderate Optokinetic	Yes	Visual Tracking & Spatial

Chicken Invaders	Variable	High	Shooting	Yes	Moderate	High Optokinetic	Yes	Search and Select
Clear It 2	Variable	High	Match 3	Yes	High	Moderate Optokinetic	No	Visual Tracking & Spatial
Egyptian Ball	Horizontal	Difficult	Brick Buster	No	Moderate	High Optokinetic	No	Search and Select
Feeding Frenzy	Variable	Difficult	Aim and Move	No	High	Low Optokinetic	Yes	Visual Tracking & Spatial
Hyperballoid 2	Horizontal	Difficult	Brick Buster	No	Moderate	High Optokinetic	No	Visual Tracking & Spatial
Invadazoid	Horizontal	Difficult	Brick Buster	No	High	Moderate Optokinetic	Yes	Visual Tracking & Spatial
Jar of Marbles	Horizontal	Easy	Match 3	Yes	Medium	Low Optokinetic	No	Matching Three, aligning
Jet Jumper	Variable	Difficult	Driving Game	Yes	High	High Optokinetic	Yes	Visual Tracking and Driving
Luxor 3	Horizontal	Moderate	Match 3	Yes	High	Moderate Optokinetic	Yes	Match 3, Aligning
Luxor HD	Horizontal	Moderate	Match 3	Yes	High	Moderate Optokinetic	Yes	Match 3, Aligning
Ozzy bubbles	Horizontal	Difficult	Aim and Move	Yes	Low	Low Optokinetic	Yes	Driving game
Ricochet Recharge	Horizontal	Moderate	Brick Buster	No	High	Moderate Optokinetic	No	Visual Tracking & Spatial

Chapter 10: Conclusion

The game-based rehabilitation platform (GRP) was developed to fulfill the need for effective upper extremity (UE) rehabilitation approaches targeting manual dexterity that motivate children with cerebral palsy (CP) to engage in long-term exercise programs. The GRP includes an embedded automated assessment tool. It provides objective measures of fine and gross motor skills and for a broad range of object manipulation tasks.

The first objective of the study was to examine the psychometric properties of the CUE assessment tool. The CUE software automatically logs the client's movement response to each game event and computes various performance-based metrics such as Success Rate, Movement Onset Time, and Movement Error. The CUE software is configurable, which helps to increase the difficulty level by adjusting a) the target and paddle size (for movement precision), b) movement speed of game objects and c) mouse sensitivity (increase/decrease movement amplitude). It produces electronic records that allow us to track change over time and provide valuable and timely feedback to clients and therapists. With few exceptions, the CUE assessment tool showed high to moderate test-retest reliability for all object manipulation tasks and performance measures with no significant difference between the first and second test's mean scores. The MDC values were notably large for most object manipulation tasks, which showed high reliability and validity for monitoring a child's performance during therapy. The lack of a significant correlation between CUE performance measures and the QUEST or PDMS-2 indicates that the three assessment tools represent distinct attributes or features of object handling and manipulation skills in children with CP.

The study's second objective was to estimate the sample size for a future full-scale RCT using the GRP-based home program to improve UE fine and gross motor function in children with CP. In this regard, a power analysis using the present results (i.e., effect sizes) was performed to determine the minimum sample size for a definitive RCT. The power calculations showed that it is reasonable to justify the current sample size (N=63) based on the CUE assessment tool variables' confidence interval width.

Overall, the quantitative component of the RCT results demonstrate a substantial, positive effect of the training program on several aspects of the children's performance. This could be because the individualized GRP protocol was created and updated based on the current fine motor challenges faced by the participants and their goals to practice a broad range of object manipulation tasks. Addition of computer games added a motivational component for improving children's participation during therapy. Motivation plays an important role in improving the children's skill development and ADL. The task specificity and precision requirements while playing computer games in addition to high number of repetitions demonstrated a positive effect on fine and gross motor UE function in children with CP.

