The Effects of an Individual Hydrotherapy Program on Static and Dynamic Balance in Children with Cerebral Palsy in Sri Lanka

By

Surandi Krishna Kumari Wadu Mesthri

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Abstract

Problem: Poor balance is considered a major issue that children with Cerebral Palsy (CP) encounter. Since balance skills constitute a crucial part of gross motor ability, compromised balance control in these children with CP have a varied impact on their everyday life. Hydrotherapy has been used in the rehabilitation of children with CP, but little is known about the effects of this rehabilitative modality on both static and dynamic balance of children with CP especially in Sri Lanka where no hydrotherapy study has been conducted. Therefore, the purpose of this present study is to examine the feasibility of a 6-week aerobic exercise-based hydrotherapy program and its effects on static and dynamic balance in children with CP in the Sri Lankan context.

Methods: A quasi-experimental pretest-post-test design without a control group was used. Five children with mild to moderate CP between the ages 7 and 11 years participated in 45-minute hydrotherapy sessions twice per week for 6 weeks. Training intensity was monitored and expressed as a percentage of Heart Rate Reserve (HRR). The primary outcome measures were static and dynamic balance as measured by the Pediatric Reach Test (PRT) and modified Timed-Up and Go (mTUG) test, respectively. As the secondary outcome measure, Health-Related Quality of Life (HRQOL) of children was assessed by the primary caregiver using 5-item Visual Analogue Scale (VAS).

Results: All participants were able to achieve and maintain an intensity level of 30% to 60% of HRR with an average intensity level of 43% during the intervention period. Except forward reach distance when sitting, all other components of the PRT showed improvement with statistical significance at $p < 0.004$ with Bonferroni correction. The mTUG test did not show statistically significant improvement even though there was a positive trend towards

improvement. All the participants showed improvement in HRQOL, but the findings were not statistically significant.

Conclusion: This 6-week aerobic exercise-based hydrotherapy program was feasible and demonstrated potential for improving static and dynamic balance abilities in children with CP.

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Dedication

This thesis is dedicated to:

My beloved parents: Mr. Ariyadasa Wadu Mesthri and Mrs. Nanda Jayawardena,

and

My sister: Mrs. Erandi Wadu Mesthri

and

My brothers: Mr. Channa and Prasanna Wadu Mesthri

for your unconditional love and support.

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List of Abbreviations

ACSM: American College of Sports Medicine

BMI: Body Mass Index

CHQ: Child Health Questionnaire

CHIP: Child Health and Illness Profile

CP: Cerebral Palsy

CPQOL: Cerebral Palsy Quality of Life

CPQOL-Child: Cerebral Palsy Quality of Life Cerebral Palsy Questionnaire for Children

ERC: Ethics Review Committee

FR: Forward Reach

FRT: Functional Reach Test

GMFCS: Gross Motor Function Classification System

GMFCS - E & R: Gross Motor Function Classification System - Expanded and Revised

GMFM: Gross Motor Funtion Measure

HR: Heart Rate

HR_{rest}: Resting Heart Rate

HR_{max}: Maximum Heart Rate

HREB: Health Research Ethics Board

HRR: Heart Rate Reserve

HRQOL: Heath-Related Quality of Life

ICF: International Classification of Functionning Disability and Health

ICC: Intraclass Correlation Coefficient

LLR: Left Lateral Reach

MCID: Minimal Clinically Important Difference

MDC: Minimal Detectable Change

MET: Metabolic Equivalent

mTUG: modified Timed-Up and Go

NCCCPDD: National Center for Children with Cerebral Palsy and other Developmental Disorders

PBS: Pediatric Balance Scale

PedsQL: Pediatric Quality of Life

PEDI: Pediatric Evaluation of Disability Inventory

PFRT: Pediatric Functional Reach Test

PRT: Pediatric Reach Test

QOL: Quality of Life

RCT: Randomised Control Trial

RLR: Right Lateral reach

ROM: Range of Motion

SPSS: Statistical Package of Social Sciences

THR: Target Heart Rate

TUDS: Timed-Up and Down Stairs

TUG: Timed-Up and Go

TUG-IC: Timed-Up and Go-In Children

VAS: Visual Analogue Scale

VO_2R: Oxygen Uptake Reserve

VO_2: Oxygen Uptake

Chapter 1 Background

Cerebral Palsy (CP) is the most common form of physical disability during childhood (Lai et al., 2014; Reddihough& Collins, 2003; Rosenbaum, 2003). It is "an umbrella term covering a group of non-progressive, but often changing, motor impairment syndromes secondary to lesions or anomalies of the brain arising in the early stages of development" (Mutch, Alberman, Hagberg, Kodama, &Perat, 1992, p. 549). Motor impairments affecting the body's movement, posture and balance are main characteristics of CP, because the brain injuries affect single or multiple locations of the brain such as the motor cortex, basal ganglia and cerebellum that control muscle tone and motor coordination (Graham et al., 2016). Also, most children with CP have many associated neurodevelopmental defects such as cognitive, visual, hearing and speech impairments affecting their functioning and health in addition to locomotor disabilities (Gowda, Kumar, Shivappa, & Srikanteswara, 2015; Kliegman, Stanton, St. Geme, Schor, & Behrman, 2011; Vargus-Adams, 2005). As such, CP is a broad term used to cover a spectrum of conditions with varying severity.

Body balance, both static and dynamic, is a basic requirement for motor development in children (Khasawneh, 2015; Westcott &Burtner, 2004; Yi, Hwang, Kim, & Kwon, 2012). "The ability to provide body balance in a specific place or position is called static balance and the ability to provide body balance while moving is called dynamic balance" (Bozkurt, Erkut, &Akkoç, 2017, p 927). According to Khasawneh (2015), "Static balance is the one in which the individual retains poise in one single situation, whereas the dynamic balance is the body's ability to retain poise or steadiness when moving or shifting from one balanced situation to another" (p. 87). Body balance is crucial in functional independence (Fournier

et al., 2010). When viewed from a developmental aspect, postural control and balance are hurdles on the developmental pathway of certain gross motor milestones such as locomotion (Geuze, 2005). While static balance is necessary to maintain body equilibrium during stationary posture, dynamic balance is essential to execute all body movements and most functional activities (Westcott &Burtner, 2004; Woollacott & Shumway-Cook, 2005). Static balance is needed to manage the internally induced perturbation such as task of keeping one's trunk over the seated surface while sitting on a stationary surface like a chair. The other type, dynamic balance, adjusts the body for both internally and externally induced perturbation such as walking and maintaining balance in a moving vehicle, respectively (Santos, Kanekar, &Aruin, 2010).

Poor balance is considered a major problem that children with CP encounter (AlSaif & Alsenany, 2015; Tarakci, Ozdincler, Tarakci, Tutuncuoglu, & Ozmen, 2013). Deficiency in balance control is frequently experienced by children with CP compared to children with normal development (Gan, Tung, Tang, & Wang, 2008; Rose et al., 2002). Since balance skills constitute a crucial part of gross motor ability, deficient or compromised balance control has a varied impact on physical tasks involved in daily living activities (AlSaif & Alsenany, 2015; Kembhavi, Darrah, Magill-Evans, & Loomis, 2002; Liao & Hwang, 2003). For children with CP of various functional severity, this phenomenon is evidenced by limited physical involvement in daily life activities, at home and in the community (Gorter & Currie, 2011).

CP is incurable (Rosenbaum, 2003). For this reason, children with CP will have to live with limited activities (Benda, McGibbon, & Grant, 2003). Physical inactivity in this population causes increased risk of developing secondary physical complications such as

pain, fatigue, pressure sores and mobility limitations as well as psychological complications such as depression and social isolation (AlSaif & Alsenany, 2015). Additionally, they are at increased risk of developing metabolic and cardiovascular complications such as hypertension, hypercholesterolemia, and obesity with aging (Verschuren, Peterson, Balemans, & Hurvitz, 2016). Muscle imbalances bring many subsequent problems such as unequal bone growth, spinal deformities (scoliosis), contractures, hip dislocation, and weight bearing difficulties. Furthermore, people with lack of muscle balance suffer from chronic pain which challenges their fundamental motor skills e.g., sitting, standing and walking (as stated in Benda et al., 2003).

Numerous therapeutic interventions targeting children with CP, are being practiced worldwide. Graham et al. (2016) and Rosenbaum (2003) described 2 goals of therapy: to promote functional abilities and avert development of secondary conditions. As already noted, CP is not curable. Therefore, children with CP commonly undergo different types of supplementary rehabilitation programs such as hippotherapy, electrical stimulation and acupuncture (Liptak, 2005). Another common form of supplemental treatment that children with CP undergo is hydrotherapy or aquatic therapy (Getz, 2006; Gorter& Currie, 2011; Hurvitz, Leonard, Ayyangar, & Nelson, 2003).

Hydrotherapy is an appealing mode of rehabilitation for children with CP (Badawy & Ibrahem, 2016; Kelly & Darrah, 2005), and it has become popular over the last couple of years (Fragala-Pinkham, Dumas, Barlow, & Pasternak, 2009; Fragala-Pinkham, Smith, Lombard, Barlow, & O'Neil, 2014). There are several reasons why hydrotherapy is very attractive. One reason is that children with CP find it easy and enjoyable to exercise in water compared to exercising on land (Fragala-Pinkham et al., 2014; Kelly & Darrah, 2005; Lai et

al., 2014). In contrast to practising on the land setting, hydrotherapy allows children with CP to exercise in the water for long periods of time before becoming fatigued. Children with CP find it easy to engage in more strenuous rehabilitation program in the water compared to the land (Badawy & Ibrahem, 2016). Also, a growing body of research involving children with CP shows significant beneficial effects of pediatric hydrotherapy programs, reporting improvements in gross motor function (Fragala-Pinkham et al., 2014; Lai et al., 2014), gait efficiency (Ballaz, Plamondon, & Lemay, 2011), functional mobility (Thorpe, Reilly, & Case, 2005) and physical activity enjoyment (Lai et al., 2014). Retarekar, Fragala-Pinkham, and Townsend (2009) reported improved body function, activity and participation, i.e., 3 major components of the International Classification of Functioning, Disability and Health (ICF) of a child affected with CP (moderate severity) after participating in a 12-weeks hydrotherapy program.

Multiple studies have reported the effects of varied interventions on balance enhancement in children with CP including hippotherapy (Zadnikar & Kastrin, 2011), neuromuscular block and neuromuscular electrical stimulation (Kazon et al., 2012), swiss ball exercises (Kim, Lee, Kim, Chang, & Lim, 2017), and Wii-based balance therapy (Tarakci et al., 2013). However, studies assessing the effects of hydrotherapy on balance of children with CP are limited in the existing literature.

Children with CP face many challenges when performing physical tasks and therefore, both static and dynamic body balance are important parts of their lives as for any other human being. To date, only 6 studies reported balance inchildren with CP following participation in hydrotherapy intervention programs. These include a Randomised Control Trial (RCT) utilizing Biodex balance system to assess dynamic balance (Badawy & Ibrahem,

2016), a study with a group aquatic intervention program evaluating balance of children and adolescents with CP using Pediatric Balance Scale (PBS), Timed Up and Go (TUG) test, and Timed Up and Down Stairs (TUDS) test (Zverev & Kurnikova, 2016), and 4 studies with aquatic intervention program utilizing outcome measures such as Functional Reach Test (FRT) (Fragala-Pinkham et al., 2009; Thorpe et al., 2005), TUG test (Adar et al., 2017; Thorpe et al., 2005), timed single limb stance test (Fragala-Pinkham et al., 2009), and Pediatric Berg Balance scale (Fragala-Pinkham et al., 2014). However, even though almost all these study outcome measures have reported positive trends towards improvement in balance, not all concluded that hydrotherapy is effective in improving the balance in children with CP.

In Sri Lanka, epidemiological evidence and research on CP are lacking; however, anecdotal evidence suggests that CP is a serious problem that affects many children and majority of them do not receive any type of treatment. Although there is no national survey conducted to assess the epidemiology of CP in Sri Lanka, it is estimated that nearly 40,000 children out of the total population of 22 million in the country live with CP (Aloysius, 2016). While hydrotherapy is a popular treatment in most western countries, in other developing countries like Sri Lanka this treatment modality has not been explored well. A significant number of children have no access to hydrotherapy treatment in Sri Lanka. Even the awareness about hydrotherapy as a treatment modality for children with CP is lacking among Sri Lankan health care providers. Also, there has not been any study on hydrotherapy conducted so far in Sri Lanka. Thus, the purpose of this study was to examine the feasibility of an individual hydrotherapy program and its effects on static and dynamic balance in children with CP in the Sri Lankan context.

Chapter 2 Literature Review

2.1. Cerebral Palsy

In 1862, an orthopedic surgeon, William James Little first described CP (as cited in Pervin et al., 2015). Since then, the definition of CP was revised by various paediatricians and neurologists (Graham & Selber, 2003). Currently the most widely used definition was proposed by the International Executive Committee for the Definition of CP in 2006 and according to that CP is defined as follows:

> Cerebral Palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain.
>
> The motor disorders of CP are often accompanied by disturbances of sensation, perception, cognition, communication and behaviour, by epilepsy, and by secondary musculoskeletal problems (Rosenbaum et al., 2007, p 11).

2.2. Etiology and Risk Factors of Cerebral Palsy

Cerebral palsy etiology can be separated into 2 categories: antenatal and perinatal (Graham et al., 2016). Some well-known antenatal causes include congenital malformations of brain development, vascular events such as middle cerebral artery occlusion, and maternal infections during first and second trimester, while important perinatal causes include intrapartum hypoxia (secondary to prolapsed cord, prolonged or traumatic delivery, etc.), infections and injuries (Reddihough & Collins, 2003). In general, among identified risk factors of CP, low birth weight, intrauterine infections and multiple gestation are most important (Odding, Roebroeck, & Stam, 2006). However, the causes of CP are not the same in both developed and developing countries. In developed countries, prematurity is the most common reason for CP (Gladstone, 2010). In contrast, prevalent risk factors in developing

countries are infections such as meningitis, septicaemia and malaria (Reddihough & Collins, 2003). Further, compared to developed countries, in developing countries higher proportion of children with CPare due to a third category, called post-neonatal pathologies such as infections which can be prevented and treated (Colver, Fairhurst, & Pharoah, 2014).

2.3. The Epidemiology of Cerebral Palsy

The global prevalence of CP has been estimated at 15 – 17 million people or 2/1000 neonates (Graham et al., 2016; Oskoui, Coutinho, Dykeman, Jette, & Prinsheim, 2013; Veličković & Perat, 2005). In Sri Lanka, it is estimated that approximately 40,000 children out of the total population of 22 million in the country live with CP (equivalent to 1.8 per 1000 live births) (Aloysius, 2016). Even with improvements in antenatal and perinatal care settings, the prevalence of CP in both developed and developing countries has plateaued around 2.0 – 3.5 per 1000 live births over the last 4 decades (Colver et al., 2014).

2.4. Classification of Cerebral Palsy

CP can be classified in many ways according to: (a) type of movement disorder, (b) anatomical region of the body with impaired motor activity and (c) extent or the severity of motor dysfunction (Graham et al., 2016; Graham & Selber, 2003; Tecklin, 2015). According to the movement disorder type, three main subtypes of CP, spastic (90%), dyskinetic (6%) and ataxic or hypotonic (4%) have been reported (Lissauer & Clayden, 2012). Depending on the topographical distribution of the impaired motor function, CP is further classified as hemiplegia, diplegia and quadriplegia (Tecklin, 2015), but sometimes it is noted that only the spastic subtype has been further divided into these 3 categories (Gladstone, 2010;

Lissauer & Clayden, 2012). Lastly, further classification of CP is done with the Gross Motor Function Classification System-Expanded and Revised (GMFCS - E & R) gradings that has been developed to classify children and youth with CP based on the severity level of their affected age-specific gross motor function (Palisano, Rosenbaum, Bartlett, & Livingston, 2007). Essentially, voluntary movements with a focus on sitting, transfers, and mobility are assessed by this scale (Palisano et al., 2007). GMFCS - E &R gradings are used by clinicians and researchers to identify and record the functional ability of individuals with CP. Considering the changes that may occur during each developmental phase of childhood, it has incorporated 5 age ranges from early childhood to the early adulthood; before 2y, 2 to 4 y, 4 to 6y, 6 to 12y, and 12 to 18y, and each range has further divided in to 5 levels (from I to V). Functional severity of CP increases with increasing the level number denoting level I as the mildest form and level V as the most severe form for all age ranges (Palisano et al., 2007).

2.5. Balance and Cerebral Palsy

Balance is an integral component of movements due to its foundational nature for the performance of motor skills such as sitting, standing, walking, running and other complex movements (Franjoine, Gunther, & Taylor, 2003; Gan et al., 2008; Jiang et al., 2018; Vasile & Stănescu, 2013).

The balance system has 3 basic elements: (a) coordinating inputs received from multiple sensory systems: visual, vestibular, and somatosensory system, (b) central nervous system processing of information and (c) movement coordination using musculoskeletal system to maintain balance (Błażkiewicz, 2013; Gribble & Hertel, 2004; Yim-Chiplis &

Talbot, 2000). Maturation of the 3 basic elements occurs non-linearly at different rates and at various stages of the development (Westcott & Burtner, 2004). By the age of 15, balance skills have developed to those seen in adults (Jiang et al., 2018).

In CP, impaired interactions between the 3 basic elements of balance results in failure to maintain balance (Woollacott & Shumway-Cook, 2005). For example, Cherng, Su, Chen, and Kuan (1999) showed children with CP experience problems with intersensory conflicts and therefore, are subjected to difficulties in maintaining static balance compared to children without disabilities. Also, motor impairments of CP frequently coexist with deficiency in balance control (Katz-Leurer, Rotem, Keren, & Meyer, 2009; Woollacott & Shumway-Cook, 2005). Children with CP suffer from problems of sensation, perception and secondary musculoskeletal problems such as muscle contractures and bony deformities in addition to impaired motor system (Rosenbaum et al., 2007). Consequently, as stated earlier, compared to children developing normally, children with CP present with a compromised ability to maintain balance. Therefore, depending on the severity of the disease, static and dynamic balance may vary among children with CP.

2.6. Health-Related Quality of Life (HRQOL) in Children with CP

Quality of Life (QOL) has been defined by World Health Organization as "individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns" (The WHOQOL Group, 1995, p 1405). The subcategory of QOL that specifically related to health status of an individual has been described as HRQOL (Bjornson & McLaughlin, 2001; Office of Disease Prevention and Health Promotion, 2010).

An increasing number of children with CP are living longer due to medical and technological advances. As such, measuring and improving the HRQOL in children with CP has become progressively important. Literature on HRQOL in children with CP has gradually increased in the recent years (Bjornson & McLaughlin, 2001). Basically, two types of measures; generic measures and condition-specific measures have been used to assess the HRQOL of children with CP. Examples for the former include Child Health Questionnaire (CHQ), Child Health and Illness Profile (CHIP), Pediatric Quality of Life (PedsQL) Questionnaire and those for the latter include Cerebral Palsy Quality of Life Questionnaire for Children (CPQOL-Child) and PedsQOL Cerebral Palsy Module (Ozdemir&Tezcan, 2017). In comparison, the sensitivity of condition-specific measures is much higher than generic measures in evaluating HRQOL of Children with CP (Ozdemir &Tezcan, 2017) especially in studies focused to investigate the effectiveness of an intervention program (Davis & Waters, 2010).

For the assessment of HRQOL researchers have used either parent/proxy version or children self-reported versions or both. However, due to children's immature cognitive level, lack of social experience and dependent nature, it is observed that parent-reported versions are capable of rating certain aspects of QOL of their children more than the child-reported version (Davis & Waters, 2010). However, parent's expectations and past experiences with the child could influence their rating. Therefore, parent-reported versions tend to either underestimate or overestimate some aspects of HRQOL, and this might affect the true representation of the real scenario (Davis & Waters, 2010).

The HRQOL of children with CP has been measured and found to be poor due to various factors (Dobhal, Juneja, Jain, Sairam, & Thiagarajan, 2014; Power et al., 2018;

Vargus-Adams, 2005). Motor disability with multiple associated comorbidities of the disease such as behavioral issues, impairment of cognition, sensory perception and epilepsy coupled with overall functional limitations adversely affect the HRQOL in children with CP (Ozdemir & Tezcan, 2017; Power et al., 2018). Vargus-Adams (2005) reported that poor HRQOL in these children is mostly due to issues that they face with physical functioning and impact of the disease on parents and caregivers such as parental worries and concerns regarding their children with disabilities plus additional time and efforts needed for caring. Another study, a systematic review that included 16 studies which investigated the HRQOL of children with CP (n = 1579) across 5 instruments revealed poor HRQOL especially in terms of physical well-being among children with CP from low and middle income countries compared to their peers without CP from similar countries ($p < 0.003$) and peers with CP from high income countries ($p < 0.001$).

2.7. Hydrotherapy

2.7.1. Physical properties

The history of therapeutic usage of water dates to the time of ancient Greece, and the 2 Greek words ‘hydro’ referring to water and ‘therapeia’ referring to healing made its derivative, hydrotherapy (Duffield, 1976). Due to the physical properties of water, it is an appropriate medium for implementing a number of rehabilitation approaches (Cameron, 2003). Some of these properties that may contribute to the effectiveness of a hydrotherapy treatment program are describe below.

Buoyancy. Buoyancy, the experience of upward thrust force exerted by a fluid on the body, acts against the gravitational force, or in the opposite direction to the weight of the body (Cameron, 2003; Campion, 1997; Schrepfer, 2002; Torres-Ronda &Alcázar, 2014). Therefore, two types of forces: gravity acting on the center of gravity and the buoyancy acting on the center of buoyancy act on the body when the body is immersed in a fluid medium (Campion, 1997; Schrepfer, 2002). Rotational force occurs when these two centers are mal-aligned, and it aids the floatation of the body (Campion, 1997; Schrepfer, 2002).

Buoyancy is a very important physical property of water that brings many advantages for rehabilitation programs mainly by reducing the effects of gravity on the body depending on the water level that an individual is immersed (Cameron, 2003). Accordingly, waist deep, chest deep and shoulder deep water reduce 50%, 70% – 75% and 90% of the individual's body weight, respectively (Bates & Hanson, 1996). Therefore, water provides feeling of lightness and facilitates easy moving of the body by reducing the impact on joints and muscles (Cameron, 2003; Norton & Jamison, 2000). As a result, individuals with CP including those with severe function limitations find it easier to do water-based exercises compared to land-based exercises (Dimitrijević et al., 2012; Getz, Hutzler, & Vermeer, 2007; Kelly & Darrah, 2005).

Viscosity and resistance. Viscosity, simply called the thickness of a liquid, results from intermolecular frictional forces and brings resistance to movement (Bates & Hanson, 1996; Norton & Jamison, 2000). When the medium of exercise is air, these resistive effects are minimal and usually disregarded, however; when the water acts as the medium, resistance plays a substantial role (Bates & Hanson, 1996; Norton & Jamison, 2000). Also, the resistance is easily modified by changing movement speed and allows the individual to

perform exercises within his or her comfort zone (Norton & Jamison, 2000) and is considered an important hydrodynamic principle for aquatic exercises.

Hydrostatic pressure. The moment an individual enters a liquid medium, fluid exerts pressure on the immersed body part, and this is called hydrostatic pressure (Torres-Ronda & Alcázar, 2014). As described in Pascal's law, when the body is submerged and at rest at a given depth, this pressure is directly proportional to the depth of immersion (Cameron, 2003; Wilcock, Cronin, & Hing, 2006a). Therefore, hydrostatic pressure on the body increases with the increasing depth of immersion. This multidimensional external pressure has numerous beneficial effects on most of the major body systems. By improving the venous return and, in turn, the efficiency of the cardiac muscle, hydrostatic pressure promotes the functioning of the cardiovascular system. On the musculoskeletal system, this exterior pressure acquires the function of external devises such as compression bandages and stabilizes the weak joints and muscles by its compressive effects (Cameron, 2003; Norton & Jamison, 2000).

2.7.2. Effects of hydrotherapy on cerebral palsy

Effects of hydrotherapy on various physiological and physical performance, and psychological aspects and QOL of children with CP have been reported. However, number of studies evaluating the psychological background and QOL of children following participating hydrotherapy programs are minimal in the current literature. In contrast, studies investigating the physiological and physical (mainly mobility related) performance are quite substantial.

Getz, Hutzler, and Vermeer (2007) conducted a study for 22 children where 12 participants underwent an aquatic intervention program, and another 10 participants

participated in a land-based exercise program (control group). The study concluded that when the 2 groups were compared, improvement gained in perceived social acceptance was more in the aquatic intervention group than the control group, however; a significant difference was not found in social function measured by social function domain of the Pediatric Evaluation of Disability Inventory (PEDI). In 2014, Lai et al. conducted an aquatic therapy study that included a land-based rehabilitation program as the control group and reported that enjoyment of the children measured by physical activity enjoyment scale was higher in the aquatic intervention group compared to the conventional group ($p = 0.015$), but there was no significant difference found in the HRQOL evaluated by the Cerebral Palsy Quality of Life (CPQOL) questionnaire-parent version. Another study (Thorpe et al., 2005), a case series with 7 participants, assessed the self-perception of children with CP using 5 components of self-perception profiles for adolescents and children and commented that except 1 component; global self-worth, all the other 4 components showed improved scores. In a more recent study by Adar et al. (2017) the QOL of children with CP (n=32) was evaluated using both the child self-reported and parent proxy-reported versions of Pediatric Quality of Life Inventory (PedsQL)-CP. Results of that study reported that compared to the control group (land-based exercise group), children who were in the aquatic exercise group demonstrated higher improvement in most of the subdomains of the PedsQL-CP in both versions.

Moreover, regarding the physiological effects of hydrotherapy intervention program, Fragala-Pinkham, Haley, and O'Neil (2008) reported improved cardiovascular endurance of a group of children with disabilities including 2 children with CP following an aquatic aerobic exercise program. Hutzler, Chacham, Bergman, and Szeinberg (1998) stated that

compared to normally developing children, children with CP had reduced lung function but, at the end of a 6-month aquatic therapy program their vital capacity improved markedly.

Throughout the literature many hydrotherapy studies have concentrated on assessing motor skills of children with CP, and this may be because it is a disorder of motor activity. Gross Motor Function Measure (GMFM) has been the most commonly used assessment tool for this purpose. Most of the studies that used this outcome measure reported significant improvement in either some Dimensions (D and/or E) or in all Dimensions of the GMFM-66 or GMFM- 88 versions (Adar et al., 2017; Ballaz et al., 2011; Dimitrijevic et al., 2012; Fragala-Pinkham et al., 2014; Fragala-Pinkham, O'Neil, & Haley, 2008; Lai et al., 2014; Retarekar, Fragala-Pinkham, & Townsend, 2009, Thorpe et al., 2005). Additionally, improved Range of Motion (ROM) (Chrysagis, Douka, Nikopoulos, Apostolopoulou, &Koutsouki, 2009; Fragala-Pinkham et al., 2009), gait efficiency (Ballaz et al., 2011), gait velocity (Thorpe et al., 2005), and walking endurance (Fragala-Pinkham et al., 2014; Retarekar et al., 2009) have been reported. Even though these hydrotherapy studies reported various balance related effects, by reviewing the history of using hydrotherapy for the children with CP, it is evident that there are limited experimental studies that were designed to measure the effects of these exercises on balance.

2.7.3. Studies on hydrotherapy, cerebral palsy and balance

In reviewing literature, only 6 studies have been conducted to assess the balance parameters of children with CP following hydrotherapy programs (Adar et al., 2017; Badawy & Ibrahem, 2016; Fragala-Pinkham et al., 2009; Fragala-Pinkham et al., 2014; Thorpe et al., 2005; Zverev & Kurnikova, 2016). One of those; a 14-week aquatic exercise-based study (n

= 8) used the Pediatric Berg Balance Scale as a secondary outcome measure to evaluate the balance of participants. The findings of that pilot study in which most participants performed exercises with moderate to vigorous intensity reported that balance improvement gained by aquatic exercises was not considerable, though all 8 participants demonstrated a positive trend toward improvement (Fragala-Pinkham et al., 2014). Thorpe, Reilly, and Case (2005) conducted another hydrotherapy study; a 10-week aquatic exercise program for 7 children with CP (6 with spastic diplegia and 1 with spastic hemiplegia belonging to GMFCS I – III levels and aged 7 – 13years) and focused on assessing balance using 2 balance assessment tests; FRT and TUG test. Results of that study reported significant improvement in TUG test in all 7 participants, but only 4 children showed improved FRT score while the other 2 tested demonstrated deterioration from the pre-intervention score. However, as in the previous study, this study did not measure the exercise intensity.

In the case series study (n = 4) of Fragala-Pinkham, Dumas, Barlow, and Pasternak (2009) which includes 2 children with CP (GMFCS level I), one child with Juvenile idiopathic arthritis and one child with Prader-Willi Syndrome, an improvement in balance measured by Timed Single Limb Stance and FRT has been reported in all 4 of them. Again, this study did not concentrate on measuring the exercise intensity levels. Zverev and Kurnikova (2016) conducted a study for a period of 24 weeks and this is a reasonable period to assess a difference in the balance function of children with CP. This study used balance training exercise and swimming as the intervention and evaluated the balance of participants (n = 13) using 3 measures; PBS, TUG test and Timed Up and Down Stairs test and reported statistically significant improvement ($p < 0.000$) in all 3 of them. However, the training

intensity, which is an important component of any exercise program was not measured in this study.

The other study that mainly focused on accessing dynamic balance (Badawy & Ibrahem, 2016) is a RCT, which included aquatic therapy group as the experimental group (15 participants) and land-based exercise group as the control group (15 participants). This study was conducted for 12 weeks and used Biodex balance system to evaluate dynamic balance of children with spastic diplegic CP and reported that stability indices (overall, mediolateral and anteroposterior stability indices) significantly improved in both groups; however, more improvement was seen in the aquatic therapy group. As in the Zverev and Kurnikova (2016) study, this study also did not measure the training intensity of the program. Also, only the dynamic balance was measured but not the static balance. Another study, again a RCT that had 32 children with CP (17 in the aquatic exercise group and 15 in the land-based exercise group as the control), carried out an aquatic exercise program for a period of 6 weeks. In addition to the various outcome measures, that study also used TUG test and reported that both the experimental group and the control group showed improved TUG score, but there was no statistically significant difference between these two groups (Adar et al., 2017).

2.8. Limitations of Studies on Hydrotherapy, Cerebral Palsy and Balance

In the available literature, evidence for the effects of hydrotherapy on balance in children with CP is limited mainly due to study designs, sample size and functional level

(GMFCS levels) of children with CP, and optimal conditions of a hydrotherapy program, i. e. frequency and duration of sessions and the exercise intensity.

