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RESEARCH ARTICLE

Pilot randomized controlled trial of the ReFresh online fatigue management programme for people with Parkinson's disease

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ABSTRACT

Aims: Fatigue is one of the most disabling symptoms experienced by people with Parkinson's disease, yet few evidence-based non-pharmacological interventions are available. This study evaluated the feasibility, acceptability, and exploratory clinical signals of the Rebalancing Fatigue and Enhancing Self-Help (ReFresh) online fatigue management programme for people with Parkinson's disease.

Patients and methods: A pilot randomized controlled trial with a wait-list control group was conducted. Participants with Parkinson's disease experiencing fatigue were randomized to either the six-week ReFresh online programme or a wait-list control. Feasibility outcomes included recruitment, retention, adherence, and participant engagement. Secondary outcomes included fatigue severity, fatigue self-efficacy, sleep quality, mood, and occupational performance.

Results: A total of 118 participants were randomized. Recruitment targets were achieved; however, retention and adherence were modest. Participants who completed the programme reported improvements in fatigue self-efficacy and perceived ability to manage fatigue, while changes in fatigue severity were smaller. Qualitative feedback indicated that participants valued the flexibility and accessibility of the online format.

Conclusions: The ReFresh programme demonstrated feasibility and acceptability as a digitally delivered fatigue management intervention for people with Parkinson's disease. Future research should explore strategies to improve engagement and evaluate the programme in a fully powered randomized controlled trial.

Clinical trial registration: ISRCTN Registry, ISRCTN62114944, https://www.isrctn.com/ISRCTN62114944.

PLAIN LANGUAGE SUMMARY

Fatigue is one of the most common and disabling symptoms experienced by people with Parkinson's disease. It can affect daily activities, concentration, and overall quality of life. Despite its impact, few treatments specifically address fatigue in Parkinson's disease.

The Rebalancing Fatigue and Enhancing Self-Help (ReFresh) programme was developed to help people with Parkinson's disease better understand and manage fatigue. The programme was adapted from an existing fatigue management programme originally designed for people with multiple sclerosis. ReFresh was delivered online over six weeks and included educational modules, practical strategies, and reflective activities aimed at helping participants manage energy levels and daily routines.

In this study, people with Parkinson's disease who experienced fatigue were randomly assigned either to take part in the ReFresh programme or to a wait-list control group. The main aim was to examine whether the programme was feasible and acceptable, and whether it showed early signs of benefit.

A total of 118 participants took part in the trial. Recruitment was successful, but some participants did not complete all modules of the programme. Participants who completed the programme reported improved confidence in their ability to manage fatigue and found the online format convenient and accessible.

These findings suggest that ReFresh may be a promising approach for supporting fatigue management in Parkinson's disease. However, further research is needed to improve participant engagement and to test the programme in a larger trial.

ARTICLE HISTORY

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Parkinson's disease; fatigue management; online fatigue intervention; self-management programme; fatigue self-efficacy; Pilot randomized controlled trial; feasibility study; non-pharmacological intervention

1. Introduction

Fatigue is a prevalent and disabling non-motor symptom in Parkinson's disease that substantially impacts daily activities and wellbeing [1–3]. Evidence for PD-specific non-pharmacological fatigue interventions remains limited to exercise [4–6]. Other effective self-management approaches have been evaluated in multiple sclerosis and related conditions, such as psychological interventions [7–11]. There may be components of these interventions that can be transferred to Parkinson's fatigue management.

Among non-pharmacological fatigue interventions in multiple sclerosis, the Fatigue: Applying Cognitive behavioral and Energy effectiveness Techniques to lifeStyle (FACETS) programme has the strongest evidence base.

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Article highlights

- Fatigue is one of the most disabling but under-recognized symptoms in Parkinson's disease.
- ReFresh is a six-week online fatigue management programme adapted from the Fatigue: Applying Cognitive behavioral and Energy effectiveness Techniques to lifeStyle (FACETS) intervention developed for multiple sclerosis.
- Participant adherence and retention were modest, highlighting the need for strategies to improve engagement in digital interventions.
- Participants reported improved confidence in managing fatigue after completing the programme.
- Future trials should explore hybrid or supported delivery models to optimize engagement and evaluate effectiveness in a fully powered randomized controlled trial.

