Hīoi | MiNT
Mindfulness Meditation
& Brainwave Training

Participant Information form

Pain Relief in Knee Osteoarthritis: Mindfulness Meditation and Neurofeedback Training (MiNT) study

Tena koe. Ko Ngāti Porou raua ko Ngāti Kahungunu oku iwi, kei raro i te maru o Ahuriri nui tonu. Ko Sharon Aroha Awatere toku ingoa. Tena koe e awhi nei i tenei kaupapa. He mahi tenei hei whakatutuki i taku tohu, ara, he Māori Interviewer.

Invitation

Hi I'm Sharon Awatere! On behalf of the Hīoi | MiNT team at Otago University's School of Physiotherapy, I would like to invite you to take part in our study. Sometimes 'wear and tear arthritis' *Osteoarthritis* can cause excruciating pain, swelling, and problems moving the knee, making everyday chores such as walking, jogging and kneeling a challenge. As time goes on, the bones can start to rub together, leading to grating sensations, difficulty standing up and increased falls.

Although there is currently no cure for *Osteoarthritis*, treatment strategies such as pain and anti-inflammatory medicines can be costly and have significant side effects. Because of this, alternative mindfulness-based interventions are receiving growing attention for addressing pain and dysfunction with people, including tāngata *Māori people* like yourself. Although, despite the promise and apparent therapeutic potential of meditation, few studies have focused on the effects of meditation, and any known preferences of Māori people with knee *Osteoarthritis* are lacking.

That is why this study aims to find out what tāngata Māori people think about the practicality of learning Hīoi|MiNT Mindfulness Meditation and Neurofeedback (brainwave) training, compared to usual care. The purpose of this study is to inform the design of a larger study that aims to examine pain and function in people, including tāngata Māori *people* like you living with knee *Osteoarthritis*. More importantly, this study is giving voice to people in our community similar to yourself – to see that meditation and pain relief research is appropriate and easily accessible for everyone, particularly tāngata *Māori people*.

This study is being conducted with people from around the Otago region at the University of Otago's School of Physiotherapy so that we can have views from a range of people. Before you decide whether you want to take part, we would like you to understand why the study is being done and what it would involve for you.

- Section 1 of this booklet tells you the purpose of this study and what will happen if you take part.
- Section 2 gives you more detailed information about the study.

Section 1

You might like to talk with whānau *family or friends* about taking part in this study. If anything is not clear or you have any questions, please ask us.

Contact Details Principal Investigators

Dr Ramakrishnan Mani, School of Physiotherapy, University of Otago
Ph: 0800 687 489
E: ramakrishnan.mani@otago.ac.nz

Dr Sharon Awatere (Ngāti Porou, Ngāti Kahungunu)
Ph: 0211836894
E: sharonawa74@gmail.com

What is involved?

Why are we doing this study?

This study aims to know more about how tāngata *Māori people* like you, living with knee Osteoarthritis think about the practicality of learning Hīoi | MiNT Mindfulness Meditation and Neurofeedback (brainwave) training, compared to usual treatment. We want to identify challenges associated with training and strategies that whakamana *protect and enhance the dignity and mana* of tāngata *Māori* participants as well as developing Māori-centred *appropriate* processes to help the design of studies with other tāngata *Māori people* about these challenges.

What will I do if I take part?

If you would like to take part, please be assured that you will be guided through every stage of the journey by our team. You will meet with myself, the kaipatapatai *Māori interviewer*/kairangahau *Māori Researcher* of the study, Sharon Awatere at the follow-up assessment (Stage-5).

