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Cleft Clinic Pilot
Information Sheet for participants – Parent Information Sheet

Kia ora,

You and/or your child (referred to from here on simply as 'you') are invited to participate in a research study which aims to understand the impact that receiving or not receiving Clinical Psychology services has on patient-reported quality of life. This study is being conducted by Kenny Ardouin from the University of Canterbury l Te Whare Wānanga o Waitaha. Other research team members include Phoebe Macrae (Senior Supervisor & Speech Language Therapist, University of Canterbury), Tika Ormond (Speech Language Therapist, University of Canterbury) and Nicola Stock (Psychologist, University of the West of England). The study is being carried out as a requirement for a Doctor of Philosophy degree (PhD).

What is the purpose of this research?

This research aims to determine if people feel differently about themselves after receiving speech language therapy treatment for cleft, and whether people who also receive psychology treatment at the same time report feeling more different about themselves than people who just receive speech language therapy. The information from this study will help to decide whether routine access to Clinical Psychology alongside existing cleft care should or should not be offered to all patients with cleft in the future.

Why have you received this invitation?

You are invited to participate in this research because you have requested to receive speech language therapy services due to cleft-related speech differences.

Your participation in the study is voluntary (your choice). If you (or your child) decide not to participate in the study, there are no consequences. Your decision will not affect your relationship with me, the University of Canterbury, any member of the research team, or your cleft team.

What is involved in participating?

Attending the clinic

If you choose to take part in this research, you will be assigned into one of two groups. Assignment into groups will be done by the research team in a way that ensures there are similar demographics in each group, not by estimating clinical need. If you are placed into group A, you will only receive Speech Language Therapy while at the University of Canterbury clinic. If you are placed into group B, you will also receive Clinical Psychology appointments while at the University of Canterbury clinic. **Please note:** our ability to assess the services is reliant on people attending. We respectfully ask, if you are assigned to group B, that you attend the Clinical Psychology appointments even if you don't feel that you need to. If you do not wish to make this commitment, you may instead opt to continue receiving your existing clinical care through the Christchurch Hospital cleft team. Please feel free to discuss this with the research team who will be happy to answer any questions you may have. If you are in group B, you will receive both appointments on the same day, so you will not need to make additional trips to the clinic. There is no cost to you for the speech language and/or clinical psychology services that you receive. Please note that both Speech Language Therapy and Clinical Psychology treatment may be provided by student clinicians. In all cases, you or your child's care will be supervised at all times by a fully qualified clinician. As is the case with all University clinics, students will be evaluated on their clinical skills through observations and feedback from their Clinical Educators. Depending on your clinical need, you will be seen for 6-8 Speech Language Therapy sessions (up to 50 minutes each). If you are enrolled in group B, you will also be seen for the same number of Clinical Psychology sessions (up to 50 minutes each).

If you are enrolled in Group B, you will receive Clinical Psychology services that are commonly used internationally with people with cleft. These therapy techniques explore how you, and your family, think and feel about your speech and appearance, and use strategies that you might have heard of such as Cognitive Behavioural Therapy (CBT) and Acceptance and Commitment Therapy (ACT) to help address any unhelpful thoughts or beliefs that people may have about themselves. These techniques have been found to work well overseas for people and their whānau living with cleft.

Short online surveys

For both groups, you will be asked to complete a short online survey before the first session, before the fourth session, at the end of the last session on one of the clinic iPads (or on your own device if you prefer), and 12 weeks after the last session (the link to the final survey will be sent to your registered email address from the clinical admin team). If you were in Group B, you will also be asked to complete the survey 6 months after you leave the clinic. The survey involves answering a series of statements and stating how much you agree or disagree with the statement. The statements ask how you (the person receiving treatment) feel about your speech, social life, and life more generally (for example, "I feel confident", "I feel good about how I look", "It's okay when people look at my face", "I feel nervous when I speak", "I need to try hard to speak well" etc.). There are no right or wrong answers. Completing the survey should take around 5-10 minutes. You will complete the same survey each time, although your answers might change at different points in time – this is normal. Your treating team at the University of Canterbury will be able to see your answers to use this information to help treat you. The research team however will not be able to see your individual answers or identify you in any way.

Exit interview and access to clinical notes

At the end of your treatment within the clinic, we would like to do a short (less than 15 minute) exit interview with you to better understand your experiences at the clinic – these will be conducted by Kenny Ardouin (a member of the research team, but not part of your treatment team). The interview is optional and can be conducted either in person or over the phone. At the end of your treatment, the research team would also like to access your clinical notes (from the cleft clinic at UC only; not your hospital notes) to review the clinical goals that were set for you to better understand the needs of the cleft community. You will be given this information sheet again, and a consent form at the end of your treatment where you can decide whether to participate in the exit interview and/or to share your clinical notes with us. If you choose not to participate in the interview or provide your clinical notes, this will not affect your treatment at the clinic. Everything that you choose to share with us will be kept confidential and will not identify you in any way.