The qualitative component of this study explored the experiences of the study participants' parents by conducting semi-structured interviews. The qualitative findings of participants' experiences helped to identify; a) benefits of the GRP and the conventional protocol perceived by parents, b) engagement and motivational value of the computer games, c) difficulties with the exercises and using the technologies, d) personal and environmental factors that influenced doing the exercises, and e) recommendations and modifications for improving the exercise programs. Parents reported that the GRP protocol showed noticeable improvements in children's object manipulation skills during their day-to-day activities. Parents from the XG perceived a change in the children's level of independence in their daily tasks at home, school, and play activities. This finding was consistent with the quantitative study results. The quantitative component of the study assessed the effects of GRP in comparison with the conventional protocol for object manipulation tasks in children with CP using the PDMS-2 as well as the CUE assessment tool outcome measures. The results showed that the GRP demonstrated greater improvements in hand-arm function as compared to the conventional therapy program. The results suggest that the main features of the GRP demonstrated the utility of the GRP to exercise a broad range of object manipulation tasks. They are a) to increase the number of repetitions, b) the requirement of precision practice, c) task specificity, and d) engaging games.

Parents reported that children loved a wide variety of computer games and often got bored or started to lose interest if they were made to play the same games after a few sessions. Parents commented that this would likely require a large pool of different computer games. In this regard, it is important to note that the GRP was designed to work with many different objects and computer games. Thus, one can select from the wealth of inexpensive common and modern computer games appropriate for a variety of therapeutic options and, importantly, personal preferences. The results of the CUE assessment tool data showed significant improvements in the XG group compared to the CG group pre-post intervention in success rate, movement error, and movement onset time for several object manipulation tasks. Both the XG and CG groups showed significant improvements in pre- to post-intervention with large effect sizes. Significant improvements in the fine motor tasks of the PDMS-2 in the XG occurred even though these tasks were not practiced during the GRP intervention.

Parents also shared the challenges they faced regarding children's participation in therapy and the experiences with the games-assisted exercise program; however, there were no dropouts in the XG. Parents from CG reported that their children became easily irritable and lacked motivation after a few sessions. Parents from XG requested to continue with this therapy program after completing the 16-week intervention. The quantitative data showed moderate to large treatment effect sizes of the GRP protocol, which demonstrates that the GRP has the potential to exhibit clinically meaningful changes.

In summary, the CUE embedded GRP program can combine many engaging UE exercise games with computer games to target the many different impairments exhibited by young children with CP and simultaneously record and assess children's performance using the CUE assessment tool.

Clinical Significance

The studies presented in this thesis demonstrate that the GRP provides effective and engaging RTP for children with CP who require therapy to improve UE function. The results showed clinically meaningful changes in manual dexterity with moderate to large effect sizes. Over time and with increased numbers of therapists and children using the GRP protocol, they can establish a database/registry and collect population information useful for driving evidence-based rehabilitation research. This would contribute to a better understanding of the development of emerging motor and cognitive skills in children with CP. The GRP design addresses the logistical issues of providing quality, engaging therapy to children at an early age of 4-10 years. The GRP is simple to use and parents can be trained to operate the GRP and supervise their child's exercise program. It provided a high amount of repetition and precision practice, which was crucial in children's object manipulation skills improvement.

Limitations

The mixed model RCT design had few limitations. They are listed below.

- The number of interviews in the XG is greater than the number of interviews in the CG. It is not known why more parents in the CG declined to consent to be interviewed as compared to parents in the XG.
- Additional outcome measures, such as health-related quality of life and level of participation, will also be required to validate the findings.
- Outcome measures such as the Children's Assessment of Participation and Enjoyment and its companion measure, Preferences for Activities of Children (PAC) could have been used for this study. However, these measures are valid for children between 6 to 21 years. This is a parent-reported scale with five subscales, a total of 55 questions to be scored (King et al., 2007).
- To monitor changes and improvements over time in terms of attainment of pre-set goals, outcome measures such as the Goal Attainment Scale should have been used. The pre-set goals of parents and children were recorded for creating the treatment protocols; however, the study design lacked an outcome measure to record these goals and the children's post-intervention improvements based on these goals.

