Participant Information Sheet

Is a digital knee brace helpful for patients with osteoarthritis?


Lead Researcher: Aidan Messenger

Study Site: The University of Auckland, Faculty of Medical and Health Sciences, Grafton, Auckland.

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Ethics committee ref.: 20/STH/237

You are invited to take part in a study on osteoarthritis. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can 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 participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will 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. 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 Participant Information Sheet and the Consent Form to keep.

This document is 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participation in this study is voluntary and is not required if you do not wish to participate. If at any time during the study you find yourself unable to complete the study or no longer wish to
participate you may withdraw from the study at any time. After withdrawing from the study you will be unable to participate again in the study.

**WHAT IS THE PURPOSE OF THE STUDY?**

This study is investigating the use of a home-based intervention for osteoarthritis of the knee. Osteoarthritis is also known as “wear and tear” arthritis and is the most common form of arthritis. It can occur at any age and in any individual and happens when the cushioning material between the bones breaks down, therefore resulting in pain. This study focuses specifically on osteoarthritis of the knee.

This study is an early feasibility study and therefore aims to assess the feasibility of using a digital knee brace device alongside a mobile application to deliver a home-based exercise program to those with knee osteoarthritis.

**HOW IS THE STUDY DESIGNED?**

We are looking for 40 total participants made up of both males and females between the age of 18 and 80.

The 40 participants will be split into 2 groups of 20. One group of participants will utilise a digital knee brace and mobile application to perform their home-based exercise intervention, while the other group will undergo standard care with a paper-based home exercise intervention. Both groups will be performing the same high-quality exercise intervention with two different forms of delivery.

The study will be based in Auckland and in-person visits will be performed on the University of Auckland Medical Sciences campus located in Grafton, Auckland.

Participation in the study will last for 8 weeks and involves three 30 to 40-minute sessions per week at home. In addition to these at-home sessions there will be 2 in person clinic visits: one at the beginning of the study to gather baseline questionnaire measurements for your current levels of pain, arthritis severity, and quality of life, answer any questions you may have, and inform you of the exercises you will need to do and how to wear the digital knee brace if you will be using it. The second in-clinic session will be at the end of the intervention to gather follow-up measurements for your pain, quality of life, and arthritis severity, as well as questions around the usefulness of the app. You will also return the digital knee brace device if you were using it.

**WHO CAN TAKE PART IN THE STUDY?**

In order to participate patients must:
- Have osteoarthritis of the knee in one or both knees.
- Be over the age of 18.
- Be under the age of 80.
- Have access to a smartphone
Participants will be unable to participate if they:
- Have a history of significant injury to either leg in the previous 6-months that required surgery.
- Are unable to read and speak English
- Are unable to commit to an 8-week intervention

Participants will be able to continue their regular medication use and lifestyle during participation in the study.

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

Participation in this study will involve different things depending on whether you are in the digital knee brace group or the standard care group.

Both groups will be invited to an initial appointment at the University of Auckland Grafton campus. This will take approximately one hour and thirty minutes and will involve:
- Coming into the campus to meet with the student researcher. (Alternatively if mobility is an issue, the researcher will come to the participant).
- Explaining the study to you and what it will involve.
- Answering any questions you may have.
- Filling in a general demographic questionnaire about your age, sex, and ethnicity.
- Filling in a WOMAC (Western Ontario and McMaster Osteoarthritis Index) questionnaire which aims to assess the level of pain and difficulty you are experiencing from your arthritis.
- Filling in the KOOS (Knee osteoarthritis outcome score) questionnaire which aims to assess various aspects of your osteoarthritis including your pain, symptoms, and quality of life.
- Filling in a questionnaire about how you perceive your osteoarthritis
- Answer a question about intention to undergo knee replacement surgery in the next 12 months.
- Performing a 6-minute walk test where we record how far you can walk in 6 minutes.

After this the process will differ depending on which group you are assigned to.

