

Participant Information Sheet

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Project Title

The effect of online delivery of the MS-Get-a-Head-Start programme on physical activity self-efficacy of people with Multiple Sclerosis: a randomised pilot trial.

An Invitation

Kia ora, talofa lava, and hello, my name is Gilly Davy, and I would like to invite you to take part in a student research study looking at physical activity levels and confidence to exercise, for people with multiple sclerosis (MS). It is not easy to find accurate information on how to exercise with MS, especially when dealing with fatigue, heat sensitivity, and symptom changes. The MS-Get-a-Head-Start (MSGHS) programme provides you with this information.

This invitation is to take part in MSGHS, which is a six-week online programme delivering education and exercise sessions designed specifically for people with MS. I am completing this research project for my master's qualification.

This information sheet will explain the research study. Please contact me and ask about anything that you do not understand, or with questions you would like to discuss.

Please remember when considering this invitation that participating in this study:

- Is entirely voluntary (your choice).
- If you agree to take part, you can withdraw at any time if you feel uncomfortable continuing without and penalty.
- Whanau/ Family/ Carers are encouraged and welcomed to be involved and engaged at any stage.

We would like to thank New Zealand Multiple Sclerosis Research Trust who have kindly provided funding to support this study.

What is the purpose of this research?

This is a pilot study that will look at the impact of the MSGHS programme on your confidence and engagement in regular physical activity.

MS can cause physical and cognitive deterioration, which can affect your ability to take part in activities you enjoy and reduce your quality of life. Research has shown that regular physical activity has many physical and cognitive benefits. However, in Aotearoa NZ there is limited access to rehabilitation or accurate information on how to exercise safely with MS. The result of this is that around 80% of people living with MS do not engage in regular physical activity, which increases the risk of other health problems.

By carrying out this pilot study, I am testing the feasibility of expanding it to a larger randomised controlled study that will test if the MSGHS programme can improve confidence and participation in physical activity in people with MS. I will be looking to see if there are any differences between those who have used MSGHS and those who are on the waiting list.

The MSGHS programme was developed by me, Gilly Davy, the primary researcher, to provide exercises and education for people with MS. Since 2013, the MSGHS programme has been used in the clinical setting for people living with MS in both individual and group therapy.

If you decide to take part in this study, you will be asked to complete the MSGHS programme over six weeks. The programme will be delivered fully online. You will receive a weekly email containing two exercise videos and a recorded education video. The email will also detail coursework to complete each week.

You will be randomly assigned to either the MSGHS programme or the waitlist. The waitlist will be for 12 weeks and then you will have access to the 6-week MSGHS programme. During the waitlist period, you will still be asked to complete the study questionnaires at the start, at week 7 and week 12.

The results of this study will help us understand the effect of the MSGHS programme, and to make any changes needed to improve the programme for future use. We will present and publish the results in both public and professional settings.

How was I identified and why am I being invited to participate in this research?

You have been invited to take part in the research because you are living with MS, aged between 18 and 70 years old, and are currently living in New Zealand. You will have expressed an interest after seeing the advertisements or hearing about this study from a health professional, via your local MS society or through word of mouth.

Before formally being part of the study, it would be beneficial for us to build a relationship (whakawhanaungatanga). You can watch the [video link](#) here so I can introduce myself and the study. You can also find out more about the MSGHS programme through the www.ms-ghs.com website. If you are interested to find out more about this study, we can also schedule a phone call.

I want to ensure your safety to participate in a remotely delivered exercise programme, so you can only participate in this study if you can still walk unaided and can get on and off the ground by yourself safely. You also need to be otherwise healthy with any other health conditions well managed. You will be asked to complete two short questionnaires to ensure you meet the entry criteria, which will check your current level of ability and readiness to safely complete exercise. I will also need find out more about you, such as your age, gender, ethnicity, the region you live in and when you were diagnosed with MS.

We are limited in the number of people who can participate in the study. If you do meet the selection criteria but miss out on being included in the study, you will still be given the opportunity to access the MSGHS programme after the study results have been collected.

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will not affect any future healthcare. You can withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

If you agree to take part in this study, please email me gilly@ms-ghs.com to indicate your willingness to be involved. As this study is measuring the digital delivery of the MSGHS programme the majority of our communication will be via email.

