Pilot RCT Protocol – ReFresh Study: Rehabilitation for Fatigue in people with Parkinson's

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Introduction

Fatigue is a common symptom reported by people with Parkinson's (PwP) (Herlofson and Kluger 2017). It has significant impact on their quality of life (Herlofson and Kluger 2017; Armstrong and Okun 2020). Patients and clinicians have reported that busy NHS Parkinson's clinics rarely have the time or resource to address this symptom, as they are usually focussing on safety (falls) and mobility issues (Parkinson's UK Audit, 2022). We have conducted a systematic literature review of the efficacy of fatigue management interventions for people with Parkinson's which suggests that CBT and balance-based exercise interventions are the most promising areas to pursue in future research although conclusions are tentative due to the moderate to poor quality and small sample sizes of the available evidence.

We propose that these non-pharmacological interventions may have beneficial effects on fatigue because a wide range of psychosocial and secondary factors contribute to fatigue in Parkinson's including poor sleep, low mood, deconditioning, and unhelpful cognitive behavioural responses to fatigue (Coe et al., 2018).

As both CBT and energy conservation (EC) techniques have evidence of efficacy we are persuaded by the manualised program investigated by Thomas et al (2013) which combined CBT with EC methods for people with multiple sclerosis (MS). The aims of the treatment were to normalise the experience of fatigue, support learning of strategies to manage energy more effectively and to explore different, more helpful ways of thinking about fatigue. Whilst the programme drew upon EC principles the overall aim was not to limit activity but rather to provide individuals with strategies to enable them to do more of the things that matter to them. The program was originally developed for MS so will be adapted to be relevant to people with Parkinson's using input from the lay and clinical advisory groups.

Hebert et al., (2011) propose that balance training in people with MS, may condition central sensory processing for efficient upright postural control, and we propose this may have similar impact in people with Parkinson's. Many patients with Parkinson's, have balance impairments and a high proportion are at risk of falling (Matinolli, M. et al., 2009). Poor balance is likely to make navigating the environment more effortful, and thus a mechanistic

argument can be developed for improvement in balance leading to reductions in fatigue (Cameron & Lord, 2010; Baer, M. et al., 2018). The exercise program will be a recommendation of at least 30 minutes exercise three times a week (in line with the findings of Wu 2020). The exercises will be integrated into the goals of the online ReFresh program. We will ensure that participants have access to a range of online exercise videos from Parkinson's UK of varying intensity. We will also make recommendations for other exercise activities that could be undertaken e.g., walking groups, swimming, dance, Tai Chi etc and provide support to participants on how to integrate exercise as a normal part of their lifestyle. The exact recommendations will be informed by input from the lay and clinical advisory groups.

Finally, this program of fatigue management techniques will be provided in an online format. This will allow people with Parkinson's to independently navigate the program, which allows flexibility in timing and location of the interventions. It removes the need for clinical staff to oversee the intervention, thus reducing its cost and improving its practicality. We recognise that some people with Parkinson's will be excluded because they lack an internet connection, or a computer/ digital phone, or appropriate computer skills to access the website. However, we believe this will be a minority of patients; OFCOM estimates that just 6% of households in the UK remained digitally excluded in regard to internet access in the home (OFCOM 2022). Therefore, we believe this online intervention will be accessible to the majority of potential participants and will provide essential recommendations in an area that is often neglected clinically at the present.

Team Members

- Sarah Alageel – PhD student and lead researcher for this project
- Dr Katherine Deane – Primary supervisor
- Dr Jane Hibberd – Secondary supervisor
- Dr Allan Clarke – Statistician

Method

Design

A pilot randomised controlled trial with **two parallel comparator groups**; the ReFresh online fatigue management program versus a wait list group who will receive treatment as usual, and then access the ReFresh online course at week 14 to ensure all end point data is gathered. We will recommend participants access one **module per week** i.e. six modules over six weeks, and undertake at **least three 30 minute sessions of exercise per week**. The primary outcome will be fatigue at 12 weeks. All measures will be unblinded as it is impossible to blind participants as to whether they have accessed the web site or not.

This pilot study will check study processes (e.g., recruitment, randomisation, treatment, follow-up assessments) all run smoothly, and determine the acceptability and practicality of the ReFresh intervention. It will also appraise the feasibility and sensitivity of two fatigue measures in order to decide which measure will be the primary outcome measure in the fully powered RCT this pilot study will inform. The fatigue measures are the Parkinson's Fatigue Scale (PFS) (Baghoori 2017) and the Modified Fatigue Impact Scale (MFIS) (Fisk et al., 1994). These will be measured at baseline and 12 weeks. Once the primary measure is selected it will inform the number of participants required for a fully powered RCT.

Development of the intervention

The development of the intervention will follow the MRC framework for complex interventions (Skivington 2021). The framework divides complex intervention research into four phases: **development or identification** of the intervention, **feasibility**, **evaluation**, and **implementation**. In this case much of the content of a fatigue management intervention has already been developed and just needs refinement for the needs of people with Parkinson's and how to deliver it in an online format. This project will develop (Morely 2004) an online intervention for the management of Parkinson's fatigue blending CBT, EC and exercise promotion that can be accessed outside of existing NHS structures.

The initial assessment of the **feasibility**, and **evaluation** will be conducted in the pilot RCT.

Assessment of the implementation will be independent of the NHS context. Much of the evidence for effective fatigue interventions consist of individual therapy or exercises conducted by a clinicians or therapists. However, in the UK National Health Service (NHS), and elsewhere, clinical resources (both of people and of time) are extremely limited for people with Parkinson's (Parkinson's UK Audit, 2022), thus this approach may prove impractical. Several pilot studies have used online programs which solve the issue of **access to therapists**, **access to transport** to the venue the intervention is held at, and a **lack of flexibility as to when the intervention is delivered**. It is acknowledged that there are other access issues (e.g., lack of access to a computer or the internet) but we believe that overall, the advantages outweigh the disadvantages for most patients.

Lay and clinical advice

The intervention and RCT design will be informed by three sets of information:

1. Evidence from the research literature. Specifically, the systematic review of fatigue management in people with Parkinson's and the scoping review of fatigue management of neurodegenerative conditions.
2. Information from lay advisors. Specifically, the panel of six people with Parkinson's will advise on the content of the intervention, design of the RCT, interpretation of the results, and dissemination.
3. Information from expert clinicians. Specifically, Ana Aragon (independent OT consultant and expert in Parkinson's) and members of the Occupational Therapy for Parkinson's **special interest group** will advise on the content of the intervention, design of the RCT, interpretation of the results, and dissemination.

The design of the RCT is evidence based, but as the evidence based was sparce in Parkinson's disease, evidence from other neurodegenerative conditions was used to ensure the proposed intervention had sufficient breadth and complexity to address the multi-factorial issue of fatigue.

We asked both the clinical and lay advisory teams to examine the proposed ReFresh program And they have suggested amendments to the draft program to ensure the

proposed intervention matches current best clinical practice, included appropriate safety measures, and was practical for patients to conduct in their own homes..

Aims

- To determine the size and variance of the difference in change in fatigue between the ReFresh group versus the waitlist group at 12 weeks. This will be used calculate the number of participants needed to fully power a randomised controlled trial to determine efficacy.
- To assess the feasibility, acceptability, and safety, of the ReFresh online fatigue management intervention.
- To assess the feasibility and acceptability of the design of the RCT protocol. In particular to determine which measure of fatigue to use as the primary outcome measure in the planned fully powered RCT.

RCT Registration

The RCT will be registered with ISRCTN.

Participants

Inclusion criteria

- People with a clinical diagnosis of idiopathic Parkinson's disease
- Any co-morbidity except those in the exclusion criteria
- Ambulatory
- Aged 18 years and over.
- Living in England
- Are English speaking and literate.
- Have access to the internet.
- Have the ability to complete online assessments. (Competency to consent will be assumed by the ability to complete the online surveys).

Exclusion criteria

- Any diagnoses of other Parkinsonian conditions e.g., vascular Parkinsonism, progressive supranuclear palsy, multiple system atrophy, Lewy body dementia
- Anyone who has been clinically recommended to not undertake exercise.

Recruitment Strategy

Participants will be recruited from Parkinson's UK using their newsletter and their Research Support Network (RSN). The RSN has over 5000 members. We will also recruit using adverts with the Cure Parkinson's charity and relevant social media groups. We have previously recruited using this method to a two-stage survey on anxiety with 205 and 341 participants recruited over 2 and 4 months respectively, and to a survey on medication adherence with 790 participants recruited over 6 months. Therefore, we believe recruiting 40 participants over 2 months is realistic. We will track the route participants took to be recruited to the study in order to identify the most effective recruitment strategies.

The participants will be directed to the project's web site: https://www.uea.ac.uk/web/groups-and-centres/projects/fatigue-management-in-parkinson-s

There they will be provided with information on the study and invited to follow a link to a survey hosted on the Qualtrics system to complete their consent and baseline assessments: https://qualtricsxm3xhpzbjcj.qualtrics.com/jfe/form/SV_bKJmAZXD5lTE43I . Qualtrics is reasonably accessible (i.e. works with most screen readers) and is UK GDPR compliant.

Randomisation and stratification

Upon completion of baseline data, participants will undergo randomisation to either the intervention arm (fatigue management) or the control arm (waitlist) utilizing the Sealed Envelope website. Sealed Envelope offers a robust online software application for randomising patients into clinical trials and capturing case report form data (EDC and ePRO).

The Simple randomisation service provided by Sealed Envelope will be employed for this trial. This uses a pseudo-randomisation number generator, and will allocate participants in a 1:1 ratio to ReFresh or wait list. To ensure a reasonably even distribution of patients in the 2 arms throughout the course of the trial, patients will be allocated in randomly permuted blocks of 4 and 6 (Sealed Envelope Ltd. 2022).

For the trial, a unique password will be assigned. Authorized personnel with the password will have the capability to conduct new randomisations. The results will be promptly displayed on-screen and emailed to both the trial administrator and the assigned individual overseeing the randomisation process, ensuring transparency and accountability.

Upon allocation participants will be sent an email informing them of their allocation. If allocated to the ReFresh group they will be sent the link to the ReFresh online program https://www.uea.ac.uk/web/groups-and-centres/projects/fatigue-management-in-parkinson-s/refresh-study-getting-started . If they are allocated to the waitlist group they will be told they will be contacted again in 12 weeks to complete the end point survey, and then at 16 weeks with the link to the ReFresh program (to ensure no contamination of the control group).

Ethical approval

As participants will be recruited outside of the NHS, ethics approval will be sought from the University of East Anglia's Faculty of Medicine and Health's Research Ethics Committee.

Intervention group

Participants randomised into this arm will gain access to the online fatigue management web page https://www.uea.ac.uk/web/groups-and-centres/projects/fatigue-management-in-parkinson-s/refresh-study-getting-started. Participants will progress through the online resources at their own pace but are recommended to complete one module per week of information, and to participate in an exercise program at least three times per week. There are six modules (see Appendix 1 for more detail)

Participants will be tracked in their use of the online resources and defined as completing the fatigue management if they accessed at least four of the six modules.

Control group

Participants in the control arm were waitlisted for 4 months to access the online fatigue management program. They received usual care for their Parkinson's, i.e., patients will attend 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 possible as participants will know whether they had 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.

Sample size

The sample size of feasibility and pilot studies is generally influenced by the need to confidently estimate outcome parameters, such as standard deviation, for use in the sample size calculation of a definitive trial. According to Lancaster, Dodd, and Williamson (2004), a sample size of 30 is often considered a good rule of thumb.

We will adhere to this guideline by recruiting 20 participants for each arm of the study, resulting in a total of 40 participants. This sample size will allow us to collect sufficient data to estimate outcome parameters effectively and inform the design of future definitive trials.

Baseline measures

Demographic and Clinical Information.

Participants will be asked questions about demographic variables (e.g., age, gender, and ethnicity) informed by the Daisy guidance (EDIS 2022). We will also ask about their Parkinson's and its treatment (e.g., time since diagnosis, disease severity, comorbidities, medication regime) and identify baseline risks e.g., falls.). Levodopa equivalent dose will be calculated (Nyholm, D., & Jost, W. H. (2021).

Outcomes

Assessments will take place at baseline and 12 weeks after randomisation.

We anticipate that the ReFresh program will improve fatigue. In this pilot RCT we will use two measures of fatigue; the Parkinson's Fatigue Scale (PFS) (Baghoori 2017) and the Modified Fatigue Impact Scale (MFIS) (Fisk et al., 1994). These two measures assess related but not identical concepts. The PFS focusses on the **experience of fatigue** with some items that examine its impact on activities. Whereas the MFIS focusses far more on the **impact having fatigue** has on physical, social, and cognitive activities. We are unsure whether the ReFresh program will just impact on the sense of fatigue, or whether it will impact on participant's activity levels, so we will use both measures to determine which is most sensitive to any changes caused by the ReFresh program. MFIS is commonly used in fatigue research, and so these results could be more easily compared against other fatigue management protocols. The MFIS has excellent psychometric properties in multiple sclerosis populations; with internal consistency, Cronbach α of 0.92 (Kos 2005), and a test-retest reliability intraclass correlation coefficient (ICC) of 0.91, (Kos 2003). Although MFIS was not developed for Parkinson's it has been validated with this patient population; where it has high internal consistency, Chronbachs α=0.96 (Schiehser 2012). However, the PFS was specifically developed and validated in people with Parkinson's (Baghoori 2017) and may therefore be more sensitive to disease specific factors. It is also a robust measure with a high internal consistency (Chronbach's α=0.98) and good test-retest reliability Spearman *R* mean 0.63±0.06). The data from this pilot will allow us to refine the design of the planned

fully powered RCT to ensure its primary outcome uses the measure most likely to be sensitive to the changes possible from the ReFresh program.

Primary Measures

Fatigue

a. *Modified Fatigue Impact Scale (MFIS):* 21 items that assess the impact of fatigue on cognitive, physical, and psychosocial functioning. The total score ranges from 0 to 84, with higher scores indicating greater impact of fatigue (Fisk et al., 1994).
b. *Parkinson's Fatigue Scale (PFS):* 16 items that mostly measure the experience of fatigue (Baghoori 2017). The total score ranges from 0 to 80, with higher scores indicating greater levels of fatigue.

Secondary measures

Parkinson's disease Questionnaire - 39:

Much research in Parkinson's has used the Parkinson's-specific quality of life scale PDQ-39 and have found it to be sensitive to a variety of treatments including therapeutic rehabilitation interventions (Fitzpatrick et al., 1997). It uses 39 items to assess eight dimensions of health: mobility, ADL, emotional wellbeing, stigma, social support, cognition, communication, and bodily discomfort.

The Parkinson Anxiety Scale (PAS):

The PAS is a self-reported outcome measure designed to assess anxiety specifically in individuals with Parkinson's disease. This tool enables participants to express their anxiety-related concerns, focusing on their unique experiences. It emphasizes individualized goal setting, self-reflection, and awareness of anxiety symptoms. The PAS concentrates on the participant's perception of their anxiety and their satisfaction level, providing a more nuanced understanding of anxiety issues relevant to our study. This approach is particularly

suitable for evaluating subjective symptoms like anxiety in Parkinson's disease, enhancing sensitivity to participants' concerns.

Previous studies in Parkinson's disease have successfully utilized the PAS to explore anxiety aspects (Moraes-Ferreira, R et. al, 2020; Leentjens, A. F et al., 2014). The PAS demonstrated good convergent and divergent validity in Cohort 2, confirming its status as a reliable and valid anxiety measure for use in PD patients. It is easy and brief to administer and exhibits better clinometric properties than existing anxiety rating scales (Leentjens, A. F et al., 2014).

THE GERIATRIC DEPRESSION SCALE-15 (GDS-15)

The GDS-15 is a self-reported outcome measure designed to assess depression in the geriatric population (Justo-Henriques, S, et al, 2023). In our context, it is customized to capture depression-related aspects in individuals with Parkinson's disease. The GDS-15 encourages focused goal setting, self-reflection, and awareness regarding depressive symptoms. It measures the participant's perception of their depression and their satisfaction level, providing a more personalized evaluation of depression issues. This approach is particularly beneficial for examining subjective symptoms like depression in Parkinson's disease.

Previous studies have successfully employed the GDS-15 in assessing depression in Parkinson's disease (Meara, J., et al, 1999; Conradsson, M., 2013). The GDS was found to have a 92% sensitivity and an 89% specificity when evaluated against diagnostic criteria. The validity and reliability of the tool have been supported through both clinical practice and research (YESAVAGE, J et al, 1982).

Pittsburgh Sleep Quality Index (PSQI)

The PSQI is a well-established tool for evaluating sleep quality and disturbances over a one-month time interval. Consisting of 19 items, the PSQI covers various aspects of sleep, and its total score indicates overall sleep quality (Zhong, Q. Y et al, 2015; Buysse, D. J. et al,, 1989). Previous studies in Parkinson's populations have demonstrated the validity and reliability of the PSQI, as evidenced by Wang, L., et al, (2022). The reliability and validity research on PSQI

are mainly based on the classical test theory (CTT). In most studies, Cronbach's α fluctuated between 0.70 and 0.85. No studies reported Cronbach's α above 0.9.

The Multiple Sclerosis-Fatigue Self– Efficacy (MS-FSE) scale:

The MS-FSE Scale is a self-reported outcome measure designed to assess self-efficacy in managing fatigue, specifically in individuals with Multiple Sclerosis. In our study, it is adapted to evaluate self-efficacy in managing fatigue in individuals with Parkinson's disease. The MS-FSE Scale encourages focused goal setting, self-reflection, and awareness regarding self-efficacy in managing fatigue. It concentrates on the participant's perception of their ability to manage fatigue, providing a more individualized evaluation of self-efficacy issues. This approach is particularly relevant for investigating subjective symptoms like fatigue in Parkinson's disease (Thomas, S et al, 2014).

The MS-FSE scale measures an individual's self-efficacy in managing fatigue related to multiple sclerosis. With 9 items and a higher total score signifies greater self-efficacy in fatigue management. At a scale level, the Multiple Sclerosis-Fatigue Self-Efficacy scale is internally valid and has good sensitivity to change (Thomas, S et al, 2015).

Canadian Occupational Performance Measure (COPM)

The COPM is a self-reported outcome measure that will be used by the ReFresh group only. This tool enables the client to identify what is meaningful for them to work on – in this context we will focus on fatigue-related goals. It encourages focussed goal setting, self-reflection, and awareness. It focuses on a person’s perception of their performance and how satisfied they are with it, rather than measuring improvement in function. For a symptom as subjective as fatigue this may be a more sensitive way to measure fatigue-associated issues of importance to our participants. It is highly individualised as it focusses on the patient’s personal goals. It has been used in Parkinson’s disease (Gaudet 2002; Alsaeed 2021).

Adherence

We will track the completion of each module of the online ReFresh program by tracking access online web page hits, documents downloaded or requested in hard copy, exercise / activity / fatigue diaries.

Acceptability

Self-reported feedback will be collected from ReFresh participants immediately after the completion of each online session via a brief evaluation questionnaire online. Using 5-point scales the items will include programme content (1 'not very relevant', 5 'very relevant'), format (1 'did not work at all', 5 'worked well'), usefulness (1 'not at all useful', 5 'very useful'), pace (1 'too slow', 5 'too fast') and duration (1 'too short', 5 'too long'). They will also be provided with an open response text box to make any further comments on the acceptability of the program.

Resource utilisation

We will use a self-reported health and social services resource utilisation survey with a 3-month recall period (collected at the 12-week follow-up point only). This will include tracking appointments with GPs, consultants, OTs, PTs, if there is a change in their medications, or if they access any complementary therapies etc during period of study.

Adverse Events

This population is particularly at risk of falls. Participants will be warned of this risk and asked to ensure they undertake all exercise and other activities with due care and caution. All participants will be asked to record any falls for the duration of the study. We will also record adverse events such as admissions to hospital and for what reason.

Data management

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. The legal basis for processing the data as listed in Article 6(1) of the UK GDPR; because this allows us to process personal data when it is necessary to perform our public tasks as a University.

- The data controller is the University of East Anglia.
- The University's Data Protection Officer can be contacted at dataprotection@uea.ac.uk
- More about participant's data protection rights is available at the Information Commissioner's Office (ICO).
- If participants are unhappy with how their personal data has been used, they will be asked to contact the University's Data Protection Officer at dataprotection@uea.ac.ukin the first instance.

Data security

Only members of the research group (members are listed at the start of this protocol) will have access to the data during the project.

Most of the assessments and consent will be recorded online using the Qualtric survey platform. However, to ensure accessibility for participants with disability access needs, participants will be offered hard copy survey and consent forms to be posted to them (including a postage paid return envelope). If participants take up this option, the information on these hard copies will be transcribed by SA into the Qualtrics surveys. 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 September 31st, 2025. The contact details will be kept only until everyone involved in the trial has been sent a link to the online fatigue management intervention i.e., 14 weeks after randomisation (September 31st, 2024, latest). After this we will destroy the contact details and keep the anonymised dataset of results.

Project data will be deleted from the UEA shared drive 10 years after the end of the project (i.e., 31st September 2035). Only anonymised data will be shared externally (e.g., in reports and publications).

Statistical analyses

Baseline Comparisons

The SPSS statistical program will be used to analyse the data. Baseline comparability of the groups by demographics will be described using descriptive statistics. Where data appears to be non-normally distributed according to the Shapiro-Wilks test, medians and inter-quartile ranges will be used to describe the data. Where data is normally distributed, means and standard deviations will be used.

Efficacy Analyses

As this is a pilot RCT an accurate assessment of the efficacy of the intervention cannot be determined as the study is insufficiently powered. However, we will analyse the primary outcome measure at 12 weeks using the parametric student-t test for comparing mean change between the two intervention groups.

Intention to Treat (ITT) analyses will be performed for all outcomes and will comprise of all patients who had been randomised. For the intervention group, this was irrespective of their compliance with the ReFresh program. The principle of ITT was adopted as it provides a pragmatic estimate of the benefit of a change in treatment policy compared to the potential benefit in patients who receive treatment exactly as planned. As the ReFresh program was planned for delivery over a six-week period, some participants may not have received all the planned sessions. As this is more likely to reflect usual practice, primary analyses of all outcomes were conducted according to the ITT principle. Per Protocol (PP) analyses was planned for participants who had not deviated from the ReFresh protocol in such a manner that the assessment of efficacy could be biased. This was defined as patients accessing at least four out of six ReFresh modules. Imputation of missing/incomplete data is planned to use last observation carried forward method for all outcome measures.

Response to PPI Comments:

We value the insights provided by our Patient and Public Involvement (PPI) advisors and have incorporated their feedback to enhance the credibility and effectiveness of our RCT protocol. Below are the key adjustments made in response to their valuable input:

1. Emphasized Importance of Commitment:

We have highlighted the significance of commitment on the ReFresh page, encouraging participants to view the program as a transformative journey towards managing fatigue effectively and achieving optimal well-being. The language has been revised to underscore the need for consistent engagement to reap the benefits of the program.

2. Addressed Concerns Regarding Vivid Dreams:

Feedback regarding vivid dreams has been carefully considered, and appropriate measures have been implemented to address this concern within the protocol.

3. Enhanced Accessibility for Devices:

To ensure inclusivity and accessibility, the program has been optimized for various devices, making it more user-friendly and accessible across different platforms.

4. Simplified Language in the Information Sheet:

The language used in the information sheet has been simplified to enhance clarity and comprehension for all participants, aligning with the feedback provided by our PPI advisors.

5. Adjusted Exercise Feedback Frequency:

In response to feedback, exercise guidance has been revised to encourage participants to engage in routines more frequently, surpassing the previous recommendation of three times a week.

These adjustments reflect our commitment to integrating diverse perspectives and ensuring that the ReFresh program meets the needs of our participants effectively. The revised RCT protocol now incorporates these modifications, reinforcing the program's credibility and efficacy.

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Appendix 1

Online Fatigue Management Program Content

We will recommend participants access one module per week i.e. six modules over six weeks and undertake at least three 30-minute sessions of exercise per week.

Modules of Fatigue Management

Based on Thomas et al 2013

Session	Title	Content	Homework
1	Introducing fatigue	General introduction; expectations; types of fatigue; contributing factors, conceptual model of fatigue in PwP	Activity/fatigue diary Exercise
2	Opening an "energy account"	Rest – functions; barriers, techniques; relaxation types and techniques; diaphragmatic breathing exercise; sleep hygiene	Rest/activity/sleep planner Exercise
3	Budgeting energy and smartening up goals	Types of activity; balancing activity and rest; moderating activity using the toolbox; lifestyle factors; goal setting	S.M.A.R.T. goal setting exercise Exercise
4	The stress response; Introducing the	The stress response (fight-or-flight); ways of coping with stress; introducing the cognitive behavioural model	Unhelpful thoughts (related to fatigue) diary Exercise

Session	Title	Content	Homework
	cognitive behavioural model		
5	Putting unhelpful thoughts on trial	Unhelpful thought patterns; challenging unhelpful thoughts; levels of belief	Thought challenge sheet Exercise
6	Recapping and taking the programme forward	Revisiting expectations; introducing the 'forcefield'; group activity to revisit themes of the programme; rationale of 'Keeping on Track' planner	'Keeping on Track' planner Exercise

1. Introducing fatigue

General introduction; expectations; types of fatigue; contributing factors, conceptual model of fatigue in PwP, Fatigue is a complex and subjective phenomenon that encompasses physical, mental, and emotional exhaustion (Armstrong and Okun 2020). Fatigue is considered pathological when it becomes abnormally severe restricting one's ability to operate optimally and independently. Research estimates that up to 50% of patients experience the symptom, which significantly impact patients' quality of life (Herlofson and Kluger 2017; Armstrong and Okun 2020). It is a common non-motor symptom experienced as significant loss of energy. PD patients experiencing fatigue show decreased ability to perform normal activities and tasks, and feelings of tiredness, weakness, and tiredness (Herlofson and Kluger 2017). The etiology of fatigue in PD is unknown and fatigue presentation can sometimes be mistaken with fatigability or a feeling present at rest. Fatigability is induced by activity (Friedman et al. 2007).

The causes and triggers of the fatigue are complex and may include a combination of medical, psychological, and environmental factors. They include poor sleep (Lin et al. 2021), busy day especially for older adults (Pauletti et al. 2023), emotions and over-heating (Friedman et al. 2007). One study (Armstrong and Okun 2020) linked fatigue in PD to

psychological distress and other behavioural disorders like anxiety and apathy that are intrinsic to PD. Research has explored the underlying neurodegenerative process of PD a trigger of fatigue (Zafar and Yaddanapudi 2022). The degeneration of dopamine-producing neurons in the brain can result in motor symptoms such as tremors, rigidity, and bradykinesia, which can be physically and mentally exhausting. It can also lead to changes in the brain's regulatory systems, which can disrupt sleep and contribute to fatigue.

Medications such as levodopa, can cause fluctuations in motor function resulting in fatigue (Pauletti et al. 2023; Lin et al. 2021; Friedman et al. 2007). Other medications, such as dopaminergic agonists, can cause side effects such as somnolence, which can result in increased feelings of fatigue. Lifestyle factors can also play a role in fatigue in people with PD (DeMaagd and Philip 2015: p.524). Poor sleep hygiene, such as irregular sleep patterns, can contribute to fatigue and make it more difficult for people with PD to manage their symptoms. Sleep disturbances, such as insomnia or sleep apnea, depression, anxiety, reduced motivation and decreased physical and cognitive functioning (Herlofson and Kluger 2017). A sedentary lifestyle can also lead to decreased physical activity and increased feelings of fatigue.

Promotion of exercise (see below for details of exercise program). This will be promoted within every module of the ReFresh Program.

Assessment of acceptability (see outcomes)

2. Opening an energy account

Rest – functions; barriers, techniques; relaxation types and techniques; diaphragmatic breathing exercise; sleep hygiene. Boom and bust cycles. Avoidance. Knowing when to stop – and how to take proper rest. Energy diary – identifying the energy load of activities. Supply and demand. Planning – off loading, prioritising, identifying what to stop doing. Pacing overall energy load of activities in a day, pacing to do more, time limits, chunking. Planned crash landings (for important events) – including pre and post event resting.

Existing literature highlights the positive impact of adopting good sleep hygiene on alleviating fatigue (Newland et al., 2019; Orlandi et al., 2012). However, it is crucial to

ensure that sleep patterns align with the circadian cycle, as disruptions in this regard can actually worsen fatigue (Van Hilten et al., 1993).

Night-time frequency and urgency – how to manage, maintaining night-time mobility, cueing, lighting, grab rails.

Promotion of exercise (see below for details of exercise program). This will be promoted within every module of the ReFresh Program.

Assessment of acceptability (see outcomes)

3. Budgeting energy and smartening up goals

Types of activity; balancing activity and rest; moderating activity using the toolbox; lifestyle factors; goal setting.

Promotion of exercise (see below for details of exercise program). This will be promoted within every module of the ReFresh Program.

Assessment of acceptability (see outcomes)

4. The stress response; Introducing the cognitive behavioural model.

The stress response (fight-or-flight); ways of coping with stress; introducing the cognitive behavioural model.

Promotion of exercise (see below for details of exercise program). This will be promoted within every module of the ReFresh Program.

Assessment of acceptability (see outcomes)

5. Putting unhelpful thoughts on trial

Unhelpful thought patterns; challenging unhelpful thoughts; levels of belief

Discussion of poor attitudes to disability – particularly invisible symptoms such as fatigue. Informed by social model, CBT and motivational interviewing tools.

Promotion of exercise (see below for details of exercise program). This will be promoted within every module of the ReFresh Program.

Assessment of acceptability (see outcomes)

6. Recapping and taking the programme forward

Revisiting expectations; introducing the 'forcefield'; group activity to revisit themes of the programme; rationale of 'Keeping on Track' planner.

Promotion of exercise (see below for details of exercise program). This will be promoted within every module of the ReFresh Program.

Assessment of acceptability (see outcomes)

Exercise

We will recommend our participants exercise for at least 30 min three times a week (in line with Wu's recommendations 2021). We will recommend that the exercises challenge their balance as these appear to have particular benefit for improving fatigue (Abasi 2020; Ribas 2017). We will recommend that participants gently increase the intensity of their exercise programs from their current level, and in line with their disease stage, and response to the exercise program. We will provide appropriate safety information to ensure participants can partake of these exercises in their own homes safely.

We will recommend exercise programs from Parkinson's UK (all led by physiotherapists) https://www.parkinsons.org.uk/information-and-support/physical-activity-and-exercise

We will also recommend the use of WiiFit games that challenge balance (Table Tilt; Tilt City; Penguin Slide; Soccer Heading; Basic Run; Obstacle Course; Basic step) for 30-minute sessions (Ribas 2017)

We will provide participants on suggestions for other exercise activities and how they can incorporate them into their everyday activities to promote long term exercise promotion and engagement.

Appendix 2

Email Templates

1. Emails for Allocation Decisions:

For Participants in ReFresh Arm:
Subject: Allocation Decision: You are in the ReFresh Arm

Dear ……

Congratulations! We are pleased to inform you that you have been allocated to the ReFresh arm of our study. Thank you for your participation and commitment. Engaging fully with the program and completing the homework requested is critically important to allow us to make a fair assessment of the program.

Please find the link to access the ReFresh program below:

Link

We will be in touch with you in 12 weeks to provide you with the endpoint survey link and further instructions. Completing the surveys requested is critically important to allow us to properly assess the ReFresh program.

Should you have any questions or require further assistance, please do not hesitate to contact us.

Best regards,

For Participants in Waitlist Group:

Subject: Allocation Decision: You are in the Waitlist Group

Dear ……..

Congratulations! We are pleased to inform you that you have been allocated to the T the waitlist group. Thank you for your participation and commitment. Being a part of the waitlist group allows us to compare your results against the group that get immediate access to the ReFresh program. In a disease as variable as Parkinson's this is critical to allow us to determine if any differences are "real" and useful,

We will be in touch with you in 12 weeks to provide you with the endpoint survey link and further instructions. Completing the surveys requested is critically important to allow us to properly assess the ReFresh program.

We will then be in touch with you in 16 weeks where we will provide your with the link to the ReFresh online program. Your participation at this point will not be recorded.

If you have any questions or concerns, please feel free to reach out to us.

Best regards,

---

2. COPM Result Emails:

Subject: COPM Survey Results

Dear …….

We are pleased to share with you the results of your personal activity survey (Canadian Occupational Performance Measure (COPM)).

[COPM Results]

You will need this with you when you complete the 12 week endpoint assessment as we will ask you to rate yourself against your personal activities at that time point as well.

If you would like to discuss your results or require further clarification, please do not hesitate to contact us.

Best regards,

---

3. Emails for 12-Week Endpoint Survey and Reminder:

For 12-Week Endpoint Survey:
Subject: Endpoint Survey: 12-Week Follow-Up

Dear ……

It's time for the 12-week follow-up survey as part of our study. Your input is invaluable to us, and we appreciate your continued participation. All of this data is critical to our understanding of the ReFresh program.

Please click on the link below to complete the survey:

[Survey Link]

Thank you for your time and contribution.

Best regards,

For Reminder:
Subject: Reminder: 12-Week Endpoint Survey

Dear ……..

We hope this email finds you well. Just a friendly reminder to complete the 12-week endpoint survey if you haven't already done so.

Your feedback is crucial to our study, and we greatly appreciate your participation.

Please click on the link below to access the survey:

[Survey Link]

Thank you for your cooperation.

Best regards,

---

4. Emails for 16-Week Waitlist Group to Access ReFresh Program:

Subject: Access to ReFresh Program: 16-Week Waitlist Group

Dear ……

We are pleased to inform you that you now have access to the ReFresh program as part of the 16-week waitlist group.

Please find the link to access the program below:

[Link]

Should you have any questions or need assistance, please feel free to reach out to us.

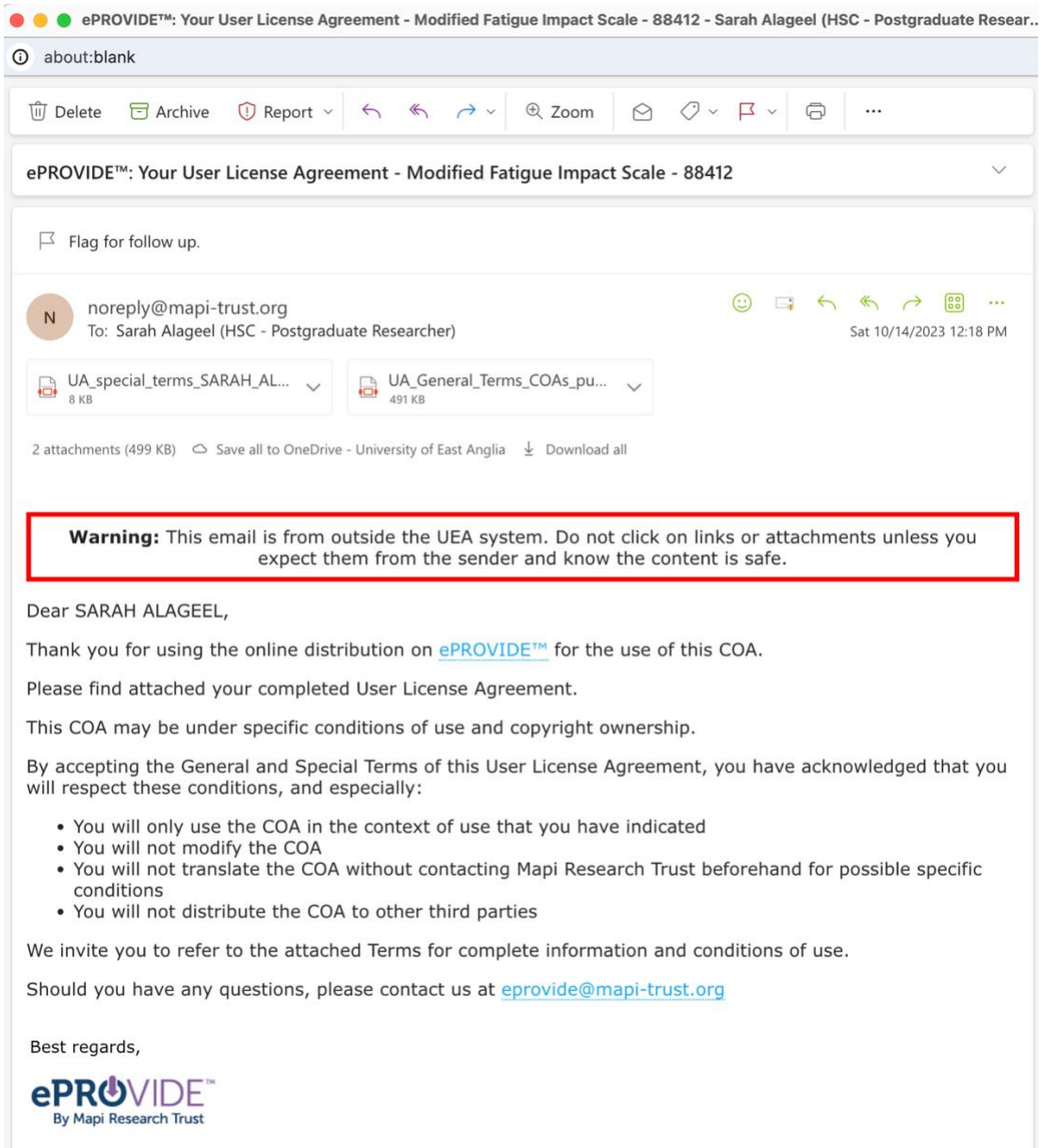
Best regards,

Appendix 3

Outcome Measures Permissions Granted

Several outcome measures will be used, and consent for their use has been obtained where required:

1. Modified Fatigue Impact Scale (MFIS)



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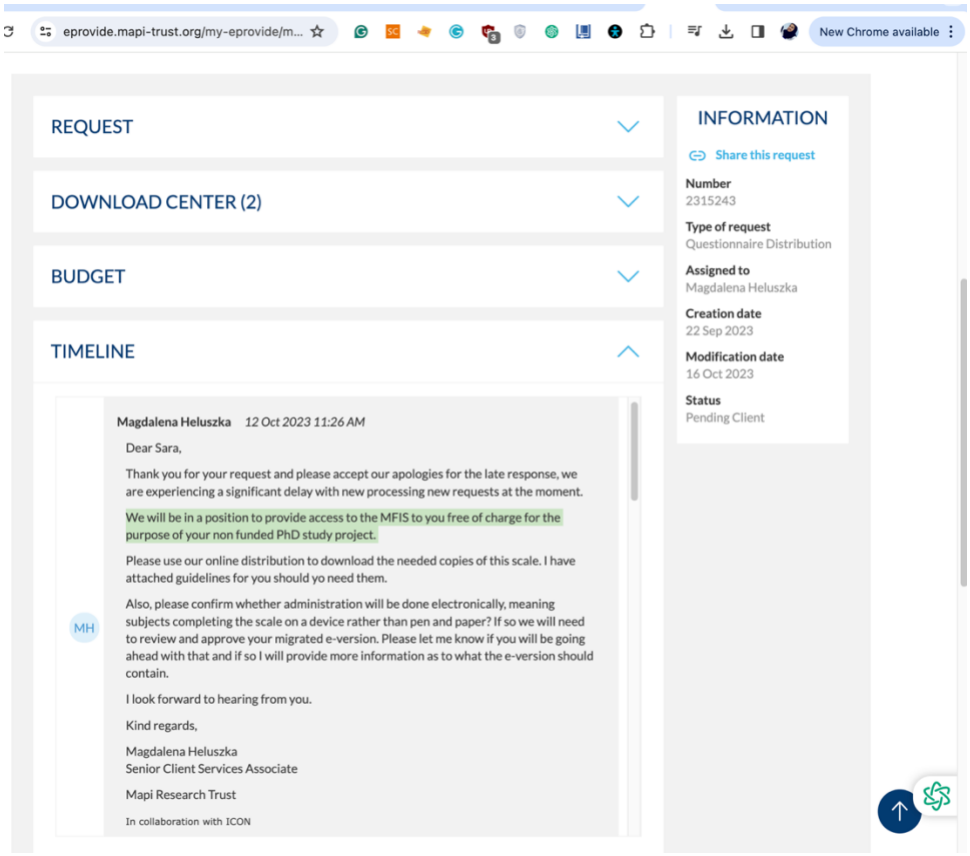
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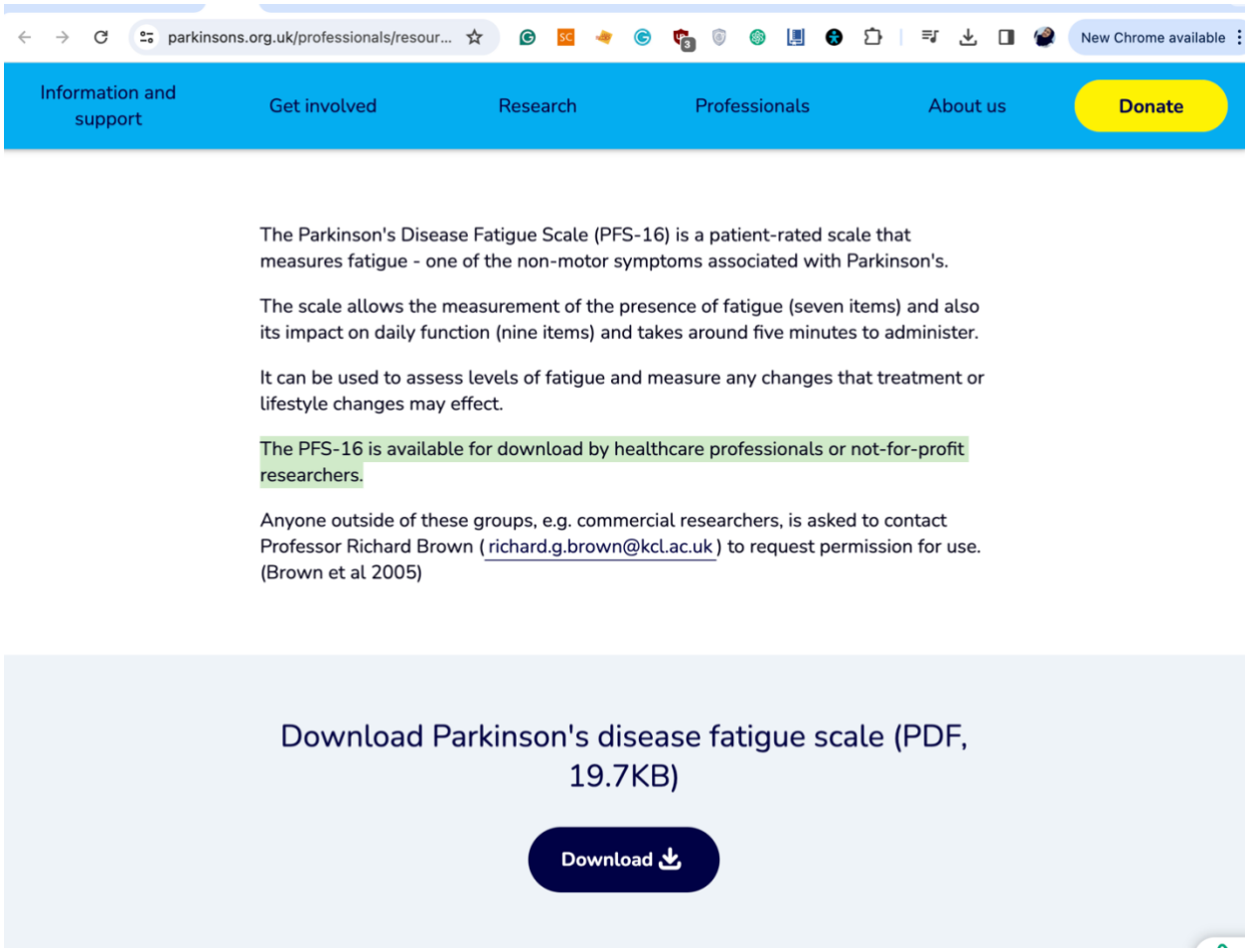
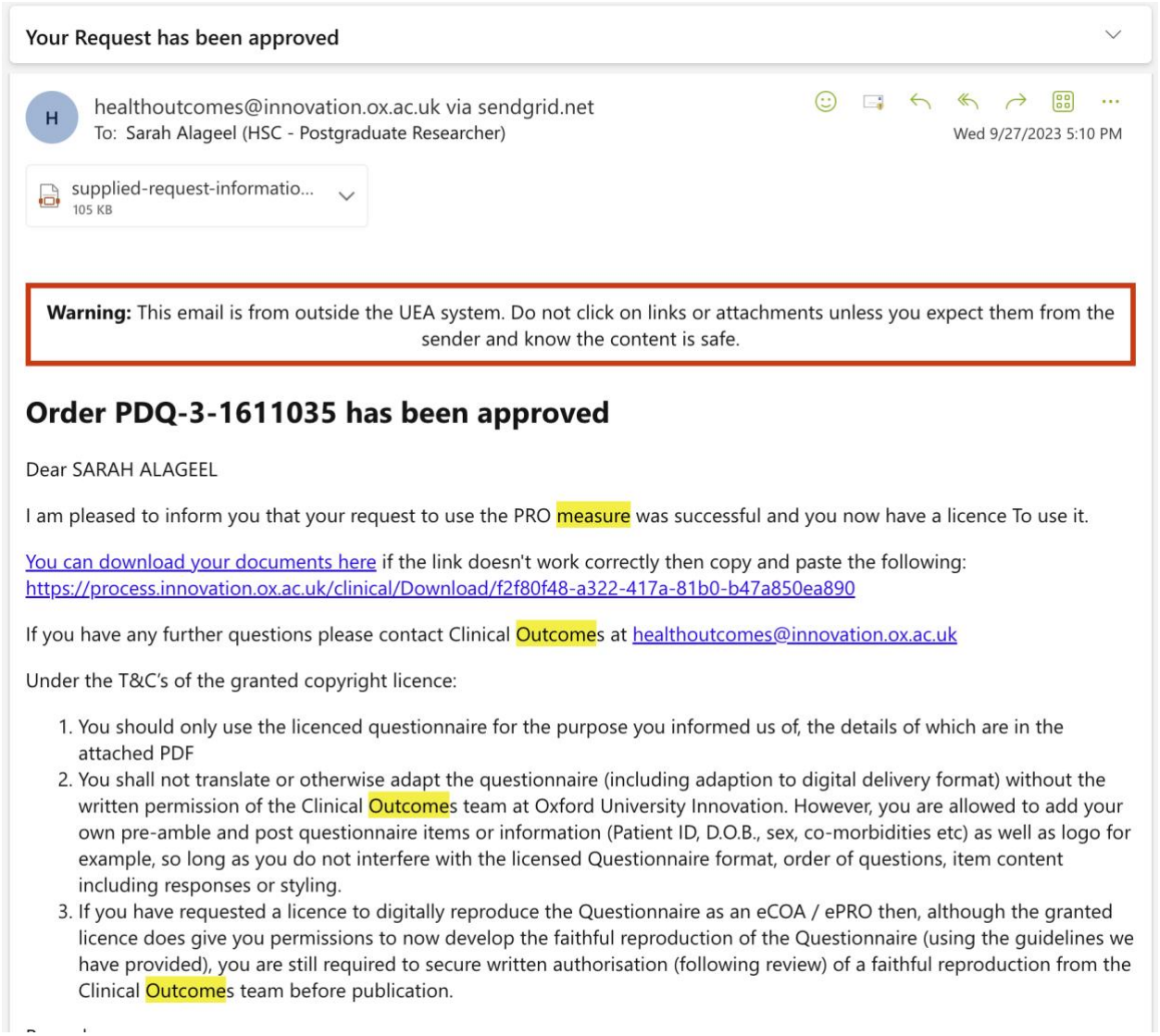
Magdalena Heluszka
Creation date
22 Sep 2023
Modification date
16 Oct 2023
Status
Pending Client
Magdalena Heluszka 12 Oct 2023 11:26 AM
Dear Sara,
Thank you for your request and please accept our apologies for the late response, we are experiencing a significant delay with new processing new requests at the moment.
We will be in a position to provide access to the MFIS to you free of charge for the purpose of your non funded PhD study project.
Please use our online distribution to download the needed copies of this scale. I have attached guidelines for you should yo need them.
MH
Also, please confirm whether administration will be done electronically, meaning subjects completing the scale on a device rather than pen and paper? If so we will need to review and approve your migrated e-version. Please let me know if you will be going ahead with that and if so I will provide more information as to what the e-version should contain.
I look forward to hearing from you.
Kind regards,
Magdalena Heluszka
Senior Client Services Associate
Mapi Research Trust
In collaboration with ICON

2. Parkinson's Fatigue Scale (PFS)



3. Parkinson's disease Questionnaire - 39 (PDQ-39)



Your Request has been approved

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Order PDQ-3-1611035 has been approved

Dear SARAH ALAGEEL

I am pleased to inform you that your request to use the PRO measure was successful and you now have a licence To use it.

You can download your documents here if the link doesn't work correctly then copy and paste the following:
https://process.innovation.ox.ac.uk/clinical/Download/f2f80f48-a322-417a-81b0-b47a850ea890

If you have any further questions please contact Clinical Outcomes at healthoutcomes@innovation.ox.ac.uk

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4. The Parkinson Anxiety Scale (PAS)

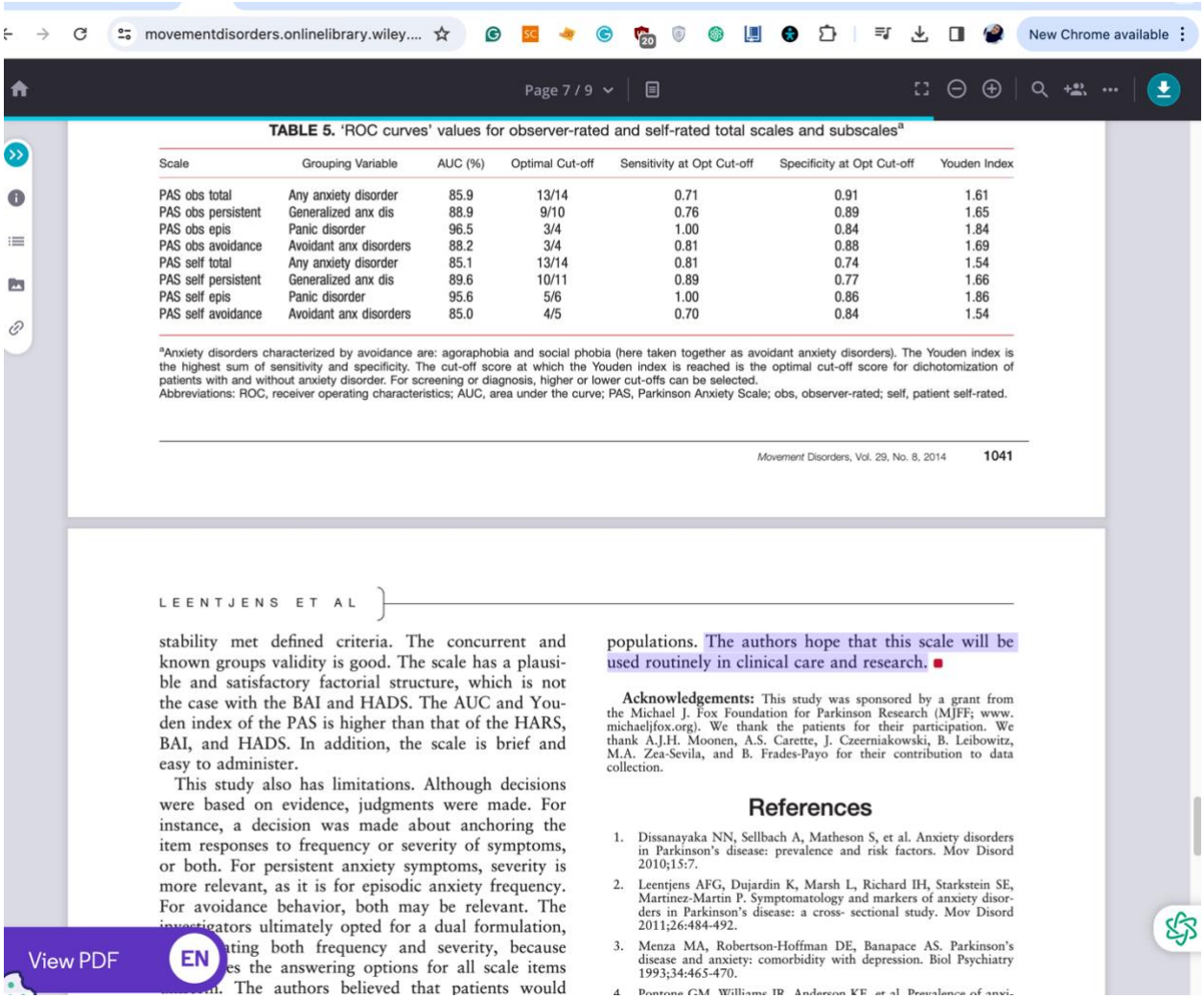

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TABLE 5. 'ROC curves' values for observer-rated and self-rated total scales and subscales[a]

Scale	Grouping Variable	AUC (%)	Optimal Cut-off	Sensitivity at Opt Cut-off	Specificity at Opt Cut-off	Youden Index
PAS obs total	Any anxiety disorder	85.9	13/14	0.71	0.91	1.61
PAS obs persistent	Generalized anx dis	88.9	9/10	0.76	0.89	1.65
PAS obs epis	Panic disorder	96.5	3/4	1.00	0.84	1.84
PAS obs avoidance	Avoidant anx disorders	88.2	3/4	0.81	0.88	1.69
PAS self total	Any anxiety disorder	85.1	13/14	0.81	0.74	1.54
PAS self persistent	Generalized anx dis	89.6	10/11	0.89	0.77	1.66
PAS self epis	Panic disorder	95.6	5/6	1.00	0.86	1.86
PAS self avoidance	Avoidant anx disorders	85.0	4/5	0.70	0.84	1.54

[a]Anxiety disorders characterized by avoidance are: agoraphobia and social phobia (here taken together as avoidant anxiety disorders). The Youden index is the highest sum of sensitivity and specificity. The cut-off score at which the Youden index is reached is the optimal cut-off score for dichotomization of patients with and without anxiety disorder. For screening or diagnosis, higher or lower cut-offs can be selected.
Abbreviations: ROC, receiver operating characteristics; AUC, area under the curve; PAS, Parkinson Anxiety Scale; obs, observer-rated; self, patient self-rated.

