



Physical Activity to Decrease Fatigue after GBS

PARTICIPANT INFORMATION SHEET

Invitation

Kia ora

You are invited to take part in a study using physical activity to decrease fatigue after Guillain-Barré Syndrome (GBS).

This information sheet will help you decide if you'd like to take part. It sets out why we are doing the study and what taking part will mean for you.

Please remember that:

- Taking part in this study is entirely voluntary—it is your choice and you do not have to give a reason.
- Not taking part won't affect your rehabilitation services.
- If you do agree to take part, you can change your mind later and pull out at any time.
- You do not have to decide if you want to take part in the study today.
- Before you decide, you may want to talk about the study with other people, such as your whānau, friends or healthcare providers.

We will go through this information with you and answer any questions you have. If you agree to take part in this study, you will be asked to sign the consent form at the end of this document.

WHAT IS THE PURPOSE OF THIS STUDY?

Even when people have made a good recovery after GBS, they can continue to experience fatigue, which is tiredness out of proportion to activity. Fatigue can really limit everyday functioning.

This study is trialling an activity coaching programme which is designed to help reduce your fatigue. It is delivered online by a physiotherapist, who will work with you to tailor the programme to fit your needs and goals.

The study is being carried out by researchers based in the Centre for Person Centred Research at Auckland University of Technology



Responsible for leading the project and running the coaching sessions

Dr Suzie Mudge

921 9999 x 7096

suzie.mudge@aut.ac.nz



Responsible for interviews and data collection

Greta Smith

921 9999 x 7676

greta.smith@aut.ac.nz



Responsible for the study concept and project oversight

Dr Gareth Parry

This study is funded by the Neuromuscular Research Fund, AUT Faculty Development Fund and the GBS Support Group and has been approved by the Health and Disability Ethics Committee [21/NTB/232]

WHAT HAPPENS IN THIS STUDY?

Getting ready

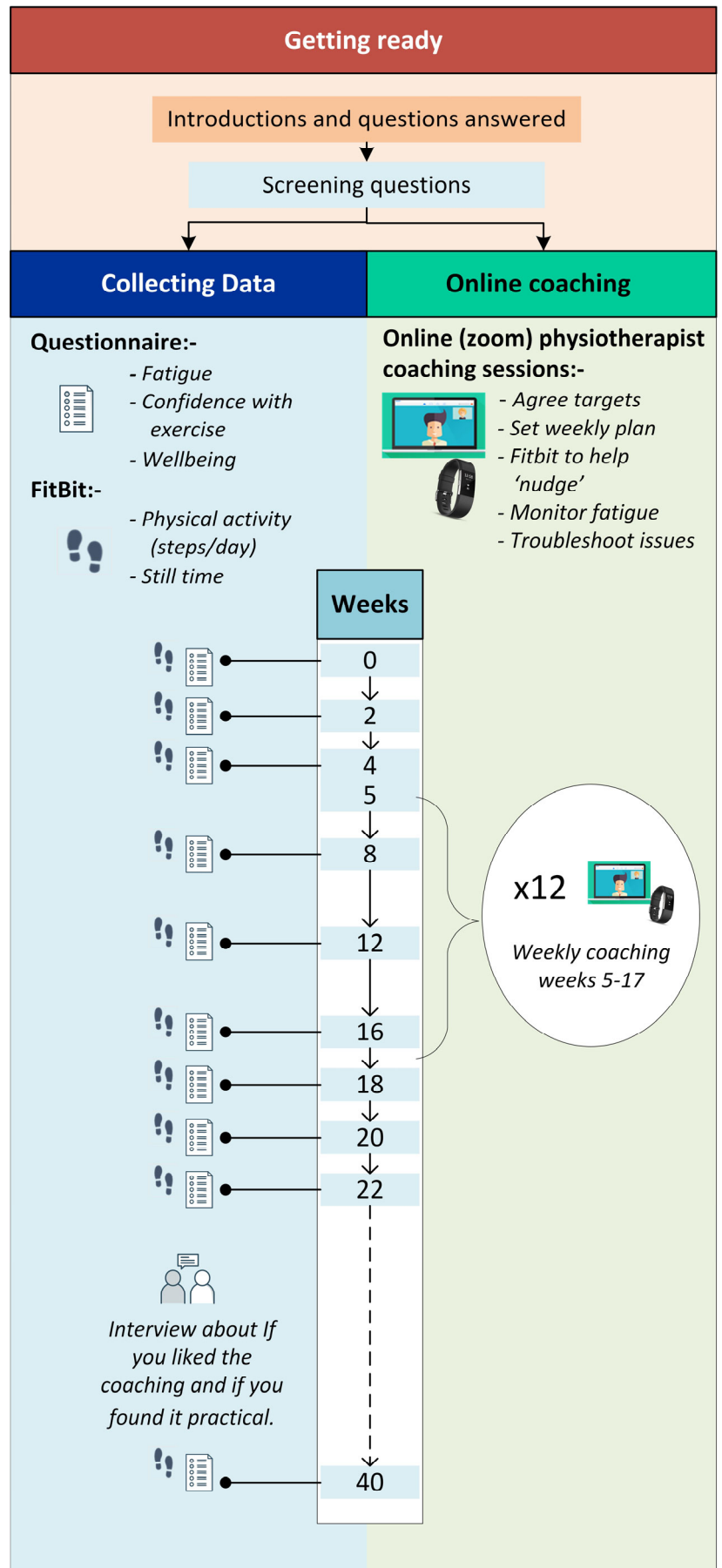
- Introducing ourselves to you: Suzie and Greta will meet with you and any support people/whānau who you would like to have along either by phone, zoom or face to face; whatever works best for you. We can talk to you about the study and answer any questions you may have.
- Screening: If you decide that you want to take part, we will ask you to complete the consent form and Greta will ask you some screening questions (which take about 45 minutes). This is so that we can select a range of participants who we think this project might help.