Stage-1 Suitability to take part **allow 15 mins**	**Stage-2 Assessment (baseline)** **allow 2-hours**	**Stage-3 Training sessions** **allow 4 x 1-hour sessions p.w. (over 3-weeks continuously)**	**Stage-4 Post-training assessment** **allow 1 x 2-hours immediately after treatment (4th-week)**	**Stage-5 Follow-up assessment** **allow 1 x 2-hours after completing your training (at 3 months)**
Brief questions: You will be contacted over the phone to undergo brief questioning about your knee (allow 5 mins) **and** **Seek your approval and obtain your consent to ask more detailed questions about your knee (allow 10 mins)** **Arrange an appointment for your first visit.**	You will visit the Physiotherapy School and undergo brief questioning about your knee (allow 10 mins) You will be asked more detailed questions about your knee (questionnaires) You will undergo: Brain activity, heart rate, blood pressure, oxygen levels Physical testing Pain testing	You will then be assigned (at random) into one of the following groups: <u>Study Group-1</u>: Mindfulness Meditation Training OR <u>Study Group-2:</u> Brainwave Training OR <u>Study Group-3:</u> Usual care (continue as you usually would do)	You will undergo another assessment (baseline)	You will undergo a final assessment (baseline)
			Te uiuinga the interview (allow One-hour) with myself, Sharon Awatere. I am the kaipatapatai Māori interviewer/kairangahau.	

Stage-1: Suitability

In the first stage of the study, a colleague will telephone you briefly (5 mins) to ask you a few questions. Once your suitability to take part is confirmed, then more detailed questions (10 mins) will be asked of you concerning your knee condition and an appointment for your first visit to the Physiotherapy School at University of Otago will be arranged.

Stage-2: Assessment

In the second stage of the study, you will undergo an assessment (baseline). This will involve you making a visit to us at the Physiotherapy School Otago University. It is expected that your visit will take 2-hrs at the most, so that we can ask questions of you briefly about your knee (10 mins).

Following brief questioning, you will be asked more detailed questions about your knee, as follows:

Individual: your age, gender, ethnicity, education, well-being will be noted.
Motivation: you will be invited to discuss your motivation of wanting to join this study for training, as well as any tautoko *support* systems at home and in the community and your internal supports (what helps you to cope with your knee pain, uplifts you, brings you meaning and hope).
Pain: pain location on the knee, nature, intensity, type and how your knee *Osteoarthritis* is affecting your everyday activities (function, quality of life, wellbeing, mood).
Medications: we will then ask you about any medications you may be taking for your knee.
Health issues: any other health issues you may be experiencing will be noted, for example diabetes.
Wellbeing: you will be asked about your sleep habits and physical activity.
GP: contact details of your health provider or another current provider will be noted, to inform them if any incidental findings are recorded during our time together, or if you experience any distress over the duration of your involvement in our study.

Brain activity testing

Brain activity testing, heart rate, blood pressure and oxygen levels will be undertaken. We will then ask you to wear a cap with electrodes attached to it, similar to Picture 1. Please be assured, that you will be guided through the whole process and we will obtain your permission, prior to positioning the cap on your head.

Picture 1. Brain wave testing cap with electrodes

The reason for us placing the cap on your head is to record your brain activity for 10 minutes, while you rest in a comfortable chair with your eyes closed. Part of applying the cap on your head will involve applying electrode gel to your scalp to capture better signal quality. Your brain activity will also be recorded while we apply repeated light touches to your wrist region using a plastic thread.

We will also fit an electrode strap around your chest, so that we can record your heart activity. We will also record your blood pressure and oxygen levels with equipment similar to what you may be used to seeing when you visit a GP or nurse practitioner.

Physical testing

The next lot of testing concerns asking you to do come physical tasks as fast as you comfortably can. For example: moving from sitting to standing position, and walking for six minutes on a sloped level. At any time, you can stop performing the task, as you wish. We will ask you about your pain levels also, and assist you into a strap that we will place around your chest so that we may record your heart activity, as well as a sensor on your finger, measuring oxygen levels in your blood.

Pain testing

The final test that you will undergo is recording your pain sensitivity. This will involve carefully applying a range of sensations over the most painful part of your knee joint, and for comparison purposes over the wrist as well. As part of the pain testing, the following tests will be done:

- Repeated light touches with a piece of nylon thread, and we will ask you about the sensation of touch and intensity of pain.
- Gradual pressure to your knee while you are resting, using a rubber-tipped pressure device, and we will ask you about the sensation of pressure after your knee has been placed into a cold-water bath, using the hand in cold-water for comparison.