FACETS is a manualised, group-based cognitive – behavioral and energy-management intervention that demonstrated sustained improvements in fatigue self-efficacy and fatigue impact in large, pragmatic randomized controlled trials, including a definitive multi-center trial ($n \approx 164$) with benefits maintained at one-year follow-up [12,13]. Subsequent implementation studies and health-economic evaluations have supported its acceptability, scalability and cost-effectiveness within routine clinical services. FACETS was therefore selected as the theoretical and structural basis for ReFresh because it targets modifiable cognitive and behavioral mechanisms underpinning fatigue, aligns closely with occupational therapy principles of self-management and participation, and has demonstrated clinically meaningful improvements in fatigue-related outcomes across diverse MS populations. Other fatigue interventions were considered; however, many focus on single components (for example exercise or education alone), lack manualisation, or have limited evidence for sustained behavioral change, making them less suitable for adaptation to a scalable, digitally delivered programme for Parkinson's disease.

FACETS is a fatigue management programme for people with MS. It was co-developed with lay advisers and is made up of cognitive behavioral therapy (CBT), activity pacing, and promotion of regular physical activity components. ReFresh adapted the FACETS programme with lay and clinician advice, into a six-week online format for people with Parkinson's [12,13]. This external pilot randomized trial primarily evaluated the feasibility and acceptability of the ReFresh intervention and trial procedures in preparation for a definitive RCT. The study was conducted and reported in line with CONSORT and TIDieR guidance, and exploratory clinical outcomes were analyzed using an estimation approach, reporting between-group mean differences with 95% confidence intervals rather than formal hypothesis testing [14,15].

1.1. Objectives

- Determine feasibility of the protocol against pre-specified progression criteria.
- Assess acceptability of the content and digital delivery.
- Explore change in fatigue severity and fatigue self-efficacy to inform the design and powering of a definitive RCT.

2. Methods

2.1. Study design and oversight

External, parallel-group, open-label pilot RCT with 1:1 allocation to ReFresh or waitlist control. Trial prospectively registered (ISRCTN62114944; 27 February 2024) [16]. The first participant was enrolled on 3 June 2024. Ethical approval: University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee (ETH2324-0159). Reporting follows the CONSORT 2010 statement for randomized trials and TIDieR for intervention description [14,15]. The CONSORT checklist and TIDieR are provided in online supplemental file 1; the full intervention specification is in online supplemental file 2. The safety monitoring plan is included in online supplemental file 6. All data handling complied with UK GDPR [17].

2.2. Stakeholders' involvement

Eleven people with Parkinson's acted as lay advisers across adaptation, recruitment messaging, outcome selection, trial materials, and dissemination planning, consistent with BMJ's patient partnership principles. In addition, two occupational therapists and one Parkinson's clinician contributed advisory input on feasibility and accessibility, broadening this to a wider stakeholder involvement model. Further PPI detail is provided in online supplemental file 7.

2.3. Participants and setting

Adults aged 18 years or older with idiopathic Parkinson's disease, and self-reported fatigue, with sufficient English proficiency and internet access. Eligibility and diagnosis were self-reported. National UK recruitment occurred via Parkinson's UK channels and targeted social media.

2.4. Randomization and masking

Randomization was conducted using the online Sealed Envelope service using permuted blocks (sizes 4 and 6) [18]. Allocation was emailed to participants. Masking was not possible. Outcomes were self-administered online using the Qualtrics platform [19].

2.5. Intervention

ReFresh comprises six online modules adapted from FACETS with permission [12,13]. Modules cover understanding fatigue mechanisms, energy conservation and pacing, cognitive restructuring, adaptive movement, and sleep management. Delivery was via prerecorded videos, downloadable resources, and reflective activities. Full intervention specification is in online supplemental file 2 and the programme logic model is available in online supplemental file 3.

Stakeholder feedback from the 11 lay advisers and the multidisciplinary research team led to several key adaptations when translating FACETS into ReFresh. First, the psychoeducational content was reworked to use Parkinson's-specific language and examples that reflected how advisers described their fatigue in everyday life. Second, activity-based components and pacing strategies were adjusted to take account of fluctuating mobility and motor symptoms. Third, the format and wording of worksheets and homework materials (for example, the activity diary, energy-measures sheet) were iteratively refined to improve clarity and ease of use. In response to advisers' comments about readability, difficulty typing into forms and limited access to software, participants were offered printed copies and a compiled "bumper pack" so that those preferring paper-based resources could still engage fully with the programme.

