



Participant Information Sheet – Parent/Caregiver/Guardian

Telehealth-delivered supports for enhancing the social communication of autistic children and caregiver wellbeing

Lead Researcher: A/Prof. Laurie McLay

Study Site: University of Canterbury

Contact phone number: (03) 369-3522

Ethics committee ref: 2022 FULL 12058

We are inviting you and your child to take part in a study that focuses on the social communication of autistic children and caregiver wellbeing. Whether or not you and your child take part is your choice. If you or your child don't want to take part, then you don't have to. Your decision to take part or not will not affect the services or supports that you or your child receive. The Participant Information Sheet will help you decide if you would like to take part in this study. It sets out:

- Why we are doing the study
- What your participation would involve
- What the benefits and risks to you and your child might be, and
- What would happen after the study ends

We have gone through some of this information with you over the phone and are happy to discuss it further and answer any questions you may have. You don't have to decide today whether you will take part in this study. Before you decide, you may want to talk about the study with other people, like your family, whānau, friends or healthcare providers. Please feel free to do this.

If you and your child agree to take part in this study, we will ask you to sign the Consent Form on the last page of this document. We will give you a copy of both the Participant Information Sheet and the Consent Form to keep. These materials are available in English only.

This document is 15 pages long, including the consent form. Please make sure you have read and understood all of the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Being part of this study is your choice. It's also your child's choice. You and your child don't have to take part in this study if you don't want to. If you and your child decide to take part, and later change your mind, you can do that. If you and your child decide not to take part in the study, or you decide to leave the study, you don't have to tell us why.

WHAT IS THE PURPOSE OF THIS STUDY?

Autistic children have a number of strengths, but can also experience difficulties related to social communication. Social communication is a term used to describe a range of skills including spoken and non-spoken (e.g., facial expressions, gestures) language which help people to effectively interact and communicate with others. The development of these skills can help build social relationships. Caregivers of autistic children can experience challenges that negatively impact their wellbeing (e.g., contributing to increased stress). The wellbeing of caregivers is essential to the wellness of children and whānau. Research shows that early supports can optimise child development and caregiver wellbeing. The Play to Learn programme has been developed for this research and is based on the principles of naturalistic developmental behaviour interventions (NDBI). NDBI are evidence-informed supports that are designed to facilitate children's social communication and behaviour. The ACTION in Caregiving programme has also been developed for this research and is based on the principles of Acceptance and Commitment Therapy (ACT). ACT is an evidence-informed support shown to enhance adult wellbeing. In this study we hope to:

1. Find out if the telehealth-delivered Play to Learn (for children) and ACTION in Caregiving (for caregivers) programmes are effective in enhancing children's social communication and caregiver wellbeing and self-confidence. Examples of telehealth-delivered supports include web-based content and online coaching and support.
2. Find out whether the Play to Learn and ACTION in Caregiving programmes are more beneficial when delivered in combination than when they are delivered separately

3. Understand whether these programmes and use of telehealth to deliver these programmes are acceptable to all caregivers, particularly Māori, Pacific, and autistic caregivers
4. Find out whether any benefits from the Play to Learn and ACTION in Caregiving programmes are maintained over time

HOW IS THIS STUDY DESIGNED?

For this study, we will recruit approximately 78 autistic children and their caregivers. This study will start with an *assessment*. In addition to the screening interview you have done, we will ask you to complete some questionnaires. These questionnaires ask about your child's social development, emotions, and behaviour. They will also ask you about your own wellbeing and experiences related to parenting. We can give you a list of these questionnaires, if you would like to learn more about them before you sign the consent form.

Once you complete the assessment, your family will be randomly assigned to one of three groups that you will then participate in, either the: (1) Play to Learn programme; (2) ACTION in Caregiving programme; or (3) Play to Learn + ACTION in Caregiving programmes. A random assignment means we do not know ahead of time which group you will be assigned to; we let the computer decide where to put you. We have three different groups so that we can compare how helpful each support option is. It will not be possible to offer you support from a different group other than the one you have been randomly assigned to. This means you may receive one type of support and not another (e.g., ACTION in Caregiving and not Play to Learn).

Each programme will run for 13 weeks. During this time, you will be provided with a web-based toolkit which you can continue to access after completing the study. This web-based toolkit is available through the Waiora Tamariki website and includes multi-media content, activities, and resources. It is divided into six modules that focus on different programme topics. In addition to being available on your computer, the website will be mobile-optimised so you can access content using your phone. If you do not have internet access, and have concerns about the cost of internet data, we can provide you with mobile data packages to complete the study.

As well as accessing the website, you will take part in small group coaching sessions over Zoom. Each group will have up to eight caregivers. The sessions will align with the web-based modules, and will include discussion about module content and activities, as well as provide an opportunity for facilitators to help you tailor strategies to the needs of your child and whānau. The identities of the people in these group meetings, and everything that is said at the meetings, will be confidential. You should not discuss these meetings with anyone who is not there.

