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MiYoga: A randomized controlled trial of a mindfulness movement program based on hatha yoga principles for children with cerebral palsy - A study protocol

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Study Protocol

Title: MiYoga: A randomized controlled trial of a mindfulness movement program based on hatha yoga principles for children with cerebral palsy - A study protocol

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ABSTRACT

Introduction: Cerebral Palsy (CP) is the most common childhood physical disability, with life-long impacts for 1.77 in 1000 children [1]. Although CP is primarily a physical disability, children with CP have an increased risk of experiencing cognitive difficulties, particularly attention and executive function deficits.[2-4] Impairment in cognitive abilities can lead to subsequent impairment in independent functioning, education, employment, and interpersonal relationships. This paper reports the protocol of a randomized controlled trial of a novel family-centered lifestyle intervention based on Mindfulness and Hatha Yoga (MiYoga). MiYoga aims to enhance child and parent outcomes for children with CP.

Methods and analysis: The aim is to recruit 36 child-parent dyads (children 6-16 years old; bilateral or unilateral CP; GMFCS I-III) who will be randomly assigned to two groups: MiYoga and waitlist control. Mindfulness and Hatha Yoga techniques in the MiYoga program will be facilitated in a group format. Assessments will be administered at baseline, following completion of MiYoga, and at 6-month follow-up (retention). The primary outcome will be the child's sustained attentional ability as measured by the Conner's Continuous Performance Test (CPT). Other outcomes of interest for children with CP consists of attentional control, physical functioning, behavioural and wellbeing. For parents, the outcomes of interest are mindfulness, psychological flexibility and wellbeing. Data will be analyzed using general linear models, specifically analysis of covariance and analysis of variance.

Ethics and dissemination: Full ethical approval for this study has been obtained by the Children's Health Queensland Hospital and Health Service Research Ethics Committee (HREC/12/QRCH/120) and The University of Queensland (2012000993). If MiYoga is

proven effective, its dissemination would assist children with CP and complement their on-going therapy by; improving the ability of the child to pay attention at school and in therapy, and alleviating environmental stressors for both the child and their parents.

Trial Registration: ACTRN12613000729729;

http://www.ANZCTR.org.au/ACTRN12613000729729.aspx

Date of Trial Registration: prospectively registered on 2/07/2013 – present (ongoing).

Findings to Date: Recruitment is complete. Data is still being collected at present. We aim to complete data collection by Feb 2017.

Strengths and Limitations of this study:

- To our knowledge this is the first randomized controlled trial exploring the benefits of a mindfulness-based movement intervention for children with cerebral palsy.
- MiYoga is designed to be a lifestyle intervention so that children and parents will be able to continue practice at home in their everyday lives after the complete of the program.
- MiYoga is fun and developmentally appropriate and is adaptable to the needs of the child and/or parent.
- All participants will be offered MiYoga before completion of the study for ethical reasons.

INTRODUCTION

Cerebral Palsy (CP) is the most common physical disability in childhood with life-long impact for 1.77 in 1000 children.[1] Cerebral palsy is caused by non-progressive damage to the fetal or infant brain that results in motor and postural difficulties.[5] In addition to the physical impairments which are the diagnostic features of CP, children can also experience cognitive and psychological difficulties.[6-8] The motor and cognitive difficulties are often accompanied by disturbances of sensation, communication, perception, behavior problems, and/or by a seizure disorder.[5 7]

Present therapies focus primarily on physical difficulties faced by children with CP[9] despite the fact that children with CP also have an increased risk of experiencing cognitive difficulties. In 2009, the Australia Cerebral Palsy Register reported that 1 in 3 children with CP experience cognitive difficulties.[3] More recent studies reported that 1 in 2 children with CP had an intellectual disability[7] and compared to typically developing children, children with CP have attention and executive function deficits.[2 4] These impairments in attention and executive function may explain why children with CP have increased social and learning problems.

Attention

Attention is the foundation of most cognitive and neuropsychological functions in our everyday life. It is a cognitive ability that underpins and influences executive function and other cognitive outcomes such as self-control (inhibition), decision-making, goal setting, planning, problem solving, emotional responses and behavior. Three basic concepts about the attention system were suggested.[10] The first is that the attention system: that it is anatomically separate from neural systems for processing incoming sensory stimuli, making decisions, and producing outputs; that it depends on a network of anatomical areas; and that

these anatomical areas carry out different functions that can be specified in cognitive terms. They further proposed that the attention system is divided into three networks, each representing a different set of attentional processes, namely alerting, orienting and executive attention (or executive control) networks.

The alerting network, is a 'bottom-up', stimulus-driven or exogenous attention system (e.g., visual, auditory, originating from any position in space). These describe attentional processing which is driven by the properties of the sensory objects themselves. For example, a sudden loud noise or motion can attract our attention and we attend to them whether we want to or not.[11] This network is thought to involve both the parietal and temporal areas of the brain, as well as the brain stem arousal systems.[10]

Orienting and executive networks are both 'top-down' processes, which are together, also known as goal-driven, endogenous attention, attentional control or executive attention.[10] These two attentional networks focus on our ability to voluntarily select and orient attention to relevant stimuli or tasks, a process mediated primarily by the frontal cortex and basal ganglia.[10 12] Orienting can be measured by the speed and accuracy of responses to cues that indicate where a stimulus may later occur on a computer screen. The executive network involves mechanisms for monitoring and resolving conflict when two responses are simultaneously called for by a stimulus among our thoughts, feelings and responses. Within this executive network, attentional switching and, the ability to disengage from distracting stimuli and re-engage attention to the relevant task/stimulus, is an important part of executive attention. Previous studies have confirmed that two networks are related to executive functions,[10 13] working memory[14] and conflict resolution and inhibition.[15]

Both orienting and executive networks of attention are critical for the ability to maintain and focus attention on a given task, referred to as sustained attention. Sustained attention is a

core executive function and can be defined as the ability to maintain an alert, goal-directed focus in the absence of an external stimulation.[16] Difficulty maintaining goal-directed attention can interfere with non-cognitive aspects of therapy and rehabilitation. For example, the capacity to self-sustain attention has been shown to predict motor recovery in adults following a right hemisphere stroke over a 2-year period[17] This finding suggests that it is imperative to address sustained attention deficits in the development of interventions and rehabilitation programs.

In the three-network model of attention,[10] each network has different implications for problems in everyday life. Impairments in attention in children, may lead to reading problems,[18] poorer math achievements[19 20] and poor self-confidence and general cognitive impairments,[21] poor executive function and executive attention such as working memory which are usually associated with poorer social skills[22 23] and problem behaviors.[23] Consequently, in order for all children to learn and benefit from school, therapy, and from their environment, they must be able to focus and sustain their attention.

Cognitive Abilities in Children with CP

Recent studies demonstrated that attention, executive function and other intellectual capabilities were impaired in children with CP.[2 4 6 7 24] A cross-sectional study evaluated sustained attention in 10 adolescents with CP through a visual Continuous Performance Test (CPT).[4] The results indicated that sustained attention and inhibition capabilities were impacted in CP even after controlling for motor deficits by using eye movements to measure sustained attention. Another study investigated attention and executive function in children with unilateral and bilateral spastic CP.[2] Four subtests from the Wechsler Intelligence Scale for Children (WISC-III), namely, information, similarities, comprehension, and vocabulary were used to measure general cognitive functioning. They also used three subtests from the

Test of Everyday Attention for Children (TEA-Ch)[25] to measure selective attention (Sky Search), sustained attention (Score!) and divided attention (Sky Search Dual Task). Executive functions were assessed by the Contingency Naming Test (CNT) and the teacher version of the Behavior Rating Inventory of Executive Function (BRIEF). The results demonstrated that impairments in sustained attention, divided attention, inhibition, switching and general executive function were present in children with CP.

Few interventions exist that aim to increase children's ability to sustain their attention on task or selectively focus their attention on appropriate stimuli. Previous research explored attention and problem-solving training for children with Attention Deficit Hyperactivity Disorder (ADHD),[26] children with learning disabilities and co-morbid ADHD.[27] In addition, some studies investigated efficacy of interventions that may increase attentional abilities in children with traumatic brain injury[26 28] and for the late effects of treatment for childhood cancer.[29] There is a paucity of research on interventions to improve attention in children with CP.

Mindfulness and Attention

In recent years, several investigators have proposed theoretical explanations of how the practice of focused attention through Mindfulness (awareness of the present moment) training can enhance and develop attention regulation.[30-33] Mindfulness practice involves sustaining attention on a chosen object, such as the breath, an object, or a mantra, and directing attention to that object while sustaining this focused attention for as long as possible. In order to sustain this focus, one must monitor the quality of this focus. For example, while focusing on the rise and fall of the chest with each breath, one might notice their attention has shifted to something that happened during the day, or what they would like for dinner later. At some point they would realize their focus has wondered and let go of their distraction and re-attend

to their breath. Mindfulness is the state of awareness of the thoughts or feelings that arise when our mind wander. This awareness gives us the opportunity to inhibit the more dominant response of rumination and switch our attention back to the point of focus.

It has been proposed[31] that this type of monitoring of one's attention and focus consists of three types of attention regulation; (i) monitoring the present-moment (i.e. detect mind wandering), (ii) attentional switching (i.e. disengage from a distracting object/thought without further involvement), and (iii) selective attention (i.e. ability to redirect focus promptly back to target object). Researchers reason that Mindfulness training entails extended practice of these attentional abilities.[34-36]

These proposed theoretical models of the cognitive mechanism of Mindfulness have inspired experimental research examining the effects of Mindfulness training on attention performance. The effects of Mindfulness practice on the three attention networks (alerting, orienting, and conflict monitoring) were examined by Jha and colleagues (2007) using the Attention Network Test (ANT).[37] Attentional efficiency was assessed before and after an eight-week Mindfulness-Based Stress Reduction (MBSR) course administered to meditation-naïve participants, as well as a one-month intensive Mindfulness retreat attended by experienced meditators, compared to an eight-week no treatment control group. The retreat group showed better conflict monitoring at baseline than participants in the control and MBSR groups, suggesting that executive attention improves with long-term exposure to Mindfulness meditation. The retreat group had improved alerting among the previously experienced meditators. The authors concluded that Mindfulness training improves voluntary (top-down; endogenous) attentional control leading to improved orienting and /or conflict monitoring, and prior experience with concentrative meditation allows for the development of improved bottom-up, receptive attention involved in alerting. It may be that Mindfulness

training improves the functioning of each of the attentional subsystems at various points in the course of Mindfulness training.

Yoga

Traditional yoga is a Mindfulness practice that directs attention towards the present moment.[38] The aim of yoga is to calm and unify the mind, body and breath to promote positive health, self-awareness and spirituality.[39] Yoga postures, known as *asana* in Sanskrit, are the third of the eight 'limbs', or practices, of yoga according to the traditional texts of the Yoga Sūtras of Patañjali. *Asana* directly translates to "posture" and was derived from the Sanskrit root word as which means "to be", "to sit", "to stay" or "to be established in a particular posture".[40] The Yoga Sūtras of Patañjali describes *asana* as having two important qualities. The first quality is steadiness and alertness, while the second quality of *asana* is the ability to remain comfortable in a posture.[39] That is, when practicing *asana*, both of these qualities should be present. The combination of performing *asana* with pranayama (breathing techniques), comprise the style of yoga commonly referred to as Hatha Yoga. Hatha Yoga unites the actions of the body, breath and mind by the synchronization of movement with the breath which in turn directs the practitioner's attention and awareness to the present. The unity of body and mind is what makes traditional Hatha Yoga an embodied mindfulness practice.

Mindfulness and Yoga for Children

In the pediatric literature, it has been documented that Mindfulness and yoga improves memory in school children,[41] cognitive function in children with mental retardation,[42] planning abilities and executive function in healthy school aged girls,[43] as well as attention, behavior and emotional control in healthy children and children with Attentional Deficit Hyperactive Disorder (ADHD).[44] It has also been documented that yoga increases balance,

motors skills and strength, as well as the quality of life and general well-being in a range of different participant groups.[45-48]

Mindfulness-based Stress Reduction (MBSR)[49] programs bring together Mindfulness and Hatha Yoga techniques. The aim of MBSR is to cultivate greater awareness of the unity of mind and body, as well as of the ways the unconscious thoughts, feelings, and behaviors can undermine emotional, physical, and spiritual health. The underlying principles for Mindfulness training in MBSR program are to (a) be non-judgmental, (b) be patient, (c) see the world as if for the first time, (f) accept seeing things as they are without trying to change anything, (g) and let go of attachment to repetitive thoughts, actions or beliefs. The features of MBSR are group interaction, formal and informal meditation practice, daily homework and a one day silent retreat.[49] The formal practice includes Mindfulness meditation and mindful movements in the form of Hatha Yoga. The informal practices include mindful eating and walking. Although a number of studies explored the effectiveness of MBSR in the adult population,[50 51] there is a paucity of randomized controlled trials that explore the effects of a developmentally appropriate MBSR program for children.

School-age children are interested in yoga as a mind-body therapy for pain and other ailments.[52] By adapting a Mindfulness-base program for children, with a focus on mindful movements through Hatha Yoga, it may provide a developmental approach to Mindfulness training. Yoga has been shown to improve body awareness in adults,[53] and it may teach children and adolescents about their growing bodies as they become more aware of their bodies and their movements. As children are also naturally more active, teaching them Mindfulness through movements using traditional Hatha Yoga postures along with the some Mindfulness exercises to begin with, may be more developmentally appropriate than teaching them the more traditional seated Mindfulness meditations. This remains to be tested.

The mindful movement program in this project, MiYoga, combines both cognitive (mindfulness) and physical (yoga postures) aspects into therapy. It has the potential to assist children with CP to alleviate any negative effects of environmental stressors by focusing their attention on the present moment so that they can fully focus on activities at school, in therapy or when interacting with peers. At the same time, Hatha Yoga may provide additional physical benefits to complement the on-going therapy for children with CP. MiYoga will also be delivered to both the child and parent, this enables parents to facilitate and monitor the MiYoga approach, which is likely to improve translation and implementation of techniques into everyday life. This project will test the efficacy of a mindful movement (MiYoga) program administered to children with CP and one of their parents. The MiYoga program would be an adjunct to children's on-going rehabilitation therapy and would provide a means of working with the whole family.

Aim

The focus of this study is to design and test a novel mindful movement program, MiYoga, and to investigate its efficacy for enhancing sustained attention in children with CP. Efficacy will be tested in a randomized controlled trial (N=36) with an intervention group (MiYoga program + standard care) compared to a wait-list control group receiving standard care alone. This enables all participating children to receive the intervention, maximizing participant recruitment and retention and fulfilling ethical obligations to participating children and families. Outcomes measures will be taken at baseline, immediately post-intervention and at follow-up 6 months post intervention.

Qualitative interviews will also be conducted with each child and parent participant individually. The aim of these interviews is to collect the participants' perceptions of the MiYoga program.

Hypotheses

It is hypothesized that, compared to the waitlist control group the MiYoga group will show improvements in the following child outcomes:

1) Sustained attention (Conner's Continuous Performance Test (CPT II)) ;
2) Executive function (information processing, attentional control, cognitive flexibility, working memory and behavioral manifestations of executive function in daily life);
3) Psychological functioning (Strengths and Difficulties Questionnaire (SDQ));
4) Physical capacity including functional strength (Sit-to-stand, Half-kneel to stand and Lateral step up tests), and flexibility (Sit and Reach test);
5) Present-moment awareness (Child and Adolescence Mindfulness Measure (CAMM));
6) Quality of life (CP-QOL-Child or CP-QOL-Teen)

In addition, it is hypothesized that the MiYoga group will show improvements in the following parent outcomes:

7) Mindfulness (Mindfulness Awareness Attention Scale (MAAS));
8) Parent psychological wellbeing (Depression Anxiety and Stress Scale (DASS));
9) Parent's psychological flexibility (Acceptance and Action Questionnaire ((AAQ-2));
10) Parent's personal wellbeing (Personal Wellbeing Index – Adults (PWI-A)); and
11) Child-parent relationship (Child-Parent Relationship Scale (CPRS)).

METHODS AND ANALYSIS

Ethics

Full ethical approval for this study has been obtained by the Behavioral and Social Sciences Ethical Review Committee of The University of Queensland (2012000993) and Children's Health Queensland Hospital and Health Service Research Ethics Committee (HREC/12/QRCH/120). Protocol modifications and amendments will be submitted to the

ethical committees for approval. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613000729729). All families will be given written informed consent to participate and their parents or guardians prior to entering into the trial.

Recruitment

Thirty-six children with a diagnosis of CP with spastic motor type, either diplegia (bilateral CP) or hemiplegia (unilateral CP) motor distribution and one of their parents will be recruited into the MiYoga study. Children must also have sufficient co-operation and cognitive understanding to follow simple instructions. The primary parent of eligible children will participate alongside their child. Children with co-morbid diagnoses to CP are included.

Children will be excluded if they have (i) received upper-limb or lower-limb surgery in the previous 6 months; (ii) unstable epilepsy (i.e. frequent seizures not controlled by medication); (iii) spinal instability or other spinal problems that would prevent them from participating safely in the MiYoga program; (iv) have a medical condition that would prevent them from participating safely in the MiYoga program; or (v) parents/guardians who are pregnant as a safety precaution. Diagnosis of CP must be confirmed by the treating pediatrician or clinician and in accordance with published recommendations.

Eligible children living in South East Queensland, Australia, will be recruited through patient databases of Queensland Cerebral Palsy Rehabilitation Research Centre (QCPRRC) at the Royal Children's Hospital and the Queensland Cerebral Palsy Register, and via referrals from clinicians in the Queensland Pediatric Rehabilitation Service (QPRS). Potential participants will be invited to participate in the study via letters and follow up phone calls. Flyers and posters will displayed in the reception areas of clinics, and clinicians will be informed of the study, and encouraged to refer appropriate patients to the program. External advertising will

include a webpage on The University of Queensland School of Psychology website and a study flyer or a brief description of the study will also be advertised in some South East Queensland schools' newsletters and notice boards.

Participants will be assessed for eligibility and enrolled in the study by the study coordinator as they provide informed consent. The study will be explained to parents by a member of the research team, and signed written consent will be obtained, acknowledging that the children and parents are aware of all study requirements, consent to take part, give permission for researchers to access their child's medical records, agree to the video-recording and photographs of sessions, and understand that they are free to withdraw their consent at any time. It is anticipated that enrolment will commence in September 2013.

Design

This study will utilize a randomized waitlist controlled trial design to evaluate the efficacy of the MiYoga program compared to waitlist control (care as usual) for children with CP, aged 6 to 16 years old (see Figure 1 for CONSORT flow chart). After each participating child and parent completes their baseline assessments they will be randomly allocated to one of two groups:

1. Immediate MiYoga Group (Group 1) – Families commence MiYoga program immediately for 8 weeks.
2. Waitlist MiYoga Control (Group 2) - Families continue care as usual for 8 weeks and then are re-assessed before commencing a future MiYoga Program. Care as usual consists of any therapies (for example, occupational therapy, physiotherapy, psychologist) usually provided by public or private services and visits to their treating pediatrician or general practitioner.

To limit confounding variables during the immediate intervention period (baseline to 8 week follow up), children scheduled to receive casting, splinting, or intramuscular botulinum toxin

type A [BoNT-A] injections during the immediate intervention period will not be eligible. Participants who have received intramuscular BoNT-A prior to beginning the study will have their baseline assessments postponed until one month after their standard follow up has been completed. Questionnaires will record the type, frequency and duration of any concurrent therapies provided by public and private services during the study for all participants.

Randomization

Prior to the intervention, participants will be asked to complete baseline assessments and questionnaires. Once these are completed, participants will be randomly assigned to either the wait-list group or immediate group and informed of the dates and times of their group. The randomization sequence will be computer-generated. Treatment allocations will be recorded pieces of paper, which will be folded and placed inside sealed, numbered, opaque envelopes by a staff member not involved in the study. A staff member not involved in the study will also open consecutive envelopes as each participant returns their baseline questionnaires. After the randomization process is complete, study personnel will be informed of group allocation and information packs will be sent out to families. Given the nature of the study, no parties will be blinded to group assignment. The experimental design and outcome measures are depicted in Figure 1.

Figure 1. INSERT FLOWCHART OF MIYOGA STUDY DESIGN

Adverse Events

There are no known health or safety risks associated with participation in the described study and the risk of adverse events is low. The ethical review process and conduct of the trial is monitored by the two ethics committees therefore no additional Data Monitoring Committee is considered necessary.

Any minor or major events associated with intervention or usual care groups will be monitored through out the 8-week program duration. The chief investigators KW and RB will review any adverse events or unintended effect detected.

Study Procedure

All participants will attend baseline assessments (T1) before being randomly allocated into either the immediate MiYoga group or the waitlist control group. Participants in the immediate group will begin the 8 week MiYoga program within three weeks of their baseline assessment, while the waitlist group will continue care as usual for the next 8 weeks. When the immediate group has completed the MiYoga program, all participants from both groups (immediate and waitlist) will be re-assessed (T2) at. The waitlist group can then commence a future MiYoga group of their choice. For each participant, data will be collected at Baseline (T1) and following the immediate MiYoga group's completion of the program at 8 weeks (T2). The waitlist group will also complete assessments after they have completed the MiYoga program at 16 weeks (T3). Both groups will complete their follow up assessments 24 weeks after completing the MiYoga program – this will be 32 weeks post-baseline for the immediate group and 40 weeks post-baseline for the waitlist group (T4). Participants will complete their assessments within three weeks of the target time-points (in weeks) listed above.

Catherine Mak (CM), the principal researcher, a registered psychologist and a qualified yoga teacher will conduct all the assessments and MiYoga sessions. A physiotherapist from the QCPRRC will perform the physical screen assessment for each child at baseline. In addition, they will be present at the initial assessment to provide professional advice to the child, the parent/guardian and to the psychologist/yoga teacher regarding the child's ability to perform various yoga postures and the adaptations that may be necessary. Either a physiotherapist or

the principal researcher (CM) will conduct the physical assessments. Participants are encouraged to complete their online questionnaires in person during their assessment session, if they prefer they may also complete them online from home (via Qualitrics Insight Platform). Registered clinical and developmental psychologist Dr Koa Whittingham (KW) will provide regular supervision. In addition, study coordinator will be able to consult with Professor Roslyn Boyd (RB), a registered physiotherapist, if there are any physical concerns.

MiYoga Intervention

Following randomization (immediate MiYoga group) or the Time 2 neuropsychological and physical assessments (waitlist control group), participants and their parents will complete the MiYoga program. All MiYoga sessions will be delivered in a group format where possible. Child-parent dyads in the waitlist control group will also receive the same intervention after a delay. In two-parent families, one of the parents will be invited to attend all sessions, and the same parent must complete all the questionnaire measures.

The MiYoga program is an 8-week program that consists of six 90-minute sessions over the initial six weeks then two phone or Skype consultations over the last 2 weeks of the program. Over these 8 weeks, children and their parent or guardian are asked to partake in a minimum of 20 minutes daily at home practices. To assist with participants' home practice, a MiYoga DVD and a MiYoga poster developed by the principal researcher will be provided at the first MiYoga session. The MiYoga DVD is based on the Mindfulness exercises and *asana* delivered in the group sessions. The MiYoga poster is also made up of the *asana* delivered in the group sessions. In addition, it includes child specific modifications identified from the initial assessment session. Each MiYoga poster will contain general instructions as well as general and specific modifications for how parents may assist their child. Where possible a

photo of the child performing the postures with their modifications will also be included. Researchers will assess the child's abilities in each of the yoga postures and provide modifications for the child as required in each posture. These modifications will be documented and put into the respective child's poster for them to take home and practice. This will ensure that participants will not attempt any new exercises or poses at home without assistance and guidance from a therapist (see Appendix A for a MiYoga program summary).