2.6. Comparator

Waitlist control participants continued usual care during 12-week follow-up and then gained access to ReFresh after week 14.

The waitlist control was selected to maximize feasibility, recruitment and ethical acceptability in this external pilot trial. During stakeholder consultation, lay advisers expressed a strong preference for a design in which all participants would ultimately receive access to the intervention, given the lack of established non-pharmacological fatigue management options in routine Parkinson's care. As the primary aims were feasibility and acceptability rather than efficacy, a waitlist design was considered appropriate to allow comparison against usual care while minimizing contamination and supporting recruitment and retention.

2.7. Outcomes

Primary feasibility outcomes were recruitment, 12-week retention, adherence to at least 4 of 6 modules, endpoint data completeness, and acceptability using brief weekly items with free-text feedback [20]. Item wording and week-level summaries are in online supplemental file 4.

For recruitment, we recorded the number of participants randomized per month during the active recruitment period. Retention was defined as the proportion of randomized participants who completed the 12-week endpoint assessment. Adherence in the intervention arm was defined as completion of at least four of the six ReFresh modules. Data completeness for the primary outcome measures was summarized as the proportion of missing endpoint data. Acceptability was assessed using weekly 5-point Likert ratings of content relevance and perceived helpfulness, supplemented by free-text comments. These feasibility outcomes and their observed values are summarized in Table 2.

Exploratory clinical outcomes were the change from baseline to 12 weeks in the Parkinson's Fatigue Scale (PFS) [21], Modified Fatigue Impact Scale (MFIS) [22,23], Multiple Sclerosis Fatigue Self-Efficacy Scale (MS-FSE), Parkinson's Anxiety Scale (PAS) [24], Geriatric Depression Scale (GDS-15) [25], Pittsburgh Sleep Quality Index (PSQI) [26], quality of life using the Parkinson's Disease Questionnaire-39 (PDQ-39) [27], and occupational performance using the Canadian Occupational Performance Measure (COPM) [28].

2.8. Sample size rationale

The pilot was not powered for effectiveness. The original target of 40 participants was pragmatic for estimating feasibility parameters; the final recruitment of 118 participants improved precision around the retention estimate.

2.9. Statistical analysis

Feasibility endpoints followed an intention-to-treat (ITT) approach, with missing data imputed using last observation carried forward (LOCF) [29]. LOCF was selected as a pragmatic and transparent approach for this external pilot to preserve the intention-to-treat principle and enable exploratory estimation of outcome behavior in the context of substantial attrition, rather than to provide definitive effectiveness estimates. Exploratory outcomes were analyzed as change scores and compared between groups using t tests, with p values and 95% confidence intervals reported. As recommended for pilot and feasibility trials, these analyses were conducted to describe signal direction, variability and data behavior rather than to support confirmatory inference regarding effectiveness or causal efficacy. A per-protocol (PP) sensitivity analysis, together with additional LOCF sensitivity checks, is presented in online supplemental file 5.

3. Results

3.1. Feasibility outcomes summary

Recruitment to the ReFresh pilot trial was strong: of the 150 people who opened the link to the recruitment web page, 118 participants were randomized (58 intervention, 60 control), exceeding the original target of 40 participants and corresponding to a mean recruitment rate of approximately 29.5 participants per month. At the 12-week endpoint, 76 participants (64.4%) completed outcome measures, with lower retention in the intervention group (55.2%) than in the control group (73.3%). Reported reasons for withdrawal included health issues, perceived programme burden, and competing responsibilities. Exploratory examination of feasibility data and free-text feedback suggested that lower retention and adherence clustered around three factors: fluctuating health status, cumulative burden of weekly tasks, and difficulties with digital access or confidence; however, the pilot was not powered to formally test predictors of disengagement. See Figure 1 and Table 1.

Adherence to the intervention was modest: 48.3% of participants in the intervention arm completed at least four of the six ReFresh modules. Primary outcome data completeness was also suboptimal, with 35.6% of primary outcome data missing at 12 weeks. Acceptability among those who engaged with the programme was high, with mean satisfaction ratings between 4.6 and 4.8 out of 5 across domains of content, usability and perceived relevance. Overall, these findings indicate strong demand and good acceptability but substantial concerns about retention, adherence, and outcome data completeness, which would need to be addressed before progressing to a definitive trial. These feasibility outcomes are summarized in Table 2.

