PARTICIPANT INFORMATION STATEMENT

HREC Project Number:	206544
Project Title:	Education and exercises to improve neck pain: A randomised controlled telehealth trial.
Division/Unit:	School of Allied Health and Human Performance, Adelaide University
Principal Investigators:	Dr Felicity Braithwaite, PhD; felicity.braithwaite@adelaide.edu.au Professor Tasha Stanton, PhD; tasha.stanton@adelaide.edu.au Professor Lorimer Moseley, PhD; lorimer.moseley@adelaide.edu.au

You are invited to participate in a randomised controlled study evaluating two different treatments that aim to improve neck pain and other symptoms. You have been invited to participate because you have been identified as having neck pain. Before you sign the consent form, it is important that you read and understand the following information.

What is the study about?

This study aims to test two different treatments that involve education and exercises for people with neck pain. Specifically, we are interested to see if these programs have long-term positive effects on neck pain and other symptoms. We are also interested to see if these treatments might reduce costs to the health system. This research is funded by the National Health & Medical Research Council of Australia Medical Research Future Fund. It involves collaboration with researchers from Adelaide University, University of New South Wales, University of Queensland, University of Notre Dame, and University of Technology Sydney.

Due to the nature of this study, some information will be withheld from you until the end of your involvement. However, there is no added risk of harm or any reason to suspect you would not consent if you had all the details at the start. After testing is completed, you will be given a full explanation of the study, including reasons for concealing some details. Prior to commencement of the study, we will ask you to provide written informed consent that states that you would like to be part of the study, based on the details provided here.

Do I have to participate?

No. As with all research at the University, participation is completely voluntary. Choosing not to take part in this study will not affect your current or future medical care in any way.

You can request to withdraw at any time without any prejudice, now or in the future, and any information collected prior to your withdrawal will not be used. You can do this by filling in the withdrawal form.

In the case of participants discontinuing the study without notification (i.e., if you do not contact us and let us know that you would no longer like to be part of the study), some of the information previously collected may be used (but without identification). If you decide to withdraw from the study more than 1 year after you commenced the study the information previously collected may be used (but without identification).

Who can participate?

Adults (over 18 years of age) who will be living in Australia for the next 12 months, and who have neck pain that has been present for at least 3 months, which did not start due to an accident or significant injury (e.g., car accident/whiplash, bad fall), may be eligible to participate. Eligible participants must also who have access to a device with internet and a front-facing camera (e.g., tablet, smartphone, laptop or desktop computer) that will enable video calls for telehealth and completion of online surveys, and a trusted person (e.g., partner, housemate) who is willing and able to assist with assessments and treatments.

People who will not be able to participate include those with: severe migraine, headache, and/or dizziness; severe psychological or mental health disorder (e.g., major depression or post-traumatic stress disorder); cognitive impairment (e.g., dementia, Alzheimer's disease); diagnosed fibromyalgia; scheduled for major surgery during the next 12 months; other serious and uncontrolled health conditions that will limit their ability to safely participate in the treatment, including neurological conditions (e.g., stroke, multiple sclerosis, Parkinson's disease), diabetes, kidney disease, cardiovascular disease, lung disease, known or suspected serious spinal pathology (e.g., fracture, cancer, inflammatory or infective diseases of the spine, widespread neurological disorder), previous spinal surgery, or radiculopathy/nerve root compromise.

Last, people who are not fluent in English, who do not have normal (or corrected to normal) vision and hearing, and who are unable to commit to study requirements (i.e., unable to attend study appointments or complete study questionnaires), will not be able to participate.

The research team will go through these thoroughly with you.

What will I have to do?

Treatments: If you choose to participate in this study you will need to attend a series of telehealth appointments within the first 12 weeks of the study, which will occur via videoconference (Zoom). All appointments will be with a registered allied health clinician (e.g., physiotherapist). Your clinician will determine how many appointments you need, and will work with you to schedule your appointments at times that are convenient for you. The treatments will involve a thorough assessment of you and your neck, discussing information about neck pain and its management, and an exercise program that is tailored to your goals.

Assessments: Participation in this study also involves completing assessments via filling in online surveys at baseline, 10 weeks, 12 weeks, 6 months, and 1 year. We will also ask you to complete a few brief questions about your view of the treatment after your first treatment session. If you complete all study assessments, will reimburse you $50 using gift vouchers at the end of your participation in the trial.

Here we describe what will occur from the start to the end of your participation:

First, you will be screened to determine your eligibility via a brief online screening survey. If you pass the online screening, you will be invited to a formal eligibility screening via a video call (Zoom) with a member of the research team. If you are eligible, you will then be asked to complete the first (baseline) online survey. During this survey, you will be asked to complete questionnaires asking you about your demographic information (e.g., age, gender, location, education, work status, cultural background, height, weight, other health conditions), your neck pain, your overall function (e.g., ability to do different activities), your mood, your beliefs about pain, your perception of your neck, and your thoughts about neck movements. The survey will take approximately 60 minutes to complete.

After you've completed the baseline survey, you will be randomised into one of two treatment groups. Both groups will receive a treatment that has been shown to be helpful in reducing pain and increasing function in people with neck pain. All participants will receive a series of one-on-one treatment sessions over a maximum of 12 weeks with an experienced allied health clinician via telehealth. Each treatment session will last between 30 and 90 minutes. You will need to attend the treatment sessions via telehealth (i.e., a Zoom video call). A member of the research team will assist you to download, set up, familiarise yourself with Zoom if you have not used it before, so that you are comfortable using the technology before your treatments start.

In order to make sure the clinician is providing the treatment correctly, we will be audio- and video-recording all telehealth treatment sessions. This recording also allows us to review the content of the sessions. Only the research team will have access to these recordings and the recordings will be stored on a secure Adelaide University server with a password protected file. You can choose not to be recorded or you can cease the recording at any time and this will not affect your treatment or participation in the study.