MiYoga is a program based on Mindfulness and Hatha Yoga techniques. There are formal and informal Mindfulness activities. The formal Mindfulness activities consist of mindful movements in the form of Hatha Yoga and short Mindfulness meditations. The informal activities present Mindfulness techniques as game-like explorations, based on exploring our internal and external worlds with the five senses as well as consciously reflecting on thoughts and feelings. These activities and games were developed based on literature on mindfulness and yoga for both children and adults.[39 40 49 54-64]

For example, children may have to guess what they are eating while blind folded. This game will involve the child to consciously notice the food with all their senses, such as by feeling the texture of the food in their hands and mouth, smelling and tasting it, and possibly even hearing the sounds the food makes when chewing it (and subsequently noticing crunchy, chewy or soft foods). Children may have to identify an object by exploring it only with their hands (sense of touch) and then describe how the object feels in their hands to another person without naming the object. This game encourages the child to use their sense of touch to explore their environment and increase their awareness of how the sense of touch provides them with information about their surroundings. Such activities are both interesting for the participants, but are also mindful practices that stimulate a state of awareness.

The Hatha Yoga techniques or postures in this study were based on Viniyoga principles[39] and they were tailored for children with cerebral palsy. The synchronization of breath and movement is a key element as it helps to focus the mind on the present (i.e. moving through yoga postures with the breath) providing a mindful movement practice. To make synchronizing breath and movement more natural and fun for children, participants were invited to make sounds along with the instructor, such as "Ahh...", in the asana sequences to assist with their exhalation. The aim of a mindful movement practice for these children and adolescence is to enhance their attentional abilities, while the yoga postures selected for the program aims to help them build strength and increase flexibility (see Appendix B for a table and illustrations of the MiYoga postures for children with cerebral palsy). The yoga postures will be modified as required for each participant. Some of the modifications consists of using supports such a wall, chair, bolster or blocks to ensure correct posture, adequate support and comfort, or to accommodate muscle shortness or postural difficulties. For example, some children sat on a block to keep their pelvis level and to accommodate their shorter hamstring muscles and leading to posture pelvic tilt within long sitting. These physical modifications are individualized to each child's need based on the baseline physical screen by a Physiotherapist. The physical adaptations may not be the same for all children with CP while some children did not require any physical modifications. For this reason Appendix B mainly consists of illustrations of the non-adapted postures with some illustrations of possible modifications. In addition to the physical modifications, verbal prompts were used to guide the children into the postures, for examples "going as far as it is comfortable for you, this may be coming forward to thighs or your knees" or "notice the sensation in the back of your legs as you fold forward, you may like to explore how it feels for you to keep your knees straight as you come forward" and a verbal prompt for children to sit with good alignment

(avoid W-sitting) may be "as we sit back onto our heels be mindful that your knees and big toes are together".

Each session will be 90 minutes with guided instruction throughout each component of Mindfulness practice. During Hatha Yoga postures, instructions will be provided on safe ways to get in and out of the positions, pose modification, and use of props to suit needs and limitations of each child. For instance the supine twist can be performed on a chair rather than on the ground. Blankets, cushions, bolsters, straps, and other props may be used to maintain body alignment, structural support, and comfort (see Appendix B's possible modification column for more details). Emphasis will be placed on building length along the spine while maintaining neutrality of spinal position, keeping awareness of the breath, and using breath and sensations within the body to anchor attention to the present moment.

Locations

It is expected that groups and assessments will be conducted in Brisbane, and various locations in South East Queensland. Locations in Brisbane will include The University of Queensland, St Lucia and Herston campuses, and the Centre for Children's Health Research in South Brisbane. If participants are located outside of Brisbane then suitable locations will be organized with the participating families in those areas.

Participation and Data Management

To maximize participation and retention, email reminders will be sent to participants three days prior to their scheduled appointments, and SMS text message reminders will be sent to participants the day prior to their appointments and their weekly MiYoga sessions. In order to further promote recruitment, participation and retention, the study offers a waitlist control group so that all participants have an opportunity to take part in the MiYoga program. It is also possible to extend the period of recruitment and the delivery MiYoga groups should

recruitment be more challenging than anticipated. The number of participants recruited and participant retention will be recorded throughout the trial period.

Treatment dose will be calculated based on participants' attendance at the weekly MiYoga sessions as well as the amount of home practice completed by participants between sessions. The therapist will record participant attendance after each weekly MiYoga session, and parent participants will record the amount of home practice they completed each week in their MiYoga diary. The MiYoga diaries will be collected weekly and monitored by the therapist. Strategies to facilitate and support engagement in the program will be discussed with the participant and their parents throughout the duration of the MiYoga program in the group sessions as well as via individual phone calls.

Paper copy data will be de-identified and physically stored in a locked file cabinet at the QCPRRC. These physical documents may be scanned (after de-identification) and password protected in a computer file on a secure server. Computer files will be de-identified and password protected on a secure server.

Video files of the MiYoga sessions will be used to monitor therapy fidelity and assess for therapist integrity and consistency across groups. These video files will be managed and and kept on a secure online database run through QCPRRC and back up files may be kept on a external harddrive or CD in a locked cabinet.

Study updates and general outcomes will be sent to participants in a newsletter format. A summary report of the overall study findings will also be sent to participants at the conclusion of the project. Feedback on the specific formal assessments will be provided when requested by the participant or parent.

Participant Characteristic Measures

The following questionnaires and assessments will be completed at baseline, prior to the intervention, to gather information about the sample of children with CP and their parents:

Gross Motor Function Classification System (GMFCS)

The GMFCS classifies, across 5 levels, a child's ability to carry out self-initiated sitting and walking movements.[65] A correlation between the GMFCS and the Gross Motor Function Measure (GMFM) of r=0.91 suggests construct validity has been obtained.[66] GMFCS also has good inter observer reliability between professionals as well as between professionals and parents in children with CP.[67]

Brief Health Questionnaire (BHQ)

The Brief Health Questionnaire (BHQ) was developed to screen for existing medical conditions that may prevent the child or the parent to participant in MiYoga, with separate questionnaires for children and parents. (see Appendix C).

Physical screening clinical examination

A physiotherapist will conduct this examination to determine if the participating child has any physical conditions that might preclude them from exercise (see Appendix D).

Wechsler Intelligence Scale for Children–Fourth Edition Short Form (WISC-IV; Wechsler, 2003)

Intellectual functioning will be assessed using the Wechsler Intelligence Scale for Children fourth edition short form (WISC-IV).[68] The WISC-IV comprises seven subtests that generate the four indices of verbal comprehension (VCI), perceptual reasoning (PRI), working memory (WM), and processing speed (PSI). From these overall short form index scores a full scale intelligence quotient (FSIQ) score can be calculated. In the WISC-IV short form the VCI index is made up of the Vocabulary and Similarities subtests. The Vocabulary subtest assesses knowledge of word meanings and will require participants to name pictures or provide spoken definitions of words (e.g., "what is a bicycle?"). The Similarities subtest

assesses verbal abstraction and reasoning and will require participants to describe how two words are similar (e.g., "how are anger and joy alike"). The Block Design and Matrix Reasoning subtests make up the PRI index in the WISC-IV short form. Block design will require participants to construct abstract visual designs with a set of red-and-white 3D blocks within a specified time period. Matrix Reasoning, will require participants to use their non-verbal abstract reasoning and problem solving skills in order to select the correct picture from an array of five options that fits into the missing space of a visual design. The WMI index is made up of the Digit Span subtest in which participants will be required to repeat a number of verbally presented digits in forward and reverse order. Finally, the PRI index is made up of the Coding and Symbol Search subtests, each of which has a two-minute time limit and therefore require participants to work as quickly as possible without making mistakes. For the Coding subtest, participants will need to match abstract symbols with a number key while for Symbol Search, participants will be required to detect the presence of one or more symbols in a sequence of five.[68]

Scaled scores will be derived from index scores in accordance with normative data based on the child's age and gender (mean=100, standard deviation [SD]=15).[69 70] All index scores of the WISV-IV SF have shown moderate to high levels of internal consistency (α=0.87–0.96) and are equivalent to those documented for the full WISV-IV, with the exception of the WMI which is marginally lower than its full length equivalent.

Primary Outcome Measures

Attention

The Conner's Continuous Performance Test (CPT II) will be used to measure sustained attention performance.[71] It is a standardized 14-minute computer administered test in which participants are asked to observe letters displayed on a computer screen and click at the appearance of each letter, except for that of the letter 'X'. The stimuli appear at random

intervals (1, 2 or 4 seconds) and the duration of each stimulus is 250 milliseconds. This test measures the time to process information (e.g. Reaction Time (RT)) and errors such as false negatives or false positives. The test is divided into six equal blocks of 20 trials.

Twelve indices from the Conners' CPT will be analyzed. These indices are: (i) Number of omissions: the number of letters, other than X, not detected; (ii) False positives/ Commissions: the number of responses to the letter X; (iii) Hit Reaction time (RT); (iv) Standard error (SE) and (v) Variability of RT: indicates consistency of RTs between blocks; (vi) Detectability: RT distribution of target vs. non-target (X); (vii) Perseverations: responses with a RT too short (5100 ms) indicating anticipatory responding or responses to a previous stimuli (suggesting very slow responses/inattentiveness); (viii) Response style: indicates an over-cautious vs. a highly impulsive response; (ix) Hit RT block change: a high score implies that, as the test progresses, RTs are longer; (x) Hit SE block change: a high score implies that as the test progresses, RT variation increases; (xi) Hit RT Inter-Stimulus Intervals (ISI) change: a high score implies that, as the stimulus interval increased, the RTs became longer; and (xii) Hit SE ISI change: a high score implies that RT variation increased as the stimulus interval increased. Some of these indices make up different variables, namely, sustained attention, inattention and vigilance.

The primary variable of interest in this study is sustained attention. This is observed through the participant's responding pattern on the CPT's Hit RT block change, commissions block change and omissions block change indices. A decrease in sustained attention performance is captured by significant slowing in participant's HitRT, and significant increase in errors (ommisions and commissions) as the task progresses. Participant's performance across blocks 1 and 2 will be compared to their performance across blocks 5 and 6 of the same administration.

The indices that measure participant's inattention are poor detectability, a high number of omission and commission errors, a slow Hit RT, and high variability in RT (HitRT SE). While the indices that measure participant's vigilance (participant's performance at different stimulus frequency or inter-stimulus intervals), is captured by performance on the Hit RT ISI change.

Secondary Outcome Measures

Executive functioning

A neuropsychological test battery will be used to evaluate executive attention and other executive function abilities that consists of selective attention, attentional control, cognitive flexibility, and working memory. This neuropsychological test battery is comprised of subtests from the Wechsler Intelligence Scale for Children Fourth Edition (WISC-IV),[68] and the Delis-Kaplan Executive Function System (D-KEFS).[72] A parent-rated questionnaire, the Behavior Rating Inventory of Executive Function (BRIEF),[73] will be used as a measure of day-to-day behavioral manifestations of executive functioning.

Digit Span (from the WISC-IV). The WISC-IV Digit Span subtest is a verbal memory task requiring participants to repeat a number of digits in the forward and backwards order. It is a measure of a child's working memory and their ability to temporarily store information. Digit Span Forward requires the child to repeat a series of numbers given verbally by the examiner, increasing one digit per item from two digits to a maximal of nine digits. Digit Span Backward requires the child to repeat given number series in the reverse order (e.g., if the examiner said "5 – 7 – 4" the child should say "4 – 7 – 5"). A score of one will be given to each string correctly answered and a total score will be generated (Digit Span Backward range = 0 – 16). Raw scores can be converted into scaled scores (M = 10, SD = 3). Digit

Span Backward has a good internal consistency (α = .80)[70] and a high test–retest reliability (r = .74).[70]

Symbol Search (from the WISC-IV). The WISC-IV Symbol Search subtest will be used as a measure of selective attention. Participants will be required to visually scan a group of symbols and indicate whether a target symbol is present in the group of symbols by placing a line through the word 'yes' or 'no' for every item on this subtest. Participant score are calculated by taking away the total number of incorrectly identified symbols from the total number of correctly identified symbols. Symbol search has adequate internal consistency (α = 0.79) and a high level of test-retest reliability (r = 0.80).[70]

Color-Word Interference Test (from the D-KEFS). The inhibition condition (cond 3) of the Color-Word Interference Test will be used to measure attentional control, while the inhibition/switching condition (cond 4) will be used to measure attentional control and cognitive flexibility. In the inhibition condition (cond 3), children will be required to name the ink color that color words are printed in. The total number of errors and the time it takes to complete the task will be used as outcome measures of attentional control, with the longer times and more errors indicating poorer attentional control. In the inhibition/switching condition (cond 4) children will be required to switch between naming the color of the ink that the word is printed in (like in cond 3) and reading the word (if it is presented in a box). The total time it takes to complete the task will be used as outcome measures of cognitive flexibility, while the total number of errors will be used as outcome measures of attentional control. The Color-Word Interference Test has excellent test-retest reliability (r = 0.90).[72]

Trail Making Test (D-KEFS). The number-letter switching condition (cond 4) from the Trail Making Test will be used to measure attentional control and cognitive flexibility. In condition 4 of the Trail Making Test, children will be required to switching back and forth between connecting numbers in numerical order and letters in alphabetical order, for

example, 1 to A to 2 to B to 3 to C and so on all the way to P. The number of errors and the time it takes to complete the task will be recorded and the more error and the longer it takes to complete the task indicates greater difficulty with attention control and cognitive flexibility. Moderate test-retest reliability for number-letter switching condition (r=0.20-0.55)[74-75] has been documented.

Brief Rating Inventory of Executive Function (BRIEF). The BRIEF is a parent-rated questionnaire for assessing day-to-day behavioral manifestations of executive function. Parents will be required to rate 86 items (e.g., "gets stuck on one topic or activity") on a three-point Likert scale, from 1 (*never)* to 3 *(often)*. The provided normative data in the manual will allow raw scores to be converted into *T* scores (M = 50, SD = 10). Eight subscales are combined to form the Behavioral Regulation Index (BRI; Initiate, Working Memory, Plan/Organize, Organization of Materials, and Monitor subscales) and the Metacognition Index (MCI; Inhibit, Emotional Control, and Shift subscales). Together these form the overall Global Executive Composite (GEC). *T* scores of 65 or more (1.5 SD above the mean) indicate elevated levels on the corresponding subscales and indices. Higher *T* scores indicate greater executive dysfunction. In this study, the GEC will be used as primary measures of executive function in everyday life. The BRIEF has been shown to be a valid measure of executive functioning and has good internal consistency (α = 0.80 – 0.98) and high test-retest reliability on the GEC (r=0.86).[73]

Mindfulness

Child and Adolescent Mindfulness Measure (CAMM)[76] assesses present-moment awareness and nonjudgmental, non-avoidant responses to thoughts and feelings. In this 10-item questionnaire, children are asked to indicate how each item reflects their experience using a 5-point scale ranging from 0 (Never true) to 4 (Always true). A total acceptance-Mindfulness

score will be generated by reverse scoring negatively worded items and summing the item total, yielding a possible range in scores from 0-100. The higher scores indicate higher levels of acceptance and Mindfulness. This test has been shown to have good internal consistency ($\alpha = 0.81$).[76]

Behavioral

Strengths and Difficulties Questionnaire (SDQ)[77 78] is a 25-item parent-report questionnaire designed to assess their child's behavior and adjustment. The items are divided into 5 scales to assess the frequency within the last six months of emotional symptoms, conduct problems, inattention/hyperactivity, peer problems and prosocial behavior. These items are rated on three-point scale, from zero (*not true*) to two (*certainly true*), allowing for a total score for each scale (0-10) to be calculated, along with an overall difficulties score that takes into account overlapping elements of each score (0-40). Higher scores indicate more distress on all scales except prosocial behavior. In this study, the SDQ total score will be used as primary measures of children's behavior. SDQ total score has been shown to have a moderate to high level of internal consistency ($\alpha = 0.73$-0.82)[79 80] and a moderate to high test-retest reliability (r=0.77 – 0.85).[78 80]

Physical Outcome Measures

Flexibility

Lower back and hamstring muscle flexibility will be assessed by the Sit and Reach test (reach distance). Participants sit on the floor with both legs extended as straight as possible in front, heels placed on the floor, and feet flat against a wall so that the ankle is dorsiflexed to approximately 90 degrees. Participants are instructed to stretch their arms straight in front with hands overlapping (middle fingers overlapping too) and slowly bend forward at the hip joint reaching as far as possible towards their toes. The maximum reach must be held for 2

seconds, and the distance between the tips of the middle fingers to the wall at the top of the toes is recorded.

Lower Limb Functional Strength

The following functional exercises will be used to assess strength.

Lateral step-up. Lateral step-up records the number of steps up on to a step from the floor that the child can perform during 30 seconds.[81] The test will be performed on a 10cm high step for all children, with a complete up and down step being one full cycle. The child stands parallel to the step with the leg being tested on the step and the non-testing leg on the floor. They are asked to extend their test leg (on the step) straight and lift their non-test leg off the ground and onto the step and then lower the non-test leg back down to the floor until the foot touches the ground.[82] This is then repeated for the other leg. Reliability for this test is strong (ICC=0.94) and mean repetitions for the lateral step up were 13.2 (SD=10.5; standard error of measurement (SEM)=2.4 reps; CV=17.8%) for the left side, and 12.6 (SD=10.4; SEM=2.6 reps; CV=22.7%) for the right side.[81]

Sit-to-stand. The Sit-to-stand functional strength test records the number of sit-stand-sit repetitions that the child can perform within 30 seconds.[81] The test will be performed on a chair where the child's knees and hips are at 90˚flexion, upper legs parallel to the floor and feet flat on the floor. The child will be asked to stand up straight so that their hips and knees are extended and then sit back down. Reliability for this test was strong (intra class correlation (ICC) =0.91) and the mean number of repetitions was 14.4 (SD=5.0; SEM=2.6 reps; CV=22.7%).[81]

Half-kneel to stand. Half-kneel to stand records the number of repetitions from half kneel to stand the child can perform within 30 seconds.[81] The child is positioned on a mat, with one leg kneeling on the floor while the other leg is in front with the knee at 90˚flexion

and foot flat on the floor. From this half-kneeling position the child is asked to assume a standing position. Repetitions are counted each time the participant achieves a standing position where both legs and hips are extended as much as possible. This is then repeated with the other leg in front. Reliability for this test was strong (ICC=0.93 to 0.96) and mean repetitions was 7.5 reps (SD=5.5; SEM=1.1 reps; CV=28.6%) for the left side and 6.0 (SD=5.3; SEM=1.4 reps; CV=39.9%) for the right side.[81]

Submaximal motor capacity test. The 6-minute walk test (6MWT) is a submaximal clinical exercise test which measures the distance the child can walk in six minutes.[83] The child will be asked to walk as many laps as they can without running for 6 minutes along a straight, flat a corridor, between two markers set 10m apart. The 6MWT will be conducted with standardized verbal encouragement and the child will be advised on the time remaining every minute and the number of laps they have completed as it happens. The 6MWT has been demonstrated to be reliable in independently ambulant adolescents with CP and the test-retest is excellent (ICC=0.98).[83]

Mobility

The MobQues28 questionnaire measures mobility limitations a child with CP experiences in everyday life as rate by their parents.[84 85] The MobQues28 is score on a 5 point scale from 0-4, with 0 being *Impossible without help*; 1 being *Very difficult*; 2 being *Somewhat difficult*; 3 being *Slightly difficult*; and 4 being *Not difficult at all*. Item scores (range 0–4) are added together and then divided by the maximum possible score and multiplied by 100 to obtain total scores on a scale of 0 to 100 (lower scores indicate severe limitations in mobility): MobQues28=(Σ item / 112)·100. Construct validity was demonstrated as MobQues28 scores decreased with increasing GMFCS level ($p<0.001$) and in a sub group of 162 children, MobQues28 score was positively correlated to GMFM-66 ($r=0.67$, $p<0.001$).[85] The

MobQues28 has been demonstrated to be reliable with high the interrater reliability (ICC=0.87), standard error of measurement (SEM) was 8.9. The intrarater reliability was higher (ICC=0.96-0.97; SEM=4.4-4.9).[84]

Quality of Life

CP QOL-Child. The CP QOL-Child is a condition-specific quality of life measure for children with cerebral palsy.[86] Two versions of the CP QOL-Child will be used in this study; the CPQOL-Child parent report version will be used for all participants under 12 years of age, and the CPQOL-Child self-report version will be used for children 9-12 years of age. The parent-report measure of child quality of life is a 66-item questionnaire and the child self-report version is a 53-item questionnaire. Results of factor analysis demonstrated that the CPQOL measures 7 broad domains of quality of life: social wellbeing and acceptance, functioning, participation, physical health, emotional wellbeing, access to services, pain, impact of disability and family health. In this study, the GEC will be used as primary measures of executive function in everyday life. The CPQOL-Child has a high internal consistency (α=0.74-0.92 for parent report and α=0.80-0.90 for child self-report), good test-retest reliability (ICC=0.76-0.89) and it is moderately correlated with generic QOL and health measures (r=0.30-0.51).[87 88]

CP QOL-Teen. The CP QOL-Teen is a condition specific quality of life measure for adolescents with cerebral palsy. Two versions of this CP-QOL will also be use: the CPQOL-Teen parent report version will be completed by parents of participants aged 13-18 and the CP-QOL-Teen self-report version will be completed by participates 13-18 years of age.[89] This measure has strong internal consistency (α=0.81-0.95 for the primary parent report, and α=0.84-0.96 for the adolescent self-report), good test re-test reliability for primary parents (ICC=0.72-0.92) and adolescents (ICC=0.84-0.87). All domains of the CPQOL-Teen parent

report (r=0.40-46) and adolescent report (r=0.58-0.68) were correlated with a generic QOL instruments.[90]

Pain

The Baker-Wong Faces™ Pain Rating Scale will be used to assess the child's pain level.[91] Children will be asked to match which of the six hand-drawn faces show their pain level, with faces ranging from smiling ('no hurt') to crying ('hurts worst'), with the scale scored from 0 to 5. It has been documented that Baker-Wong Faces™ Pain Rating Scale has an excellent test–retest reliability over 15 minutes, 8 hours and immediately post-procedure in children 3–18 years old ($r = 0.90 – 0.84$).[92 93] There are also strong positive correlations between the Wong–Baker FACES Pain Scale and other well-established self-report measures ($r = 0.74 – 0.78$) (e.g., Pieces of Hurt tool, Faces Pain Scale, and a visual analogue scale).[92 94-96]

Parent Outcome Measures

The following tests will be used to assess the psychological well-being of parents of children with CP. These assessments will be completed at baseline, pre-intervention, post-intervention, and at a 6-month follow-up.

Mindfulness Attention Awareness Scale (MASS)

The Mindfulness Attention Awareness Scale (MASS) will be used to measure each parents' tendency to be mindful of moment-to-moment experiences.[97] The MAAS is a 15 item instrument focusing on the presence or absence of attention and awareness of their present immediate environment. Participants are asked to indicate how frequently they have the experience described in each of the 15 statements using a 6-point Likert scale from 1 (almost always) to 6 (almost never). For example, one statement is "It seems I am 'running on

automatic', without much awareness of what I'm doing", while another is "I snack without being aware that I am eating". The total score is used as outcome measure, with higher scores reflecting more Mindfulness. This scale has been shown to relate to various aspects of well-being and to how effectively people deal with stressful life events.[97] The MAAS also has good internal consistency, with alphas ranging of .82 in student sample.[97]

Acceptance and Action Questionnaire (AAQ-II)

The Acceptance and Action Questionnaire (AAQ) assesses the construct referred to as, variously, acceptance, experiential avoidance, and psychological inflexibility.[98] This 7 item questionnaire has been documented to have a satisfactory structure, reliability, and validity with a mean alpha coefficient of 0.84 (0.78–0.88), and the 3- and 12-month test–retest reliability is 0.81 and 0.79, respectively.[98]

Depression Anxiety Stress Scale (DASS)

The Depression Anxiety Stress Scale (DASS) is a 42-item questionnaire that assesses the presence of psychological symptoms in adults.[99] In this study, a total score will be computed, range 0–126, higher scores indicate suboptimal states. The measure has shown high internal consistency for depression ($\alpha = 0.91$), anxiety ($\alpha = 0.84$) and stress ($\alpha = 0.90$) scales. The DASS also has good discriminate and concurrent validity.[99 100]

Personal Wellbeing Index – Adult (PWI-A)

The Personal Wellbeing Index – Adult (PWI-A) is an eight item questionnaire that assesses the ones' level of satisfaction with life as a whole.[101] Each item corresponds to a quality of life domain, such as: standard of living, health, achieving in life, relationships, safety, community-connectedness, future security, and spirituality/religion.