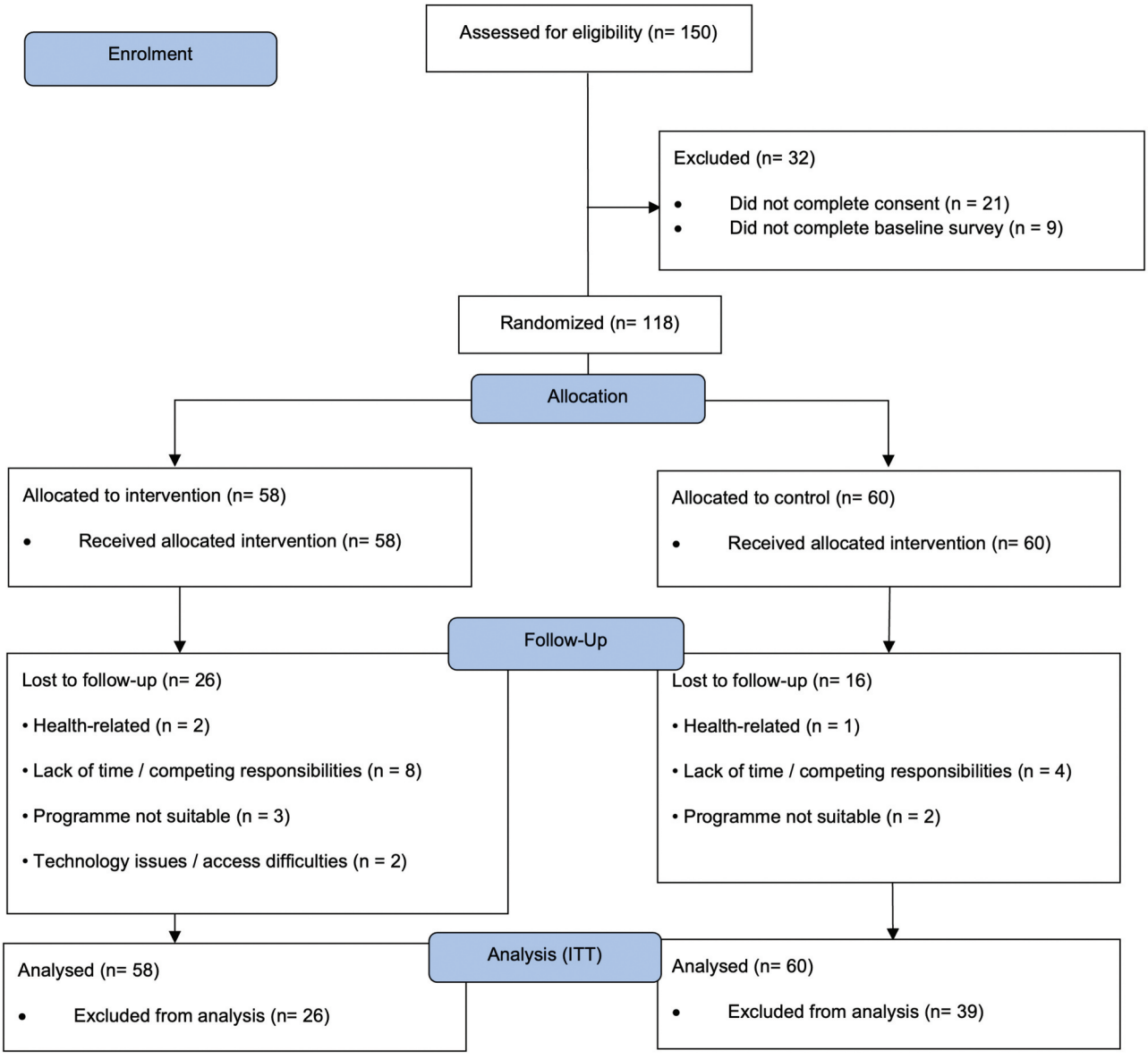

Figure 1. CONSORT flow diagram of participants through the ReFresh pilot trial.

Table 1. Baseline characteristics of the randomized sample.