Stage-3: Training

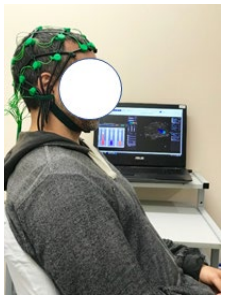
The first step in Stage-3 training will involve you being assigned (at random) into one of three groups: Study Group-1 (Mindfulness Meditation Training); or, Study Group-2 (Brainwave Training); or, Study Group-3: (Usual care - no mindfulness meditation training or brainwave training). Being assigned at random means that you will have equal chances of being allocated to one of the three groups, and you cannot change the group. But if you are assigned to receive the usual care group (i.e., continue as you usually do), you will be offered training (Mindfulness Meditation Training or Brainwave Training) at the end of the study, should you wish.

Group-1: Mindfulness Meditation Training

You will be carefully guided through training, which is to be offered as 12 x 20-minute sessions. Each week, four sessions of 1-hour duration will be provided over three successive weeks. You will be lead throughout each session, for example you will be asked to focus on your breath, occurring at the tip of your nose; the "full flow of your breath"; and sensations in your body. In the process of doing this, if you experience thoughts, feelings or emotions then you will be encouraged to focus all your attention back onto your breathing sensations.

Group-2: Neurofeedback (Brainwave) training

You will be supported with training, that will be provided as 4 x 1-hour sessions a week, over three successive weeks. You will be sensitively guided through the process of putting on a head-cap with electrodes attached to it, similar to Picture 2, and we will obtain your permission, prior to touching your head at each session. In order to capture better signal quality, electrode gel will need to be applied to your scalp and we will also ask you some questions concerning side effects that you may have experienced from previous sessions. Following the set-up of the head-cap, you will be asked to close your eyes and relax for 30 minutes without falling asleep. The neurofeedback computer program will play a distinct sound.



Picture 2. Neurofeedback training set-up

Group-3: Usual care

If you are assigned to this group, then you will continue to receive healthcare interventions and carry out whakamana hauora *self-management strategies*. You will be asked to refrain from practising any mindfulness/meditation strategies during the study period, to strengthen the results of the study. We will contact you weekly to ask questions about any healthcare that you received and whakamana hauora *self-management strategies* carried out. At the end of the study, you will be offered a chance to undergo either brainwave training or mindfulness meditation training, and you will be able to choose your preferred treatment.

We need your tautoko too

To strengthen the results of the study, we need your tautoko *support.* Please, we kindly request that you not to disclose to anybody on the study that is assessing you, as to which group you have been assigned to. If you are asked whether you are in Group-1 Mindfulness Meditation training or Group-2 Neurofeedback (Brainwave) Training or Group-3 Usual Care, please advise that you have been asked not to share this detail. This includes those people who are conducting the assessments of you. The reason for this to prevent any influence on any of the questions that you have answered concerning your health.

Stage-4: Post-training assessment

In the fourth week, you will be invited to attend post-training assessment. This will take up to 2-hours at the School of Physiotherapy. The same tests done at the assessment (baseline, Stage-2) will be repeated.

Stage-5: Follow-up assessment

Follow-up assessment: After completing your training (at three months), you will be invited to attend a follow-up assessment. This will take up to two-hours duration and will be held at the School of Physiotherapy. The same tests that were that were done (brain activity, heart rate, blood pressure, oxygen levels,

physical and pain testing at Stage-2), prior to you commencing the treatment sessions will be repeated.

Te uiuinga Interview: You will be invited to an informal chat with myself, Sharon Awatere. I am the kaipatapatai Māori interviewer/kairangahau Māori supporter of the study. This will happen face-to-face or you may prefer a telephone or videoconference call (e.g. Zoom or Skype), which is fine too.

Te uiuinga *the interview* will take between 30 min – 1 hour. You can also arrange for your whānau to be present at the same time. I will talk to you about your experiences of learning Hīoi | MiNT Mindfulness Meditation and Neurofeedback (brainwave) training, or usual care. You will be able to talk freely about your perceptions of the assessment and treatment practices for tāngata *Māori people*. You can refuse to answer any question(s) if you wish. Te uiuinga *the interview* will be recorded with audio recorders. After completion of the written-out interview, the audio recording will be deleted. You will be sent the transcript *typed up copy* of te uiuinga *the interview* and if you need to edit this, you can do so and return it to us within a week.