One limitation of the GRP platform is that it requires an inertial-based (IB) computer mouse, a computer, and a source of common/modern computer games. The IB mouse detects angular motion; therefore, it is not possible to practice tasks that require only linear motion. Parents reported difficulties related to the unavailability of these resources in remote areas of India.

Strengths of the study

The study had the following strengths

- Since the GRP is embedded with the CUE, it can be easily transferred from a supervised to an unsupervised protocol.

- Since the GRP is designed to provide a high number of repetitions (on an average thirty repetitions per minute) while focusing on a broad range of gross and fine motor function improvements, it reduces the therapy time per session and helps with therapy compliance.
- The GRP provided goal-directed RTP-based manipulation tasks to create engaging experiences and practice object handling and manipulation.
- Many inexpensive, engaging, and easily accessible computer games with a variety of visual-spatial tasks and require choice and other planning type activities can be used for the GRP; therefore, the variety of games is larger than other commercially available gaming consoles.
- Zero dropouts from the GRP intervention group and parents' interviews suggest that the GRP assisted in improving children's therapy compliance.

Future Directions

Goal Setting

For the powered RCT, the goals mentioned by the participants and their parents need to be documented using reliable and valid measures such as the Goal Attainment Scale for children.

Level of Participation

The current study design did not use an outcome measure to record the changes in the level of participation in these children. The changes in the children's level of activities and participation needs to be addressed in the next phase of the RCT. The future RCT will also provide insight on whether the transition from a clinical facility-based to a home-based protocol using the GRP is effective.

International Classification of Function Model

The GRP platform is designed to improve not only the body structure and function component in children, but also the level of activities and participation and, in the end, effects of the personal and environmental factors on the participants' health. The upper extremity fine and gross motor function and performing a given task as a part of the therapy session fall under the body structure and function category while the object manipulation tasks and level of activity categories. The computer games assisted play and level of motivation is focused on the levels of participation. The ability of the GRP protocol to easily transfer from a clinical facility to a home or school setting is meant to bring a positive change in child's ADLs and overall health. Providing therapy at home rather than a clinical facility has shown positive changes in previous studies (Barzel et al., 2015; Preston, Weightman, Gallagher, Levesley, et al., 2016). Children's everyday environments have been shown to be more effective for providing therapy than clinical settings. Therefore, overall, the GRP protocol fits into the ICF model under the categories of "structure and function, "activity and levels of participation" as well as "personal and environmental factors". However, he ICF model of the GRP is not well explained in the current study. In the future RCT, this needs to be well explained and followed.

Motivation Theories

The inclusion of a gaming element in the GRP is intended to provide extra motivation for children in the form of a challenge and a more enjoyable means of encouraging them to follow tedious, repetitive movements that are part of the rehabilitation process. Specific therapeutic value can be derived from both the types of object manipulation tasks, as well as the choice of computer game. However, it is important to understand the various theories of motivation and types of motivation to best utilize the GRP platform for children with CP. The current study relied on the qualitative interviews to understand whether or not children found the protocol motivating. The behavioral indicators, zero dropout rate and anecdotes from parents interviews were the only indicators of the level of motivation. This study did not measure levels of motivation in the participants in the XG versus CG groups. Thus, it is important to use psychometrically evaluated measures to assess children's and parents' levels of motivation. In order to better understand the effectiveness of the GRP protocol to increase the intrinsic and extrinsic level of motivation in children and in parents, theories of motivation such as Bandura's self-efficacy theory (Bandura, 1977), achievement goal theory (Palmer et al., 2017), self-determination theory (Flannery, 2017), or the flow model (Fortier, 2000) need to be studied in detail and applied when creating protocols (Tatla et al., 2013).

