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ReFresh study: rehabilitation for fatigue in people with Parkinson's

Submission date
12/02/2024

Recruitment status
No longer recruiting

Registration date
27/02/2024

Overall study status
Completed

Last Edited
17/12/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to assess the acceptability and practicality of the ReFresh online fatigue management program and the research design of the fully-powered randomized controlled trial (RCT). It will identify the best fatigue measure to use as the primary outcome. It will also provide the information needed to conduct a power calculation to inform the design of a fully-powered RCT. This research focuses on improving fatigue levels and hence the quality of life for people with Parkinson's disease by investigating the ReFresh Online Fatigue Management Program.

Who can participate?
Adults aged 18 years and over with Parkinson's disease and self-identified fatigue

What does the study involve?
Participants will fill in a survey at the start about their Parkinson’s, their experiences of fatigue, and their everyday activities and quality of life. It will take about 30 minutes to complete. Participants will then be put into the ReFresh program or waitlist groups by chance (randomization). They 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 six 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.

What are the possible benefits and risks of participating?
The researchers will encourage everyone who takes part in the ReFresh online program to undertake around 30 minutes of exercise three times a week. They 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 participants manage will be measured as part of the study. If participants have any concerns about taking on an exercise program (particularly if they have another health condition that may increase risk such as lung or heart disease) they are recommended to talk to their GP or clinical team about what exercise is

appropriate for them. If they are unable to undertake any exercise, this research project is not suitable for them.
Additionally, people with Parkinson’s are at increased risk of falls, and participants are asked to be mindful of this risk. For example, they are recommended to clear a generous space if doing exercise at home, and maybe place a phone nearby if they don’t have anyone at home with them when exercising. The researchers will be asking about any falls and injuries resulting from a fall as part of the study.
The participants will be asked to think about how they cope mentally and physically with fatigue and Parkinson’s. This can sometimes be distressing. If participants think they might benefit from talking to someone about their mental health and wellbeing the researchers 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, they recommend reaching out to Parkinson's UK (https://www.parkinsons.org.uk/information-and-support/support-you). They can be contacted 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.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
January 2023 to August 2024

Who is funding the study?
King Saud University (Saudi Arabia)

Who is the main contact?
1. Sarah Alageel, S.alageel@uea.ac.uk
2. Dr Katherine Deane, k.deane@uea.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Pilot randomized controlled trial protocol – ReFresh Study: rehabilitation for fatigue in people with Parkinson’s

Study objectives
This study is a pilot randomized controlled trial (RCT). Its purpose is to assess the acceptability and practicality of the ReFresh online fatigue management program and the research design of the RCT evaluation. It will identify the best fatigue measure to use as the primary outcome. It will also provide us with the information needed to conduct a power calculation to inform the design of a fully powered randomised controlled trial.

The ReFresh online fatigue management program, when compared to standard care, will result in a statistically significant reduction in perceived fatigue levels among individuals diagnosed with Parkinson's disease. Specifically, it is hypothesised that participants engaging in the ReFresh program will demonstrate a greater decrease in fatigue severity scores over 12 weeks. This hypothesis is based on the assumption that the targeted strategies and interventions included in the ReFresh program will positively influence fatigue management in this population.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/04/2024, University of East Anglia’s Faculty of Medicine and Health’s Research Ethics Committee (University of East Anglia Norwich Research Park, Norwich, NR4 7TJ, United Kingdom; +44 (0)1603 456161; University.secretary@uea.ac.uk), ref: ETH2324-0159

Study design
Pilot randomized controlled trial with two parallel comparator groups

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions

Participants will be randomized using the Sealed Envelope website in a 1:1 ratio to either the intervention (ReFresh program) or control (waitlist) group. The ReFresh group will access online modules and exercise recommendations, while the waitlist group receives usual care.

Upon completion of the baseline data collection phase, participants will be subjected to randomization into either the intervention arm (fatigue management) or the control arm (waitlist) using the Sealed Envelope website. Sealed Envelope provides a robust online software application for randomizing patients in clinical trials and capturing case report form data (EDC and ePRO). For this trial, the Simple randomization service offered by Sealed Envelope will be utilized. This employs a pseudo-randomization number generator and will allocate participants in a 1:1 ratio to either the ReFresh program or the waitlist.

To ensure a balanced distribution of patients between the two arms throughout the trial, participants will be allocated in randomly permuted blocks of 4 and 6 (Sealed Envelope Ltd. 2022). A unique password will be assigned for the trial, allowing authorized personnel to conduct new randomizations. The results will be promptly displayed on-screen and emailed to both the trial administrator and the assigned individual overseeing the randomization process, ensuring transparency and accountability.