Section 2

Do I have to take part?

You or your whānau *family* do not have to take part in this study. If you would rather not take part, that is fine. It will not affect your health care in the future. If you would like to take part, we would appreciate your help. Kia ora *Thank you*! You can change your mind at any time and stop the session. You don't have to give a reason.

Who will take part?

We hope that 10-15 tāngata *Māori people* and whānau *their family* will take part in the study. We are seeking tāngata *Māori people* who are aged 45 – 85 years, with a diagnosis of wear and tear arthritis *Osteoarthritis,* living with significant pain on a daily basis with movement difficulties of their knee for an at least three months. I will conduct te uiuinga *the interview* with you and whānau, and arrange a convenient time that is suitable for you. Te uiuinga *the interview* will

be audio taped and if conducted on the phone, OR video recorded, if it is be recorded on Zoom. During te uiuinga *the interview*, you have the right to choose not to answer a question or to leave te uiuinga *the interview* at any time.

What are the risks and benefits of taking part?

Both mindfulness meditation and neurofeedback training effectively manage chronic pain, in general. There are minimal known risks or adverse events associated with training used in this study. The common side-effects of neurofeedback training reported by previous studies include short-lasting headaches. Other risks include that there may be no benefits, including no changes to your pain or functional levels, or any initial improvements may wear off.

Electrode cap

Another aspect for you to consider is that your brain activity will be recorded using an electrode cap. This is a safe and harmless procedure. Application of electrode gel may cause inconvenience, and you are welcome to use the shower facilities at the school should this be a problem. All the same, we do not anticipate any discomfort following the test procedures in pain sensation testing.

Sensations

During pain sensation testing, you may feel momentary pain, tingling, or pins and needles sensation in your hand during or immediately following immersion in a cold-water bath. These ranges of sensations should usually disappear quickly following the testing. A slight reddening of the skin may stay following pain sensation testing, and it should go within minutes to hours of testing.

Side effects

You will be closely monitored for your responses during all the testing procedures, and sufficient rest will be provided between each testing procedure. Any side effects of the assessments and training will be formally recorded and addressed if medical attention is required.

Challenges

I cannot promise that the study will help you, but the information I get from the study will allow us to identify challenges associated with learning Hīoi│MiNT Mindfulness Meditation and Neurofeedback (brainwave) training for tāngata *Māori people* like you living with knee *Osteoarthritis,* so that support can be strengthened in Aotearoa New Zealand in the future.

Information

We will record information about you and your participation over the duration of this study. This will include the results of various measures (e.g., pain, function, mood, response to pain testing, brain activity) through questioning you, as well as undergoing assessments. Any information that could identify you (e.g., your name, date of birth, or address) will only be available to the team involved in the research program.

Protecting your identity

To ensure your personal information is kept confidential, any information that identifies you will not be included in any report generated by our study. Instead, you will be determined by a code. The researcher will keep a list linking your code with your name if needed.

Study results

The study results may be published in an international scientific journal or presented, but not in a form that could identify you. A summary of the data will be mentioned in any research publications. The data would in no way be linked to any specific person, and your identity will not be recorded with the data. You are welcome to request a copy of the study results. These will be available once all the data is analysed, approximately 1.5 years following the commencement of the study, most likely in the second quarter of 2023.

Future research

The data collected from this study may be helpful for future research. Any new research would need to obtain ethical approval. Your information that has been de-identified (stripped of any personal information) may be used for future research. Your de-identified information may also be used for other medical and scientific research, that is unrelated to the current study, to answer questions formulated after the data collection. This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers. Your information may also be added to data from other studies, to form much larger sets of data. You will not get reports or additional information about any research done using your information. Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information or withdraw consent for its use once your information has been shared for future research.

Security and Storage of Your Information

Your identifiable information is held at the University of Otago during the study. After the study, it is transferred to a secure archiving site, stored for ten years, and then destroyed. Your coded information will be entered into electronic case report forms. Coded study information will be kept in secure, cloud-based storage indefinitely. All storage will comply with local and international data security guidelines.

