

Participant Information Sheet – Parent / Caregiver

Eat, Sleep, Play: Investigating nutrition and body composition in children with Hōkai Nukurangi - cerebral palsy

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| Study site: | The University of Auckland | Ethics committee ref.: 2023 FULL 15406 |
| Lead investigator: | Dr Sian Williams | Contact phone number: +64 9 923 6929 |

Eat, Sleep, Play- CP

You are invited to take part in a study seeking to understanding more about nutritional intake and body composition in tamariki / children with cerebral palsy. Whether or not you and your child take part is entirely your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. 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, 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 page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

We all know that what we EAT (nutrition) can be important for good health, as well as maintaining a healthy body weight. How well we SLEEP, and how much we do (PLAY), is also important for our health and development. But we don't often pay much attention to how we EAT in relation when we SLEEP and PLAY, and there seems to be very little nutritional advice in general given to tamariki (children) with Hōkai Nukurangi (cerebral palsy) and their families.

Childhood can be such an important time for learning healthy behaviours, so it is important for us to understand how some of these behaviours in children with cerebral palsy might actually be helping (or hindering) their health- specifically how this might be related to their body composition (how much muscle and body fat they may have, and how strong their bones are). This study seeks to find out how **body composition** in children with cerebral palsy relates to what they EAT, how they SLEEP, and when they PLAY. We aim to recruit up to 15 children in the study.

This project brings together a multidisciplinary team of clinical researchers from the University of Auckland. Dietetics Masters students' **Rebecca Diaz-Rodriguez** and **Maggie Copeland** will be running this project as part of their Master's degree. The project is being overseen by Dr **Fiona Lithander** is a nutrition scientist and dietitian, and Dr **Sian Williams**, an exercise scientist with over 10 years of research experience working with cerebral palsy.

If you have any further questions, contact details can be found on page 5. This study is approved by the Northern A Health and Disability Ethics Committee: **2023 FULL 15406**.

WHO IS ELIGIBLE FOR THE STUDY?

To be in the study, children must meet all of the following criteria:

- ✓ Be diagnosed with cerebral palsy.
- ✓ Be between the ages of 5 and 12.
- ✓ Be happy to lie still for 10 minutes.
- ✓ Be able to travel to the University of Auckland, Grafton on two occasions (free parking will be made available).
- ✓ Have access to a smart phone, tablet or laptop/computer with internet.

To be in the study, children must **not** meet **any** of the following criteria:

- ✗ Have uncontrolled seizure activity.
- ✗ Have a feeding tube (a PEG or similar), or other implanted device (such as a pacemaker), that could interfere with the body composition scan.
- ✗ Be currently under any clinical dietary guidance or textured modified foods and/or fluids
- ✗ Had any recent (within 6 months prior to the study) surgery or another health condition that currently limits their normal eating, sleeping and play activity. This includes any planned surgery over the 3-month study period.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

We are looking to measure your child's nutritional intake (**eat**), their sleeping patterns (**sleep**) and activity behaviours (**play**) to see how this might be related to their body composition.

If you and your child agree to participate in this study, we will ask that you both attend **TWO** appointments at the University of Auckland, Grafton, approximately **three months** apart. We will work around your schedule and book the appointments at a convenient time for you and your child.

Before both appointments, we will ask you to complete a 3-day food diary, recording the type, amount, and timing of food intake for your child. **At each appointment**, we will ask you to complete a questionnaire about your child's health, mobility, sleep and activity, and your child will have a DXA (pronounced "decsa") scan. DXA is Dual-energy X-ray Absorptiometry. It is a low energy, x-ray-based technique, originally developed to measure bone mineral density (BMD). It is the gold standard for assessing body composition and bone strength.