Child–Parent Relationship Scale (CPRS)

The Child–Parent Relationship Scale (CPRS)[104] is a 15-item questionnaire that use a 5-point rated scale and it is completed by the parent to assess the quality of the parent–child relationship.[102 103] The CPRS is an adaptation of the Student–Teacher Relationship Scale (STRS) , which has been used extensively in studies of relationship quality in the US (National Institute of Child Health and Development Early Child Care Research Network, n.d.).[104] In this study, the overall conflict score and closeness score will be used as measures of parent-child relationship quality.

MiYoga Session Measures

The following tests were developed to measure the mechanism of change due to the MiYoga intervention. Both child and parent participants will complete these measures either before and after or just after each MiYoga session.

Mindfulness

MiYoga Session Mindfulness Measure is a 5-item scale adapted from the CAMM. It measures children and parent's Mindfulness in the MiYoga session they have just completed. Each child and parent will complete this Mindfulness scale at the end of each MiYoga session (see Appendix E).

Mood

The Mood Scale is a short scale used to measure participants' mood or how they are feeling before and after each MiYoga session. It is a 1 to 5 scale with 5 being very good and 1 being very bad where 5 matched with a happy face, 3 is matched with a neutral face and 1 is matched with a sad face (see Appendix F).

Session feedback

At the end of each MiYoga session, children and parents will each be asked to complete a Session Feedback Scale. This is a short four item questionnaire asking the participants about the session in regards to comfort, enjoyment, body awareness and overall satisfaction. Each of these questions is also on a 0 to 10 scale, with 10 being high (or very good) and 0 being low (or very bad; see Appendix G).

Qualitative Interviews

A short interview will be conducted with individual participants post-MiYoga program at the end of the program by a registered psychologist or a probationary psychologist under supervision. The interviewer will be unrelated to the MiYoga study to avoid bias and to encourage participants to express their view and opinions about the program freely. The aim of these interviews is to gather qualitative information such as what the participants liked or disliked about the program and what worked and what did not work for them. This qualitative information will help with program refinement and translation. For example, it will provide information on how Mindfulness and yoga can be integrated into participants' everyday life (see Appendix H for qualitative interview script and questions).

STATISTICAL ANALYSIS

Sample Size

It has been documented that the reaction time of children with CP was two standard deviations below healthy controls on the Continuous Performance Test (CPT) [4]. The present study is interested in detecting a difference of one standard deviation between the immediate treatment and control group at Time 2 (post-intervention) to determine the clinical significance of the MiYoga program compared to waitlist control. Based on Lehr's equation with alpha set at 0.05 and power set at 0.80, to detect a difference of one standard deviation

between groups, a sample size of 16 participants per group would be needed [105]. If a retention rate of 90% is assumed, a total of 36 children will need to be recruited.

RCT data analysis

Analysis will follow standard principles for RCTs, using two-group comparisons on all participants on an intention-to-treat basis. Any missing data in the event of withdrawal or loss to follow up, a participant's assessment from the last available time-point will be carried forward. External and internal validity of results will be checked using baseline and general descriptive information available for all eligible families; comparing the characteristics of families who completed the study with those who enrolled in the study but did not complete, and those who did not enroll. The primary comparison immediately post intervention (T2) will be scores from the Continuous Performance Test.

Analysis will follow standard methods for randomized controlled trials using comparisons between the two groups (MiYoga and wait-list control). The experimental unit will be the child and their participating parent. Attrition analysis will be conducted. Data will be analysed using Statistical Package for the Social Sciences (SPSS). The hypotheses relating to intervention efficacy will be tested using general linear models, specifically via analysis of covariance (ANCOVA). In addition, predictors of treatment outcome will be explored using regression analyses. Non-parametric methods will be used for simple comparisons in cases where continuous data exhibit substantial skewness not overcome by transformation.

Qualitative data analysis

The qualitative interviews will be audio recorded and transcribed verbatim. Transcripts will be read and coded by two study investigators. Coding will involve identifying themes or patterns, such as ideas, concepts, terminology or phrases. Once these themes are identified,

the investigators will discuss the appropriateness of their themes and develop a coding framework based on their themes until consensus is achieved. The researchers will then re-read the transcripts and organize the themes into categories and sub categories based on the coding framework they have developed.

ETHICS AND DISSEMINATION

Full ethical approval for this study has been obtained by the Behavioral and Social Sciences Ethical Review Committee of The University of Queensland (2012000993) and Children's Health Queensland Hospital and Health Service Research Ethics Committee (HREC/12/QRCH/120). Protocol modifications and amendments will be submitted to the ethical committees for approval. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613000729729). All families will be given written informed consent to participate and their parents or guardians prior to entering into the trial. If found to be effective, MiYoga has the potential to be disseminated as a lifestyle intervention for families. The study results will be disseminated through publication in scientific journals, presentation at relevant conferences and directly to the families who participated in the study. The dissemination would assist children with CP and complement their on-going therapy by; improving the ability of the child to pay attention at school and in therapy, and alleviating environmental stressors for both the child and their parents.

DISCUSSION

This proposed study presents the background and design for a randomized waitlist controlled trial investigating the efficacy of an 8 week Mindfulness and Yoga program to for children and adolescence with an CP and one of their parents. To our knowledge this study is the first to investigate the effects of a family centred Mindfulness-based yoga program for children and adolescence with CP. Furthermore, we will be evaluating children's cognitive, physical,

behavior and emotional outcomes as well as parents' psychological well-being. The qualitative information, such as what the participants liked or disliked about the program, will help provide information on how Mindfulness and yoga can be integrated effectively into participants' everyday lives. It is anticipated that the results of this study will be disseminated through peer reviewed journals and national and international academic conferences.

Current models of rehabilitation for children with CP solely focus on physical rehabilitation. MiYoga provides a holistic approach while the Mindfulness and yoga techniques can be integrated easily into the child and their families' everyday life. If MiYoga is found to be effective, multi-disciplinary teams will have an evidence-based mode of therapy to offer that is an engaging lifestyle intervention, incorporates cognitive rehabilitation, and tools to teach families valuable skills for the rest of their lives.

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Contributions

CM is the chief investigator (CI) and together with KW and RB designed and established this research study. CM was responsible for ethics applications and reporting. CM was responsible for recruitment. CM was responsible for data collection and implementation of the training program. CM will take lead roles on preparation for publications on the clinical outcomes of the study. KW, RB and RC will contribute to the preparation of publications

within their respective fields of expertise. CM will take on a lead role of the statistical analysis for the study. CM drafted the final version of this manuscript. All authors critically reviewed and approved the final version. All data from this study will be submitted to peer review journals. CM will use the data from this study to contribute to her PhD thesis.

Competing Interests

MiYoga was developed by first author. There are no other competing interests to declare.

Ethics approval and consent to participate

Full ethical approval for this study has been obtained by the Behavioral and Social Sciences Ethical Review Committee of The University of Queensland (2012000993) and Children's Health Queensland Hospital and Health Service Research Ethics Committee (HREC/12/QRCH/120). All families will be given written informed consent to participate and their parents or guardians prior to entering into the trial.

Consent for Publication

Consent to publish was obtained from both the individual and from the parent of the child whose photographs are presented in this manuscript.

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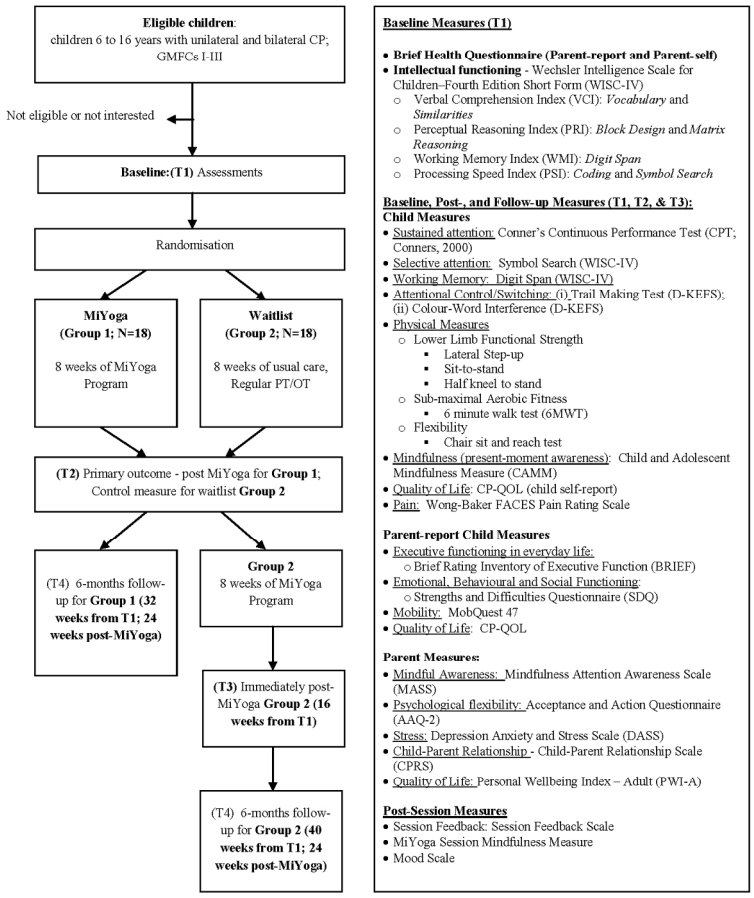

Figure 1. Flow chart of MiYoga study design

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Appendix A
MiYoga Program Summary

Week 1	Theme	Welcome	Introduction to Mindfulness	Hatha Yoga	End of Session
	Explore our everyday life with awareness in the present moment Focus of session is on being mindful while performing yoga postures; and to teach participants their individualised modifications	Getting to know you – pass the ball around in a circle. Explain the that over the next 6 weeks we are be training to be explorers of our feelings, our thoughts and things in our everyday life • Housekeeping • Give out MiYoga packs • Set group rules	Introduction to mindfulness and mindful movements ie. raise arms with awareness and discuss if they feel any different.	Go through yoga postures. Therapist will teach participant their modifications to each posture and teach participants how to safely go in and out of each posture. **Mindfulness relaxation** Progressive muscle relaxation exercise	Discussion - what they experienced through their exploration today and time for any questions. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 2	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Senses: Feel/Touch	Review last session and briefly discuss home practice in the last week. Introduction to Feel/Touch Exploration exercises 1) Feel and describe object with hands 2) Whose hands are they? 3) Mirror Me	Practise yoga postures. Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Body Scan	Discuss what they experienced during the body scan and from the session. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 3	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Hearing	Review last session and briefly discuss home practice in the last week. Exploration exercises What do you hear? Sound exercises - clasp hands over ears, what do you notice? Make sounds with our breath – practice the ocean breath, pranayama (yogic breathing exercises)	Practise yoga postures. Incorporate ocean breath into the postures by linking movement with inhalation and exhalation. Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Mindfulness of sound – Tibetan bowl	Discuss what they experienced/heard during the mindfulness exercise and from the session today. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 4	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Seeing	Review last session and briefly discuss home practice in the last week. Introduction to Seeing Exploration exercises What colour eyes do your friends have? What did you see? Mindfulness of the hand	Sound exercises Pranayama exercises Incorporate sound into the postures by linking sounds with exhalation. Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Short body scan and short imagery script	Discuss what they experienced from the session today. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 5	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Taste & smell	Review last session and briefly discuss home practice in the last week. Introduction to taste and smell Exploration exercises 1) What are you eating? 2) Mindful eating 3) Mindful drinking	Eye movements Sound exercises Pranayama exercises Practise yoga postures Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Body Scan or Progressive muscle relaxation or Mindfulness of breath or Mindfulness of sound	Discuss their experienced from the session today. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

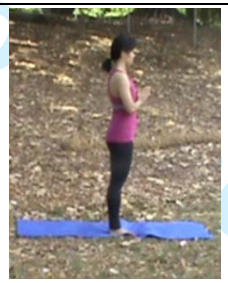
Week 6	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Thoughts & feelings	Review last session and briefly discuss home practice in the last week. Introduction to feelings – can be pleasant and unpleasant but like senses it is helpful. Exploration exercises 1) Explore thoughts and feelings through listening to short stories and/or music 2) Discussion of thoughts and feelings that arise in our lives. 3) Bubbles of thoughts and feelings exercise	Eye movements Sound exercises Pranayama exercises Practise yoga postures Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Short body scan and finding a comfortable place	Discuss thoughts and feelings about the session. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Organise times for phone/skype consultations Complete end of session questionnaires.

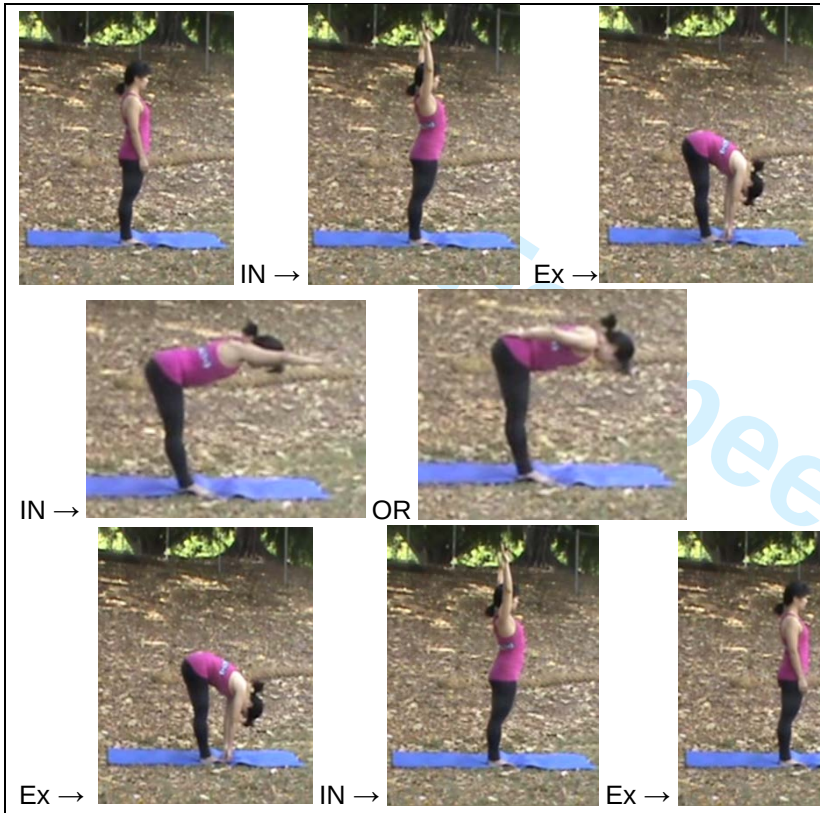
Week 7	Theme	Review	Q & A and problem solve obstacles to practice	Planning and Setting Goals
Phone consultation	Maintaining MiYoga practice	Review and briefly discuss home practice in the last week Was daily practice maintained? What were barriers to practice? What helped/encourage practice? Any other questions regarding mindfulness or their practice?	Address participants questions Problem solve ways to overcome barriers to practice – be as specific as possible Revisit – reasons for practice - Benefits of yoga and mindfulness	Goals and plans in regards to practice for the next week - be as specific as possible
Week 8	**Theme**	**Review**	**Q & A and problem solve obstacles to practice**	**Planning and Setting Goals**
Phone consultation	Maintaining MiYoga practice	Review and briefly discuss home practice in the last week Was daily practice maintained? What were barriers to practice? What helped/encourage practice? Any other questions regarding mindfulness or their practice?	Address participants questions Problem solve ways to overcome barriers to practice – be as specific as possible Revisit – reasons for practice - Benefits of yoga and mindfulness	Goals and plans to continue practice - be as specific as possible Discuss maintaining practice over time

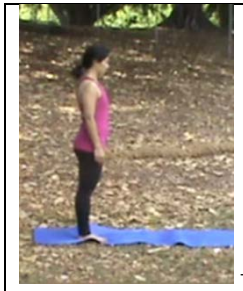
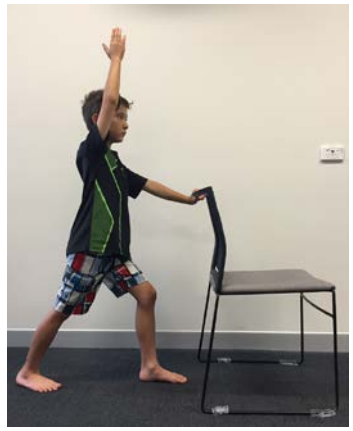
Appendix B

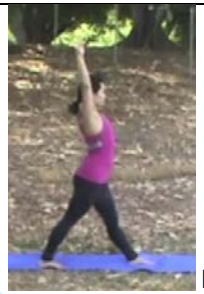
Table 1

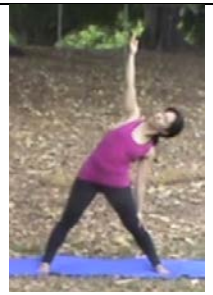
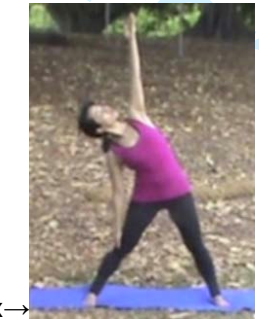
MiYoga Postures

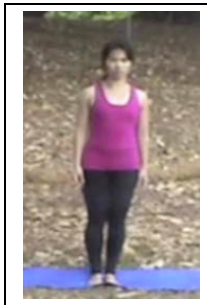
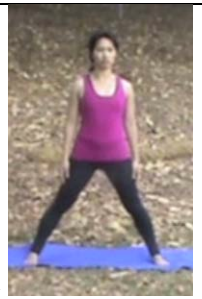
Illustration of Posture	Posture	Physical Benefits	Possible Modifications
Inhale (IN)  Exhale (Ex) →  IN →  Ex →  IN →  Ex → 	**Warm-Up**	**Strengthens:** • legs • arms • torso **Lengthens**: • back of the body • back of the legs Induces balance	If required, have support (e.g. table/chair/wall) in front or to the required side.  This posture can also be performed in a chair or wheelchair  Provide prompts for children to keep their knees straight in forward bend (if standing) and only to go as far as they are comfortable when bending forward. Encourage children to bear weight evenly on both left and right sides.

	**Half Forward Bend**	**Strengthens:** • legs • arms • torso **Lengthens**: • back of the body • back of the legs Induces balance	If required, have support (e.g. table/chair/wall) in front or to the required side.  Provide prompts for children to keep their knees straight in forward bend (if standing) and only to go as far as they are comfortable when bending forward. Encourage children to bear weight evenly on both left and right sides.

 →  IN →  OR  Ex →  (repeat) 4x; To finish, Ex →  	**Warrior sequence**	**Strengthens:** • quadricep muscles • arms • torso **Lengthens**: • hip flexor muscles • calve muscles	If required, have support (e.g. table/chair/wall) in front or to the required side.   Provide prompts for children to keep both of their feet pointing forward if possible and aim to have the back heel on the ground. Encourage children to bear weight evenly on both left and right sides.

 →  IN →  EX→  IN →  (repeat 4x) to finish, Ex →  → 	**One sided forward bend**	**Strengthens:** • legs • arms • torso **Lengthens**: • hip flexor muscles • calve muscles Induces Balance	If required, have support (e.g. table/chair/wall) in front or to the required side.  Provide prompts for children to keep both of their feet pointing forward if possible and aim to have the back heel on the ground. Ask the children to explore with having the front knee as straight as it is comfortable for them. Encourage children to bear weight evenly on both left and right sides.

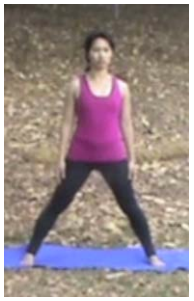
 →  IN →  Ex →  IN→  Ex→  IN →  (Repeat 4x each side) To finish,  IN → → →	**Triangle**	**Strengthens:** • legs • arms • torso **Lengthens**: • muscles along the side of the body Induces Balance Increases hip flexibility	If required, this pose can be down with back gently against a wall and/or have support (e.g. table/chair) on either side.   Provide prompts for children to keep their knees straight in forward bend and only to go as far as they are comfortable when bending forward. Encourage children to bear weight evenly on both left and right sides.


→ IN →

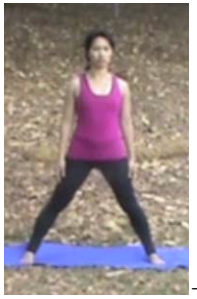


Ex → OR IN →



Ex → (Repeat 4x)

To finish,


IN → → →

Feet apart Forward Bend

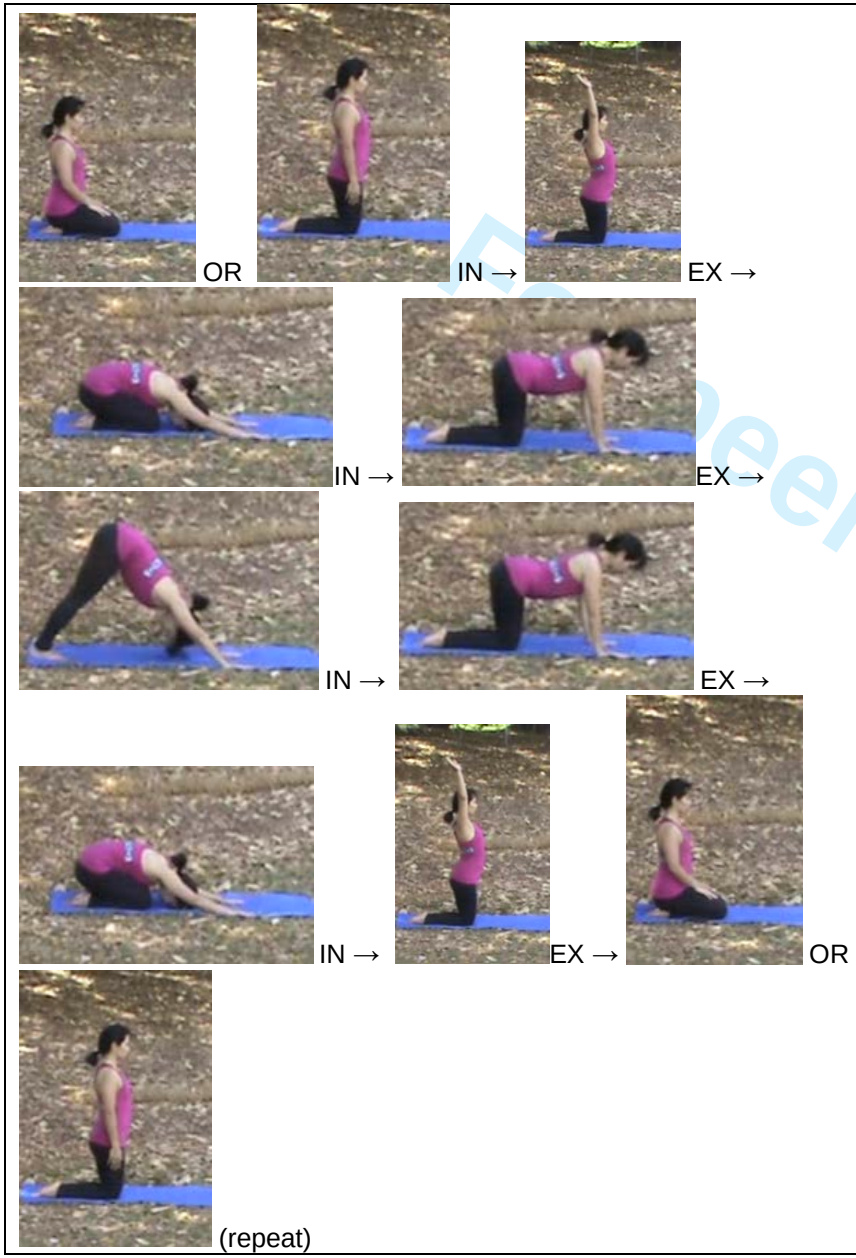
Strengthens:
- legs
- arms
- torso

Lengthens:
- muscles of the inner thighs and hamstrings

Induces Balance
Increases hip flexibility

If required, have support (e.g. table/chair/wall/blocks) in front.

