

PROJECT INVESTIGATOR:

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The ECU Late-Talking Study: Information Sheet

Research Ethics Approval Number: 2021-02166-MELDRUM

A parent-administered cross-situational statistically based word learning treatment
for children with late language emergence.

Dear Parent/Guardian,

You and your child are invited to participate in a research project examining the effectiveness of a new speech therapy method for teaching vocabulary to 1.5-3-year-old children.

What is the purpose of the study?

Up to 13% of children do not acquire language at the same rate as other children, and around half of these children will not 'grow out' of this condition. Current speech pathology therapy can take a long time (>8 weeks of therapy). Research has found that a new therapy method may be effective, but it needs to be administered by Speech Pathologists. We want to test if parents can be trained in a group to do this therapy at home. Two ECU final year speech therapy students will do the training with you and your child in a group with three other families under the supervision of Dr. Suzanne Meldrum, a Speech Pathologist and Lecturer at ECU.

Do I have to take part?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you do decide to take part, you will be given this Participation Information letter and a Consent Form to sign and you will be given a copy to keep.

What will I have to do if I decide to take part?

If you are interested in participating in this study, first you will fill in two forms about your child. The first form asks about your child's language, family, and medical background. The second form asks which words your child understands or says (it is called the OZI Australian English Communicative Development Inventory) and the form take about 30 minutes to fill in. You will then send these two forms and the consent form (see the next page) back to Suzanne Meldrum at ECU. You will be consenting on behalf of yourself and your child.

We will score the vocabulary form and if your child's score shows that he or she is slower at learning to talk than other children, and meets other eligibility criteria (is not preterm, has no hearing loss or other developmental disability) will telephone you to organize the clinical visits which will all take place at ECU Joondalup, at the School of Medical and Health Sciences.

They consist of:

1. An assessment and initial training session.

At this visit we will ask you about your child's language and you will complete another OZI vocabulary survey. We will also make a video of your child playing with you and the speech therapy student. We use the video to write down all the words that your child says. This will take around 45 minutes to complete. You will then receive individual training in how to deliver the speech pathology treatment at home. We will give demonstrations, written instructions and you will be given opportunities to practice with your child. This will take around 45 minutes to complete, making the whole session around 1.5 hours long.

2. Eight weekly group training sessions.

Every week you will come to the clinic and receive group training with your child and three other families. We will demonstrate how to complete the intervention at home, and give you new materials and ideas. We will also ask your child to say some words, you will let us know if they have acquired any new words. This will take around one hour.

3. At home intervention.

You will be asked to do the intervention at home, twice per week for 30 minutes. We will ask you to keep a record of when you do the treatment, and how you found the experience.

4. Two video recording sessions

After two of the group training sessions, we will ask you to stay and administer the treatment to your child at ECU. We will videotape this, and see if we have been successful in training you to complete the intervention.

5. Final assessment

After the 8 weeks of training, we will do another assessment, where we ask you about your child's language and you will complete another OZI vocabulary survey. We will also make a video of your child playing with you and the speech therapy student. We use the video to write down all the words that your child says. This will take around 45 minutes to complete.

What if we are not eligible?

If your child is not eligible for the study, your child's data will be destroyed and not used for any future research purposes. If we score your child's vocabulary form and it does not show that he or she is slower at learning to talk than other children, but you are still concerned for their language development, we will provide you with information about local Speech Pathologists for you to contact.

What should I consider?

You should consider if you have the time and ability to bring your child to the training each week and complete therapy at home twice per week for 30 minutes. We ask you not to participate in other speech therapy services or provide your child with additional speech therapy intervention for the duration of the study.

Are there any possible disadvantages or risks from taking part?

You may become more concerned about your child's language development by focusing your attention on it. Study investigators are trained Speech Pathologists and can talk to you about these concerns. A list of external counsellors will be provided if needed. The group training component may be found challenging for both parents and children due to interacting and learning with other people. Every effort will be made to ensure that both children and parents feel comfortable and supported, and you are free to withdraw at any time.

Will our taking part in the study be kept confidential?

The research records (including video footage) will only be seen by members of the research team. In future when publishing the results of the study, we will not be describing individual results, but rather the overall findings, and no identifying information will be included in any publications.

What will happen to my data?

Parents and/or guardians have the right to review and erase the records at any time. A number will be given to your child's data and children's names will never be used in any reports. All forms and video records will be stored in an anonymous form on USB disks with encryption in a locked cupboard in Dr Meldrum's locked office, with access only given to research personnel.

Your data may be used for additional research analyses in the field of late language emergence only. Access to this data may be undertaken by Dr Meldrum or her collaborators and/or undergraduate or postgraduate students. Your data will remain anonymous at all times.

All information, including those containing names and numbers will be disposed when your child reaches 25 years of age, as per the Western Australian University Sector Disposal Authority (WAUSDA).

What will happen to the results of this study?

We plan to publish our findings at conferences and in scientific journals. You will receive a letter or email (whichever you prefer) detailing the results of the study, and you are free to contact us if you would like more information.

What will happen if I don't want to carry on with the study?

Participation is entirely voluntary, and all information obtained will be used for research purpose only. Participants can withdraw from the study at any time without any negative consequences. If you decide to withdraw from the study, please notify a member of the research team before you withdraw. If you withdraw from the study, unless otherwise stated, any data which has been collected whilst you have been in the study will be used for research as detailed in this information sheet. You are free to request that your data is destroyed at any time during or after the study.

Who is organizing and funding the study?

This project is an ECU study which has been approved by the ECU Human Research

Ethics Committee. Funding has not been obtained to conduct this research from any party.

Who has reviewed the study?

This project has been approved by the ECU Human Research Ethics Committee (reference number XXXX).

Participation in future research?

You will be asked if you want your name and details to be kept for future participation in research within Speech Pathology at ECU. This information will not be provided or sold to any third parties.

Further information and contact details?

If you want to join the study or have any questions about the research, *please contact Dr Suzanne Meldrum (+61 8 6304 5101; s.meldrum@ecu.edu.au)*.

If you want to know more about your rights as a research participant, or you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

Research Ethics Officer
Edith Cowan University
270 Joondalup Drive
JOONDALUP WA 6027
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Your help is very much appreciated.

Yours sincerely,

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