Parent/Caregiver Information

Investigators: Dr Alison Leversha, Dr Anneka Anderson, Ms Jacinta Fa'alili-Fidow

You are invited to take part in a project that explores how well a new developmental assessment tool works for New Zealand parents and children/tamariki. We want to learn if this new tool, the **kiwiASQ**, is culturally appropriate, easy to understand and use, and can identify developmental areas that may need further assessment and referral to services. We hope it will become the new way we look at child development and behaviour in the free well child checks. Your involvement will help us make it the best way to check children's development in Aotearoa New Zealand.

It is your choice whether you take part. If you change your mind anytime during the process, you may withdraw. No worries or questions.

This Information Sheet will help you decide if you would like to take part. It explains the project, what your involvement will mean, and what happens after the assessment. We will discuss everything you need to know and answer all your questions. Please read and understand this information sheet. If you agree to participate, you will be asked to sign the Consent Form on page 5. The first few pages of this Participant Information Sheet are yours to keep.

Who can participate?

We are looking for parents/caregivers of a three-year-old child: 34 months to 38 months. Caregivers include birth parents, whangai or adopted parents, another adult caregiver and/or other family members or caregivers involved in the care of the child. If your child already has a developmental problem and is seeing a paediatrician, child development therapist, or learning support from the Ministry of Education, they may still be able to be involved. We can discuss that before we go further and may need to check their hospital records to decide.

The assessment will mostly be done in English; however, an interpreter will be provided if you wish. We will play with your child and speak to your child in the language you use at home to give your child instructions. English does not need to be their main language.

What will my participation in the project involve?

We will invite you and your child to spend a morning at either a local clinic or the Infant, Child & Adolescent Research (iCARE) unit at the University of Auckland. You are welcome to bring other members of your family if you wish. We may be able to offer a home visit if other transport options are not an option. A series of developmental and language assessments will be done over the morning, and you will be asked some questions about your child, their development, and your family situation. This is so we can see if the **kiwiASQ** works for all groups in our community. You get to do the **kiwiASQ** in the clinic and hear what it shows: '**development on track**', '**monitor**', or '**may require further assessment**'. We would like your feedback about what it was like to hear about your child's developmental progress this way, especially if the **kiwiASQ** suggested further assessment was needed.

Your feedback about the questionnaire with suggestions for any improvements are welcomed. The whole process will be ~2-3 hours with plenty of rest breaks. Food and drinks will be provided. Hearing and vision will also be checked. The assessments and discussions will be audio recorded to make sure we capture all your and your child's comments about the tool as we go. Comments and feedback will be typed into files using pseudonyms (made up names): we will not use you or your child's real names. One week before the appointment, you will be sent an online version of the **kiwiASQ** to complete at home.

The formal language and development assessments are quite complex to score thus we can't give you those results that day. We will therefore touch base with you about a week later to go through a summary of the findings, answer any questions, and talk about any support or referrals if needed.

Participation in this study is entirely voluntary: It is your choice. If you choose not to take part, you and your child will not be affected in any way. If you agree to take part, you will be free to withdraw at any time without giving a reason. You can request return of any data collected up to that point if you wish. If you complete the assessment, you can withdraw your data up to the point of data analysis. All information collected will be stored in a locked filing cabinet in a locked office for ten years after the youngest participant turns 16 years. No material will personally identify participants.

What are the risks?

Please note the assessments and information will remain deidentified and confidential. The main possible risk is that we identify a developmental concern you weren't aware of. We will always discuss what we find, what it means, potential further assessments, and refer you and your child to other supports and services if needed e.g., a paediatrician, child development therapist, hearing or eye test, or Ministry of Education learning support. This will all be done with discussion and your consent. Some services currently have long wait times. We will let you know the approximate wait, supply alternative private options if available, and provide guidance re activities to do in the interim. We will let your family doctor know the results so they can follow up as required.

If the discussions raise uncomfortable feelings (such as being worried or whakamā), you are welcome to talk to any of the researchers who will be listen to your concerns and/or refer you to specialist services that could help. We have the numbers of people you can contact if you want.

What happens after the assessment?

Assessments will be electronically recorded. Audio recording will be transcribed by the researchers, who sign a confidentiality agreement, and the audio recordings will then be destroyed. All parents and children will have access to their information. A summary report of your child's assessment will be sent to you, your family doctor, and will be stored on their electronic health record.