Upon allocation, participants will receive an email notifying them of their assignment. Those allocated to the ReFresh group will be provided with the link to access the online program. Conversely, participants assigned to the waitlist group will be informed that they will be contacted again in 12 weeks to complete the endpoint survey. At 16 weeks, they will receive the link to the ReFresh program to prevent contamination of the control group.

Intervention Group:
Participants randomized to this arm will gain access to the online fatigue management webpage. They will progress through the online resources at their own pace, although it is recommended they complete one module per week and participate in an exercise program at least three times per week. The program consists of six modules. Participants' usage of the online resources will be tracked, and completion of the fatigue management program will be defined as accessing at least four of the six modules.

Control Group:
Participants in the control arm will be placed on a waitlist for 4 months to access the online fatigue management program. They will receive usual care for their Parkinson’s, attending consultant and nurse specialist appointments as scheduled based on their clinical needs. No additional contact or information regarding fatigue management will be provided.

Blinding:
Blinding to group allocation will not be feasible, as participants will be aware of whether they have access to the online fatigue management program. All assessments will be completed by participants via online surveys. The trial data will be analysed by SA, who will not be blinded to allocation.

The study aims to assess the implementation of study processes, evaluate the acceptability and practicality of the ReFresh intervention, and determine the best fatigue measure to use in a fully powered RCT. The primary outcome, fatigue at 12 weeks, is measured using the Parkinson’s Fatigue Scale (PFS) and the Modified Fatigue Impact Scale (MFIS) at baseline and 12 weeks. Given the nature of the intervention (online educational program), blinding is not feasible. The study aims to assess the implementation of study processes, determine the acceptability and practicality of the ReFresh intervention, and evaluate the best fatigue measure to use as the

primary outcome measure for a fully powered randomized controlled trial. The selected primary measure's data will inform the sample size calculation for the subsequent fully powered RCT.

Intervention Type
Behavioural

Primary outcome(s)
Fatigue assessed using the Parkinson's Fatigue Scale (PFS) and the Modified Fatigue Impact Scale (MFIS) at 12 weeks

Key secondary outcome(s))
1. Quality of life measured using the Parkinson's Disease Questionnaire (PDQ-39) at baseline and 12 weeks
2. Anxiety measured using the Parkinson Anxiety Scale (PAS) at baseline and 12 weeks
3. Depression measured using the Geriatric Depression Scale-15 (GDS-15) at baseline and 12 weeks
4. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and 12 weeks
5. Self-efficacy measured using Multiple Sclerosis-Fatigue Self– Efficacy (MS-FSE) at baseline and 12 weeks
6. Fatigue-related goals measured using the Canadian Occupational Performance Measure (COPM) at baseline and 12 weeks
7. Incidence of falls measured using self-report throughout the study

Completion date
01/08/2024

Eligibility

Key inclusion criteria
1. People with a clinical diagnosis of idiopathic Parkinson's disease
2. Aged 18 years and over
3. Living in England
4. English speaking
5. Literate
6. Internet access

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit

120 years

Sex
All

Total final enrolment
109

Key exclusion criteria
1. Any diagnoses of other Parkinsonian conditions (e.g., vascular Parkinsonism, progressive supranuclear palsy, multiple system atrophy, Lewy body dementia)
2. Anyone who has been clinically recommended to not undertake exercise

Date of first enrolment
14/06/2024

Date of final enrolment
25/06/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Online
38 Skipper House
130 Ber Street
Norwich
England
NR1 3EZ

Sponsor information

Organisation
King Saud University

ROR

https://ror.org/02f81g417

Funder(s)

Funder type
University/education

Funder Name
King Saud University

Alternative Name(s)
, KSU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 17/12/2025:

De-identified participant-level data (baseline characteristics and outcome scores at baseline and 12-week endpoint), a data dictionary, and the Statistical Analysis Plan will be available after journal publication of the main trial manuscript and for 5 years thereafter. Access is for academic, non-commercial use on request to the corresponding author (s.alageel@uea.ac.uk), subject to a brief analysis plan and a data-sharing agreement (confidentiality, secure storage, no re-identification). No direct identifiers will be shared; data will be transferred via secure encrypted methods. Data will not be placed in a public repository at this stage.

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Previous IPD sharing plan:

The anonymized datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. Access to the datasets can be requested from the principal investigator, PGR Student Sarah alageel at S.alageel@uea.ac.uk. The data-sharing plan includes sharing relevant data with qualified researchers for further analysis, subject to approval based on research objectives and ethical considerations. Consent from participants includes provisions for data sharing while ensuring privacy and confidentiality. Access to the data will be granted based on established criteria, and efforts will be made to anonymize the data

appropriately. Ethical and legal restrictions will be upheld to protect participant confidentiality and comply with data protection regulations.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			15/07/2025	No	No
Participant information sheet	version 1	14/12/2023	20/02/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			20/02/2024	No	No
Statistical Analysis Plan			20/02/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes