

Participant information sheet and Consent Form - Parent/ Guardian

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

Sponsor:	<i>Auckland University of Technology</i>		
Name and address:	<i>90 Akoranga Drive, Northcote, Auckland</i>		
Lead investigator:	Dr Nusrtnaaz Shaikh	Ethics committee ref:	2024 Full 15231 (Northern A. HDEC)
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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 Participant 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 Consent Form on the last page of this document. You will be given a copy of both the Participation Information Sheet and the Consent Form to keep.

This document is 13 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

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 is being completed as part of a Masters of Health Science research project through Auckland University of Technology (AUT) led by Louise Pearce, who is a Paediatric Physiotherapist. The team also includes Dr Nusratnaaz Shaikh from AUT, who will be her primary supervisor, Associate Professor Dr Richard Ellis from AUT, Dr Sian Williams from the Liggins Institute and Dr Jimmy Chong who is a Paediatric Rehabilitation Consultant from the National Paediatric Rehabilitation Service.

This research is funded by Physiotherapy New Zealand Neurology Special Interest Group, Physiotherapy New Zealand North Shore Branch Special Interest group and Visiting Neurodevelopmental Therapy Association of New Zealand.

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

Why is my baby/ pēpē and I being invited to take part in this study?

You and your baby/ pēpē are being invited to participate because your baby was born moderate to late pre-term (born between 32 to 36 weeks gestation).

To be in the study we are looking for baby's/ pēpē that;

- ✓ Are younger than 12-weeks of age.
- ✓ Live in Auckland and are able to attend the in-person NEOgrads playgroup classes and the two assessments over a 4-month period.
- ✓ Have English-speaking parents/ whānau
- ✓ Have no known genetic or neurological condition that will affect their motor development (i.e., Trisomy 21, cerebral palsy).

What will happen in this research?

Prior to being in the study, 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 from estimated due date of delivery)
2. NEOgrads Playgroup Intervention 12-week exercise 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 from estimated due date of delivery)

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 or West Auckland). You will be placed in a group class that is the closest to your home.

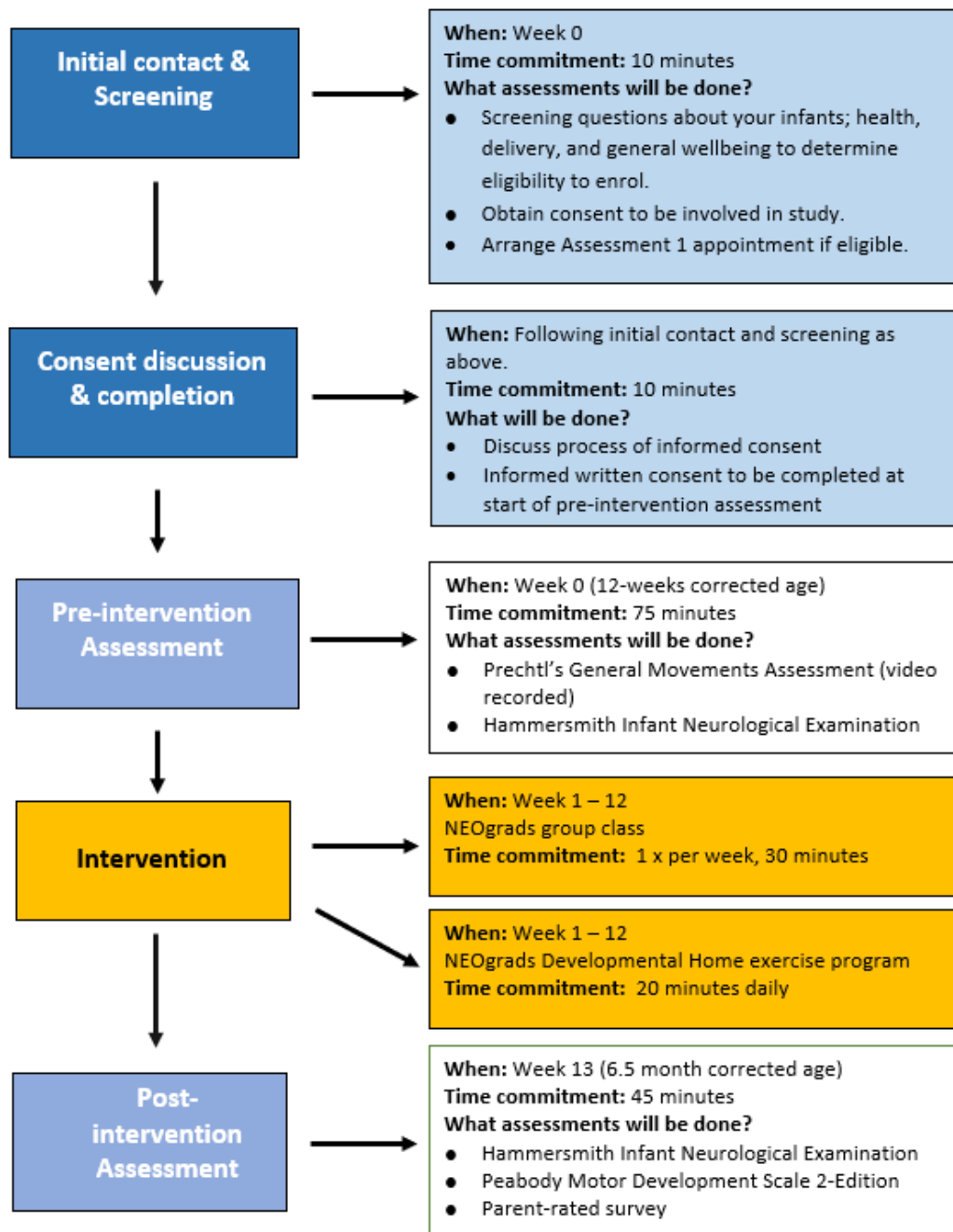
In addition to we will ask you to complete the following:

- Filling out a **daily logbook** of your home exercise program practice,
- Committing to being available for the - weekly group class appointments for 12 weeks (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.

Flow chart of the study protocol can be found below:



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 baby's/ pēpē's movement skills might improve and help them meet their developmental milestones for example how well they roll or reach for toys.

If you already have experience with baby development, there is always the possibility to gain new knowledge especially when helping preterm baby/ pēpē. 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 baby's/ pēpē's development collected during the study. Information about unexpected findings from your baby's/ pēpē's assessments will be provided to their primary health care provider (GP or paediatrician).

This study is the first of its kind within Aotearoa New Zealand. The information gathered from this study will advance our knowledge on how suitable and acceptable a program aimed to support the development of early movement skills is for preterm baby's/ pēpē and their family / whānau in Aotearoa New Zealand.

What compensation is available for injury or negligence?

If you or your baby/ pēpē are injured during the study, which is unlikely you may be eligible for compensation from ACC. We will support you to contact you or your baby's GP to lodge a claim with ACC. The GP will complete the ACC claim on your behalf. It may take time for ACC to assess and accept the claim , prior to receiving treatment by an ACC accredited provider.

If you or your baby/ pepe have private health or life insurance, you may wish to check with your policy provider prior to taking part in this study.

What will happen to my baby/ pēpē information?

Over the study, we will record information about your baby/ pēpē study results and information that you have provided.

The type of data we collect includes:

- Demographic and personal information about you, your baby/ pēpē and your family/ whānau provided during pre-screening and assessment questionnaires (electronic and paper)
- Study assessment outcome measure (electronic and paper)
- Video recording of Prechtl's Qualitative Assessment of General Movements (GMs) (electronic)
- Video recording of Playgroup classes
- Data from survey.

Identifiable Information

Identifiable information is any information that could identify you or your baby/pēpē (e.g. their name, date of birth or contact details).

The following groups may have access to you and your baby/pēpē identifiable information:

- Research staff- to make appointments and complete study assessments.
- Referral of your baby/ pēpē to Early Intervention services if abnormal findings are found during the assessments for ongoing therapy services. This will only be done with your informed written consent.
- The coordinating and associate investigators and project manager, to make sure the study is being run properly and that the data collected is accurate.
- The sponsor and its representatives, if you make a compensation claim for study-related injury. Identifiable information is required in order to assess your claim i.e. ACC.
- The sponsor, 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, the study is run properly, and the data collected is correct.
- Rarely, it may be necessary for the principal investigator to share your infant's information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of your baby/ pēpē or another person OR if the information is required in certain legal situations.

De-identified (Coded) information

After gaining written consent, we will assign your baby/ pēpē a unique participant number that only the researchers know, is assigned to your baby/ pēpē. This participant number is used to label all of you and your baby's/ pēpē's data (instead of their name). That way, your data is not joined to your identity.