Even though RCT is the ideal study design for this type of experimental studies, only 2 studies have been published on RCTs (Adar et al., 2017, Badawy & Ibrahem, 2016). Whereas 3 studies used quasi-experimental pretest-post test designs (Fragala-Pinkham et al., 2014; Thorpe et al., 2005; Zverev & Kurnikova, 2016), and one study used single case series design (Fragala-Pinkham et al., 2009).

Regarding the sample size, the highest number of participants involved in a study is 32 (17 in the aquatic exercise group and 15 in the land-based exercise group) (Adar et al., 2017) followed by 30 (15 in the aquatic exercise group and 15 in the land-based exercise group) (Badawy & Ibrahem, 2016). All other 4 studies included 13, 8, 7 and 2 children with CP.

In addition to that, as explained earlier, children with CP are divided in to 5 levels as GMFCS I – V according to functional severity. Among available studies, only one included children with GMFCS level IV (Adar et al., 2017), while other studies confined to the children from GMFCS level I – III. However, none of those studies covered most severely affected children, i.e., V groups. Therefore, generalization of the current evidence on the effects of hydrotherapy to all children with CP is not reasonable.

Furthermore, there is no apparent consensus on optimal frequency and duration of hydrotherapy programs for children with CP (Dimitrijević et al., 2012). In the reported research studies that were aimed to assess the balance of children with CP, duration of the programs was ranged from 6 weeks to 6 months with one session duration of 45 to 60 minutes and a session frequency of 2 to 5 sessions per week (Adar et al., 2017; Badawy & Ibrahem,

2016; Fragala-Pinkham et al., 2009; Fragala-Pinkham et al., 2014; Thorpe et al., 2005; Zverev & Kurnikova, 2016). Nevertheless, the systematic review by Jorgić et al. (2012) that analyzed 13 studies (from 1990 to 2011) which investigated the effects of hydrotherapy program on children and adolescents with CP reported optimal conditions for a hydrotherapy program as entire program duration of 10 weeks, single session duration of 45 minutes and frequency of 3 times per week.

The intensity of exercise is also as important as the frequency and duration of exercise. However, except the study by Fragala-Pinkham, Smith, Lombard, Barlow, and O'Neil (2014) none of the above studies that focused on assessing balance of children with CP following an aquatic exercise program assessed the exercise intensity levels.

Chapter 3 Study Purpose, Objectives and Hypotheses

3.1. Study Purpose

Based on the evidence from the review of literature and due to the limited information available on the effects of hydrotherapy programs on static and dynamic balance in children with CP, this study intends to fill the knowledge gaps in rehabilitating children with CP, particularly in the context of a developing society such as Sri Lanka, where access to such therapy is limited. Thus, the purpose of this study is to examine the feasibility of a 6-week individual hydrotherapy program and its effects on static and dynamic balance in children with CP in the Sri Lankan context.

3.2. Objectives

The first step of this study was to invesitigate the feasibility of a 6-week hydrotherapy program in children with CP in the Sri Lankan context.

The second step involves investigating 4 objectives:

1. To investigate the effects of a 6-week hydrotherapy program on static balance, as assessed by PRT, in children with CP.
2. To investigate the effects of a 6-week hydrotherapy program on dynamic balance, as assessed by mTUG test, in children with CP.
3. To determine whether the effects of a 6-week hydrotherapy program on static and dynamic balance differ among children with CP of various functional levels (GMFCS I – III).
4. To investigate the effects of a 6-week hydrotherapy program on HRQOL, as assessed by 5-item VAS, in children with CP.

3.3. Hypotheses

Four objectives of this study will be addressed with following testable hypotheses.

1. Hydrotherapy will improve static balance in children with CP.
2. Hydrotherapy will improve dynamic balance in children with CP.
3. There will be a difference in the static and dynamic balance for children with CP depending on their functional severity level (GMFCS I, II, and III) following a 6-week hydrotherapy program.
4. Hydrotherapy exercise will improve HRQOL in children with CP.

Chapter 4 Methods

4.1. Ethics Approval

The protocol of this study was approved by Health Research Ethics Board (HREB), Research Ethics-Bannatyne, University of Manitoba (H2018:332) and Ethics Review Committee (ERC), University of Kelaniya, Sri Lanka (P/134/07/2018).

4.2. Study Design

This is a quasi-experimental pretest-posttest design without a control group. Assessment of outcome measures was at 2time points; once before the hydrotherapy intervention program was commenced (pre-test assessment) and once at the end of the 6-weeks intervention period but within one week of completion of the program (post-test assessment). At the end, pre-test values were compared with post-test values to evaluate the effects of hydrotherapy program.

4.3. Sample Size Calculation

Participants for this study were children with CP and their primary caregivers (all primary caregivers were parents of children) registered at the National Center for Children with Cerebral Palsy and other Developmental Disorders (NCCCPDD) in Colombo, Sri Lanka.

Although the total number of children with CP registered at NCCCPDD was roughly 50 during the time of recruitment for this study, based on the facility records, most of them were severely impaired (with GMFCS IV and V) in terms of functional abilities. Out of these

50 children, only 15 children belonged to GMFCS levels I, II, and III (mild to moderate impairment) while the rest were categorised as having GMFCS IV and V (severe impairment). The planned hydrotherapy program for this study contained tasks that were not practically possible for a child with GMFCS IV or V. For this reason, a formal sample size calculation was not used for this study with the intent of recruiting all those with GMFCS levels below IV.

4.4. Study Participants

4.4.1. Inclusion criteria

1. Diagnosis of CP
2. Age of 6 – 12years
3. Gross Motor Functional Classification System (GMFCS) levels of I, II and III
4. Ability to follow simple instructions
5. Having no medical contraindication for exercising in water

4.4.2. Exclusion criteria

1. Having a fear of being in a pool
2. Having undergone an orthopedic surgery in the preceding 6-months
3. Having active infection, or open wounds, or risk of aspiration or swallowing difficulties

4.5. Study Setting

The hydrotherapy intervention program was carried out at an institution called NCCCPDD in Colombo, Sri Lanka. This facility has an outdoor shallow therapeutic pool:

rectangular 12 × 22.5 feet with the depth ranging from 1 foot to 4 feet maximum (Appendix K) where this hydrotherapy program was implemented. For water entry and exit, this pool has a ramp and stairs. However, this pool does not have a temperature regulation system. Therefore, pool water temperature varied with the air temperature and usually this ranged from 27^{0} C to 30^{0} C during the 6-week period that this hydrotherapy program was implemented.

4.6. Recruitment and Obtaining Consent and Assent

Initially, 13 Children with CP who matched the inclusion criteria were identified through the facility via existing client records maintained by the facility**.** Then, depending on their primary language (Sinhala, Tamil or English), a package which contained a letter of invitation to participate (Appendix C), participant information sheet (Appendix D) and consent form (Appendix E) was given in a sealed envelop to take home to the primary caregiver/parent of each potential participant through the facility. Primary caregivers who were willing to participate were asked to contact the principal investigator within the next two weeks via the contact details provided. However, within the next day, 11 primary caregivers expressed willingness to involve their children in this study while 2 primary caregivers informed their inability to participate since their children were sick for some time.

Next day, a meeting was conducted for the 11 interested parents by the primary investigator with the support from the chief physiotherapist to explain the details of the study. At the end of the meeting, one parent did not want to involve her child in this study since she was concerned that this hydrotherapy program would cause exercise-induced seizures which could be potentially harmful to her child's epilepsy status. Except one parent,

all other parents gave their informed written consent on the same day. On the following day, informed consent was obtained from the remaining parent by the principal investigator. On the same day, 10 children were screened and noted that 4 of them had communication impairment. Therefore, at the end of the screening process, only 6 children met all inclusion criteria. Subsequently, all 6 of them were enrolled after obtaining the assent (Appendix F) by the principal investigator using the developmentally appropriate terms with the support from the parents and the chief physiotherapist.

4.7. Hydrotherapy Intervention Program

This hydrotherapy program was designed with pre-determined intensity ranges which were calculated using the HRR method. The intensity range of entire program was targeted to maintain within 40% – 80% of HRR with varying intensity ranges for each phase of the program. To obtain the intended intensity level, Target Heart Rate (THR) Zone; upper and lower limit of the THR range was calculated. A water-resistant Polar H10 heart rate sensor attached to a chest strap and a Polar A300 heart rate monitor wristwatch receiverwere used for heart rate monitoring and recording (Polar Electro, 2018). Additionally, Polar Beat application installed in a mobile phone was also used for heart rate recordings.

Before entering the pool, chest strap was fastened around child's chest followed by attaching the heart rate sensor to the strap and wearing the wristwatch. Just before entering the water, wristwatch was switched on. Therefore, heart rate monitoring was started while the child is still on the land. Throughout the training session, after every 5 minutes, the assistant checked the heart rate monitor to make sure that the child was exercising within the predetermined THR Zone. To maintain heart rate within the predetermined heart rate limits,

the physiotherapist and the training assistant encouraged the child to engage in pool sessions by making the event more enjoyable.

The initial plan of the study was to conduct hydrotherapy intervention sessions twice per week for 6 continuous weeks with at least 2 – 3 days maximum gap between sessions. However, to fit in with the school's schedule and to avoid children suffering from common cold entering the pool, occasionally, maximum gap between sessions varied from 1 – 7 days for some participants. During the 6 weeks period each child underwent 12 hydrotherapy sessions. Three certified physiotherapists with experience in pediatric rehabilitation conducted the hydrotherapy program. For assistance and to ensure optimal participation and safety always there was a physiotherapist in the pool with the child; 1:1 child: physiotherapist ratio.

Additionally, the principal investigator or a volunteer participated as training assistants. While waiting at the pool boundary, parents also participated in the pool activity to help children when needed. Throughout the intervention program, children wore standard life jackets and used aquatic devices such as aquatic noodle, swim ring and kickboard accordingly to facilitate aquatic exercises. During the program, whenever the participant was tired and could not continue exercising, he/she was allowed to rest for 1 – 2 minutes.

Each single session of this intervention program comprised of 3 basic components: Warm-up, aerobic exercise activities, and cool-down and stretching exercises, which were developed based on previous studies (Badawy & Ibrahem, 2016; Fragala-Pinkham et al., 2008; Fragala-Pinkham, O'Neil, & Haley, 2010; Fragala-Pinkham et al., 2014; Retareka et al., 2009). The 3 exercise components were performed in the order mentioned below.

Warm-up exercise (in waist deep water for 5 minutes at 40% – 60% intensity): This includes walking slowly on the pool floor (pool walking) in all directions, i.e., forwards, backwards and sideways while holding onto underwater parallel bars and stepping up and down on a pool step in waist deep water.

Aerobic exercises (in ankle deep to shoulder deep water for 30 minutes at 60%–80% intensity): These exercises were performed in ankle deep to shoulder deep water and include kicking, jumping, shuttle running, running, and swimming. The participant did flutter kicks while holding the kickboard at the sides near the top in prone position or participant sat on a pool stair and splashed out water as much as possible by kicking with both legs. Jumping activities were performed by jumping forward and backward and sideways in ankle deep to waist deep water. Shuttle running involved transferring pool toys such as water ducks and water balls from one side of the pool to the opposite side either by walking as fast as possible or running in waist-shoulder deep water. Running activities were performed both in waist deep water and shoulder deep water. Waist deep water running mimicked a play activity like racing a family member or an assistant who was at the pool boundary outside. For running in shoulder deep water, physiotherapist supported the participant to move forward by maintaining her/his body in the upright posture. Swimming activity was performed in waist deep to shoulder deep water and included swimming in competition with the assistant while maintaining a horizontal position with the aid of aquatic equipment and the physiotherapist.

Cool down and stretching exercises (in waist deep water for 10 minutes at 40% – 60% intensity): Same exercises performed for warm-up were repeated to cool-down.

Additionally, activities such as marching in water, arm and leg circles were performed at slow pace. Muscles or muscle groups and tendons targeted for stretching exercises varied with the individual participant's affected body structures and included internal rotators of shoulder, triceps, flexors of elbow and wrist and upper limb pronators, hamstring, quadriceps, lower limb adductors and flexors, and Achilles tendon. All stretches were performed bilaterally by the physiotherapist. Each stretch was held for 20 – 30 seconds and repeated twice. The training assistant stabilized the subject as required by the physiotherapist.

And at the end of the 45 minutes intervention program, the child left the pool and took a shower and rested in the changing room roughly for 15 minutes. During this period, each child received some candy and fruit juice.

At the end of each single-day session, saved training data in the Polar A300 heart rate monitor (wristwatch) was synced with Polar Flow web service using a password-protected personal computer of the principal investigator. Subsequently, data from Polar Flow web service was downloaded, exported and saved in a specific folder of the same computer as Microsoft Excel files.

During the study period, children were asked to undergo this new hydrotherapy program instead of the bi-weekly hydrotherapy treatment that they were receiving at the NCCCPDD. Basically, the therapy that children received at the facility was individualized according to their level of impairment and based on various hydrotherapy concepts such as

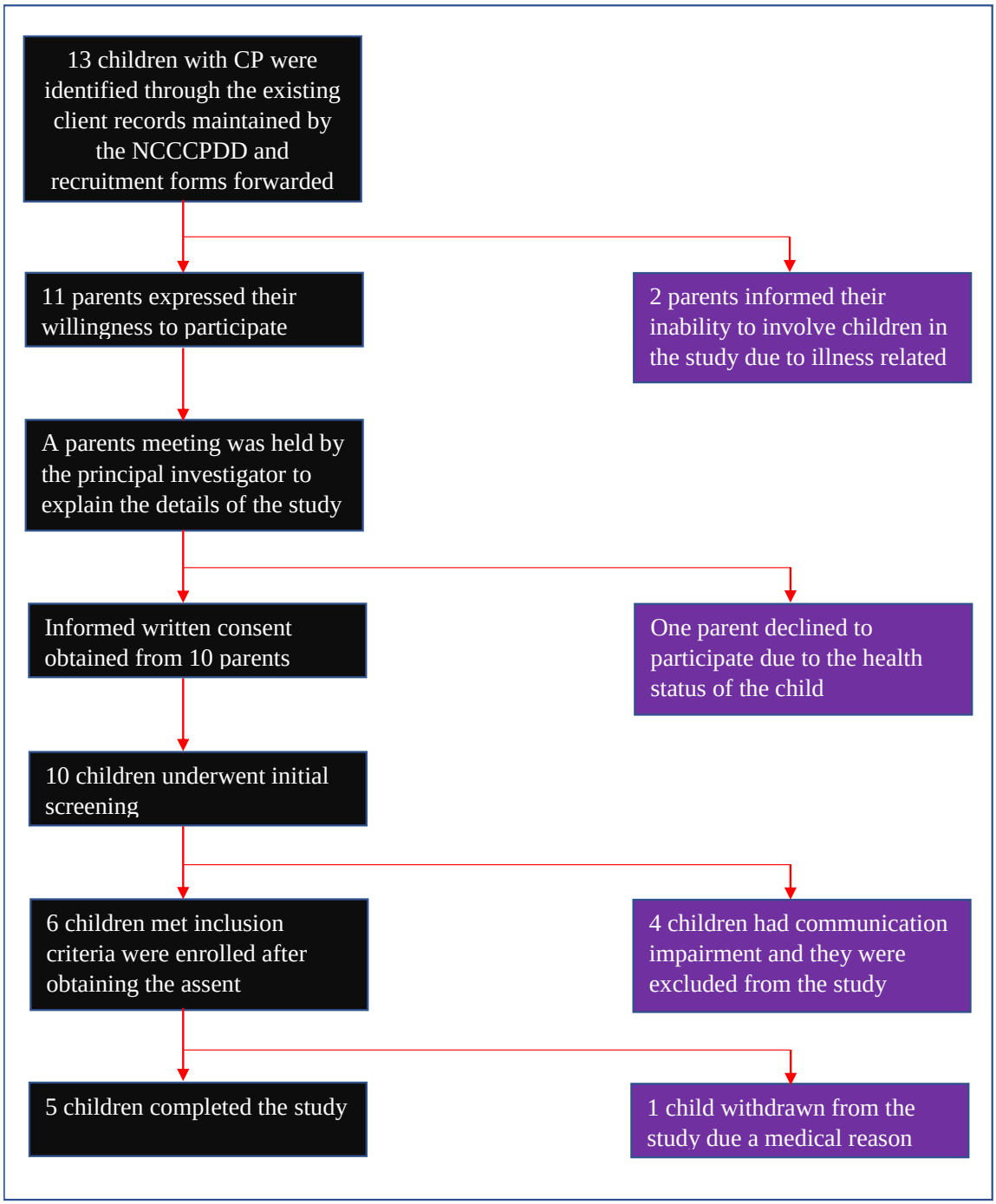

Figure 4.1 Flow chart of participants throughout the study

Halliwick method, Bad Ragaz ring method and Ai Chi. Because of this bi-weekly program at the facility, all children were used to being in pool environment. However, the regular program offered by the facility was not framed on the intensity level of aerobic exercise.

Also, participants did not receive any other land-based therapy during the study period.

4.8. Exercise Intensity of Hydrotherapy Program

According to the American College of Sports Medicine (ACSM) (2014) there are 5 ways to monitor the intensity of an exercise program: 1. Heart Rate Reserve (HRR) method 2. Heat Rate (HR) method, 3. Oxygen Uptake Reserve (VO_2R) method, 4. Oxygen Uptake (VO_2) method, and 5. Metabolic Equivalent (MET) method. In the published literature HRR method (Ballaz et al., 2011; Fragala-Pinkham et al., 2008; Retareka et al., 2009) and HR method (Fragala-Pinkham et al., 2014) have been used to assess the exercise intensity levels of children with CP during hydrotherapy programs.

HRR is obtained by deducting resting heart rate (HR_{rest}) from the maximum heart rate (HR_{max}) ($HRR = HR_{max} – HR_{rest}$) (ACSM, 2014). The best time to measure the HR_{rest} is when the subject wakes up in the morning and before leaving the bed (American Heart Association, 2019). The HR_{max} is age dependent and can be obtained by deducting the age of the subject from 220 ($HR_{max} = 220 – Age$). Therefore, HRR equation comes as; $HRR = (220 – Age) – HR_{rest}$ (ACSM, 2014).

To obtain the Target Heart Rate (THR) range for a desired intensity level of an exercise program, this HRR equation needs to be modified as below.

HRR method: $THR = [(220 – Age – HR_{rest}) \times \%\ intensity\ desired] + HR_{rest}$

Therefore, depending on the expected range of intensity level THR will have anupper limit and a lower limit; THR zone.

As defined by the ACSM, HRR between 30% – <40%, 40% – <60% and 60% –<90% are light, moderate and high intensity exercises, respectively. The centers for disease control and prevention (2019) and American Heart Association (2018) explained that children should engage in physical activity within the range of moderate to vigorous intensity for more than 60 minutes per day. According to the ACSM (2014), individuals with CP of mild to moderate functional impairment should engage in aerobic exercise programs with moderate to high intensity.

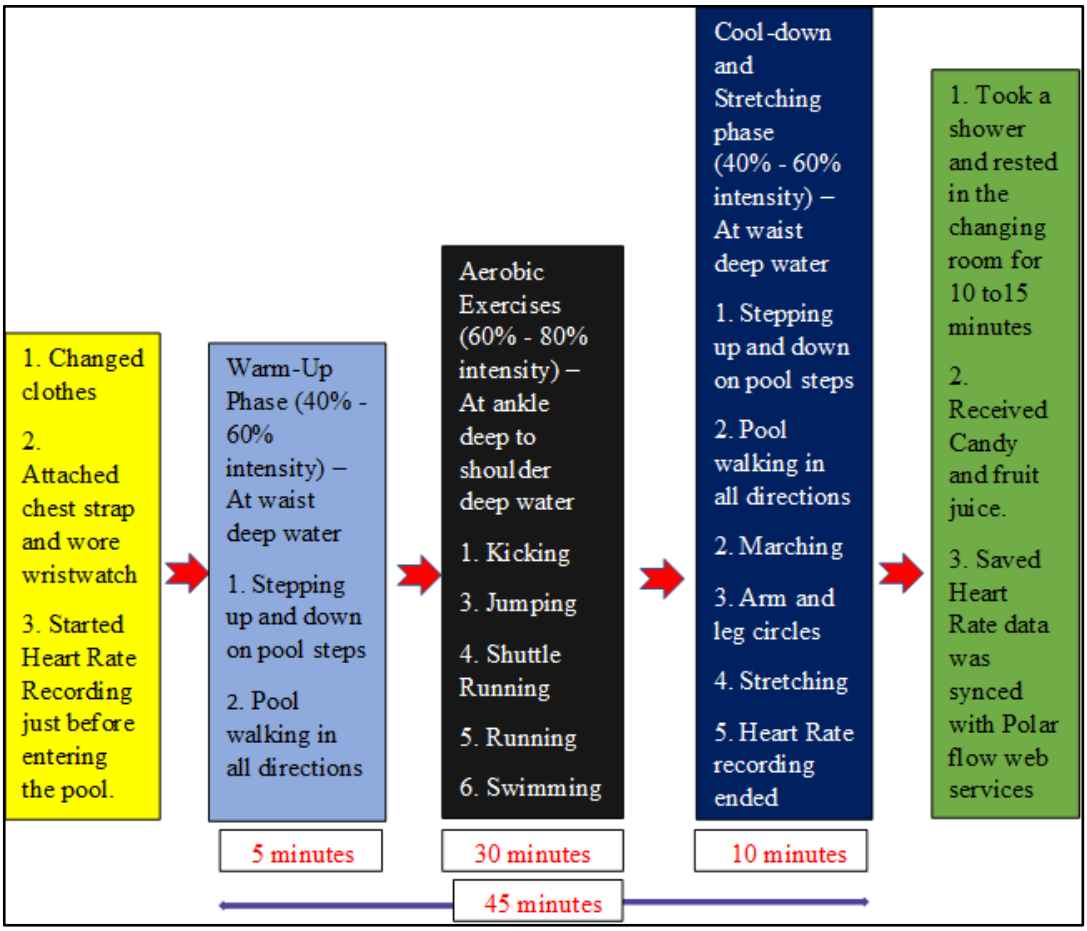

Figure 4.2 Components of a single hydrotherapy session

Therefore, considering all those factors, this hydrotherapy program was developed to achieve intensity level of 40% – 80% of HRR with different intensity ranges for the 3 phases of the intervention: warm-up (40% – 60%), aerobic exercise (60% – 80%) and cool down and stretching (40% – 60%). Hence, to obtain the intended range of intensity levels, THR Zone; upper and lower limit of the THR range was calculated (Table 5.2).

4.9. Instrumentation

4.9.1. Primary outcome measures

4.9.1.1. Pediatric Reach Test (PRT)

In 1990, Functional Reach Test (FRT), the foundation of the PRT was developed to examine the standing balance in adults (Duncan, Weiner, Chandler, &Studenski, 1990). Later, FRT was used for the pediatric population of normal development (Donahoe, Turner, & Worrell, 1994) and neurological diseases (Niznik, Turner, & Worrell, 1996) and reported as a reliable tool that can be used to evaluate balance function of children with or without neural disabilities.

FRT measures the maximum distance (starting from the level of the acromion) that an individual can reach in the forward direction (forward reaching) while maintaining the balance in standing position and keeping the base of support structure fixed (Duncan et al., 1990). In 2003, Bartlett and Birmingham expanded original FRT by incorporating another dimension that assesses subject's ability to reach maximally in lateral directions, i.e. right and left (lateral / side reaching) in both standing and sitting postures and named it as PRT, also called Pediatric Functional Reach Test (PFRT) (Kaya, Alemdaroğlu, Yılmaz, Karaduman, & Topaloğlu, 2015). The average distance that the child can reach in forward,

right lateral and left lateral directions is considered as PRT scores for each direction. Therefore, for both sitting and standing positions, PRT has 6 reaching activities, giving 6 PRT scores (Bartlett & Birmingham, 2003).

According to Bartlett and Birmingham (2003), PRT has moderate to excellent test-retest and interrater reliability for children with CP (ICC values ranged from 0.54 – 0.88 and 0.50 – 0.93 respectively). However, this study was conducted only for 10 children with CP belonging to GMFCS I, III and IV. Another study conducted for 28 children with CP from all 5 GMFCS categories (I – V) aged 2 –7 years reported excellent test-retest reliability (ICC = 0.94) and interrater reliability (ICC = 0.84) of PRT (Randall, Bartlett, & McCoy, 2014). In 2009, Katz-Leurer, Rotem, Keren, and Meyer investigated the reliability of 3 standing subcomponents of PRT: forward, left and right reach, and reported excellent intrarater reliability both in children with traumatic brain injury (ICC = 0.92 – 0.98) and normal development (ICC = 0.94 – 0.95). Later, in 2012, Rajendran, Roy, and Jeevanantham investigated reliability of standing forward reach and lateral reach (only in one direction) components of the PRT among 65 children with hearing impairment and reported excellent intrarater reliability; ICC = 0.94 – 0.98 for forward reach and ICC = 0.95 – 0.96 for lateral reach, and interrater reliability: ICC = 0.9 for forward reach and ICC = 0.97 for lateral reach.

In terms of concurrent validity of PRT, moderate to high positive correlation (r = 0.42 – 0.77) between standing component of the PRT and standing balance tests (performed on a force platform) was found. In addition, the evidence for the construct validity was demonstrated by the high correlation noted between: (a) standing component of PRT and steadiness element of force platform test (r = – 0.79) and age (r = 0.83), and (b) total score of PRT and GMFCS levels (r = – 0.88) (Bartlett & Birmingham, 2003).

In the existing literature, Minimal Detectable Change (MDC) and Minimal Clinically Important Difference (MCID) values and responsiveness of each PRT scores have not been established.

In this study, the protocol prescribed by Bartlett and Birmingham (2003) was followed to perform the PRT. Permission for using this tool was obtained from the correspondence author.

To administer the PRT, the child sat down on a wooden bench (without armrest or back rest) keeping his feet flat on the floor, with hips and knees at 90^0 and handssitting on the lap. Only if the child was able to maintain this seated position independently for 15 seconds, were the sitting components of the PRT administered. To begin the test, tip of the measuring tape was secured to the tip of the middle finger of the child's dominant hand with a piece of adhesive tape. The therapist kneeled stably behind the child facing his back. Next, child sat up straight and lifted his/her hand to 90^0 shoulder flexion and held this position for 3 seconds. After the child held this position for 3 seconds, the therapist took the first measurement; the distance between the tip of the middle finger and the acromion process. Next, child reached forward direction as far as possible aiming to touch a motivating object such as a toy held by the assistant and held the maximum distance reached for 3 seconds. Again, after child held this position for 3 seconds, the therapist took the second measurement. To obtain measurements, the therapist supported his forearm with the opposite hand. Subsequently, the difference between first and the second measurements was taken as the PRT score for the sitting-forward direction. These same steps were repeated to obtain the PRT scores for the sitting-left lateral direction and right lateral directions.

This was followed by administering the standing subsections of the PRT. For this, child stood on a sheet of paper taped to the floor, and child's footprint (in this case the footwear print) +/– contact position of the mobility aids was traced on the paper sheet taped to the floor. As for the sitting components, the next step was to check whether the child could stand independently for 15 seconds. If the child was able to stand for 15 seconds, standing components of PRT were administered as for the sitting components. This time, the therapist positioned steadily behind the child and followed the same steps mentioned above to obtain the PRT scores for the standing Forward Reach (FR), Left Lateral Reach (LLR) and Right Lateral Reach (RLR). All the participants in this study took one practice trial, followed by 3 test trials on the same day with 5 minutes break between trials.

4.9.1.2. modified Timed Up and Go (mTUG) Test

The Get-up and Go test, designed to clinically access elderly people's dynamic balance while performing tasks associated with risk of falling (Mathias et al., 1986), was the foundation for the TUG test which was developed in 1991 by Podsiadlo and Richardson. This standard TUG test was modified for children with disabilities and named as modified TUG test (also called TUG-In Children / TUG - IC) (Dhote, Khatri, &Ganvir, 2012; Williams, Carroll, Reddihough, Phillips, & Galea, 2005; Zverev & Kurnikova, 2016).

Due to the simplicity and ease of application, TUG test is being widely used in pediatrics (Nicolini-Panisson & Donadio, 2013). Moreover, the validity and the reliability of this test have been reported by many studies on children with cerebral palsy. TUG has excellent test-retest reliability (ICC = 0.99) between 5 to 12 years old children with CP (Gan et al., 2008). Similarly, mTUG test shows excellent test-retest reliability (ICC = 0.99) and

intra-class reliability (ICC = 0.99) for children with CP between 2 to 12 years old (Dhote et al., 2012). In supplement to that, in the Williams, Carroll, Reddihough, Phillips, and Galea (2005) study conducted for children with CP (n = 33) and spina bifida (n = 8), it was reported that test-retest reliability and intra-class reliability of mTUG test as ICC = 0.99 and 0.98, respectively.

In 2016, Carey, Martin, Combs-Miller, and Heathcock reported that MDC and MCID value ranges of the mTUG test for the children with CP of GMFCS I – III vary between 1.40 – 8.74 s and 0.22 – 5.31s, respectively and concluded that this test can be used as a reliable and responsive measure to evaluate the balance function of children with CP aged 3–10 years in GMFCS I – III levels. Further, some studies have reported the significant variability in the TUG scores among children with CP of GMFCS I, II and III, and that TUG score is directly proportional to the GMFCS level (Carey, Martin, Combs-Miller, &Heathcock, 2016; Dhote&Ganvir, 2013; Dhote et al., 2012). However, according to Hassani et al. (2013), TUG cannot differentiate children with CP of GMFCS I and II who are independent ambulators.

For the present study, the protocol of the mTUG test described by Williams et al. (2005) was performed to assess the dynamic balance of children with CP. Permission to use this tool was obtained from the corresponding author.

To begin the test, child sat on a seat without armrests but with a backrest. The height of the seat was considered appropriate when the child's feet were level on the ground with 90^0 knee joint flexion. Next, child was asked to stand and walk along the 3m distance marked on the floor and touch a star on the wall. Immediately after, child returned along the same path and sat down on the same seat. Time taken for this entire process was counted in seconds

and considered as mTUG test scores. One practice trial and 3 test trials were conducted on the same day with a resting period of 5 minutes between trials. Including resting periods, total time that took for these 4 test trials was approximately 30 minutes. One physiotherapist who also involved in the hydrotherapy intervention program applied the test to all children pre and post-intervention.

4.9.2. Secondary outcome measure

4.9.2.1. Visual Analogue Scale (VAS)

In children, VAS has been used to measure perceived enjoyment of physical activity (Winkels, Kottink, Temmink, Nijlant, & Buurke, 2013), emotionally distressing symptoms such as anxiety, anger, sadness, worry, fatigue and pain intensity (Sherman, Eisen, Burwinkle, & Varni, 2006) and HRQOL of children (Wehby, Naderi, Robbins, Ansley, & Damiano, 2014). Upon examining the literature, VAS is considered as a reliable and valid measure (Klimek et al., 2017). Both children self-reported version and parent-proxy reported version of VAS showed preliminary test-retest reliability, internal consistency reliability and construct validity (Sherman et al., 2006). Wehby, Naderi, Robbins, Ansley, and Damiano (2014) reported the correlation ($r = 0.67$) between VAS and Pediatric Quality of Life Inventory 4.0 (PedsQL TM) in assessing overall HRQOL in children with oral clefts. VAS has been used widely in various settings due to its simplistic nature and easy-to-use feature (Wehby, Ohsfeldt, & Murray, 2006).