Characteristic	Intervention ($n = 58$)	Control ($n = 60$)	Total ($n = 118$)
Male, %	46.7	53.8	50.0
White ethnicity, n (%)	55 (94.8%)	54 (90.0%)	109 (92.4%)
Years since diagnosis, mean (SD)	6.4 (3.1)	6.7 (3.5)	6.6 (3.3)
Living alone, n (%)	20 (34.5%)	18 (30.0%)	38 (32.2%)
Uses assistive device, n (%)	15 (25.9%)	12 (20.0%)	27 (22.9%)

Key: SD = standard deviation; n = number of participants.

3.2. Acceptability

Participants were asked weekly to assess content, clarity, and usefulness. Across 149 forms, pooled five-point Likert ratings were high for content (4.10/5), clarity (4.32/5), and usefulness (4.27/5).

Twelve participants requested printed packs due to readability or software issues. This is consistent with UK evidence on digital exclusion in older adults [30–32]. Item wording and week-level summaries are in online supplemental file 4.

3.3. Exploratory clinical outcomes

Consistent with the pilot design, these analyses are intended to inform outcome selection and trial design rather than to test efficacy.

Table 2. Summary of feasibility outcomes.

Feasibility domain	Observed value	Interpretation
Recruitment	118 participants randomized; approximately 29.5 participants per month	Recruitment exceeded the initial target (40 participants) and indicates strong interest in fatigue management among people with Parkinson's.
12-week retention	64.4% (76/118) completed 12-week outcome measures; 55.2% in the intervention group and 73.3% in the control group	Retention was lower than desired overall, with particularly high dropout in the intervention arm, raising concerns about sustaining engagement over time.
Adherence (intervention arm)	48.3% of participants completed at least four of the six ReFresh modules	Adherence to the full intervention content was modest and suggests that additional support or programme modifications are needed to improve completion.
Primary outcome data completeness	35.6% of primary outcome data missing at 12 weeks	High levels of missing primary outcome data limit confidence in the preliminary efficacy estimates and would need to be reduced in a definitive trial.
Acceptability	Mean satisfaction scores between 4.6 and 4.8 out of 5 for programme content, usability and relevance	Among participants who engaged with ReFresh, perceived acceptability and relevance of the programme were high.

As this was a feasibility-focused external pilot trial, all clinical outcome analyses are exploratory and should be interpreted cautiously; the study was not powered to detect statistically significant between-group effects.

Table 3 summarizes the between-group mean differences in change from baseline to 12 weeks and the corresponding between-group comparisons. The exploratory analyses suggested no clear between-group differences in fatigue severity (PFS, MFIS), while fatigue self-efficacy (MS-FSE) showed a between-group difference of 6.72 points (95% CI 1.67 to 11.77), suggesting a potential improvement in fatigue self-efficacy in the intervention group. However, as this pilot study was not powered to test treatment effectiveness, this finding should be interpreted cautiously. No significant between-group differences were seen in quality of life, sleep quality, anxiety or depression, and the trial was not powered for a definitive assessment of efficacy. Occupational performance was explored using a self-completed version of the COPM in a small subgroup of 10 intervention participants. This showed mean increases of 2.28 points in performance and 2.44 points in satisfaction scores, consistent with clinically important improvements at group level. However, the small sample size and nonstandard, self-directed administration mean these data must be interpreted cautiously. Per-protocol results are summarized in online supplemental file 5.

3.4. Safety

No adverse events were reported at 12 weeks.

4. Discussion

4.1. Feasibility

Recruitment is clearly feasible. The study massively over recruited past the target 40 participants ($n = 118$). This shows substantial interest in interventions for fatigue in the Parkinsonian population. However, retention and adherence are not yet adequate for a definitive trial without some modification of the intervention. This pattern of participant withdrawal is typical of unguided digital behavioral interventions [33–36]. Other online interventions have benefited from added support, e.g., online video meetings with lay or clinical advisers [33,34], which has been shown to improve participant engagement. We are also aware that this aged population may not be sufficiently digitally literate [30–32], so hard copy resources in addition to the online program may be of use so participants can track progress.

Despite successful recruitment, retention presented a substantial challenge. At 12 weeks, more than one-third of participants had withdrawn, with higher attrition in the intervention arm than in the control arm. Participants described

Table 3. Exploratory outcomes at 12 weeks (ITT observed data).