Provide prompts for children to have the feet pointing forward and to keep their knees straight in forward bend and only to go as far as they are comfortable when bending forward. Encourage children to bear weight evenly on both left and right sides.

	**Downward Dog**	**Strengthens:** • legs • arms • upper body • torso **Lengthens**: • muscles in back of the body and legs	Provide prompts for children to keep their heels and big toes together in the kneeing postures. Encourage children to bear weight evenly on both left and right sides. Downward dog pose can also be performed separately. Downward dog can be performed from standing or seating in a chair by placing both hands against a wall or on a table/chair in front with the aim to flex hips,with back straight and shoulder blades back and down (retracted).  .

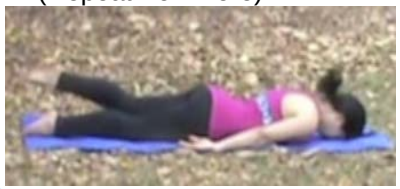
Bent legs with strap (or towel)  →   Place rolled towel/strap under Left foot (Repeat from here) EX →  IN →  EX →  IN →  EX →  IN Stay  Ex →  (Repeat) To Finish: Release towel/strap from under foot  →  EX → Repeat on other leg	**Supine Leg lift**	**Strengthens:** • arms • torso **Lengthens**: • muscles in back of the legs Provides full range of motion from the hip to the toes. Increase circulation and release any tightness in the hips, knees, and ankles.	A rolled towel or belt is required for this sequence. If possible keep the resting leg straight along the floor instead of bent. Feet of resting leg can be placed flat on a wall so that the ankle is at approximately 90degree dorsiflexion and prompt children to push their feet into the wall while they are lifting the other leg. This will help them keep the resting leg active and straight. 

(Repeat from here)  →  IN →  EX →  (Repeat) To finish EX down: 	**Bridge**	**Strengthens:** • core back muscles • gluteal muscles **Lengthens**: • hip flexor muscles • quadriceps muscles	Children can hold the block between their knees while moving the hips up and down will help them engage their core muscles. 

(Repeat from here)  IN→  EX→  IN →  EX →  (One round; Repeat 4x) To finish: 	**Supine Spinal Twist**	**Lengthens and relaxes**: • back and spine	It is also possible to place rolled up blankets or a bolster on the floor in line with the knees (a few inches from the hip) on both sides to prevent any discomfort from rotating too far. This spinal twist can also be performed from standing or seating in chair. If standing place feet hip width apart, place hand across the body to the opposite waist and twist body (without moving feet). If seating in a chair place feet flat on the floor or on blocks. With back straight, place hand on opposite knee and twist body pass the knee the hand is on. 

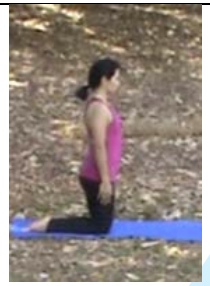
 →  (Repeat from here) IN→  EX→  (repeat) To finish: IN →  → 	**Apanasana**	**Lengthens and relaxes**: • back and spine	Verbal prompts to invite children to experiment with some hip movements, such as rocking slightly from side to side, or move knees and hips in small circles or simply staying still and observing sensations in their bodies while in this pose.

 →  (Repeat from here) IN →  EX →  (Repeat) To Finish: 	**Cobra**	**Strengthens:** • torso • back muscles • neck muscles **Lengthens**: • muscles in the front of the body	A blanket can be place under hips and lower ribs for comfort.

(Repeat from here)  IN →  (lift RIGHT leg) EX →  IN →  EX →  (One round; Repeat four times) To finish: 	**Prone with legs**	**Strengthens:** • torso • back muscles • gluteal muscles **Lengthens**: • muscles in the front of the body	A folded blanket can be used to help support the lifted leg if placed under the front of thighs (of the lifted leg).

 →  (Repeat from here)  IN → EX →  (Repeat) To Finish: 	**Lotus 2**	**Strengthens:** • torso • back muscles • neck muscles • gluteal muscles **Lengthens**: • muscles in the front of the body	A blanket can be place under hips and lower ribs for comfort

 →  (Repeat from here) IN →  EX→  (Repeat 4x) To Finish:  → 	**Superman**	**Strengthens:** • arms • torso • back muscles • neck muscles • gluteal muscles **Lengthens**: • muscles in the front of the body	A blanket can be place under hips and lower ribs for comfort.

 OR  EX →  (repeat from here) IN→  EX→  (Repeat) To finish: IN →  OR 	**Cat – back**	**Strengthens:** • arms • quadriceps muscles **Lengthens and relaxes**: • neck muscles • shoulders • back muscles and spine	If required, provide physical support at elbow on the involved side to help children maintain straight arm.  Also, verbal prompts to remind children to have hands flats on the floor.

(repeat from here)  EX →  IN →  EX→  IN →  EX→  (One round; Repeat four times) To finish:  IN →	**Cat - legs**	**Strengthens:** • arms • back muscles • quadriceps muscles • leg muscles **Lengthens and relaxes**: • back muscles and spine (in child's pose)	Children may find lifting their legs straight up one at a time in this sequence too difficult, they may like to try to extend it straight out behind them by sliding their foot along the floor without lifting their legs. 


rest hands behind→



bend knees →
flex toes →


Stay for 4 to 6 breaths

Alternative boat:


Lift one foot off the floor, swap legs


Balance with both feet off the floor
Stay for 4 to 6 breaths

to finish:


→


Boat Pose

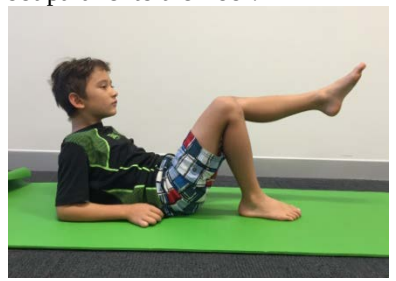
Strengthens:

- abdominal muscles
- back muscles
- quadriceps muscles

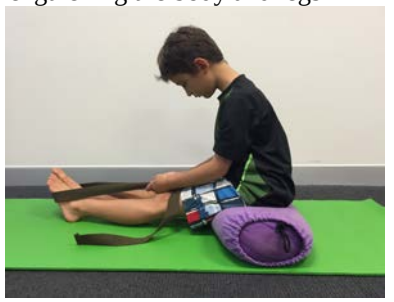
Lengthens:

- back muscles and spine (in child's pose)

This posture may be done with elbows and forearm on the floor or with back rest on the floor arms by the side. With knees bent and feet flat on the floor, lift one heel off the floor at a time - aim to have shin and foot parallel to the floor.



One leg at a time (Repeat from here)  →  IN →  EX →  (Repeat 4x) To finish: IN →  EX →  IN → 	**Seated forward bend – one leg at a time** **Rowing boat**	**Strengthens:** • arms • torso **Lengthens**: • back of the body • hamstring muscles • calf muscles	This posture can be performed sitting on firm cushions, bolsters or folded blankets to help lift pelvis  A strap or belt can also be used to assist with lengthening the body and leg  Verbal prompts may be provided to help children keep their legs straight.

(Repeat from here)  IN →  EX →  IN →  →  EX →  (Repeat 4 x) To finish: IN →  →  EX → 	**Seated forward bend – both legs** **Rowing boat**	**Strengthens:** • arms • torso **Lengthens**: • back of the body • hamstring muscles • calf muscles	This posture can be performed sitting on firm cushions, bolsters or folded blankets to help lift pelvis and a strap or belt can be used to assist with lengthening the body and legs  Verbal prompts may be provided to help children keep their legs straight.

(Repeat from here)  →  →  →  (Repeat a few times) To finish: 	**Butterfly**	**Lengthens**: • inner thigh muscles Increases flexibility in the hips.	This posture can be performed sitting on firm cushions, bolsters or folded blankets to help lift pelvis and lengthen the body.  If required, this posture can also be performed sitting with back against a wall for support.
	**Shavasana or the relaxed star pose**	This pose helps to assimilate the benefits of all the movements in the practice.	A rolled blanket, bolster or pillow can be placed under the knees and/or under head for comfort..Children may also like to be covered with a blanket for warmth. Props such as belts, rolled mats or towels and bolsters may also be used for alternate supported relaxation postures. 

Appendix C

BRIEF HEALTH QUESTIONNAIRE (BHQ) - Caregiver

Name: _____
Address: _____
_____
_____

Phone: ( ) _____ (W)
Phone: ( ) _____ (H)

Age: _____
DOB: _____

Relationship to Child: _____

Please read the following questions very carefully. If you have any difficulty please advise the health professional.

1. **Personal medical history.** Indicate symptoms that apply to you.

☐ Pain or discomfort in chest following exercise
☐ Poor exercise tolerance
☐ Frequent dizziness
☐ Frequent headaches
☐ Frequent backache
☐ Frequent aches or pains in an joints

Details _____

☐ Other current symptoms that exercise may affect

Details _____

2. **Lungs: Do you have any of the following conditions?**

Asthma
☐ Yes
☐ No
Details _____

Emphysema
☐ Yes
☐ No
Details _____

Bronchitis
☐ Yes
☐ No
Details _____

Shortness of Breath
☐ Yes
☐ No
Details _____

3. **Do you have any heart condition/problems that might preclude you from exercise?**
☐ Yes
☐ No
Details _____

4. **Seizures, fainting, blackouts and loss of consciousness?**
☐ Yes
☐ No
Details _____

5. **Headaches**
☐ Yes
☐ No
Details _____

6. **Sight or hearing difficulties**
☐ Yes
☐ No
Details _____

7. **Cervical Spine instability (e.g. Atlanto-axial)**
☐ Yes
☐ No
Details _____

8. **Spinal problems that cause pain or preclude exercise**
☐ Yes
☐ No
Details _____

9. **Are you pregnant?**
☐ Yes (number of weeks ___; due_____)
☐ No
Details _____

10. **Medication.** Are you taking any medication prescribed by your Doctor or other Health Care provider? If so, list details, i.e., type of drugs, dosage.
_____
_____
_____
_____

BRIEF HEALTH QUESTIONNAIRE – Child (caregiver report)

Name (child): _____
Address: _____
_____
_____

Phone: ( ) _____ (W)
Phone: ( ) _____ (H)

Age: _____
DOB: _____

Please read the following questions very carefully. If you have any difficulty please advise the health professional.

1. **Personal medical history.** Indicate symptoms that apply to you.

☐ Pain or discomfort at rest or with exercise

Details _____

☐ Frequent dizziness
☐ Frequent colds or flu
☐ Frequent headaches
☐ Frequent backache
☐ Other current symptoms that exercise may affect

Details _____

2. **Seizures, fainting, blackouts and loss of consciousness?**

☐ Yes
☐ No
Details _____

3. **Headaches**

☐ Yes
☐ No
Details _____

4. **Sight or hearing difficulties**

☐ Yes
☐ No
Details _____

5. **Cervical Spine instability (e.g. Atlanto-axial)**

☐ Yes
☐ No
Details _____

6. **Spinal problems that cause pain or preclude exercise**

☐ Yes

☐ No

Details _____

7. **Medication.** Are you taking any medication prescribed by your Doctor or other Health Care provider? If so, list details, i.e., type of drugs, dosage.

_____

_____

_____

_____

Appendix D

Participant ID: _____

DOB: _____ Age at Assessment:_____

Date		**Examiner:**	
CLASSIFICATION			
CP motor type:	1st	2nd	Comments:
No. of limbs involved	Comments:		
GMFCS level	Comments:		
FMS level			
Handedness	Right / Left / Mixed		
MACS			
Preferred sitting position	W-sitting Ring sitting Side sitting- right left Long sitting- symmetrical Asymmetrical (right/left)		
STANDING			
Unaided/ Aided Equipment Used:			
GAIT			
Unaided/ aided Typically developing **Comments:** **Gait pattern:** True Equinus/ Apparent Equinus / Jump Knee / Crouch gait; Gage Type:			
SUPINE			**Comments**
Thomas Test (FFD)			
Abduction in Flex			
Dynam Abd in Flex			
Abduction in Ext			
Dynam Abd in Ext			
Popliteal angle			
Dynamic Hamstrings			
Kn Exten (Hip 0 deg)			
Dorsiflex (Kn in Ext)			
Dynam DF (Kn in Ext)			
PRONE			
Hip Int Rotation			
Hip Ext Rotation			
Femoral Neck angle (FNA)			
Staheli test			
SPINE			
Scoliosis	Yes / No	Convex to R/L	
Rotation	Yes / No	To R / L	
Spondylolisthesis	Yes/ No		
Other	Yes/No		
Current skills:			
Medical Hx Check: Past surgery Pain levels Seizures Medication Botox Past therapy Compliance in therapy			
Comments: **Spine at Risk: Yes/ No** **Action:**			

Appendix E

MiYoga Session Mindfulness Measure

We are interested in your experiences what you just experienced during our group session. **Read** each sentence. Then, circle the number that tells **how true each sentence is about your experience during our group session.**

	Never True	Rarely True	Some-times True	Often True	Always True
1. I stopped myself having thoughts or feelings that I don't like.	0	1	2	3	4
2. I was moving without noticing what I was doing.	0	1	2	3	4
3. I noticed my thoughts or feelings.	0	1	2	3	4
4. It was hard for me to pay attention to what I was meant to be doing.	0	1	2	3	4
5. I was focused on what I was doing.	0	1	2	3	4

Appendix F

Mood Scale

1 **2** **3** **4** **5**

Very Bad Bad Neutral Good Very Good

Appendix G

Session Feedback Scale

Name _____Age (Yrs):___ Gender:_____

Session # ___ Date: _____

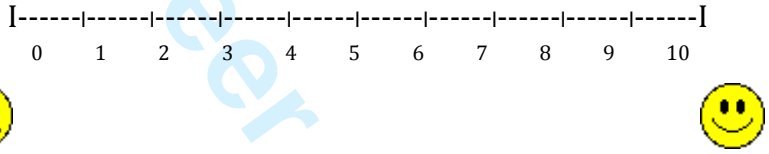
Who is filling out this form? Please check one: Child_____ Caretaker_____

If caretaker, what is your relationship to this child? _____

How was our time together today? Please put a mark on the lines below to let us know how you feel.

Comfort

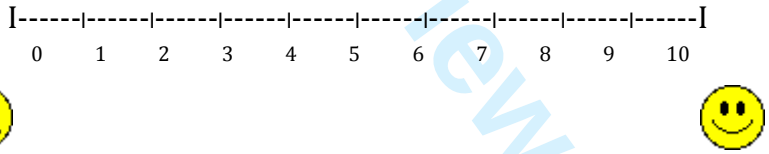
What we did today was uncomfortable and did not suit my needs and



What we did today was comfortable and suited my needs and ability

Enjoyment

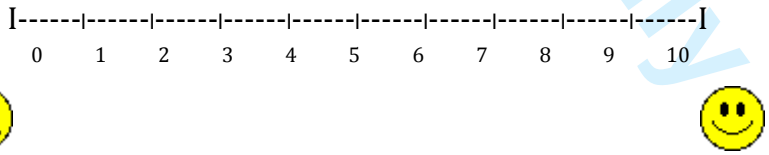
I did not like what we did today.



I liked what we did today.

Body Awareness

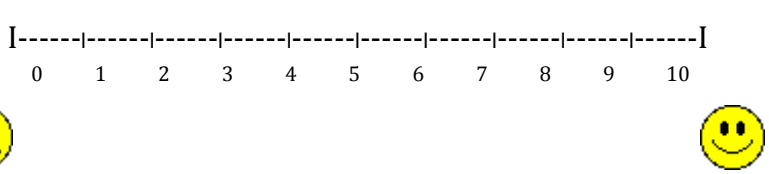
I did not always notice how my body was moving during



I noticed how my body was moving during the session.

Overall

Overall I disliked this .



Overall I liked the session

Appendix H

MiYoga
Qualitative Interview Script and Questions

Interviewer - Introduce yourself

- I am post-graduate student from School of Psychology at The University of Queensland who is unrelated to the MiYoga study in anyway. Advise participants to express their views and opinions about the program freely.
- I would like to find out from you how your experienced your involvement in MiYoga. This will help us to ensure that we are optimizing this therapy.
- To make sure that I accurately report your views, with your permission I would like to audio record our conversation.
- This recording will be transcribed and your name replaced by a number to make sure the information remains confidential.

Questions for parents:

1) What did you like best about the MiYoga program?
Potential Follow Up Questions: "Why did you like X the best?"

2) What did you NOT like about the MiYoga program?
Potential Follow Up Questions: "Why did you not like X?"

3) What do you think could have been different in the MiYoga program?
Potential Follow Up Questions: "What are your reasons for thinking X could have been different?"
   - *Amount of home practice expected?*
   - *Number of sessions per week?*
   - *Therapist interaction?*

4) Did you notice any changes in yourself after participating in MiYoga?
If so, ask: "In what way?" or "What changes have you noticed after participating in MiYoga?"
   - *Personal tasks?*
   - *Work tasks?*
   - *Leisure tasks?*

5) Did you notice changes in mindfulness in everyday life?
Potential Follow Up Questions: "Would you be able to provide some examples of these changes you have noticed in mindfulness in your everyday life please?"
   - *Personal tasks?*
   - *Work tasks?*
   - *Leisure tasks?*

6) Did you notice any changes in your child after participating in MiYoga?
If so, ask: "In what way?" or "What were the changes you noticed in your child after participating in MiYoga?"
   - *Personal care tasks?*
   - *School tasks?*
   - *Leisure tasks?*

7) Did you notice any changes in your child's mindfulness in everyday life?
Potential Follow Up Questions: "Would you be able to provide some examples of these changes you have noticed in your child's mindfulness in their everyday life please?"

- *Personal care tasks?*
- *School tasks?*
- *Leisure tasks?*

8) Is your child better or worse at paying attention after participating in MiYoga?
Potential Follow Up Questions: "Would you be able to provide some examples of these changes in your child's ability at paying attention please?"

9) Did you enjoy participating in MiYoga with your child?

10) Did your child enjoy participating in MiYoga?

11) Have you noticed any changes in your relationship with your child since participating in MiYoga?
Potential Follow Up Questions: "How has your relationship with your child changed?" or "Would you be able to provide some examples of these changes in your relationship with your child please?"

12) How did you find integrating MiYoga practices into your daily life?

13) Would you participate in this program again?

14) Would you recommend MiYoga to other families?

15) Are you planning on continuing to practice Yoga with your child?
If so, why? If not, why not?

16) Anything else you would like to tell me?

Questions for children:

1) What did you like best about the MiYoga program?
   Potential Follow Up Questions: "Why did you like X the best?"
   - *Any particular postures you liked best?*
   - *Any particular games you liked best?*

2) What did you NOT like about the MiYoga program?
   Potential Follow Up Questions: "Why did you not like X?"
   - *Any particular games you didn't like?*
   - *Any particular postures you didn't like?*
   - *How often the sessions were?*
   - *How often you had to practice at home?*

3) What do you think could have been different in the MiYoga program?
   Potential Follow Up Questions: "Why do you think X could have been different?"
   - *Amount of home practice expected?*
   - *Number of times per week?*
   - *Therapist interaction?*

4) Can you tell me about anything that made it hard for you to practice MiYoga at home?
   - *Other commitments - homework/extracurricular activities?*

5) Did you notice any changes in yourself after participating in MiYoga?
   If so, ask: "In what way?" or "What changes have you noticed after participating in MiYoga?"
   - *At home?*
   - *At School?*
   - *Leisure tasks?*

6) Did you enjoy participating in MiYoga?

7) What was it like to do MiYoga with your mum/dad?

8) Would you participate in this program again?

9) Would you recommend MiYoga to other children?

10) Do you want to keep practicing Yoga?

    If so, why? If not, why not?

11) Anything else you would like to tell me?

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____✓_p1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____✓_p3_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____✓_p3, p1, p13-14, p17, p23-34, p35, p37, ____
Protocol version	3	Date and version identifier	_____✓_footer__
Funding	4	Sources and types of financial, material, and other support	_____✓_p37____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____✓_ p1____
	5b	Name and contact information for the trial sponsor	____N/A_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___ N/A _____

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___ N/A _____
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	____✓_p4-11___
	6b	Explanation for choice of comparators	____✓_p20_____
Objectives	7	Specific objectives or hypotheses	____✓_p11-12__
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	____✓_p14_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	____✓_p20_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	____✓_p13_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	____✓_p17-20__
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	____N/A_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	____✓__p20 (MiYoga diaries), p21 (video recording)_____

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	____✓_p14_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	____✓_p23-34__
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	____✓__p14 & Figure 1_____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	____✓__p35____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	____✓__p20____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____✓__p15____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	____✓__p15____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	____✓__p15____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	____N/A_p15____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	____N/A_____

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	____✓_p20_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	____✓_p20_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	____✓_p20-21__
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	____✓_p35-36__
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	____N/A_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	____✓_p35_____

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	____✓_p15_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	____N/A_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	____✓_p15_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	____ N/A_____

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____✓_p1, 12, 36_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____✓_p12____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	____✓_p12_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	____ N/A_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	____✓_p21_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	____✓_p39_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	____ N/A_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	____✓_p15_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	____✓_p37_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	____ N/A_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	____ N/A_____

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	____✓_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	____N/A_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

BMJ Open

MiYoga: A randomized controlled trial of a mindfulness movement program based on hatha yoga principles for children with cerebral palsy - A study protocol

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Study Protocol

Title: MiYoga: A randomized controlled trial of a mindfulness movement program based on hatha yoga principles for children with cerebral palsy - A study protocol

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ABSTRACT

Introduction: Cerebral Palsy (CP) is the most common childhood physical disability, with life-long impacts for 1.77 in 1000 children. Although CP is primarily a physical disability, children with CP have an increased risk of experiencing cognitive difficulties, particularly attention and executive function deficits. Impairment in cognitive abilities can lead to subsequent impairment in independent functioning, education, employment, and interpersonal relationships. This paper reports the protocol of a randomized controlled trial of a novel family-centered lifestyle intervention based on Mindfulness and Hatha Yoga principles (MiYoga). MiYoga aims to enhance child and parent outcomes for children with CP.

Methods and analysis: The aim is to recruit 36 child-parent dyads (children 6-16 years old; bilateral or unilateral CP; GMFCS I-III) who will be randomly assigned to two groups: MiYoga and waitlist control. The MiYoga program will be facilitated in a group format for 8 weeks. Assessments will be administered at baseline, prior to MiYoga, following completion of MiYoga, and at 6-month follow-up (retention). The primary outcome will be the child's sustained attentional ability as measured by the Conner's Continuous Performance Test (CPT II). Other outcomes of interest for children with CP consists of attentional control, physical functioning, behavioural and wellbeing. For parents, the outcomes of interest are mindfulness, psychological flexibility and wellbeing. Data will be analyzed using general linear models, specifically analysis of covariance and analysis of variance.

