**ReFresh Online Fatigue Management Program**

**INFORMATION ABOUT PARTICIPATION IN THE REFRESH ONLINE FATIGUE MANAGEMENT PROGRAM**

**Introduction**

This project, part of Sarah Alageel's PhD studentship, aims to address the significant fatigue experienced by individuals with Parkinson's disease, impacting their quality of life and activity levels. Fatigue management programs have been successful in other health conditions.

You are invited to participate in this research project to assess whether an online program might help people with Parkinson’s better manage fatigue. The study compares those who complete the online ReFresh fatigue management program with a waitlisted group.

To join, you must be over 18, reside in England, and have a diagnosis of idiopathic Parkinson's disease **(**the most common Parkinson's disease diagnosis (idiopathic means of unknown cause)**)**. Please note exclusion criteria apply, such as Parkinson's plus diseases. Participants should not volunteer to participate if their clinical team advises them against exercise.

This pilot study, involving 40 participants, will examine the program's practicality. While not allowing us to make a definite conclusion as to the effectiveness of the fatigue management program, this project will inform the design of future research and tell us how large these need to be.

**What will happen to me if I take part?**

You can participate in this online research project entirely from the comfort of your home. At the start of the research project, you will be asked to agree to take part in the ReFresh study and complete a baseline survey covering various aspects of your life, including your Parkinson's condition, experiences of fatigue, daily activities, and overall quality of life. This survey should take approximately 30 minutes to complete.

After completing the baseline survey, participants will be randomly assigned (by chance) to either the ReFresh program or the waitlist group. A computer program conducts this random assignment tosses a virtual coin to see which group any individual will be in.

This allows us to be sure that the two groups are as similar as possible, strengthening the project's statistical robustness. You will receive an email notification of your group assignment. If you are in the ReFresh program group, you will receive a web link to access the online program. Conversely, if you are in the waitlist group, you will be asked to continue managing your Parkinson’s until the 12-week follow-up survey.

Participants in the ReFresh program group will engage in six online sessions spread over six weeks, each lasting about 30 minutes, with an additional 30-60 minutes allocated for homework tasks, including exercises. Feedback on each week's content will be collected through short surveys. After the initial 12-week period, both groups will complete a follow-up survey.

At the end of the 16-week study period, the waitlist group will receive a link to access the online ReFresh program. Participation is optional, and uptake will not be recorded.

All surveys are designed to allow participants to stop partway through and continue later. If you prefer to complete surveys on paper, please contact Sarah Alageel at s.alageel@uea.ac.uk, and we will arrange for them to be sent to you. We hope this will help manage any fatigue you experience when completing the surveys.

The study will compare the results of the participants who undertake the ReFresh program and those who do not. The waitlist group allows us to observe the normal variability of fatigue and then see if the ReFresh program makes a substantial difference in fatigue levels compared to this.

**Are there any risks for me?**

As part of the ReFresh online program, we encourage all participants to exercise for approximately 30 minutes three times a week. To support this, we will provide links to online videos of exercise programs led by physiotherapists and recommend other types of exercise.

It is important to note that these are recommendations, and your level of exercise will be measured as part of the study. If you have any concerns about participating in the exercise, especially if you have another health condition that may increase risk, such as lung or heart disease, we strongly advise you to consult your GP or clinical team to determine what level of exercise is appropriate for you. If you cannot undertake any exercise, this research project is unsuitable for you.

Additionally, we want to emphasise the importance of being careful when exercising, as some people with Parkinson’s are prone to falling easily. Therefore, we recommend informing a family member or friend that you are participating in this research project. We suggest clearing a generous space around you if you are exercising at home and keeping a phone nearby in case of a fall. The endpoint survey will ask about falls and any consequences of them.

We will also ask you to reflect on how you cope mentally and physically with fatigue and your Parkinson's. We understand that thinking about your Parkinson’s symptoms and how you cope with them can sometimes be distressing. If you would benefit from talking to someone about your mental health and well-being, we highly recommend accessing the services provided by the mental health charity MIND: (<https://www.mind.org.uk/information-support/>).

For support related to Parkinson's disease, we recommend contacting Parkinson's UK: (<https://www.parkinsons.org.uk/information-and-support/support-you>).