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stability met defined criteria. The concurrent and known groups validity is good. The scale has a plausible and satisfactory factorial structure, which is not the case with the BAI and HADS. The AUC and Youden index of the PAS is higher than that of the HARS, BAI, and HADS. In addition, the scale is brief and easy to administer.

This study also has limitations. Although decisions were based on evidence, judgments were made. For instance, a decision was made about anchoring the item responses to frequency or severity of symptoms, or both. For persistent anxiety symptoms, severity is more relevant, as it is for episodic anxiety frequency. For avoidance behavior, both may be relevant. The investigators ultimately opted for a dual formulation, ating both frequency and severity, because es the answering options for all scale items . The authors believed that patients would

populations. The authors hope that this scale will be used routinely in clinical care and research.

Acknowledgements: This study was sponsored by a grant from the Michael J. Fox Foundation for Parkinson Research (MJFF; www.michaeljfox.org). We thank the patients for their participation. We thank A.J.H. Moonen, A.S. Carette, J. Czeerniakowski, B. Leibowitz, M.A. Zea-Sevila, and B. Frades-Payo for their contribution to data collection.

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3. Menza MA, Robertson-Hoffman DE, Banapace AS. Parkinson's disease and anxiety: comorbidity with depression. Biol Psychiatry 1993;34:465-470.
4. Pontone GM, Williams JR, Anderson KE, et al. Prevalence of anxi-

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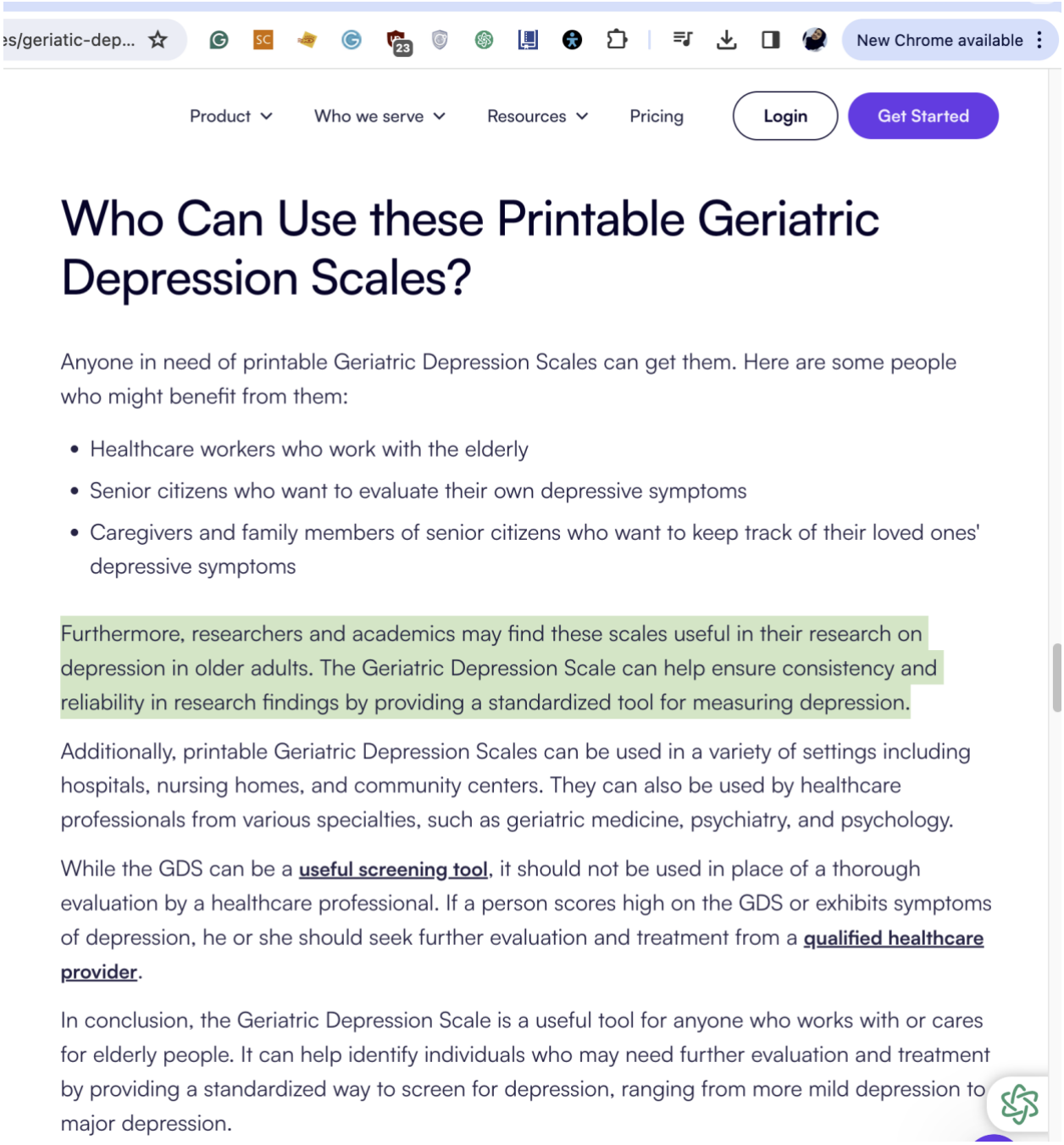
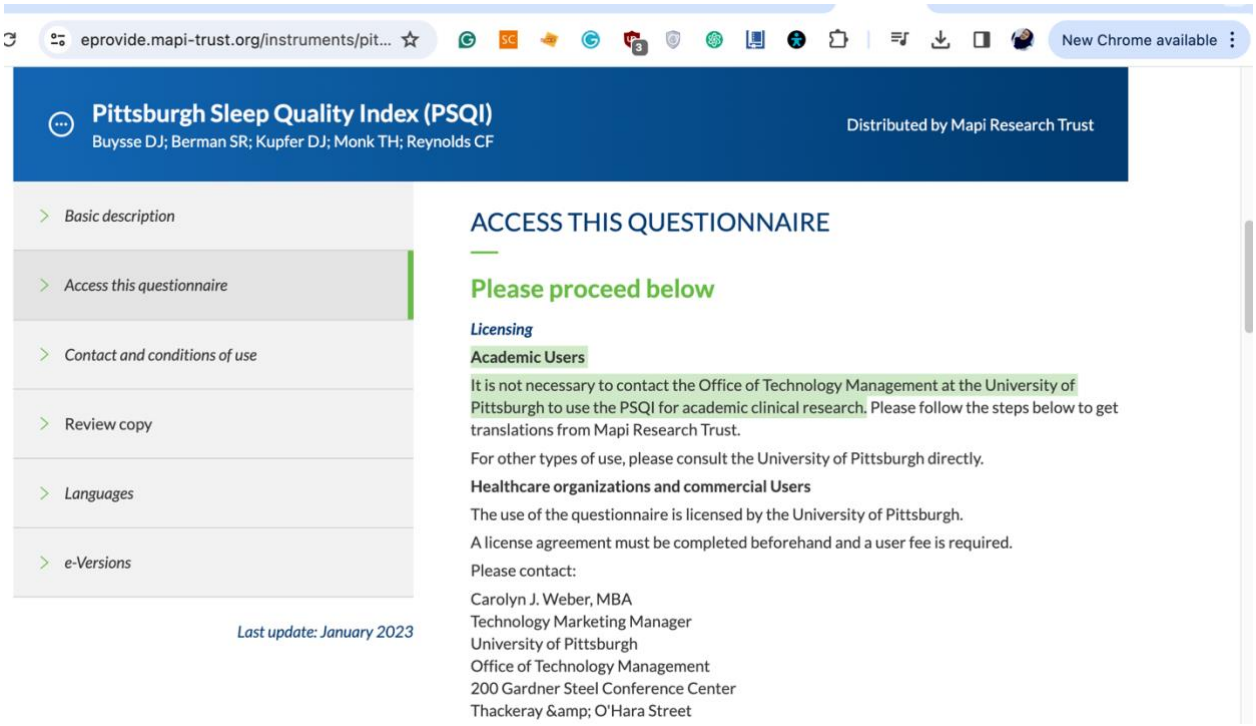
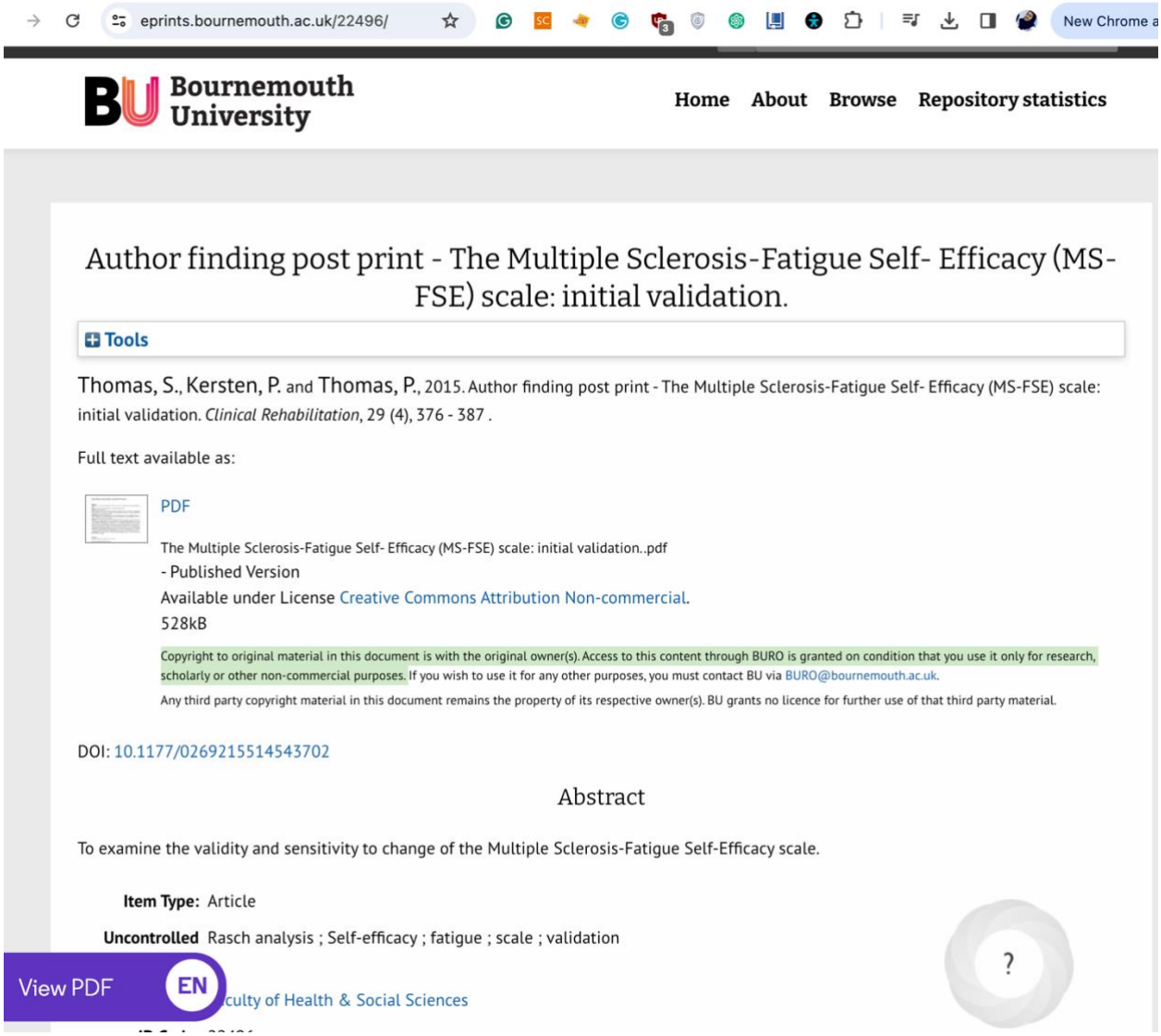
5. The Geriatric Depression Scale-15 (GDS-15)



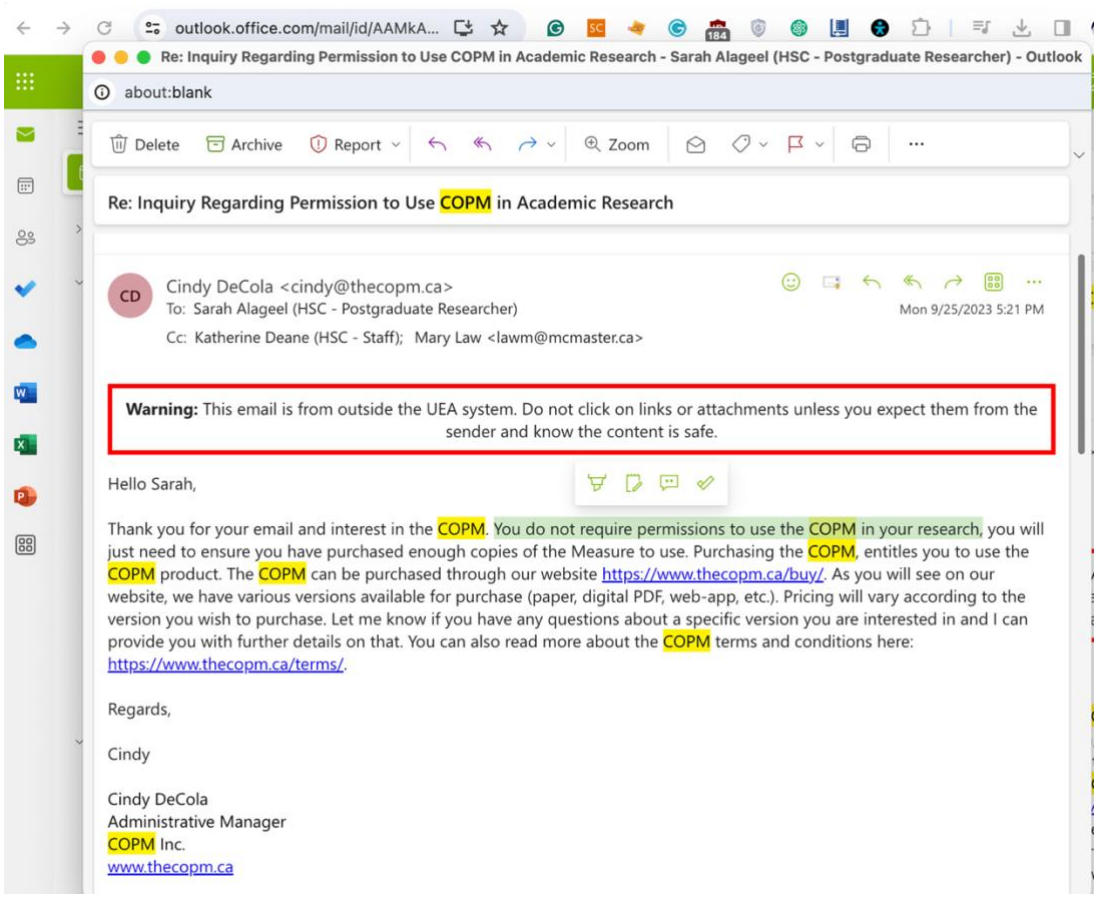
6. Pittsburgh Sleep Quality Index (PSQI)



7. The Multiple Sclerosis-Fatigue Self– Efficacy (MS-FSE) scale



8. Canadian Occupational Performance Measure (COPM)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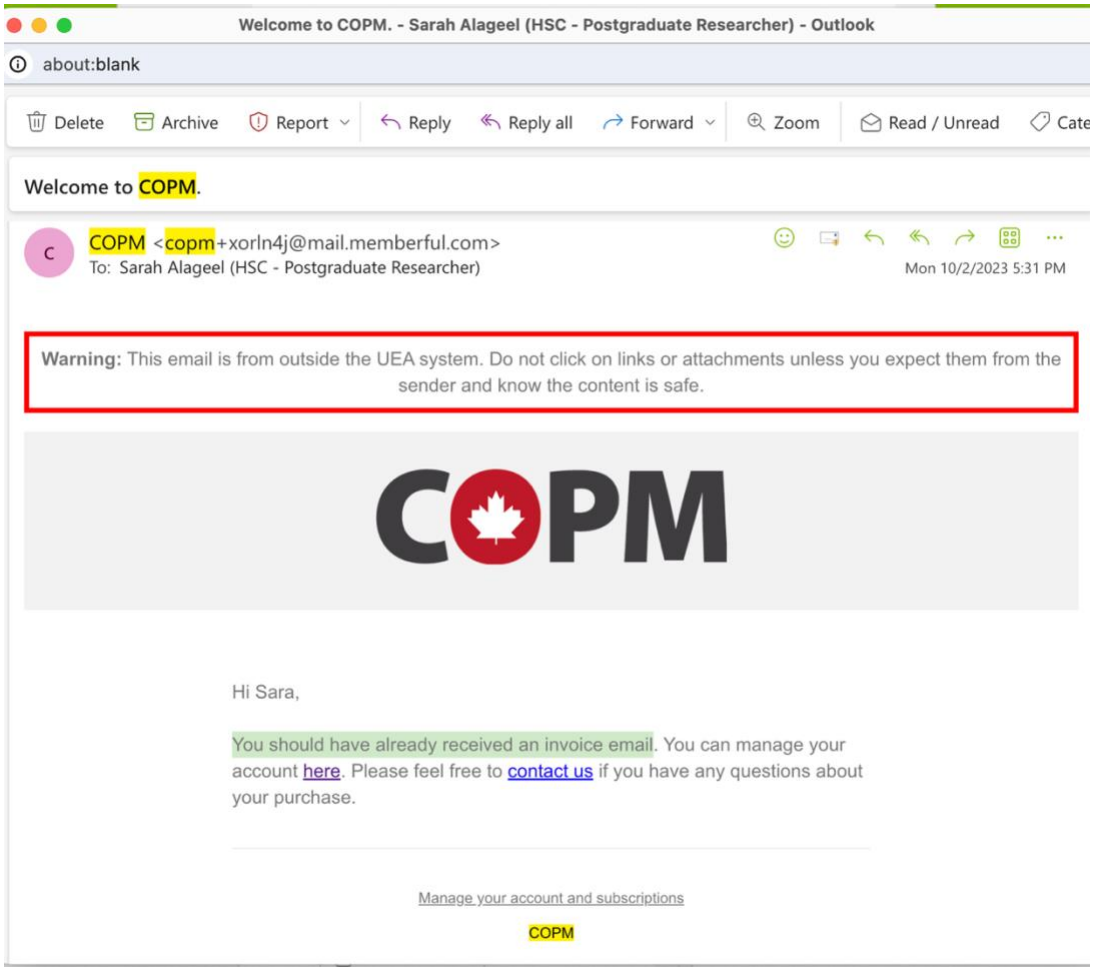
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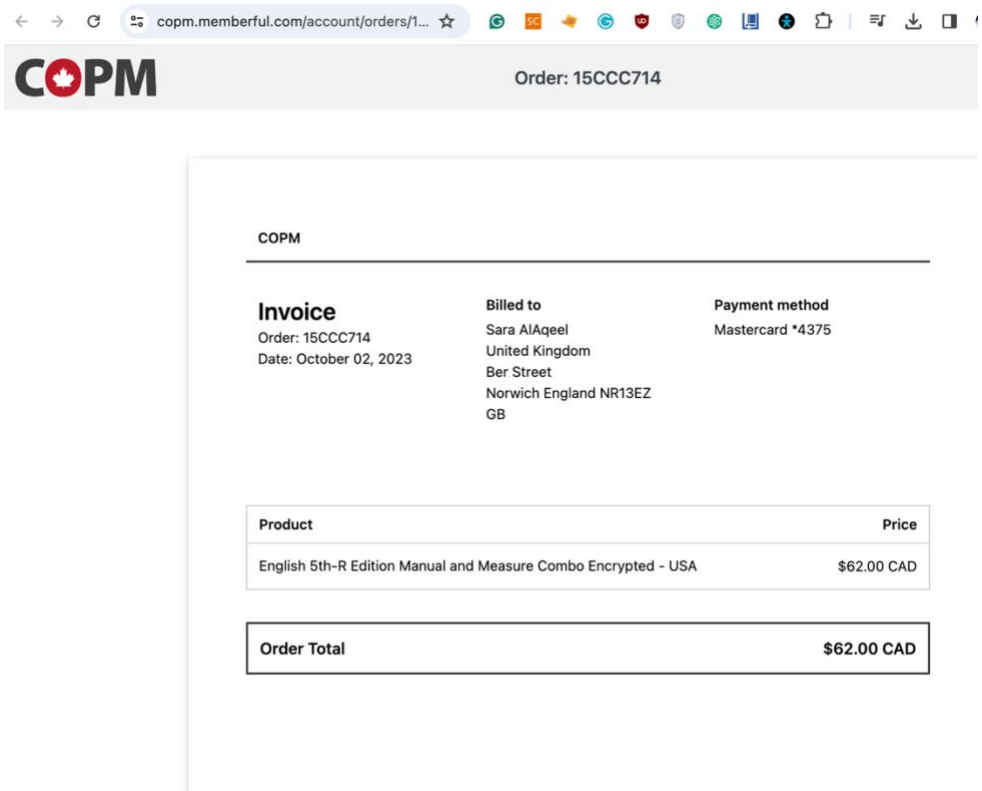
COPM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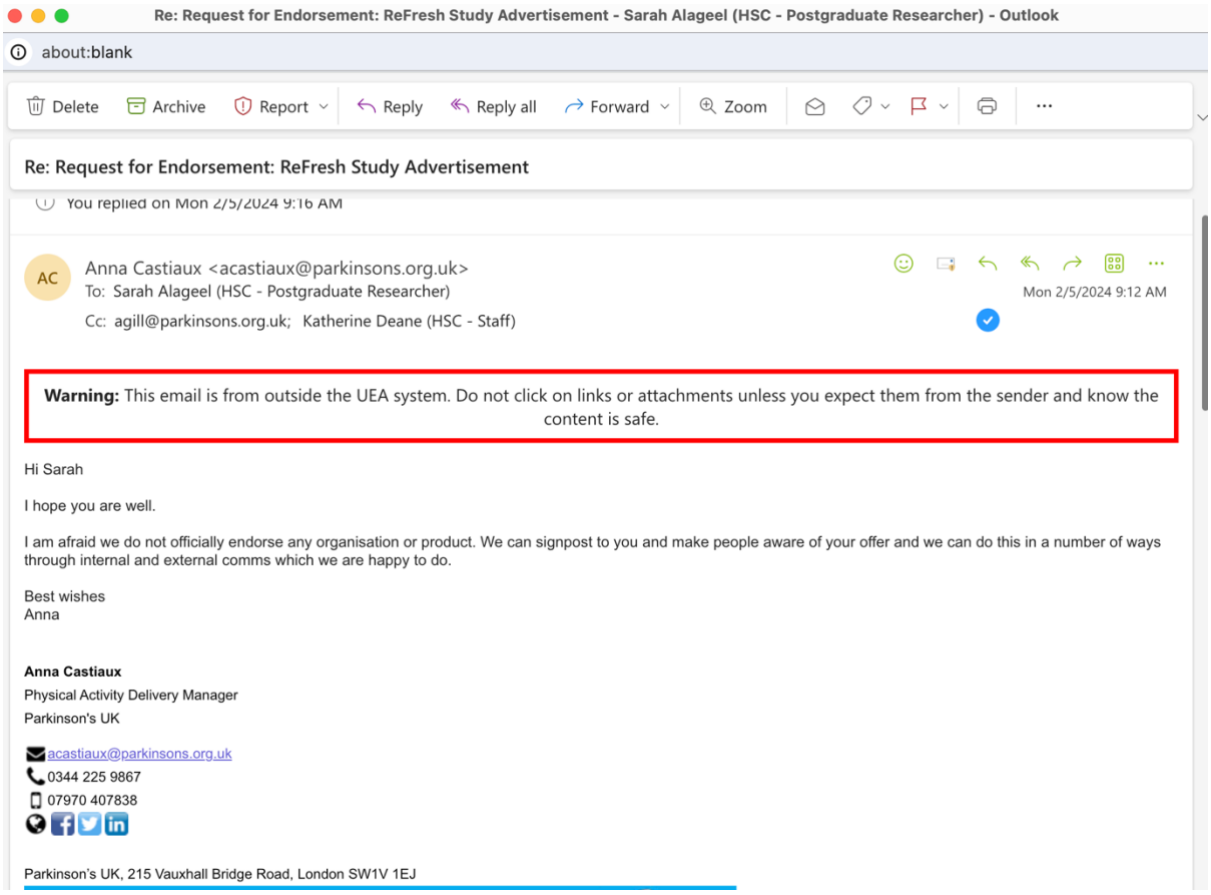
COPM
Order: 15CCC714
COPM
Invoice
Order: 15CCC714
Date: October 02, 2023
Billed to
Sara AlAqeel
United Kingdom
Ber Street
Norwich England NR13EZ
GB
Payment method
Mastercard *4375
Product
Price
English 5th-R Edition Manual and Measure Combo Encrypted - USA
$62.00 CAD
Order Total
$62.00 CAD

Appendix 4

Advertising Approvals

1. Parkinson's UK approval



Re: Request for Endorsement: ReFresh Study Advertisement - Sarah Alageel (HSC - Postgraduate Researcher) - Outlook

about:blank

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Re: Request for Endorsement: ReFresh Study Advertisement

You replied on Mon 2/5/2024 9:16 AM

AC

Anna Castiaux <acastiaux@parkinsons.org.uk>
To: Sarah Alageel (HSC - Postgraduate Researcher)
Cc: agill@parkinsons.org.uk; Katherine Deane (HSC - Staff)

Mon 2/5/2024 9:12 AM

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content is safe.

Hi Sarah

I hope you are well.

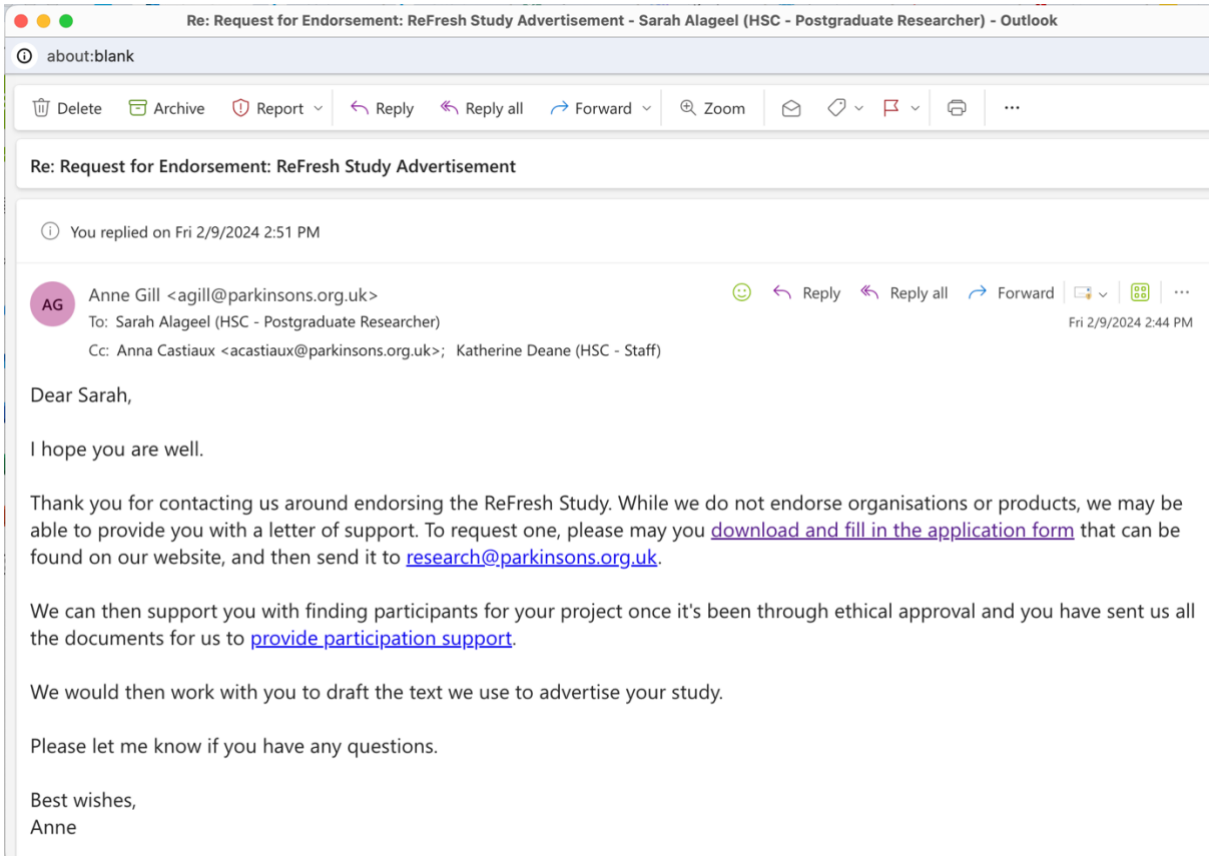
I am afraid we do not officially endorse any organisation or product. We can signpost to you and make people aware of your offer and we can do this in a number of ways through internal and external comms which we are happy to do.

Best wishes
Anna

Anna Castiaux
Physical Activity Delivery Manager
Parkinson's UK

acastiaux@parkinsons.org.uk
0344 225 9867
07970 407838

Parkinson's UK, 215 Vauxhall Bridge Road, London SW1V 1EJ



Re: Request for Endorsement: ReFresh Study Advertisement - Sarah Alageel (HSC - Postgraduate Researcher) - Outlook

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Re: Request for Endorsement: ReFresh Study Advertisement

You replied on Fri 2/9/2024 2:51 PM

AG

Anne Gill <agill@parkinsons.org.uk>

To: Sarah Alageel (HSC - Postgraduate Researcher)

Cc: Anna Castiaux <acastiaux@parkinsons.org.uk>; Katherine Deane (HSC - Staff)

Reply Reply all Forward

Fri 2/9/2024 2:44 PM

Dear Sarah,

I hope you are well.

Thank you for contacting us around endorsing the ReFresh Study. While we do not endorse organisations or products, we may be able to provide you with a letter of support. To request one, please may you download and fill in the application form that can be found on our website, and then send it to research@parkinsons.org.uk.

We can then support you with finding participants for your project once it's been through ethical approval and you have sent us all the documents for us to provide participation support.

We would then work with you to draft the text we use to advertise your study.

Please let me know if you have any questions.

Best wishes,
Anne