If you would like to discuss the study over a phone call we can then schedule a time to speak. Otherwise, I will reply to your email with the link to complete the screening questionnaires. Once you have completed these, I will review them and let you know if you have met the study criteria. If you have met the criteria, I will email you a consent form to complete and return. I will then let you know by email if you will be able to start the programme straight away or if you are in the control group and will have access to the programme after 12 weeks.

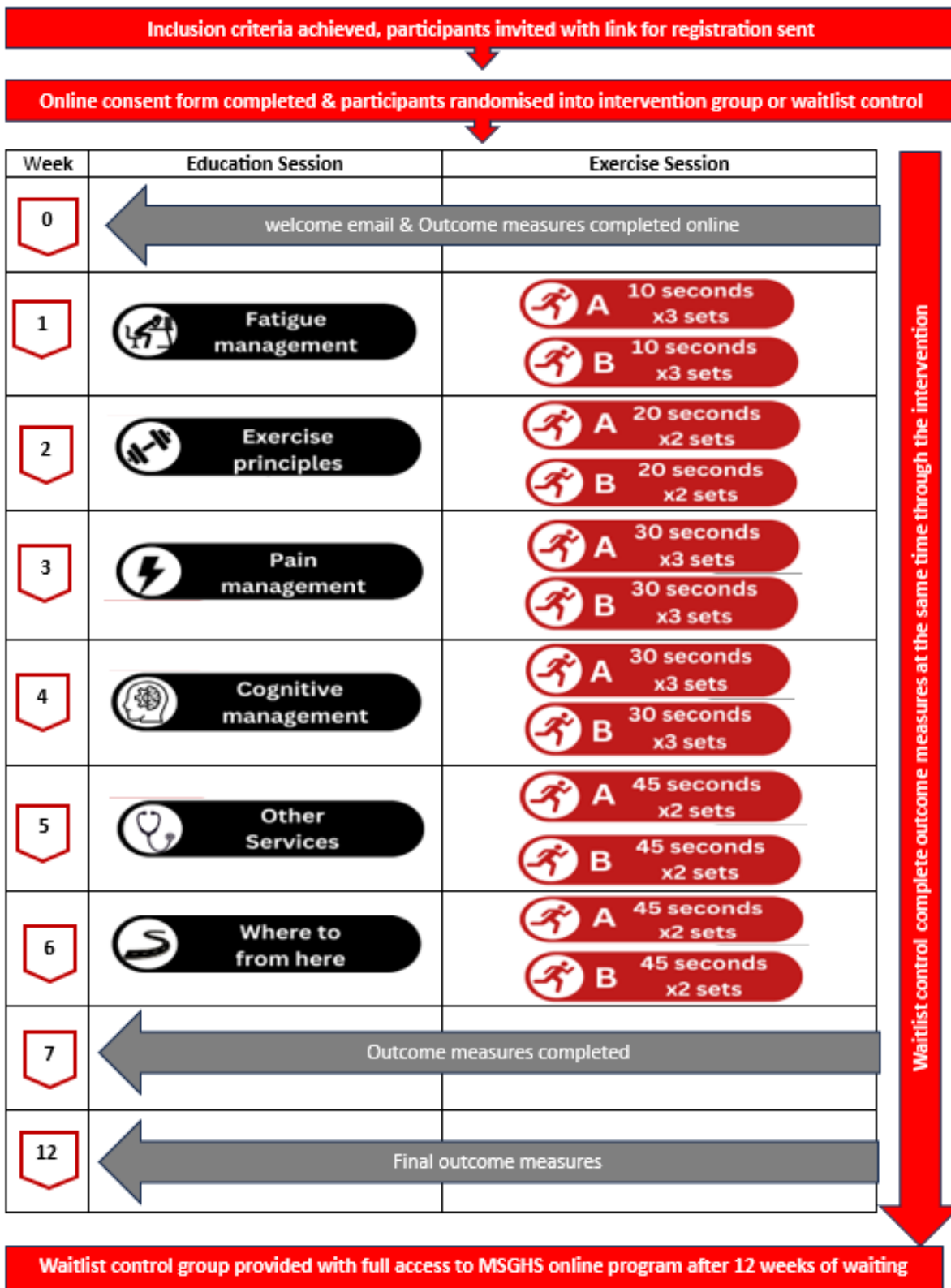
What will happen in this research?

The MSGHS programme will be delivered fully online over 6 weeks. You will receive a weekly email containing two exercise videos of approximately 45 -60 minutes and an education video of approximately 30 -45 minutes. You will also be asked to fill out some course work, which will take approximately 30 minutes a week. The whole programme will take approximately 2.5 hrs a week.

We recommend you complete at least two exercise sessions each week. Each exercise video is made up of 9 exercises delivered in intervals and includes strengthening, balance, and fitness. You will be encouraged to work hard during each exercise. However, you only need to work as hard as you feel comfortable. You repeat each exercise for a short interval of time, rest and then repeat the same exercise three times. As the weeks continue the exercise and rest time increases. You do not require any specific equipment, only a sturdy chair and an exercise mat or towel to use on the floor.

Alongside the education videos, an online digital (PDF) copy of the MSGHS workbook will be provided which you can download and save on your computer. We do not gather any of the information you fill into the workbook. If you prefer, we will post you a physical copy of the workbook. This contains all the supporting educational material for the programme. The six educational topics cover a range of MS symptoms and practical management strategies: fatigue management, exercise prescription, pain management, cognitive and psychological well-being, multi-disciplinary services and finally “where to from here” in the final week.

The figure below shows the process of the study.



To help you understand what this research study is about please watch the short video by clicking on [this link](#).

What are the discomforts and risks?

The exercise programme intensity is gradually increased over the six weeks to minimise potential discomfort. However, you may experience muscle soreness for up to 48 hours after the exercise sessions. You are encouraged to work hard during the sessions and to get out of breath. However, you are in control of how hard you work during the exercise sessions.

If participating in this amount of exercise is new for you then you may experience a temporary increase in fatigue levels. However, the MSGHS programme has been specifically designed to minimise increases in fatigue.

You will be completing the exercise sessions unsupervised by a health professional in an environment that suits you. This could have potential hazards and I will remind you at the start of each video to ensure your environment is clear of items to minimise any risk of falling during this programme. I encourage you to have someone present with you if you have any concerns.

You may find information delivered in the education videos confronting or helpful. If you do find some information distressing, or struggle to move forward with the information, I encourage you to reply to the weekly email and we can try to answer any questions you may have.

How will these discomforts and risks be alleviated?

You will be asked to watch a welcome video at the start to help prepare you for the programme. In the exercise videos you will be shown how to set up your exercise area to be safe. Each exercise is demonstrated, and options of making the exercise easier or harder are provided, so you can tailor the exercise to your own abilities. You are welcome to rest at any time by pausing the video or by missing an exercise if you do not think it is appropriate for you to complete.

To monitor issues, events or injuries that might arise while participating in this programme, you will be asked in each of the automated emails;

“Have you experienced any incidents that has affected your health this week such as a fall, injury or illness?”

If yes, you will simply click the “yes” button below. Our research assistant will then contact you within 48 hours to discuss the incident and ask a few questions. However please be aware the research assistant is not a medical professional and will not be able to assist you medically.

If sensitive or distressing issues do arise during the programme, and you would like to discuss these with someone, please let us know so we can connect you with some support.

AUT Student Counselling and Mental Health is able to offer three free sessions of confidential counselling support for adults participating in an AUT research project. These sessions are only available for issues that have arisen directly as a result of participation in the research and are not for other general counselling needs. Should you wish to access these services, you will need to:

- drop into our centre at WB203 City Campus, email counselling@aut.ac.nz or call 09-921 9292.
- let the receptionist know that you are a research participant and provide the title of my research and my name and contact details as given in this Information Sheet.

You can find out more information about AUT counsellors and counselling on <https://www.aut.ac.nz/student-life/student-health-and-wellbeing/counselling-and-mental-health-support>

If the counselling by AUT proved to be not sufficient to address directly linked to this study please contact Gilly Davy for information on further options at no cost to you.