For future studies, the GRP protocol can be grounded in one of the theories of motivation such as the achievement goal theory. Palmar et al., (2017) reviewed studies that used the achievement goal theory based therapy interventions in children (Palmer et al., 2017). The achievement goal theory uses intrinsic motivation by using one's goals to learn and master a given task and improve performance by observing the amount of success. Many clinical trials that have used computer games and virtual reality-based therapy with achievement goal theory as the theoretical approach were reviewed. They concluded that all studies which used achievement goal theory-based interventions for fine and gross motor skills development in children showed significant improvements which were sustained for a long period of time post intervention.

Therapy compliance

This study was useful in predicting participant retention, exercise adherence rates for a future GRP based novel in-home exercise program for children with CP. Previous studies have seen better long term therapy compliance for home-based therapy (Ferre et al., 2015; Gerber et al., 2016a; Lopes et al., 2018). For future studies, a powered RCT can be performed based on the results of this exploratory RCT to take advantage of the GRP protocol for creating well-designed telerehabilitation systems to provide therapy in a home-based setting. Home-based therapist-monitored protocols can dramatically decrease the cost of providing high-quality treatments to children with CP. This will make it possible to provide home therapy using combinations of task-specific exercises, with a high number of repetitions and precision practice, that are most effective for children with CP. The GRP can transition from in-clinic use to the home and schools because the hardware is inexpensive, simple to use compared to other commercially available products. Importantly, the therapists' quality of therapy can be monitored by the therapists in-person or remotely. The necessary hardware for the GRP and telemonitoring applications are simple to use, commercialized, and available for purchase from Mobility Research Inc.

Chapter 11: References

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Appendix 1

S. D. M. EDUCATIONAL SOCIETY'S

SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF PHYSIOTHERAPY

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Affiliated to: RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, BANGALORE

Estd: 1996

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Innovative Game-Based Rehabilitation Platform for children with motor and cognitive impairments due to neuro-developmental disorders and acquired brain injuries"

Dr. Mrs. Anuprita Kanitkar PhD student, Applied Health Sciences, University of Manitoba, Canada (kanitkaa@umanitoba.ca), Dr. Tony Szturm College of Rehabilitation Sciences, University of Manitoba, Canada (tony.szturm@umanitoba.ca), Dr. Sanjay T. Parmar , Associate Professor S.D.M. College of Physiotherapy, Rajiv Gandhi University of Health Sciences, Karnataka, India. (sanjayparmar777@gmail.com), Dr. Ravi Savadatti, Principal, S.D.M. College of Physiotherapy, Rajiv Gandhi University of Health Sciences, Karnataka, India. (sdmcpt@gmail.com), Nilashri naik, Pediatric Physiotherapist, USHAS Centre for Exceptional Children, Hubli, India. (nilashrinaik@yahoo.co.in).

This is to certify that I, _______________ on behalf of my minor Child _______________ have been given the following information with respect to my child's participation as a volunteer in this study.

Purpose of this study- The study in which your child will be participating is designed to examine the effectiveness and usefulness of two different exercise programs in children with neurodevelopmental disorders or acquired brain injuries. We have developed an innovative game based rehabilitation platform for children with difficulty in using hand and arm for play and activities of daily living due to neurodevelopmentall disorders and acquired brain injuries.

This is based on an interactive exercise and educational computer gaming system that learns and adapts to the skill level of children. It allows for the collection of outcome measures on a moment-to moment basis for each training session, permitting one to track changes within each session and over time. It uses computer games that: (a) make therapy and practice fun (b) helps increase the intensity and volume of practice and (c) helps increase focus and attention during the training and learning process. The purpose of this study is to evaluate the effectiveness and usefulness of this new interactive exercise and education computer gaming system with children age 4-11diagnosed with cerebral palsy or acquired brain injury.

11/4/2016 Initial's _____________ Page 1of 3

Procedure to be followed:

If your child takes part in this study he/she will be randomly selected to be in either one of the 2 groups. We intend to recruit 30 participants in the experimental and 30 in the control group. Children assigned to the experimental group will be asked to play 4-5 interactive education computer games for 45 minutes each session, 3-4 days a week, for a total of 16 weeks. We will bring a standard laptop computer and selected children's computer games. An assistant will be present to guide each child as he/she plays the computer games. The control group will receive Stretching, Hand arm bimanual activities, Weight Bearing Exercises and guided manual dexterity exercises.