Measure	Group	Baseline mean (SD)	Endpoint mean (SD)	Change mean (SD)	p value (between-group comparison of change)
Fatigue measures					
PFS	Intervention ($n = 58$)	56.18 (14.93)	53.13 (16.24)	−3.05 (9.54)	$p = 0.102$
	Control ($n = 60$)	57.31 (13.09)	57.52 (13.04)	0.21 (7.84)	
MFIS	Intervention ($n = 58$)	40.61 (15.60)	39.85 (18.62)	−0.75 (11.38)	$p = 0.33$
	Control ($n = 60$)	42.70 (14.01)	42.87 (15.43)	0.16 (8.25)	
Secondary measures					
MS-FSE	Intervention ($n = 58$)	47.06 (25.12)	52.52 (24.13)	5.45 (13.80)	$p = 0.05$
	Control ($n = 60$)	45.77 (20.60)	44.50 (20.28)	−1.27 (14.18)	
PSQI	Intervention ($n = 58$)	9.47 (3.03)	9.17 (2.99)	−0.30 (1.21)	$p = 0.09$
	Control ($n = 60$)	10.49 (3.24)	10.16 (3.02)	−0.39 (1.46)	
PDQ-39	Intervention ($n = 58$)	26.10 (15.92)	29.34 (20.84)	3.25 (15.35)	$p = 0.47$
	Control ($n = 60$)	29.49 (16.09)	32.00 (24.56)	2.84 (17.27)	
PAS	Intervention ($n = 58$)	24.79 (11.72)	25.26 (11.31)	0.48 (5.06)	$p = 0.72$
	Control ($n = 60$)	25.59 (10.71)	25.95 (9.73)	0.36 (5.78)	
GDS-15	Intervention ($n = 58$)	4.41 (3.80)	5.00 (4.54)	0.59 (1.86)	$p = 0.25$
	Control ($n = 60$)	4.91 (3.66)	5.91 (4.18)	1.00 (1.94)	

Key: GDS-15 = Geriatric Depression Scale; MFIS = Modified Fatigue Impact Scale; MS-FSE = Multiple Sclerosis Fatigue Self-Efficacy Scale; PAS = Parkinson's Anxiety Scale; PDQ-39 = Parkinson's Disease Questionnaire-39; PFS = Parkinson's Fatigue Scale; PSQI = Pittsburgh Sleep Quality Index; SD = standard deviation; ITT = intention-to-treat; n = number of participants.

health problems, perceived programme burden and competing responsibilities as common reasons for disengagement, alongside difficulties with digital literacy and sustaining motivation once the initial novelty had worn off. Similar patterns of high dropout have been reported in other digital health interventions, including telerehabilitation trials in Parkinson's disease and large-scale internet-delivered psychological programmes, where attrition rates of 30–50% are typical. In that literature, adherence improves when programmes incorporate structured human support, such as scheduled facilitator check-ins or peer contact, consistent with Eysenbach's 'law of attrition' describing systematic loss of participants over time in unguided eHealth interventions. These findings support future ReFresh iterations adding light-touch human support (for example, group sessions or brief telephone/video calls) to enhance accountability and engagement. Taken together, these findings indicate that disengagement was driven primarily by delivery-related factors rather than dissatisfaction with intervention content, identifying modifiable design features rather than limitations of the underlying intervention rationale.

Digital accessibility also emerged as a constraint. Several participants reported difficulties navigating the website, reading on screen or editing electronic worksheets, and 12 requested printed materials. These experiences are consistent with national data showing that older adults and people with long-term conditions are disproportionately affected by low digital confidence and limited internet use [30,31]. Reports from Age UK and Ofcom indicate that a sizable minority of older people either lack internet access altogether or use it infrequently, often due to concerns about complexity, online safety and low perceived skills [30,31]. These data reinforce the need for hybrid delivery models that routinely offer print-ready resources and simple digital support as standard when delivering online interventions to older populations.

4.2. Fatigue

Whilst recruitment exceeded the original feasibility target, the study remained insufficiently powered to support statistically robust efficacy conclusions, particularly given differential withdrawal favoring the intervention group. These factors substantially limit interpretation of between-group effects. Within these constraints, fatigue self-efficacy showed a between-group difference suggestive of potential improvement in the intervention group. However, as this pilot study was not powered to test treatment effectiveness, this finding should be interpreted cautiously. This finding is consistent with the ReFresh programme's underlying theory of change and with self-management approaches used in multiple sclerosis fatigue interventions, where improvements in confidence and perceived control often precede measurable reductions in fatigue severity [7–11].