The VAS is a 10cm long straight horizontal line with word anchor point of worst imaginable health (Score 0) and perfect health (Score 100) on the left and right ends, respectively. Except 0 and 100 marked either side, the line is not gauged in between. When

using VAS as a measure of HRQOL, evaluator is instructed to mark a vertical line at the point that is most representative of HRQOL of the respective subject. To measure the HRQOL as a score, the distance between the 0 and the marked vertical line on the scale is measured and divided by the full length of the scale that corresponds to 10 cm (Wehby et al., 2014; Wehby et al., 2006).

In the current study, HRQOL of children was assessed under 5 items: 1. Pain or discomfort during physical activity 2. Enjoyment of physical activity 3. Self-confidence in participating in physical activity 4. Comfort level at social settings and 5. Overall HRQOL. For each item, one VAS was used. Therefore, it was a 5-item VAS with separate scales for each item. Instead of using 10 cm long VAS described before, for this study 20 cm long VAS was used (score 0 at 0 cm and score 1 at 20 cm). Therefore, to get the final score of each item, the distance between the 0 cm and the marked vertical line on the scale was divided by 20 cm. The word anchor points of each VAS were varied depending on the item (Appendix J). For all items, a higher score indicated improvement, e.g. higher score in the VAS item 01 means reduced pain and discomfort during physical activity. Depending on the primary language, each primary caregiver was given 5-item VAS before and after the hydrotherapy program to assess their children's HRQOL. Permission for using this description of VAS was obtained from the correspondence author.

4.10. Study Procedure

At the end of the recruitment process, each child was given an identification number. Next, child's basic demographic data: age (in years), sex, height and weight and some clinical data (type of CP; whether spastic, dyskinetic or ataxic and hemiplegic, diplegic or quadriplegicand functional level according to the GMFCS classification) were recorded

from the charts available in the facility. At the same time, type and frequency of current rehabilitation treatments that children were receiving was obtained from thefacility records. During the same time period, the 5-item VAS of HRQOL of the participating children, was distributed and completed forms collected from parents.

Subsequently, child's HR_{rest} was recorded after subject had been quietly and comfortably seated for 4.5 minutes. After 4.5 minutes of resting, for the next 30 seconds 3 heart rate recordings were obtained (one recording for each 10 seconds) and then, the average of these 3 values was taken as the HR_{rest} (Ballaz et al., 2011). Next, depending on the predetermined range of intensity levels for each phase of the hydrotherapy intervention program, THR zones were calculated using the HRR method.

Next step was balance assessment. Balance was examined by a physiotherapist involved with the hydrotherapy program using two clinical tests: mTUG test and PRT test. All the children performed mTUG test first, followed by the PRT on two different days with 4 day's maximum gap between two tests. For the first test, the child was asked to stand from a sitting position and then walk for a total of 6 meter and then sit down on the same chair. The second test was conducted on a different day. During this test, the maximum distance that the child could reach in various directions in both sitting and standing positions was assessed. Each test was repeated 4 times with 5 minutes break between trials.

Thereupon, 1 – 2 days after completion of the pre-intervention balance assessment, the hydrotherapy intervention program was started and continued twice per week for 6 consecutive weeks; during the day time, with 1 – 7 day's maximum gap between each 2 sessions. Each session lasted 45 minutes. However, including the 15 minutes of resting period, single pool session took an hour to complete.

Within 5 days following completion of the program, balance was reassessed by the same physiotherapist using the same two clinical tests in the same order described above. During this period, the 5-item VAS was provided to each primary caregiver for post-intervention assessment of HRQOL of their children.

4.11. Data Analysis

Descriptive statistics (mean and standard deviation (SD)) were calculated and reported for the age, height and weight of participants and for both pre and post test scores of each primary and secondary measures. Participant-specific data were plotted on bar graphs.

For the inferential statistical analysis, 2 approaches were chosen: binomial probability distribution and paired t-test. Binomial probabilities were calculated to determine the likelihood of number of children showing improvement by chance. This method was chosen as an initial step due to the inability of the study data to meet the assumptions for parametric testing. As a second step, paired t-tests were performed to assess the magnitude of differences between pretest and posttest outcome scores.

The success or failure of the hydrotherapy program for each child was considered to follow a binomial distribution, with probability of success equal to 50%. This assumption is reasonable if one speculates an equal chance of improvement (success) or non-improvement (failure) for each child, and outcomes for each child are independent from another child.

To compare mean pre-post scores and to determine the significance of mean differences in all 3 outcome measures a paired t test was used. A Bonferroni correction was used to minimize the risk of type I error which could result from multiple paired

comparisons. This resulted in significance level (alpha) of $p < 0.05$ to reduce to $p < 0.004$ (0.05/12).

Also, effect size for each of the outcome variable was calculated to identify the magnitude of group differences and interpreted according to the Cohen's d guidelines: 0.2, 0.5, and 0.8 as small, medium, and large effects, respectively (Ferguson, 2009).

All statistical analyses were carried out with the aid of the Statistical Package for Social Sciences (SPSS), version 17.0 (SPSS Inc., Chicago, IL, USA).

However, due to the inadequacy of the sample size leading to very limited number of children participated from each 3 categories of GMFCS levels (two participants from GMFCS level I and II, and 3 participants from GMFCS level III), a comparison of pre- post test score differences of static and dynamic balance measures by GMFCS levels of participants were not carried out.

Chapter 5 Results

5.1. Demographic and Clinical Data Description

Basic demographic and clinical information of individual participants are shown in Table5.1. Though 6 children with CP were recruited initially (as represented in the flow chart of the participants (Figure 4.1), only 5 children (age: 9.6 ± 1.3 years (mean ± SD), height: 122 ± 6.3 cm, weight: 24 ± 8.1 kg), with male to female ratio of 4:1, completed the hydrotherapy program.

Table 5.1

Demographic and Clinical Information of the Participants

Case No	1	2	3	4	5
Age (years and months)	9y 4m	9y 5m	7y 8m	11y 2m	10y 4m
Gender	Male	Male	Male	Male	Female
Height (cm)	132	116	119	124	119
Weight (kg)	20	17.5	38	22	22
GMFCS Level	I	II	III	III	III
BMI (kg/m^2)	11.5	13	27	14.3	15.5
Types of CP	Dyskinetic	Dyskinetic	Spastic Diplegic	Spastic Diplegic	Spastic Diplegic
Ambulation	Independent	Independent	Walker	Walker	Walker

5.2. Training Intensity of the Hydrotherapy Program

Heart rate was used to define the exercise intensity of this program. Although it was planned to collect 12 heart rate recordings per participant during the period of 6-weeks, which comes as 60 recordings per all 5 participants, only 45 recordings were able to be collected despite 100% attendance. While the minimum number of successful recordings obtained from a single participant were 8, the maximum number of successful recordings were 11 (Table 5.2). Some heart rate data was incomplete due to some technical and feasibility issues. Even though the smallest chest strap available was used, it fitted properly only to a single child. Therefore, for each session, the length of the chest strap was adjusted using some cloth bands to suit them individually. Since none of theses children had chest wall deformities, shortening the strap resolved this problem. However, since children were wearing life jackets on top of the chest strap and using flotation devices, in certain times, these caused displacement of the chest strap or interfered with heart rate recordings. Occasionally, children pressed the wristwatch recording buttons which resulted in losing some heart rate data.

Average exercising heart rate and intensity level achieved during the 6-week hydrotherapy program are plotted in Figure 5.1 and 5.2, respectively.

Generally, throughout all sessions, all 5 children exercised within light intensity (>30% – <40% of HRR) to moderate intensity (>40% – <60% of HRR) range with an average intensity level of 43% of HRR for a period of 50 minutes (Figure 5.2). For the warm-up, aerobic exercise and cool down and stretching phases, the performing average intensity levels were 40%, 47% and 41% of HRR, respectively.

Table 5.2

Heart Rate Data of Individual Participant

Case No	1	2	3	4	5
Number of heart rate recoding per participant (out of 12 total recordings)	10	8	9	8	11
Average HR_{rest} (bpm)	80	81	83	86	81
THR Zone (bpm) for each phase of the program					
Warm-up (40% – 60% intensity)	133-159	135-157	135-161	135-160	133-158
Aerobic exercise (60% – 80% intensity)	159-186	157-186	161-187	160-184	158-184
Cool-down and stretching (40% – 60% intensity)	133-159	135-157	135-161	135-160	133-158
Average HR (bpm) achieved during each phase of the program					
Warm-up	134	151	122	121	137
Aerobic exercise	142	153	133	133	152
Cool-down and stretching	136	144	127	123	143
Average HR intensity achieved across all 3 phases of the program	137	149	127	126	144
Average exercise intensity (as a % of HRR) achieved during each phase of the program					
Warm –up	42%	54%	30%	29%	44%
Aerobic exercise	48%	56%	39%	39%	55%
Cool-down and stretching	38%	44%	31%	28%	44%
Average exercise intensity (as a % of HRR) achieved across all 3 phases of the program	44%	52%	36%	34%	50%
Time spent (minutes) at different intensity levels across all 3 phases of the Program					
Light	10	5	35	30	10
Moderate	40	45	15	20	40
High	0	0	0	0	0

Note.HR_{rest}: Resting Heart Rate, THR: Target Heart Rate

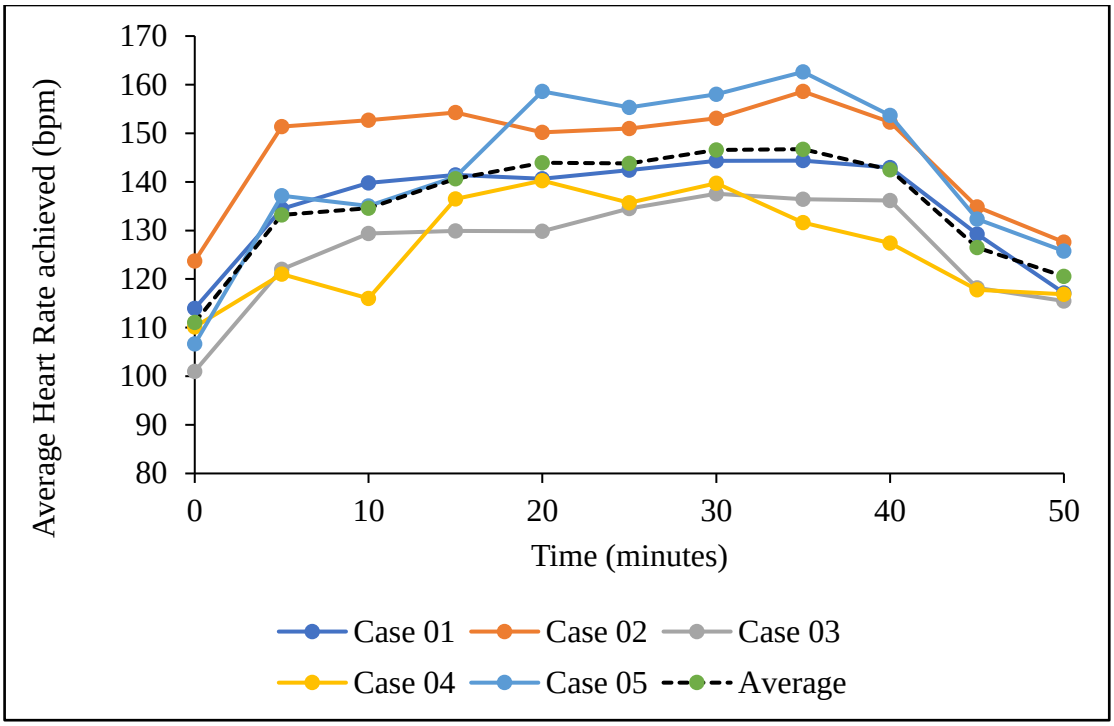

Figure 5.1 Exercising heart rate during the hydrotherapy program

5.3. Outcome Measures

Following completion of a 6-week hydrotherapy program, regardless of the outcome measure used, all 5 children showed some improvement (success) (Figure 5.3 – 5.14). The probability of achieving 5 successes among the 5 children is $(0.5)^5 = 0.031$. Thus, the 5 successes of the hydrotherapy program are quite unlikely ($p < 0.05$) to occur by chance.

5.3.1. Primary outcome measures

5.3.1.1. PRT

Post intervention distance reached in all directions: Forward Reach (FR), Left Lateral Reach (LLR), and Right Lateral Reach (RLR) in both the sitting and standing position showed an improvement. And, for all paired comparisons, except forward reach distance when sitting (p=0.015), all other components of the PRT showed statistical significance

where p value is < 0. 004. Table 5.3 represents mean difference, mean standard deviation, 95% CI, p value and effect size for each section of the PRT. Table 5.4 shows the percentage of relative change, i.e., pre and post score difference divided by pre-score for PRT.

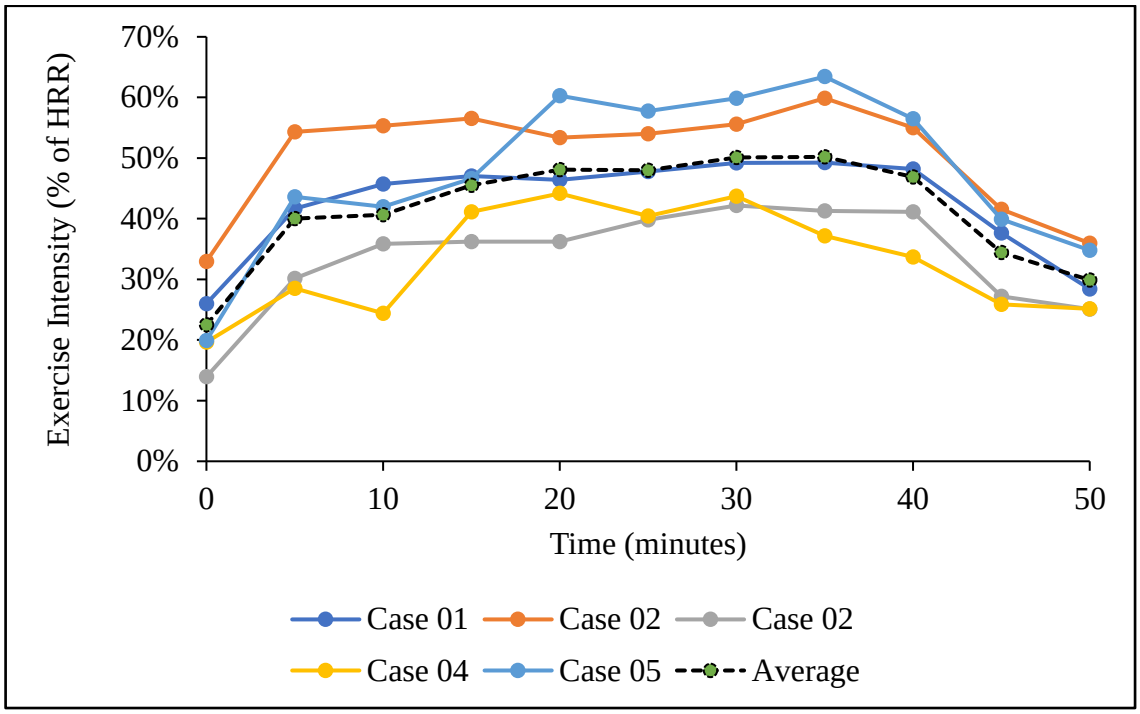

Figure 5.2 Exercise intensity during the hydrotherapy program

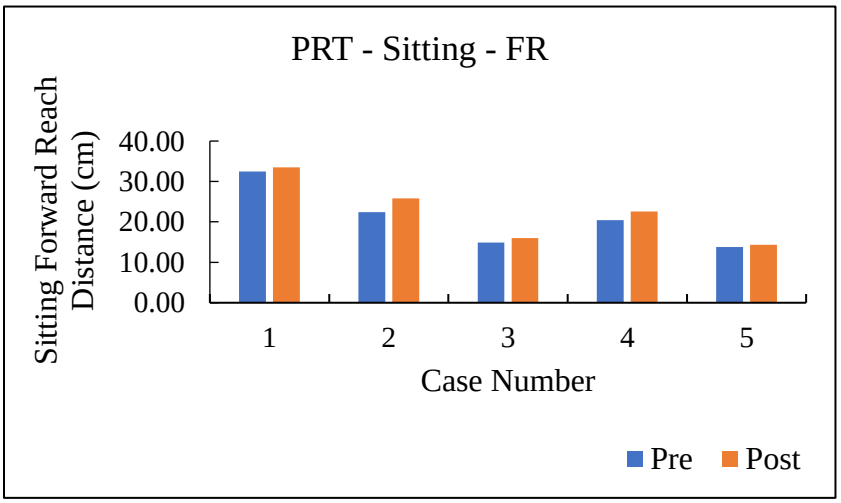

Figure 5.3 Pretest and post-test comparison of sitting -FR component of PRT

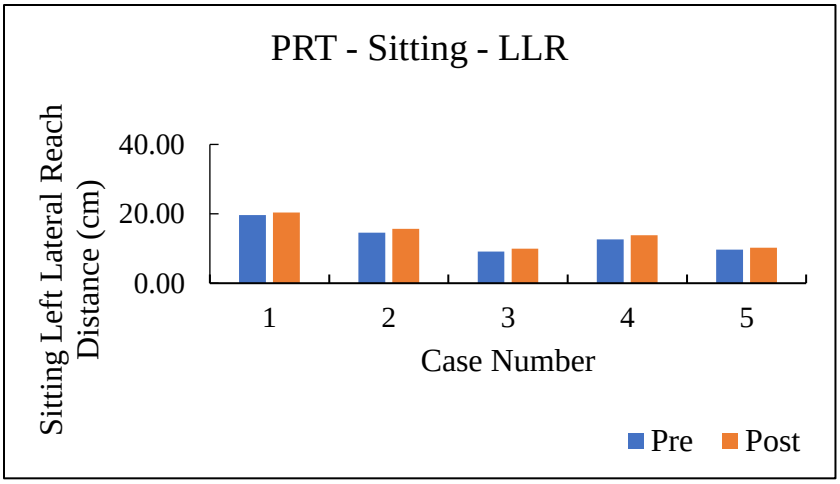

Figure 5.4 Pretest and post-test comparison of sitting - LLR component of PRT

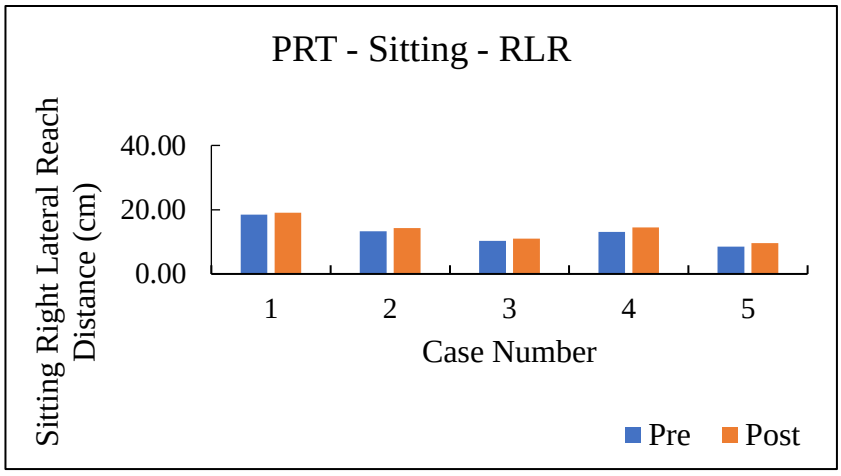

Figure 5.5 Pretest and post-test comparison of sitting - RLR component of PRT

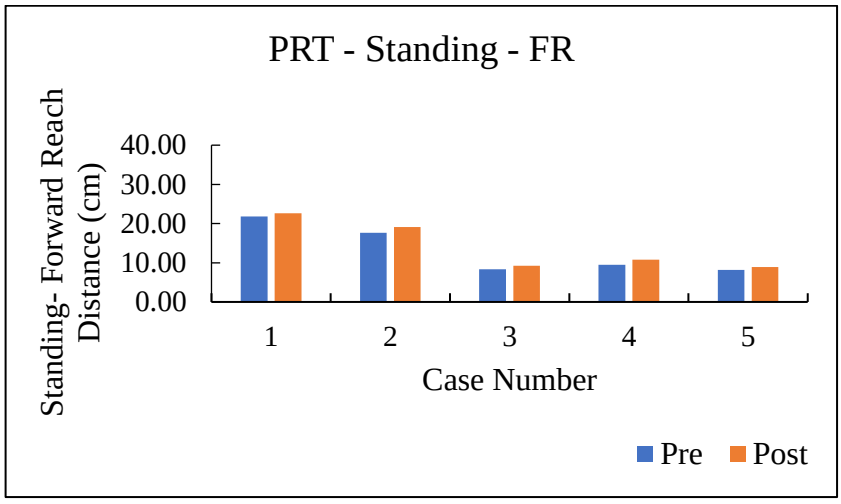

Figure 5.6 Pretest and post-test comparison of standing -FR component of PRT

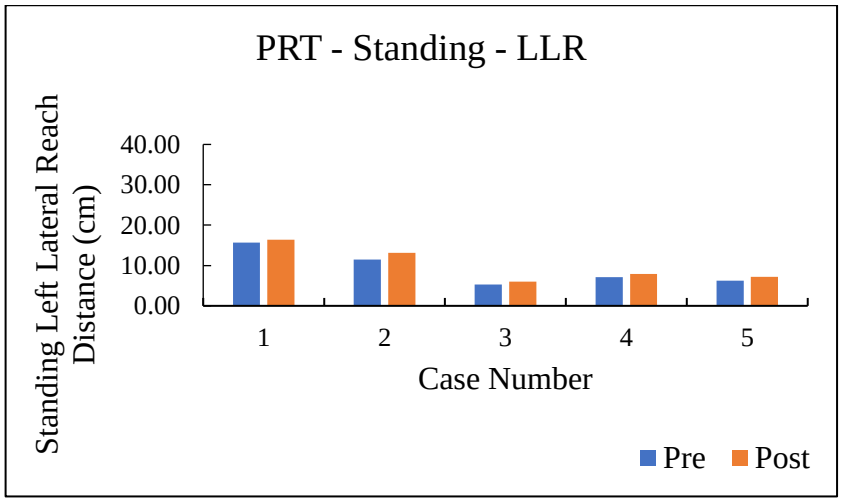

Figure 5.7 Pretest and post-test comparison of standing -LLR component of PRT

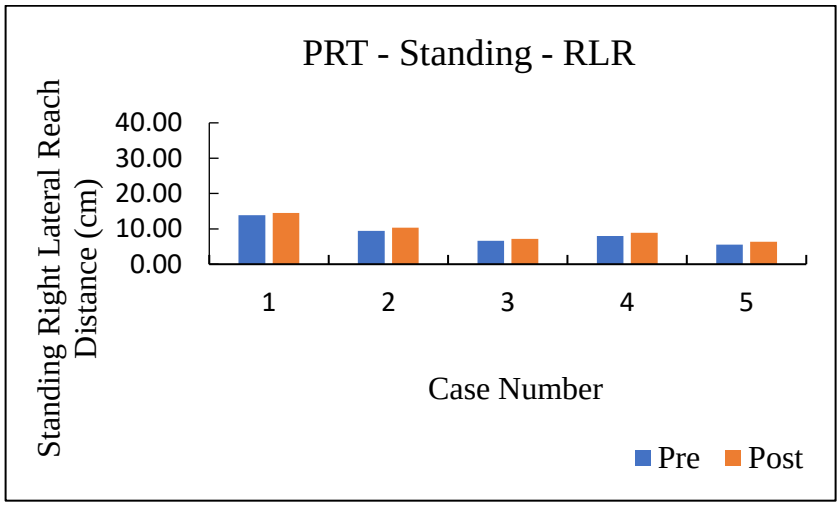

Figure 5.8 Pretest and post-test comparison of standing -RLR component of PRT

5.3.1.2. mTUG

With reference to mTUG test, results showed time to complete this test before the intervention (39.5 ±28.88; mean ± SD) was reduced (i.e., improved) after the intervention (30.91 ±23.05) (Figure 5.9). However, a paired t-test revealed (Table 5.3) that mean pre-post difference of mTUG test was not statistically different from zero (p = 0.07, effect size = 0.81, 95% CI = – 4.57 to 21.92). Table 5.4 shows the percentage of relative change, i.e., pre and post score difference divided by pre-score for mTUG test.

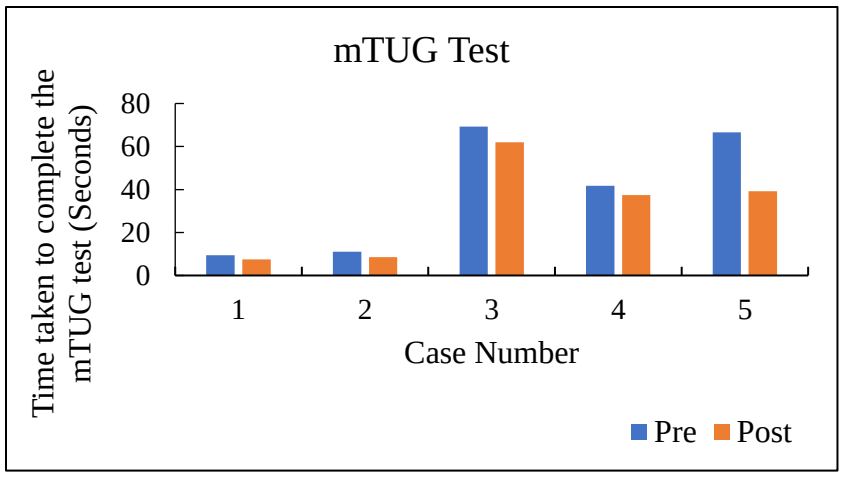

Figure 5.9 Pretest and post-test comparison of mTUG test

Table 5.3

Paired Sample t-test Results for mTUG test and PRT

Paired Sample Test									
	Paired Differences								
				95% CI of the Difference					
Variable	Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t value	df	Significance(1-tailed)	Effect size
mTUG Pre and Post	8.68	10.67	4.77	-4.57	21.92	1.819	4	0.0715	0.8
PRT-Sitting FR Pre and Post	-1.66	1.12	0.50	-3.05	-0.27	-3.304	4	0.0150	1.5
PRT-Sitting LLR Pre and Post	-0.89	0.29	0.13	-1.26	-0.53	-6.809	4	0.0012*	3.0
PRT-Sitting RLR Pre and Post	-0.94	0.31	0.14	-1.33	-0.55	-6.687	4	0.0013*	3.0
PRT-Standing FR Pre and Post	-1.03	0.33	0.15	-1.44	-0.62	-6.986	4	0.0011*	3.1
PRT-Standing LLR Pre and Post	-0.95	0.41	0.18	-1.47	-0.44	-5.182	4	0.0033*	2.3
PRT-Standing RLR Pre and Post	-0.76	0.15	0.07	-0.95	-0.57	-11.087	4	0.0002*	4.9

Note. *Statistically significant (Bonferroni corrected α level is $p < 0.004$). Units for the mTUG test is in seconds and for the PRT is in centimeters (cm).

In terms of GMFCS level, both before and after the intervention, 2 children with GMFCS I and II (independent ambulation) spent the least time to complete the mTUG test than the other 3 children with GMFCS III (walker-dependent ambulation) who showed substantial variability in their timing.

Table 5.4

Percentage of Relative Change for mTUG Test and PRT

% of Relative Change				
			95% CI	
Variable	Mean	SD	Lower Limit	Upper Limit
mTUG	20.8	12.72	5.01	36.59
PRT - Sitting – FR	6.0	5.48	-0.8	12.8
PRT - Sitting – LLR	7.2	2.59	4	10.41
PRT - Sitting – RLR	8.0	3.61	3.52	12.48
PRT - Standing – FR	9.2	3.7	4.6	13.8
PRT - Standing – LLR	11.8	4.66	6.02	17.58
PRT - Standing – RLR	9.8	3.42	5.55	14.05

Overall, during both pre and post intervention, 2 children with GMFCS I and II showed lower mTUG test scores than those 3 children with GMFCS III.

4.3.2. Secondary outcome measure

4.3.2.1. *VAS*

For all the participants across all 5 items (pain and discomfort during physical activity, enjoyment of physical activity, self-confidence in participating in physical activity, comfort level at social setting and overall HRQOL), pre-post comparison of mean VAS scores showed improvement following the 6-week hydrotherapy program (Figure 5.10 – 5.14).

However, paired t test results demonstrate that mean pre-post differences of 5-item VAS has no statistical significance ($p > 0.004$). Table 5.5 represents mean difference, mean standard deviation, 95% CI, p value and effect size for each item of the VAS.