What are the benefits?

For You: You will hopefully feel benefits from regular exercise, which may be reflected in noticeable physical improvements. You will learn how exercise can positively influence management of your MS and be aware of ways you can exercise to make being physically active more achievable and enjoyable. You will also learn some

alternate ways to manage your fatigue, pain, and mental health, and have an increased understanding of which healthcare providers can assist you to keep engaged in regular physical activity. If you involve your whānau/family/cares, this could assist them in their understanding of your MS and how to support you. Once you have completed the MSGHS programme you will continue to have access to the resources for a further 12-month period.

For the researcher: the results will help me find out the effect of the MSGHS programme on confidence and engagement in regular physical activity for people with MS. It will help to highlight any further work or changes to the programme to achieve good outcomes for people with MS and help make a decision whether we progress to a larger randomised control trial. This study is the final part of my Master's qualification. MS GHS is a commercial company, and all intellectual property remains the property of MS Get a Head Start. This programme or any portion thereof may not be reproduced or used in any manner whatsoever without the express written permission of Gilly Davy, Copyright© 2019 MS Get a Head Start. After this research study is completed, there is the potential that this online MS GHS programme for people living with MS may be delivered commercially. This may lead to some potential financial gain for the researcher. There are no financial benefits or costs for your participation in this study.

For the wider community: The wider community includes people living with and supporting those with MS, MS societies, MS Nurses, Neurologists and Allied health professionals. The MSGHS programme is already established for face-to-face delivery and this study will help establish whether the programme can be delivered online in an automated fashion. This will significantly improve access to evidence-based education and exercise guidance for those living with MS throughout Aotearoa, filling a significant gap in access to rehabilitation. The online delivery may also change how practices can work through their waiting lists and what services they offer. As this programme is being delivered in people's homes, it could also benefit whānau of PwMS and those caring/supporting PwMS by helping to increase their knowledge and understanding of MS and self-management strategies.

What compensation is available for injury or negligence?

In the unlikely event of a physical injury as a result of your participation in this study, rehabilitation and compensation for injury by accident may be available from the Accident Compensation Corporation, providing the incident details satisfy the requirements of the law and the Corporation's regulations.

How will my privacy be protected?

Once you are formally invited to participate in this study, you will be asked to create an online account on the MSGHS website which is a secured server and only Gilly Davy, the research assistant and website IT support individual have access to this information. You will set your own unique password and you will be assigned an exclusive identifier, so your results can be reported without being able to be linked to you. You do not need to provide your full name at any point.

No material that could personally identify you will be used in any reports from this study. On completion of the study all primary data will be deleted from the MSGHS secure server after 6 months. The collated results from all participants will be electronically stored for 6 years in a secure AUT password protected folder. All the information collected will only be used for this study. We will not be collecting any meta-data such as such as time-spent with the videos while you are logged in.

What are the costs of participating in this research?

There will be no financial costs to taking part in this research except the existing costs of accessing the emails and videos through your normal internet data provider. The programme will take approximately two and half hours a week for 6 weeks.

What opportunity do I have to consider this invitation?

Once you have expressed your interest to take part in the study and you have been emailed the link to complete the screening questionnaires you will have 2 weeks to consider if you would like to take part. If you have not completed the screening questionnaires after 2 weeks, I will contact you and I will be happy to answer any further questions you may have.

You are welcome to take extra time to consider your involvement however study recruitment will close on the 30th June 2024.

Will I receive feedback on the results of this research?

You will have the option on the consent form to confirm if you would like to receive a copy of your individual results and a one-page summary of the results of the study once it has been completed.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Nicola Saywell, nicola.saywell@aut.ac.nz, 09 921- 9502.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, ethics@aut.ac.nz , (+649) 921 9999 ext 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researcher Contact Details

Support:

Gilly Davy
Gilly@ms-ghs.com

Administrative or IT

Lisa Pocq Saint Jean
Admin@ms-ghs.com

Project Supervisor Contact Details:

Nicola Saywell, nicola.saywell@aut.ac.nz

Verna Stavric, verna.stavric@aut.ac.nz

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**New Zealand
Multiple Sclerosis
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Knowledge brings hope