You can reach 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 helo@parkinsons.org.uk.

**Access Arrangements**

We believe that research should be accessible to everyone, regardless of disability. Our surveys meet online accessibility standards and are compatible with screen readers. You are welcome to ask for assistance from family members or caregivers to complete the surveys.

If you prefer a paper copy of the survey, please contact Sarah Alageel at s.alageel@uea.ac.uk, and we will promptly send you a paper copy in either standard or large font size, along with a stamped addressed envelope for your convenience in returning it to us.

We are committed to accommodating any other accessibility requirements you may have for the surveys or participation in the ReFresh program. Please don't hesitate to contact Sarah Alageel (s.alageel@uea.ac.uk), and we will do our best to accommodate your needs.

**Can I stop?**

Your participation in the research study is entirely voluntary, and you can withdraw at any point up to and including the endpoint (12-week) survey. If you decide to cancel, contact Sarah Alageel at s.alageel@uea.ac.uk, and we will promptly delete your data from the project. After the endpoint survey at 12 weeks is completed and submitted, the data cannot be removed from our study.

We understand that completing surveys can sometimes be challenging, so we want to assure you that you can pause completing them partway through and resume at a later time.

**Ethics Approval**

This research has undergone a thorough review by a Research Ethics Committee at the University of East Anglia to protect your safety, rights, well-being, and dignity. The Faculty of Medicine and Health Sciences Research Ethics Subcommittee (FMHS-REC) approved this study under reference ETH2324-0159.

**Complaints or concerns**

If you have any complaints or concerns about the research project, please don't hesitate to contact us:

1. Contact my Primary Supervisor, Dr. Katherine Deane, via email at k.deane@uea.ac.uk or by post to the School of Health Sciences, University of East Anglia, Norwich, NR4 7TJ.
2. If you prefer to escalate your concerns or complaints to someone independent from the study, please contact the Head of the School of Health Sciences, Prof Kenda Crozier, at k.crozier@uea.ac.uk.

**Data Management**

Ensuring the security and confidentiality of your data is of the utmost importance to us.

* Paper copies of surveys and consent forms will be securely destroyed once the data is transferred to the Qualtrics platform.
* The data will be stored on a secure UEA server, and the original data will be deleted from the Qualtrics platform by 01/01/2025.
* Participant contact details will only be accessible to the project team and deleted after the data collection period ends (i.e., by 01/11/2024). After this point all data will be anonymised.
* All project data will be deleted from the UEA shared drive ten years after the end of the project (by 31st September 2034).
* Only anonymised data will be shared externally, such as in reports and publications.
* Our data management practices adhere to the Data Protection Act 2018 (DPA 2018), the UK General Data Protection Regulations (UK GDPR), and the [University of East Anglia's Research Data Management Policy](https://www.uea.ac.uk/documents/20142/130807/RINopen-researchresearch-data-management-policy.pdf/f1b1f3d6-4b8e-d2f7-2dfc-8512d6249bd8?t=1590588842221).

As required by data protection legislation, here are some additional details:

* The data controller is the University of East Anglia.
* For further information, contact the University's Data Protection Officer at dataprotection@uea.ac.uk.
* You can learn more about your data protection rights at the Information Commissioner's Office (ICO).
* If you have any concerns about how your 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 about the research project, please do not hesitate to contact Sarah Alageel at s.alageel@uea.ac.uk or by post to the School of Health Sciences, University of East Anglia, Norwich, NR4 7TJ.

This information sheet was last updated on 10/04/2024.

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>

**What are you consenting to?**

Participating in this study is entirely voluntary, and you are not obliged to participate. Your participation will not impact your current or future relationships with the researchers or anyone else at the University of East Anglia.

By providing consent to be involved in this project, you are confirming the following:

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| --- | --- |
|  | **Tick to agree** |
| I understand what I have read in the information sheet |  |
| I agree to take part in the ReFresh research project |  |
| I agree to fill in the surveys at the start and end of the project |  |
| I agree to the use of my personal information as described |  |
| I have downloaded a copy of the Participant Information Sheet to keep |  |

Your Name:

Your Signature:

Your Email address:

Date:

**Thank you for considering participation in our research project.**