Time duration of the procedure- Each therapy session will take 45-60 minute sessions. Frequency will be three times per week for 16 weeks

Benefit to volunteer- There may be no effect/benefits to your son/daughter secondary to the therapy and no financial benefit if he/she participates in the game based study.

Time duration of the procedure- 45-60 minutes per session

Statement of confidentiality- Your child's participation in this research is confidential. Only the investigators will have access to your child's identity and to information that can be associated with his/her identity. In the event of publication of this research, no personally identifying information will be disclosed.

Right to ask question- You may ask any questions about the study procedures and the questions will be answered. Further questions should be directed to Anuprita Kanitkar, kanitkaa@umanitoba.ca & Dr.Sanjay Parmar, sanjayparmar777@gmail.com (9845340450).

For questions about your son's/daughter's rights as a research participant, you may contact the University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389 or Ethical Committee, S.D.M. College of Medical Sciences and Hospital, Dharwad, India. (0836-2464799)

Compensation- There is no compensation, financial or otherwise, for participating in this study.

Injury clause- There is no chance of any injury resulting from this study.

11/4/2016 Initial's ______________

Voluntary participation- Your child's participation in this study is voluntary, and you may withdraw him/her from this study at any time notifying the investigator. Your child's withdrawal from this study or refusal to participate will in no way affect your child's care or access to medical services.

Name of the Child: ___________ ________________

Parent's sign: ____________________________ ___ Date________________

Name of the Therapist: __________________________________

Sign _____________________________ Date ______________________

Appendix 2

UNIVERSITY OF MANITOBA

Faculty of Health Sciences
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Telephone (204) 789-3897
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Department of Occupational Therapy
Department of Physical Therapy
Department of Respiratory Therapy

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Computer Game-Based Rehabilitation Platform for children with motor and cognitive impairments due to neuro-developmental disorders

Dr. Mrs. Anuprita Kanitkar PhD student, Applied Health Sciences, University of Manitoba, Canada (kanitkaa@umanitoba.ca), Dr. Tony Szturm College of Rehabilitation Sciences, University of Manitoba, Canada (tony.szturm@umanitoba.ca), Dr. Gayle Restall, Ph.D. College of Rehabilitation Sciences, University of Manitoba, Winnipeg, Dr. Gina Rempel MD, University of Manitoba, Winnipeg.

This is to certify that I, ________________on behalf of my minor Child ________________ have been given the following information with respect to my child's participation as a volunteer in this study.

Purpose of this study

The study in which your child will be participating is designed to examine the feasibility and benefits of a new computer game based rehabilitation program designed for children with difficulty in using hand and arm for play and activities of daily living. It is often difficult to engage young children in tedious, long-term therapy; there is a need for effective approaches that motivate children to participate in therapy and to perform their exercises at home. In this regard, engaging game-based exercises to have the potential to improve child participation because they are enjoyable, fun, and can be extended to the home supported by a clinician. For this purpose, we have developed a low-cost computer game-based rehabilitation and learning platform (CRP). This approach combines fine manipulation and gross movement exercises with attention and planning game activities appropriate for young children with cerebral palsy. The purpose of this study is to evaluate its feasibility for home therapy and to provide evidence for its therapeutic value in rehabilitation. Of hand-arm function.

Procedure to be followed:

If you and your child agrees to participate in this study, then your child will be asked to undertake a 16 week home- program of hand and arm exercises described below. Before starting the program your child will be asked to complete a series of physical assessments of arm and hand function. The purpose of these assessments is to measure range of motion, strength, and manual dexterity (fine and gross motor skills).

__/__/201_ Initial's ______________ Page 1of 4

Updated on November 1st 2016

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First session

The following assessments will be conducted on your child's first visit at the Specialized Services for Children and Youth center:

Gross Motor Function Classification Scale (GMFCS) from level 2-4 will be used to screen and select the participants.