Ethics and dissemination: Full ethical approval for this study has been obtained by the Children's Health Queensland Hospital and Health Service Research Ethics Committee (HREC/12/QRCH/120) and The University of Queensland (2012000993). If MiYoga is proven effective, its dissemination would assist children with CP and complement their on-

going therapy by; improving the ability of the child to pay attention at school and in therapy, and alleviating environmental stressors for both the child and their parents.

Trial Registration: ACTRN12613000729729;

http://www.ANZCTR.org.au/ACTRN12613000729729.aspx

Date of Trial Registration: prospectively registered on 2/07/2013 – present (ongoing).

Findings to Date: Recruitment is complete. Data is still being collected at present. We aim to complete data collection by Feb 2017.

Strengths and Limitations of this study:

- To our knowledge this is the first randomized controlled trial exploring the benefits of a mindfulness-based movement intervention for children with cerebral palsy.
- MiYoga is designed to be a lifestyle intervention so that children and parents will be able to continue practice at home in their everyday lives after the complete of the program.
- MiYoga is fun and developmentally appropriate and is adaptable to the needs of the child and/or parent.
- All participants will be offered MiYoga before completion of the study for ethical reasons.
- Participants in this study span across a broad age range (6-16 years) and within which there maybe variability in cognition and executive function. EF is a secondary measure in the study.
- There is a high number of secondary outcomes in this study which would be exploratory in nature as this is the first RCT to investigate the effects of mindfulness and yoga in children with cerebral palsy.

INTRODUCTION

Cerebral Palsy (CP) is the most common physical disability in childhood with life-long impacts for 1.77 in 1000 children.[1] Cerebral palsy is caused by non-progressive damage to the fetal or infant brain that results in motor and postural difficulties.[2] In addition to physical impairments, which are the diagnostic features of CP, children can also experience cognitive and psychological difficulties.[3-5] The motor and cognitive difficulties are often accompanied by disturbances of sensation, communication, perception, behavior problems, and/or by a seizure disorder.[2 4]

Present therapies focus primarily on physical difficulties faced by children with CP,[6] despite the fact that children with CP also have an increased risk of experiencing cognitive difficulties. In 2009, the Australia Cerebral Palsy Register reported that 1 in 3 children with CP experience cognitive difficulties.[7] More recent studies reported that 1 in 2 children with CP had an intellectual disability,[4] and compared to typically developing children those with CP are more likely to have attention and executive function deficits.[8-10] The deficits may explain why children with CP have increased social and learning problems.[11] It is therefore important to consider interventions that target attention, in addition to the existing physical therapy, for children with CP.

Attention

The attention system underpins most cognitive and neuropsychological functions in everyday life, such as self-control (inhibition), decision-making, goal setting, planning, problem solving, emotional responses and behavior. Typically, the attention system is understood using the 'three network model', comprising the alerting network, and the orienting and executive networks.[12]

The alerting network is a 'bottom-up', stimulus-driven (or exogenous) attention system that automatically responds to external stimulus, such as visual, auditory input.[13] For example, a sudden loud noise or motion can attract our attention and we attend to them whether we want to or not. This network is thought to involve both the parietal and temporal areas of the brain, as well as the brain stem arousal systems.[12]

Orienting and executive networks are the other networks in this model. In contrast to the alerting network, they are both 'top-down' processes, responding to internally determined goals. Together, these two attentional networks are also known as goal-driven, endogenous attention, attentional control or executive attention networks.[12] They determine our ability to voluntarily select, and orient, attention to relevant stimuli or tasks, mediated primarily by the frontal cortex and basal ganglia.[12 14]

The orienting network determines our ability to consciously orient attention in a spatial setting. Functionality of this network can be measured by the speed and accuracy of responses to cues that indicate where a future stimulus may occur on a computer screen.

In contrast, the executive network involves mechanisms for monitoring and resolving conflict when two responses are simultaneously called for by an external stimulus. This network aids attentional switching, and provides the ability to disengage from distracting stimuli and re-engage attention to the relevant task or stimulus. Previous studies have confirmed that these two 'top down' networks are related to executive functions,[12 15] working memory[16] and conflict resolution and inhibition.[17]

Both orienting and executive networks of attention are involved in sustained attention, which is the ability to maintain and focus attention on a given task. Sustained attention is a core executive function, typically defined as the ability to maintain an alert, goal-directed focus in the absence of an external stimulation.[18] Difficulty maintaining sustained attention can

interfere with non-cognitive aspects of therapy and rehabilitation, including for children with CP. Impairments in attention in children may lead to reading problems,[19] poor math achievements,[20 21] poor self-confidence and cognitive impairments,[22] poor executive function and executive attention (such as working memory) leading to poor social skills,[11 23] as well as problem behaviors.[11] Furthermore, the capacity to self-sustain attention has been shown to predict motor recovery in adults following a right hemisphere stroke over a 2-year period.[24] These findings suggests sustained attention deficits in the development of interventions and rehabilitation programs are a worthwhile target for interventions, particularly in children with CP, where poor attention may hinder their ability to benefit from existing physical therapies.

Cognitive Abilities in Children with CP

Attention, executive function, and other intellectual capabilities, are impaired in 1 in 2 children with CP.[3 4 8 9 25] One cross-sectional study of sustained attention in 10 adolescents with CP, using a visual Continuous Performance Test (CPT),[26] indicated that sustained attention ability was affected by CP, even after controlling for motor deficits by using eye movements to measure sustained attention.[9] Another study investigated attention and executive function in children with unilateral and bilateral spastic CP.[8] Four subtests from the Wechsler Intelligence Scale for Children (WISC-III)[27] – information, similarities, comprehension, and vocabulary – were used to measure general cognitive functioning. They also used three subtests from the Test of Everyday Attention for Children (TEA-Ch)[28] to measure selective attention (Sky Search), sustained attention (Score!) and divided attention (Sky Search Dual Task). Executive functions were assessed by the Contingency Naming Test (CNT) and the teacher version of the Behavior Rating Inventory of Executive Function (BRIEF)[29]. The results demonstrated that impairments in sustained attention, divided

attention, inhibition, switching and general executive function were present in children with CP.

Few therapeutic interventions aim to increase a child's ability to sustain their attention on task, or selectively focus their attention on appropriate stimuli. Previous research has explored attention and problem-solving training for children with Attention Deficit Hyperactivity Disorder (ADHD),[30] children with learning disabilities and co-morbid ADHD.[31] In addition, some studies investigated efficacy of interventions that may increase attentional abilities in children with traumatic brain injury[30 32] and for the late effects of treatment for childhood cancer.[33] There is a paucity of research on interventions to improve attention in children with CP.

Mindfulness and Attention

Several investigators have recently proposed theoretical explanations of how the practice of focused attention through Mindfulness (awareness of the present moment) training can enhance and develop attention regulation.[34 35] Mindfulness practice involves sustaining attention on a chosen object, such as one's breath, an object, or a mantra, and directing attention to that object while sustaining this focused attention for as long as possible.[34-38] In order to sustain this focus, one must monitor the quality of this focus. For example, while focusing on the rise and fall of the chest with each breath, one might notice their attention has shifted to something that happened during the day, or what they would like for dinner later. At some point they would realize their focus has wondered and let go of their distraction and re-attend to their breath. Mindfulness is the state of awareness of the thoughts or feelings that arise when our minds wander. This awareness provides the opportunity to inhibit the more dominant response of rumination and switch our attention back to the point of focus.
It has been proposed[35] that this type of monitoring of one's attention and focus consists of

three types of attention regulation; (i) monitoring the present-moment (i.e. detect mind wandering), (ii) attentional switching (i.e. disengage from a distracting object/thought without further involvement), and (iii) selective attention (i.e. ability to redirect focus promptly back to target object). Researchers reason that Mindfulness training entails extended practice of these attentional abilities.[34 35 37]

These proposed theoretical models of the cognitive mechanism of Mindfulness have inspired experimental research examining the effects of Mindfulness training on attention performance. The effects of Mindfulness practice on the three attentional networks (alerting, orienting, and executive) were examined by Jha and colleagues (2007)[37] using the Attention Network Test (ANT).[39] Attentional efficiency was assessed before and after an eight-week Mindfulness-Based Stress Reduction (MBSR)[40] course administered to meditation-naïve participants, as well as a one-month intensive Mindfulness retreat attended by experienced meditators, compared to an eight-week no treatment control group. The retreat group (experienced meditators) showed better conflict monitoring at baseline than participants in the control and MBSR groups (both groups with meditation-naïve participants), suggesting that executive attention improves with long-term exposure to Mindfulness meditation. The retreat group had improved alerting among the previously experienced meditators. The authors concluded that Mindfulness training improves voluntary (top-down; endogenous) attentional control leading to improved orienting and conflict monitoring, and prior experience with concentrative meditation allows for the development of improved bottom-up, receptive attention involved in alerting. It may be that Mindfulness training improves the functioning of each of the attentional subsystems at various points in the course of Mindfulness training.

Yoga

Traditional yoga is a Mindfulness practice that directs attention towards the present moment.[41] The aim of yoga is to calm and unify the mind, body and breath to promote positive health, self-awareness and spirituality.[42] Yoga postures, known as *asana* in Sanskrit, are the third of the eight 'limbs', or practices, of yoga according to the traditional texts of the Yoga Sūtras of Patañjali. *Asana* directly translates to "posture" and was derived from the Sanskrit root word as which means "to be", "to sit", "to stay" or "to be established in a particular posture".[43] The Yoga Sūtras of Patañjali describe *asana* as having two important qualities. The first is steadiness and alertness, and the second is the ability to remain comfortable in a posture.[42] When practicing *asana*, both of these qualities should be present. The combination of performing *asana* with pranayama (breathing techniques), comprise the style of yoga commonly referred to as Hatha Yoga. Hatha Yoga unites the actions of the body, breath and mind by the synchronization of movement with the breath which in turn directs the practitioner's attention and awareness to the present. The unity of body and mind is what makes traditional Hatha Yoga an embodied mindfulness practice.

Mindfulness and Yoga for Children

In the pediatric literature, it has been documented that Mindfulness and yoga improves memory in school children,[44] cognitive function in children with mental retardation,[45] planning abilities and executive function in healthy school aged girls,[46] as well as attention, behavior and emotional control in healthy children, and children with ADHD.[47] Yoga has been shown to improve balance, motors skills and strength, as well as the quality of life and general well-being, in a range of different participant groups.[48-51]

Mindfulness-based Stress Reduction[52] programs combine Mindfulness and Hatha Yoga techniques to cultivate greater awareness of the unity of mind and body, as well as of the ways the unconscious thoughts, feelings, and behaviors can undermine emotional, physical,

and spiritual health. The underlying principles for MBSR programs are to (a) be non-judgmental, (b) be patient, (c) see the world as if for the first time, (d) accept seeing things as they are without trying to change anything, (e) and let go of attachment to repetitive thoughts, actions or beliefs. MBSR programs usually feature group interaction, formal and informal meditation practice, daily homework, and/or silent retreats.[52] The formal practice includes Mindfulness meditation and mindful movements in the form of Hatha Yoga. The informal practices include mindful eating and walking. Although a number of studies explored the effectiveness of MBSR in the adult population,[53 54] there is a paucity of randomized controlled trials that explore the effects of a developmentally appropriate MBSR program for children.

A systematic review[55] investigating the efficacy of mindfulness-based interventions identified thirteen randomized control trials that met the inclusion criteria. Out of the thirteen identified studies,[56-68] five studies found a statistically significant intervention effect for at least one outcome measure of attention or executive function with medium to large effects sizes (0.3 – 32.03).[57 59 61 63 66] The overall findings from the review suggested that mindfulness-based interventions targeting attention are a promising approach for children and adolescents. This systematic review did not find RCT of mindfulness-based interventions with children or adolescents with CP. Quality trials are therefore needed to assess the effectiveness of mindfulness-based interventions targeting attention in children and adolescents with CP.

By adapting a Mindfulness-base program for children, with a focus on mindful movements through Hatha Yoga, it may provide a developmental approach to Mindfulness training. Yoga has been shown to improve body awareness in adults,[69] and it may teach children and adolescents about their growing bodies as they become more aware of their bodies and their movements. School-age children have also been found to be interested in yoga as a mind-body therapy for pain and other ailments.[70] As children are naturally more active, teaching

them Mindfulness through movements using traditional Hatha Yoga postures along with the some Mindfulness exercises to begin with, may be more developmentally appropriate than teaching them the more traditional seated Mindfulness meditations. This remains to be tested.

The mindful movement program in this project, MiYoga, combines both cognitive (mindfulness) and physical (yoga postures) aspects into therapy. It has the potential to assist children with CP to alleviate negative effects of environmental stressors by improving their ability to focus attention on the present moment, ultimately helping them to focus on activities at school, in therapy, or when interacting with peers. At the same time, Hatha Yoga may provide additional physical benefits to complement the on-going therapy for children with CP.

MiYoga will be delivered to both the children and their parents, to enable parents to facilitate and monitor the MiYoga approach, which is may improve translation and implementation of techniques into everyday life. This project will test the efficacy of a mindful movement (MiYoga) program administered to children with CP, and one of their parents. The MiYoga program would be an adjunct to children's on-going rehabilitation therapy.

Aim

The focus of this study is to design and test a novel mindful movement program, MiYoga, and to investigate its efficacy for enhancing sustained attention in children with CP. Efficacy will be tested in a randomized controlled trial (N=36) with an intervention group (MiYoga program + standard care) compared to a wait-list control group receiving standard care alone. This enables all participating children to receive the intervention, maximizing participant recruitment and retention, and fulfilling ethical obligations to participating children and families. Outcomes measures will be taken at baseline, immediately post-intervention and at follow-up 6 months post intervention.

Qualitative interviews will also be conducted with each child and parent participant individually. The aim of these interviews is to collect the participants' perceptions of the MiYoga program.

Hypotheses

It is hypothesized that, compared to the waitlist control group, the MiYoga group will show improvements in the following child outcomes:

1) Sustained attention (Conner's Continuous Performance Test II (CPT II))[26];
2) Executive function (information processing, attentional control, cognitive flexibility, working memory and behavioral manifestations of executive function in daily life);
3) Psychological functioning (Strengths and Difficulties Questionnaire (SDQ))[71];
4) Physical capacity including functional strength (Sit-to-stand, Half-kneel to stand and Lateral step up tests),[72] and flexibility (Sit and Reach test);
5) Present-moment awareness (Child and Adolescence Mindfulness Measure (CAMM))[73];
6) Quality of life (CP-QOL-Child or CP-QOL-Teen)[74 75]

In addition, it is hypothesized that the MiYoga group will show improvements in the following parent outcomes:

7) Mindfulness (Mindfulness Awareness Attention Scale (MAAS))[76];
8) Parent psychological wellbeing (Depression Anxiety and Stress Scale (DASS))[77];
9) Parent's psychological flexibility (Acceptance and Action Questionnaire ((AAQ-2))[78];
10) Parent's personal wellbeing (Personal Wellbeing Index – Adults (PWI-A))[79]; and
11) Child-parent relationship (Child-Parent Relationship Scale (CPRS))[80].

METHODS AND ANALYSIS

Ethics

Full ethical approval for this study has been obtained by the Behavioral and Social Sciences Ethical Review Committee of The University of Queensland (2012000993) and Children's Health Queensland Hospital and Health Service Research Ethics Committee (HREC/12/QRCH/120). Protocol modifications and amendments will be submitted to the ethical committees for approval. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613000729729). All families will be given written informed consent to participate and their parents or guardians prior to entering into the trial.

Recruitment

Thirty-six children with a diagnosis of CP with spastic motor type, either diplegia (bilateral CP) or hemiplegia (unilateral CP) motor distribution, and one of their parents, will be recruited into the MiYoga study. Children must also have sufficient co-operation and cognitive understanding to follow simple instructions. The primary parent of eligible children will participate alongside their child. Children with co-morbid diagnoses to CP are included.

Children will be excluded if they have (i) received upper-limb or lower-limb surgery in the previous 6 months; (ii) unstable epilepsy (i.e. frequent seizures not controlled by medication); (iii) spinal instability or other spinal problems that would prevent them from participating safely in the MiYoga program; (iv) have a medical condition that would prevent them from participating safely in the MiYoga program; or (v) parents/guardians who are pregnant as a safety precaution. Diagnosis of CP must be confirmed by the treating pediatrician or clinician and in accordance with published recommendations.

Eligible children living in South East Queensland, Australia, will be recruited through patient databases of Queensland Cerebral Palsy Rehabilitation Research Centre (QCPRRC) at the

Royal Children's Hospital and the Queensland Cerebral Palsy Register, and via referrals from clinicians in the Queensland Pediatric Rehabilitation Service (QPRS). Potential participants will be invited to participate in the study via letters and follow up phone calls. Flyers and posters will displayed in the reception areas of clinics, and clinicians will be informed of the study, and encouraged to refer appropriate patients to the program. External advertising will include a webpage on The University of Queensland School of Psychology website and a study flyer or a brief description of the study will also be advertised in some South East Queensland schools' newsletters and notice boards.

Participants will be assessed for eligibility and enrolled in the study by the study coordinator. The study will be explained to parents by a member of the research team, and signed written consent will be obtained, acknowledging that the children and parents are aware of all study requirements, consent to take part, give permission for researchers to access their child's medical records, agree to the video-recording and photographs of sessions, and understand that they are free to withdraw their consent at any time. It is anticipated that enrolment will commence in September 2013.

Design

This study will utilize a randomized controlled trial design to evaluate the efficacy of the MiYoga program compared to waitlist control (care as usual) for children with CP, aged 6 to 16 years old (see Figure 1 for Flowchart of MiYoga Study Design). After each child and parent completes their baseline assessments they will be randomly allocated to one of two groups:

1. Immediate MiYoga Group (Group 1) – Families commence MiYoga program immediately for 8 weeks.
2. Waitlist MiYoga Control (Group 2) - Families continue care as usual for 8 weeks and then are re-assessed before commencing a future MiYoga Program. Care as usual

consists of any therapies (for example, occupational therapy, physiotherapy, psychologist) usually provided by public or private services and visits to their treating pediatrician or general practitioner.

To limit confounding variables during the immediate intervention period (baseline to 8 week follow up), children scheduled to receive casting, splinting, or intramuscular botulinum toxin type A [BoNT-A] injections during the immediate intervention period will not be eligible. Participants who have received intramuscular BoNT-A prior to beginning the study will have their baseline assessments postponed until one month after their standard follow up has been completed. Questionnaires will record the type, frequency and duration of any concurrent therapies provided by public and private services during the study for all participants.

Randomization

Prior to the intervention, participants will be asked to complete baseline assessments and questionnaires. Once these are completed, participants will be randomly assigned to either the wait-list group or immediate group and informed of the dates and times of their group. The randomization sequence will be computer-generated. Treatment allocations will be recorded pieces of paper, which will be folded and placed inside sealed, numbered, opaque envelopes by a staff member not involved in the study. A staff member not involved in the study will also open consecutive envelopes as each participant returns their baseline questionnaires. After the randomization process is complete, study personnel will be informed of group allocation and information packs will be sent out to families. Given the nature of the study, no parties will be blinded to group assignment. The experimental design and outcome measures are depicted in Figure 1.

Figure 1. INSERT FLOWCHART OF MIYOGA STUDY DESIGN

Adverse Events

There are no known health or safety risks associated with participation in the described study, and the risk of adverse events is low. The ethical review process and conduct of the trial is monitored by the two ethics committees, therefore no additional Data Monitoring Committee is considered necessary.

Any minor or major events associated with intervention or usual care groups will be monitored throughout the 8-week program duration. The chief investigators KW and RB will review any adverse events or unintended effect detected.

Study Procedure

All participants will attend baseline assessments (T1) before being randomly allocated into either the immediate MiYoga group or the waitlist control group. Participants in the immediate group will begin the 8 week MiYoga program within three weeks of their baseline assessment, while the waitlist group will continue care as usual for the next 8 weeks. When the immediate group has completed the MiYoga program, all participants from both groups (immediate and waitlist) will be re-assessed (T2) at. The waitlist group can then commence a future MiYoga group of their choice. For each participant, data will be collected at Baseline (T1) and following the immediate MiYoga group's completion of the program at 8 weeks (T2). The waitlist group will also complete assessments after they have completed the MiYoga program at 16 weeks (T3). Both groups will complete their follow up assessments 24 weeks after completing the MiYoga program – this will be 32 weeks post-baseline for the immediate group and 40 weeks post-baseline for the waitlist group (T4). Participants will complete their assessments within three weeks of the target time-points (in weeks) listed above.

The principal researcher (CM) is a registered psychologist and a qualified yoga teacher, will conduct all the assessments and MiYoga sessions. A physiotherapist from the QCPRRC will

perform the physical screen assessment for each child at baseline. In addition, they will be present at the initial assessment to provide professional advice to the child, the parent/guardian and to the psychologist/yoga teacher regarding the child's ability to perform various yoga postures and the adaptations that may be necessary. Either a physiotherapist or the principal researcher (CM) will conduct the physical assessments. Participants are encouraged to complete their online questionnaires in person during their assessment session, if they prefer they may also complete them online from home (via Qualitrics Insight Platform). Registered clinical and developmental psychologist (KW) will provide regular supervision. In addition, study coordinator will be able to consult with Professor Boyd (RB), a registered physiotherapist, if there are any physical concerns.

MiYoga Intervention

Following randomization (immediate MiYoga group), or the Time 2 neuropsychological and physical assessments (waitlist control group), participants and their parents will complete the MiYoga program. All MiYoga sessions will be delivered in a group format where possible. Child-parent dyads in the waitlist control group will also receive the same intervention after a delay. In two-parent families, one of the parents will be invited to attend all sessions, and the same parent will complete all the questionnaire measures.

The MiYoga program itself is an 8-week program that consists of six 90-minute sessions over the initial six weeks, then two phone or Skype consultations over the last 2 weeks of the program. Over these 8 weeks, children and their parent or guardian are asked to partake in a minimum of 20 minutes daily home practice. To assist with participants' home practice, a MiYoga DVD and a MiYoga poster developed by the principal researcher will be provided at the first MiYoga session. The MiYoga DVD is based on the Mindfulness exercises and *asana* delivered in the group sessions. The MiYoga poster shows pictorially the *asana* delivered in

the group sessions. In addition, it includes child specific modifications identified from the initial assessment session. Each MiYoga poster will contain general instructions as well as general and specific modifications for how parents may assist their child. Where possible a photo of the child performing the postures with their modifications will also be included. Researchers will assess the child's abilities in each of the yoga postures and provide modifications for the child as required in each posture. These modifications will be documented and put into the respective child's poster for them to take home and practice. This will ensure that participants will not attempt any new exercises or poses at home without assistance and guidance from a therapist (see Appendix A for a MiYoga program summary).

There are formal and informal Mindfulness activities in MiYoga. The formal Mindfulness activities consist of mindful movements in the form of Hatha Yoga and short Mindfulness meditations. The yoga postures selected for the program aim to help them build strength and increase flexibility (see Appendix B for a table and illustrations of the MiYoga postures for children with cerebral palsy). The informal activities present Mindfulness techniques as game-like explorations, based on exploring our internal and external worlds with the five senses as well as consciously reflecting on thoughts and feelings. These activities and games were developed based on literature on mindfulness and yoga for both children and adults.[42 43 52 81-91]

One of the informal activities involves children having to guess what they are eating while blind folded. This game will involve the child to consciously notice the food with all their senses, such as by feeling the texture of the food in their hands and mouth, smelling and tasting it, and possibly even hearing the sounds the food makes when chewing it (and subsequently noticing crunchy, chewy or soft foods). Children may have to identify an object by exploring it only with their hands (sense of touch) and then describe how the object feels in their hands to another person without naming the object. This game encourages the child to

use their sense of touch to explore their environment and increase their awareness of how the sense of touch provides them with information about their surroundings. Such activities are both interesting for the participants, but are also mindful practices that stimulate a state of awareness.