Are there any potential benefits from taking part in this research?

A benefit is that you will receive Speech Language Therapy and/or Clinical Psychology assessment and/or treatment services free of charge for the duration of the clinic. Your involvement in this study also will result in recommendations for improving cleft care in New Zealand which ultimately will benefit the cleft community, of which you are a member.

Are there any potential risks involved in this research?

Some questions ask you to reflect how you currently feel about appearance, speech, school life and social life. This may cause some participants to become upset or distressed. If you (or your child) becomes upset or distressed we recommend you/they stop and talk to one of the treating team. You may also want to consider contacting one of the support agencies listed below.

Support Agency	**Contact Information**
Cleft New Zealand	Phone: 0800 425 338, or www.cleft.org.nz
Youthline	Phone: 0800 376 633, free text 234, or www.youthline.org.nz

Please note: If you are assigned to group A (Speech Language Therapy only), you will have the option to access Clinical Psychology services at the completion of the study. There will be no cost to you for this, and there will be no requirement for you to do so if you don't want to. This service will be offered to you 3 months after you complete your SLT treatment (once you have completed your post-treatment survey). If you do access Clinical Psychology, you will also be asked to complete a survey at the end of your Clinical Psychology treatment.

Just to let you know, the student clinicians providing treatment to you will also be interviewed at the end of the clinic to understand the impact of the pilot clinic from a clinician's perspective. They will not discuss your case specifically or identify you (or your child) in any way, but they may speak generally about the clinic.

What if you change your mind during or after the study?

Short online surveys

You are free to withdraw at any time. To do this, simply close your browser window or the application (App) the survey is presented on. Any information you have entered up to that point will be deleted from the data set. If you have already submitted the data and wish to have it removed, please email kenny.ardouin@pg.canterbury.ac.nz with your participant code, and ask for your data to be removed. Please note: once data analysis begins in October 2023, it may no longer be possible to remove your individual data. **Please also notify the Clinical Admin team and/or your treatment team if you wish to withdraw from the study.** Withdrawing from the study will not impact your treatment, however it is important for the clinical team to know if you no longer wish to participate so that you are not sent future surveys.

Exit interview and/or access to clinical notes

Participating in an interview or providing access to your clinical notes are optional and you can choose to discontinue the interview at any time. To do this, simply let the interviewer know that you no longer wish to participate. If you have already participated in the interview or granted access to your clinical notes and wish to revoke access, please email kenny.ardouin@pg.canterbury.ac.nz and ask for your data to be removed. Please note: once data analysis begins in October 2023, it may no longer be possible to remove your individual data as it will have been anonymised and mixed with other participants' data.

What will happen to the information you provide?

All data will be anonymous to the research team. We will not be able to identify you or link your identity with any responses you provide (unless you provide us with your participant code for the sole purpose of deleting your data from the study). All data will be stored on the University of Canterbury's computer network in password-protected files.

All survey data will be destroyed 10 years after completion of the study/publication of study findings. Your health information related specifically to your treatment (such as clinical notes) that is kept in your medical file will not automatically be destroyed. I will be responsible for making sure that only members of the research team use your data for the purposes mentioned in this information sheet.

Will the results of the study be published?

The results of this research will be published in a Doctoral thesis. This thesis will be available to the general public through the UC library. Results may be published in peer-reviewed, academic journals. Results will also be presented during conferences or seminars to wider professional and academic communities. You will not be identifiable in any publication.

I will send a summary of the research to you at the end of the study, if you request this. If you provide an email address for this purpose, it will not be linked with your survey responses.

Who can I contact if I have any questions or concerns?
If you have any questions about the research, please contact: Kenny Ardouin: kenny.ardouin@pg.canterbury.ac.nz; or for any concerns, please contact Phoebe Macrae: phoebe.macrae@canterbury.ac.nz.

This study has been reviewed and approved by the University of Canterbury Human Research Ethics Committee (HREC). If you have concerns or complaints about this research, please contact the Chair of the HREC at human-ethics@canterbury.ac.nz .

What happens next?
Please read the following statement of consent and start the survey.

Statement of consent

I have read and understood the above study information and wish to participate in this study. By completing the survey and submitting my responses, I consent to my/my child's participation in the study.

When completing the survey online, you will be asked to please select the appropriate box(es) below

- ☐ I am aged 18 or over and I consent to participate in this study; OR
- ☐ I have discussed the study with my child who is aged under 18, and I consent to them participating in the study. I understand that my child will also be asked for their own assent to participate, in addition to my consent on their behalf. I have reminded them that they can decide at any time that they no longer wish to participate.

When you become eligible to participate in an exit interview and/or release your clinical notes to the research team, you'll be asked to complete and return the attached consent form.