ReFresh Online Fatigue Management Program

INFORMATION ABOUT PARTICIPATION IN THE REFRESH FATIGUE MANAGEMENT PROGRAM

Introduction

This project is being conducted as part of Sarah Alageel’s PhD. We know that people with Parkinson’s can experience significant fatigue, and this can have a substantial impact on their quality of life and activity levels. We know that in other health conditions a program similar to the ReFresh fatigue management program has been shown to be helpful.

You are invited to join this research project to investigate whether an online program will help people with Parkinson’s better manage their fatigue. The research will compare a group of people with Parkinson’s who complete the online ReFresh fatigue management program with a group that are asked to wait for four months (wait list) before starting the program. We will compare the results from the two groups to see if one is better.

To join this study, we need you to be over 18 years of age, living in England, and have a diagnosis of idiopathic Parkinson's disease. You cannot have a diagnosis of any of the Parkinson's plus diseases (vascular Parkinsonism, progressive supranuclear palsy, multiple system atrophy, Lewy body dementia). However you can have any other disease e.g. high blood pressure, arthritis, cancer. Because we are recommending you undertake exercise as part of the program, you should not take part if your clinical team have said you should not do exercise.

This study is a pilot study because designing research like this is complex. This pilot study will have just 40 participants (20 in each group). It will check that the program is understandable, practical, and check that we are using the right measures to detect any changes. It will also tell us how variable the results are, and so how large a full-sized study will have to be to give results we can be certain of.

To try to make sure the groups are the same to start with, each participant is put into a group by chance (randomly). You have an equal chance of being in either group (ReFresh or waitlist). This study will investigate whether the ReFresh program improves levels of fatigue at three months after the start of the program compared to the waitlist group.

What will happen to me if I take part?

Everyone that agrees to take part in our ReFresh study will fill in a survey at the start. The survey will ask about you, your Parkinson's, your experiences of fatigue, and your everyday activities and quality of life. It will take about 30 minute to complete. You will then be put into the ReFresh program or waitlist groups by chance (randomization). You will receive an email either with the link to the online ReFresh program or be asked to be part of the waitlist group.

The ReFresh online program will ask participants to watch 6 online sessions and undertake some homework over 6 weeks. Each session will last around 30 minutes with a further 30-60 minutes of homework (including exercise).

After 12 weeks both groups will be asked to complete another survey similar to the baseline survey. Those who accessed the online ReFresh program will be asked their opinion of it. After 16 weeks the waitlist group will be emailed a link to the online ReFresh program which they can undertake if they wish. Uptake will not be recorded.

Are there any risks for me?

We will encourage everyone who takes part in the ReFresh online program to undertake around 30 minutes of exercise three times a week. We will provide links to online videos of exercise programs led by physiotherapists, and recommend other types of exercise. These are recommendations and how much exercise you manage will be measured as part of the study. If you have any concerns about taking on an exercise program (particularly if you have another health condition that may increase risk such as lung or heart disease) we recommend you talk to your GP or clinical team about what exercise is appropriate for you. If you are unable to undertake any exercise, this research project is not suitable for you. Additionally, people with Parkinson's are at increased risk of falls, and we ask everyone undertaking exercise to be mindful of this risk. For example, we recommend clearing a generous space if doing exercise at home, and maybe placing a phone nearby if you don't have anyone at home with you when exercising. We will be asking about any falls, and any injuries resulting from a fall as part of the study.

We will be asking you to think about how you cope mentally and physically with fatigue and your Parkinson’s. We recognize that this can sometimes be distressing. If you think you might benefit from talking to someone about your mental health and wellbeing we highly recommend the services provided by the mental health charity MIND https://www.mind.org.uk/information-support/. For support related specifically to Parkinson's disease, we recommend reaching out to Parkinson's UK https://www.parkinsons.org.uk/information-and-support/support-you. You can contact them through their free confidential helpline at 0808 800 0303 (Monday to Friday, 9 am to 6 pm, and 10 am to 2 pm on Saturdays) or by emailing hello@parkinsons.org.uk

Access Arrangements

We strongly believe that research should be accessible to everyone no matter what disability they may have. The surveys are screen reader compatible, and we are perfectly happy for you to have someone (e.g. family or a carer) help you complete the surveys. However, if you would prefer to have a paper copy of the survey please email Sarah Alageel s.alageel@uea.ac.uk and we will post you a paper copy (either in standard or large font size) along with a stamped addressed envelope for you to return it to us.