As part of your involvement in this study, you and your child will be given feedback on their EAT, SLEEP, PLAY profile, along with individualised information about how they might want to try to change their eating behaviour (or keep it the same). We will give you written information to take home to help you follow the advice given, and over the 12 weeks in between your visits, our research team will check in with you up to four times (via your preference of text, phone, zoom or email), to see if you and your child have any questions or any additional help in following the advice given to you.

| Timing | What will happen? |
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| You decide to enrol into the study | <ul style="list-style-type: none"> • We will ask you to complete a consent form. • We will arrange a time for your first in-person visit at the university. • We will explain how to complete the food diary. • You will be sent a 3-day food diary and asked to complete this within 2 days of the visit to the university. |
| Visit 1 to the University (Approximately 1.5 hours) | <ul style="list-style-type: none"> • Your child: Complete the assent form • Your child: have a DXA scan to assess body composition. • You and your child: Complete questionnaire (~15 minutes). • You and your child: receive feedback & "Eat, Sleep, Play" advice |
| 12 weeks between the visits | Over the 12 weeks, we will check in with you up to four times to see how you are going with the "Eat, Sleep, Play" advice. |

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|---|---|
| | At around week 11, you will be sent the 3-day food diary again and you will be asked to complete this within 2 days of the visit to the university. |
| Visit 2 to the University (Approximately 1 hour) | <ul style="list-style-type: none"> Your child: have a DXA scan to assess body composition. You and your child: Complete questionnaire (~15 minutes) |

More information about what is involved with the assessments

3-Day Food Diary (a daily recall)

We will set you up a link to a program called *Intake24* that allows you to easily record your child's food intake for a full day over three days. You will need internet connection for this, and it is easiest to complete on computer or tablet, but can also be completed using a smartphone. We will ask you to complete this 3-day food diary **two times** during the ~3 months of the study.

It is important that you try to complete the food diary before your scheduled visits to us (at least 2 days before) at the university, so that we can review the diary and provide feedback.

DXA scan

The DXA (pronounced "decsa") scan will be at completed at the University of Auckland, Grafton. Parking is free, and we will provide you with a map, directions and parking information. To begin with, we will run through some safety screening questions to make sure it is suitable for your child to have the scan, and for you to be in the room. If there is any possibility that you may be pregnant, you will not be able to sit in the same room as the DXA scanner. Ideally, your child will wear loose-comfortable clothing, and clothing that is free of any metal buttons or zippers (otherwise we will have gown available). We will also need them to remove any jewellery, belts or watches. We will measure your child's height and weight, and then prepare them for the scan.

Your child will need to lie down as straight as possible and remain still during the scan, which will take about 10 minutes.

Questionnaires

At the start of the study, we will give you a questionnaire that asks you some general questions about you and your child, and their type of cerebral palsy and health. The questionnaire will also ask about how active they are (and when) and their sleeping behaviour. We will also ask you about what kind of nutritional advice (if any) or guidance you/your child has received in the past.

At the end of the study, the questionnaire will ask you some of the same questions about how active they are (and when) and their sleeping behaviour, as well as your feedback on the Eat, Sleep, Play advice given.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Risks

The DXA scan involves exposure to a very small amount of ionising radiation (x-rays), but the safety of DXA scans have been well documented. The amount of x-rays that your child will be exposed to is minimal when compared to having usual x-rays for bone fractures. People are exposed to background radiations from everyday living in New Zealand. The radiation your child will receive from the DXA scan is equal to one thousandth of the background radiation you would receive in one year, and is well within the safe levels of allowance of radiation over a year. Before the scan, you will complete an x-ray safety pre-screening form to assess your child's suitability. Your child will be excluded from participating if they do not meet these safety requirements. If there is a chance that you (/the accompanying parent/caregiver) may be pregnant, you will not be able to be in the same room as your child during their DXA scan.

With new environments and unfamiliar equipment, there is chance that your child may feel uneasy throughout the assessment. We hope to minimise the risk by providing clear explanations prior to

and during the assessment and encouraging him/her and you to ask questions throughout. The DXA scanner itself is very open and quiet, but should your child feel intimidated we will provide play preparation (known to minimize anxiety) and if he/she should become uncomfortable throughout we will cease the scan immediately.

Your child will be safe and supervised throughout the session. If you or your child become uncomfortable during the assessments, we can cease them at any time. If, for whatever reason, we are unable to achieve a successful DXA scan of your child, you and your child will still be welcome to return to subsequent assessments and remain in the study as we will still be able to collect valuable information from your involvement.

Benefits

This study is the first of its kind, and the information gathered will advance our knowledge on the role of nutrition for supporting healthy body composition for children with cerebral palsy. By measuring the current eating behaviours of children with cerebral palsy living in Aotearoa New Zealand, how this links with important health measures of body composition, and learning about what – if any – advice is provided for children with cerebral palsy and their Whānau (family), we may be better prepared to provide information that is more specific for children with cerebral palsy to help improve their health.

