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| **Exploring the impact of animal assisted therapy for preschool children with speech and language delay** |
| The research is being carried out in partial fulfilment of a Masters degree under the supervision of Professor Pauleen Bennett and Dr. Tanya Serry. The following researchers will be conducting the study: |
| **Role** | **Name** | **Organisation** |
| Student | Cheye Paoli | La Trobe University |
| **Research funder** | This research is supported by in kind support by La Trobe University. |

1. **What is the study about?**

This is an invitation for you to consider whether your child might take part in a study. The study is about examining the effect of therapy dogs in the treatment of speech and language delay in preschool children. We hope to learn whether the presence of the animal has a positive impact on communicative behaviours in young children.

Your contact details were obtained from Gippsland Lakes Community Health after you had a discussion with the speech pathologist Lyn Nicol about this trial and gave her your permission to pass on your details.

1. **Does my child have to participate?**

Being part of this study is voluntary. We ask that you discuss the study with your child when you are deciding if you want your child to take part. If you decide together for your child to be part of the study we ask that you read this information carefully and ask us any questions.

If you decide together you do not want your child to take part this won’t affect the speech therapy treatment your child is currently receiving or will receive. This decision also won’t affect your relationship with Gippsland Lakes Community Health or La Trobe University. You can read the information below and decide at the end if you do not want your child to take part.

1. **Who is being asked to participate?**

Your child has been asked to participate because:

* Your child is within the age range being studied (over three years of age and currently in preschool)
* Your child has been identified as having a delay in speech and/or language
* Your child has no stated fears, aversions or allergies to dogs, as discussed in your initial consultation with the speech pathologist
1. **What will my child be asked to do?**

If you and your child both want to take part in this study, we will ask you both to attend weekly, video-recorded sessions at Gippsland Lakes Community Health for one-to-one sessions with a qualified speech pathologist (the student researcher, Cheye Paoli) alongside a certified therapy dog that belongs to Cheye Paoli. Your child will be asked to participate in various play-based speech therapy activities using best-practice treatments. Your child will also be asked to complete regular home practice tasks aimed at optimising and maintaining improvements made during these sessions. It will take a maximum of 1 hour a week for 10 weeks, plus 15 minutes daily practice at home of your child’s time to be part of this study. We require you to be present at all sessions with the speech pathologist.

 Your child will receive 10 weekly sessions of speech therapy. 5 of these sessions will be with a therapy dog present, and 5 will be without. The dog might be in the first five weeks, of the second five weeks of the treatment block.

1. **What are the benefits?**

The purpose of the trial is to see what, if any, impact the therapy dog has on your childs’ motivation, enjoyment and engagement with speech pathology activities with the hope that it will have a positive effect on these areas.

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The expected benefits to society in general are to better understand what the relationship is between therapy dogs and speech and language skills in preschool children. If this intervention is shown to be effective, we may be able to offer a valuable alternative to standard speech pathology intervention for children with language delay.

1. **What are the risks?**

With any treatment there are (1) risks we know about, (2) risks we don’t know about, and (3) risks we don’t expect. We don’t expect there to be any risks associated with your child being involved in this study, because of the lengthy training and assessment of the dogs involved, and the experience of the speech pathologist. Both therapy dogs have had therapy dog training and certification through Lead the Way Institute, which assessed their temperament, obedience and willingness to work well with a variety of clients including children and older people. Both dogs have had experience since then working directly with children with additional needs. The student researcher, Cheye Paoli, has owned both dogs for over 6 years and has had several years’ experience working in animal-assisted interventions with her dogs. Furthermore, both dogs have passed veterinary screening to ensure they are fit and well to work with your child.

If your child experiences something that you or your child aren’t sure about, please contact us immediately so we can discuss the best way to manage your concerns.

1. **Will we be paid to be part of this study?**

You will not be paid to participate in this study. As you will be accessing fully qualified speech pathology services at Gippsland Lakes Community Health, you will continue to pay for your child’s sessions at the cost determined by the service access team.

1. **What will happen to information about my child?**

We will collect and store information about your child in ways that only we will know who your child is. Any information that reveals your child’s identity will be kept confidential, and will only be disclosed with your permission, unless we are required by law to reveal this information. The Human Research Ethics Committee, monitors and regulatory bodies may also access information about your child, if possible, these people will not know who your child is.

With your permission, information gained from this trial might be used in future related studies, only by members of this research team.

The way we store and find out the results of the study means your child cannot be identified in any type of publication from this study.

We will keep your child’s information for 25 years after their date of birth, however this information will be de-identified. After this time we will destroy all of your child’s data.

We will collect, store and destroy your child’s data in accordance with La Trobe Universities Research Data Management Policy which can be viewed online using the following link: <https://policies.latrobe.edu.au/document/view.php?id=106/>.

The information you and your child provide is personal information for the purposes of the Privacy and Date Protection Act 2014 (Vic). You and your child have the right to access personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the Information Privacy Act.

