

Queensland Cerebral Palsy & Rehabilitation Research Centre
Royal Children's Hospital
Herston Road
HERSTON QLD 4029
Tel: (07) 3646 5539
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STANDARD PARTICIPANT (CHILD) INFORMATION STATEMENT

Project Title: MiYoga - Randomised Controlled Trail of a Mindfulness Yoga Program for Children with Cerebral Palsy

Investigators: Catherine Mak, Dr Koa Whittingham, Professor Roslyn Boyd, and A/Professor Ross Cunnington, Dr Lynne McKinlay, and Laura Pareezer

You are invited to participate in a Research Project called MiYoga

What is MiYoga?

MiYoga is a mindfulness yoga program, it will teach us how to pay more attention to what we are doing. This study will test whether a 6 week MiYoga program will enhance attention, physical strength and fitness, behaviour and emotional control in children with diplegia.

Why am I being asked to be in this research project?

We are inviting you to take part because you:

- are between 8 and 12 years old
- have diplegia
- do not have uncontrolled epilepsy

What will I have to do in the MiYoga study?

We will ask you to attend 3-4 assessment sessions (approximately 2 hours sessions) over a 7-9 month period. After the first assessment session you will be allocated to either the **immediate** or the **waitlist** MiYoga group. This will be decided by chance. Similar to a toss of a coin, neither you or your family, nor the researchers can decide which group you will be in. Regardless of which group you are in, you will have access to the MiYoga program. The difference will be when you access the MiYoga program. The **immediate** group will access MiYoga immediately after the first baseline assessment. The **waitlist** group will access MiYoga after a 6-week delay. If you are in the **Waitlist** MiYoga group it would be expected you are able to attend an additional assessment session (after an initial 6 week waiting period and just before starting the MiYoga program). This is very important, as it will allow us to compare the effects of the program.

When you begin your MiYoga program you will be attending 6 x 90 minute MiYoga group session with one of your parents/guardians over six weeks (one session per week). You and your parent/guardian will do daily home practices with a MiYoga DVD for a minimum of 20 minutes during the 6 week intervention period. Yoga poses will be modified and adjusted to suit each participant and their ability to ensure that there's no pain or discomfort. One of the researchers will be there to assist you in the group sessions while your parent/guardian will be there to assist you at home with the movements.

You and your family will have an opportunity to talk to staff at any time during the study to discuss how you are managing with the program. We are particularly interested in your views about this novel type of treatment.

What are my alternatives to participating in this project?

You do not have to take part in this project if you do not want to. If you do not take part, it will not affect your access to care and treatment at the Royal Children's Hospital (RCH).

Will there be any benefits for me or other people in the future?

We hope that the program will benefit you and your parent/guardian. It is possible that participation may not benefit you directly. However, you will receive around 21 hours of therapy in the MiYoga program (9 hours of group sessions and 12 hours home practice) if practiced for 20 minutes per day. Based on previous research studies on mindfulness and yoga, you are likely to see improvements in concentration, ability to focus on task, physical strength and fitness, how we act and react to everyday events, as well as improvements in overall well-being.

We also hope that the results of our project will help other children with CP and their families in the future.

Are there any side effects?

There are no known side effects and the researcher will be sensitive to your needs and provide breaks during assessments and the group sessions as needed.

What are the possible discomforts and/or inconveniences?

The only inconvenience is the time that the assessment and program will take. The assessments will take approximately 2 hours in total, on 3-4 separate occasions over the 7-9 months of the study, at the Royal Children's Hospital (RCH) or at the University of Queensland (UQ) at St Lucia. The MiYoga program itself consists of 6 x 90-minute sessions over a six week period. The sessions will be conducted at RCH or UQ St Lucia. We will also ask you to practice 20 minutes of MiYoga at home every day during this six week period. This home practice can be performed at any time during the day that suits you and your family.

Will it be confidential?

You will be given an study number and all the information you provide us and records of what we do will be linked to that number. So it will all be kept confidential.

Will I be informed of the results of the study?

You can request your results at anytime by organising an appointment with one of the researchers. You and your parent/guardian will also receive a newsletter every 6 months. At the end of the study, all families will be sent a summary of the results. The newsletter and end of study summary will talk about the results as a group and you will not be identified in person.

You can decide whether or not to give permission to take part in this research project. You can decide whether or not you would like to withdraw at any time without explanation.

If you would like more information about the study please contact:

Ms Catherine Mak

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OR

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Email: koawhittingham@uq.edu.au

What are my rights as a participant?

- I am informed that except where stated above, no information regarding my medical history will be released. This is subject to legal requirements.
- I am informed that the results of any tests involving me will not be published so as to reveal my identity. This is subject to legal requirements.
- The detail of the procedure proposed has also been explained to me. This includes how long it will take, how often the procedure will be performed and whether any discomfort will result.
- It has also been explained that my involvement in the research may not be of any benefit to me. I understand that the purpose of this research project is to improve the quality of medical care in the future.
- I have been asked if I would like to have a family member or a friend with me while the project is explained to me.
- I understand that this project follows the guidelines of the National Statement on Ethical Conduct in Research Involving Humans (2007).
- I understand that this research project has been approved by the Royal Children's Hospital Ethics in Human Research Committee on behalf of the Royal Children's Hospital Board.
- I have received a copy of this document.

Ethics Contact:

The Human Research Ethics Committee of the Royal Children's Hospital and Health Services District has approved this study. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study or your rights as a participant, or if you wish to make a confidential complaint, please contact:

RCH&HSD Ethics Committee Coordinator
Royal Children's Hospital and Health Services District
C/- Dept of Pediatrics and Child Health
Level 3, RCH Foundation Building,
Royal Children's Hospital
Herston Road
Herston QLD 4029
Tel: (07) 3636 9167 (Monday to Friday 9am-5pm)

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**STANDARD PARTICIPANT (CHILD) INFORMED CONSENT FORM TO PARTICIPATE
IN A RESEARCH PROJECT**

Project Number

Children's Health Services Human Research Ethics Committee (CHS HREC):

HREC/12/QRCH/120

The University of Queensland, Behavioural & Social Sciences Ethical Review Committee:

#2012000993

Title of Project

MiYoga: A Randomised Controlled Trail of a Mindfulness Yoga Program for Children with Cerebral Palsy

Investigator(s)

Ms Catherine Mak, Dr Koa Whittingham, Professor Roslyn Boyd, A/Professor Ross Cunnington, Dr Lynne McKinlay and Laura Pareezer

For child 10 years or older: I (name) _____ voluntarily
consent to take part in the above titled Research Project, explained to me by
Mr/Ms/Dr/Prof _____.

I (parent/guardian name) _____ voluntarily consent for
my child to take part in the above titled Research Project, explained to me by
Mr/Ms/Dr/Prof _____.

- I have received a Participant Information Statement to keep and I believe I understand the purpose, extent and possible effects of my involvement
- I have been asked if I would like to have a family member or friend with me while the project was explained
- I have had an opportunity to ask questions and I am satisfied with the answers I have received
- I understand that the researcher has agreed not to reveal results of any information involving me, subject to legal requirements
- If information about this project is published or presented in any public form, I understand that the researcher will not reveal my identity
- I understand that if I refuse to consent to my participation, or if I withdraw myself from the project at any time without explanation, this will not affect my access to the best available treatment options and care from the Royal Children's Hospital
- I understand I will receive a copy of this consent form

- I consent to participate in the MiYoga program YES NO
- I consent to have video recordings of their assessments being taken and
digitally stored for research evaluation purposes YES NO
- I consent to the use of my data in other studies that are approved by a Human
Research Ethics Committee. YES NO

PARTICIPANT (child 10 years or older)

SIGNATURE: _____

Date _____

PARENT/GUARDIAN

SIGNATURE: _____

Date _____

I have explained the study to the participant and the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible effects of their involvement in this study.

RESEARCHER'S SIGNATURE: _____

Date _____

Note: All parties signing the Consent Form must date their own signature.