Play to Learn

Play to Learn consists of a range of support strategies that are based on the principles of NDBI. Play to Learn uses play- and routine-based learning strategies, which means that opportunities for your child to learn new skills and behaviours are incorporated into everyday activities and parent-child interactions, such as one-on-one play and care routines (e.g., dressing, bathing, eating). It also includes behavioural strategies such as modelling (i.e., demonstrating to your child how to perform a new skill/behaviour) and rewards (e.g., praise, preferred items) to enhance children's social communication and behaviour. A lot of research shows these strategies are effective in enhancing social communication, language, learning, play and behaviour in young autistic children. In this programme, you will be taught strategies to use with your child in your own home.

ACTion in Caregiving

ACTion in Caregiving is based on ACT and is designed to support adults to find ways of effectively responding to challenging thoughts and feelings so they can break unhelpful habits and create a meaningful life. ACTion in Caregiving teaches people a number of strategies they can use to respond to unpleasant thoughts and feelings, allowing them to take helpful action without being controlled by their emotional experiences. This can help caregivers remain true to the caregiver/person they want to be in the face of parenting stress. Research shows ACT can help to reduce stress and anxiety, and improve overall mood, parenting self-confidence, and wellbeing in caregivers of autistic children. This has also been shown to benefit children's wellbeing.

Once you finish the programme, we will ask you to complete the same questionnaires you completed during the assessment. This allows us to tell whether there

have been any changes to your child's social communication, emotions, and behaviour, and/or your own wellbeing and parenting experiences since receiving support through the programme. We will also ask you to do a post-support interview after you finish the programme. We will do this interview to see how families felt about the online programme, what was helpful, and what could be improved.

We will follow up to check how you and your child are doing and if the strategies are still working 3 months after you finish the programme and will ask you to complete the assessment questionnaires again.

WHO CAN TAKE PART IN THIS STUDY?

We are inviting you and your child to take part in this study because you have a child aged 2-5 years who is autistic and is not yet attending primary school. Your child may have received a diagnosis of autism, or may have been identified by a professional (e.g., paediatrician, psychologist, psychiatrist) as highly likely to be autistic (e.g., awaiting diagnosis). If your child does not have a diagnosis of autism, we will confirm there is a high likelihood with a measure that checks for features of autism. We will discuss this with you by phone. You cannot take part in this study if your child already receives more than 15 hours of support per week through another early support intervention, or if you are currently completing another parenting programme (e.g., Triple P). Only one child per family will be able to participate in this study.

WHAT WILL MY PARTICIPATION IN THIS STUDY INVOLVE?

You will have already completed a screening interview to determine that this study is a good fit for you and your whānau. For caregivers of children who are identified as likely to be autistic (but not diagnosed), an assessment measure will be completed with you to confirm this likelihood. This measure will take up to 30 minutes to complete. Please note that this measure will not be used to make a diagnosis of autism, it will simply confirm there is a possibility that your child is autistic. If your child does not meet our criteria for having a likelihood of autism this does not mean that your child is not autistic. It only means that

they may not meet our criteria for inclusion in this study. It will also have no effect on the services that you receive.

During the study we will ask you to complete a range of questionnaires relating to your child's social development, emotions and behaviour, your own wellbeing and experiences related to parenting. The time it takes to complete each questionnaire will differ ranging from approximately 5 to 45 minutes. We expect it to take you up to 1.5 hours maximum to complete all of the questionnaires. We will ask you to complete these questionnaires again immediately after you finish the programme and then again 3 months after the programme has finished.

During the screening call we asked you to provide demographic information, such as how you identify your child's ethnicity and whether or not you identify as autistic. This is so we can evaluate whether the support programmes are acceptable and effective for people from a range of ethnicities and both autistic and non-autistic caregivers. If you prefer, information about whether you identify as autistic or not can be excluded from data analyses (i.e., evaluation of programme effectiveness for autistic caregivers compared with non-autistic caregivers). You can indicate this in the Consent Form at the end of this document.

The programme you participate in (i.e., to receive either Play to Learn, ACTION in Caregiving, or Play to Learn + ACTION in Caregiving supports) will last for 13 weeks. During this time, we will expect you to engage with the web-based module content. You will mostly do this by yourself, though you will be able to contact a member of the research team at any stage, and you can post questions in an online forum on the website. Each of the six modules for the Play to Learn and ACTION in Caregiving programmes takes 1-2 hours to complete and will include tasks to practise at home. The seven small group coaching sessions for each of the Play to Learn and ACTION in Caregiving programmes will be up to 2 hours and will be delivered fortnightly via Zoom. For caregivers in the Play to Learn + ACTION in Caregiving group, you will have access to both Play to Learn and ACTION in Caregiving content, and the group coaching sessions will run on alternate weeks (i.e., Play to Learn one week and ACTION in Caregiving the next). We will ask your permission to collect audio-visual recordings of the small group coaching sessions. This is so we can evaluate the performance of the facilitators (i.e., how well they followed the intended plan). These recordings will only

be viewed by members of the research team for the sole purpose of observing facilitators (i.e., participant information shared in the sessions won't be analysed). These recordings will be deleted after they have been viewed.