1. **Will we hear about the results of the study?**

We will let you know about the results of the study by email and you will be provided with a copy of the research article, if you express interest in receiving this. Please advise the student researcher if you would like to learn of the results of the study by ticking the box on the consent form below.

1. **What if we change our minds?**

At any time you or your child can choose to no longer be part of the study.

You can let us know by:

1. Completing the ‘Withdrawal of Consent Form’ (provided at the end of this document);
2. Calling us;
3. Emailing us

Your or your child’s decision to withdraw at any point will **not** affect your relationship with Gippsland Lakes Community Health or La Trobe University. Therapy will still be provided as usual for your child without any negative consequences or delay in treatment (unless due to circumstances outside of GLCH control ),

Should you wish to withdraw your child’s data once it has been collected, please contact us within 4 weeks of completing the treatment block.

1. **What happens if the study needs to be stopped?**

The study may be stopped if we find out:

* The risks from side effects outweigh any benefits to your child;
* The treatment you are receiving doesn’t give you any benefits
1. **What happens when the study ends?**

When the study ends you will be offered to continue with speech pathology services at Gippsland Lakes Community Health to receive ongoing support for you and your child. If you and your child feel that you have made adequate gains during the course of the study, you may be discharged from Gippsland Lakes Community Heath if that is your wish.

1. **What happens if you find out new information about the study?**

To ensure your child’s safety we will make sure we look at the information we collect about this study. This may mean that we find out new information that you and your child should know about. If this happens we will contact you and discuss what it means for your child. New information may mean that we recommend your child withdraw from the study, or that you and your child may choose to withdraw.

1. **Who can we contact for questions or want more information?**

If you or your child would like to speak to us, please use the contact details below:

| **Name/Organisation** | **Position** | **Telephone** | **Email** |
| --- | --- | --- | --- |
| Cheye Paoli (La Trobe University) | Student researcher/Speech pathologist | 03 51558370 (Gippsland Lakes Community Health) | 16111055@students.latrobe.edu.au |

1. **What if we have a complaint?**

If you or your child have a complaint about any part of this study, please contact:

| **Ethics Reference Number** | **Position** | **Telephone** | **Email** |
| --- | --- | --- | --- |
| [INSERT - Ethics Number] | Senior Research Ethics Officer | 03 9479 1443 | humanethics@latrobe.edu.au  |

**Consent Form – Declaration by Parent/Guardian**

I (the parent/guardian) have read (or, where appropriate, have had read to me) and understood the parent/guardian information statement, and any questions have been answered to my satisfaction. I understand I am being asked to provide consent for my child to be part of this study. I agree for my child to participate in the study, I know either myself or my child can withdraw at any time. I agree information provided by my child or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that my child cannot be identified.

[ ]  I give permission for my child’s doctors and allied health professionals to release information concerning my child’s health and treatment for the purposes of this study. I understand this information will remain confidential.

[ ]  I give permission for my child to be video and audio recorded during the study

[ ]  I would like to receive a summary of the research findings

**I would like my child’s information collected for this research study to be:**

[ ]  Only used for this specific study (up until my child turns 18, and then they will be asked for their own consent);

[ ]  Used for future related studies (up until my child turns 18, and then they will be asked for their own consent);

**Parent/Guardian Signature**

**[ ]** I have received a signed copy of the Parent/Guardian Information Statement to keep

**[ ]** I have discussed the study with my child and through these discussions they have shown to me they want to be part of the study.

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| --- | --- |
| Parent/Guardian printed name |  |
| Parent/Guardian signature |  |
| Date |  |
| EMAIL (if requesting a summary of findings |  |

**Witness Signature**

[ ]  I have been present for the entire discussion about this study

[ ]  I confirm all written information was accurately explained, and apparently understood by the participant or their legal representative and informed consent was given freely and without coercion.

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| Witness’ printed name |  |
| Witness’ signature |  |
| Date |  |

**Declaration by Researcher**

[ ]  I have given a verbal explanation of the study, what it involves, and the risks and I believe the participant has understood;

[ ]  I am a person qualified to explain the study, the risks and answer questions

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| Researcher’s printed name |  |
| Researcher’s signature |  |
| Date |  |

\* All parties must sign and date their own signature

**Withdrawal of Consent**

I wish to withdraw my consent for my child to participate in this study. I understand withdrawal will not affect my or my child’s relationship with Gippsland Lakes Community Health or La Trobe University. I understand my child’s information will be withdrawn as outlined below:

 I understand my information will be withdrawn as outlined below:

* Any identifiable information about my child will be withdrawn from the study
* The researchers will withdraw my contact details and my child’s contact details so we cannot be contacted by them in the future.

I would like my child’s already collected and unanalysed data

[ ]  Destroyed and not used for any analysis

[ ]  Used for analysis

**Parent/Guardian Signature**

|  |  |
| --- | --- |
| Parent/Guardian printed name |  |
| Parent/Guardian signature |  |
| Date |  |

**Please forward this form to:**

|  |  |
| --- | --- |
| CI Name |  |
| Email | [INSERT - work email address] |
| Phone | [INSERT - work phone] |
| Postal Address | [INSERT - work postal address] |