Participant Information Sheet – Video Recording Group

Study title: Automating the General Movements Assessment

Locality: Auckland/Waikato DHBs

Ethics committee ref.: 000146

Lead investigator: Angus McMorland

Contact phone number: 021 919 337

You are invited to take part in a study: Automating the General Movements Assessment. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, who we are, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last 2 pages of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Healthy infants under 5 months exhibit spontaneous movements called General Movements (GMs). These movements indicate a normally developing motor system (brain, nerves, and muscles). The General Movements Assessment (GMA) is used clinically with children who have been identified to be at-risk of developing cerebral palsy. We are inviting your child to participate in the study to help us establish baseline measurements using new technology to perform the GMA. This is not a medical test to determine if your child has any condition, and we have no reason to think that they have any condition.

In the GMA, a short video (10-20 minutes long) is taken of the infant while they lie quietly on their backs. A trained observer then rates the movements captured in the video as either normal, abnormal or absent. Abnormal or absent GMs is a strong predictor that the infant is at-risk of developing cerebral palsy, and that early intervention should start.
Cerebral palsy is the most common physical disability in childhood, affecting approximately 1 in every 500 babies, or one every two days in NZ. Early intervention may be able to improve outcomes with the disease, but research into and implementation of early intervention relies on early diagnosis, which has not been reliably possible without the GMA.

The aim of this study is to apply recent advances in artificial intelligence to the GMA which provide two important advantages. Firstly, reducing the involvement of trained human observers, who are a limited resource in NZ, will make the assessment more accessible across the country. Secondly, by making precise measurements about infants movement patterns, the computer-based approach has the potential to be more sensitive than the existing GMA, telling us more about the infant’s health and, possibly, offering strategies for therapy.

**WHO IS PERFORMING THIS STUDY?**

The research team performing this study is made up of two Masters students, supervised by academics at the University of Auckland, and in collaboration with clinicians in Newborn Services at Auckland City Hospital and the Child Development Centre at Waikato Hospital.

*Lilian Lim* is doing her Master of Engineering in Bioengineering degree. She recently completed her Bachelor of Engineering in Biomedical Engineering, at the Auckland Bioengineering Institute, doing a fourth year research project looking at individualized scaling of models of people’s bones to create better biomechanical models of the forces acting inside joints.

*Roopa Thakker* is doing her Master of Science in Clinical Exercise Physiology in the University of Auckland’s Exercise Sciences Department. Roopa has previously trained as a physiotherapist.

*Dr Angus McMorland* is a lecturer in the Exercise Sciences Department at the University of Auckland, a Principal Investigator in the Centre for Brain Research, and an Honorary Academic at the Auckland Bioengineering Institute. His research interests are in how the brain controls movement, and how the physical (the musculoskeletal system) and control (the brain) systems of humans interact to produce movement and behaviour, how movement control is affected in motor disorders, and how technology can be used to improve the movement capacity of impaired individuals.

*Associate Professor Thor Besier* is head of the Musculoskeletal Group at the Auckland Bioengineering Institute. His research combines medical imaging with computational modelling to understand mechanisms of musculoskeletal injury and disease.

*Karli Joll* and *Nikki Laker* are physiotherapists at the Child Development Centre at Waikato Hospital. They are certified General Movements Assessors, and conduct the GMA there as part of the clinical care pathway for children identified as being at-risk of developing cerebral palsy. *Dr Malcolm Battin* is a neonatologist at Auckland City Hospital. He conducts research into the prevention and treatment of neurological conditions associated with the period around birth.

For further information about the study, please contact Dr Angus McMorland, via email a.mcmorland@auckland.ac.nz or phone (09) 923 6865.
**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

You and your infant have been invited to participate because your child is the right age to perform General Movements (0-5 months old). Your infant is eligible to take part in the study if there are no conditions that you are aware of that limit the movement of their arms and legs or that affect their ability to lie on their backs for up to 20 minutes at a time, and they have not displayed hypersensitivity to sticky tape. If you volunteer to be involved, we will ask you about these in the initial conversation. In this initial stage of the project we are developing methods to quantify the movement patterns of infants, and these general methods apply equally well to healthy babies.

Participation in this study involves attending a single measurement session at the University of Auckland’s Department of Exercise Sciences. A session should take less than 1.5 hours. During the session, we will record, using two different methods, the spontaneous movements made by your child while they lie undisturbed on an infant mattress and blanket. Each recording block will take 5 – 20 minutes. We will perform 1 – 3 blocks. For some blocks we will also tape, using low-irritation sticky tape, a number of small reflective balls (markers) on to your child’s hands and feet, wrists, arms and legs, shoulders and hips. These markers can be easily tracked by our motion capture system. If you wish, you can perform the attaching of the balls yourself, following guidance from the researchers. We may also try a few times to deliberately distract your infant with a bright, noisy soft toy.

Once videoing is complete, we will copy the electronic video files to a secure, password-protected server managed by the University of Auckland and accessible only to the researchers. The video files will then be deleted from the cameras. All data we collect will be de-identified before further analysis, meaning that the participant’s names will be removed, their faces will be blanked out of video data, and no identifying information (names or date-of-birth) will be stored with any of the data. We will present de-identified quantitative data in scientific publications, Masters theses, conferences, and lay summaries. We will ask you in the Consent Form if you consent to us using non-identifying images of your child in these publications to illustrate how accurately the method performs. We will keep the data, including videos, on these secure servers indefinitely, in case we need to revisit the study, or for further analyses addressing the same research problem.