The Hatha Yoga techniques or postures in this study were based on Viniyoga principles[39] and they were tailored for children with cerebral palsy. The synchronization of breath and movement is a key element as it helps to focus the mind on the present (i.e. moving through yoga postures with the breath) providing a mindful movement practice. To make synchronizing breath and movement more natural and fun for children, participants will be invited to make sounds along with the instructor, such as "Ahh...", in the asana sequences to assist with their exhalation. The yoga postures will be modified as required for each participant. Some of the modifications will use supports such a wall, chair, or blocks, to ensure correct posture, adequate support and comfort, or to accommodate muscle shortness or postural difficulties. For example, some children may sit on a block to keep their pelvis level and to accommodate their shorter hamstring muscles and leading to posture pelvic tilt within long sitting. These physical modifications will be individualized to each child's need based on the baseline physical screen by a Physiotherapist. The physical adaptations may not be the same for all children with CP while some children did not require any physical modifications. For this reason Appendix B mainly illustrates non-adapted postures and only some examples of possible modifications. In addition to the physical modifications, verbal prompts will guide the children into the postures. For example "going as far as it is comfortable for you, this may be coming forward to thighs or your knees" or "notice the sensation in the back of your legs as you fold forward, you may like to explore how it feels for you to keep your knees straight as you come forward". A verbal prompt for children to sit with good

alignment (avoid W-sitting) may be "as we sit back onto our heels be mindful that your knees and big toes are together".

Each session will be 90 minutes with guided instruction throughout each component of Mindfulness practice. During Hatha Yoga postures, instructions will be provided on safe ways to get in and out of the positions, pose modification, and use of props to suit needs and limitations of each child. For instance the supine twist can be performed on a chair rather than on the ground. Blankets, cushions, bolsters, straps, and other props may be used to maintain body alignment, structural support, and comfort (see Appendix B's possible modification column for more details). Emphasis will be placed on building length along the spine while maintaining neutrality of spinal position, keeping awareness of the breath, and using breath and sensations within the body to anchor attention to the present moment.

Locations

It is expected that groups and assessments will be conducted in Brisbane, and various locations in South East Queensland. Locations in Brisbane will include The University of Queensland, St Lucia and Herston campuses, and the Centre for Children's Health Research in South Brisbane. If participants are located outside of Brisbane then suitable locations will be organized with the participating families in those areas.

Participation and Data Management

To maximize participation and retention, email reminders will be sent to participants three days prior to their scheduled appointments, and text message reminders will be sent to participants the day prior to their appointments and their weekly MiYoga sessions. To further promote recruitment, participation, and retention, the study offers a waitlist control group so that all participants have an opportunity to take part in the MiYoga program. It is also possible to extend the period of recruitment and the delivery MiYoga groups should

recruitment be more challenging than anticipated. The number of participants recruited and participant retention will be recorded throughout the trial period.

Treatment dose will be calculated based on participants' attendance at the weekly MiYoga sessions, as well as the amount of home practice completed by participants between sessions. The therapist will record participant attendance after each weekly MiYoga session, and parent participants will record the amount of home practice they completed each week in their MiYoga diary. The MiYoga diaries will be collected weekly and monitored by the therapist. Strategies to facilitate and support engagement in the program will be discussed with the participant and their parents throughout the duration of the MiYoga program in the group sessions as well as via individual phone calls.

A protocol checklist will be completed by the therapist (first author) at the end of each MiYoga session. This protocol checklist will be used to monitor therapy fidelity and to ensure that all the MiYoga content was delivered as per protocol.

Paper copy data will be de-identified and physically stored in a locked file cabinet at the QCPRRC. These physical documents may be scanned (after de-identification) and password protected in a computer file on a secure server. Computer files will be de-identified and password protected on a secure server.

Video files of the MiYoga sessions will be used to assess for therapist integrity and consistency across groups. These video files will be managed and and kept on a secure online database run through QCPRRC and back up files may be kept on a external harddrive or CD in a locked cabinet.

Study updates and general outcomes will be sent to participants in a newsletter format. A summary report of the overall study findings will also be sent to participants at the conclusion

of the project. Feedback on the specific formal assessments will be provided when requested by the participant or parent.

Participant Characteristic Measures

The following questionnaires and assessments will be completed prior to the intervention to gather baseline information about the sample of children and their parents:

Gross Motor Function Classification System (GMFCS)[92]

The GMFCS classifies, across 5 levels, a child's ability to carry out self-initiated sitting and walking movements.[92] A correlation between the GMFCS and the Gross Motor Function Measure (GMFM) of r=0.91 suggests construct validity has been obtained.[93] GMFCS also has good inter observer reliability between professionals as well as between professionals and parents in children with CP.[94]

Brief Health Questionnaire (BHQ)

The Brief Health Questionnaire (BHQ) screens for existing medical conditions that may prevent the child or the parent to participant in MiYoga, with separate questionnaires for children and parents. (see Appendix C).

Physical screening clinical examination

A physiotherapist will conduct this examination to determine if the participating child has any physical conditions that might preclude them from exercise (see Appendix D).

Wechsler Intelligence Scale for Children–Fourth Edition Short Form (WISC-IV; Wechsler, 2003)[95]

Intellectual functioning will be assessed using the Wechsler Intelligence Scale for Children fourth edition short form (WISC-IV).[95] The WISC-IV comprises seven subtests that generate the four indices of verbal comprehension (VCI), perceptual reasoning (PRI), working memory (WM), and processing speed (PSI). From these overall short form index scores a full scale intelligence quotient (FSIQ) score can be calculated. In the WISC-IV short

form the VCI index is made up of the Vocabulary and Similarities subtests. The Vocabulary subtest assesses knowledge of word meanings and will require participants to name pictures or provide spoken definitions of words (e.g., "what is a bicycle?"). The Similarities subtest assesses verbal abstraction and reasoning and will require participants to describe how two words are similar (e.g., "how are anger and joy alike"). The Block Design and Matrix Reasoning subtests make up the PRI index in the WISC-IV short form. Block design will require participants to construct abstract visual designs with a set of red-and-white 3D blocks within a specified time period. Matrix Reasoning, will require participants to use their non-verbal abstract reasoning and problem solving skills in order to select the correct picture from an array of five options that fits into the missing space of a visual design. The WMI index is made up of the Digit Span subtest in which participants will be required to repeat a number of verbally presented digits in forward and reverse order. Finally, the PRI index is made up of the Coding and Symbol Search subtests, each of which has a two-minute time limit and therefore require participants to work as quickly as possible without making mistakes. For the Coding subtest, participants will need to match abstract symbols with a number key while for Symbol Search, participants will be required to detect the presence of one or more symbols in a sequence of five.[96]

Scaled scores will be derived from index scores in accordance with normative data based on the child's age and gender (mean=100, standard deviation [SD]=15).[95 97] All index scores of the WISV-IV SF have shown moderate to high levels of internal consistency (α=0.87–0.96) and are equivalent to those documented for the full WISV-IV, with the exception of the WMI which is marginally lower than its full length equivalent.

Primary Outcome Measures

Attention

The Conner's Continuous Performance Test II (CPT II)[26] will be used to measure sustained

attention performance. It is a standardized 14-minute computer administered test in which participants are asked to observe letters displayed on a computer screen and click at the appearance of each letter, except for that of the letter 'X'. The stimuli appear at random intervals (1, 2 or 4 seconds) and the duration of each stimulus is 250 milliseconds. This test measures the time to process information (e.g. Reaction Time (RT)) and errors such as false negatives or false positives. The test is divided into six equal blocks of 20 trials.

Twelve indices from the Conners' CPT will be analyzed. These indices are: (i) Number of Omissions: the number of letters, other than X, not detected (test retest correlation coefficients $r = 0.84$); (ii) False positives/ Commissions: the number of responses to the letter X ($r = 0.65$); (iii) Hit Reaction time (RT; $r = 0.55$); (iv) Hit RT Standard error (Hit RT SE; $r = 0.65$) and (v) Variability of RT: indicates consistency of RTs between blocks ($r = 0.60$); (vi) Detectability (*d* prime): RT distribution of target vs. non-target (X) ($r = 0.76$); (vii) Perseverations: responses with a RT too short (5100 ms) indicating anticipatory responding or responses to a previous stimuli (suggesting very slow responses/inattentiveness) ($r = 0.43$); (viii) Response style: indicates an over-cautious vs. a highly impulsive response ($r = 0.62$); (ix) Hit RT block change: a high score implies that, as the test progresses, RTs are longer ($r = 0.28$); (x) Hit SE block change: a high score implies that as the test progresses, RT variation increases ($r = 0.08$); (xi) Hit RT Inter-Stimulus Intervals (ISI) change: a high score implies that, as the stimulus interval increased, the RTs became longer ($r = 0.51$); and (xii) Hit SE ISI change: a high score implies that RT variation increased as the stimulus interval increased ($r = 0.05$).[26] Some of these indices make up different variables, namely, sustained attention, inattention and vigilance.

The primary variable of interest in this study is sustained attention. This is observed through the participant's responding pattern on the CPT's Hit RT block change, Commissions block change, and Omissions block change indices. A decrease in sustained attention performance

is captured by significant slowing in participant's Hit RT, and significant increase in errors (omissions and commissions) as the task progresses. Participant's performance across blocks 1, 2 and 3 will be compared to their performance across blocks 4, 5 and 6 of the same administration.

The indices that measure participant's inattention are poor detectability, a high number of omission and commission errors, a slow Hit RT, and high variability in RT (Hit RT SE). While the indices that measure participant's vigilance (participant's performance at different stimulus frequency or inter-stimulus intervals), is captured by performance on the Hit RT ISI change.

Secondary Outcome Measures

Executive functioning

A neuropsychological test battery will be used to evaluate executive attention abilities such as selective attention, attentional control, cognitive flexibility, and working memory. This neuropsychological test battery is comprised of subtests from the Wechsler Intelligence Scale for Children Fourth Edition (WISC-IV),[97] and the Delis-Kaplan Executive Function System (D-KEFS).[98] A parent-rated questionnaire, the Behavior Rating Inventory of Executive Function (BRIEF),[99] will be used as a measure of day-to-day behavioral manifestations of executive functioning.

Digit Span (from the WISC-IV).[97] The WISC-IV Digit Span subtest is a verbal memory task requiring participants to repeat a sequence of digits in forwards and backwards order. It measures a child's working memory and their ability to temporarily store information. Digit Span Forward requires the child to repeat a series of numbers given verbally by the examiner, increasing one digit per item from two digits to a maximal of nine digits. Digit Span Backward requires the child to repeat given number series in the reverse

order (e.g., if the examiner said "5 – 7 – 4" the child should say "4 – 7 – 5"). A score of one will be given to each string correctly answered and a total score will be generated (Digit Span Backward range = 0 – 16). Raw scores can be converted into scaled scores (M = 10, SD = 3). Digit Span Backward has a good internal consistency (α = .80)[97] and a high test–retest reliability (*r* = .74).[97]

Symbol Search (from the WISC-IV).[97] The WISC-IV Symbol Search subtest will be used as a measure of selective attention. Participants will be required to visually scan a group of symbols and indicate whether a target symbol is present in the group by placing a line through the word 'yes' or 'no' for every target item on this subtest. Participant scores are calculated by taking away the total number of incorrectly identified symbols from the total number of correctly identified symbols. Symbol search has adequate internal consistency (α = 0.79) and a high level of test-retest reliability (*r* = 0.80).[97]

Color-Word Interference Test (from the D-KEFS).[98] The inhibition condition (cond 3) of the Color-Word Interference Test will be used to measure attentional control, while the inhibition/switching condition (cond 4) will be used to measure attentional control and cognitive flexibility. In the inhibition condition (cond 3), children will be required to name the ink color that color words are printed in. The total number of errors and the time it takes to complete the task will be used as outcome measures of attentional control, with the longer times and more errors indicating poorer attentional control. In the inhibition/switching condition (cond 4) children will be required to switch between naming the color of the ink that the word is printed in (like in cond 3) and reading the word (if it is presented in a box). The total time it takes to complete the task will be used as outcome measures of cognitive flexibility, while the total number of errors will be used as outcome measures of attentional control. The Color-Word Interference Test has excellent test-retest reliability (*r* = 0.79-0.90).[100]

Trail Making Test (D-KEFS).[98] The number-letter switching condition (cond 4) from the Trail Making Test will be used to measure attentional control and cognitive flexibility. In condition 4 of the Trail Making Test, children will be required to switching back and forth between connecting numbers in numerical order and letters in alphabetical order, for example, 1 to A to 2 to B to 3 to C and so on all the way to P. The number of errors and the time it takes to complete the task will be recorded and the more error and the longer it takes to complete the task indicates greater difficulty with attention control and cognitive flexibility. Trail Making Test has moderate test-retest reliability (r=0.20-0.82) has been documented.[100]

Brief Rating Inventory of Executive Function (BRIEF).[29] The BRIEF is a parent-rated questionnaire for assessing day-to-day behavioral manifestations of executive function. Parents will be required to rate 86 items (e.g., "gets stuck on one topic or activity") on a three-point Likert scale, from 1 (*never)* to 3 *(often)*. The provided normative data in the manual will allow raw scores to be converted into *T* scores (M = 50, SD = 10). Eight subscales are combined to form the Behavioral Regulation Index (BRI; Initiate, Working Memory, Plan/Organize, Organization of Materials, and Monitor subscales) and the Metacognition Index (MCI; Inhibit, Emotional Control, and Shift subscales). Together these form the overall Global Executive Composite (GEC). *T* scores of 65 or more (1.5 SD above the mean) indicate elevated levels on the corresponding subscales and indices. Higher *T* scores indicate greater executive dysfunction. In this study, the GEC will be used as primary measures of executive function in everyday life. The BRIEF has been shown to be a valid measure of executive functioning and has good internal consistency (α = 0.80 – 0.98) and high test-retest reliability on the GEC (r=0.86).[101]

Mindfulness

Child and Adolescent Mindfulness Measure (CAMM)[73] assesses present-moment awareness and nonjudgmental, non-avoidant responses to thoughts and feelings. In this 10-item questionnaire, children are asked to indicate how each item reflects their experience using a 5-point scale ranging from 0 (Never true) to 4 (Always true). A total acceptance-Mindfulness score will be generated by reverse scoring negatively worded items and summing the item total, yielding a possible range in scores from 0-100. The higher scores indicate higher levels of acceptance and Mindfulness. This test has been shown to have good internal consistency ($\alpha = 0.81$).[73]

Behavioral

Strengths and Difficulties Questionnaire (SDQ)[71 102] is a 25-item parent-report questionnaire designed to assess their child's behavior and adjustment. The items are divided into 5 scales to assess the frequency within the last six months of emotional symptoms, conduct problems, inattention/hyperactivity, peer problems and prosocial behavior. These items are rated on three-point scale, from zero (*not true*) to two (*certainly true*), allowing for a total score for each scale (0-10) to be calculated, along with an overall difficulties score that takes into account overlapping elements of each score (0-40). Higher scores indicate more distress on all scales except prosocial behavior. In this study, the SDQ total score will be used as primary measures of children's behavior. SDQ total score has been shown to have a moderate to high level of internal consistency ($\alpha = 0.73$-0.82)[103 104] and a moderate to high test-retest reliability (r=0.77 – 0.85).[102 104]

Physical Outcome Measures

Flexibility

Lower back and hamstring muscle flexibility will be assessed by the Sit and Reach test (reach distance). Participants sit on the floor with both legs extended as straight as possible in front,

heels placed on the floor, and feet flat against a wall so that the ankle is dorsiflexed to approximately 90 degrees. Participants are instructed to stretch their arms straight in front with hands overlapping (middle fingers overlapping too) and slowly bend forward at the hip joint reaching as far as possible towards their toes. The maximum reach must be held for 2 seconds, and the distance between the tips of the middle fingers to the wall at the top of the toes is recorded.

Lower Limb Functional Strength

The following functional exercises will be used to assess strength.

Lateral step-up. Lateral step-up records the number of steps up on to a step from the floor that the child can perform during 30 seconds.[72] The test will be performed on a 10cm high step for all children, with a complete up and down step being one full cycle. The child stands parallel to the step with the leg being tested on the step, and the non-testing leg on the floor. They are asked to extend their test leg (on the step) straight and lift their non-test leg off the ground and onto the step and then lower the non-test leg back down to the floor until the foot touches the ground.[105] This is then repeated for the other leg. Reliability for this test is strong (ICC=0.94) and mean repetitions for the lateral step up were 13.2 (SD=10.5; standard error of measurement (SEM)=2.4 reps; CV=17.8%) for the left side, and 12.6 (SD=10.4; SEM=2.6 reps; CV=22.7%) for the right side.[72]

Sit-to-stand. The sit-to-stand functional strength test records the number of sit-stand-sit repetitions that the child can perform within 30 seconds.[72] The test will be performed on a chair where the child's knees and hips are at 90˚flexion, upper legs parallel to the floor and feet flat on the floor. The child will be asked to stand up straight so that their hips and knees are extended and then sit back down. Reliability for this test was strong (intra class

correlation (ICC) =0.91) and the mean number of repetitions was 14.4 (SD=5.0; SEM=2.6 reps; CV=22.7%).[72]

Half-kneel to stand. Half-kneel to stand records the number of repetitions from half kneel to stand the child can perform within 30 seconds.[72] The child is positioned on a mat, with one leg kneeling on the floor while the other leg is in front with the knee at 90˚flexion and foot flat on the floor. From this half-kneeling position the child is asked to assume a standing position. Repetitions are counted each time the participant achieves a standing position where both legs and hips are extended as much as possible. This is then repeated with the other leg in front. Reliability for this test was strong (ICC=0.93 to 0.96) and mean repetitions was 7.5 reps (SD=5.5; SEM=1.1 reps; CV=28.6%) for the left side and 6.0 (SD=5.3; SEM=1.4 reps; CV=39.9%) for the right side.[72]

Submaximal motor capacity test. The 6-minute walk test (6MWT)[106] is a submaximal clinical exercise test which measures the distance the child can walk in six minutes.[106] The child will be asked to walk as many laps as they can without running for 6 minutes along a straight, flat a corridor, between two markers set 10m apart. The 6MWT will be conducted with standardized verbal encouragement and the child will be advised on the time remaining every minute and the number of laps they have completed as it happens. The 6MWT has been demonstrated to be reliable in independently ambulant adolescents with CP and the test-retest is excellent (ICC=0.98).[106]

Mobility

The MobQues28 questionnaire measures mobility limitations a child with CP experiences in everyday life as rate by their parents.[107 108] The MobQues28 is score on a 5 point scale from 0-4, with 0 being *Impossible without help*; 1 being *Very difficult*; 2 being *Somewhat difficult*; 3 being *Slightly difficult*; and 4 being *Not difficult at all*. Item scores (range 0–4) are added

together and then divided by the maximum possible score and multiplied by 100 to obtain total scores on a scale of 0 to 100 (lower scores indicate severe limitations in mobility): MobQues28=(Σ item / 112)·100. Construct validity was demonstrated as MobQues28 scores decreased with increasing GMFCS level ($p<0.001$) and in a sub group of 162 children, MobQues28 score was positively correlated to GMFM-66 ($r=0.67$, $p<0.001$).[108] The MobQues28 has been demonstrated to be reliable with high the interrater reliability (ICC=0.87), standard error of measurement (SEM) was 8.9. The intra-rater reliability was higher (ICC=0.96-0.97; SEM=4.4-4.9).[107]

Quality of Life

CP QOL-Child. The CP QOL-Child is a condition-specific quality of life measure for children with cerebral palsy.[74] Two versions of the CP QOL-Child will be used in this study; the CPQOL-Child parent report version will be used for all participants under 12 years of age, and the CPQOL-Child self-report version will be used for children 9-12 years of age. The parent-report measure of child quality of life is a 66-item questionnaire and the child self-report version is a 53-item questionnaire. Results of factor analysis demonstrated that the CPQOL measures 7 broad domains of quality of life: social wellbeing and acceptance, functioning, participation, physical health, emotional wellbeing, access to services, pain, impact of disability and family health. In this study, the GEC will be used as primary measures of executive function in everyday life. The CPQOL-Child has a high internal consistency ($\alpha=0.74$-0.92 for parent report and $\alpha=0.80$-0.90 for child self-report), good test-retest reliability (ICC=0.76-0.89) and it is moderately correlated with generic QOL and health measures ($r=0.30$-0.51).[109 110]

CP QOL-Teen. The CP QOL-Teen is a condition specific quality of life measure for adolescents with cerebral palsy.[75] Two versions of this CP-QOL will also be use: the

CPQOL-Teen parent report version will be completed by parents of participants aged 13-18 and the CP-QOL-Teen self-report version will be completed by participates 13-18 years of age.[75] This measure has strong internal consistency (α=0.81-0.95 for the primary parent report, and α=0.84-0.96 for the adolescent self-report), good test re-test reliability for primary parents (ICC=0.72-0.92) and adolescents (ICC=0.84-0.87). All domains of the CPQOL-Teen parent report (r=0.40-46) and adolescent report (r=0.58-0.68) were correlated with a generic QOL instruments.[111]

Pain

The Baker-Wong Faces™ Pain Rating Scale will be used to assess the child's pain level.[112] Children will be asked to match which of the six hand-drawn faces show their pain level, with faces ranging from smiling ('no hurt') to crying ('hurts worst'), with the scale scored from 0 to 5. It has been documented that Baker-Wong Faces™ Pain Rating Scale has an excellent test–retest reliability over 15 minutes, 8 hours and immediately post-procedure in children 3–18 years old (r = 0.90 – 0.84).[113 114] There are also strong positive correlations between the Wong–Baker FACES Pain Scale and other well-established self-report measures (r = 0.74 – 0.78) (e.g., Pieces of Hurt tool, Faces Pain Scale, and a visual analogue scale).[113 115-117]

Parent Outcome Measures

The following tests will be used to assess the psychological well-being of parents. These assessments will be completed at baseline, pre-intervention, post-intervention, and at a 6-month follow-up.

Mindfulness Attention Awareness Scale (MASS)[76]

The Mindfulness Attention Awareness Scale (MASS) will be used to measure each parents' tendency to be mindful of moment-to-moment experiences.[76] The MAAS is a 15 item instrument focusing on the presence or absence of attention and awareness of their present immediate environment. Participants are asked to indicate how frequently they have the experience described in each of the 15 statements using a 6-point Likert scale from 1 (almost always) to 6 (almost never). For example, one statement is "It seems I am 'running on automatic', without much awareness of what I'm doing", while another is "I snack without being aware that I am eating". The total score is used as outcome measure, with higher scores reflecting more Mindfulness. This scale has been shown to relate to various aspects of well-being and to how effectively people deal with stressful life events.[76] The MAAS also has good internal consistency, with alphas ranging of .82 in student sample.[76]

Acceptance and Action Questionnaire (AAQ-II)[78]

The Acceptance and Action Questionnaire (AAQ) assesses the construct referred to as acceptance, experiential avoidance, or psychological inflexibility.[118] This 7 item questionnaire has been documented to have a satisfactory structure, reliability, and validity, with a mean alpha coefficient of 0.84 (0.78–0.88), and the 3- and 12-month test–retest reliability is 0.81 and 0.79, respectively.[118]

Depression Anxiety Stress Scale (DASS)[77]

The Depression Anxiety Stress Scale (DASS) is a 42-item questionnaire that assesses the presence of psychological symptoms in adults.[77] In this study, a total score will be computed, falling in the range 0–126, with higher scores indicating suboptimal states. The measure has shown high internal consistency for depression ($\alpha = 0.91$), anxiety ($\alpha = 0.84$) and stress ($\alpha = 0.90$) scales. The DASS also has good discriminate and concurrent validity.[77 119]

Personal Wellbeing Index – Adult (PWI-A)[79]

The Personal Wellbeing Index – Adult (PWI-A) is an eight item questionnaire that assesses the ones' level of satisfaction with life as a whole.[79] Each item corresponds to a quality of life domain, such as standard of living, health, achieving in life, relationships, safety, community-connectedness, future security, and spirituality/religion.

