

Participant Information Sheet and Assent Form Adolescent (under 16 years)- Providing Assent

Sponsor:	Auckland University of Technology		
Name and address:	90 Akoranga Drive, Northcote, Auckland		
Lead investigator:	Dr Nusrtnaaz Shaikh	Ethics committee ref:	2024 Full 15231 (Northern A. HDEC)
	+64 (9) 921 999 ext (5252)		

An Invitation

Kia ora, talofa lava, mālō e lelei, fakalofa atu, kia orana, ni hao, hello.

You are invited to take part in a study to see how practical and acceptable (feasible) it is to deliver a very early developmental program called the *NEOgrads playgroup* to 3-month-old babies/ pēpē. It is entirely your choice if you and your baby / pēpē take part in this study. If you do not want to take part, you do not have to give a reason. If you do want to take part now, you can change your mind and pull out of the study at any time.

This Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your involvement will be, what the benefits and risks to you and your baby/ pēpē, and what would happen after the study ends. We will go through this information with you and answer any questions you might have. You do not have to decide today whether or not to participate in this study. Before you decide you may want to talk about the study with other people such as family, whānau, friends, or healthcare providers. Please feel free to do this.

If you agree to take part in this study, you will be asked to sign the Assent Form on page 8 of this document. You will be given a copy of both the Participation Information Sheet and the Consent Form to keep.

Why are we doing this research?

Movement development occurs rapidly from birth and provides babies/pēpē's with the ability to interact and explore their new environment. We know that some babies/pēpē's that are born early find this more challenging and may benefit from Early Intervention (therapy to encourage movement) when they start to fall behind. To learn new movement skills, therapists use repetition of practice at the right level of difficulty, and this can help to promote the nerve pathways (neurological networks) and build muscle strength. Each new skill that a baby/ pēpē learns provides them with the building blocks for learning more movement skills, such as learning to crawl or walk.

We know that we can help support and teach early movement skills to babies/ pēpē who are born preterm however, we do not know if providing a guided program (NEOgrads playgroup) at a very young age is suitable for our families/whānau in Aotearoa New Zealand

(AoNZ). This study will research how feasible the NEOgrads playgroup intervention is through family/ whānau acceptability, attendance, and participation in the program.

This study has been approved by the Northern A Health and Disability Ethics Committee New Zealand.

How do I agree to participate in this research?

It is important that you please read this information and discuss it with your whānau and friends. If you have any questions, please let us know. If you are happy for you and your baby/ pēpē to participate, please sign and date the Informed Assent Form at the end of this study information. We will also need your parent or guardian to provide informed written consent by completing the Parental/ Guardian Consent Form.

It is completely your choice if you and your baby/ pēpē participate. If you don't want to take part you do not have to give a reason, it won't affect any of the care you receive. If you agree to take part now, and change your mind, you can stop at any time. If you stop, we will not do any further tests or record any more information about your baby/ pēpē. But the information collected about you and your baby/ pēpē in till this point will continue to be used.

What will happen in this research?

Before we can start, we will ask you to complete a brief screening assessment about your baby's / pēpē's delivery and health to determine if the study is best suited to your baby / pēpē.

We will also need you to complete a consent form before starting the study.

There are three parts to this study:

1. Pre- Intervention assessment (infants age; 12 weeks corrected age)
2. NEOgrads Playgroup Intervention 12-week program
 - a. Playgroup class, 30-minutes, once per week developmental group class
 - b. Personalised developmental home exercise program (daily practice)
3. Post- Intervention assessment (infants age; 6.5 months corrected age)

All infants who are eligible to be involved will receive the intervention.

The main things that involved in this study are:

You and your baby/ pēpē will be involved in the study for 4-months which will require you to:

- Participating in the **two assessment** visits (around when your baby/ pēpē is about 3 months corrected age, and then again 3 months later at around 6 months corrected age) 45 to 75 minutes to complete.
- Attending **developmental group classes** once weekly, over the 12-week intervention period (30-minute class, once per week, for 12- weeks).
- Practicing the **home exercise program** at least daily (minimum 4 times per week) for a duration of up to 20 minutes over the baby's/ pēpē awake period, per day.

The developmental class and home exercise program will provide play and movement exercises that are specific to promote your baby's/ pēpē's developmental skills. The home program will be designed to be included into you and your baby's/ pēpē's daily care routine and should take no more than 20 minutes each day. The assessments and group classes will be held across Auckland at AUT (Akoranga campus), Auckland Children's Physiotherapy clinic (North Shore), Community centres (across South, Central and West Auckland). You will be placed in a group class that is the closest to your home.

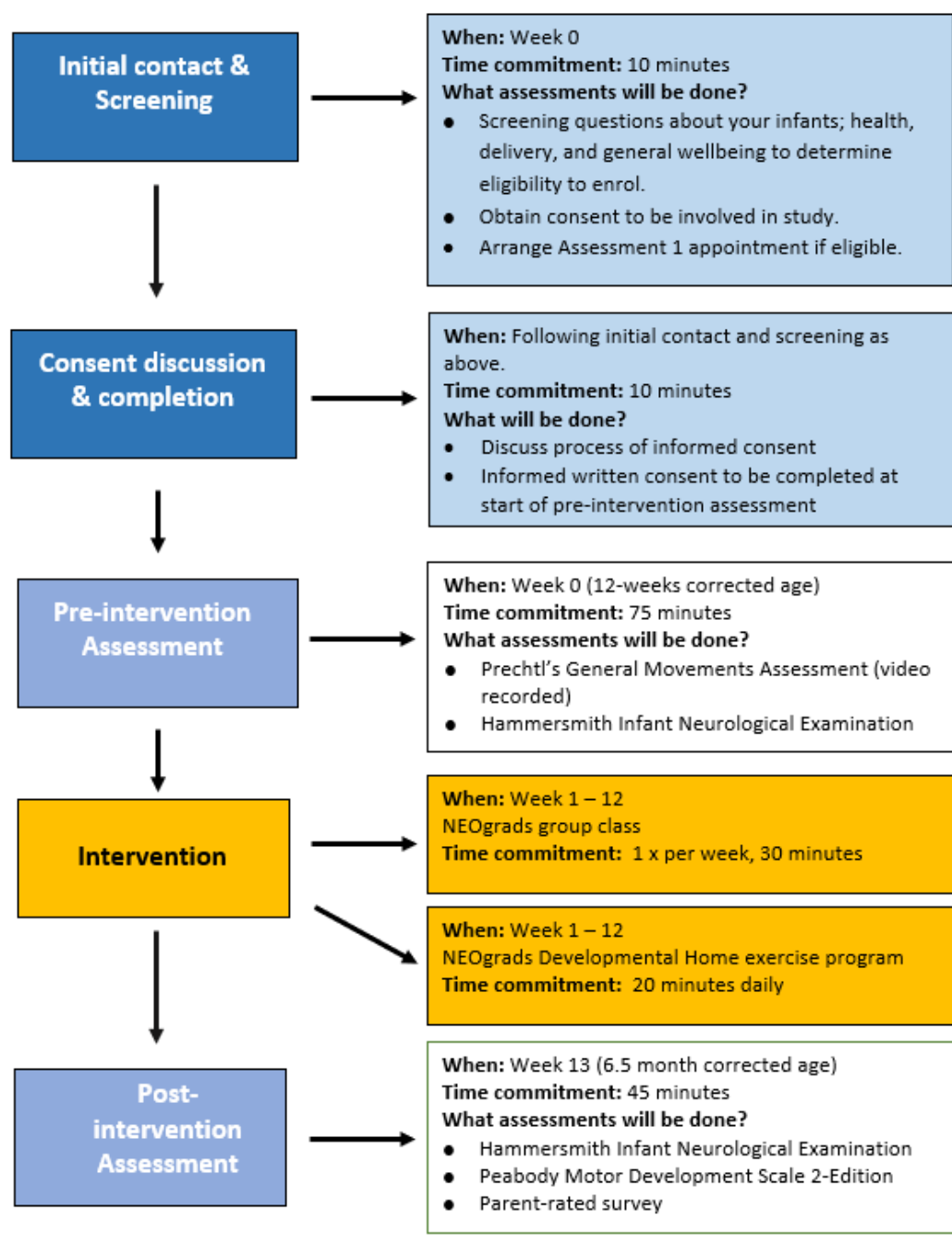
In addition to we will ask you to complete the following:

- Filling out a **daily logbook** of your home exercise program practice,
- Committing to being available for as many of the 12- group class appointments (we will offer a make-up class on an alternate day if possible to account for sickness or other appointments).