Security and Storage of your information

All electronic data and paper data will be stored securely in a locked cabinet in the primary supervisors office and all electronic video files (GMs) during the study. All videos and photos are stored on a double authentication password encrypted university server and can only be viewed by study authorised researchers and therapists. Each file is identified via the participants' study ID number. We understand that many Māori consider health information taonga. Use of information for research, and sending information overseas, may require careful consideration. There are a range of views held by Māori around these issues; however, it is acknowledged that individuals have the right to choose. It may be appropriate to discuss this with your family / whanau. Alternatively, you may wish to contact the Simone Skelton whose details are listed below. It is possible that an ethics committee, funding body, or external researcher may ask for the study data. This is important for future research and discoveries, and to check the validity of the research. If this happens, we send them data that is completely de-identified and there is no way to connect you with the information. We use group-level data when we report the study to others, such as at conferences, research papers, newsletters and media releases. Data from the study will not be destroyed. Once the data has been collected and analysed at the group level, it is not possible to ask for it to be deleted.

All information collected in this study will be kept under secure conditions at Auckland University of Technology 10 years after the babies/ pēpē in the study reach 16 years of age and then it will be destroyed. All storage will comply with local data security guidelines.

Risks

Every effort will be made to protect you and your baby/ pēpē's privacy, absolute confidentiality of your information cannot be guaranteed. As you and your baby/ pepe will be participating in a group class in the community nearby your home, this may introduce concerns for you and your baby/pepe's privacy. This research includes basic information such as your ethnic group, geographic region, age range, sex, and delivery information about your baby's birth. It is possible that this research could one day help people in the same groups as your baby/ pēpē. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as 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).

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).

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 may 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 Access Your Information.

You have the right to access all information about you and your baby/ pēpē collected as part of the study. You also have the right to request that any information you disagree with is corrected. You will be informed of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on your baby/ pēpē health.

What are the costs of participating in this research?

The cost of this study is your and your baby/ pēpē's 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), use during class sessions and to keep after the research has been completed.

What opportunity do I have to consider this invitation?

We encourage you to take your time to consider being part of this research and to discuss it with your family/whānau. If you have any questions, please feel free to contact us below. If you would like your baby/ pēpē to be part of this study please contact us so we can gain your written consent and organise the initial assessments prior to your baby/ pēpē turning 11 weeks old (corrected age if they had been born on their expected date of birth).

Will I receive feedback on the results of this research?

At the completion of the baby/ pēpē study, participants will be provided with a plain English summary of study results, and general developmental feedback regarding their baby/ pēpē. Please ask if you would like to access to the results of your baby/ pēpē's assessments during the study. Overall research results will not be available till up to 18 months after the study completion and will be made available.

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 Nusrtnaaz 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 Health and Disability Ethics Committee) that approved this study.

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

NEOgrads Playgroup -Parent/ Guardian Informed Consent Form

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

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

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

- I have read and understand the Participation Information Sheet.
- I have been given sufficient time to consider whether or not to participate in the study.
- I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheets.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw my baby/ pēpē from the study at any time without this affecting my infant's medical care.
- I consent to the research staff collecting and processing my baby's/ pēpē information, including information about my baby/ pēpē health.
- I consent to my baby/ pēpē being video recorded as part of their initial neurological screening assessment and understand this will be kept confidential and safe.
- I consent to my baby/ pēpē being video recorded during the playgroup classes to help assess the quality of program delivery.
- I consent to being video recorded during the playgroup classes to help assess the quality of program delivery.
- 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.
- If I decide to withdraw my infant from the study, I agree that the information collected about them up to the point when I withdraw, may continue to be processed.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded from the study.
- I understand that my baby/ pēpē participation in this study is confidential and that no material, which could identify me, or my baby personally will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.

- I know who to contact if I have any questions about the study in general.
- I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study regarding my baby/ pēpē assessment findings.

Yes No

I wish to receive a generalised summary of the results from following the completion of the study.

Yes No

Declaration by parent/guardian of participant: I hereby consent for my child to take part in this study.

Participant's name (baby's name):

Parent/Guardians name:

Signature:

Date:

Declaration by member of research team: I have given a 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:

Approved by the Northern A, Health and Disability Ethics Committee reference 2024 Full 15231.

Note: The Participant should retain a copy of this form.