None of the individual personal information will be made publicly available. All information obtained for this project will be stored for ten years after the last person turns 16, in a secure manner in password-protected computer at Starship Community. Only the researchers and those conducting the assessments will see the information. To make sure your child's personal information is kept confidential, information that identifies them will not be included in any report generated by the research team. Instead, you will be identified by a code or a pretend name (and thus 'deidentified'). The research team will keep a list linking your code with your name, so we can go back to the information if needed. The results of the study will be published and presented, but in a grouped way, and not in a form that would identify you or your child.

At the end of the assessment, koha will be presented to your family as thanks for you sharing your time and knowledge. A voucher receipt form will need to be signed for the koha. Your child will receive a gift to recognise their time and experiences. We will arrange a suitable time to check back with you to discuss the findings.

We will check your child's health records again when your child is 4, to see if they have any developmental or behavioural difficulties diagnosed and what support you and they are getting. This will include checking with the Ministry of Education Learning Support to see if your child is receiving supports and intervention such as speech therapy, behaviour support, an education support worker, or an early intervention teacher. This will help to prove that the **kiwiASQ** is identifying children early, and they are getting support and intervention they need.

What happens if I change my mind?
Participation in this project is entirely voluntary, and you are free to withdraw at any time. The assessment will stop at the time you withdraw, and you can ask to have the information collected up to that point deleted if you wish. If you complete the assessment, you can withdraw your data up to the point data analysis has commenced.

Please note that we will always be accessible if you have any questions about this project.

Who do I contact if I have more questions or if I have concerns?
If you have any questions, concerns, or complaints about the project, you can call, text, or email us:

Alison Leversha (alisonl@adhb.govt.nz 021 629 047)

Anneka Anderson (a.anderson@auckland.ac.nz 027 706 7932)

Jacinta Fa'aili-Fidow (Jacinta@moanaconnect.co.nz 021 748 627)

If you want to talk to someone who is not involved with the study, you can contact any of the following helplines:

- **Support from a trained counsellor -** Free call or text 1737 any time
- **Healthline** - 0800 611 116
- **Plunket line** - 0800 933 922

For Māori Cultural support please contact the administrator for He Kamaka Waiora (Māori Health Team) by calling 09 307 4949 ext. 29200. State Title of the study and name of the primary investigator.

For Pacific Cultural support, please talk to one of our researchers, who will suggest appropriate support services.

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

- Email: hdecs@health.govt.nz

Approved by the Southern Health and Disability Ethics Committee on x/6/2023 for two years. Reference number **13996. Approved by the Research Offices at Starship Child Health, Counties Manukau, and Waitemata.**

I have read and understand the Participant Information Sheet.
I have been given enough time to consider my participation in this project.
I am satisfied with the answers I have been given about the project and I have a copy of this information sheet.
I understand that my participation in this study is voluntary (my choice) and that I may withdraw myself and my child at any time without this affecting me or them in any way.
I consent to the research staff collecting and processing the information I give in the questionnaires.
I agree to the researchers accessing my child's electronic health records at the hospital to check previous contacts including vision and hearing checks, clinic appointments, diagnoses etc.
I agree to the researchers accessing my child's health records at 4 years of age to check new results including vision and hearing checks, clinic appointments, diagnoses, supports etc.
I agree to the researchers contacting the Ministry of Education Learning Support team to see what educational assessments, intervention, and supports my child is receiving at both 3 and 4 years of age.
I consent to the research staff audio recording the assessments and understand this will include spontaneous comments by myself and my child about the process.
I understand that I will not be given the option of editing the transcripts of the conversations and assessments due to the contextual nature of the discussions.
If I decide to withdraw from the project, I understand I can request withdrawal of data prior to data analysis should I wish.
I understand that my participation in this study is confidential and that no material that could identify me or my child personally will be used in any reports on this project.
I know who to contact if I have any questions about the project in general.
I agree to a summary of my child's assessment going to my family doctor and being on my child's electronic health record.
I wish / do not wish to receive a summary of study findings, which can be emailed or mailed to me at this email/postal address:

Statement by participant:

I consent for me and my child to take part in this study.

Caregiver's name:	
Signature:	
Date:	

Statement by researcher:

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 caregiver understands the study and has given informed consent to participate.

Researcher's name:	
Signature:	
Date:	