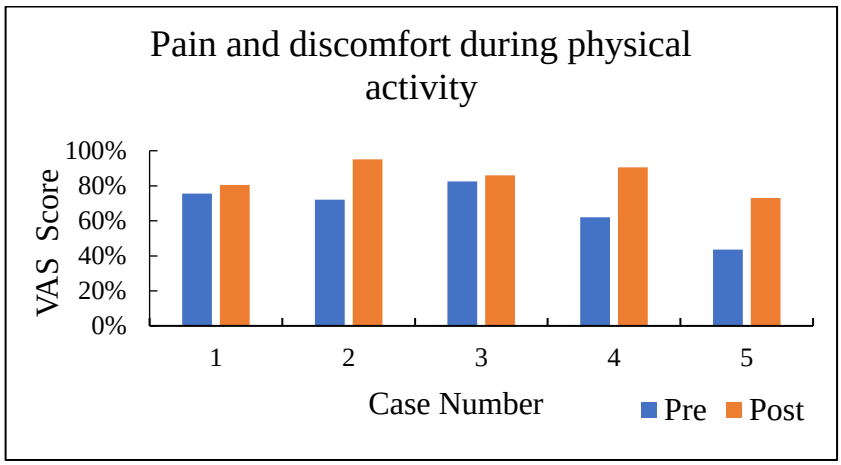

Figure 5.10 Pretest and post-test comparison of pain and discomfort during physical activity (High score indicates less pain and discomfort)

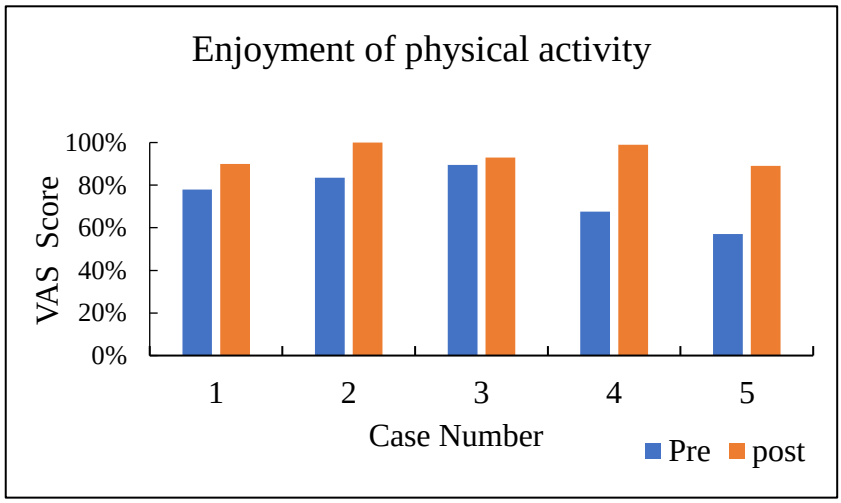

Figure 5.11 Pretest and post-test comparison of enjoyment of physical activity (High score indicates increased enjoyment)

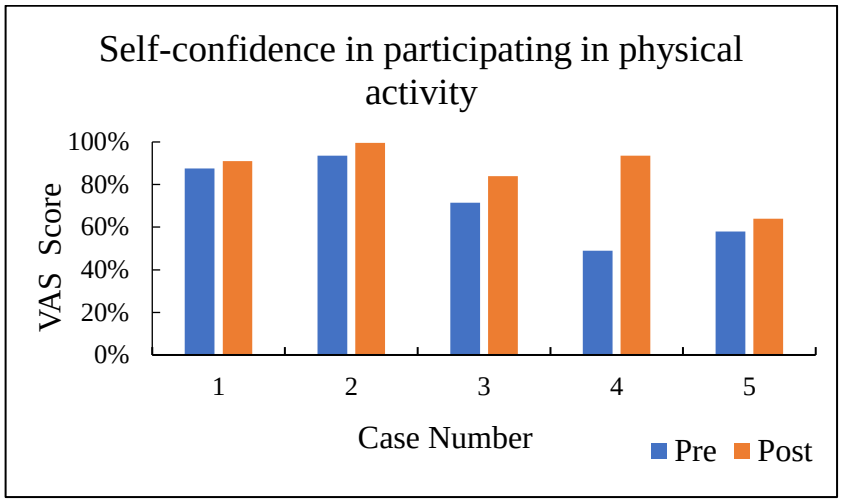

Figure 5.12 Pretest and post-test comparison of self-confidence in participating in physical activity (High score indicates improved self-confidence)

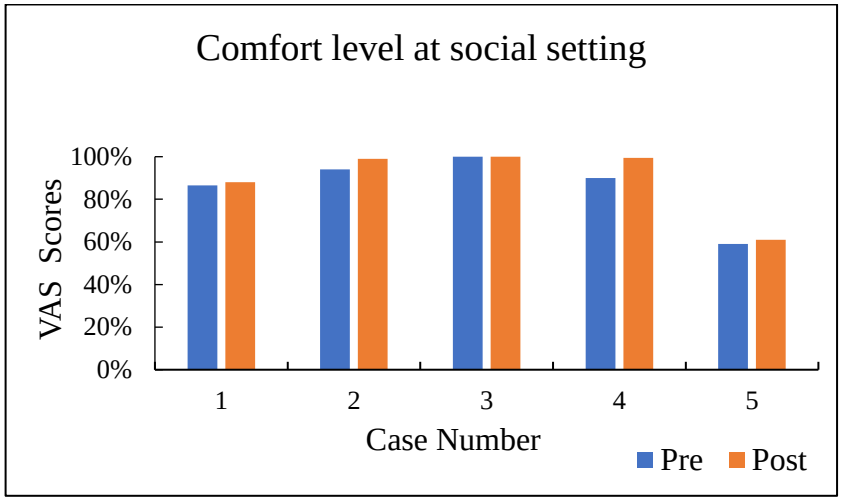

Figure 5.13 Pretest and post-test comparison of comfort level at social setting (High score indicates improved comfort level)

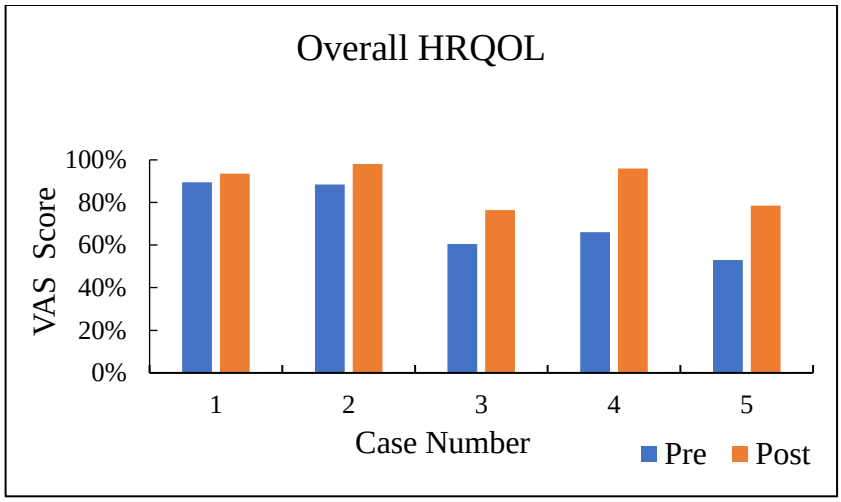

Figure 5.14 Pretest and post-test comparison of overall HRQOL (High score indicates improved overall health)

Table 5.5

Paired sample t-test Results for 5-item VAS

Paired Sample Tests									
	Paired Differences								
				95% CI of the Difference					
Variable	Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t value	df	Significance (1-tailed)	Effect Size
Pain and discomfort Pre – Post	-18%	0.13	0.06	-0.34	-0.02	-3.097	4	0.018	1.4
Enjoyment Pre – Post	-19%	0.12	0.06	-0.35	-0.04	-3.429	4	0.0135	1.5
Self-confidence Pre – Post	-14%	0.17	0.08	-0.36	0.07	-1.849	4	0.069	0.8
Comfort level Pre – Post	-04%	0.04	0.02	-0.09	0.01	-1.994	4	0.0585	1.0
Overall HRQOL Pre – Post	-17%	0.11	0.05	-0.31	-0.03	-3.456	4	0.013	1.6

Note: Means are in percentage.

5.4. Safety/ Adverse effects

None of the children or parents complained of any physical pain, discomfort or injuries during the study period. Three participants started drinking pool water from the first session and for them, throughout all sessions, repeated reminders were needed to prevent this happening. Two children developed common cold during the intervention period and refrained from entering the pool for 1 week.

Chapter 6 Discussion

The goal of this study was to investigate the feasibility of a 6-week aerobic exercise-based hydrotherapy program and its effects on static and dynamic balance in children with CP in Sri Lanka. Good feasibility was demonstrated through consistent achievement of target exercise intensities throughout this program. Specifically, all 5 participants were able to achieve and maintain a meaningful heart rate (30% – 60% of HRR with an average intensity level of 43%) during the intervention period of 45 minutes for 6 weeks. Following completion of the program, all 5 children showed improvement in all 3 outcome measures used irrespective of their statistical significance. Regarding the PRT, except forward reach distance when sitting, all other 5 components showed improvement with statistical significance denoting improved static balance. However, the mTUG test used to assess the dynamic balance did not show statistically significant improvement even though there was a positive trend towards improvement. Moreover, all the participants showed improvement in the 5-item VAS used to evaluate the HRQOL, but the findings were not statistically significant.

This study gives evidence for the feasibility of a 6-week hydrotherapy program in children with CP of mild to moderate functional impairment in Sri Lankan context. Primary support for feasibility is taken from the HR data collected during the exercise. The observation that participants maintained an exercise intensity of 30% – 60% of HRR throughout the 6-week program indicated that the children could be suitably engaged in the exercises. Excluding the warm-up and cool-down phases, children achieved 47% intensity level during the aerobic phase of the intervention. Also, no consistent drop-off in HR was

seen from first to last session indicating exercises were suitably progressed and the children's interest was maintained.

The training intensity plays a critical role in any aerobic exercise program whether it is land-based or water-based. American College of Sports Medicine (2014) recommends moderate to high intensity aerobic exercise for individuals with mild to moderate physical impairments. In the present study, to achieve and maintain moderate to high training intensity levels, children performed aerobic exercises (walking, running, jumping, and swimming) at a relatively fast speed with the supports received from the physiotherapists, assistant and parents. This increased speed exaggerated the already existing natural resistance to move in the water (Retarekar et al., 2009) making aquatic performance more challengeable. However, children of the current study couldn't achieve the high intensity levels but maintained their average training intensity at moderate levels. This suggests that these children received a good dose of aerobic exercises during this 6-week period. As noted previously in the literature section, among 6 available studies that assessed balance in children with CP following a hydrotherapy program, only one study (Fragala-Pinkham et al., 2014), focused on evaluating the exercise intensity level, and it used the HR method instead of HRR method as in the present study. In that study, which included 8 children with CP (GMFCS I and III), reliable heart rate data was available only for 5 children, and according to those available data, 4 out of 5 participants of the study performed at or above the THR, (i. e., 70% to 80% of HR_{max} determined using the Shuttle Run Test) for more than 20 minutes during the total session duration of 60 minutes. This, and the current study support the use of hydrotherapy in terms of achieving a good exercise intensity level especially for children with disabilities, like CP.

Additional support for the feasibility of the intervention can be discussed from several observations. The intervention program was considered desirable based on the strong interest in the program given the high response rate to initial delivery of the information package to parents. Also, the 100% attendance and good compliance evidenced by the achieved exercise intensity levels denote that the intervention was engaging for participants. Lastly, the hydrotherapy program was perceived as beneficial based on both children's and parents' interest in continuing therapy. Parents anecdotally reported that their children vastly preferred exercising in the pool compared to exercising on land. Even at the end of the 6-week program, none of the parents or children wanted to discontinue it, and even 3 parents started to find alternatives to continue hydrotherapy for their children.

Aside from feasibility, this study also sought to collect preliminary data regarding the effectiveness of the hydrotherapy program to improve balance outcomes. Static balance was assessed using the PRT, and all children showed some improvement for all 6 components of the test with varying degrees of relative change (Table 5.4). Further, all the components of the test except sitting forward component demonstrated statistical significance ($p < 0.004$). In the available literature, there were no published studies reported to have used the PRT for assessing the balance of children following hydrotherapy programs except a PhD dissertation carried out in Seoul, South Korea (Jeon, 2013). It was based on the Halliwick concept of hydrotherapy and included 10 children with CP (GMFCS II – IV) aged 4 to 10 years and was conducted for 6 weeks. However, instead of 6 components of the PRT, that study used only the 3 sitting components of the test (forward, left and right reach when sitting) and reported improvement ($p < 0.05$) following the intervention which is consistent with the current study.

Due to the scarcity of using PRT in hydrotherapy studies, comparison of findings of the current study with other studies is limited. In the available literature, 2 hydrotherapy studies have used FRT which was carried out while the subject is standing and is similar to the forward reach components of the PRT when standing. The first study by Thorpe et al. (2005) conducted a10-week aquatic exercise program for 7 children with CP (6 with spastic diplegia and 1 with spastic hemiplegia belonging to GMFCS I to III levels and aged 7 to 13years) and reported improvement in FRT in 4 out of 6 children evaluated. The second study, a case series by Fragala-Pinkham et al. (2009) applied FRT to a single child with CP (GMFCS I) and reported clinically significant improvement after a 6-week hydrotherapy program.

Non-hydrotherapy studies have also use the PRT to assess balance. One such study is a RCT (n = 60 with each group having 30 children aged 3 to 8 years) that has used PRT to assess sitting balance following a 9 months of postural training compared to conventional therapy in children with spastic diplegic CP (Dixit, Senapati, & Kumar, 2018). Since this study focused on sitting balance, only the 3 sitting subcomponents of the PRT were used. A total score for sitting balance was also obtained by adding PRT scores of each sitting subcomponent. The results of that study revealed statistically significant improvement in PRT scores in both experimental and conventional therapy groups ($p < 0.004$ and $p < 0.014$, respectively). Another non-hydrotherapy study, an 8-week virtual reality-based video-game system conducted to examine the psychomotor status of children with CP, reported using PRT as a balance assessment tool. PRT results of that study showed a statistically significant increase in forward movements of the center of gravity ($p=0.003$) (Luna-Oliva et al., 2013). Another study, a RCT that was carried out by Pin and Butler (2019) to investigate the sitting

balance of children with CP of moderate to severe functional impairment (GMFCS III and IV) used the PRT following a 6-week interactive computer-based training. According to that study, sitting balance of both the experimental and control group was improved as indicated by increased PRT scores that were assessed by a single blinded accessor. Therefore, it is seen that some studies have used only the sitting component of the PRT (as mentioned above) while some other studies used only the standing components. For example, Rajendran, Roy, and Jeevanantham (2012) used forward and lateral standing components of PRT for children with hearing impairment to investigate the effectiveness of a 6-week vestibular specific neuromuscular training and reported statistically significant improvement ($p = 0.001$) in the experimental group. Collectively, these studies provide evidence that the PRT can be used to assess balance function in response to various interventions.

Dynamic balance was assessed using the mTUG test. All 5 participants showed an improvement with a mean reduction of 8.7 seconds to complete the test. Although absolute times varied widely across GMFCS levels, the mean relative reduction in time was 21% ± 13% (mean ± SD). Moreover, even though TUG test and mTUG test are slightly different, the mTUG test results of this study are in accordance with the 10-week hydrotherapy study ($n = 7$) conducted by Thorpe et al. (2005). In that study Thorpe et al. (2005) found improvement in TUG test of all the participants ($P < 0.02$). Another study demonstrated improved TUG test ($p < 0.000$) following completion of a 24-week hydrotherapy program which included mainly swimming and some balance-based aquatic exercises (Zverev & Kurnikova, 2016). However, according to the 6-week RCT that had 32 children with CP from GMFCS I to IV levels, both the experimental group and the control group showed significant improvement in TUG scores (13% ± 14% Vs 16% ± 13%, respectively), but no

statistically significant difference between the groups (Adar et al., 2017). Therefore, although the mean difference of pre-post mTUG test scores is not statistically significant in the current study, the large effect size and the percentage of relative change (21% ± 13%) may suggest that the present hydrotherapy intervention program was able to improve the dynamic balance of children with CP.

The improvement gained by all the participants in all 5-item VAS measures suggested that this hydrotherapy exercise program also improved the HRQOL of the children. Water provides a desirable environment to perform motor activities (Adar et al., 2017) due to its physical properties, and therefore what a child feels physically as well as mentally while in the water is quite different from what he or she feels on the land. For example, engaging in physical activities in water increases the level of confidence an individual has in performing more physically challenging tasks (Fragala-Pinkham et al., 2009). Additionally, performing exercises aerobically and at higher intensity levels is easier in the water than on the land, and this is a result of the desirable environment that water creates for patients by reducing the loads on joints. Further, the fun environment that water activities can create enhances the motivation as well as interest (Retarekar et al., 2009) which play a crucial role for children with CP. (32). Ultimately, all these factors might have contributed to the improved HRQOL in children with CP.

An important consideration of this study is the use of water-based aerobic exercise to improve balance in children with CP. Specifically, aerobic exercises that did not incorporate components intended to develop balance skills directly.

Although limited, the current literature reports two hydrotherapy studies that used water-based balance training activities to improve balance in children with CP. One of those

showed significant improvement in dynamic balance, as measured by Biodex balance system, following the balance specific hydrotherapy program (Badawy & Ibrahem, 2016). Similarly, the second study that implemented balance training-based water activities reported improved balance as assessed by 3 tests namely PBS, TUG test, and TUDS test (Zverev & Kurnikova, 2016). However, it should be noted that those studies included some aerobic exercise components such as water walking, running, and swimming. Thus, separating effects due to balance verses aerobic components can be challenging. The question of whether water-based aerobic exercise without specific balance components improve balance in this population of children has been addressed in 3 prior hydrotherapy studies, all of which reported positive effects. Fragala-Pinkham et al. (2014) reported improved PBS outcome ($p < 0.005$), and Thorpe et al. (2005) and Adar et al. (2017) reported improved TUG test scores ($p < 0.02$ and $p < 0.001$, respectively). The aerobic exercise component of those studies consisted of water activities such as pool walking, running, kicking, jumping and swimming. Thus, to the extent that balance is required to perform any given aerobic activity, the aerobic activity can serve to challenge and improve balance.

Further, evidence that concurrent balance improvement can be seen with aerobic water exercise is available in the adult population. To evaluate balance in the elderly, Kaneda, Sato, Wakabayashi, Hanai, and Nomura (2008) implemented a 12-week aquatic program which included different water exercises: water-walking (forward, backward and sideways), kicking and deep water running which were similar to those of current study. They reported improvement in both static and dynamic balance as measured by postural-sway test (postural-sway distance and postural sway area were measured) and Tandem-walking time, respectively. Bigongiari et al. (2018) also investigated aerobic gait training by comparing

walking in deep water verses walking on a treadmill in 2 groups of patients with stroke and reported that gait training in water improved knee joint position sense and suggested it as an important rehabilitation mode for developing postural stability. In Australia, Merom et al. (2014) studied the association between common sports activities and rate of falls in older men. Their results revealed improved static and dynamic balance as indicated by reduced postural sway and improved timing in narrow walk test (walking a 6-meter distance), respectively, among the group of swimmers compared to the group who underwent just lifestyle physical activities and concluded that falls may be prevented by swimming. Further, they reported that swimming strengthens the core muscles of the body and this may result in lowering postural sway and subsequent improved balance. Therefore, results of these studies support the fact that aquatic aerobic exercise can improve the balance in humans.

6.1. Study Limitations

The findings of this study are limited by several potential factors that can be categorized as primary and secondary limitations. While major primary limitations include lack of a control group, lack of random assignment, small sample size and lack of blinding leading different types of possible bias, secondary limitations are due to participant attributes, time constraints leading to low frequency (twice per week) and short duration of the study (6 weeks), absence of gold standard laboratory measures for accurate balance evaluation, using VAS that was newly developed and not validated, and lack of a follow – up assessment.

As mentioned under the sample size calculation of the methodology section, most children with CP at the NCCCPDD had severe impairments. Among those children with

mild to moderate impairment, most of them did not match with the inclusion criteria. This created a situation where a limited population was available for sampling and having a control group or random sampling was not practical. In the literature, this common limitation is evident in many other hydrotherapy studies conducted for children with CP (Ballaz et al., 2011; Fragala-Pinkham et al., 2014; Thorpe et al., 2005; Zverev & Kurnikova, 2016). Further, the small sample size and that the sample was not population-based, i.e., convenience sample (children who had enrolled in the NCCCPDD), means that the results of this study cannot be generalized to the universal population of children with CP.Lastly, children with CP are not alike and represent a group of children with marked heterogeneity though they are categorised into similar groups by GMFCS classification. i. e., every single child with CP is unique and making it difficult to compare to another child with CP who even has approximately similar characteristics. Therefore, due to this reason and sample size being very small (n = 5) which resulted in having markedly limited number of children for each GMFCS group, the results of this study may not be representative of a given GMFCS level.

Three physiotherapists conducted the hydrotherapy intervention sessions and one of them assessed all the children for pre and post-intervention balance measures. There was no blinding in this study and both participants (children and parents of those children) and therapists knew to which category they belonged. Therefore, results of two balance measures and VAS are at risk of detection bias. Additionally, these positive results of VAS may have been influenced by knowledge and expectation bias (Renjith, 2017), and acquiescence bias, a type of response bias that occurs due to respondents (in this case parents) trying to please

the researcher by providing positive answers to the all the survey questions (Knowles & Nathan, 1997).

As mentioned previously in the literature section of this study, the systematic review by Jorgić et al. (2012) reported optimal conditions for a hydrotherapy program as entire intervention duration of 10 weeks, single session duration of 45 minutes and frequency of 3 times per week. However, the current program was conducted for a total duration of 6 weeks with a frequency of 2 sessions per week and each session lasted for 45 minutes. These time limits were based on several feasibility issues. As implied by the name, the NCCCPDD where this study was conducted is a school for more than 100 children with various forms of disabilities including CP, Down syndrome and autism spectrum disorders. According to the school schedule, each child undergoes hydrotherapy once in two weeks for 20 minutes. This regular time duration limits are a result of having had to give equal opportunities for all the children studying at the institution. Therefore, conducting this current study for more than 6-weeks was practically not possible due to time constraints. Additionally, the total number of physiotherapists available at the time of the study duration was three which also limited the study-time. Further, very occasionally, the gap between pool sessions was 1 – 7 days, and one reason for this was that the facility had a fixed school schedule due to which incorporating sessions in between or increasing the gap between sessions were not practically possible due to limited physiotherapy time and the inability to have the program going on after school (after 1 pm) since all children left the institution at 1 pm during weekdays. Therefore, sometimes, some participants underwent a single session per week, but they managed to complete all 12 sessions within the 6 weeks. However, due to theses multiple reasons, it was not practically possible to achieve the optimal standards of a

hydrotherapy program reported by Jorgić et al. (2012) further limiting the quality of this current study.

The other limitation of this study is the absence of gold standard laboratory measures such as Biodex stability system for accurate evaluation of results in terms of static and dynamic balance, and this is due to the unavailability of such measures in this clinical setting.

Moreover, even though VAS had been used in the literature to assess the HRQOL of children, the 5-item VAS used to assess the HRQOL in this study was a new measure developed specifically for this study, and it has not been validated for children with CP. Also, it is questionable whether the proxy-administered VAS truly represent the HRQOL of children if they were to be self-administered it.

Additionally, since there was no follow-up assessment, in contrast to many other hydrotherapy studies, the present study did not evaluate the long-term effects of this hydrotherapy program; sustainability of the improvement gained after the intervention was not assessed for any outcome measures. Therefore, it is unknown whether the improvement gained is transient or permanent, and if transient, what is the maintenance duration of the improvement. Therefore, in future studies, it is important to periodically assess the improvement gained to understand the sustainability of the results.

6.2. Conclusion and Recommendations

In conclusion, regardless of some limitations, this 6-week aerobic exercise-based hydrotherapy program demonstrated feasibility in the Sri Lankan context and showed positive effects on static and dynamic balance and HRQOL of children with CP. Even though this study does not give confirmatory evidence due to numerous study limitations, it provides

preliminary evidence that hydrotherapy is beneficial for the children with CP irrespective of their age and functional limitations. However, this needs to be further studied in the future addressing these limitations, ideally with a RCT, a bigger sample size, standard laboratory balance measures, and periodic follow-up. Additionally, since the current study was beneficial for all the children who participated, this program could be expanded islandwide in Sri Lanka benefiting many affected children with CP.

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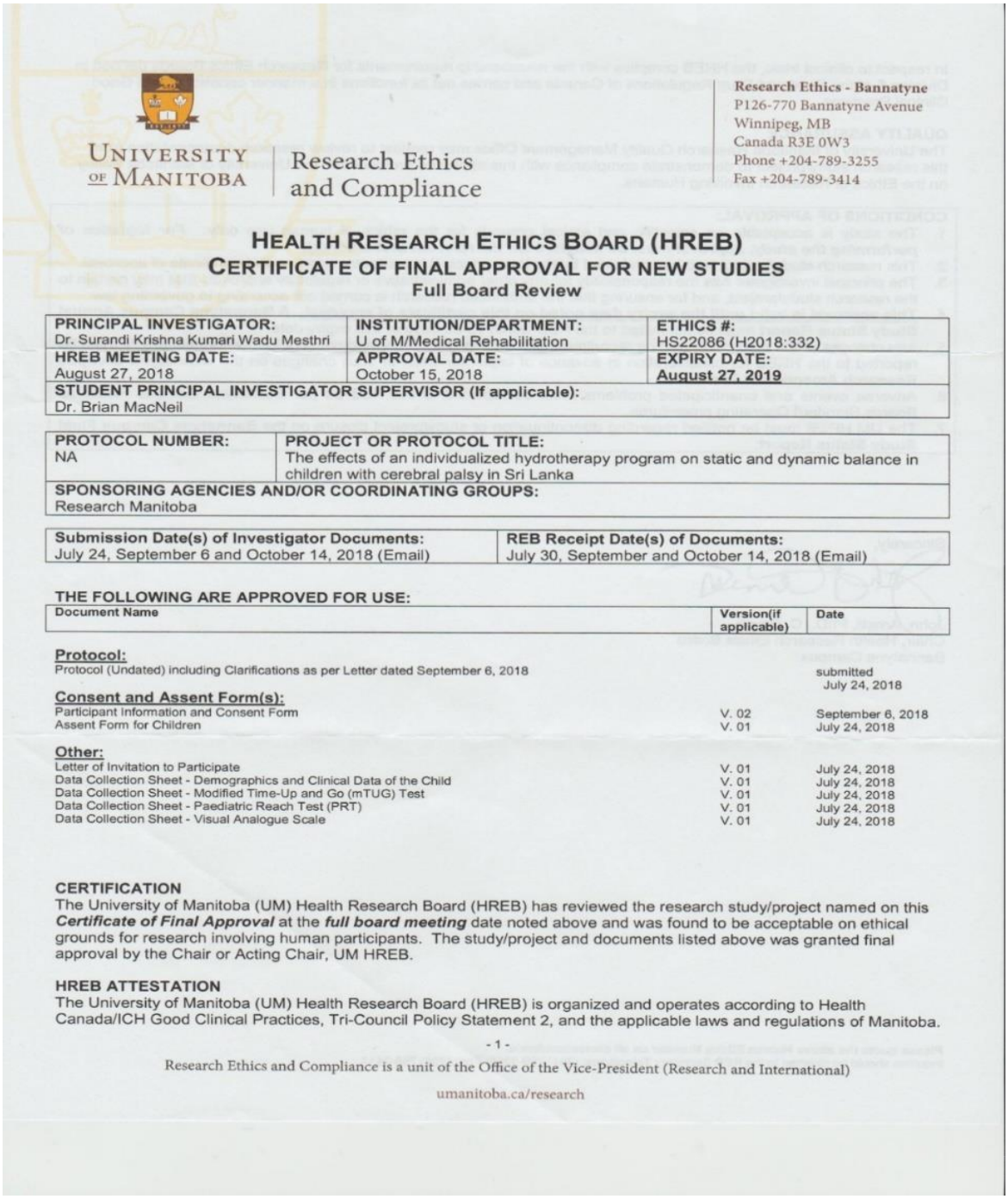
A: Ethical Clearance Letter-University of Manitoba



UNIVERSITY OF MANITOBA | Research Ethics and Compliance

Research Ethics - Bannatyne
P126-770 Bannatyne Avenue
Winnipeg, MB
Canada R3E 0W3
Phone +204-789-3255
Fax +204-789-3414

HEALTH RESEARCH ETHICS BOARD (HREB)
CERTIFICATE OF FINAL APPROVAL FOR NEW STUDIES
Full Board Review

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. Surandi Krishna Kumari Wadu Mesthri	U of M/Medical Rehabilitation	HS22086 (H2018:332)
HREB MEETING DATE:	**APPROVAL DATE:**	**EXPIRY DATE:**
August 27, 2018	October 15, 2018	**August 27, 2019**
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. Brian MacNeil		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE:
NA	The effects of an individualized hydrotherapy program on static and dynamic balance in children with cerebral palsy in Sri Lanka
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: Research Manitoba	

Submission Date(s) of Investigator Documents:	REB Receipt Date(s) of Documents:
July 24, September 6 and October 14, 2018 (Email)	July 30, September and October 14, 2018 (Email)

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version(if applicable)	Date
Protocol:		
Protocol (Undated) including Clarifications as per Letter dated September 6, 2018		submitted July 24, 2018
Consent and Assent Form(s):		
Participant Information and Consent Form	V. 02	September 6, 2018
Assent Form for Children	V. 01	July 24, 2018
Other:		
Letter of Invitation to Participate	V. 01	July 24, 2018
Data Collection Sheet - Demographics and Clinical Data of the Child	V. 01	July 24, 2018
Data Collection Sheet - Modified Time-Up and Go (mTUG) Test	V. 01	July 24, 2018
Data Collection Sheet - Paediatric Reach Test (PRT)	V. 01	July 24, 2018
Data Collection Sheet - Visual Analogue Scale	V. 01	July 24, 2018

CERTIFICATION
The University of Manitoba (UM) Health Research Board (HREB) has reviewed the research study/project named on this ***Certificate of Final Approval*** at the ***full board meeting*** date noted above and was found to be acceptable on ethical grounds for research involving human participants. The study/project and documents listed above was granted final approval by the Chair or Acting Chair, UM HREB.

HREB ATTESTATION
The University of Manitoba (UM) Health Research Board (HREB) is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement 2, and the applicable laws and regulations of Manitoba.

In respect to clinical trials, the HREB complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

QUALITY ASSURANCE

The University of Manitoba Research Quality Management Office may request to review research documentation from this research study/project to demonstrate compliance with this approved protocol and the University of Manitoba Policy on the Ethics of Research Involving Humans.

CONDITIONS OF APPROVAL:

1. The study is acceptable on scientific and ethical grounds for the ethics of human use only. ***For logistics of performing the study, approval must be sought from the relevant institution(s).***
2. This research study/project is to be conducted by the local principal investigator listed on this certificate of approval.
3. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to the research study/project, and for ensuring that the authorized research is carried out according to governing law.
4. **This approval is valid until the expiry date noted on this certificate of approval. A Bannatyne Campus Annual Study Status Report** must be submitted to the REB within 15-30 days of this expiry date.
5. Any changes of the protocol (including recruitment procedures, etc.), informed consent form(s) or documents must be reported to the HREB for consideration in advance of implementation of such changes on the **Bannatyne Campus Research Amendment Form.**
6. Adverse events and unanticipated problems must be reported to the REB as per Bannatyne Campus Research Boards Standard Operating procedures.
7. The UM HREB must be notified regarding discontinuation or study/project closure on the **Bannatyne Campus Final Study Status Report**.

Sincerely,

[redacted]

Chair, Health Research Ethics Board
Bannatyne Campus

Please quote the above Human Ethics Number on all correspondence.
Inquiries should be directed to the REB Secretary **Telephone**: (204) 789-3255/ **Fax:** (204) 789-3414

Appendix B: Ethical Clearance Letter-University of Kelaniya

Ethics Review Committee

SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC

Faculty of Medicine,University of Kelaniya, Ragama, Sri Lanka

FWA00013225

04.12.2018

Our Ref No: **P/134/07/2018**

Dr. S.K.K. Wadu Mesthri
Graduate Student
College of Rehabilitation Sciences
R 106-771 McDermot Avenue
University of Manitoba
Winnipeg
MB R3E 0T6
Canada.

Dear Dr. Wadu Mesthri,

Title: The effects of an individualized hydrotherapy program on static and dynamic balance in children with cerebral palsy in Sri Lanka

Investigators: Dr. S.K.K. Wadu Mesthri, Dr. S.P. Sumanasena, Dr. Brian MacNeil

I am pleased to inform you that Ethics Review Committee which met on 13.11.2018 has approved amendments to the following documents.