Child–Parent Relationship Scale (CPRS)[80]

The Child–Parent Relationship Scale (CPRS) is a 15-item questionnaire that use a 5-point rated scale and it is completed by the parent to assess the quality of the parent–child relationship.[80 120] The CPRS is an adaptation of the Student–Teacher Relationship Scale (STRS) , which has been used extensively in studies of relationship quality in the US (National Institute of Child Health and Development Early Child Care Research Network, n.d.).[121] In this study, the overall conflict score and closeness score will be used as measures of parent-child relationship quality.

MiYoga Session Measures

The following tests have been developed in order to measure the mechanism of change due to the MiYoga intervention. Both child and parent participants will complete these measures either before and after or just after each MiYoga session.

Mindfulness

MiYoga Session Mindfulness Measure is a 5-item scale adapted from the CAMM. It measures children and parent's Mindfulness in the MiYoga session they have just completed. Each child and parent will complete this Mindfulness scale at the end of each MiYoga session (see Appendix E).

Mood

The Mood Scale is a short scale used to measure participants' mood or how they are feeling before and after each MiYoga session. It is a 1 to 5 scale with 5 being very good and 1 being very bad where 5 matched with a happy face, 3 is matched with a neutral face and 1 is matched with a sad face (see Appendix F).

Session feedback

At the end of each MiYoga session, children and parents will each be asked to complete a Session Feedback Scale. This is a short four item questionnaire asking the participants about the session in regards to comfort, enjoyment, body awareness and overall satisfaction. Each of these questions is also on a 0 to 10 scale, with 10 being high (or very good) and 0 being low (or very bad; see Appendix G).

Qualitative Interviews

A registered psychologist (or a probationary psychologist under supervision) will conduct a short interview with individual participants at the end of the MiYoga program. The interviewer will be unrelated to the MiYoga study to avoid bias, and to encourage participants to express their view and opinions about the program freely. The aim of these interviews is to gather qualitative information about the participants' views of the program, such as what they liked or disliked, and which parts worked (or not) for them. This qualitative information will help with program refinement and translation. For example, it will provide information on how Mindfulness and yoga can be integrated into participants' everyday life (see Appendix H for qualitative interview script and questions).

STATISTICAL ANALYSIS

Sample Size

The reaction time of children with CP was two standard deviations below healthy controls on the Continuous Performance Test (CPT).[9] The present study is interested in detecting a difference of one standard deviation between the immediate treatment and control group at Time 2 (post-intervention) to determine the clinical significance of the MiYoga program compared to waitlist control.[122] Based on Lehr's equation, with alpha set at 0.05, and power set at 0.80, to detect a difference of one standard deviation between groups, a sample size of 16 participants per group would be needed.[123] If a retention rate of 90% is assumed, a total of 36 children will need to be recruited.

RCT data analysis

Analysis will follow standard principles for RCTs, using two-group comparisons on all participants on an intention-to-treat basis. All the participants will be analysed within the group they were randomized for all the outcome measures. Any missing data in the event of withdrawal or loss to follow up, a participant's assessment from the last available time-point will be carried forward. External and internal validity of results will be checked using baseline and general descriptive information available for all eligible families. This will be done by comparing the characteristics of families who completed the study with those who enrolled in the study but did not complete, and those who did not enroll. The primary comparison immediately post intervention (T2) will be scores from the Continuous Performance Test.

Analysis will follow standard methods for randomized controlled trials using comparisons between the two groups (MiYoga and wait-list control). The experimental unit will be the child and their participating parent. Attrition analysis will be conducted. Data will be analyzed using Statistical Package for the Social Sciences (SPSS). The hypotheses relating to intervention efficacy will be tested using general linear models, specifically via analysis of

covariance (ANCOVA). In addition, predictors of treatment outcome will be explored using regression analyses. Non-parametric methods will be used for simple comparisons in cases where continuous data exhibit substantial skewness not overcome by transformation.

Qualitative data analysis

A descriptive thematic analysis will be undertaken to analyze the qualitative data collected in this study (as per Braun and colleagues[124]). The interviews will be audio recorded and transcribed verbatim. Transcripts will be read and coded by two study investigators. Coding will involve identifying thematic patterns, such as ideas, concepts, terminology or phrases. Once these themes are identified, the investigators will discuss the appropriateness of the themes and develop a coding framework based on their themes until consensus is achieved. The researchers will then re-read the transcripts and organize the themes into categories and sub categories based on the coding framework they have developed.

ETHICS AND DISSEMINATION

Full ethical approval for this study has been obtained by the Behavioral and Social Sciences Ethical Review Committee of The University of Queensland (2012000993) and Children's Health Queensland Hospital and Health Service Research Ethics Committee (HREC/12/QRCH/120). Protocol modifications and amendments will be submitted to the ethical committees for approval. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613000729729). All families will be given written informed consent to participate and their parents or guardians prior to entering into the trial. If found to be effective, MiYoga has the potential to be disseminated as a lifestyle intervention for families. The study results will be disseminated through publication in scientific journals, presentation at relevant conferences and directly to the families who participated in the study. The dissemination would assist children with CP and complement

their on-going therapy by; improving the ability of the child to pay attention at school and in therapy, and alleviating environmental stressors for both the child and their parents.

DISCUSSION

This paper has presented the background and design for a randomized waitlist controlled trial investigating the efficacy of an 8 week Mindfulness and Yoga program to for children and adolescents with an CP and one of their parents. To our knowledge this study is the first to investigate the effects of a family-centered Mindfulness-based yoga program for children and adolescents with CP. Furthermore, we will be evaluating the children's cognitive, physical, behavior and emotional outcomes, as well as parents' psychological well-being. The qualitative information, such as what the participants liked or disliked about the program, will help provide information on how Mindfulness and yoga can be integrated effectively into participants' everyday lives. It is anticipated that the results of this study will be disseminated through peer reviewed journals and national and international academic conferences.

Current models of rehabilitation for children with CP solely focus on physical rehabilitation. MiYoga provides a more holistic approach by combining Mindfulness and yoga techniques that can be integrated easily into the child and their families' everyday life. If MiYoga is found to be effective, multi-disciplinary teams will have an evidence-based mode of therapy to offer that is an engaging lifestyle intervention, incorporates cognitive rehabilitation, and provides valuable tools and skills to families.

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Contributions

CM is the chief investigator (CI) and together with KW and RB designed and established this research study. CM was responsible for ethics applications and reporting. CM was responsible for recruitment. CM was responsible for data collection and implementation of the training program. CM will take lead roles on preparation for publications on the clinical outcomes of the study. KW, RB and RC will contribute to the preparation of publications within their respective fields of expertise. CM will take on a lead role of the statistical analysis for the study. CM drafted the final version of this manuscript. All authors critically reviewed and approved the final version. All data from this study will be submitted to peer review journals. CM will use the data from this study to contribute to her PhD thesis.

Competing Interests

MiYoga was developed by first author. There are no other competing interests to declare.

Ethics approval and consent to participate

Full ethical approval for this study has been obtained by the Behavioral and Social Sciences Ethical Review Committee of The University of Queensland (2012000993) and Children's Health Queensland Hospital and Health Service Research Ethics Committee (HREC/12/QRCH/120). All families will be given written informed consent to participate and their parents or guardians prior to entering into the trial.

Consent for Publication

Consent to publish was obtained from both the individual and from the parent of the child whose photographs are presented in this manuscript.

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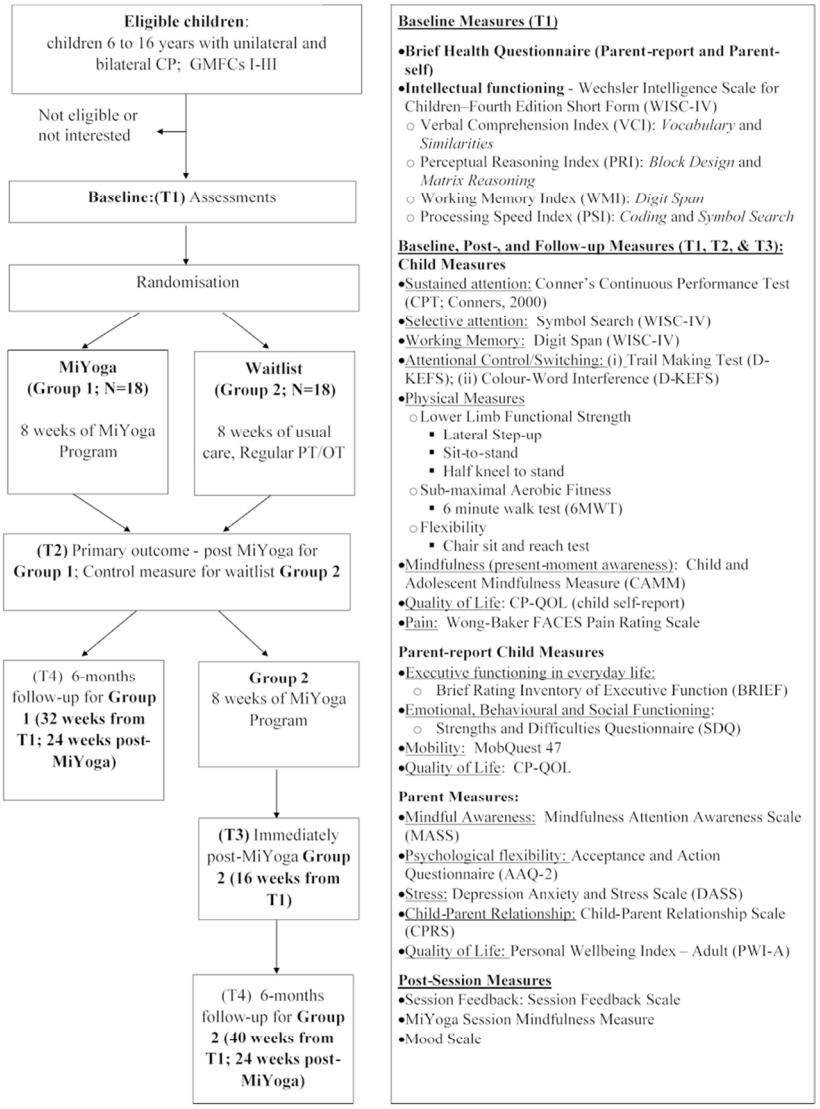


Figure 1. Flow chart of MiYoga study design

54x79mm (600 x 600 DPI)

Appendix A
MiYoga Program Summary

Week 1	Theme	Welcome	Introduction to Mindfulness	Hatha Yoga	End of Session
	Explore our everyday life with awareness in the present moment Focus of session is on being mindful while performing yoga postures; and to teach participants their individualised modifications	Getting to know you – pass the ball around in a circle. Explain the that over the next 6 weeks we are be training to be explorers of our feelings, our thoughts and things in our everyday life • Housekeeping • Give out MiYoga packs • Set group rules	Introduction to mindfulness and mindful movements ie. raise arms with awareness and discuss if they feel any different.	Go through yoga postures. Therapist will teach participant their modifications to each posture and teach participants how to safely go in and out of each posture. **<u>Mindfulness relaxation</u>** Progressive muscle relaxation exercise	Discussion - what they experienced through their exploration today and time for any questions. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 2	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Senses: Feel/Touch	Review last session and briefly discuss home practice in the last week. Introduction to Feel/Touch Exploration exercises 1) Feel and describe object with hands 2) Whose hands are they? 3) Mirror Me	Practise yoga postures. Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Body Scan	Discuss what they experienced during the body scan and from the session. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 3	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Hearing	Review last session and briefly discuss home practice in the last week. Exploration exercises What do you hear? Sound exercises - clasp hands over ears, what do you notice? Make sounds with our breath – practice the ocean breath, pranayama (yogic breathing exercises)	Practise yoga postures. Incorporate ocean breath into the postures by linking movement with inhalation and exhalation. Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Mindfulness of sound – Tibetan bowl	Discuss what they experienced/heard during the mindfulness exercise and from the session today. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 4	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Seeing	Review last session and briefly discuss home practice in the last week. Introduction to Seeing Exploration exercises What colour eyes do your friends have? What did you see? Mindfulness of the hand	Sound exercises Pranayama exercises Incorporate sound into the postures by linking sounds with exhalation. Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Short body scan and short imagery script	Discuss what they experienced from the session today. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 5	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Taste & smell	Review last session and briefly discuss home practice in the last week. Introduction to taste and smell Exploration exercises 1) What are you eating? 2) Mindful eating 3) Mindful drinking	Eye movements Sound exercises Pranayama exercises Practise yoga postures Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Body Scan or Progressive muscle relaxation or Mindfulness of breath or Mindfulness of sound	Discuss their experienced from the session today. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Complete end of session questionnaires.

Week 6	Theme	Review and Mindfulness Explorations	Hatha Yoga	Mindfulness relaxation	End of Session
	Thoughts & feelings	Review last session and briefly discuss home practice in the last week. Introduction to feelings – can be pleasant and unpleasant but like senses it is helpful. Exploration exercises 1) Explore thoughts and feelings through listening to short stories and/or music 2) Discussion of thoughts and feelings that arise in our lives. 3) Bubbles of thoughts and feelings exercise	Eye movements Sound exercises Pranayama exercises Practise yoga postures Therapist will monitor participant's progress and continue to modify the poses as the child progresses in each posture.	Short body scan and finding a comfortable place	Discuss thoughts and feelings about the session. Remind them of their homework 20 minutes of practice a day along with poster and CD and to record their daily practices in their diary. Organise times for phone/skype consultations Complete end of session questionnaires.

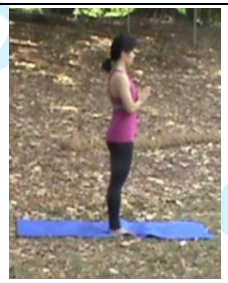
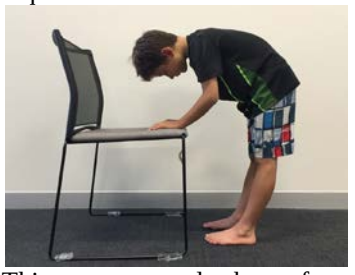
Week 7	Theme	Review	Q & A and problem solve obstacles to practice	Planning and Setting Goals
Phone consultation	Maintaining MiYoga practice	Review and briefly discuss home practice in the last week Was daily practice maintained? What were barriers to practice? What helped/encourage practice? Any other questions regarding mindfulness or their practice?	Address participants questions Problem solve ways to overcome barriers to practice – be as specific as possible Revisit – reasons for practice - Benefits of yoga and mindfulness	Goals and plans in regards to practice for the next week - be as specific as possible

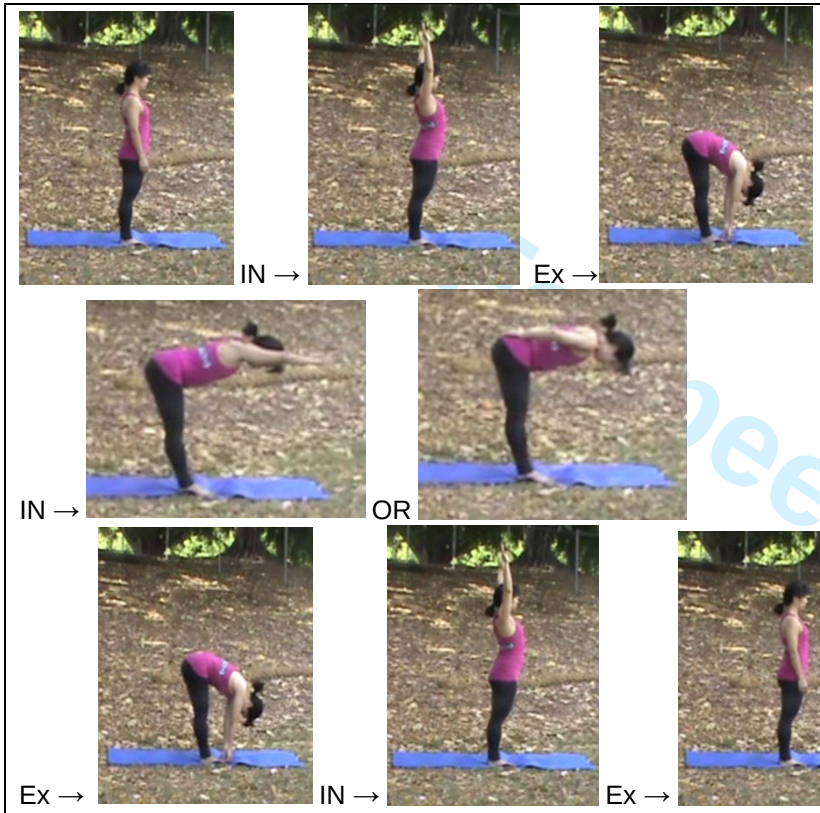
Week 8	Theme	Review	Q & A and problem solve obstacles to practice	Planning and Setting Goals
Phone consultation	Maintaining MiYoga practice	Review and briefly discuss home practice in the last week Was daily practice maintained? What were barriers to practice? What helped/encourage practice? Any other questions regarding mindfulness or their practice?	Address participants questions Problem solve ways to overcome barriers to practice – be as specific as possible Revisit – reasons for practice - Benefits of yoga and mindfulness	Goals and plans to continue practice - be as specific as possible Discuss maintaining practice over time

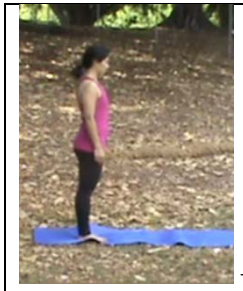
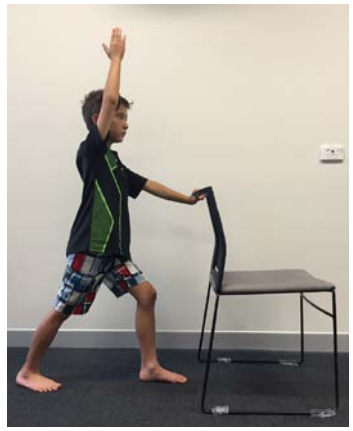
Appendix B

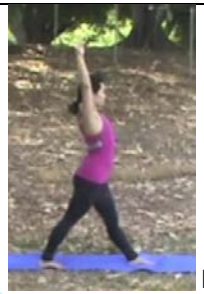
Table 1

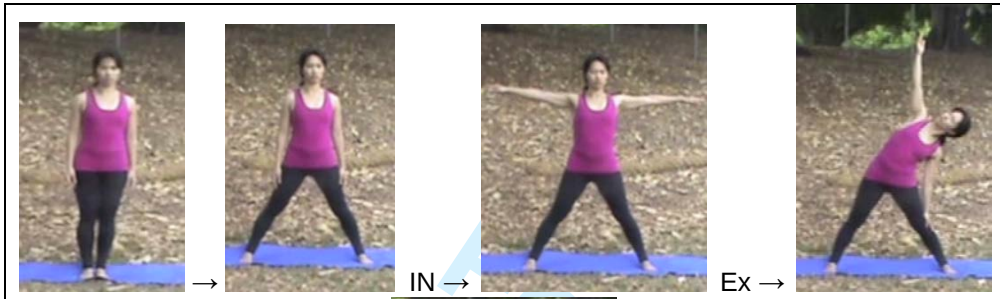
MiYoga Postures

Illustration of Posture	Posture	Physical Benefits	Possible Modifications
Inhale (IN)  Exhale (Ex) →   IN → Ex →  IN →  Ex → 	**Warm-Up**	**Strengthens:** • legs • arms • torso **Lengthens**: • back of the body • back of the legs Induces balance	If required, have support (e.g. table/chair/wall) in front or to the required side.  This posture can also be performed in a chair or wheelchair  Provide prompts for children to keep their knees straight in forward bend (if standing) and only to go as far as they are comfortable when bending forward. Encourage children to bear weight evenly on both left and right sides.

	**Half Forward Bend**	**Strengthens:** • legs • arms • torso **Lengthens**: • back of the body • back of the legs Induces balance	If required, have support (e.g. table/chair/wall) in front or to the required side.  Provide prompts for children to keep their knees straight in forward bend (if standing) and only to go as far as they are comfortable when bending forward. Encourage children to bear weight evenly on both left and right sides.

 →  IN →  OR  Ex →  (repeat) 4x; To finish, Ex →  	**Warrior sequence**	**Strengthens:** • quadricep muscles • arms • torso **Lengthens**: • hip flexor muscles • calve muscles	If required, have support (e.g. table/chair/wall) in front or to the required side.   Provide prompts for children to keep both of their feet pointing forward if possible and aim to have the back heel on the ground. Encourage children to bear weight evenly on both left and right sides.

 →  IN →  EX→  IN →  (repeat 4x) to finish,  Ex →  →	**One sided forward bend**	**Strengthens:** • legs • arms • torso **Lengthens**: • hip flexor muscles • calve muscles Induces Balance	If required, have support (e.g. table/chair/wall) in front or to the required side.  Provide prompts for children to keep both of their feet pointing forward if possible and aim to have the back heel on the ground. Ask the children to explore with having the front knee as straight as it is comfortable for them. Encourage children to bear weight evenly on both left and right sides.



(Repeat 4x each side)

To finish,

Triangle

Strengthens:

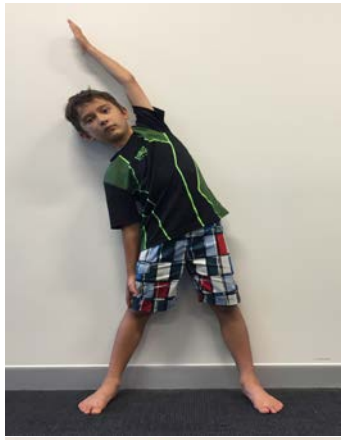
- legs
- arms
- torso

Lengthens:

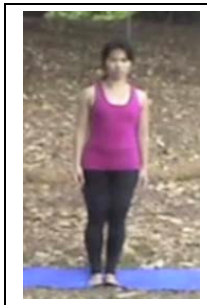
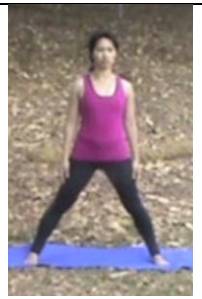
- muscles along the side of the body

Induces Balance
Increases hip flexibility

If required, this pose can be down with back gently against a wall and/or have support (e.g. table/chair) on either side.



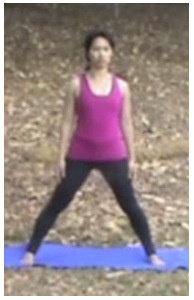
Provide prompts for children to keep their knees straight in forward bend and only to go as far as they are comfortable when bending forward. Encourage children to bear weight evenly on both left and right sides.


→

IN →


Ex →

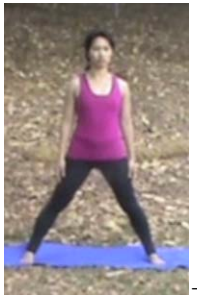
OR

IN →


Ex →

(Repeat 4x)

To finish,

IN →

→

→


Feet apart Forward Bend

Strengthens:

- legs
- arms
- torso

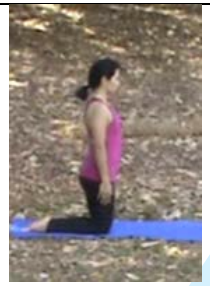
Lengthens:

- muscles of the inner thighs and hamstrings

Induces Balance
Increases hip flexibility

If required, have support (e.g. table/chair/wall/blocks) in front.