Participants were not required to meet a predefined fatigue severity threshold at enrollment. Consequently, the sample included individuals with mild to moderate fatigue, which may have diluted observable intervention effects and reduced the likelihood of detecting clinically meaningful change in fatigue outcomes. This approach was consistent with the feasibility aims of the external pilot trial, which sought to evaluate recruitment, retention, acceptability and outcome performance across a broad Parkinson's population rather than to maximize treatment effect size. However, the absence of a fatigue severity eligibility criterion limits interpretation of intervention effects and should be addressed in future trials.

This feasibility-oriented approach, which did not impose a fatigue severity threshold at enrollment, enabled broad recruitment and assessment across the Parkinson's population, but necessarily reduced sensitivity for detecting clinically meaningful change in fatigue outcomes.

The observed pattern of change aligns with behavior-change models in which cognitive reframing, pacing and energy-conservation strategies first enhance perceived control over fatigue, with symptom intensity changing more gradually. When consulted, lay advisers prioritized 'being able to manage fatigue' over absolute fatigue reduction as the most meaningful outcome and indicated that improved self-efficacy could enable greater participation in personally valued activities even when fatigue levels remained relatively stable. These perspectives, together with the MS-FSE signal observed, suggest that fatigue self-efficacy is a theoretically coherent candidate primary outcome for evaluation in a future fully powered trial.

For a future definitive trial, these findings indicate the need to incorporate a validated Parkinson's disease – specific fatigue measure at screening, alongside a predefined fatigue severity threshold and/or stratification by baseline fatigue level. This would ensure inclusion of participants for whom fatigue is a clinically salient target and improve the ability to evaluate intervention efficacy.

4.3. Fatigue measures

Although the PFS and MFIS have been used in Parkinson's disease, fatigue self-efficacy was measured using the Multiple Sclerosis Fatigue Self-Efficacy Scale (MS-FSE), which was originally developed and validated for people with multiple sclerosis [37] and has yet to be validated for use in Parkinson's. This limits the strength of inferences about fatigue self-efficacy in this population and highlights the need either to validate MS-FSE in Parkinson's disease or to develop a Parkinson's-specific fatigue self-efficacy measure. In addition, all fatigue outcomes were collected at discrete time points using self-report questionnaires. Future work could add more frequent, technology-enabled assessment such as wearable devices, smartphone-based symptom tracking and instrumented platform analytics (for example, automated logging of module usage) to provide finer-grained and more objective insight into day-to-day fatigue fluctuations and response to the intervention.

4.4. Secondary measures

Although secondary outcomes such as sleep, mood, and quality of life did not differ significantly between groups, lay advisers considered them essential for describing the broader impact of fatigue and its management, so they remain important for future trials. These findings are consistent with the

idea that self-management interventions may affect coping and participation before measurable change appears in global quality-of-life or mood indices, particularly over short follow-up periods.

Within the small subgroup of 10 intervention participants who self-completed the COPM, mean improvements of 2.28 points in performance and 2.44 points in satisfaction suggested that some individuals were able to translate fatigue-management strategies into meaningful changes in personally valued activities. Given the optional, self-directed completion, absence of control-group data and small sample, these COPM findings should be interpreted as cautiously indicative rather than robust evidence of clinical effectiveness. They do, however, align with the occupational therapy emphasis of the programme and support further, better supported use of occupational performance outcomes in a fully powered trial. No serious adverse events were reported, but safety monitoring relied on passive self-report at 12 weeks; larger trials should adopt prospective, structured adverse-event logging to ensure more complete capture of falls and other potential harms.