	English		Sinhala		Tamil	
	Version	Date	Version	Date	Version	Date
Protocol	03	24/10/18				
Instruments	01	10/06/18	01	10/06/18	01	10/06/18
Participant Information sheet	03	24/10/18	03	24/10/18	03	24/10/18
Consent form	01	10/06/18	01	10/06/18	01	10/06/18

Please note that the ERC approval period and condition of approval remains as stated in the previous approval letter.

Thank you.
Yours sincerely,

[redacted]

Secretary, ERC

SECRETARY
Ethics Review Committee
Faculty of Medicine
University of Kelaniya.

Address all correspondence to: Secretary, Ethics Review Committee, Faculty of Medicine, Univer: ity of Kelaniya, PO Box 06, Thalagolla Road, Ragama, Sri Lanka.
Telephone: +94 -112961267/ +94 -112961000, Fax: +94-112958337 /+94-112955280

Appendix C: Letter of Invitation to Participate-English, Sinhala and Tamil

Letter of Invitation to Participate in a Study on Hydrotherapy and Cerebral palsy

Study Title: The Effects of an Individual Hydrotherapy Program on Static and Dynamic Balance in Children with Cerebral Palsy in Sri Lanka

My name is Surandi Krishna Kumari Wadu Mesthri. I am a graduate student in the College of Rehabilitation Sciences at the University of Manitoba, Canada.

I am conducting a research study on hydrotherapy and cerebral palsy. This study will look at the effects of hydrotherapy on balance in children with cerebral palsy in Sri Lanka. You and your child have been identified as suitable to take part in this study because your child enrolled in the National Center for Children with Cerebral Palsy and other Developmental Disorder (NCCCPDD) where this study will be conducted, and your child meets the inclusion criteria of this study.

This study involves your child's participation in a 6-weeks hydrotherapy program. During this 6-weeks, your child will be asked to participate in 2 hydrotherapy pool sessions per weekduring his/her regular attendance at the NCCCPDD. Before and after the hydrotherapy program, your child's balance will be assessed using 2 clinical tests. The total time commitment for the study would be 26 hours (2 hours per day for 4 days of balance assessments, and 1.5 hours per day for 12 days for the 6-weeks of hydrotherapy program). All the study participation time will occur during the regularly allotted physiotherapy time when the child is at the NCCCPDD.

This will also involve your rating of your child's health related quality of life.

Participation in this research is completely voluntary and you may choose to withdraw your child from the study at any time.

If you would like your child to participate in this study, please contact me via email at ……... or on my mobile ……...

For more details, please refer to the attached Participant Information Sheet and Consent Form.

Thank you.

…….. (Signature of the Principal Investigator)
Surandi Krishna Kumari Wadu Mesthri

Principal Investigator
College of Rehabilitation Sciences,
University of Manitoba, Canada.
Email: ……
Cell Phone: …….

ජලචිකිත්සාව හා මස්තිෂ්ක ආඝාතය පිළිබඳ කෙරෙන අධ්‍යයනයක් සඳහා සහභාගිවීමට ආරාධනා කෙරෙනා ලිපිය

අධ්‍යයන ශීෂර්ය**:** ශ්‍රී ලංකාවේ මස්තිෂ්ක ආඝාතයෙන් පෙළෙන දරුවන්ගේ ස්ථිතික හා ගතික සමතුලිතතාව කෙරෙහි පුද්ගල ජලචිකිත්සක වැඩසටහනෙන් ඇති බලපෑම්

මගේ නම සුරන්දි ක්‍රිෂ්ණා කුමාරි වඩු මෙස්ත්‍රි. මම කැනඩාවේ මැනිටෝබා විශ්වවිද්‍යාලයේ පුනුරුත්තාපන විද්‍යා අධ්‍යයන පීඨයේ පශ්චාත් උපාධි ශිෂ්‍යාවක්.

මම මස්තිෂ්ක ආඝාතය සහ ජලචිකිත්සාව පිළිබඳ පර්යේෂණයක් දියත් කරනවා. මෙම අධ්‍යයනය මගින් ශ්‍රී ලංකාවේ මස්තිෂ්ක අඝාතයෙන් පෙළෙන දරුවන්ගේ සමතුලිතතාව කෙරෙහි පුද්ගල ජලචිකිත්සක වැඩසටහනෙන් ඇති බලපෑම් ගැන සොයා බලනවා. ඔබත් ඔබේ දරුවාත් මෙම අධ්‍යයනයට සහභාගිවීමට සුදුසු යැයි හඳුනාගනු ලැබුවේ ඔබේ දරුවා දැනටමත් මස්තිෂ්ක ආඝාතය හා අනෙකුත් වධර්න අපහසුතා සහිත දරුවන් සඳහා වූ ජාතික මධ්‍යස්ථානයේ (NCCCPDD) ලියාපදිංචිවී සිටීම නිසායි. මෙම අධ්‍යයනය සිදුකරන්නේ එම ආයතන පරිශ්‍රය තුලම වන අතර ඊට සහභාගී විමට අවශ්‍ය සුදුසුකම් ඔබේ දරුවා සපුරා තිබෙනවා.

මෙම අධ්‍යයනයේදී ඔබේ දරුවා සති 6ක ජලචිකිත්සක වැඩසටහනකට සහභාගී විය යුතු වෙනවා. මේ සඳහා, ඔබේ දරුවා NCCCPDD ආයතනට එදිනෙදා පැමිණෙන සති 6ක කාලය ඇතුලතදී සෑම සතියකම ජලතටාකය තුල සිදුකරන අභ්‍යාස සැසිවාර 2කට සහභාගී විය යුතු වෙනවා. ජලචිකිත්සක වැඩසටහනට පෙර සහ පසු, සායනික පරීක්ෂණ 2ක් මගින්, ඔබේ දරුවාගේ සමතුලිතභාවය මැන බැලීම සිදු වෙනවා. මෙම අධ්‍යයනය සඳහා කැප කිරීමට සිදුවන සම්පුර්ණ කාලය පැය 26කි (සමතුලිතතාවය පරීක්ෂා කිරීම සඳහා දිනකට පැය 2ක බැගින් දින 4කුත්, සහ සති 6 ක ජල අභ්‍යාස සඳහා දිනකට පැය එකහමාරක බැගින් දින 12කුත් වශයෙන් වේ). අධ්‍යයනයට සහභාගී වීම සඳහා ගතවන මුළු කාලය, දරුවා NCCCPDD ආයතනය තුල ගතකරන කාලය ඇතුලතදී , එම ආයතනය මගින් ඔබේ දරුවාගේ එදිනෙදා භෞතිකචිකිත්සක කටයුතු සඳහා වෙන්කර ඇති කාලය තුල සිදුවනු ඇත.

මේ සඳහා ඔබ විසින් ඔබේ දරුවාගේ සෞඛ්‍ය සම්බන්ධ ජීවන ගුණාත්මකභාවය පිළිබඳ තත්ව ඇගයීමක් සිදුකල යුතු වෙනවා.

මෙම අධ්‍යයනයට සහභාගිවීම සම්පුණර්යෙන්ම ස්වේච්ඡාවෙන් සිදුකල යුතු අතර ඔබ කැමති ඕනෑම වේලාවක ඔබේ දරුවා මෙම අධ්‍යයනයෙන් ඉවත් කරගත හැකියි.

ඔබ කැමතිනම් ඔබේ දරුවා මෙම අධ්‍යයනය සඳහා සහභාගි කරවීමට, මාගේ email ලිපිනය ..... තුලින් හෝ මගේ ජංගම දුරකථන අංකය …….. මගින් මා හා සම්බන්ධ විය හැකියි.

වැඩි තොරතුරු සඳහා, මේ සමග අමුණා ඇති සහභාගීවන්නන්ගේ තොරතුරු පත්‍රිකාව හා අනුමැතිය ලබාගැනීමේ පත්‍රිකාව කියවා බලන්න.

ස්තූති,

…….. (ප්‍රධාන විමශර්කගේ අත්සන)
සුරන්දි ක්‍රිෂ්ණා කුමාරි වඩු මෙස්ත්‍රි,

ප්‍රධාන විමශර්ක,
පුනුරුත්තාපන විද්‍යා අධ්‍යයන පීඨය,
මැනිටෝබා විශ්වවිද්‍යාලය, කැනඩාව

E- තැපෑල: ……
ජංගම දුරකථන අංකය: ……..

நீரியல்மருத்துவம் மற்றும் மூளையச்சோர்வாதம் பற்றிய ஆய்வொன்றில் பங்கேற்பதற்கான அழைப்பிதழ் கடிதம்

ஆய்வின் தலைப்பு: இலங்கையில் மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் இயக்கமற்ற மற்றும் இயக்க சமநிலை பற்றி தனிமைபடுத்தப்பட்ட நீரியல்மருத்துவ நிகழ்ச்சியொன்றின் தாக்கங்கள்

எனது பெயர் சுரந்தி கிருஷ்ணா குமாரி வது மேஸ்திரி நான் கனடாவின் மினிடோபா பல்கலைக்கழகத்தின் புனருத்தாபன விஞ்ஞான கல்லூரியின் பட்டாதாரி மாணவரொருவராகும்.

நீரியல்மருத்துவம் மற்றும் மூளையச்சோர்வாதம் பற்றிய ஆய்வொன்றை நான் செய்கின்றேன். இலங்கையில் மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் இயக்கமற்ற மற்றும் இயக்க சமநிலை மீது நீரியல்மருத்துவ நிகழ்ச்சித்திட்டமொன்றின் தாக்கங்கள் பற்றி இவ் ஆய்வு ஆராயும். இவ்வாய்வு நடாத்தப்படுகின்ற மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் உங்களது குழந்தை பதிவுசெய்யப்பட்டுள்ளதால் இவ்வாய்வில் பங்கேற்பதற்கு நீங்களும் உங்களது குழந்தையும் பொருத்தமானவர்களாக இனங்காணப்பட்டுள்ளீர்கள் அத்துடன் இவ்வாய்வில் கலந்துகொள்ளச் செய்தற்கான மூலப்பிரமாணத்தை உங்கள் குழந்தை நிறைவு செய்கின்றது.

இவ் ஆய்வு, உங்களது குழந்தையினை 6 - வாரங்கள் கொண்ட நீரியல்மருத்துவ நிகழ்ச்சித்திட்டமொன்றில் பங்கேற்பதனை ஈடுபடுத்துகின்றது. இவ் 06 வாரங்களின் போது, மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் பிள்ளை வழமைபோன்று சமூகமளித்தளிக்கின்ற போது உங்களது குழந்தை வாரத்திற்கு 2 நீரியல்சிகிச்சை நிகழ்வுகளில் பற்கேற்க வேண்டியிருக்கும். நீரியல்சிகிச்சைக்கு முன்னரும் பின்பும் 2 மருத்துவப் பரிசோதனைகளைப் பயன்படுத்தி உங்களது குழந்தையின் சமநிலை கணிப்பிடப்படும். இவ் ஆய்வுக்கான மொத்தமாக எடுத்துக்கொள்ளப்படும் நேரம் 26 மணித்தியாலங்களாலவிருக்கும். (4 நாட்கள் கொண்ட சமநிலை மதிப்பீட்டுக்காக நாளொன்றுக்கு 2 மணித்தியாலங்கள், மற்றும் 6 - வாரங்கள் கொண்ட நீரியல்மருத்துவ நிகழ்ச்சித் 12 நாட்களுக்காக நாளொன்றுக்கு 1.5 மணித்தியாலங்கள்). அனைத்து ஆய்வுப் பங்கேற்பு காலமும் மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் பிள்ளையின் சிகிச்சைகாக வழமையாக ஒதுக்கப்பட்ட காலத்தின் போதே நிகழும்.

உங்களது குழந்தையின் வாழ்க்கைத்தரத்துடன் தொடர்புடைய ஆரோக்கியம் பற்றிய உங்களது தரப்படுத்தப்படுத்தலையும் இது ஈடுபடுத்தும்.

இவ் ஆராய்ச்சியில் பங்குபற்றுவது பூரணமாக தன்னார்வ அடிப்படையிலானது என்பதுடன் உங்களது பிள்ளையினை இவ் ஆய்வில் இருந்து எந்நேரத்திலும் விலகிக்கொள்வதற்கு சந்தரப்பமுண்டு.

இவ் ஆய்வில் உமது பிள்ளையினை பங்கேற்கச் செய்வதற்கு நீங்கள் விரும்புவீர்களாயின், தயவு செய்து .....என்ற மின்னஞ்சல் ஊடாக அல்லது ..... என்ற தொலைபேசி இலக்கத்தில் என்னுடன் தொடர்பு கொள்ளவும்.

மேலதிக தகவல்களுக்கு தயவுசெய்து இணைக்கப்பட்டுள்ள பங்கேற்பாளர் தகவல் அறிக்கையினையும் சம்மதப் படிவத்தினையும் பார்க்கவும்.

நன்றி

……. (முதன்மை ஆய்வாளரின் கையொப்பம்)

சுரந்தி கிரு'னா குமாரி வது மேஸ்திரி,

முதன்மை ஆய்வாளர்

புனருத்தாபன விஞ்ஞான கல்லூரி

மினிடோபா பல்கலைக்கழகம், கனடா

மின்னஞ்சல்: **……**

தொலைபேசி இலக்கம்: .....

Appendix D: Participants Information Sheets-English, Sinhala and Tamil

The Effects of an Individual Hydrotherapy Program on Static and Dynamic Balance in Children with Cerebral Palsy in Sri Lanka

I am Surandi Krishna Kumari WaduMesthri, a graduate student of the College of Rehabilitation Sciences, University of Manitoba, Canada. I would like to invite you to take part in the research project titled "The Effects of an Individual Hydrotherapy Program on Static and Dynamic Balance in Children with Cerebral Palsy in Sri Lanka" conducted by me with the assistance of the staff at National Center for Children with Cerebral Palsy and other Developmental Disorders (NCCCPDD), Rajagiriya, Colombo, Sri Lanka.

1. **Purpose of the Study**

The purpose of this research project is to examine the effects of an individual hydrotherapy program on static and dynamic balance in children with cerebral palsy in the Sri Lankan context.

2. **Voluntary Participation**

You and your child's participation in this study is voluntary. You and your child are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. If you chose not to participate, there will be no loss of medical care or any other available treatment for your child's illness or condition to which your child is otherwise entitled.

3. **Participant Selection**

You and your child have been identified as suitable to take part in this study because your child enrolled in the NCCCPDD where this study will be conducted, and your child meets the inclusion criteria of this study.

4. **Duration, Procedures of the Study and Participant's Responsibilities**

Once your child has been identified as a suitable participant through the existing records at NCCCPDD, you will be given a package in a sealed envelop that contains a letter of invitation to participate, a participant information sheet and a consent form to take home. If you are willing to participate you will be asked to contact the principal investigator within next 2 weeks by phone or email. Subsequently, consent from you and the assent from your child will be obtained by the principal investigator. At the end of this process, your child will be given an identification number.

You will rate your child's health-related quality of life using a 5 scales tool called Visual Analogue Scale (VAS). This will take 5 to 10 minutes.

Your child's resting heart rate will be recorded. Your child's balance will then be examined by a physiotherapist using 2 clinical tests. The total time to complete each test, including resting periods, would be approximately 2 hours.

As the next step, hydrotherapy program will be started and conducted in 3 phases; warm-up exercises, aerobic exercises, and cool-down and stretching exercises. During the hydrotherapy program, your child will be asked to exercise with moderate to high intensity. The exercise intensity levels will be monitored using a heart rate sensor with chest strap and a wristwatch. Three certified physiotherapists with experience in pediatric hydrotherapy will conduct the hydrotherapy program. Parents/guardians and volunteers will also be invited to participate in the pool activities to help children when needed.

During the program, whenever the child is tired and cannot continue exercising, your child will be allowed to rest for 2 minutes. And at the end of the program, your child will leave the pool and take a shower and rest in the changing room for roughly 20 minutes.

This program will take place twice per week for 6 continuous weeks during your child's regular attendance at the NCCCPDD with at least 2-3 day's gaps between each two sessions. Your child will be asked to undergo 12 hydrotherapy sessions during these 6 weeks. Each session will last an hour. However, including the 20 minutes of resting period, single pool session will take an hour and a half to complete. Within 5 days following completion of the program, your child's balance will be reassessed by the same physiotherapist using the same 2 tests describe above. During this period, you will be asked to re-evaluate your child's health-related quality of life using same 5 scales tool.

The total time commitment for the study would be 26 hours; 2 hours per day for 4 days of balance assessments, and 1.5 hours per day for 12 days for the 6-weeks of hydrotherapy program. During the study period, your child will be asked to undergo this new hydrotherapy program instead of regular hydrotherapy treatment that your child receives at the facility. Since all the study participation time will occur during the regularly allotted physiotherapy time when the child is at the NCCCPDD, participating in the hydrotherapy program will not affect your child's academic activities.

You can stop the testing at any time you would like. If you or child decide to stop participating in the study, we encourage you to talk to the study staff first.

5. Potential Benefits

By participating in this study, you will learn your child's ability to control the balance. Exercising in the pool will be a fun activity for your child. However, there may or may not be direct benefits to you or your child from participating in this study, and your child's balance may or may not improve. We hope the information learned from this study would

help other children with cerebral palsy and hydrotherapy rehabilitation programs in the future.

6. Risks, Hazards and Discomforts

Training sessions and balance assessment may be tiring to your child. Child may feel some pain or discomfort or dizzy during or after doing exercises in the pool, or during or after the assessment of balance. Child may feel cold and chilly when he/she is in the pool for an hour. Wearing the chest strap, the wristwatch and the life jacket continuously for an hour may be uncomfortable to the child. Some children may feel some frustration if they are unable to perform all the tests and the training sessions well. Your child may experience loss of balance during the assessment but, in addition to the accessor, a vigilant assistant will always be there to hold the child to prevent injury.

This study will be conducted in a shallow therapeutic pool with the depth ranges from 1 to 4 feet maximum. Throughout the pool sessions children will be wearing standard life jackets, and the therapist will always be present working one-on-one with the child with at least one other adult present. Therefore, children's safety in the pool will be assured, and there will not be a risk of drowning. You must tell study staff or principal investigator if your child feels pain or discomfort or unwell while participating in the study. For any injury related to the study, we will refer your child to the proper medical care through the facility. You are not waiving any of your legal rights by signing the consent form or releasing the investigators from their legal and professional responsibilities for any injury related to the study.

7. Reimbursements

You or your child will receive no payment to take part in this study.

8. Confidentiality

Confidentiality of all records is guaranteed and no information by which you and your child can be identified will be released and only anonymous data will be published. These data will never be used in such a way that you and your child could be identified in any way in any public presentation or publication without your express permission. Data without identification information may be shared with other researchers as many journals expect the authors to make their data available to other researchers.

9. Sharing the Results

The results will be available with the principal investigator and can be reviewed by the participants at the end of the study.

10. Termination of Study Participation

You may withdraw your consent to participate in this study at any time, with no penalty or effect on medical care or loss of benefits. Please notify the investigator as soon as you decide to withdraw your consent.

11. Clarification

You may take your time to make your decision about participating in this study and you may discuss it with your friends, family or your doctor before you make your decision. If you have questions about any of the tests / procedures or information, or if any questions come up during or after the study please feel free to ask any of the persons listed below.

Principal investigator: Surandi Krishna Kumari Wadu Mesthri at ……..
Study staff: Rajkaran Mahendran (physiotherapist) at ……

12. If you have any complaints about unethical conduct related to this research, you may make a complaint to Ethics review committee, Faculty of Medicine, University of Kelaniya using information given below.

ERC Office Address: Ethics review committee, Faculty of Medicine, University of Kelaniya, Sri Lanka.

Telephone No: 0112-961267 (please contact during working hours 8 am – 4 pm)
Email**:** **ercmed@kln.ac.lk**

Signed

Surandi Krishna Kumari Wadu Mesthri, Graduate student, College of Rehabilitation Sciences,

University of Manitoba

Principal Investigator

……. (Signature of the Principal Investigator)

Overseas Office Address: …….

Local Address: …….

Phone: ……

Email: …….

සහභාගිවන්නන් සඳහා වූ තොරතුරු පත්‍රිකාව

ශ්‍රී ලංකාවේ මස්තිෂ්ක ආඝාතයෙන් පෙළෙන දරුවන්ගේ ස්ථිතික හා ගතික සමතුලිතතාව කෙරෙහි පුද්ගල ජලචිකිත්සක වැඩසටහනෙන් ඇති බලපෑම්

මගේ නම සුරන්දි ක්‍රිෂ්ණා කුමාරි වඩු මෙස්ත්‍රි. මම කැනඩාවේ මැනිටෝබා විශ්වවිද්‍යාලයේ පුනුරුත්තාපන විද්‍යා අධ්‍යයන පීඨයේ පශ්චාත් උපාධි ශිෂ්‍යාවක්. මම කැමතියි 'ශ්‍රී ලංකාවේ මස්තිෂ්ක ආඝාතයෙන් පෙළෙන දරුවන්ගේ ස්ථිතික හා ගතික සමතුලිතතාව කෙරෙහි පුද්ගල ජලචිකිත්සක වැඩසටහනෙන් ඇති බලපෑම්' යන ශීෂර්යෙන් යුතු පයෙර්ෂණයට සහභාගී වන මෙන් ඔබට ආරාධනා කරන්න. මා විසින් මෙම වැඩසටහන කොළඹ, රාජගිරියේ පිහිටි මස්තිෂ්ක ආඝාතය හා අනෙකුත් වධර්න අපහසුතා සහිත දරුවන් සඳහා වූ ජාතික මධ්‍යස්ථානයේ (NCCCPDD) ද සහය ඇතිව සිදුකරන්නක්.

1. අධ්‍යයනයේඅභිප්‍රාය

මෙම පයෙර්ෂණ ව්‍යාපෘතියේ අභිප්‍රාය නම්, ශ්‍රී ලංකාවේ මස්තිෂ්ක ආඝාතයෙන් පෙළෙන දරුවන්ගේ ස්ථිතික හා ගතික සමතුලිතතාව කෙරෙහි පුද්ගල ජලචිකිත්සක වැඩසටහනෙන් ඇති බලපෑම්' විමසා බැලීමයි.

2. ස්වේච්ඡා සහභාගිත්වය

මෙම අධ්‍යයනය සඳහා ඔබගේ සහ ඔබේ දරුවාගේ සහභාගිත්වය ස්වේච්ඡාවෙන් සිදු විය යුතුය. ඔබ සහා ඔබේ දරුවා මෙම අධ්‍යයනයට සහභාගිවීමට අකමැති නම් ඒ සඳහා සහභාගී නොවී සිටිය හැකිය. මුලින් කැමැත්ත දී තිබුනද, අධ්‍යයනය අතරතුර, ඔබ කැමති ඕනෑම වෙලාවක ඉන් ඉවත් වීමටද ඔබට සම්පුණර් අයිතිය ඇත. මෙම අධ්‍යයනයට සහභාගී නොවුවා කියා ඔබේ දරුවාට ලැබිය යුතු ප්‍රතිකාර වල හෝ වෛද්‍ය සේවා පහසුකම්වල කිසිදු අඩුකිරීමක් හෝ අහිමිකිරීමක් සිදුවන්නේ නැත.

3. සහභාගිවන්නන්තෝරාගැනීම

ඔබත් ඔබේ දරුවාත් මෙම අධ්‍යයනයට සහභාගිවීමට සුදුසු යැයි හඳුනාගනු ලැබුවේ ඔබේ දරුවා දැනටමත් NCCCPDD ආයතනයේ ලියාපදිංචිවී සිටීම නිසාවෙනි. මෙම අධ්‍යයනය සිදුකරන්නේ NCCCPDD ආයතන පරිශ්‍රය තුල වන අතර ඊට සහභාගී විමට අවශ්‍ය සුදුසුකම් ඔබේ දරුවා සපුරා ඇත.

4. අධ්‍යයන සිදුකෙරෙන කාලපරාසය, ක්‍රමවේදය සහ සහභාගිවන්නන්ගේ වගකීම්.

NCCCPDD ආයතනයේ දැනට ඇති වාතර්ා අනුව, ඔබත් ඔබේ දරුවාත් මෙම අධ්‍යයනයට සහභාගී වීමට සුදුසු යැයි හඳුනාගත් පසුව, ඔබට මුද්‍රාතැබූ ලිපිකවරයක බහාලූ ලිපිලේඛන කිහිපයක් ගෙදර ගෙන යාමට ලබාදෙනු ඇත. එම ලිපිකවරය තුල ඇත්තේ, සහභාගිවීම සඳහා ආරාධනා කරන ලිපිය, සහභාගිවන්නන් සඳහා වූ තොරතුරු පත්‍රිකාව හා අනුමැතිය පලකිරීමේ පත්‍රිකාවයි. ඔබ සහාභාගීවීමට කැමති නම්, මෙය ලැබී සති 02ක් ඇතුලත, ලේඛනවල සඳහන් e-තැපෑලෙන් හෝ දුරකතනයෙන් ප්‍රධාන විමශර්ක සමග සම්බන්ධවන්න. ඉන්පසුව, ඔබගේ අනුමැතිය හා ඔබේ දරුවාගේ එකඟත්වය ප්‍රධාන විමශර්ක විසින් ලබාගනු ඇති. මෙම ක්‍රියාවලිය අවසානයේ, ඔබේ දරුවාට හඳුනාගැනීමේ අංකයක් නිකුත් කරනු ඇත.

ඔබ විසින්, දෘශ්‍ය සමකාරක පරිමාණයනම් පරිමාණ 5කින් යුතු මෙවලමක් ආධාරයෙන් ඔබේ දරුවාගේ සෞඛ්‍ය සම්බන්ධ ජීවගුණාත්මක මට්ටම ඇගයීමක් කල යුතුය. මේ සඳහා විනාඩි 5ක් 10ක් පමණ ගතවනු ඇත.

ඔබේ දරුවා විවේකිව සිටින විට හෘද ස්පන්දන වේගය මැන බලනු ඇත. ඔබගේ දරුවාගේ ශරීරයේ සමබරතාවය, සායනික පරීක්ෂණ දෙකක් යොදාගනිමින් භෞතිකවිකිත්සකවරයෙකු විසින් පරීක්ෂා කරනු ලැබේ. විවේක කාලය ඇතුළුව, එක් පරීක්ෂණයක් සම්පූර්ණ කිරීම සඳහාගතවන මුළුකාලය පැය 2 ක් පමණ වනු ඇත.

මීලඟ පියවර ලෙස, ජලචිකිත්සක වැඩසටහන ආරම්භ කරනු ලැබේ. මෙම ජලචිකිත්සක වැඩසටහන අදියර 3ක් තුළ සිදු කෙරේ. ඒවා නම්, ශරීරය උණුසුම් කිරීමේ ව්‍යායාම, ඇරෝබික්ස් අභ්‍යාස සහ ශරීරය සිසිල් කරන හා ලිහිල් කරන අභ්‍යාස වේ. ජලචිකිත්සක වැඩසටහන අතරතුර, ඔබගේ දරුවාට මධ්‍යස්ත මට්ටමේ ව්‍යායාම් වල සිට ඉහළ තීව්‍රතාවයකින් යුතු ව්‍යායාම් දක්වා කිරීමට සිදු වේ. දරුවාගේ පපුව වටා යන පටියකට සම්බන්ධ කරන හෘද ස්පන්දන සංවේදකයක් සහ අත්ඔරලෝසුවක් මගින්ව්‍යායාමයේ තීව්‍රතා මට්ටම් අධීක්ෂණය කරනු ලැබේ. ළමුන් සඳහාවූ ජලචිකිත්සාව පිළිබඳ අත්දැකීම් සහිත සහතික කරන ලද භෞතිකවිකිත්සකයින් තිදෙනෙකු විසින් ජලචිකිත්සක වැඩසටහන ක්‍රියාත්මක කරනු ඇත. දෙමාපියන් / භාරකරුවන් සහ ස්වේච්ඡා සේවකයන්ට, අවශ්‍ය විට දරුවන්ට උපකාර කිරීමට පිහිනුම් තටාකයේ ක්‍රියාකාරකම් වලට සහභාගීවීමට ආරාධනා කරනු ලැබේ.

වැඩසටහන අතර තුරදී, දරුවා වෙහෙසට පත්වී ව්‍යායාම දිගටම කරගෙන යාමට අපහසු වූ ඕනෑම විටක, ඔබේ දරුවාට විනාඩි 2ක විවේකයක් ලබා ගත හැකිය. වැඩසටහන අවසානයේ දී, ඔබේ දරුවාට පිහිනුම් තටාකයෙන් පිටව, ශරීරය දොවාගෙන ඇඳුම් මාරු කරන ස්ථානයේ රැඳී සිටිමින් විනාඩි 20ක පමණ කාලයක් විවේක ගත හැකියි.

ඔබේ දරුවා NCCCPDD ආයතනට එදිනෙදා පැමිණෙන දිනවල මෙම වැඩසටහන ක්‍රියාත්මක වනු ඇති අතර සතියකට දෙවරක් බැගින්, සති 6 ක් පුරා, සෑම සැසිවාර 2ක් අතරම දින 2-3ක පරතරයක් තබාගනිමින් එයපැවැත්වේ. මෙම සති 6 ක කාලය තුලදී ජලචිකිත්සක සැසිවාර 12කට පමණ සහභාගී වීමට ඔබේ දරුවාගෙන් ඉල්ලා සිටිනු ඇත. සෑම සැසිවාරයක් සඳහාම පැයක පමණ කාලයක් ගතවේ. කෙසේ වෙතත්, විවේක කාලය ලෙස ලබාදෙන විනාඩි 20ත් ඇතුලත්ව, එක් සැසිවාරයක් සම්පූර්ණ කිරීමටපැය එකහමාරක පමණ කාලයක් ගතවනු ඇත. වැඩසටහන අවසන් වීමෙන් පසු, දින 5 ක් ඇතුලත ඔබගේ දරුවාගේ සමබරතාවය පෙර භෞතිකවිකිත්සකවරයා විසින්ම ඉහත සඳහන් කරන ලද පරීක්ෂණ 2කම නැවත යොදා ගනිමින් ඇගයීමට ලක්කරනු ඇත.මෙම කාල පරිච්ඡේදය තුලදී, ඔබේ දරුවාගේ සෞඛ්‍ය සම්බන්ධ ජීවගුණාත්මකභාවය කලින් භාවිතා කල පරිමාණ මෙවලම් 5ම නැවත භාවිතා කරමින් ඇගයීමට ලක් කරන ලෙස ඔබෙන් ඉල්ලා සිටිනු ඇත.