During these assessment time points, we will use formal motor development and neurological assessments to gain a greater understand their development stage prior to starting the study and compare this to after the study. We will also ask you to complete a parent rated satisfaction survey at the end of the program (when your baby is 6 months old). We will keep a record of class attendance and how the therapist is running each class ensuring they are following the NEOgrads playgroup class protocol (set way the program is delivered). As part of ensuring that the NEOgrad playgroup classes are being delivered accurately, we will video record the first three weeks of group classes. This may mean that you are video recorded with your baby/ pēpē during this time.

The flowchart of the study protocol can be found below, followed by the details of each assessment.

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Motor Development and neurological assessments

At both assessment appointments we will observe your baby's /pēpē movements and ask you some questions about their motor development. We will use a developmental assessment called the Peabody Motor Development Scale 2nd edition to assess your baby's motor development.

At the first assessment, we will also use two neurodevelopment assessments that are commonly used on babies/ pēpē that are good predictors of future movement skills; Prechtl's General Movements Assessment completed at 3 months only and the Hammersmith Infant Neurological Examination that will be completed at the 3- and 6-month assessments. The Prechtl's General Movements Assessment requires us to take video recording of your baby/ pēpē lying on their back (in their nappy) when awake, calm and alert for 3-5 minutes. The video is reviewed to look for special movements and will be scored by two certified assessors who are part of the research team.

Pre intervention		Assessment / Activity
Initial contact (20 minutes)	Phone screening	<ul style="list-style-type: none"> • Screening questions about your baby's/ pēpē health, delivery, and general wellbeing to determine eligibility to enrol. • Obtain consent to be involved in study. • Arrange Assessment 1 appointment if eligible. • Informed consent discussion to be completed at Assessment 1 time point.
Assessment 1 (75 minutes)	Face to face assessment	<ul style="list-style-type: none"> • Completion of informed signed consent. • Developmental & Neurological Assessments <ul style="list-style-type: none"> ✓ Peabody Motor Development Scale 2nd Edition ✓ Hammersmith Infant Neurological Examination ✓ Prechtl's General Movement Assessment (video recording) • General development questions i.e. preferred play position, preferred sleep position.
Intervention (12- weeks) Face to face and individual practice		NEOgrads playgroup <ul style="list-style-type: none"> • 30 minute weekly developmental classes (1 x per week for 12 weeks) • Daily developmental home exercise program (20 minutes per day, minimum of 4 separate days practice per week). Daily record of home exercise program practice (participant to complete) and class attendance record (therapist complete)
Post intervention		
Assessment 2 (45 minutes)	Face to face assessment	<ul style="list-style-type: none"> • Developmental & neurological Assessments <ul style="list-style-type: none"> ✓ Peabody Motor Development Scale 2nd Edition ✓ Hammersmith Infant Neurological Examination • General development questions i.e. preferred play position, preferred sleep position. • Parent-rated satisfaction scale

What are the discomforts and risks and how will these be managed?

During the hands-on assessments (Peabody Motor Developmental Scale and Hammersmith Infant Neurological Examination), some baby/ pēpē become overwhelmed or tired and will require a short rest or comforting. Our research therapists will be guided by you on how best to sooth and calm your baby. To complete the General Movements video recording, we will require you to undress your baby. We will ensure that the room temperature is comfortable for your baby/ pēpē to be undressed. During the playgroup classes we will also check the room temperature is suitable for all attendee's comfort. If your baby/ pēpē is not able to complete the assessments during the allotted time, we will make arrangements that are convenient to you both to complete the assessment at the next possible time.

What are the benefits?

Participation in this study may not have any benefits for you or your baby/ pēpē, but based on what we have learnt from similar studies, your infant's movement skills might improve and help them meet their developmental milestones for example how well they roll or reach for toys.

The developmental exercises and class may provide new learning experiences and help build your confidence and play skills when interacting with your preterm baby / pēpē. In addition, the group classes may provide you with the opportunity to connect with other family/ whānau of preterm baby's/ pepe.