2. Manual Ability Classification System (MACS) from level 2-4 will be used to screen and select the participants.

3. Modified Ashworth scale will be used to determine the level of spasticity from grade 1 to 1+ in the clients which will also be used as a screening tool.

4. The pediatric version of the Mini Mental assessment scale will be used to screen level of cognitive function.

Exclusion Criteria

1. Child with visual impairment
2. Auditory impairment
3. Orthopedic condition
4. Non willing parents
5. Severe cognitive impairment

Training sessions

Your child will be asked to attend 4 to 6 Physiotherapy sessions each lasting approximately 45-60 minutes. Mrs. Anuprita Kanitkar will conduct these sessions. During these sessions, your child will be taught a set of game-based hand-arm exercises, and how to perform them at home correctly and safely. The game exercises require the use of a specialized miniature computer mouse. The computer games are common commercial games suited for young children.

It will be seen to that your child can perform the exercises properly before we begin the home program. You will also be provided opportunities to discuss and ask any questions regarding the exercise programs. Once you child is ready to perform the game exercises at home

The computer mouse and all computer games will be provided to you at no cost. We can provide you with clear instructions on how to set-up your home computer and load the exercise games. Alternatively, if you have a laptop and you can bring it to the clinic, together we can set-up the computer mouse and install the computer games

Home exercise sessions

After the training sessions, a list of clearly illustrated hand exercises will be given to you. We will ask that your child performs the exercises at home for 30 minutes, four times per week for 16 weeks. During this period we will maintain contact by phone or by e-mail to answer any questions you or your child may have, or to help with any technical difficulties. Also, an additional training session can be scheduled if required. Anuprita Kanitkar will contact you every week by phone to help you progress your exercises safely and answer any concerns or questions you have about your exercises.

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Your child will be asked to play a hand function assessment game for two (2) minutes at the beginning of each home exercise session. The assessment game will save the game data to a computer file on your computer. The file names will be anonymized, consisting of code numbers and letters. This information will allow us to evaluate your child's performance and their progress during the home program. You will be asked to copy these data files to a USB flash drive (memory stick), which we will provide. You will be asked to return the USB flash drive with your data files to Anuprita Kanitkar after completion of the 16-week exercise program.

A personal exercise diary will also be provided for you to log when you performed your exercise program and the duration.

Final Session

On completion of the 16-week exercise program, you will be invited to take part in an individual interview on a separate day to discuss the experiences you had on receiving the specific hand exercise program. The whole interview session will be audiotaped for transcription purposes. You will be given a separate form to give your written consent for participation in the interview process. Your identity will be protected and your privacy will be maintained. All the information discussed and shared during the interview will be kept confidential and safely protected.

Benefit to volunteer

There may be no effect/benefits to your son/daughter secondary to the therapy and no financial benefit if he/she participates in the game based study.

Statement of confidentiality

Your child's participation in this research is confidential. Only the investigators will have access to your child's identity and to information that can be associated with his/her identity. In the event of publication of this research, no personally identifying information will be disclosed.

Right to ask question

You may ask any questions about the study procedures and the questions will be answered. Further questions should be directed to Anuprita Kanitkar, kanitkaa@umanitoba.ca & Dr. Tony Szturm at tony.szturm@umanitoba.ca
For questions about your son's/daughter's rights as a research participant, you may contact the University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389.

Compensation

There is no compensation, financial or otherwise, for participating in this study.

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Injury clause

There is no chance of any injury resulting from this study.

Voluntary participation

Your child's participation in this study is voluntary, and you may withdraw him/her from this study at any time notifying the investigator. Your child's withdrawal from this study or refusal to participate will in no way affect your child's care or access to medical services.

Name of the Child: ___________ ________________

Parent's sign: ____________________________ ___   Date________________

Name of the Therapist: __________________________________

Sign _____________________________   Date ______________________