Provide prompts for children to have the feet pointing forward and to keep their knees straight in forward bend and only to go as far as they are comfortable when bending forward. Encourage children to bear weight evenly on both left and right sides.

 OR  IN →  EX →  IN →  EX →  IN →  EX →  IN →  EX →  OR  (repeat)	**Downward Dog**	**Strengthens:** • legs • arms • upper body • torso **Lengthens**: • muscles in back of the body and legs	Provide prompts for children to keep their heels and big toes together in the kneeing postures. Encourage children to bear weight evenly on both left and right sides. Downward dog pose can also be performed separately. Downward dog can be performed from standing or seating in a chair by placing both hands against a wall or on a table/chair in front with the aim to flex hips,with back straight and shoulder blades back and down (retracted).  .

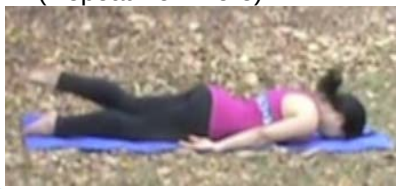
Bent legs with strap (or towel)  →   Place rolled towel/strap under Left foot (Repeat from here) EX →  IN →  EX →  IN →  EX →  IN Stay  Ex →  (Repeat) To Finish: Release towel/strap from under foot EX →  →  Repeat on other leg	**Supine Leg lift**	**Strengthens:** • arms • torso **Lengthens**: • muscles in back of the legs Provides full range of motion from the hip to the toes. Increase circulation and release any tightness in the hips, knees, and ankles.	A rolled towel or belt is required for this sequence. If possible keep the resting leg straight along the floor instead of bent. Feet of resting leg can be placed flat on a wall so that the ankle is at approximately 90degree dorsiflexion and prompt children to push their feet into the wall while they are lifting the other leg. This will help them keep the resting leg active and straight. 

(Repeat from here)  →  IN →  EX →  (Repeat) To finish EX down: 	**Bridge**	**Strengthens:** • core back muscles • gluteal muscles **Lengthens**: • hip flexor muscles • quadriceps muscles	Children can hold the block between their knees while moving the hips up and down will help them engage their core muscles. 

(Repeat from here)  IN→  EX→  IN →  EX →  (One round; Repeat 4x) To finish: 	**Supine Spinal Twist**	**Lengthens and relaxes**: • back and spine	It is also possible to place rolled up blankets or a bolster on the floor in line with the knees (a few inches from the hip) on both sides to prevent any discomfort from rotating too far. This spinal twist can also be performed from standing or seating in chair. If standing place feet hip width apart, place hand across the body to the opposite waist and twist body (without moving feet). If seating in a chair place feet flat on the floor or on blocks. With back straight, place hand on opposite knee and twist body pass the knee the hand is on. 

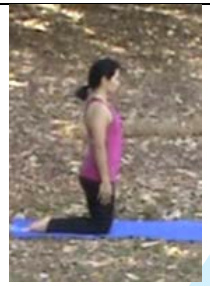
 →  (Repeat from here) IN→  EX→  (repeat) To finish: IN →  → 	**Apanasana**	**Lengthens and relaxes**: • back and spine	Verbal prompts to invite children to experiment with some hip movements, such as rocking slightly from side to side, or move knees and hips in small circles or simply staying still and observing sensations in their bodies while in this pose.

 →  (Repeat from here) IN →  EX →  (Repeat) To Finish: 	**Cobra**	**Strengthens:** • torso • back muscles • neck muscles **Lengthens**: • muscles in the front of the body	A blanket can be place under hips and lower ribs for comfort.

(Repeat from here)  IN →  (lift RIGHT leg) EX →  IN →  EX →  (One round; Repeat four times) To finish: 	**Prone with legs**	**Strengthens:** • torso • back muscles • gluteal muscles **Lengthens**: • muscles in the front of the body	A folded blanket can be used to help support the lifted leg if placed under the front of thighs (of the lifted leg).

 →  (Repeat from here) IN →  EX →  (Repeat) To Finish: 	**Lotus 2**	**Strengthens:** • torso • back muscles • neck muscles • gluteal muscles **Lengthens**: • muscles in the front of the body	A blanket can be place under hips and lower ribs for comfort

 →  (Repeat from here) IN →  EX→  (Repeat 4x) To Finish:  → 	**Superman**	**Strengthens:** • arms • torso • back muscles • neck muscles • gluteal muscles **Lengthens**: • muscles in the front of the body	A blanket can be place under hips and lower ribs for comfort.

 OR  EX →  (repeat from here) IN→  EX→  (Repeat) To finish: IN →  OR 	**Cat – back**	**Strengthens:** • arms • quadriceps muscles **Lengthens and relaxes**: • neck muscles • shoulders • back muscles and spine	If required, provide physical support at elbow on the involved side to help children maintain straight arm.  Also, verbal prompts to remind children to have hands flats on the floor.

(repeat from here)  EX →  IN →  EX→  IN →  EX→  (One round; Repeat four times) To finish:  IN →	**Cat - legs**	**Strengthens:** • arms • back muscles • quadriceps muscles • leg muscles **Lengthens and relaxes**: • back muscles and spine (in child's pose)	Children may find lifting their legs straight up one at a time in this sequence too difficult, they may like to try to extend it straight out behind them by sliding their foot along the floor without lifting their legs. 


rest hands behind→



bend knees →

flex toes →

Stay for 4 to 6 breaths

Alternative boat:


Lift one foot off the floor, swap legs


Balance with both feet off the floor

Stay for 4 to 6 breaths

to finish:


→


Boat Pose

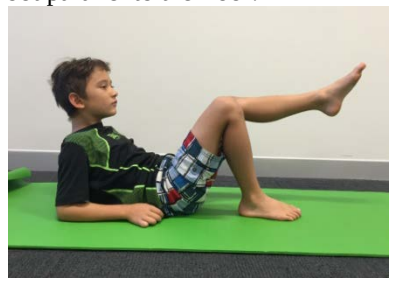
Strengthens:

- abdominal muscles
- back muscles
- quadriceps muscles

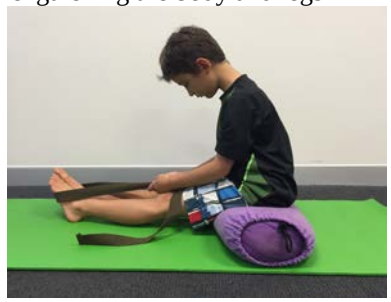
Lengthens:

- back muscles and spine (in child's pose)

This posture may be done with elbows and forearm on the floor or with back rest on the floor arms by the side. With knees bent and feet flat on the floor, lift one heel off the floor at a time - aim to have shin and foot parallel to the floor.



One leg at a time (Repeat from here)  →  IN →  EX →  (Repeat 4x) To finish: IN →  EX →  IN → 	**Seated forward bend – one leg at a time** **Rowing boat**	**Strengthens:** • arms • torso **Lengthens**: • back of the body • hamstring muscles • calf muscles	This posture can be performed sitting on firm cushions, bolsters or folded blankets to help lift pelvis  A strap or belt can also be used to assist with lengthening the body and leg  Verbal prompts may be provided to help children keep their legs straight.

(Repeat from here)  IN →  EX →  IN →  →  EX →  (Repeat 4 x) To finish: IN →  →  EX → 	**Seated forward bend – both legs** **Rowing boat**	**Strengthens:** • arms • torso **Lengthens**: • back of the body • hamstring muscles • calf muscles	This posture can be performed sitting on firm cushions, bolsters or folded blankets to help lift pelvis and a strap or belt can be used to assist with lengthening the body and legs  Verbal prompts may be provided to help children keep their legs straight.

(Repeat from here)  →  →  →  (Repeat a few times) To finish: 	**Butterfly**	**Lengthens**: • inner thigh muscles Increases flexibility in the hips.	This posture can be performed sitting on firm cushions, bolsters or folded blankets to help lift pelvis and lengthen the body.  If required, this posture can also be performed sitting with back against a wall for support.
	**Shavasana or the relaxed star pose**	This pose helps to assimilate the benefits of all the movements in the practice.	A rolled blanket, bolster or pillow can be placed under the knees and/or under head for comfort..Children may also like to be covered with a blanket for warmth. Props such as belts, rolled mats or towels and bolsters may also be used for alternate supported relaxation postures. 

Appendix C

BRIEF HEALTH QUESTIONNAIRE (BHQ) - Caregiver

Name: _____
Address: _____
_____
_____

Phone: ( ) _____ (W)
Phone: ( ) _____ (H)

Age: _____
DOB: _____

Relationship to Child: _____

Please read the following questions very carefully. If you have any difficulty please advise the health professional.

1. **Personal medical history.** Indicate symptoms that apply to you.

☐ Pain or discomfort in chest following exercise
☐ Poor exercise tolerance
☐ Frequent dizziness
☐ Frequent headaches
☐ Frequent backache
☐ Frequent aches or pains in an joints

Details _____

☐ Other current symptoms that exercise may affect

Details _____

2. **Lungs: Do you have any of the following conditions?**

Asthma
☐ Yes
☐ No
Details _____

Emphysema
☐ Yes
☐ No
Details _____

Bronchitis
☐ Yes
☐ No
Details _____

Shortness of Breath
☐ Yes
☐ No
Details _____

3. **Do you have any heart condition/problems that might preclude you from exercise?**
☐ Yes
☐ No
Details _____

4. **Seizures, fainting, blackouts and loss of consciousness?**
☐ Yes
☐ No
Details _____

5. **Headaches**
☐ Yes
☐ No
Details _____

6. **Sight or hearing difficulties**
☐ Yes
☐ No
Details _____

7. **Cervical Spine instability (e.g. Atlanto-axial)**
☐ Yes
☐ No
Details _____

8. **Spinal problems that cause pain or preclude exercise**
☐ Yes
☐ No
Details _____

9. **Are you pregnant?**
☐ Yes (number of weeks ___; due_____)
☐ No
Details _____

10. **Medication.** Are you taking any medication prescribed by your Doctor or other Health Care provider? If so, list details, i.e., type of drugs, dosage.
_____
_____
_____
_____

BRIEF HEALTH QUESTIONNAIRE – Child (caregiver report)

Name (child): _____
Address: _____
_____
_____

Phone: ( ) _____ (W)
Phone: ( ) _____ (H)

Age: _____
DOB: _____

Please read the following questions very carefully. If you have any difficulty please advise the health professional.

1. **Personal medical history.** Indicate symptoms that apply to you.

☐ Pain or discomfort at rest or with exercise

Details _____

☐ Frequent dizziness
☐ Frequent colds or flu
☐ Frequent headaches
☐ Frequent backache
☐ Other current symptoms that exercise may affect

Details _____

2. **Seizures, fainting, blackouts and loss of consciousness?**

☐ Yes
☐ No
Details _____

3. **Headaches**

☐ Yes
☐ No
Details _____

4. **Sight or hearing difficulties**

☐ Yes
☐ No
Details _____

5. **Cervical Spine instability (e.g. Atlanto-axial)**

☐ Yes
☐ No
Details _____

6. **Spinal problems that cause pain or preclude exercise**

☐ Yes

☐ No

Details _____

7. **Medication.** Are you taking any medication prescribed by your Doctor or other Health Care provider? If so, list details, i.e., type of drugs, dosage.

_____

_____

_____

_____

Appendix D

Participant ID: _____

DOB: _____ Age at Assessment:_____

Date		**Examiner:**	
CLASSIFICATION			
CP motor type:	1st	2nd	Comments:
No. of limbs involved	Comments:		
GMFCS level	Comments:		
FMS level			
Handedness	Right / Left / Mixed		
MACS			
Preferred sitting position	W-sitting Ring sitting Side sitting- right left Long sitting- symmetrical Asymmetrical (right/left)		
STANDING			
Unaided/ Aided Equipment Used:			
GAIT			
Unaided/ aided Typically developing **Comments:** **Gait pattern:** True Equinus/ Apparent Equinus / Jump Knee / Crouch gait; Gage Type:			
SUPINE			**Comments**
Thomas Test (FFD)			
Abduction in Flex			
Dynam Abd in Flex			
Abduction in Ext			
Dynam Abd in Ext			
Popliteal angle			
Dynamic Hamstrings			
Kn Exten (Hip 0 deg)			
Dorsiflex (Kn in Ext)			
Dynam DF (Kn in Ext)			
PRONE			
Hip Int Rotation			
Hip Ext Rotation			
Femoral Neck angle (FNA)			
Staheli test			
SPINE			
Scoliosis	Yes / No	Convex to R/L	
Rotation	Yes / No	To R / L	
Spondylolisthesis	Yes/ No		
Other	Yes/No		
Current skills:			
Medical Hx Check: Past surgery Pain levels Seizures Medication Botox Past therapy Compliance in therapy			
Comments: **Spine at Risk: Yes/ No** **Action:**			

Appendix E

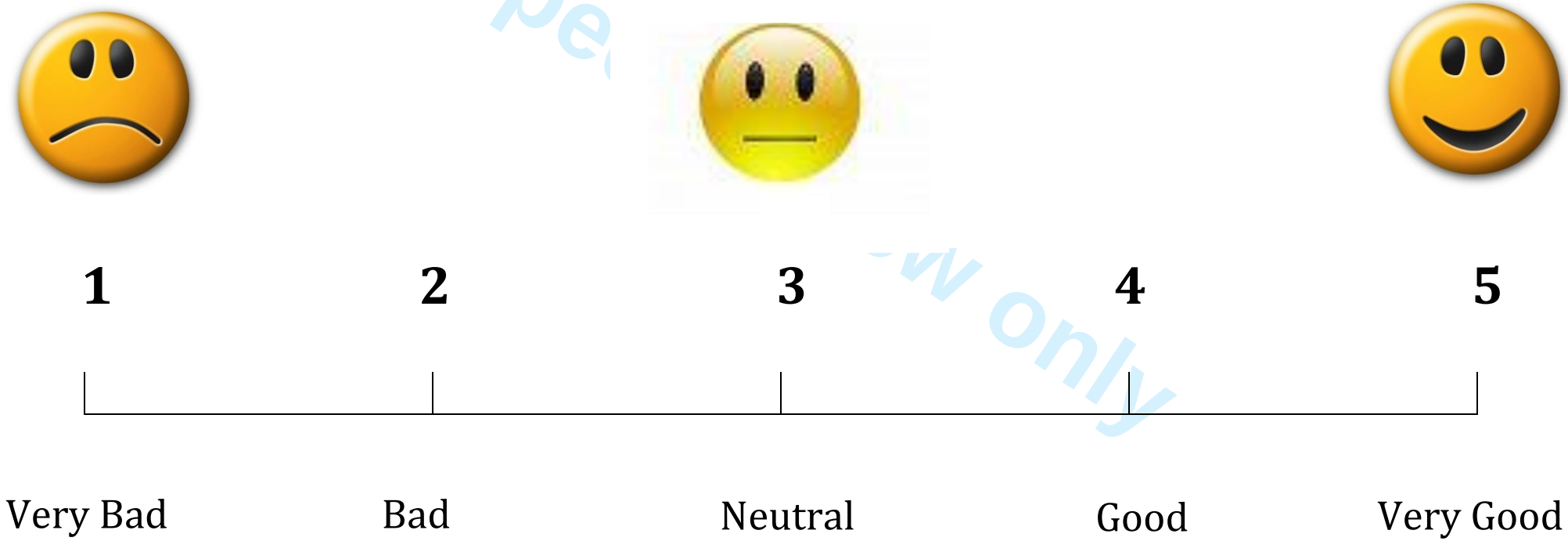
MiYoga Session Mindfulness Measure

We are interested in your experiences what you just experienced during our group session. **Read** each sentence. Then, circle the number that tells **how true each sentence is about your experience during our group session.**

	Never True	Rarely True	Some-times True	Often True	Always True
1. I stopped myself having thoughts or feelings that I don't like.	0	1	2	3	4
2. I was moving without noticing what I was doing.	0	1	2	3	4
3. I noticed my thoughts or feelings.	0	1	2	3	4
4. It was hard for me to pay attention to what I was meant to be doing.	0	1	2	3	4
5. I was focused on what I was doing.	0	1	2	3	4

Appendix F

Mood Scale



Appendix G

Session Feedback Scale

Name _____Age (Yrs):___ Gender:_____

Session # ___ Date: _____

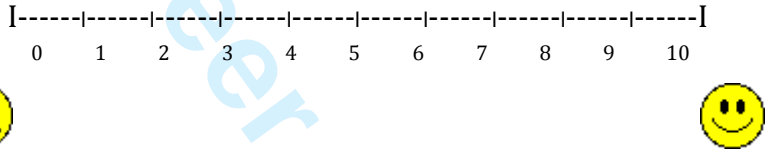
Who is filling out this form? Please check one: Child_____ Caretaker_____

If caretaker, what is your relationship to this child? _____

How was our time together today? Please put a mark on the lines below to let us know how you feel.

Comfort

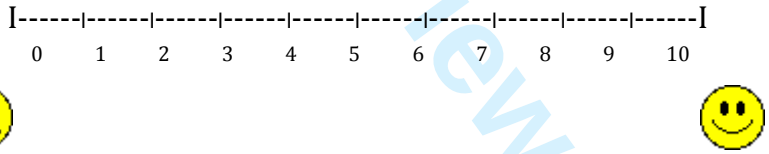
What we did today was uncomfortable and did not suit my needs and



What we did today was comfortable and suited my needs and ability

Enjoyment

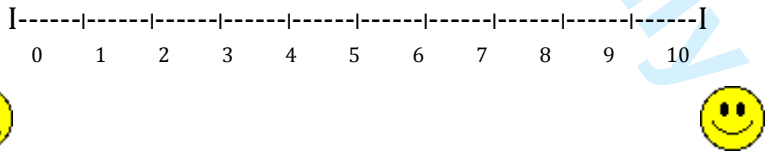
I did not like what we did today.



I liked what we did today.

Body Awareness

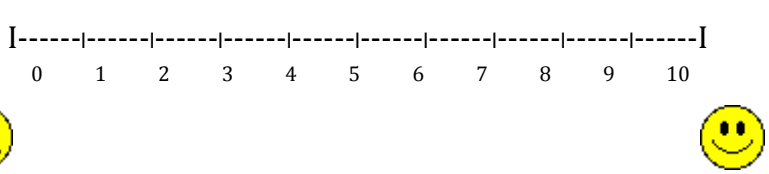
I did not always notice how my body was moving during



I noticed how my body was moving during the session.

Overall

Overall I disliked this .



Overall I liked the session

Appendix H

MiYoga
Qualitative Interview Script and Questions

Interviewer - Introduce yourself

- I am post-graduate student from School of Psychology at The University of Queensland who is unrelated to the MiYoga study in anyway. Advise participants to express their views and opinions about the program freely.
- I would like to find out from you how your experienced your involvement in MiYoga. This will help us to ensure that we are optimizing this therapy.
- To make sure that I accurately report your views, with your permission I would like to audio record our conversation.
- This recording will be transcribed and your name replaced by a number to make sure the information remains confidential.

Questions for parents:

1) What did you like best about the MiYoga program?
Potential Follow Up Questions: "Why did you like X the best?"

2) What did you NOT like about the MiYoga program?
Potential Follow Up Questions: "Why did you not like X?"

3) What do you think could have been different in the MiYoga program?
Potential Follow Up Questions: "What are your reasons for thinking X could have been different?"
   - *Amount of home practice expected?*
   - *Number of sessions per week?*
   - *Therapist interaction?*

4) Did you notice any changes in yourself after participating in MiYoga?
If so, ask: "In what way?" or "What changes have you noticed after participating in MiYoga?"
   - *Personal tasks?*
   - *Work tasks?*
   - *Leisure tasks?*

5) Did you notice changes in mindfulness in everyday life?
Potential Follow Up Questions: "Would you be able to provide some examples of these changes you have noticed in mindfulness in your everyday life please?"
   - *Personal tasks?*
   - *Work tasks?*
   - *Leisure tasks?*

6) Did you notice any changes in your child after participating in MiYoga?
If so, ask: "In what way?" or "What were the changes you noticed in your child after participating in MiYoga?"
   - *Personal care tasks?*
   - *School tasks?*
   - *Leisure tasks?*

7) Did you notice any changes in your child's mindfulness in everyday life?
Potential Follow Up Questions: "Would you be able to provide some examples of these changes you have noticed in your child's mindfulness in their everyday life please?"

- *Personal care tasks?*
- *School tasks?*
- *Leisure tasks?*

8) Is your child better or worse at paying attention after participating in MiYoga?
Potential Follow Up Questions: "Would you be able to provide some examples of these changes in your child's ability at paying attention please?"

9) Did you enjoy participating in MiYoga with your child?

10) Did your child enjoy participating in MiYoga?

11) Have you noticed any changes in your relationship with your child since participating in MiYoga?
Potential Follow Up Questions: "How has your relationship with your child changed?" or "Would you be able to provide some examples of these changes in your relationship with your child please?"

12) How did you find integrating MiYoga practices into your daily life?

13) Would you participate in this program again?

14) Would you recommend MiYoga to other families?

15) Are you planning on continuing to practice Yoga with your child?
If so, why? If not, why not?

16) Anything else you would like to tell me?

Questions for children:

1) What did you like best about the MiYoga program?
   Potential Follow Up Questions: "Why did you like X the best?"
   - *Any particular postures you liked best?*
   - *Any particular games you liked best?*

2) What did you NOT like about the MiYoga program?
   Potential Follow Up Questions: "Why did you not like X?"
   - *Any particular games you didn't like?*
   - *Any particular postures you didn't like?*
   - *How often the sessions were?*
   - *How often you had to practice at home?*

3) What do you think could have been different in the MiYoga program?
   Potential Follow Up Questions: "Why do you think X could have been different?"
   - *Amount of home practice expected?*
   - *Number of times per week?*
   - *Therapist interaction?*

4) Can you tell me about anything that made it hard for you to practice MiYoga at home?
   - *Other commitments - homework/extracurricular activities?*

5) Did you notice any changes in yourself after participating in MiYoga?
   If so, ask: "In what way?" or "What changes have you noticed after participating in MiYoga?"
   - *At home?*
   - *At School?*
   - *Leisure tasks?*

6) Did you enjoy participating in MiYoga?

7) What was it like to do MiYoga with your mum/dad?

8) Would you participate in this program again?

9) Would you recommend MiYoga to other children?

10) Do you want to keep practicing Yoga?

    If so, why? If not, why not?

11) Anything else you would like to tell me?

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____✓_p1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____✓_p3_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____✓_p3, p1, p13-14, p17, p23-34, p35, p37, ____
Protocol version	3	Date and version identifier	_____✓_footer__
Funding	4	Sources and types of financial, material, and other support	_____✓_p37____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____✓_ p1____
	5b	Name and contact information for the trial sponsor	____N/A_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___ N/A _____

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___ N/A _____
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	____✓_p4-11___
	6b	Explanation for choice of comparators	____✓_p20_____
Objectives	7	Specific objectives or hypotheses	____✓_p11-12__
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	____✓_p14_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	____✓_p20_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	____✓_p13_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	____✓_p17-20__
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	____N/A_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	____✓__p20 (MiYoga diaries), p21 (video recording)_____

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	____✓_p14_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	____✓_p23-34__
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	____✓__p14 & Figure 1_____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	____✓__p35____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	____✓__p20____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____✓__p15____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	____✓__p15____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	____✓__p15____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	____N/A_p15____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	____N/A_____

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	____✓_p20_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	____✓_p20_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	____✓_p20-21__
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	____✓_p35-36__
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	____N/A_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	____✓_p35_____

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	____✓_p15_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	____N/A_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	____✓_p15_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	____ N/A_____

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____✓_p1, 12, 36_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____✓_p12____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	____✓_p12_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	____ N/A_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	____✓_p21_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	____✓_p39_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	____ N/A_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	____✓_p15_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	____✓_p37_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	____ N/A_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	____ N/A_____

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	____✓_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	____N/A_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.