මෙම අධ්‍යයනය සඳහා කැපකිරීමට සිදුවන සම්පූර්ණ කාලය පැය 26කි; සමතුලිතතාවය පරීක්ෂා කිරීම සඳහා දිනකටපැය 2ක බැගින් දින 4කුත්, සහ සති 6 ක ජල අභ්‍යාස සඳහා දිනකට පැය එකහමාර බැගින් දින 12කුත් වශයෙන් වේ. අධ්‍යයන කාලය තුල, ඔබේ දරුවා දැනට NCCCPDD ආයතනය තුල එදිනෙදා සිදුකරන ජල ක්‍රියාකාරකම් වෙනුවට නව ජල අභ්‍යාස වැඩසටහනේ ක්‍රියාකරම් වල යෙදීමට සිදුවනු ඇත. අධ්‍යයනයට සහභාගී වීම සඳහා ගතවන මුළු කාලය, NCCCPDD ආයතනය ඔබේ දරුවාගේ එදිනෙදා භෞතිකවිකිත්සක කටයුතු සඳහා වෙන්කර ඇති කාලය තුල සිදුවනු ඇතිබැවින්මෙම ජලචිකිත්සක වැඩසටහනට සහභාගීවීම නිසාවෙන්ඔබේ දරුවාගේ අධ්‍යාපන කටයුතුවලට කිසිදු බලපෑමක්සිදුනොවනු ඇත.

ඔබ කැමති ඕනෑම වෙලාවක මෙම පරීක්ෂණයට සහභාගිවීම නැවත්විය හැකිය.අධ්‍යයනය සඳහා සහභාගී වීම නතර කිරීමට ඔබ හෝ ඔබේ දරුවා තීරණය කළහොත්, පළමුව ඒ පිළිබඳ අධ්‍යයන කායර් මණ්ඩලය සමඟ කතා කරන මෙන් ඔබව දිරිමත් කිරීමට අප කැමතිය.

5. ලැබිය හැකි ප්‍රතිලාභ

මෙම අධ්‍යයනයට සහභාගි වීමෙන්, සමබරතාවය පාලනය කරගැනීමට ඔබේ දරුවාට ඇති හැකියාව පිළිබඳ අවබෝධයක් ලබාගත හැකිය. පිහිනුම් තටාකයේ කරනු ලබන ක්‍රියාකාරකම් ඔබේ දරුවාට විනෝදජනක අත්දැකීමක් වනු ඇති. කෙසේ වෙතත්, මෙම අධ්‍යයනයට සහභාගි වීම නිසා ඔබේ දරුවාට සෘජු ප්‍රතිලාභයක් තිබීමට මෙන්ම නොතිබීමටද හැකිය. එමෙන්ම දරුවාගේ සමබරතාවය පාලනය කරගැනීමට ඇති හැකියාවේ වධර්නයක් වීමට හෝ නොවීමට හැකිය. අපේ බලාපොරොත්තුව මෙම අධ්‍යනය තුලින් ඉගෙනගන්නා තොරතුරු, අනාගතයේ මස්තිෂ්ක ආඝාතය සහිත දරුවන්ට හා ජල අභ්‍යාස වැඩසටහන් වලට ප්‍රයෝජනවත් වෙනු ඇති කියායි.

6. අවදානම්, උවදුරු සහ අපහසුතා

පුහුණු සැසි සහ සමබරතාවය ඇගයීමේ පරීක්ෂණ වලින් ඔබේ දරුවා වෙහෙසට පත්විය හැකියි. පිහිනුම් තටාකයේ පුහුණුවීම් කරන අතරතුර හෝ ඉන් පසුව, සමබරතාවය ඇගයීමේ පරීක්ෂණ කරන අතරතුර හෝ ඉන් පසුව දරුවාට යම් වේදනාවක් අපහසුවක් හෝ ක්ලාන්ත ගතියක් දැනීමට හැකිය. පැයක් පමණ කාලයක් පිහිනුම් තටාකය තුල ගත කිරීම නිසා දරුවාට සීතලක් වෙව්ලීමක් ඇතිවිය හැකියි. පපු වැස්ම සහ අත්ඔරලෝසුව පැයක පමණ කාලයක් එක දිගට පැළඳ සිටීම නිසා දරුවාට අපහසුතාවයක් ඇති විය හැකිය. පුහුණු සැසි හෝ පරීක්ෂණ වලට සාථර්කව මුහුණ දීමට බැරිවීම නිසා ඔබේ දරුවා යම් මානසික අසහනයකට පත්විය හැකියි. ඇගයීම් සිදුකරන අවස්ථාවල ඔබේ දරුවාගේ සමබරතාවය ගිලිහි යා හැකි අතර ඒවන් අවස්ථාවල දරුවා වැටීමට නොදී සුරක්ෂිතව අල්ලා ගැනීමට පරීක්ෂාව සිදුකරන්නාට අමතරව තවත් සහයකයකු අවධානයෙන් යුතුව නිතරම දරුවා අසලම සිටිනු ඇත.

ගැඹුර අඩි 01 සිට උපරිමය අඩි 04 දක්වා පරාසයනින්යුතු නොගැඹුරු ජල තටාකයක මෙම අධ්‍යයනය සිදුකරනු ලබනු ඇත. වැඩසටහන පුරාවටම දරුවන් ප්‍රමිතියකින්යුතු ජීවිතාරක්ෂක කබා පැළඳ සිටිනු ඇත. සෑම විටම එක් භෞතිකචිකිත්සකවරයකු එක්දරුවෙක් සමඟ රැඳෙනු ඇති අතර, අමතරව, යටත්පිරිසයෙන්තවත්එක්වැඩිහිටියෙක්ජලතටාකයේ සිදුකරන වැඩසටහන පුරාවටම සහභාගිවනු ඇත. එමනිසා, ජලතටාකය තුලදී දරුවන්ගේ ආරක්ෂාව සහතික වන අතර දරුවන් දියේ ගිලීමේ අවධානමක් නොමැත. ඔබේ දරුවා අධ්‍යයනයට සහභාගීවන අතරතුර දරුවාට යම්වේදනාවක්, අපහසුතාවයක්හෝ අසනීපතත්වයක්ඇතිවුවහොත්වහාම ඒබව අධ්‍යයන කායර්මණ්ඩලයට හෝ ප්‍රධාන විමශර්කට දැන්විය යුතුය. අධ්‍යයනයට සම්බන්ධ ඕනෑම අනතුරකදී ආයතනය හරහා ඔබේ දරුවාව සුදුසු වෛද්‍ය ප්‍රතිකාර සඳහා යොමු කෙරෙනු ඇත. අනුමැතිය ලබාදෙන පත්‍රය අත්සන් කිරීම නිසා අධ්‍යයනට සම්බන්ධව සිදුවන අනතුරකදී ඔබ සතු කිසිදු නිත්‍යානුකූල හිමිකමක් අවලංගු වන්නේවත් විමශර්කවරු ඔවුන්ගේ නීතිමය හා වෘතිමය වගකීම් වලින් නිදහස් වන්නේවත් නැත.

7. මුදල්ගෙවීම

ඔබට හෝ ඔබේ දරුවාට මෙම අධ්‍යනයට සම්බන්ධ වීම සඳහා කිසිදු මුදල් ගෙවීමක් සිදු කරන්නේ නැත.

8. රහස්‍යභාවය

සියලු වාතර්ාවල රහසයභාව පිළිබඳ වගකියනු ලැබේ. ඔබ හෝ ඔබේ දරුවා හඳුනාගත හැකි වන ආකාරයේ කිසිදු තොරතුරක් ප්‍රසිද්ධ නොකරන අතර නිනර්ාමික තොරතුරු පමණක් ප්‍රකාශයට පත්කරනු ඇත. ඔබ විසින් දුන් අවසරයකින් තොරව, මෙම දත්ත කිසිදු ආකාරයකින් ඔබ සහ ඔබේ දරුවාගේ අනනයතාවය හෙළිවන පරිදි ප්‍රසිද්ධියේ ඉදිරිපත් කිරීම හෝ ප්‍රකාශයට පත්කිරීමක් සිදුවන්නේ නැත. හඳුනාගැනීමේ තොරතුරු වලින් තොරව මෙම දත්ත අනෙකුත් පයෙර්ෂකයන් හා හුවමාරු කරගැනීමට ඉඩ ඇත. මන්දයත්, කතුවරුන් විසින් ඔවුන්ගේ දත්ත අනෙකුත් පයෙර්ෂකයන් සමග හුවමාරු කරගනු ඇතැයි අධ්‍යයන වාතර්ා සහරාවලින් බොහෝවිට බලාපොරොත්තු වේ.

9. ප්‍රතිඵල දැනුම් දීම

අධ්‍යයනය අවසානයේදී ලැබූ ප්‍රතිඵල සහභාගිවුවන්ගේ විමසුම සඳහා ප්‍රධාන විමශර්කවරයාගෙන් ලබාගත හැකියි.

10. අධ්‍යයනට සහභාගිවීම අත්හිටුවීම

ඔබ කැමති ඕනෑම වෙලාවක මෙම අධ්‍යයනය සඳහා සහභාගිවීමෙන් ඉවත් විය හැකිය. ඒ සඳහා දඬුවම් මුදලක් අයකිරීමක් හෝ ඔබේ දරුවාට දැනට ලැබෙන වෛදය ප්‍රතිකාර වල කිසිදු කප්පාදු කිරීමක් හෝ සිදුවන්නේ නැත.

11. පැහැදිලි කර ගැනීම්

ඔබට මෙම අධ්‍යයනට සහභාගිවනවාද නැද්ද යන්න තීරණය කිරීම සඳහා කාලය ලබා ගත හැකිය. ඔබට මේ පිළිබඳ ඔබේ මිතුරන් සමග හෝ පවුලේ අය සමග හෝ, නැතහොත් ඔබේ වෛදයවරයා සමග සාකච්ඡාකර තීරණයක් ගැනීමට හැකියාව ඇත. ඔබට මෙම පරීක්ෂණ ගැන හෝ, ක්‍රියාවලිය ගැන හෝ, මේ දී නිබෙන තොරතුරු පිළිබඳ හෝ කිසියම් ප්‍රශ්නයක් ඇත්නම්, අධ්‍යයනය අතරතුර හෝ ඉන්පසු යම් ගැටළුවක් පැනනැගී ඇත්නම් ඒ ගැන පහත සඳහන් අයගෙන් විමසා දැනගත හැකිවේ.

ප්‍රධාන විමශර්ක: සුරන්දි ක්‍රිෂ්ණා කුමාරි වඩු මේස්ත්‍රි දුරකථන අංකය .....
අධ්‍යයන කායර්මණ්ඩලය: රාජ්කරන් මහේන්ද්‍රන් (භෞතිකවිකිත්සක) දුරකථන අංකය .....

12. ඔබට මෙම අධ්‍යයනය සිදුකරන ආකාරය, පිළිගත් ආචාරධමර් වලට පටහැනි යැයි සිතේ නම්, පහත සඳහන් තොරතුරු මගින්, ඒ පිළිබඳ කැලණිය විශ්වවිදයාලයේ, වෛදය පීඨයේ, ආචාරධමර් සමාලෝචන කමිටුවට පැමිණිලි කල හැකයි.

ERC කායර්ාල ලිපිනය: ආචාරධමර් සමාලෝචන කමිටුව, වෛදය පීඨය, කැලණිය විශ්වවිදයාලය, ශ්‍රී ලංකා.

දුරකථන අංකය : 0112-961267 (කරුණාකර පෙ.ව. 8ත් ප.ව. 4ත් අතර කායර්ාල වෙලාවේදී අමතන්න)

E-තැපෑල: ercmed@kln.ac.lk

අත්සන

සුරන්දි ක්‍රිෂ්ණා කුමාරි වඩු මෙස්ත්‍රි.
කැනඩාවේ මැනිටෝබා විශ්වවිද්‍යාලයේ පුනුරුත්තාපන විද්‍යා අධ්‍යයන පීඨයේ පශ්චාත් උපාධි ශිෂ්‍යා.

ප්‍රධාන විමශර්ක

…… (ප්‍රධාන විමශර්කගේ අත්සන)

විදෙස් කායර්ාල ලිපිනය: ……..

දේශීය ලිපිනය: ……..

දුරකථන අංක: ……
E- තැපෑල: …….

பங்கேற்பாளர் தகவல் அறிக்கை

இலங்கையில் மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் இயக்கமற்ற மற்றும் இயக்கச் சமநிலை பற்றி தனிமைப்படுத்தப்பட்ட நீரியல்மருத்துவ நிகழ்ச்சித்திட்டமொன்றின் தாக்கங்கள்

எனது பெயர் சுரந்தி கிரு'னா குமாரி வது மேஸ்திரி, நான் கனடாவின் மினிடோபா பல்கலைக்கழகத்தின் புனருத்தாபன விஞ்ஞான கல்லூரியின் பட்டாதாரி மாணவரொருவராகும். "இலங்கையில் மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் இயக்கமற்ற மற்றும் இயக்க சமநிலை பற்றிய தனிமைப்படுத்தப்பட்ட நீரியல்மருத்துவ நிகழ்ச்சியொன்றின் தாக்கங்கள்" என்ற தலைப்பில் இலங்கை, கொழும்பு ராஜகிரிய மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் உள்ள அலுவலர்களின் உதவியுடன் என்னால் நடத்தப்படுகின்ற ஆராய்ச்சி கருத்திட்டத்தில் பங்கேற்பதற்கு நான் உங்களை அழைக்க விரும்பகின்றேன்.

1. ஆய்வின் நோக்கம்

இலங்கையை மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் இயக்கமற்ற மற்றும் இயக்க சமநிலை பற்றிய தனிமைப்படுத்தப்பட்ட நீரியல்மருத்துவ நிகழ்ச்சியொன்றின் தாக்கங்களை பரிசோதிப்பது இவ் ஆராய்ச்சிக் கருத்திட்டத்தின் நோக்கமாகும்.

2. தன்னார்வஅடிப்படையில் பங்கேற்றல்

இவ்வாய்வில் உங்களதும் உங்களது பிள்ளையினதும் பங்களிப்பு தன்னார்வ அடிப்படையிலானதாகும். உங்களுக்கும் உங்களது பிள்ளைக்கும் பங்குபற்றாமல் இருப்பதற்கும் அதேபோன்று பங்குபற்றுவதற்கு ஏற்கனவே சம்மதத்தினை தெரிவித்திருந்த போதிலும் எந்நேரத்திலும் இவ் ஆய்விலிருந்து பின்வாங்குவதற்கும் சுதந்திரம் உண்டு. நீங்கள் பங்கேற்பதற்கு விரும்பவில்லையாயின் உங்களது பிள்ளையின் நலக்குறைவிற்கான அல்லது நிலமைக்கான மருத்துவ கவனிப்பில் அல்லது உங்களது பிள்ளை வேறுவகையில் உரித்துடைய கிடைக்கத்தக்க ஏதேனும் வேறு சிகிச்சையில் எவ்வித குறைவும் இருக்காது.

3. பங்கேற்பாளரை தெரிவுசெய்தல்

இவ்வாய்வு நடாத்தப்படுகின்ற மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் உங்களது குழந்தை பதிவுசெய்யப்பட்டுள்ளதால் இவ்வாய்வில் பங்கேற்பதற்கு நீங்களும் உங்களது குழந்தையும் பொருத்தமானவராக இனங்காணப்பட்டுள்ளீர்கள் அத்துடன் இவ்வாய்வில் கலந்துகொள்ளச் செய்தற்கான மூலப்பிரமாணத்தை உங்கள் குழந்தை நிறைவு செய்கின்றது.

4. ஆய்வின் காலம், நடைமுறைகள் மற்றும் பங்கேற்பாளரின் பொறுப்புகள்

மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் தற்போது காணப்படும் பதிவுகளைக் கொண்டு பொருத்தமான பங்கேற்பாளர் ஒருவராக உங்களது குழந்தை இனங்காணப்பட்டதுடன், பங்கேற்பதற்கான அழைப்பிதழ் கடிதம், பங்கேற்பாளர் தகவல் அறிக்கை மற்றும் ஒப்புதல் படிவம் ஆகியவற்றை உள்ளடக்குகின்ற முத்திரையிடப்பட்ட கடித உறையில் இடப்பட்ட பொதியொன்றினை உங்களது வீட்டுக்கு எடுத்துச் செல்வதற்காக உங்களுக்கு வழங்கப்படும். பங்கேற்பதற்கு நீங்கள் விரும்புவீர்களாயின், அடுத்து வருகின்ற இரண்டு வாரங்களுக்குள் தொலைபேசியூடாக அல்லது மின்னஞ்சல் ஊடாக முதன்மை ஆய்வாளரை தொடர்புகொள்வதற்கு உங்களிடம் கேட்கப்படும். அதனைத் தொடர்ந்து, உங்களது

ஒப்புதலும் உங்களது பிள்ளையிடமிருந்து இசைவும் முதன்மை ஆய்வாளரினால் பெற்றுக்கொள்ளப்படும். இச் செயன்முறையின் இறுதியில் உங்களது குழந்தைக்கு அடையாள இலக்கமொன்று வழங்கப்படும்.

கற்புல உருவக அளவுமுறை என்று அழைக்கப்படுகின்ற 05 அளவுகள் கொண்ட கருவியொன்றினை பயன்படுத்தி உங்களது பிள்ளையின் ஆரோக்கித்துடன் தொடர்புடைய வாழ்கைத் தரம் உங்களால் தரப்படுத்தப்படும். இது 5-10 நிமிடங்கள் வரை எடுக்கும்.

உங்களது பிள்ளையை ஓய்வில் வைத்து இதயத் துடிப்பு வீதம் பதிவு செய்யப்படும். பின்னர் 2 சிகிச்சைப் பரிசோதனைகளைப் பயன்படுத்தி இயன்மருத்துவர் ஒருவர் மூலம் உங்கள் பிள்ளையின் சமநிலை பரிசோதிக்கப்படும். ஒவ்வொரு பரிசோதனையினையும் பூர்த்தி செய்வதற்கு ஓய்வெடுக்கும் காலம் உட்பட ஏறக்குறைய 2 மணித்தியாலங்கள் எடுக்கும்.

அடுத்த கட்டமாக நீரியல்மருத்துவ முறை ஆரம்பிக்கப்பட்டு 3 கட்டங்களில் நடாத்தப்படும் ஆயத்தமாதல் உடற்பயிற்சி, காற்றுப்பயிற்சி மற்றும் தணிதல் மற்றும் நீட்டுதல் பயிற்சி. நீரியில் சிகிச்சையின்போது நடுத்தர அளவு முதல் அதிக தீவிர அளவு வரை உடற்பயிற்சி செய்வதற்கு உங்களது பிள்ளையிடம் கேட்கப்படும். உடற்பயிற்ச்சியின் தீவிர மட்டங்கள் இதயத்துடிப்பு வீத உணரியுடன் கூடிய நெஞ்சுப்பட்டி, மணிக்கூடு போன்ற சாதனம் என்பவற்றை பயன்படுத்தி கண்காணிக்கப்படும். குழந்தை நீரியல் சிகிச்சையில் அனுபவம் பெற்ற 03 சான்றுபடுத்தப்பட்ட இயன்மருத்துவர்கள் நீரியல் சிகிச்சை நிகழ்ச்சித்திட்டத்தினை நடாத்துவர். பெற்றார்.ஃ. பாதுகாவலர்.ஃ. மற்றும் தொண்டர்களும் அவசிமான போது குழந்தைக்கு உதவுவதற்காக தடாகச் செயற்பாடுகளில் பங்கேற்பதற்காக வரவழைக்கப்படுவர்.

இந் நிகழ்ச்சியின் போது குழந்தை களைப்படையுமாயின் மற்றும் உடற்பயற்சி தொடர்ந்து செய்ய முடியாதிருப்பின் இரண்டு நிமிடங்களுக்கு ஓய்வெடுப்பதற்காக உங்களது குழந்தைக்கு அனுமதிக்கப்படும். அத்துடன் இந் நிகழ்ச்சியின் இறுதியில் உங்களது குழந்தை தடாகத்தை விட்டு வெளியேறி குளித்து கிட்டத்தட்ட 20 நிமிடங்கள் உடைமாற்றும் அறையில் ஓய்வெடுக்கும்.

இந்நிகழ்ச்சி மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தற்கு பிள்ளை வழமையாக சமூகமளிக்கின்ற காலத்தின்போது தொடர்ச்சியாக ஆறு வாரங்களுக்கு, வாரத்துக்கு இரண்டு தடவைகள் என்ற அடிப்படையில் நடைபெறும் அதாவது இரண்டு நிகழ்வுகளுக்கு இடையில் குறைந்தது 2 – 3 நாட்கள் இடைவெளியிருக்கும். இவ் 06 வாரங்களின் போது 12 நீரியல்சிகிச்சை நிகழ்வுகளுக்கு உட்படுவதற்கு உங்களது குழந்தையிடம் கோரப்படும். ஒவ்வொரு நிகழ்வும் ஒரு மணித்தியாலம் நீடிக்கும். எனினும், 20 நிமிடங்கள் கொண்ட ஓய்வு நேரங்கள் உள்ளடங்கலாக தனியொரு நீர்த்தடாக நிகழ்வு 1 1/2 மணித்தியாலங்களைக் கொண்டதாகவிருக்கும். இந் நிகழ்ச்சித்திட்டத்தினை நிறைவு செய்து 05 நாட்களினுள் மேலே விபரிக்கப்பட்ட அதே இரண்டு பரிசோதனைகளைப் பயன்படுத்தி அதே இயன்மருத்துவர் மூலம் உங்களது குழந்தையின் சமநிலை கணிப்பிடப்படும். இச்சந்தர்ப்பத்தின்போது போது அதே வகையான 05 அளவீட்டுமுறையைப் பயன்படுத்தி

உங்களது குழந்தையின் ஆரோக்கியத்துடன் தொடர்புபட்ட வாழ்க்கைத் தரத்தினை மீள மதிப்பிடுவதற்கு உங்களிடம் கேட்கப்படும்.

இவ் ஆய்வுக்காக அர்ப்பணிக்கப்படும் மொத்த நேரம் 26 மணித்தியாலங்கள்: 4 நாட்கள் கொண்ட சமநிலை மதிப்பீடுகளுக்காக நாளொன்றுக்கு மணித்தியாலங்கள், மற்றும் 6- வார நீரியல் சிகிச்சைக்காக 12 நாட்களுக்கு நாளொன்றுக்கு 1.5 மணித்தியாலம். இவ்வாய்வுக் காலப் பகுதியின் போது இவ்விடத்தில் உங்களது குழந்தை பெற்றுக்கொள்ளுகின்ற வழமையான நீரியல் சிகிச்சைக்குப் பதிலாக இப்புதிய நீரியல் சிகிச்சைக்கு உட்படுத்தப்படுவதற்கு உங்கள் குழந்தையிடம் கேட்கப்படும். மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் பிள்ளை இருக்கின்றபோது வழமையாக ஒதுக்கப்பட்ட சிகிச்சை நேரத்தின் போது அனைத்து ஆய்வுப் பங்கேற்கும் நேரமும் நிகழும் என்பதனால் இந் நீரியல் சிகிச்சையில் பங்கேற்றல் உமது பிள்ளையின் கல்வி நடவடிக்கைகளை பாதிக்காது.

நீங்கள் விரும்புவீர்களாயின் எந்நேரதிலும் பரிசோதனையினை நிறுத்த முடியும். நீங்கள் அல்லது உங்கள் குழந்தை இவ்வாய்வில் பங்குபற்றுவதனை நிறுத்துவதற்கு தீர்மானிப்பதாயின் முதலில் ஆய்வு செய்யும் அலுவலரிடம் பேசும்படி நாம் உங்களை ஊக்கப்படுத்தகின்றோம்.

5. சாத்தியமான நன்மைகள்

இவ்வாய்வில் பங்குபற்றுவதன் மூலம் சமநிலையினை கட்டுப்படுத்துவதற்கான உங்களது குழந்தையின் இயலுமையினை நீங்கள் கற்றுக்கொள்கின்றீர்கள். தடாகத்தில் உடற்பயிற்சி செய்வது உங்களது குழந்தைக்கு விளையாட்டுபோன்ற செயற்பாடொன்றாக அமையும். எனினும், இவ் ஆய்வில் கலந்து கொள்வதிலிருந்து உங்களுக்கு அல்லது உங்களது பிள்ளைக்கு நேரடியான நலன்கள் கிடைக்கலாம் அல்லது கிடைக்காது போகலாம் அத்துடன் உங்களது குழந்தையின் சமநிலை மேம்படலாம் அல்லது மேம்படாது போகலாம். இவ் ஆய்விலிருந்து நாம் கற்றுக்கொள்கின்ற தகவல்கள் மூளையச்சோர்வாதத்துடன் கூடிய வேறு பிள்ளைகளுக்கும் எதிர்காலத்தில் நீரியல் சிகிச்சை புனருத்தாபான நிகழ்ச்சித் திட்டங்களுக்கும் உதவுமென நாம் நம்புகின்றோம்.

6. இடர் நேர்வுகள், ஆபத்துகள் மற்றும் அசௌகரியங்கள்

பயிற்சி நிகழ்வுகளும் சமநிலை மதிப்பீடும் உங்களது குழந்தையினை களைப்படையச் செய்யலாம். உங்களது குழந்தை, தடாகத்தில் உடற்பயிற்சியினை செய்கின்ற போது அல்லது செய்த பின்னர் அல்லது சமநிலை மதிப்பீட்டின் போது அல்லது சமநிலை மதிப்பீட்டின் பின்னர் சில வலிகளை அல்லது அசௌகரியத்தினை அல்லது தலை சுற்றினை உணரலாம். உங்களது குழந்தை ஒரு மணித்தியாலத்திற்கு தடாகத்தில் இருப்பதனால் குளிரினை அல்லது கூதலினை உணரலாம். ஒரு மணித்தியாலத்திற்கு நெஞ்சுப் பட்டி, மணிக்கூடு அத்துடன் பாதுகாப்பு அங்கியினை தொடர்ச்சியாக அணிவது குழந்தைக்கு அசௌகரியமிக்கதாகவிருக்கலாம். அனைத்து பரிசோதனைகளையும். பயிற்சி நிகழ்ச்சிகளையும் நன்றாக செயலாற்றுவதற்கு அவர்களுக்கு இயலாமலிருப்பின் சில பிள்ளைகள் சில நம்பிக்கையின்மையினை உணரலாம். மதிப்பீட்டின் போது உங்களது குழந்தை சமநிலை இழக்கலாம். ஆயினும் மதிப்பீட்டாளருக்கு மேலதிகமாக நன்கு

கண்காணிக்கின்ற உதவியாளர் ஒருவர் எப்போதும் காயங்களை தடுக்கும் பொருட்டு குழந்தையினை பற்றிப்பிடிப்பதற்கு இருப்பார்.

இவ் ஆய்வானது 1 தொடக்கம் அதிகூடியது 4 அடிக்கு இடைப்பட்ட ஆழத்துடன் கூடிய ஆழங்குறைந்த சிகிச்சைத் தடாகமொன்றில் நடாத்தப்படும். தடாகச் செயற்பாடுகள் முழுவதும் பிள்ளை, தரநியமமான உயிர்காப்பு அங்கியினை அணிந்திருக்கும் என்பதுடன் தடாகச் செயற்பாடுகள் முழுவதும் சிகிச்சையளிப்பவர் நேருக்கு நேர் பணியாற்றும் அடிப்படையில் எப்போதும் பிள்ளையுடன் இருப்பார் அத்துடன் வேறொரு வயதுவந்த ஆளும் பிரசன்னமாகி இருப்பார். எனவே, தடாகத்தில் பிள்ளையின் பாதுகாப்பு உத்தரவாதமளிக்கப்பட்டுள்ளது மற்றும் நீரில் மூழ்கும் இடர்நேர்வு காணப்படாது. ஆய்வில் பங்கேற்கின்ற போது உங்களது குழந்தை, வலிகளை அல்லது அசௌகரியத்தினை அல்லது சுகயினத்தினை உணருமாயின், ஆயுவுப்பதவினரிடம் அல்லது முதன்மை ஆய்வாளரிடம் கூறவேண்டும். சம்மதப் படிவத்தினை கையொப்பமிடுவதன் மூலம் நீங்கள் ஏதேனும் சட்டரீதியான உங்களது உரிமைகளை விட்டுக்கொடுக்கவோ இல்லது ஆய்வுடகன் தொடர்புபட்ட ஏதேனும் காயங்களுக்கான இவர்களது சட்டரீதியான அல்லது தொழில்சார் பொறுப்புகளில் இருந்து ஆய்வாளர்களை விடுவிக்கவோ இல்லை.

7. கொடுபனவுகள்

இவ்வாய்வில் கலந்துகொள்வதற்காக உங்களுக்கு அல்லது உங்களது குழந்தைக்கு கொடுப்பனவு எதுவும் வழங்கப்படமாட்டாது.

8. இரகசியம்

அனைத்து பதிவுகளுக்கும் இரகசியத்தன்மையினை உத்தரவாதமளிக்கப்பட்டுள்ளதுடன் உங்களை அல்லது உங்களது பிள்ளையினை அடையாளம் காணக்கூடிய வகையிலான தகவல்களும் எதுவும் வெளியிடப்படமாட்டாது என்பதுடன் பெயரற்ற தகவல்கள் மாத்திரம் வெளியிடப்படும். இத்தரவுகள் உங்களது வெளிப்படுத்தல் அனுமதியின்றி ஏதேனும் பொது மக்கள் எடுத்துரைப்பில் அல்லது வெளியீடுகளில் எந்த விதத்திலும் உங்களை அல்லது உங்களது பிள்ளையினை இனங்காணக்கூடிய விதத்தில் எவ்வகையிலேனும் ஒரு போதும் பயன்படுத்தப்படமாட்டாது. ஏனைய ஆராய்ச்சியாளர்களுக்கு அவர்களது தரவுகளை கிடைக்கச் செய்வதற்காக பல சஞ்சிகைகள் எழுத்தாளர்களை எதிர்பார்ப்பதனால் அடையாள தகவல்கள் அல்லாததரவுகள் ஏனைய ஆராய்ச்சியார்களுடன் பகிர்ந்துகொள்ளப்படலாம்.

9. பெறுபேறுகளை பகிர்தல்

பெறுபேறுகள் முதன்மை ஆய்வாளரிடம் கிடைக்கப்பெறும் என்பதுடன், ஆய்வின் இறுதியில் பங்கேற்பாளர்களால் மீளாயப்படக்கூடியதாகவிருக்கும்.

10. ஆய்வுப் பங்கேற்பினை முடிவுறுத்தல்

எவ்விதமான தண்டனைகளோ அல்லது மருத்துவ கவனிப்புக்கான தாக்கங்களோ அல்லது நலன்கள் இழப்போ இன்றி எவ்வேளையிலும் இவ் ஆய்வில் பங்குபற்றுவதற்கான உங்களது சம்மதத்தினை நீங்கள் பின்வாங்கிக் கொள்ளமுடியும். உங்களது சம்மதத்தினை நீங்கள் பின்வாங்குவதற்கு தீர்மானிப்பீர்களாயின் தயவுசெய்து உடனடியாக ஆய்வாளருக்கு அறிவிக்கவும்.