After the study is completed, you will be given a report of the information collected on your infant's development collected during the study. Information about unexpected findings from your infant's assessments can be provided to their primary health care provider (GP or paediatrician) with your permission.

How will my information be protected?

All information collected about you and your baby/ pepe will be given a study code so your name and your infant's name will not appear anywhere to protect your privacy. We collect information on your infant's birth, play and sleep positions, set, age, general health as well as information about you (name, contact information).

We will keep a separate file on a password protected computer that connects your study code to you and your infant. All paperwork will be stored in a locked cabinet and any electronic information will be password protected on the university secure system. If you require any information or test results specific to your infant, we will provide these to you.

Rights to Access Your Information.

You have the right to request access to your baby/ pēpē information held by the research team. You have the right to request any information that you disagree with is corrected. Please ask if you would like access to your baby/ pēpē results during the assessments. If you have any questions about the collection and use of information about your baby/ pēpē, please ask the coordinating investigator (Dr Naaz Shaikh).

Māori Data Sovereignty.

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with AUT Mātauranga Māori Committee about the collection, ownership and use of study data.
- We allow Māori organisations to access de-identified study data for uses that my benefit Māori.
- Your baby's/ pēpē personal data safety and data sovereignty will be protected through our study.

If you wish to discuss Māori data sovereignty and your baby's/ pēpē data, we welcome you to speak with our research team.

Rights to Withdraw Your Information.

You and your baby's/ pēpē participation in this research is voluntary, it is your choice whether you both take part. You are free to decline to participate, or to withdraw from the research at any practical time, without experiencing any disadvantage to any future participation in research or to any treatment you and your baby may receive. To withdraw from the study please contact Louise Pearce by telephone (0221551677).

What are the costs of participating in this research?

The cost of this study is your and your infants time to attend the two assessments, 12 playgroup classes and daily home exercise program practice. There may be transport cost involved getting to and from the assessments and classes. **As part of our appreciation of your participation you will be compensated by means of a \$50 per assessment and \$75 worth of toys/ equipment to use during practice of the home program (provided at the first playgroup class) that you will be able to keep.**

What do I do if I have concerns about this research?

If you have any concerns about this project, please contact the Project Supervisor Naaz Shaikh, Dr Nurtnaaz Shaikh (preferred name: Naaz)

nshaikh@aut.ac.nz

+649) 921 999 ext (5252)

AUT University

Private Bag 92006

Auckland 1142

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Freephone: 0800 555 050

Email: advocacy@advocacy.org.nz

Website: [https:// www.advocacy.org.nz](https://www.advocacy.org.nz)

For Māori health support please contact:

Simone Skelton

waea pūkoro: 021 840 391

Email: Simone.Skelton@waitematadhb.govt.nz

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

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

NEOgrads Informed Assent Form for Adolescent Parent (under the age of 16 years).

Project title: The *NEOgrads playgroup* program- promoting early motor development for preterm babies.

Project Supervisor: Nusratnaaz Shaikh (Naaz) (09 921 9999 ext 5252)

Co-investigators: Louise Pearce, Sian Williams, Jimmy Chong, Richard Ellis.

- I have read and understood the information sheet telling me what will happen in this study and why it is important.
- I have been able to ask questions and to have them answered.
- I understand that my baby/ pēpē can stop being part of this study whenever I want and that it is perfectly ok for me to do this.
- I understand that I will be offered the choice between having any information that other people know about me or my baby/ pēpē removed or letting the researcher keep using it. I also understand that sometimes, if the results of the research have been written, some information about my baby/ pēpē may not be able to be removed.
- I understand that my baby/ pēpē will be videoed as part of their initial assessments and these will be kept confidential and safe.
- I understand that video recordings will be made during the NEOgrads play group classes to help check how the quality of the sessions being delivered to you and your baby.
- I understand that the videos will be used for academic purposes only and will not be published in any form outside of this project without my written permission.
- I agree for my baby/ pēpē to take part in this research.

Signature (signature of the adolescent parent for baby participant) :

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Name (Adolescent parent of the participant) :

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Parent of the Participant Contact Details (if appropriate):

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Date:

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Approved by Northern A, Health, and Disability Ethics Committee reference 2024 Full 15231. Note: The Participant should retain a copy of this form.