**Digital knee-brace group:**
If you are randomly assigned to the digital knee group your initial appointment will also involve the study researcher teaching you how to use the app, put on the digital knee brace (pictured below), and pair the device via Bluetooth to your phone. You will then be set up with the application and shown how it works and how to do the exercises.

Once you are back at home you will be required to perform the exercises with the digital knee brace three times a week for 30-40 minutes. For the first two weeks the intervention contains a cognitive behavioural therapy component. This is a 10-minute educational component that you will go through before beginning your exercises which is designed to help teach you a variety of psychological tools to improve your ability to function with osteoarthritis. After this you will perform the exercises given to you by the application which have been selected by a physiotherapist based on existing evidence. For the remaining 6 weeks you will perform exercises but will not be required to do any education sessions. Every two weeks the exercises
will be adjusted to allow for you to continually make progress in the strengthening of your muscles and coordination as designed by a physiotherapist.

The digital knee brace can be seen in the below picture:

![Digital Knee Brace](image)

**Standard care group**

If you are randomly assigned to the standard care group your initial appointment will also involve the student researcher going through the detailed paper-based documentation containing the exercises for you to complete and how to complete them. It is expected you will perform the exercises three times a week for 30 minutes. The exercise program is exactly the same as the digital knee group.

**After the intervention:**

After 8 weeks you will be invited back to the University of Auckland campus for a follow up appointment with the student researcher which will take about one hour.

At this appointment participants will:

- Fill in a follow up WOMAC (Western Ontario and McMaster Osteoarthritis Index) questionnaire which aims to assess the level of pain and difficulty you are experiencing from your arthritis after the intervention.
- Fill in the KOOS (Knee osteoarthritis outcome score) questionnaire which aims to assess various aspects of your osteoarthritis including your pain, symptoms, and quality of life after the intervention.
- Filling in a questionnaire about how you perceive your osteoarthritis
- Answer a question about intention to undergo knee replacement surgery in the next 12 months
- Perform a 6-minute walk test where we record how far you can walk in 6 minutes.
- Fill in a questionnaire asking how often they performed the exercises and for how long.

In addition, those who were in the digital knee brace group will:

- Return the digital knee brace to the student researcher
- Fill in a system usability questionnaire about the application and digital knee brace device
- Fill in a survey about likelihood of recommending the digital knee device to someone in the future.

At the end of this appointment participants will be given a koha (gift) of $30 to assist in the costs of transportation to the in-person appointments.

**WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?**

Participating in this study involves you performing accepted and commonly used exercises. There is a minor risk of experiencing “delayed onset muscle soreness” or “DOMS” which is a mild muscle soreness that is often experienced after physical exercise particularly when exercising a muscle that has not been exercised recently. This pain is typically mild and will subside within 48-72 hours and should reduce in frequency as you get used to performing the exercises. If you have any concerns about this pain, please inform your regular physiotherapist or health professional.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

You may experience improvements in health, because the exercises that will be provided to both groups have previously been shown to reduce pain and improve quality of life in patients with osteoarthritis. The results of the study may benefit future patients if the device is shown to increase these benefits. However, there may be no benefit provided by participating in this study.

**WHAT ARE THE ALTERNATIVES TO TAKING PART?**

There are a variety of treatments for osteoarthritis. Home or group-based exercise programs are a common way of managing osteoarthritis. Additionally, you may wish to seek help from a registered physiotherapist to devise a specific treatment plan for you or perform in-person exercise sessions.

**WILL ANY COSTS BE REIMBURSED?**

Participants who complete this study will be provided with a koha (gift) of $30 to aid in the costs associated with attending the two in-person appointments at the University of Auckland campus.

**WHAT IF SOMETHING GOES WRONG?**

If you were injured in this study, 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 at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, 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.

**WHAT WILL HAPPEN TO MY INFORMATION?**

During this study the researchers will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

**Identifiable Information**

Identifiable information is any data that could identify you (e.g., your name, date of birth, or address). Only the student researcher will have access to your identifiable information.