Risks to privacy

Although efforts will be made to protect participants privacy, absolute confidentiality of information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that participants cannot be identified. The risk of people accessing and misusing participants information (making it harder for a participant to get or keep a job or health insurance) is currently very small but may increase in the future as people find new ways of tracing information. Considering this, if there were to be any privacy breach, then you will be notified by the principal investigator (see Section 1).

Can whānau stay with me?

Your whānau are welcome to be present while we talk about the study. Your whānau are welcome to ask any questions about the study. If you or whānau request, we can conduct te uiuinga *the interview* at a different time according to your availability and convenience.

Are there any restrictions during the study?

During your training, we ask that you avoid the following actions, because these will affect the training conditions:

- No large meals are to be eaten for 2-hours before any session
- No drinking of alcohol for 24-hours before any session
- No smoking/use of any form of nicotine products for 4-hours before the session
- No Consuming caffeinated drinks within 1-hour before the session
- No applying any hair products (oil, gel) before the session (for group-1 participants only)

If you are unable to complete any of the above actions, your training session will need to be rescheduled at a suitable time. For your comfort, we will offer you refreshments (e.g., tea/coffee or juice) at each session.

Compensation for your time?

There will be no costs to you for participating in the study. You will receive in total $200 vouchers/gift card ($10 per session hour), as a way of compensating for your time and saying Kia Ora *Thank you* at the end of the study as a reimbursement for your travel and parking expenses. If you are in the usual care group (group-3), you will receive in total $80 vouchers/gift card ($10 per hour of session) at the end of the study as a reimbursement for your travel and parking expenses.

What if something goes wrong?

In the scenario that you sustained an injury in the course of participating in this study, then you would be eligible to apply for compensation from ACC, just as you would be if you were injured in an accident at work or home. This does not mean that your claim will automatically be accepted. You would need to lodge a claim with your GP for ACC, which may take some time to assess. If your claim is accepted, then you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover. Any incidental findings/observations of potential clinical significance that are unexpectedly discovered during the research duration will be notified to you and your GP.

What are my rights?

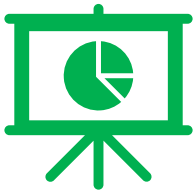
Your participation in this study is voluntary. You may withdraw from this project at any time and without any disadvantage to you of any kind. If you experience side effects from the assessment or treatment or any other concerns, we may need to withdraw you from the study.

You have the right to access the information collected about you as part of the study. You also have the right to request that any information you disagree with be corrected. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

If you have any questions about the collection and use of information about you, you should ask the researcher. You will have full rights to correct or withdraw the information until the research is completed or we begin to analyse the data. We will inform you if any new information becomes available during the study, that may impact your health. You will have the right to request and access any of your screening and safety monitoring results during the study, that does not impact the scientific validity of the study.

What will happen to the results of this study?

We will only keep a copy of te uiuinga *interview*, without your name included. This will be stored on the University of Otago's managed storage. This is a secure password protected cloud storage for data. Only researchers in the study team will have access to this copy of te uiuinga *the interview* to analyse during the 3 years of the funded study and for a six year period beyond. After that, the copy of te uiuinga *the interview* will be erased.



We will write up a report of the study to let professionals know about the results. We are likely to present the findings at conferences, on our website and in journal articles. We will not use your name or any other information that might identify you in these publications. We will send you a summary of the results of the study, if you wish.

What happens if I stop taking part?

You can stop taking part or withdraw from the study at any time without explanation, by informing the lead investigator (see Section 1). If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. You may ask for information collected to be removed when you withdraw, provided you withdraw before the study analyses have been undertaken. After this time the data will have been analysed and it will not be possible to extract it from the results. If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study.

Who is running this study?

This research is led by Dr Ramakrishnan Mani (see Section 1 for his contact details). The other people in the research team are listed below. You can contact any of them with any questions or concerns. All of their contact details are below. The research costs are being supported by the Health Research Council of New Zealand *HRC*.