11. சான்றுப்படுத்தல்

இவ்வாய்வில் பங்குபற்றுவது பற்றிய உங்களது தீர்மானத்தை எடுப்பதற்காக நீங்கள் காலம் எடுத்துக்கொள்ளலாம் என்பதுடன் உங்களது தீர்மானத்தை எடுப்பதற்கு முன்னர் இது பற்றி உங்களது நண்பர்கள் உங்களது குடும்பம் அல்லது உங்களது வைத்தியருடன் கலந்துரையாடலாம். ஏதேனும் பரிசோதனைகள்.்.நடைமுறைகள் அல்லது தகவல்கள் பற்றி உங்களிடம் ஏதேனும் கேள்விகள் இருப்பின் அல்லது ஆய்வின் போது ஆய்விற்கு பின்னர் எவையேனும் கேள்விகள் எழுமாயின் கீழே அட்டவணைப்படுத்தப்பட்டுள்ள எவரேனும் ஆட்களிடம் உங்களுக்கு இலகுவாக கேட்டுக் கொள்ள முடியும்.

முதன்மை ஆய்வாளர் : சுரந்தி கிரு'னா குமாரி வது மேஸ்திரி ……..

அலுவலர்: ராஜ்கரன் மஹேந்திரன் (இயன்மருத்துவர்) ……..

12. இவ் ஆராய்ச்சியுடன் தொடர்புபட்ட ஒழுக்கநெறியற்ற நடவடிக்கை பற்றி ஏதேனும் முறைபாடுகள் உங்களிடம் இருப்பின் கீழே தரப்பட்டுள்ள தகவல்களை பயன்படுத்தி களனி பல்கலைகழகத்தின் மருத்துவ பீடத்தின் ஒழுக்க மீளாய்வுக் குழுவிற்கு முறைபாடொன்றை நீங்கள் செய்யலாம்.

ஒழுக்க மீளாய்வுக் குழு அலுவலக முகவரி : ஒழுக்க மீளாய்வுக் குழு, மருத்துவ பீடம், களனி பல்களைகழகம், இலங்கை

தொலைபேசி இலக்கம் 0112-961267 (தயவு செய்துமு.ப 08.00 பி.ப 04.00 இடையில் தொடர்புகொள்ளவும்)

மின்னஞ்சல்: ercmed@kln.ac.lk

ஒப்பமிடப்பட்டது.

சுரந்தி கிரு'னா குமாரி வடு மேஸ்திரி, பட்டதாரி மாணவி புனருத்தாபன விஞ்ஞான கல்லூரி, மினிடோபா பல்கலைக்கழகம்

முதன்மை ஆய்வாளர்

……. (முதன்மை ஆய்வாளரின் கையொப்பம்)

வெளிநாட்டு அலுவலக முகவரி: …….

உள்நாட்டு முகவரி : ……..
தொலைபேசி: ……
மின்னஞ்சல் : …….

Appendix E: Consent Form-English, Sinhala and Tamil

The Effects of an Individual Hydrotherapy Program on Static and Dynamic Balance in Children with Cerebral Palsy in Sri Lanka

To be completed by the proxy
The proxy should complete the whole of this sheet himself / herself.

1. Have you read the information sheet? (Please keep a copy for yourself)	YES/NO
2. Have you had an opportunity to discuss this study and ask any questions?	YES/NO
3. Have you had satisfactory answers to all your questions?	YES/NO
4. Have you received enough information about the study?	YES/NO
5. Who explained the study to you? ……	
6. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your child's future medical care?	YES/NO
7. You and your child's information held by the investigators relating to your child's participation in this study may be examined by other study team members. All information regarding you and your child's personal identity will be treated as STRICTLY CONFIDENTIAL. Do you give your permission for these individuals to have access to you and your child's records?	YES/NO
8. Have you had sufficient time to come to your decision?	YES/NO

9. Do you agree to take part in this study? YES/NO

Signature of the Proxy……...…… Date……

Name of the Proxy (BLOCK CAPITALS) ……

To be completed by the investigator
I, the undersigned, have fully explained the relevant details of this research study to the proxy named above and believe the proxy has understood and has knowingly given their consent.

Signature of Principal Investigator……....
Date…….
Name (BLOCK CAPITALS) …….

අනුමැතිය ලබාදීමේ පත්‍රිකාව

ශ්‍රී ලංකාවේ මස්තිෂ්ක අඝාතයෙන් පෙළෙන දරුවන්ගේ ස්ථිතික හා ගතික සමතුලිතතාව කෙරෙහි පුද්ගල ජලචිකිත්සක වැඩසටහනෙන් ඇති බලපෑම්

භාරකාරයා විසින් පිරවිය යුතුය

භාරකාරයා විසින් මුළු පත්‍රිකාවම ඇය හෝ ඔහු විසින්ම පිරවිය යුතුය.

1. පත්‍රිකාවේ සඳහන් තොරතුරු ඔබ කියවුවාද? (කරුණාකර එහි පිටපතක් ඔබ තබාගන්න) ඔව් /නැත

2. ඔබට මෙම අධ්‍යයනය පිළිබඳ කතාබස් කර ප්‍රශ්න ඇසීමට අවස්ථාවක් ලැබුනාද? ඔව් / නැත

3. ඔබේ සියලු ප්‍රශ්න සඳහා සෑහීමකට පත්විය හැකි පිළිතුරු ලැබුනාද? ඔව් / නැත

4. ඔබට අධ්‍යයනය පිළිබඳ ප්‍රමාණවත් තරම් තොරතුරු ලැබුනාද? ඔව් / නැත

5. ඔබට මෙම අධ්‍යයනය පිලිබඳ පැහැදිළි කලේ කවුද?

……

6. ඔබට කැමති ඕනෑම වෙලාවක මෙම අධ්‍යයනයෙන් ඉවත් වීමට හැකි බවත්, එසේ කිරීම සඳහා නිදහසට කරුණු කීමට අවශ්‍ය නොවන බවත්, ඉවත් වීම නිසා ඔබේ දරුවාට අනාගතයේදී ලැබීමට නියමිත වෛද්‍ය පහසුකම් සඳහා කිසිදු බලපෑමක් සිදු නොවන බවත් ඔබ දන්නේද? ඔව් / නැත

7. ඔබේ දරුවාගේ සහභාගිත්වයට අදාළව විමශර්කයන් සතුව ඇති, ඔබත් ඔබේ දරුවාත් පිළිබඳ තොරතුරු, අධ්‍යයන කණ්ඩායමේ අනෙකුත් සාමාජිකයන් විසින්ද පරික්ෂා කිරීමකට ලක්විය හැකියි. ඔබත් ඔබේ දරුවාත් පිළිබඳ සියලු පුද්ගලික තොරතුරු වල **රහස්‍යභාවය උපරිමයෙන්** සුරකිනු ඇත.මෙම පුද්ගලයන්ට ඔබේ සහ ඔබේ දරුවාගේ තොරතුරු වාතර්ා ලබාගැනීමට ඔබ අවසර දෙනවාද? ඔව් / නැත

8. ඔබට තීරණයක් ගැනීමට ප්‍රමාණවත් කාලයක් ලැබුනාද? ඔව් / නැත

9. ඔබ මෙම අධ්‍යයනයට සහභාගී වීමට එකඟ වෙනවාද? ඔව් / නැත

භාරකරුවාගේ අත්සන ……..…… දිනය ……
භාරකරුගේ නම (ඉංග්‍රීසි කැපිටල් අකුරුවලින්) .....

විමශර්කයා විසින් සම්පුණර් කලයුතු වේ

පහත අත්සන් කල මා විසින්, මෙම පයෙර්ෂණාත්මක අධ්‍යයනයට අදාළ සියලු තොරතුරු ඉහත නම සඳහන් භාරකරුවාට සම්පුණර්යෙන් පැහැදිළි කල අතර භාරකරුවා කරුණු තේරුම් ගෙන අවබෝධයෙන් ඒ සඳහා අනුමැතිය දුන් බවට විශ්වාස කරමි.

ප්‍රධාන විමශර්කගේ අත්සන …… දිනය ……
නම (ඉංග්‍රීසි කැපිටල් අකුරුවලින්)……

ஒப்புதல் படிவம்

இலங்கையில் மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் இயக்கமற்ற மற்றும் இயக்கச் சமநிலை பற்றி தனிமைப்படுத்தப்பட்ட நீரியல்மருத்துவ நிகழ்ச்சித்திட்டமொன்றின் தாக்கங்கள்

ஊரிமை பிரதிநிதியால் பூர்த்திசெய்யப்படவேண்டியது
ஊரிமை பெற்ற பிரதிநிதி இவ்வறிக்கையினை சுயமாக முழுமையாக பூர்த்திசெய்யப்பட வேண்டும்.

1. நீங்கள் தகவல் அறிக்கையினை வாசித்துள்ளீரா? (தயவுசெய்து பிரதியொன்றினை உங்களுடன் வைத்திருக்கவும்.)	ஆம் / இல்லை
2. இவ்வாய்வு பற்றி கலந்தாராய்வதற்க்கும், ஏதேனும் கேள்விகளை கேட்பதற்கும் உங்களுக்கு வாய்ப்பு கிடைத்ததா?	ஆம் / இல்லை
3. உங்களது அனைத்து கேள்விகளுக்கும் கிடைத்த விடைகளுடன் நீங்கள் திருப்தியடைந்தீரா?	ஆம் / இல்லை
4. ஆய்வுபற்றிய போதிய தகவல்கள் உங்களுக்கு கிடைக்கப்பெற்றதா?	ஆம் / இல்லை
5. ஆய்வுபற்றி உமக்கு விளக்கியது யார்?	ஆம் / இல்லை
6. காரணம் ஒன்றினை முன்வைக்காது அத்துடன் உமது குழந்தையின் எதிர்கால மருத்துவக் கவனிப்பு பாதிப்படையாது எந்நேரத்திலும் ஆய்விலிருந்த விலகுவதற்கு உமக்கு முடியும் என்பதனை நீங்கள் புரிந்துகொள்கின்றீர்களா?	ஆம் / இல்லை
7. இவ்வாய்வில் உமது பிள்ளையின் பங்கேற்பு தொடர்பில் ஆய்வாளர்களினால் வைத்திருக்கப்படும் உங்களதும் உங்களது பிள்ளையினதும் தரவுகளும் ஆய்வுக் குழுவின் வேறுஉறுப்பினர்களால் பரிசோதிக்கப்படலாம் உங்களதும் உங்களது பிள்ளையினது தனிப்பட்ட அடையாளத்துடன் தொடர்புடைய அனைத்த தகவல்களும் **கண்டிப்பாக இரகசியமானதாகக்** கொள்ளப்படும். உங்களதும் உங்களது பிள்ளையினதும் பதிவுகளை பெற்றுக்கொள்வதற்கு இத் தனிப்பட்டவர்களுக்கு நீங்கள் அனுமதி வழங்குகின்றீரா?	ஆம் / இல்லை
8. உங்களது தீர்மானத்தை எடுப்பதற்கு உங்களுக்கு போதிய காலம் அவகாசம் இருந்ததா?	ஆம் / இல்லை
9. இவ்வாய்வில் பங்குபற்றுவதற்க்கு நீங்கள் உடன்படுகின்றீர்களா?	ஆம் / இல்லை

ஊரிமை பெற்ற பிரதிநிதி கையொப்பம் ……... திகதி……

ஊரிமை பெற்ற பிரதிநிதி பெயர் (பெரிய எழுத்துக்களில்) ……

ஆய்வாளரினால் பூர்த்திசெய்யப்பட வேண்டியது
கீழே கையொப்பமிடும் நான் மேலே பெயர் குறிப்பிடப்பட்ட உரிமை பெற்ற பிரதிநிதிக்கு இவ் ஆராய்ச்சி ஆய்வு பற்றிய தொடர்புடைய விபரங்களை முழுமையாக விளக்கியுள்ளதுடன், உரிமை பெற்ற பிரதிநிதி புரிந்து கொண்டு அறிந்து தனது ஒப்புதலை வழங்கியுள்ளார்.

முதநிலை ஆய்வாளரின் கையொப்பம்……... திகதி……

பெயர் (பெரிய எழுத்துக்களில்) ……

Appendix F: Assent Form-English, Sinhala and Tamil

The Effects of an Individual Hydrotherapy Program on Static and Dynamic Balance in Children with Cerebral Palsy in Sri Lanka

1. **Why you are here?**
   I want to tell you about a study about children with cerebral palsy. I want to see if you would like to be in this study. This form tells you about the study. If there is anything you do not understand, please ask your parent or your guardian or me.

2. **Why are you asking me?**
   We are going to study about children with cerebral palsy who are at your age – between 6 and 12 years old – who are registered at the National Center for children with Cerebral Palsy and other Developmental Disorders (NCCCPDD).

3. **Why are they doing this study?**
   We want to learn more about whether exercising in water can improve balance of children with cerebral palsy. For this, we have a new water exercise program and are hoping it might improve your balance. In order to find out whether it improves balance we have to test it.

4. **What will happen to you?**
   If you want to be in the study, these things will happen:

- Your basic information such as age, height, weight, and cerebral palsy type and functional level will be obtained from the NCCCPDD. Then your heartbeat at rest will be checked.

- Next your balance will be assessed using 2 tests in 2 different days. To complete each test, it will take nearly 2 hours.

- For the first test, you will be asked to stand from sitting position and then walk total of 6 meter and then sit down on the same chair.

- During the second test, the maximum distance that you can reach in various directions while you are sitting and standing will be assessed.

- Next, water exercise program will be started. While you are doing these exercises in the pool, your heartbeat will be checked after every 5 minutes. You will be asked to wear a chest strap, a wristwatch and a life jacket before entering the pool.

- You will not be alone in the pool. Always there will be one physiotherapist with you. Additionally, sometimes your parents or guardian will also be in the pool.

- When you are in the pool, you will be asked to perform different exercises such as walking, kicking, jumping, running and swimming. The entire water activity program will last an hour.

- While you are in the pool, whenever you are tired and cannot continue exercising, you will be allowed to rest for few minutes.

- Once you have completed water exercises, you will leave the pool and take a shower and rest in the changing room for 20 minutes.

- The study will last about 6 weeks. You will be asked to come to the NCCCPDD 2 days per week for consecutive 6 weeks. During each visit you will have to spend approximately 1 hour and 30 minutes at the facility.

- Within 5 days following completion of the water exercise program, your balance will be reassessed using the same 2 tests describe above in 2 different days.

- In total you will have to come to the facility for 16 days; 4 days for the balance assessment and 12 days for water exercise program.

- During the study period, you will be asked to undergo this new water exercise program instead of routine water activities that you are currently undergoing at the NCCCPDD.

5. Will the study hurt you?

- Exercising in the pool may be tiring and you may feel some pain or discomfort.

- You may feel cold and chilly when you are in the pool for an hour.

- You may feel uncomfortable when you wear the chest strap and the wrist watch continuously for an hour.

- During or after doing exercises in the pool, or during or after the assessment of balance you may feel dizzy.

- You may feel angry if you are unable to perform all the tests and the water exercises well.

- You must tell your parents or the study staff if you feel pain or discomfort or unwell while participating in the study.

6. **Will you get better if you are in the study?**
   This study may or may not make you feel better or get well. But we hope the information learned from this study would help other children with cerebral palsy and water exercise programs in the future.

7. **What if you have any questions?**
   You can ask questions any time, now or later. If you want to talk to someone else that you know like your parents/guardian or teacher or doctor or auntie, that's okay too.

8. **Who will know what I did in the study?**
   Any information you provide to the study staff will be kept private. Your name will not be on any study paper and no one but the study staff will know that it was you who was in the study.

9. **Do you have to be in the study?**
   You do not have to be in the study. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just say so. We will also ask your parents/guardian if they would like you to be in the study. Even if your parents/guardian want you to be in the study you can still say no. The staff at this institution will still take care of your health condition. Even if you say yes now you can change your mind later. It's up to you.

If you choose to be part of this study, I will also give you a copy of this paper to keep for yourself. You can ask your parents or guardians to look after it if you want.

Assent

I want to take part in this study. I know I can change my mind at any time.

_____ Verbal assent given Yes □

Print Name of Child

Written assent if the child chooses to sign the assent.

_____ _____ _____

Signature of Child Age (years) Date

I confirm that I have explained the study to the participant to the extent compatible with the participants understanding, and that the participant has agreed to be in the study.

_____	_____	_____
Printed name of Principal Investigator	Signature of Principal Investigator	Date

දරුවාගේ එකඟතාවය ලබා ගැනීමේ පත්‍රිකාව

ශ්‍රී ලංකාවේ මස්තිෂ්ක අඝාතයෙන් පෙළෙන දරුවන්ගේ ස්ථිතික හා ගතික සමතුලිතතාව කෙරෙහි පුද්ගල ජලචිකිත්සක වැඩසටහනෙන් ඇති බලපෑම්

1. **ඇයි ඔබ මෙහි පැමිණියේ**?

   මස්තිෂ්ක ආඝාතය සහිත දරුවන් සම්බන්ධයෙන් කල අධ්‍යයනයක් ගැන ඔබට පැවසීමට මම කැමතියි. මෙම අධ්‍යයනය සඳහා සහභාගී වීමට ඔබ කැමතිදැයි දැනගැනීමට මට අවශ්‍යයි. මෙම පත්‍රිකාවෙන් ඔබට මෙම අධ්‍යයනය පිළිබඳ තොරතුරු ලබා දී තිබෙනවා. මෙහි ඔබට නොතේරෙන යමක් ඇත්නම්, කරුණාකර ඔබේ දෙමාපියන්ගෙන් හෝ භාරකරුවගෙන් හෝ මාගෙන් විමසීමක් කරන්න.

2. **ඇයි ඔබ මගෙන්අසන්නේ**?

   මස්තිෂ්ක ආඝාතය හා අනෙකුත් වධර්න අපහසුතා සහිත දරුවන් සඳහා වූ ජාතික මධ්‍යස්ථානයේ (NCCCPDD) ලියාපදිංචි වූ අවුරුදු 6ත් 12ත් අතර ඔබේ වයසේ පසුවෙන මස්තිෂ්ක ආඝාතය සහිත දරුවන් පිළිබඳවයි අපි අධ්‍යයනය කිරීමට යන්නේ.

3. **ඇයි ඔවුන්මෙම අධ්‍යයනය කරන්නේ**?

   ජලය තුල ව්‍යායාම්කිරීමෙන්මස්තිෂ්ක ආඝාතය සහිත දරුවන්ගේ සමතුලිතතාවය වැඩිදියුණුවේදැයි දැනගැනීමට අපට අවශ්‍යයි. මේ සඳහා, අපට අලුත්ජල ව්‍යායාම්වැඩසටහනක්තිබෙනවා. අප බලාපොරොත්තු වෙනවා ඒ තුලින්ඔබේ සමබරතාවය වැඩි දියුණුවෙනැයි කියා. ඒවන්වැඩිදියුනුවක්සිදුවේදැයි දැනගැනීමට අපට එය පරික්ෂා කර බැලීමට සිදුවෙනවා.

4. **ඔබට කුමක්සිදුවේවිද ?**

   ඔබ අධ්‍යයනයට සහභාගිවුවහොත්, මේ දේවල් සිදුවනු ඇති.

- NCCCPDD ආයතනයෙන් ඔබගේ වයස, උස, බර, මස්තිෂ්ක ආඝාත වගර්ය හා හැකියා මට්ටම යනාදී තොරතුරු ලබාගනු ඇති. ඊට පසු විවේකීව සිටින විට ඔබගේ හෘද ස්පන්දන වේගය මැන බැලේ.

- ඊළඟට දින 2ක් තුල පරීක්ෂණ 2ක් යොදාගනිමින් ඔබගේ සමතුලිත මට්ටම මැන බැලේ. එක පරීක්ෂණයක් සම්පුර්ර කිරීම සඳහා පැය 2ක් පමණ ගතවේ.

- පලමු පරික්ෂණයේ දී, ඔබට හිඳ සිටින ස්ථානයෙන් නැගිට මීටර් 6ක් පමණ ඇවිද ගොස් කලින් හිඳ සිටි පුටුවේම අසුන් ගැනීමට කියනු ඇති.

- දෙවන පරීක්ෂණයේදී, ඔබ හිඳ සිටින හෝ නැගිට සිටින විට විවිධ දිශා වෙත ඔබට යාහැකි උපරිම දුර පරික්ෂා කර බැලේ.

- ඉන්පසු ජල අභ්‍යාස පුහුණුව පටන් ගනු ඇති. ඔබ පිහිනුම් තටාකයේ මෙම අභ්‍යාස කරන අතරතුර සෑම විනාඩි 5කට වරක් ඔබගේ හෘද ස්පන්දන වේගය මැන බැලේ. පිහිනුම් තටාකයට බැසීමට පෙර ඔබට පපුව ආවරණය වන වැස්මක්, අත්ඔරලෝසුවක් හා ජීවිත ආරක්ෂක කබායක් හැඳීමට සිදුවේ.

- කිසිවිටකත් ඔබට තනිව පිහිනුම් තටාකයේ සිටීමට සිදු නොවේ. සෑමවිටම ඔබ සමග භෞතිකචිකිත්සකවරයකු සිටිනු ඇති. මීට අමතරව ඔබගේ දෙමාපියන්ට හෝ භාරකරුවාට ද සමහරක්විට තටාකයේ රැඳී සිටිය හැකියි.

- ඔබ පිහිනුම් තටාකයේ සිටින විට ඔබට ඇවිදීම, කකුල් ගැසීම, පැනීම, දිවීම සහ පිහිනීම වැනි නොයෙක් ක්‍රියාකාරම් කිරීමට කියනු ඇත. මුළු ජල ක්‍රියාකාරකම් වැඩසටහනටම පැයක පමණ කාලයක් ගතවේ.

- ඔබ පිහිනුම් තටාකයේ සිටින විට, ඔබට වෙහෙසක් දැනී ක්‍රියාකාරකම් දිගටම කරගෙන යාමට අපහසු වන සෑම විටම ඔබට විනාඩි කිහිපයක විවේකයක් ලබාදෙනු ඇති.

- ඔබ ජල අභ්‍යාස සම්පූර්ණ කල පසු, ඔබ පිහිනුම් තටාකයෙන් ගොඩට විත්, ශරීරය සෝදාගෙන, ඇඳුම් මාරු කරන ස්ථානයේ විනාඩි 20ක් පමණ විවේක ගත යුතුය.

- අධ්‍යයනය සති 6ක් පමණ කාලයක් පවතිනු ඇත. ඔබට සතියකට දින 2ක් බැගින්, ඉරිදා දින හැර, නොකඩවා සති 6ක් **NCCCPDD** වෙත පැමිණීමට සිදුවේ. පැමිණෙන සෑම දිනකම ඔබට ආයතනය තුල පැයකුත් විනාඩි 30ක් පමණ කාලයක් රැඳී සිටීමට සිදුවේ.

- ජල අභ්‍යාස වැඩසටහන සම්පූර්ණ කල දිනයේ සිට දින 5ක් ඇතුලත, ඔබගේ සමතුලිතතාවය නැවත ඇගයීමක් කිරීම සඳහා කලින් කල පරීක්ෂණ 2කම නැවතත් දින 2ක් තුල කෙරෙනු ඇති.

- ඔබට ආයතනයට පැමිණීමට සිදුවන සම්පූර්ණ දින ගණන 16කි. සමතුලිතතාවය පරීක්ෂා කිරීම සඳහා දින 4කුත්, ජල අභ්‍යාස සඳහා දින 12කුත් වෙන්වේ.

- අධ්‍යයන කාලය තුල, ඔබ දැනට NCCCPDD ආයතනය තුල කරන ජල ක්‍රියාකාරකම් වෙනුවට නව ජල අභ්‍යාස වැඩසටහනේ ක්‍රියාකරම් වල යේදීමට සිදුවනු ඇත.

5. මෙම අධ්‍යයනයෙන්ඔබට හානියක්සිදුවේද ?

- පිහිනුම් තටාකයේ අභ්‍යාස කිරීම තුලින් ඔබට වෙහෙසක්, අපහසුතාවයක් හෝ වේදනාවක් දැනීමට හැකියි.

- පැයක් පිහිනුම් තටාකය තුල ගත කිරීම නිසා ඔබට සීතලක් වෙව්ලීමක් ඇතිවිය හැකියි.

- පපු වැස්ම සහ අත්ඔරලෝසුව පැයක පමණ කාලයක් එක දිගට පැළඳ සිටීම නිසා අපහසුතාවයක් ඇති විය හැකියි.

- පිහිනුම් තටාකය තුල අභ්‍යාස කරන අතරතුර හෝ ඉන්පසුව, නැතහොත් සමතුලිතතාවය පරීක්ෂා කර බලන ක්‍රියාකාරම් අතරතුර ඔබට ක්ලාන්ත ගතියක් ඇති විය හැකියි.

- ඔබට සියලු පරීක්ෂණ වලට සාථර්කව මුහුණ දීමට බැරිවීම නිසා හෝ ජල අභ්‍යාස නිවැරදිව කිරීමට නොහැකිවීම නිසා තරහක් ඇති විය හැකියි.

- අධ්‍යයනයට සහභාගී වන අතරතුර ඔබට වේදනාවක්, අපහසුතාවක්, අසනීප ගතියක් දැනුනහොත් ඔබ ඒ බව වහාම ඔබේ දෙමාපියන්ට හෝ අධ්‍යයන කායර්මණ්ඩලයට දැනුම් දිය යුතුය.

6. **මෙම අධ්‍යයනයට සහභාගිවීමෙන් ඔබ සුවපත්වේද?**

මෙම අධ්‍යයනය තුලින් ඔබට වඩා සුවයක් දැනීමට හෝ කිසිදු වෙනසක් නොවීමට ඉඩ ඇත. නමුත් අපේ බලාපොරොත්තුව මෙම අධ්‍යනය තුලින් ඉගෙනගන්නා තොරතුරු, අනාගතයේ මස්තිෂ්ක ආඝාතය සහිත දරුවන්ට හා ජල අභ්‍යාස වැඩසටහන්වලට ප්‍රයෝජනවත් වෙනු ඇති කියායි.

7. **ඔබට ප්‍රශ්නයක්ඇත්නම් ?**
ඔබට ඕනෑමවෙලාවක ප්‍රශ්න ඇසිය හැකියි, දැන්හෝ පසුව**.** ඔබට මේ පිලිබඳ වෙන කිසිවකු සමග කතා කිරීමට අවශ්‍ය නම්, ඔබේ දෙමාපියන්, භාරකරු, ගුරුවරයා, වෛද්‍යවරයා හෝ වෙනත් වැඩිහිටියකු සමග ඔබට මේ ගැන කතා කල හැකියි. එසේ කතා කිරීම යහපත්.

8. **මම මේ අධ්‍යනය තුලදී කල ක්‍රියාකාරම්පිළිබඳ විස්තරදැනගන්නේ කවුද?**
ඔබ අධ්‍යයන කායර්මණ්ඩලයට සපයන සියලු තොරතුරුවල රහස්‍යභාවය ආරක්ෂාවේ. ඔබේ නම කිසිදු අධ්‍යයන වතර්ාවක සඳහන්නොවන අතර අධ්‍යයන කායර්මණ්ඩලය හැර අන්කිසිවකු ඔබ මෙම අධ්‍යයනය සඳහාසහභාගීවූබව දැනගන්නේ නැත.

9. **ඔබ අනිවාර්යෙන්මෙම අධ්‍යයනයට සහභාගීවිය යුතුද?**
ඔබ අනිවාර්යෙන් මෙම අධ්‍යයනයට සහභාගීවිය යුතු නැත. ඔබ මෙයට සහභාගීවීමට අකමැතිවුවා කියා කිසිවකු ඔබ සමග තරහා වන්නේ නැත. ඔබ මෙම අධ්‍යයනයට සහභාගීවීමට අකමැතිනම්, ඒබව පවසන්න. අපි මෙම වැඩසටහනට ඔබව සම්බන්ධ කරගැනීමට ඔබගේ දෙමාපියන්ගෙන් / භාරකරුවන්ගෙන්ද අවසර ගන්නෙමු. ඔබේ දෙමාපියන් / භාරකරුවන්ඒසඳහා අවසරදුන්නද ඔබ සහභාගීවීමට අකමැතිනම්ඔබට වැඩසටහනට සම්බන්ධ නොවී සිටිය හැකිය. එය එසේවුවත්මෙම ආයතනයේ කායර් මණ්ඩලය කිසිදු වෙනසකින්තොරව ඔබට සෞඛ්‍ය සේවා සපයනු ඇත. ඔබ දැන්කැමතිවුවත්, ඔබට පසුව ඔබේ තීරණය වෙනස්කිරීමට අවශ්‍යවුවහොත්එසේ කල හැක. තීරණය සම්පුණර්යෙන්ම ඔබේ අතේය.

ඔබ මෙම අධ්‍යයනයට සහභාගිවීමට කැමති වුවහොත්, ඔබට මා විසින් මෙම ලියවිල්ලේ පිටපතක් තබාගැනීමට ලබාදෙන්නෙමි. එය ප්‍රවේසම් කර තබාගැනීමට ඔබට එය ඔබේ දෙමාපියන්ට හෝ භාරකරුවාට ලබාදිය හැකිය.

මම මෙම අධ්‍යයනයට සහභාගීවීමට කැමැත්තෙමි. මට කැමති වෙලාවක එම තීරණය වෙනස් කිරීමට හැකි බව මම දනිමි.

_____ වාචික එකඟත්වය ලැබුනිද ඔව් □

දරුවාගේ නම

දරුවා තම අත්සන යෙදීමට කැමති නම්, ලිඛිත එකඟත්වය

_____ _____ _____

දරුවාගේ අත්සන වයස (අවුරුදු) දිනය

සහාගිවන්නාගේ තේරුම් ගැනීමේ හැකියාවට උචිත ආකාරයෙන් මම මෙම අධ්‍යයනයට අදාළ කරුණු පැහැදිළි කල බවත්, දරුවා අධ්‍යයනයට සහභාගීවීමට එකඟත්වය පලකල බවටත්, මෙයින් සහතිකවෙමි

_____ _____ _____

ප්‍රධාන විමශර්කගේ නම දිනය අත්සන

பிள்ளைகளுக்கான இசைவுப் படிவம்

இலங்கையில் மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் இயக்கச்மற்ற மற்றும் இயக்கச் சமநிலை பற்றி தனிமைப்படுத்தப்பட்ட நீரியல்மருத்துவ நிகழ்ச்சித்திட்டமொன்றின் தாக்கங்கள்

1. **நீங்கள் இங்கே இருப்பதற்கான காரணம் என்ன?**
   மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகள் பற்றிய ஆய்வொன்று பற்றி நான் உங்களுக்கு சொல்ல வேண்டும். நீங்கள் இந்த ஆய்வில் கலந்து கொள்வதற்கு விருப்பமா என்பதனை நான் அறிய வேண்டும். இப்படிவம் இவ்வாய்வு பற்றி உங்களுக்கு கூறும். நீங்கள விளங்கிக்கொள்ளாத ஏதாவது இருக்குமாயின், தயவுசெய்து உங்களது பெற்றோரிடம் அல்லது உங்களது பாதுகாவலரிடம் அல்லதுஎன்னிடம் கேட்கலாம்.