**De-identified (Coded) Information**

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

**Future Research Using Your Information.**

Your information provided will only be used for the purpose of this study and will not be used in any future research.

**Security and Storage of Your Information.**

Your identifiable information is held at the University of Auckland during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. All storage will comply with local and/or international data security guidelines.

**Risks.**

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g., making it harder for you 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.

This research includes basic information including your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same groups as you. 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 information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study.

If you have any questions about the collection and use of information about you, you should ask the student researcher.

**Rights to Withdraw Your Information.**

You may withdraw your consent for the collection and use of your information at any time, by informing the researcher.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. If you have been given a digital knee brace device this will need to be returned as soon as possible.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

**Ownership Rights.**

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to Opum Technologies. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

**Use of New Technologies (e.g., Artificial Intelligence and Health Apps).**

Participants in the digital knee brace group will be using a mobile application to receive their exercise plan and perform the digital program. This will require the setup of a personal account with your own unique username and password. This password will only be known by you and will be stored securely in the application’s database. The username will be an email address that is generated by the research team for use in this study and will be deleted after the study’s completion. The application will not require you to use your existing personal email address to ensure your privacy.

The application will collect basic information against your username such as how often you use the application, whether you complete the exercises, how often you complete the exercises, and whether you completed the CBT part of the program. This will be stored securely in an encrypted database. This information can only be accessed by the researchers.

The use of the mobile application will require internet access. The application does include video resources which require internet access to stream. The repeated watching of videos may result in increased data usage. There are no other costs associated with the use of the application or digital knee brace device.

For use in this study this information will be stored with your randomised personal identifier number which only the student researcher will be able to link back to you. Published results will be de-identified and therefore not directly linked to you as an individual.

The mobile application is owned and developed by Opum Technologies. The data will not be shared with any third parties and will only be accessible by the research team. The mobile application is HIPAA compliant, which means that the data is stored securely on an
encrypted cloud-based database and is only accessible to the researchers or HIPAA compliant personnel.

Participants in the standard home-care group will not be utilising this mobile application.

**WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?**

Other than names on the consent form, your data will be de-identified using a unique alphanumeric code. Only the primary investigator (Aidan Messenger) will be able to match your name to your data. All de-identified data will be securely stored in an electronic database and only the research team will have access to it. We will retain this data for at least 10 years in secure storage (on the primary investigator’s password-protected University computer and the secure data storage of the School of Psychological Medicine). This data may be used in future research studies.

Any personal information (such as contact details) may be destroyed at the completion of the research even though the data derived from the research will, in most cases, be kept for much longer or possibly indefinitely. We may submit the summarised (group) results for publication in a scientific journal or presented at conferences. We will make every attempt to preserve your anonymity.

**CAN I FIND OUT THE RESULTS OF THE STUDY?**

We can send you a summary of the overall study findings, should you be interested in these, via email. The overall study findings should be available one year after data collection is completed. The findings of the study may inform future, larger scale research studies and help researchers better understand movement patterns.

**WHO IS FUNDING THE STUDY?**

This study is being performed for submission as part of a master’s thesis and is therefore not a funded study.

**WHO HAS APPROVED THE STUDY?**

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Southern Health and Disability Ethics Committee has approved this study.

**WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?**

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

Aidan Messenger – Masters Candidate  
Phone: 027 865 3898  
Email: ames232@aucklanduni.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:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Maori health support please contact:
Evora Morunga - Māori Health Psychologist
Email: emorunga@adhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:
Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz
Consent Form

Is a digital knee brace helpful for patients with osteoarthritis?

Please tick to indicate you consent to the following:

- I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
- I have been given sufficient time to consider whether or not to participate in this study.
- I have had the opportunity to use a legal representative, whanau/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 sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw 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.
- 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.
- I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.
- I understand that there may be risks associated with the treatment such as sore muscles.
- I understand that technology use is a mandatory part of this study.
- 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 for the study.
- 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.
- 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 understand that I must return the digital knee device at the end of the study.

I wish to receive a summary of the results from the study. Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant’s 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: ____________