Your decision to participate or not will not affect any health care you might receive in any way.
WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The (small) benefit you will receive from this study is getting a General Movements Assessment (GMA) performed. The GMA is typically only performed with children who have identified risk-factors for developing cerebral palsy, such as prematurity. In these infants, absence or abnormality of GMs predicts the development of cerebral palsy. In infants who have no identified risk factors for cerebral palsy, the rate of developing cerebral palsy anyway is about 1 in 1000. A normal GMA would another piece-of-mind check that your infant’s motor development is occurring normally. In the unlikely event that something of clinical significance was found in the GMA, participants would be referred to appropriate clinicians for follow-up assessments.

The potential broader benefits of this study are that it could make the GMA more accessible to people, and more sensitive or specific, providing either more accurate results or more specific information about the participant’s health. All of these would result in better provision of care and better health outcomes for people with CP. Techniques developed in this study could also give us more insight into what causes CP, which could lead us to develop better therapies that lessen the consequences of the disease.

One risk associated with this study is that your infant might experience some mild discomfort from the tape used to stick the motion capture markers to their skin. To minimize this risk, we will use sensitive skin tape recommended for paediatric use. Any discomfort should be short-lasting. One potential risk is to privacy and confidentiality of information. We will remove participants’ names from their data and store the data, including any videos of participants, separately from identifying information, and will not release from the study any data that could be used to identify individuals. Another potential risk is that, given that your child cannot consent on their own behalf and that you will have to give consent for them, they might feel that your consent was given inappropriately. We believe that the likelihood of this is small, since the other risks associated with participation are being minimized. If we are still storing the data when your child turns 16, we will attempt to contact them again to ask their permission to continue to store and use the data.

WHO PAYS FOR THE STUDY?

This study has received funding from the Auckland Bioengineering Institute (funding Ms Lim), NVIDIA (computer hardware) and the University of Auckland Faculty of Science (research costs). There is no cost to be involved in the study, and participants will be given a $50 voucher to reimburse them for their time and travel expenses.

WHAT ARE MY RIGHTS?

Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

Participation in this study is entirely voluntary and you have the right to decline to participate with no consequences. You may end the recording at any time during the session. You may also change your mind and withdraw from the research for up to two weeks after the data (measurements and video) have been collected. After this time, your child’s de-identified data
(including video) will have been incorporated into analyses for a Masters dissertation and withdrawing the data from that write-up will not be possible. We also would like to store your child’s de-identified data indefinitely for future analyses, in case we need to revisit the study, or for further analyses addressing the same research problem. You have the right to, at any time, request that your child’s data are deleted from our servers and not used for future analyses.

Throughout the study you will retain the right to access any information that is collected from you and your infant as part of the study.

All information about your infant will be de-identified before further analysis, and information that could identify you or your child will not be published in any outcomes of this study.

**WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?**

All the data, including video, collected in this study will be de-identified, which means it will be labelled with a unique ID code and stored separately from the names and personal information of the participants, to protect the identity of the individuals. Only the principal investigator will have access to the database linking the ID codes with identifying information, so that your child’s de-identified data can be deleted later if you request. Data will be collected on password-protected devices and stored on secure password-protected servers.

The findings of this study will be published in Masters theses, written up as academic journal articles, presented at conferences, and may be discussed in mainstream and social media. These outcomes are likely to be produced in 2020 and beyond. A lay summary of the results will be written. In the Consent Form, you will be asked if you would like an electronic copy of the summary. Copies of other products of this research can also be requested through the principal investigator: a.mcmorland@auckland.ac.nz.
WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact either:

Principal Investigator
Dr Angus McMorland
a.mcmorland@auckland.ac.nz
(09) 923 6865

Head of Department, Exercise Sciences
Associate Professor Greg Anson
g.anson@auckland.ac.nz
(09) 923 2975

If you require Māori cultural support, talk to your whanau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning (09) 486 8324 ext 2324. If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning (09) 486 8920 ext 3204.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at (09) 3737 599 ext 83711, or at:
Auckland Health Research Ethics Committee
University of Auckland
Private Bag 92019, Auckland 1142.

Approved by the Auckland Health Research Ethics Committee on 23/10/2019 for three years. Reference number 000146.
Consent Form – Video Recording Group

Study title: Automating the General Movements Assessment
Researchers: Ms Lilian Lim, Ms Roopa Thakker, Dr Angus McMorland, Dr Malcolm Battin, Associate Professor Thor Besier, Ms Nikki Laker, Ms Karli Joll

If you wish to have one, an interpreter can be made available to translate this document and to help discuss its contents.

Consent checklist
Please read the following statements:

- I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
- I have been given sufficient time to consider whether or not to participate in this study.
- I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time, including during the recording session.
- I consent to the research staff collecting and processing my information, including information about my child’s health.
- I understand that my child will be video-recorded, and that I can request any video collected of them to be shared with me.
- I understand that I may withdraw my data from the study for up to two weeks after collection, at which point it will be included in analyses for a thesis and other publications.
- I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
- I understand that my data, including video, will be stored indefinitely unless requested to be withdrawn.
- I understand that I will receive a $50 voucher to reimburse travel expenses.
- I know who to contact if I have any questions about the study in general.
Please tick Yes or No to the following options:

I consent to the publication, in journal articles, presentations, and student theses, of images of my child with their face blanked out and containing no identifying features. Yes ☐ No ☐

I wish to receive a summary of the results from the study, which can be emailed to the following address: Yes ☐ No ☐

We are required to collect ethnicity information as part of this study. Which ethnic group do you belong to? Mark the space or spaces which apply to you.

- ☐ New Zealand
- ☐ European
- ☐ Māori
- ☐ Samoan
- ☐ Cook Island Māori
- ☐ Tongan
- ☐ Niuean
- ☐ Chinese
- ☐ Indian
- ☐ other, such as DUTCH, JAPANESE, TOKELAUAN. Please state: [ ]

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date:

Approved by the Auckland Health Research Ethics Committee on 23/10/2019 for three years. Reference number 000146.