While you are completing the support programme, we will ask you to keep a weekly log of the strategies you are using. We will also ask your permission to collect 10-minute video samples of you and your child engaging in one-on-one play at home three times in total (once during the assessment phase, once immediately after you finish the programme, and once 3 months after the programme has finished). This is so we can observe the outcomes of the programme on your child's social communication and behaviour. It will not be possible to take part in this study if you do not agree to you and your child being videoed.

Your participation will last at least four months. This includes the assessment phase and the programme itself.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There is a small risk that the programme will cause you or your child distress. The new strategies and expectations might upset your child or cause you emotional discomfort. If you or your child experience distress while participating in this research, you can contact a member of the research team for guidance. If we feel that you or your child are in danger, then we may take steps that involve us contacting another agency and we will do our best to discuss this with you at the time. We have a detailed safety plan for this study. The safety plan also includes details on when we have to contact another agency. We can provide you with a copy of the plan if you would like to see it.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Your involvement in this study is likely to enhance your child's social development and/or your wellbeing. If it does, you might notice other benefits such as to the overall wellness of your whānau. If your child is communicating more and using adaptive behaviour, it is possible that this will reduce your own stress. If your own wellbeing improves, it is possible

that this might improve your child's interactions and behaviour. However, it is also possible that the study will not help you or your child, and that you will get no benefits from it.

If the programmes are effective, the website we have developed for this study will be rolled out to families across Aotearoa/New Zealand who experience similar support needs. So, this study might help other families of children who are autistic in the future, including families who live in areas that are far away from clinics and specialist care.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

You can choose not to take part in this study. In this case, you may seek out services from another provider with expertise in autism or adult mental health and wellbeing.

WILL ANY COSTS BE REIMBURSED?

You will not have any expenses connected with this study.

WHAT IF SOMETHING GOES WRONG?

If you or your child were hurt in this study you would be eligible **to apply** for compensation from ACC, just as you would be if you were hurt in an accident at work or at home. This does not mean that your claim will automatically be accepted. 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 your recovery, or your child's 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 INFORMATION?

During this study, the researchers and other staff will keep records of information about you and your child. This includes information gathered during interviews, weekly logs, analysis of video recordings and questionnaires. We will also collect information on how often and for

how long you used the website. You 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 or your child (e.g., name, date of birth, address). The following groups may have access to your identifiable information, or your child's identifiable information:

Associate Professor (A/Prof.) Laurie McLay (Principal Investigator, University of Canterbury)

Dr Lisa Emerson (Associate Investigator, University of Canterbury)

Dr Hannah Waddington (Associate Investigator, Victoria University of Wellington)

Dr Jenna van Deurs (Child and Family Psychologist, University of Canterbury)

Dr Jolene Hunter (Child and Family Psychologist, University of Canterbury)

Emeritus Prof Neville Blampied (Project Advisor, University of Canterbury)

Aaron Hāpuku (Associate Investigator, University of Canterbury)

Post-graduate research students identified for this project

Research assistants identified for this project

Child and family psychology interns or registered psychologists

Ethics committees or government agencies from New Zealand, if the study or site is audited.

Audits are done to make sure that participants are protected, that the study is run properly, and the data collected is correct.

Rarely, it may be necessary for A/Prof. McLay to share your information, or your child's information, with other people – for example, if there is a serious threat to safety, or to the life or health of you, your child, or another person, or if the information is required in certain legal situations.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you or your child will not be included in any report generated by the researchers. Instead, you and your child will be identified by a code. A/Prof. McLay will keep a list linking your code

with your name, so that you can be identified by your coded data if needed. The list will be stored in a password protected computer. Only the people named above (under 'Identifiable Information') will have access to this list.

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

Future Research Using Your Information

If you agree, your coded information may be used for future research related to autism and/or the wellbeing of caregivers of autistic children.

You will not get reports or other information about any future research that is done using your information.

Your de-identified information (and your child's) may be used for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information or withdraw consent for its use once your information has been shared for future research.