The online coaching

- The first session you have with the physiotherapist (Suzie) will be by zoom and will be to work out a programme with you that suits your specific needs and goals. It will take 30–60 minutes.
- Over the next 12 weeks, Suzie will meet with you by zoom/phone once a week for a coaching session; each will take around 15-30 minutes. The total time you meet with Suzie will be about 6 hours over the 12 weeks.

Collecting data

- To test if this coaching programme works, we need to collect information before, during and after the coaching period from questionnaires and from the Fitbit we will give you. The questionnaires should take 5-10 minutes each time and will be done 10 times either online or over the phone. There is also a one-off interview that will take up to one hour.
- The entire time that you will be involved in the study is 40 weeks. The picture opposite shows how this all fits together.



WHAT IS DIFFERENT ABOUT THIS INTERVENTION?

We are planning to run this study remotely (via zoom or phone) for both the coaching sessions and to collect the data. This is for a few reasons:

- People with GBS live all over New Zealand and this way it will not matter where you live.
- It means that participants won't need to travel to a research centre and so we hope many participants will find this more convenient.
- We think that it will be easier to keep going with an exercise programme that is based on what you like doing and in places that are easy for you to access.
- Remote health consultations have become more common since the Covid-19 pandemic. This way of doing things will allow us to keep the project going, even if we go into another lockdown.

Can I still take part if I don't have internet access?

We don't want to exclude anyone who doesn't have the technology needed for this study. So, we have thought of a number of ways we can help people if this is stopping you from taking part. Please talk to us about these options.

Is there any cost involved?

The only cost to you will be your time.

WHO CAN TAKE PART IN THIS STUDY?

If you are an adult who had GBS more than two years ago you live in New Zealand and you still experience fatigue, then you are eligible to take part.

Unfortunately, people who are currently getting rehabilitation or have a health condition which means it is not safe to exercise or limits your ability to exercise, won't be able to participate.

WHAT ARE THE BENEFITS OF TAKING PART?

We expect that you will become more physically active and fitter as a consequence of taking part. We hope that as you become more active, your fatigue will decrease, and you will have more energy to do the things you want to do. We also hope that confidence to exercise and your general wellbeing will improve and that you will continue to exercise in the long-term.

This is a great opportunity to be part of receiving rehabilitation online, which might improve access to services in the future.

WHAT ARE THE POTENTIAL RISKS OF TAKING PART?

There are a few things that are important to consider before taking part. It is possible physical activity can make your fatigue worse, however, we will check in with you regularly about your fatigue, so we can quickly make changes to your activity in response. We will also discuss early signs of fatigue and what to do if you notice them, so that you can make changes to your exercise immediately.

You may find the repeated questionnaires we do a little boring, but they are critical to the research. We will try to keep them as short as we can.

It is possible, but not very likely that if you set a goal that you don't reach, then you may develop a sense of failure. We will try and prevent this happening by regularly discussing potential barriers and how you might manage them and how to adjust goals in response. It is less likely the physio might identify distressing thoughts, in which case, she would refer you to your GP or another health professional as would be done in usual clinical practice.

WHAT ARE MY RIGHTS?

You have the right to access information we collect about you as part of the study.

Anything you share to the physiotherapist or the researcher will be kept confidential by the study team and your name will not be known to anyone outside the study.

We will not use your name in any reports we write about the study, and we will make sure you cannot be identified.

WHAT IF SOMETHING GOES WRONG?

If you were injured while taking part in this study, which is unlikely, you would be eligible for compensation from ACC, just as you would be if you were injured in an accident at work or at home.

WHAT WILL HAPPEN AFTER THE STUDY?

The intervention will stop after 12 weeks, however if you have found the exercise helpful, we hope that you will then have the skills and confidence to keep going. You keep the Fitbit at the end of the study.