4.5. Strengths and weaknesses

This pilot has several strengths. The ReFresh programme was co-produced with people with Parkinson's and clinicians, and was deliberately multi-faceted, targeting cognitive, behavioral, pacing, and lifestyle factors that contribute to fatigue. Online delivery enabled national recruitment, reduced travel burden and allowed participants to complete modules at home and at their own pace. However, important limitations temper the findings. Recruitment through online channels and the need for internet access mean that people who are digitally excluded or less confident with technology were likely under-represented [31]. Retention and adherence to the unguided online intervention were modest, and the intention-to-treat analysis relied on last observation carried forward (LOCF) to impute missing data. LOCF can introduce bias when dropout is related to outcome or differs between groups and is not always recommended as a primary strategy for handling missing longitudinal trial data [19]. In line with CONSORT guidance for pilot and feasibility trials, the extent and pattern of missing data are therefore interpreted as key feasibility outcomes rather than solely as statistical limitations, including identification of barriers to retention and adherence. These data provided important insight into participant burden, engagement challenges and barriers to retention and adherence that must be addressed before progression to a definitive trial and directly informed the design recommendations for enhanced engagement strategies and more robust analytical approaches.

The use of a waitlist control supported recruitment and ethical acceptability for this feasibility-focused pilot, particularly given the absence of established non-pharmacological fatigue management pathways in routine Parkinson's care and strong lay adviser preference that all participants ultimately receive access to the intervention. However, this design limits the ability to control for nonspecific effects such as expectancy or attention and therefore constrains causal inference regarding intervention effects.

4.6. Recommendations for future research

This pilot identified specific, modifiable contributors to poor retention and adherence, directly informing targeted design modifications for a future fully powered RCT.

To directly address the retention and adherence challenges identified in this pilot, the following design modifications are proposed:

- Light-touch human support at scheduled intervals to create structure and accountability. This could take the form of brief online video meetings with peers and a trained facilitator (occupational therapist or trained lay facilitator).
- Digital inclusion measures at onboarding, including print-ready materials and simple technical support as standard for participants at risk of digital exclusion [30–32].
- Instrumented platform analytics to capture objective adherence, engagement and intervention fidelity.
- Digital tools for more continuous data collection relating to activity and fatigue symptoms.
- Prospective, structured safety monitoring, rather than reliance on passive self-report at endpoint.
- More robust missing-data methods than LOCF (for example, mixed-effects models or multiple imputation) to reduce bias in the presence of differential dropout [19].

5. Conclusions

ReFresh is acceptable and recruitable, but unguided delivery is not yet scalable in PD without support. The exploratory fatigue self-efficacy signal supports prioritizing fatigue self-efficacy for evaluation as a candidate primary endpoint in a definitive RCT that adds structured support and proactive digital inclusion.

6. Strengths and limitations of this study

- External pilot randomized design with a priori progression criteria and reporting to CONSORT and TIDieR improves transparency and reproducibility [14,15].
- Co-creation of intervention and evaluation with people with Parkinson's and clinicians strengthens patient relevance and acceptability.
- Recruitment exceeded target using national patient advocacy networks, demonstrating strong demand for structured fatigue support.
- Retention and adherence were modest, reflecting known challenges in unguided digital interventions. This informs the recommendation of supportive components for a future fully powered trial [33–36].

- Exploratory clinical outcomes were not powered for hypothesis testing and are reported to characterize signal direction and variability.

Use of artificial intelligence tools

The authors used ChatGPT (OpenAI) for language editing and assistance with manuscript structuring during the preparation of this manuscript. All content was critically reviewed and approved by the authors.

Author contributions

CRediT: **Sarah Alageel:** Conceptualization, Formal analysis, Investigation, Methodology, Writing – original draft; **Jane Hibberd:** Methodology, Supervision, Writing – review & editing; **Katherine H.O. Deane:** Conceptualization, Methodology, Supervision, Writing – review & editing.

Disclosure statement

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Provenance and peer review

Not commissioned. Externally peer reviewed.

Ethics statements

University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee approved the study (ETH2324-0159). Participants gave electronic informed consent before participation.

Trial registration

ISRCTN62114944. Public record: ISRCTN registry.

Patient and public involvement statement

Eleven people with Parkinson's acted as lay advisers across intervention co-adaptation, wording and accessibility, recruitment routes, outcome burden, interpretation of acceptability data, and dissemination plans. After the trial they prioritized outcomes for a definitive RCT, favoring ability to manage fatigue over fatigue reduction. We will disseminate results to advisers and via Parkinson's UK channels.

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Data availability statement

De-identified participant data, statistical analysis scripts, the TIDieR checklist and the logic model will be deposited on the Open Science Framework upon publication. Prior to publication, reasonable requests can be directed to the corresponding author.

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