2. **நீங்கள் என்னிடம் ஏன் கேட்க வேண்டும்?**
   மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் பதிவுசெய்த 6 தொடக்கம் 12 வயதுடைய மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகள் பற்றிய ஆய்வொன்றினை நாம் மேற்கொள்ளப் போகின்றோம்.

3. **ஏன் இவ் ஆய்வினை அவர்கள் செய்கின்றார்கள்?**
   நீரியல் உடற்பயிற்சி செய்வது மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் சமநிலையினை மேம்படுத்தக்கூடியதா என்பது பற்றி நாங்கள் மேலும் கற்க விரும்புகின்றோம். இதற்காக எம்மிடம் புதிய நீரியல் உடற்பயிற்சி நிகழ்ச்சித்திட்டமொன்று காணப்படுவதுடன், உமது சமநிலையினை இது மேம்படுத்தலாம் என நாம் நம்புகின்றோம். இது சமநிலையினை மேம்படுத்துகின்றதா என்பதனை கண்டறியும் பொருட்டு இதனைநாம் பரிசோதிக்க வேண்டும்.

4. **உங்களுக்கு என்ன நடக்கும்?**
   இவ் ஆய்வில் நீங்கள் பங்குபற்ற வேண்டுமாயின் பின்வரும் விடயங்கள் உங்களுக்கு நடக்கும்.

- வயது, உயரம், நிறை மற்றும் மூளையச்சோர்வாதத்தின் வகை அத்துடன் இயக்கச் மட்டம் போன்ற உமது அடிப்படை தகவல்கள் மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்திலிருந்து பெற்றுக்கொள்ளப்படும். பின்னர் ஓய்வின் போது உமது இதயத்துடிப்பு பரிசோதனை செய்யப்படும்.

- அதன் பின்னர் உமது சமநிலையானது 2 பரிசோதனைகளைப் பயன்படுத்தி 2 வெவ்வேறு தினங்களில் கணிப்பிடப்படும். ஓவ்வொரு பரிசோதனையினையும் நிறைவுசெய்வதற்கு கிட்டத்திட்ட 2 மணித்தியாலங்கள் எடுக்கும்.

- முதலாவது பரிசோதனைக்காக உட்காரும் நிலையிலிருந்து எழுந்து நிற்பதற்கு உங்களிடம் கூறப்படும். அதன் பின்னர் மொத்தமாக 6 மீற்றர்களுக்கு நடந்துசெலவதற்கும் பின்னர் அதே கதிரையில் உட்காருவதற்கும் கூறப்படும்.

- இரண்டாவது பரிசோதனையின் போது நீங்கள் உட்கார்ந்து இருக்கும்போதும் நிற்கும் போதும் பல திசைகளை நோக்கி நீங்கள் அடையக்கூடிய அதிகூடிய தூரம் கணிப்பிடப்படும்.

- இதனைத் தொடர்ந்து நீரியல் உடற்பயிற்சி நிகழ்ச்சித்திட்டம் ஆரம்பிக்கப்படும். இவ் உடற்பயிற்சிகளை நீர்த்தடாகத்தில் செய்கின்ற வேளையில் உமது இதயத்துடிப்பு ஒவ்வொரு 05 நிமிடங்களின் பின்னரும் பரிசோதனை செய்யப்படும். தடாகத்தினுள் நீங்கள் செல்வதற்கு முன்னர் நெஞ்சுப்பட்டையொன்று, மணிக்கூடு மற்றும் உயிர்காக்கும் அங்கியொன்று என்பவற்றை அணியும் படி உங்களிடம் கேட்கப்படும்.

- தடாகத்தில் நீங்கள் மாத்திரம் இருக்க மாட்டீர்கள். எப்போதும் உங்களுடன் இயன் மருத்துவரொருவர் இருப்பார். இதற்கு மேலதிகமாக, சில சந்தர்பங்களில் உமது பெற்றோர்கள் அல்லது பாதுகாவலரும் தடாகத்தில் இருப்பர்.

- நீங்கள் தடாகத்திலிருக்கின்றபோது நடத்தல், உதைத்தல், பாய்தல், ஓடுதல் மற்றும் நீந்துதல் போன்ற வேறுபட்ட உடற்பயிற்சிகளை செய்யும்படி கேட்கப்படுவீர்கள் ஒட்டுமொத்தநீர் செயற்பாட்டு நிகழ்ச்சித்திட்டமும் ஒரு மணித்தியாலத்தை கொண்டதாகவிருக்கும்.

- நீங்கள் தடாகத்திலிருக்கின்றபோது எப்போதாவது களைப்படைவீர்களாயின் மற்றும் உடற்பயிற்ச்சியை தொடர்ந்தும் செய்யமுடியாதாயின் சில நிமிடங்களுக்கு ஓய்வெடுப்பதற்கு உங்களுக்கு அனுமதியளிக்கப்படும்.

- நீர் உடற்பயிற்ச்சிகளை நீங்கள் பூர்த்திசெய்ததன் பின்னர் தடாகத்திலிருந்து நீங்கள் வெளியேறி குளித்து 20 நிமிடங்களுக்கு உடை மாற்றும் அறையில் ஓய்வெடுக்கலாம்.

- இவ் ஆய்வுசுமார் 6 வாரங்களுக்கு நீடிக்கும். வாரத்தின் ஞாயிற்றுகிழமை தவிர வாரமொன்றுக்கு 2 நாட்கள் வீதம் தொடர்ச்சியாக 6 வாரங்களுக்கு மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்திற்கு வருமாறு உங்களிடம் கேட்கப்படும். ஒவ்வொரு வருகையின் போதும் இவ்விடத்தில் ஏறக்குறைய 1 மணித்தியாலம் 30 நிமிடங்கள் நீங்கள் செலவிடவேண்டிருக்கும்.

- நீர் உடற்பயிற்சி நிகழ்ச்சித்திட்டம் முடிவடைந்த பின்னர் 5 நாட்களுக்குள் உங்களது சமநிலை மேலே விவரிக்கப்பட்ட அதே 2 பரிசோதனைகளை பயன்படுத்தி 2 வெவ்வேறு தினங்களில் மீண்டும் கணிப்பிடப்படும்.

- மொத்தமாக 16 நாட்கள் இவ்விடத்திற்கு நீங்கள் வரவேண்டியிருக்கும் அதாவது, சமநிலையினை கணிப்பிடுவதற்காக 04 நாட்களும் நீர் உடற்பயிற்சி நிகழ்ச்சித்திட்டத்திற்காக 12 நாட்களும்.

- ஆய்வுக் காலத்தின் மூளையச்சோர்வாதம் மற்றும் ஏனைய விருத்தியிடையும் குறைபாடுகளுடன் கூடிய பிள்ளைகளுக்கான தேசிய நிலையத்தில் ற்போது நீங்கள்

செய்கின்ற வழமையான நீர் செயற்பாடுகளுக்குப் பதிலாக இப் புதிய நீர் நிகழ்ச்சித் திட்டத்தினை செய்யுமாறு வேண்டப்படுவீர்கள்.

5. இவ்வாய்வு உங்களுக்கு வலியை ஏற்படுத்துமா?

- தடாகத்தில் உடற்பயற்சி செய்வது உங்களை களைப்படையச் செய்யலாம். நீங்கள் சில வலிகளை அல்லது அசௌகரியத்தை உணரலாம்.

- ஒரு மணித்தியாலம் தடாகத்தில் நீங்கள் இருக்கின்ற போது நீங்கள் குளிரை மற்றும் கூதலை உணரலாம்.

- ஒரு மணித்தியாலத்திற்கு நெஞ்சுப்படடை மற்றும் மணிக்கூடு தொடர்ச்சியாக அணிந்திருக்கின்ற போது அசௌகரியமின்மையினை உணரலாம்.

- தடாகத்தில் உடற்பயிற்சியின் போது அல்லது உடற்பயிற்சியின் பின்னர் அல்லது சமநிலை கணிப்பீட்டின் போது அல்லது பின்னர் தலைசுற்றினை உணரலாம்.

- அனைத்து பரிசோதனைகளையும் அத்துடன் நீர் உடற்பயிற்சினையும் செலாற்றுவதற்கு முடியாதிருப்பீர்களாயின் உங்களுக்கு கோபம் வரலாம்.

- ஆய்வில் பங்கேற்கின்ற போது வலியை உணர்ந்தால் அல்லது அசௌகரியத்தை உணர்ந்தால் அல்லது நலக்குறைவினை உணர்ந்தால் உங்களின் பெற்றோருக்கு அல்லது ஆராய்ச்சி அலுவலர்களுக்கு கட்டாயம் சொல்ல வேண்டும்.

6. இவ்வாய்வில் கலந்து கொள்வீர்களாயின் நீங்கள் சுமகடைவீர்களா?

இவ்வாய்வின் மூலம் நீங்கள் சுகத்தை உணரலாம் அல்லது உணராதிருக்கலாம் அல்லது நீங்கள் சுகமடையலாம். ஆனால் இவ்வாய்விலிருந்து நாம் கற்றுக்கொள்கின்ற தகவல்கள் எதிர்காலத்தில் மூளையச்சோர்வாதத்துடன்கூடிய ஏனைய பிள்ளைகளுக்கும் நீர் உடற்பயிற்சி நிகழ்ச்சித் திட்டங்களுக்கும் உதவும் எனநாம் நம்புகின்றோம்.

7. உங்களிடம் ஏதேனும் கேள்விகள் இருப்பின் என்னசெய்வது ?

கேள்விகளை நீங்கள் தற்போது அல்லது பின்னர் ஏந்நேரத்திலும், கேட்கலாம். உமது பெற்றோர்கள்.. அல்லது பாதுகாவலர் அல்லது ஆசிரியர் அல்லது வைத்தியர் அல்லது உமது அத்தை போன்ற உங்களுக்கு தெரிந்த வேறுயாருடனாவது உங்களுக்கு கதைக்க வேண்டுமாயின் அதுவும் செய்யலாம்.

8. ஆய்வில் நான் என்னசெய்தேன் என்று யார் அறிவர்?

ஆய்வு அலுவலர்களுக்கு நீங்கள் வழங்குகின்ற ஏதேனும் தகவல் இரகசியமாக வைக்கப்படும். உங்கள் பெயர் எவ்வித ஆவணங்களிலும் இடம்பெறாது அத்துடன் ஆய்வில் கலந்து கொண்டது நீங்கள் தான் என்பதனை ஆய்வுஅலுவலர்கள் தவிர வேறு யாரும் அறியமாட்டார்கள்.

9. நீங்கள் ஆய்வில் கலந்து கொள்ளத்தான் வேண்டுமா?

நீங்கள் ஆய்வில் கலந்து கொள்ளத் தேவையில்லை. உங்களுக்கு இதைச் செய்யத் தேவையில்லையென்றால் யாரும் உங்கள் மீது கோபப்படமாட்டார்கள். நீங்கள் இவ் ஆய்வில் கலந்துகொள்ள விரும்பவில்லையாயின் அதனை சாதாரணமாக சொல்லிவிடலாம். நீங்கள் இந்த அய்வில் கலந்து கொள்ள விருப்பமா என்பது பற்றி நாம் உங்களது பெற்றோரிடம்.'. பாதுகாவலரிடம் வினவுவோம். உங்கள் பெற்றோர்கள்.'. பாதுகாவலர் நீங்கள் இவ்வாய்வில் கலந்து கொள்வதனை விரும்புவதாயினும் நீங்கள் மறுக்கலாம். நிறுவனத்தில் உள்ள அலுவலர்கள் உங்களது ஆரோக்கிய நிலைமையினை தொடர்ந்தும் கவனிப்பர். நீங்கள் தற்போபோது ஆம் என்று சொல்லிவிட்டு பிறகு உங்களது மனதை மாற்றிக்கொள்ளலாம். அது உங்களை பொறுத்தது.

இவ்வாய்வில் கலந்து கொள்வதற்கு நீங்கள் விரும்புவீர்களாயின் நீங்கள் வைத்துக் கொள்வதற்காக இவ் ஆவணத்தின் பிரதியொன்றை உங்களுக்கும் நான் தருவேன். உங்களுக்கு தேவையாயின் இதனை பாதுகாப்பதற்கு உங்களது பெற்றோர்களை அல்லது பாதுகாவலரை கேட்கலாம்.

இசைவு

இவ்வாய்வில் நான் கலந்து கொள்ளப்போகின்றேன். எனது மனதை எச் சந்தர்பத்திலேனும் மாற்றிக்கொள்ள முடியுமென்பதை நான் அறிவேன்

…….. வாய்மொழிமூல இசைவு வழங்கப்பட்டது ஆம் □

பிள்ளையின் பெயர்

இசைவினை ஒப்பமிடுவதற்கு பிள்ளை விரும்புவதாயின் எழுத்திலான இசைவு

…… …… ……

பிள்ளையின் கையொப்பம் வயது (வருடங்கள்) திகதி

பங்கேட்பாளர் புரிந்துகொள்ளும் விதத்தில் ஆய்வு பற்றி பங்கேற்பாளர்களுக்கு நான் விளக்கியுள்ளதுடன் ஆய்வில் பங்கேற்பாளர் கலந்து கொள்வதற்கு உடன்பட்டுள்ளார் என்றும் நான் உறுதிப்படுத்துகின்றேன்.

…… …… ……

முதன்மை ஆய்வாளரின் பெயர் முதன்மை ஆய்வாளரின் திகதி

கையொப்பம்

Appendix G: Data Collection Sheet-Demographic and Clinical Data of the Child

Data Collection Sheet - Demographic and Clinical data of the Child

Protocol title: The effects of an individual hydrotherapy program on static and dynamic balance in children with cerebral palsy in Sri Lanka

Data to be collected on paper: Yes ☐ No ☐

Data to be entered directly into computer spread sheet Yes ☐ No ☐

Child's Identification Number: …….

Data elements to be collected:

Demographic data of children:

1. Age (years): ……
2. Gender: ……...
3. Height:
4. Weight: ……...

Clinical data elements from chart or database:

1. Cerebral Palsy Type: …….
2. Functional level of the child according to GMFCS classification (GMFCS I, II, or III): ……...

Data to be measured:

1. Resting Heart rate - 1st reading: …….
2. Resting Heart rate - 2nd reading: ……...
3. Resting Heart Rate – 3rd reading: ……...
4. Average Resting Heart Rate – …….

Data collected by (printed name and signature): _____

Date Data collected: _____

Appendix H: Data Collection Sheet-Pediatric Reach Test

Data Collection Sheet – Pediatric Reach Test (PRT)

Study title: The effects of an individual hydrotherapy program on static and dynamic balance in children with cerebral palsy in Sri Lanka

Data to be collected on paper: Yes ☐ No ☐

Data to be entered directly into computer spread sheet Yes ☐ No ☐

Data elements to be collected: Pediatric Reach Test (PRT) Scores

Child's Identification Number: …….

Assistive Device and/or Bracing Used: ……

Sitting (Distance reached in cm):

	Trial one			Trial two			Trial three			Mean Difference
	Start	End	Difference	Start	End	Difference	Start	End	Difference	
Reaching forward										
Reaching to the left										
Reaching to the right										
Total Score										

Standing (Distance reached in cm):

	Trial one			Trial two			Trial three			Mean Difference
	Start	End	Difference	Start	End	Difference	Start	End	Difference	
Reaching forward										
Reaching to the left										
Reaching to the right										
Total Score										

Data collected by (printed name and signature): …….

Date Data collected: ……

Appendix I: Data Collection Sheet- modified Timed -Up and Go test

Data Collection Sheet – modified Timed-Up and Go (mTUG) Test

Study title: The effects of an individual hydrotherapy program on static and dynamic balance of children with cerebral palsy in Sri Lanka

Data to be collected on paper: Yes ☐ No ☐

Data to be entered directly into computer spread sheet Yes ☐ No ☐

Data elements to be collected: modified Timed Up and Go (mTUG) Test Scores

Child's Identification Number: …….

Assistive Device and/or Bracing Used: ……

mTUG Test Time in Seconds:

Trial One	Trial Two	Trial Three	Average of Three trials

Data collected by (printed name and signature): …….

Date Data collected: ……

Appendix J: Data Collection Sheets-Visual Analogue Scale – English, Sinhala and Tamil

Data Collection Sheet – Visual Analogue Scale

Study title: The effects of an individual hydrotherapy program on static and dynamic balance in children with cerebral palsy in Sri Lanka

Data to be collected on paper: Yes ☐ No ☐

Data to be entered directly into computer spread sheet Yes ☐ No ☐

Data elements to be collected: Health-Related Quality of Life of Children

Child's Identification Number: …….

Date of assessment: ……...

Instructions:

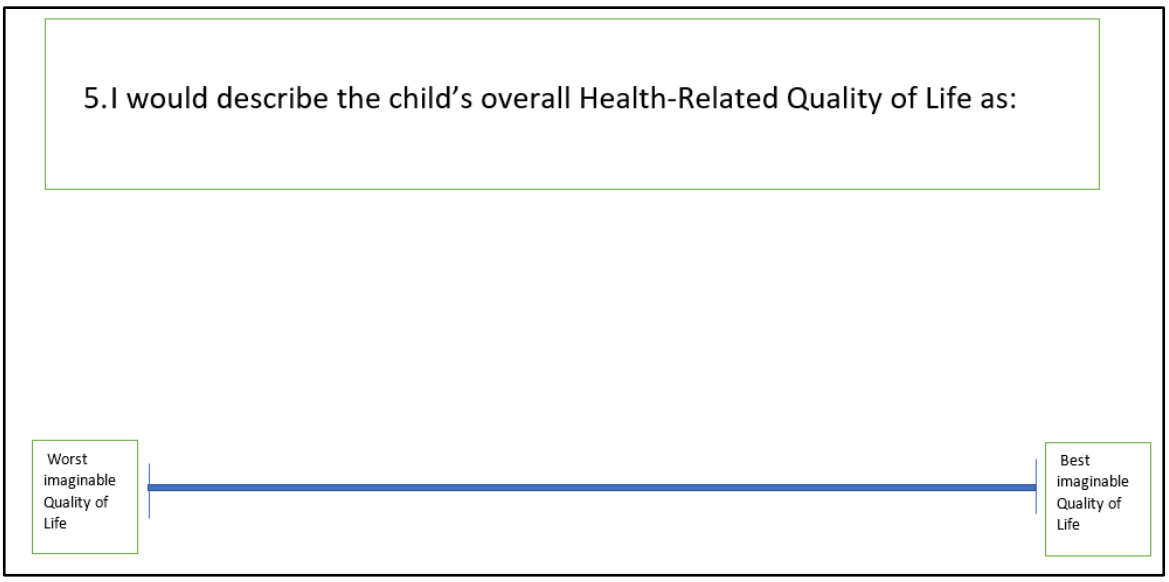
We have given you 5 scales to rate the 5 domains of the health-related quality of life of your child. What is represented by left and right ends of the scale differs according to the type of domain of health-related quality of life that you are going to rate. On each scale, we ask you to draw a vertical line at the point that is most representative of the particular domain of the health-related quality of life of your child.

1.I would describe the child's pain or discomfort during physical activity as:

2.I would describe the child's enjoyment of physical activity as:

3.I would describe the child's self-confidence in participating in physical activity as:

4.I would describe the child's comfort level at social setting as:


5.I would describe the child's overall Health-Related Quality of Life as:
Worst imaginable Quality of Life
Best imaginable Quality of Life

දත්ත රැස්කිරීමේ පත්‍රිකාව - දෘශ්‍ය සමකාරක පරිමාණය

අධ්‍යයන ශීෂර්ය: ශ්‍රී ලංකාවේ මස්තිෂ්ක ආඝාතයෙන් පෙළෙන දරුවන්ගේ ස්ථිතික හා ගතික සමතුලිතතාව කෙරෙහි පුද්ගල ජලචිකිත්සක වැඩසටහනෙන් ඇති බලපෑම්

දත්ත රැස්කිරීම සඳහා පත්‍රිකා යොදා ගන්නවාද : ඔව්☐නැත☐

දත්ත කෙලින්ම පරිගණක වගුවකට ඇතුලත් කරනවාද ? ඔව් ☐නැත ☐

රැස්කර ගතයුතු දත්ත **:** දරුවන්ගේ සෞඛ්‍ය හා අදාළ ජීවන ගුණාත්මකභාවය

දරුවාගේ හැඳුනුම් අංකය: .....

ඇගයීම කරන දිනය : .....

උපදෙස් **:**

ඔබේ දරුවාගේ සෞඛ්‍යයට අදාළ ජීවන ගුණාත්මකභාවය පිළිබඳ මැන බැලීමට අංශයන් 5ක් සඳහා අප විසින් ඔබට පරිමාණයන් 5 ක් ලබා දී තිබෙනවා. ඔබ ඇගයීමට ලක්කරන සෞඛ්‍යයට අදාළ ජීවන ගුණාත්මකභාවය අනුව පරිමාණයේ වම්පස සහ දකුණුපස කෙළවරෙන් අදහස් කරනු ලබන්නේ කුමක්ද යන්න වෙනස් වේ. එක් එක් පරිමාණයෙහි, අදාළ අංශය අනුව ඔබේ දරුවාගේ සෞඛ්‍යයට අදාළ ජීවන ගුණාත්මකභාවය පිළිබඳ වඩා නිවැරදිව පෙන්වන ස්ථානය සිරස් රේඛාවකින් ලකුණු කරන්න.

1. ශාරීරික ක්‍රියාකාරකම් කිරීමේදී දරුවාට ඇතිවන වේදනා හෝ අපහසුතා මා විසින් විස්තර කරන්නේ:

2. දරුවා ශාරීරික ක්‍රියාකාරකම් වලින් ලබන චින්දනය මා විසින් විස්තර කරන්නේ:

3. ශාරීරික ක්‍රියාකාරකම් සඳහා සහභාගිවීමට දරුවාට ඇති ආත්මවිශ්වාසය පිළිබඳ මා විසින් විස්තර කරන්නේ:

4. දරුවාගේ සමාජශීලිභාවය මා විසින් විස්තර කරන්නේ:

5. දරුවාගේ සෞඛ්‍ය සම්බන්ධ ජීවන ගුණාත්මකභාවය සමස්ථයක් වශයෙන් මා විසින් විස්තර කරන්නේ:

தரவுசேகரித்தல் அறிக்கை- கற்புலஉருவகஅளவுமுறை

ஆய்வுத் தலைப்பு: இலங்கையில் மூளையச்சோர்வாதத்துடன் கூடிய பிள்ளைகளின் இயக்கமற்ற மற்றும் இயக்கச் சமநிலை பற்றி தனிமைப்படுத்தப்பட்ட நீரியல்மருத்துவ நிகழ்ச்சித்திட்டமொன்றின் தாக்கங்கள்

தாளொன்றில் தரவுசேகரிக்கப்படும்: ஆம் ☐ இல்லை☐

தரவு நேரடியாக கணனி விரிதாளில் பதியப்படும் ஆம் ☐ இல்லை☐

சேகரிக்கப்படவுள்ள தரவுக் கூறுகள்: பிள்ளையின் வாழ்க்கைத்தரத்துடன் தொடர்புடைய ஆரோக்கிம்

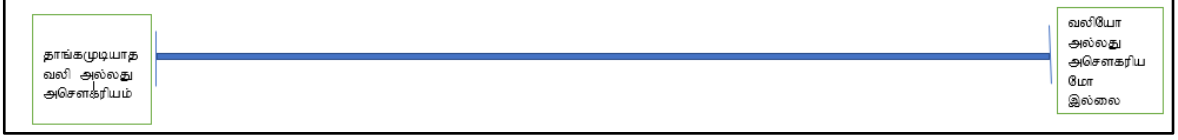
பிள்ளையின் அடையாள இலக்கம்: .....

கணிப்பிடும் திகதி: .....

அறிவுறுத்தல்கள்

உங்களது பிள்ளையின் வாழ்க்கைத் தரத்துடன் தொடர்புபட்ட ஆரோக்கியத்தின் 5 எல்லையங்களை தப்படுத்துவதற்காக நாம் உங்களுக்கு 5 அளவீடுகளை கொண்ட முறையொன்றினை வழங்கியுள்ளோம். அளவீட்டுமுறையின் இட மற்றும் வலப்பக்கங்களில் காட்டப்படுவது யாதெனில் நீங்கள் தரப்படுத்தப்போகின்ற வாழ்க்கை தொடர்படைய ஆரோக்கிய எல்லைய வகைக்கு அமைவாக வேறுபடுகின்றமையாகும். ஒவ்வொரு அளவீட்டுமுறையிலும் உங்களது குழந்தையின் வாழ்க்கைத் தரத்தடன் தொடர்புபட்ட ஆரோக்கியத்தின் குறித்த எல்லையத்தினை மிகச் சரியாக காட்டுகின்ற புள்ளியில் நேரான கோடொன்றினை வரைவதற்கு உங்களிடம் நாம் கேட்போம்

1. உடலியல் செயற்பாட்டின்போது பிள்ளையின் வலியினை அல்லது அசௌகரியத்தினை இவ்வாறு விவரிக்கின்றேன்:



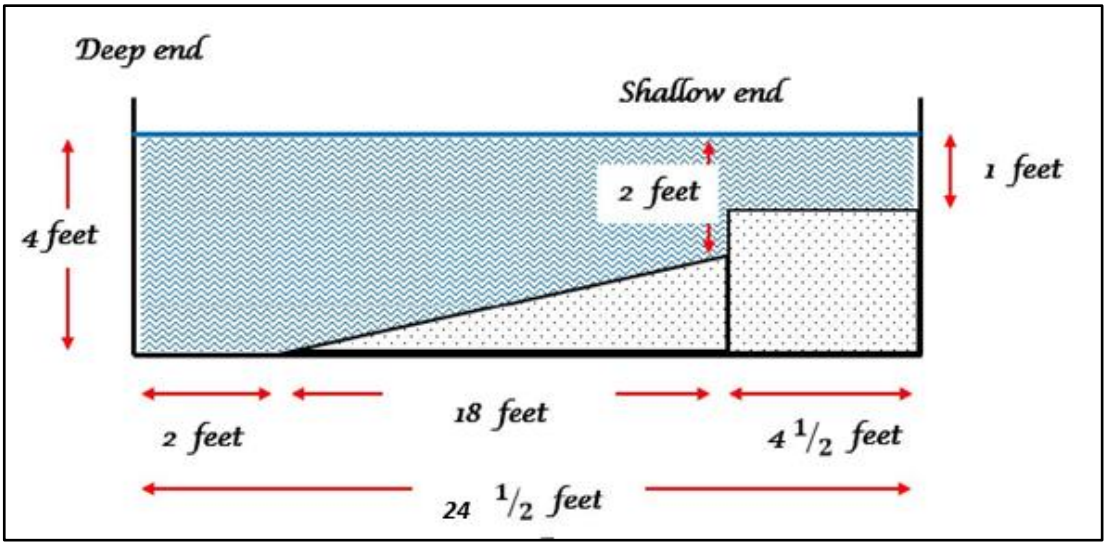
2. உடலியல் செயற்பாட்டின்போது பிள்ளை மகிழ்ச்சியடைந்ததை நான் இவ்வாறு விவரிக்கின்றேன்:

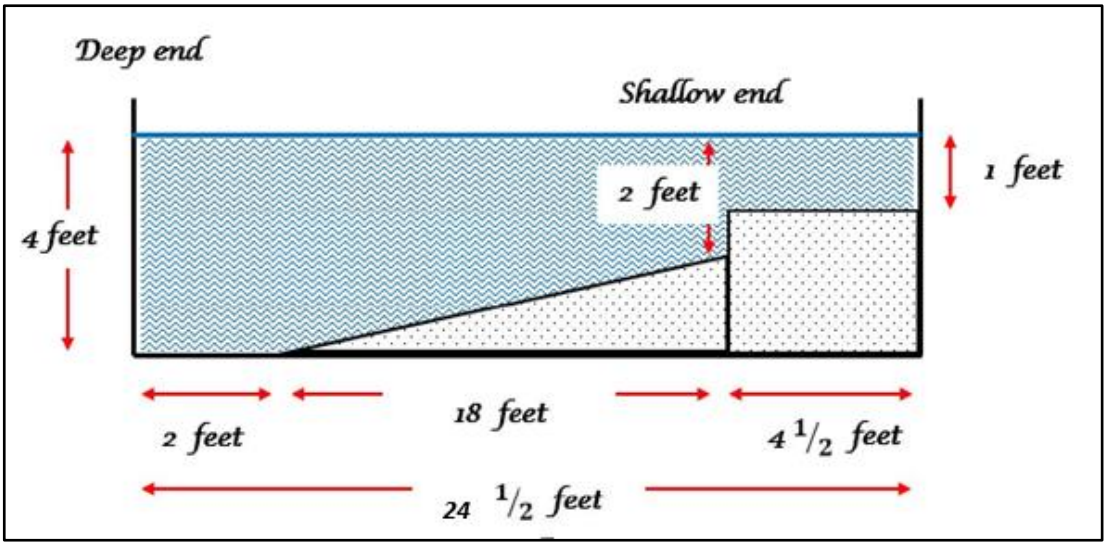
3. உடலியல் செயற்பாட்டில் பங்கேற்கையில் பிள்ளையின் சுய-நம்பிக்கையினை இவ்வாறு விவரிக்கின்றேன்:

4. சமூக அமைப்பில் பிள்ளையின் சௌகரியத்தினை இவ்வாறு விவரிக்கின்றேன்

5. பவாழ்க்கைத் தரத்துடன் தொடர்புபட்ட பிள்ளையின் ஒட்டுமொத்த ஆரோக்கியத்தினை நான் இவ்வாறு விவரிக்கின்றேன்

Appendix K: Swimming Pool Structure at NCCCPDD





Appendix L: Features of Polar H10 Heart Rate Sensor

Features of Polar H10 Heart Rate Sensor	
Bluetooth low energy	+
5 kHz Transmission (Gymlink)	+
HR measurement method	ECG, chest strap
Operation time/ Battery life	400 hours (replaceable batteries)
Waterproof	30 meters
Weight	Connector 21 g, Polar Pro Strap 30g (Size X-SS – 51-66cm)
Built-in memory	For a single training session
Training analysis in Polar Flow	When session is saved in internal memory and transferred to Polar Flow via Polar Beat

Appendix M: Features of Polar A300 Heart Rate Monitor

Features of Polar A300 Heart Rate Monitor	
Bluetooth low energy	+
Detect heart rate via 5 kHz transmission (Gymlink)	+
Heart rate measuring range	15 – 240 bpm
Watch accuracy	+/- 0.5 seconds/day at 25 degree Celsius
Accuracy of heart rate monitor	+/- 1% or 1 bpm
USB connector and cable	For charging the battery and syncing data between Polar A300 and Polar Flow web service via Polar Flow Sync software
Waterproof	30 meters
Weight	35 g
Memory capacity	60 hours training with heart rate