Security and Storage of Your Information

Your identifiable information will be stored for 10 years after the youngest participant in the study has turned 16 years old. It will be stored on a secure, personal device. This storage is password protected. Your coded information will be in a secure electronic online database. This database is also password protected. Information collected on paper (e.g., questionnaires) will be stored in a locked filing cabinet in a secure office at the University of Canterbury and will be destroyed after being coded and saved in the secure password-protected online database. Only the people named above (under 'Identifiable Information') will have access to the storage and database passwords. A/Prof. McLay will keep all your password protected coded information for 10 years after the youngest participant has turned 16 years old. All storage will comply with local and international data security guidelines.

Risks

We will make every effort to protect your privacy and that of your child. However, we cannot guarantee absolute confidentiality of your information. Even with coded and anonymised information there is no guarantee that you or your child cannot be identified.

Please note that other caregivers in the small group coaching sessions will have access to any identifying information that is provided by you during the sessions or in the online discussion forum. However, we ask that anything which is said at the meetings or online is kept confidential. There will be up to eight caregivers in total in your group.

Rights to Access Your Information

You have the right to request access to information held by the research team about you and your child. You also have the right to request that any information you disagree with be corrected.

If you have any questions about the collection and use of information about you or your child, you should ask A/Prof. McLay.

Rights to Withdraw Your Information

You may withdraw your consent for the collection and use of your information at any time, by informing A/Prof. McLay.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until you withdraw from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw unless you withdraw after the study analyses have been undertaken. Once we start analysing data, it may not be possible to delete your information.

Ownership Rights

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to the lead research investigators. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

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

If you change your mind about being in the study, you will need to talk to A/Prof. McLay. You do not have to give a reason for not wanting to stay in the study. You can simply tell her that you would like to withdraw. A/Prof. McLay may be able to give you information about alternative services that could help you or your child. You can also contact the research team again in the future if you wish though there is no guarantee that you will be able to be included in the study at this point.

CAN I FIND OUT THE RESULTS OF THE STUDY?

You can ask to get results of the study. When we publish the results, we will send you a summary in plain English. You can choose to get the results even if you leave the study without finishing it.

WHO HAS APPROVED THE STUDY?

An independent group of people called a Health and Disability Ethics Committee (HDEC) approved this study. HDEC check that studies meet current ethical standards.

WHO IS FUNDING THE STUDY?

The study is being co-funded by *Cure Kids* and *A Better Start E Tipu e Rea: National Science Challenge* (<https://curekids.org.nz/latest-grants/a-better-start-2021-successful-projects/>).

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:

A/Prof. Laurie McLay (Principal Investigator)

(03) 369 3522

laurie.mclay@canterbury.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

Email: advocacy@advocacy.org.nz

Fax: 0800 2 SUPPORT (0800 2787 7678)

Website: <https://www.advocacy.org.nz/>

For Māori health support please contact:

Te Puawaitanga Ki Ōtautahi Trust

(03) 344 5062 or 0800 66 99 57

Email: reception@omwwl.maori.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study:

Phone: 0800 4 ETHIC

Email: hdecs@health.govt.nz



Consent Form: Parent/Caregivers/Guardians

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Lead Researcher: A/Prof. Laurie McLay

Study Site: University of Canterbury

Contact phone number: (03) 369-3522

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Please tick to indicate that you consent to the following

- I have read or have had read to me the Participant Information Sheet. I understand it.
- I had enough time to decide whether to take part in this study.
- I had the opportunity to use resources to help me ask questions and understand the study (these resources may have been a lawyer, whānau/family support, or friend).
- I am satisfied with the answers I received regarding the study. I have a copy of this consent form and information sheet.
- I understand that taking part in this study is my choice. I may withdraw from the study at any time, and it will not affect my child's medical care.
- I understand that I will be randomly assigned to receive support from one of three groups, either the: (1) Play to Learn programme; (2) ACTION in Caregiving programme; or the (3) Play to Learn + ACTION in Caregiving programme. I understand that it is not possible to choose my group or to receive support from a different group other than the one I have been randomly assigned to.
- I give permission to the research staff to collect and process the information I give them. This includes information I give them about my child's health.
- I give permission to the research staff to collect and analyse data according to whether I identify as autistic or not
- I give permission for audio-visual recordings of my child and I (e.g., during play interactions) to be collected and processed by research staff.

- I give permission for audio-visual recordings of the group coaching sessions to be collected and processed by research staff.
- I understand that my part in this study is private. No material that can identify my child or I will be used in any reports on this study.
- I know whom to contact if I have any questions about the study in general.
- I understand my responsibilities as a study participant.
- The research team may contact me after I complete the study to gather additional information. Yes No
- If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. Yes No
- I agree to have my coded information, or that related to my child, used in future related research (e.g., research about children's social communication or caregiver wellbeing). Yes No
- I agree to have my coded information, or that of my child, used in future research not connected to this study. Yes No
- I would like to receive a summary of the study results. Yes No

Declaration by participant:

I hereby consent to take part in this study.

Participant's name.....

Signature..... Date.....

Declaration by member of the research team:

I have given 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.....