Your clinician will provide activities (e.g., specific exercises) for you to complete at home between each treatment session and after your treatment sessions have finished. Your clinician will ask you to report your progress with the at-home activities during each treatment session.

After you have completed the first treatment session, you will be asked to complete an online survey with a few brief questions about your view of the treatment (approximately 10 minutes to complete). You will then be asked to complete a brief survey at 10 weeks after starting the study (approximately 15-20 minutes to complete), and then another survey at 12 weeks after starting the study (approximately 45 minutes to complete) – in both of these surveys, you will answer similar questions to the ones you completed at baseline. The final surveys will occur at 6 months and 12 months after you started the study (approximately 45 minutes to complete) – these final surveys will allow us to understand if the treatments had longer lasting effects.

We will be evaluating the cost effectiveness of these treatments. This involves collecting information on what type of medical services and prescriptions that you have accessed over the study period. You will be asked to fill out a separate consent form authorising the study to access your complete Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data provided by Services Australia, see the separate Services Australia Participant Information Document and Participant Consent Form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to Services Australia who holds this information confidentially.

Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide to participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee (HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC).

Your identifiable personal information is required in the data linkage process to ensure that the data is as accurate as possible. However, the linked health information provided to the team conducting the analysis at University of Technology Sydney will be de-identified (personal details removed) and kept separately from other project data at Adelaide University.

At the end of the study, you might be invited via email to participate in a 60-minute interview to provide feedback about the study and the treatment. If you are invited, you will be provided with further details at that time, and will be asked to sign another consent form. Participation in this interview is also completely voluntary, and choosing not to take part will not affect your current or future medical care in any way.

What are the risks in participating?

As with any exercise intervention, there is a risk that you may sustain a physical injury. However, all treatments are provided by an experienced, licensed allied health clinician and you will be screened for any conditions that might make exercise or movement unsafe. This makes the risk of such injury very small. If you suffer a physical injury, please let the treating clinician know as soon as possible. The clinician will provide you with advice and if needed, will arrange a time to see you. Further, if necessary, the study team will also coordinate a medical follow-up with your GP.

There is also a risk that you may experience increased pain or discomfort as a result of the treatment. This pain or discomfort is commonly short-lasting (<2 days). The clinician will monitor this very closely and will help you to make changes to your treatment should an increase pain or discomfort not abate.

Last, there is a small risk that you may find talking about your neck pain with your clinician or answering survey questions about your neck pain distressing. If this is the case, please contact the researchers via the contact details on the top of this form. Please know that if you do not wish to answer a survey question, you may choose to not continue the survey.

Should you feel upset at any point, you may like to discuss these feelings with your doctor or one of the following organisations:

- Your general practitioner (GP doctor). If needed, the study team will coordinate a follow-up with your GP.
- Lifeline: 13 11 14 or https://www.lifeline.org.au
- Beyond Blue: 1300 22 4636 or https://www.beyondblue.org.au

What are the benefits to participating?

All participants will receive treatments that have been shown to increase function and reduce pain in people with neck pain. Therefore, you may receive personal benefit from participating. Your participation will also provide wider benefits to the community by providing important information on the treatment so that we can determine if this type of treatment should be provided to those with neck pain.

Who will have access to my information?

The researcher will take every care to remove any identifying material from the responses you provide as early as possible. Likewise, individuals' responses will be kept confidential by the researcher and participants will not be identified in the reporting of the research. That is, information on the questionnaires will be grouped for reporting (e.g., we will present only group averages). Direct quotes may be included in the reporting of results with your age and gender, but no other identifying information will be provided. All records containing personal information will remain confidential and no information which could lead to the identification of any individual will be released, unless as required by law. However, the researcher cannot ultimately guarantee the confidentiality or anonymity of material transferred by email or the internet.

The survey data information supplied will be stored securely in a locked cabinet at SAHMRI or in electronic format on a password protected file on the Adelaide University secure server. We will use Adelaide University Research Data Storage to allocate access to our co-investigators for analysis at the University of New South Wales and the University of Technology Sydney, using the 'NextCloud' application for secure, remote access to share data. Only non-identifiable data (raw and aggregated) will be uploaded and shared.

This data will be stored for 15 years and the researcher will not supply this information to the public without explicit permission, unless required by law. The video-recordings of treatment sessions will be stored for 15 years on an Adelaide University secure server. MBS and PBS data will be stored for 15 years from the publication of the projects' final report. After these time periods, confidential information related to this research project will be completely destroyed. Hard-copy data and related information will be disposed of using a commercial secure document disposal service while electronic data will be properly deleted from the network and associated storage by University IT staff. Every effort is made so that the information you supply will remain completely confidential. Non-identifiable data may be used for future purposes, for which ethics approval will be sought (for example, we may combine this data with other similar datasets to explore things that can better predict treatment outcome).

Will you tell me the results of the research?

Yes. A summary of the results can be provided to you at the completion of the study if you indicate your interest at the end of the survey together with an email or home address.

If you would like your results to be sent to your general practitioner or medical team, please inform the researcher about this and provide the researcher with the medical team's relevant contact information so that this can be undertaken.

This project has been approved by Adelaide University's Human Research Ethics Committee (Ethics Protocol 206544). If you have any ethical concerns about the project or questions about your rights as a participant please contact the Executive Officer of this Committee (Tel: (08) 8313 6028; Email: hrec@adelaide.edu.au).

If you wish to lodge a complaint about either the study or the way it is being conducted please contact the Executive Officer of Adelaide University HREC in the first instance, email: hrec@adelaide.edu.au or tel: (08) 8313 6028.