Who can I talk to if I have questions or concerns?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Name: Dr Ramakrishnan Mani **Position**: Senior Lecturer (Principal investigator) **Department:** School of Physiotherapy, University of Otago, Dunedin.	**Ph: 0800 687 489** **E**: Ramakrishnan.mani@otago.ac.nz
Name: Dr Sharon Awatere (Ngāti Porou, Ngāti Kahungunu) **Position:** Co-principal investigator The Health Boutique Ltd, New Zealand.	**Ph:** 06 844 6678 **E**: sharonawa74@gmail.com
Name: Professor Dirk De Ridder **Position**: Neurosurgery, Co-principal investigator **Department:** Department of Surgical Sciences, University of Otago, Dunedin.	**Ph:** 03 470 9337 **E:** dirk.deridder@otago.ac.nz
Name: Dr Divya Adhia **Position:** Research Fellow, co-investigator **Department:** School of Physiotherapy, University of Otago, Dunedin	**Ph:** 03 470 9337 **E:** divya.adhia@otago.ac.nz
Name: Dr Nicola Swain **Position:** Associate Professor, co-investigator. **Department:** School of Physiotherapy, University of Otago, Dunedin	**E:** Nicola.swain@otago.ac.nz

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

Ph : 0800 555 050
F: 0800 2 SUPPORT (0800 2787 7678).
E: advocacy@advocacy.org.nz
W: advocacy.org.nz/

For Māori health support, please contact :

Name: Dr Sharon Awatere (Ngāti Porou, Ngāti Kahungunu)
Position: Co-principal investigator.
Ph: 0211836894
E: sharonawa74@gmail.com

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Ph: 0800 4 ETHICS
E: hdecs@moh.govt.nz

Approved by Health and Disability Ethics Committee on 11th January 2022 for three years. Reference Number **2021 EXP 11367**

Hīoi | MiNT
Mindfulness Meditation
& Brainwave Training

Consent form

Mindfulness Meditation and Brainwave Training Hīoi | MiNT for Pain Relief in Knee Osteoarthritis: A Safety and Feasibility Randomised Control Trial.

Principal Investigator: Dr Ramakrishnan Mani
Kairangahau (Māori interviewer): Sharon Awatere

Co-investigators: Professor Dirk De Ridder, Dr Divya Adhia, Associate Professor Nicola Swain

I have read, or have had read to me, and I understand the Participant Information Sheet.	
I have had enough time to think about whether or not to participate in this study.	
I have had a chance to use a legal representative, whanau/ family tautoko *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 sheet.	
I understand that taking part in this study is voluntary (my choice) and that I may pull out from the study at any time without this affecting my medical care.	
I consent to the research staff collecting and processing my information, including information about my health.	
I understand the risks associated with the testing and treatment procedures explained in the Participant Information Sheet.	
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	

Group-1 Mindfulness Meditation Group: I know that I will be given vouchers/gift card (*a value of 200$*) to cover travel expenses associated with study participation.	
Group-2 Brainwave Training Group: I know that I will be given vouchers/gift card (*a value of 200$*) to cover travel expenses associated with study participation.	
Group-3 Usual care (control) group: I know that I will be given vouchers/gift card (*a value of 80$*) to cover travel expenses associated with study participation.	
I understand the compensation provisions in case of injury during the study.	
I know whom to contact if I have any questions about the study in general.	
I understand my responsibilities as a study participant.	
I agree with my current health provider being informed of my participation in this study.	
I agree for the researchers to contact my GP or another current provider if needed to determine my eligibility for participation in the study and be notified if any incidental findings are recorded.	
I understand data collected from me in this study may be used for future research.	

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I wish to receive a summary of the results of the study.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature:

Date:

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature:

Date:

Note: A copy of the consent form is to be retained by participant

Emergency contact / Support person:

Please specify a contact person (a friend or a relative) in case of an emergency during the study participation. After completing the study phases, the contact details will be deleted from the file.

Name of a friend or relative:

Contact number:

Declaration by a member of the research team:

I have given a verbal explanation of the research project to the participant and answered the participant's questions.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

_____

Signature:

_____

Date:

_____

*Only to be completed if a transcript, recording or summary of the findings is requested:

Participant's Name:_____

Address **or** Email (depending on preferred form of contact):

_____

_____

_____

Approved by Health and Disability Ethics Committee on 11th January 2022 for three years. Reference Number **2021 EXP 11367**