If we find the intervention is successful in reducing fatigue, we want to tell as many people as possible about our findings. Firstly, we will share our findings with those who have participated in the study by sending a summary of the findings (this normally happens about six months after the study ends). We will offer to hold a hui for you and your support people so you have an opportunity to ask us questions directly. We will then talk to the GBS community at study days and write an article for the regular newsletter. We will offer to hold meetings in the services that have expressed interest or helped us with the study.

We will plan to talk to health professionals like physios, neurologists and GPs to tell them about our results. We will make the details of the coaching available so that it can be used by health professionals working with people with GBS.

The data we collect will be stored in secure files for at least 10 years after the study has ended.

HOW DO I AGREE TO TAKE PART?

The research team will check that you understand the study information and answer your questions. If you wish to take part, then they will ask you to complete the attached consent form. If you need an interpreter to help you understand this information sheet or consent form, please let us know.

Who do I contact for more information about this research?

If you would like more information about this research, please feel free to contact the Study Lead:



Dr Suzie Mudge
09 921 9999 ext 7609
suzie.mudge@aut.ac.nz

Or the study Data Manager:



Greta Smith
09 921 9999 ext 7676
greta.smith@aut.ac.nz

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, we will collect information about you as you participate in the study. Some of that will be information that could identify you (e.g. your name, date of birth). Only the researchers will have access to your identifiable information and this will not be shared with anyone else at any time.

The information we collect through screening, questionnaires and the Fitbit will be stored separately from your identifiable information and this data will be given a code. Codes will be linked to your identifiable information in only one place that will be stored separately from your coded information.

After the online coaching sessions, we will interview you to ask about what you liked about the coaching. The interview will also be done via phone or computer and so we will record it using audio or video recording, depending on your preference and technology. The recordings and the transcripts will be stored in individually password protected files.

All your information will be saved on secure servers at AUT that are password protected. We follow these steps to ensure that your personal and health information remains private. In the unlikely event of a breach of your privacy, we will follow the guidelines from the Office of the Privacy Commissioner.

If you withdraw from the study, you can choose whether your information is removed from the study or is included. At the completion of the study, your data will be stored securely for 10 years on AUT servers and then it will be deleted.

THANK YOU

**Thank you for taking the time to read all this information.
We are really happy to answer any other questions you may have, and look forward to speaking with you soon.**

Suzie & Emma

on behalf of the GBS study team.

Who do I contact for if I have concerns about this research?

If you want to talk to someone about how this study is conducted, you can contact:



Dr Suzie Mudge
09 921 9999 ext 7609
suzie.mudge@aut.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:
0800 555 050
advocacy@hdc.org.nz

Alternately, you can contact the Health and disability ethics committee (HDEC) that approved this study on:
0800 4 ETHICS
hdec@moh.govt.nz



Consent form

Please tick to show that you consent to the following

<input type="checkbox"/>	I have read or had read to me and I understand the information sheet.
<input type="checkbox"/>	I have had enough time to consider whether I want to take part in this study.
<input type="checkbox"/>	I have had the opportunity to talk with my family, whānau or a friend to help me ask questions and understand this study.
<input type="checkbox"/>	I have had the opportunity to ask questions and am happy with the answers I have been given.
<input type="checkbox"/>	I understand that I can decide to withdraw from the study at any time.
<input type="checkbox"/>	I understand that if I withdraw from the study, any information that has already been collected and processed will remain.
<input type="checkbox"/>	I understand that taking part in this study is confidential and private, and that nothing that can identify me personally will be used in reports from this study.
<input type="checkbox"/>	I know who to contact if I have any questions about the study in general.
<input type="checkbox"/>	I understand what is involved in this study.
<input type="checkbox"/>	I understand that I can choose to include my whānau, family or other support person in sessions with the coach or the researcher.
<input type="checkbox"/>	I understand my responsibilities as a study participant.
	I am happy to be contacted for a more in-depth interview. I understand that if I take part in an interview that will be audio-recorded and transcribed: Yes <input type="checkbox"/> No <input type="checkbox"/>
	I wish to receive a summary of findings: Yes <input type="checkbox"/> No <input type="checkbox"/>

Declaration by participant:

I hereby consent to take part in this study.

Name:	
Address:	
Phone (landline and mobile):	
Email:	
Alternate contact person name:	
Alternate contact phone (landline and mobile):	
Alternate contact email:	
Participant Signature:	Date:

Do you want to be contacted about any other related research that the Centre for Person Centred Research may be doing? Yes No

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:

You will be given a copy of this form

The study is run by researchers from AUT and is funded Neuromuscular Research Fund, AUT Faculty Development Fund and the GBS Support Group and has been approved by the Health and Disability Ethics Committee Ref 21/NTB/232