The online ReFresh program is highly accessible and compatible with screen readers. Again, it is fine if you wish for carers, family, or friends to help you engage with the program.

If you have any other access needs for either the surveys or to take part in the ReFresh program, please contact us and we will try to accommodate them (s.alageel@uea.ac.uk).

Can I stop?

You are free to stop and withdraw from the research study at any point up to and including the endpoint (12 week) survey. Just contact Sarah Alageel s.alageel@uea.ac.uk and your data will be deleted. However, once the endpoint survey responses are submitted, we can no longer withdraw your data from the project.

Ethics Approval

To protect your safety, rights, wellbeing and dignity, all research in the University of East Anglia is reviewed by a Research Ethics Body. This research was approved by the FMHS- REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee), reference ETH2324-0159

Complaints or concerns

If you have a complaint or any concerns about the project, please let us know. You can contact my Primary Supervisor, Dr Katherine Deane, by email at k.deane@uea.ac.uk or by post to School of Health Sciences, University of East Anglia, Norwich, NR4 7TJ. If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the Head of School of Health Sciences: Prof Kenda Crozier (k.crozier@uea.ac.uk).

Data Management

All hard copy surveys and consent forms will be destroyed as soon as the data is transcribed to the Qualtrics platform. The data will be downloaded from the Qualtrics platform to the secure UEA server, and the original data will be deleted from the Qualtrics platform by 01/01/2025. Only the project team will have access to participant's contact details. The contact details for participants will only be kept until the end of the data collection period (i.e., 01/10/2024 at the latest). After this we will destroy the contact details and keep the anonymised dataset of results. All project data will be deleted from the UEA shared drive 10 years after the end of the project (i.e., 31st September 2034). Only anonymised data will be shared externally (e.g. in reports and publications). Data management will follow the Data Protection Act 2018 (DPA 2018) and UK General Data Protection Regulation (UK GDPR), and the University of East Anglia's Research Data Management Policy. According to data protection legislation, we are required to inform you that the legal basis for processing your data as listed in Article 6(1) of the UK GDPR is because this allows us to process personal data when it is necessary to perform our public tasks as a university. In addition to the specific information provided above about why your personal data is required and how it will be used, there is also some general information which needs to be provided for you:

- The data controller is the University of East Anglia.

- For further information, you can contact the University’s Data Protection Officer at dataprotection@uea.ac.uk
- You can also find out more about your data protection rights at the Information Commissioner's Office (ICO).
- If you are unhappy with how your personal data has been used, please contact the University’s Data Protection Officer at dataprotection@uea.ac.uk in the first instance.

Queries

For any questions or concerns, please do not hesitate to contact Sarah Alageel s.alageel@uea.ac.uk or by post to School of Health Sciences, University of East Anglia, Norwich, NR4 7TJ.

This information sheet was last updated on 27/01/2024.

To download a copy of this information sheet please click here: https://www.uea.ac.uk/web/groups-and-centres/projects/fatigue-management-in-parkinson-s

This information sheet was last updated on 11/02/2024.

PARTICIPANT CONSENT FORM

I, ... [PRINT NAME], **am** willing to participate in this research study.

In giving my consent I state that:

- I understand the purpose of the study, what I will be asked to do, and any risks/benefits involved.
- I have read the Participant Information Sheet, which I may keep, for my records, and have been able to discuss my involvement in the study with the researchers if I wished to do so.
- The researchers have answered any questions that I had about the study and I am happy with the answers.
- I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my relationship with the researchers or anyone else at the University of East Anglia (or University of East Anglia, Parkinson's UK, Cure Parkinson's Charity) now or in the future.
- I understand that I am completing a non-anonymous questionnaire I can withdraw from the study at any time.
- I understand that the results of this study will be used in the way described in the information sheet.
- I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.

I consent to:

Completing a questionnaire YES ☐ NO ☐

Experiments YES ☐ NO ☐

....
Signature

....
PRINT name

....
Date

Version 1: 14/12/2023
Ethics ETH2324-0159