During the study, you and your child will be given a printout report of their DXA scan results, which will show the scores of their body fat percentage, fat mass percentage, and bone mineral density. You and your child will also be provided a summary report of their 'Eat, Sleep, Play profile', and information on how they could change (or keep the same) what they eat and when. You and your child will not receive any nutritional supplements or food as part of this study, only nutritional information and advice.

Please note that none of the included assessments are diagnostic, which means that no diagnosis will be able to be made from them.

WHO PAYS FOR THE STUDY?

Participation in this study will not incur any costs to you. Your parking at the University will be free, and your time will be compensated in this study by means of a \$30 voucher each time you attend the scheduled appointment at the University of Auckland. The funding of this study is being supported by research development funds held by Dr Williams.

WHAT IF SOMETHING GOES WRONG?

If you or your child were injured in this study, which is unlikely, you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY CHILD'S INFORMATION

During this study, our research team will record information about you and your child that we will collect. This includes the results of our study assessments of your child's nutritional intake and body composition. You and your child cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or post-code). Only our research team will have access to your identifiable information.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you and your child will not be included in any report generated by the research team. Instead, you will be identified by a code. The lead-investigator of the study will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Research Using You and your child's Information.

In the future, you and your child's coded information may be used for future research related to nutrition and body composition for people with cerebral palsy. This future research may be conducted overseas. Your coded information may be shared with other researchers, and / or may also be added to information from other studies, to form much larger sets of data. You may not be told when future research is undertaken using you and your child's coded information, and you will not get reports or other information about other research that is done using your information.

Security and Storage of Your Information.

Your identifiable information is held at the Liggins Institute, University of Auckland during the study. Coded study information will be kept by the sponsor in a secure cloud-based storage. After the study it is transferred to a secure archiving site and stored for at least 10 years after the youngest participant turns 16. All storage will comply with local data security guidelines.

Deidentified data may be sent overseas to Australia, though there are potential risks and cultural issues associated with sending data overseas, only the Principal Investigator will access data if sent to Australia.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

WHAT ARE MY RIGHTS?

You and your child's participation is completely voluntary, you are free to decline to participate, or to withdraw from the research at any practical time, without experiencing any judgment, or disadvantage. Your decision will not affect your health care, or any relationship you have with any of the investigators involved in the study. You have the right to access and correct all information about you and your child collected as part of the study.

You and your child's privacy will be protected, and identities kept confidential. All the information collected will be de-identified with a participant identification number, and only accessible to the research team. Any information we collect and use during this research will be treated as confidential. The following people will have access to the information we collect in this research: the research team and the Ethics Committee.

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

As mentioned above, if you or your child change your minds about participating in the study then you are able to withdraw at any time. Any data that we have collected prior to you withdrawing from the study will still be used in the study. Electronic data collected from this study will be password-

protected and hard copy data will be in locked storage. The information we collect in this study will be kept under secure conditions at The University of Auckland until at least 10 years after the youngest child in the study reaches 16 years of age, and then it will be destroyed.

The results of this research may be presented at conferences and published in professional journals. You and your child will not be identified in any results that are published or presented. Data generated from this study may be made available for use in future research, however all data will be coded to ensure confidentiality.

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:

Dr Sian Williams

Principle Investigator

sian.williams@auckland.ac.nz

Associate Professor Fiona Lithander

Co-Investigator

fiona.lithander@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz.

For Māori cultural support please contact :

For support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waioira Māori Health Team on 09 486 8324 ext 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitemata Te Whatu Ora ' Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

Eat, Sleep, Play: Investigating nutrition and body composition in children with Hōkai Nukurangi - cerebral palsy

- I have read or have had read to me in my first language, and 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 my child from the study at any time without this affecting my child's medical care or future participation in research studies.
- I consent to the research staff collecting and processing my child's information, including information about my child's health.
- If I decide to withdraw my child from the study, I agree that the information collected about them up to the point when I withdraw may continue to be processed.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I understand that my child's participation in this study is confidential and that no material, which could identify me or my child personally will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general.
- I understand my responsibilities as a study participant.
- I understand that my child's coded information may be used within future research.

I wish to receive a summary of the results from the study. Yes No

Declaration by parent/guardian of participant: I hereby consent for my child to take part in this study.

Participant's name (child's name): _____

Parent/Guardians 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: _____