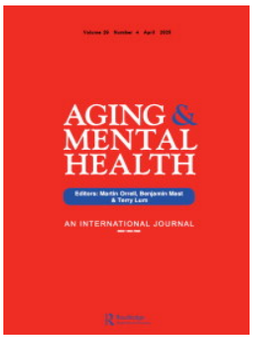

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Evaluating a digital mental health intervention for people with Parkinson's (PACT): acceptability and feasibility randomised controlled trial

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ABSTRACT

Objectives: We developed a web application (PACT app) based on Acceptance and Commitment Therapy to support mental health for people with Parkinson's. Here, we assess the app's acceptability and the feasibility of conducting a randomised controlled trial to evaluate its effectiveness.

Method: This was a two-armed parallel group design with 2:1 allocation to the PACT app or waiting-list control and a single, post-intervention follow-up. Feasibility outcomes included recruitment and retention rate, intervention engagement and satisfaction. Secondary outcomes included measures of anxiety, depression, quality of life, and cost-effectiveness. Treatment effects for secondary outcomes were estimated using linear regression, following the intention-to-treat principle.

Results: Fifty-seven people with Parkinson's were randomised to 4 weeks of PACT app ($n = 38$) or waiting-list control ($n = 19$). Recruitment, retention rate, intervention use, and acceptability met our progression criteria. Intervention effects were in the expected direction for all outcomes and largest for measures of depression (Hedges g = −0.96; 95% CI = −1.47 to −0.46) and committed action (Hedges g = 0.87; 95% CI = 0.38 to 1.35).

Conclusion: Progression criteria were met, and PACT was acceptable to people with Parkinson's. It has potential efficacy and cost-effectiveness. A future larger trial to fully evaluate efficacy is needed. Trial registration: ISRCTN65177345 (01/09/2023).

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Parkinson's; mental health; web application; randomised controlled trial; acceptance and commitment therapy

Introduction

Parkinson's is a neurodegenerative disease that can lead to a wide range of motor (for example, rigidity, tremor, difficulties balancing, slow movement) and 'non-motor' symptoms (for example, pain, fatigue, bowel and bladder difficulties, psychological symptoms). People with Parkinson's (PwP) frequently experience psychological distress, including anxiety, depression, and apathy (Simpson et al., 2013). Receiving a diagnosis of Parkinson's and having to cope with the unpredictable and debilitating symptoms can exert a significant psychological impact for PwP (Dissanayaka et al., 2014). The prevalence of anxiety can be as high as 50–55% (van der Hoek et al., 2011; Yamanishi et al., 2013) and 50–56% for depression (Dissanayaka et al., 2014; Yamanishi et al., 2013). Despite these challenges, meta-ethnographic methods highlighted the determination of individuals to self-manage their condition and maintain positive well-being (Wieringa et al., 2022).

To support individuals to maintain their positive well-being a number of psychological interventions have been developed and tested. A recent review on psychological interventions for PwP showed that cognitive behavioural therapy (CBT) can be effective for treating depression and sleep disorders, however, we have little evidence on its effectiveness on quality of life and impulse control (Roper et al., 2024; Zarotti et al., 2021). Acceptance and Commitment Therapy (ACT) is an empirically based psychological intervention that improves psychological well-being (Stenhoff et al., 2020) by focusing on personal growth, and enhancing psychological flexibility (Hayes, 2004). It includes acceptance, mindfulness, motivation, and behaviour change methods. Individuals are encouraged to face problems head-on rather than avoiding the stress or distress this can include and to engage in actions that help them live the life they want. ACT may be more useful than other existing psychotherapeutic models in the context of Parkinson's. For example, negative illness beliefs and distress may be realistic at certain times. Thus, ACT's focus on instigating valued behaviours while accepting such thoughts and feelings may prove more effective than attempts to directly alter them, as in traditional CBT (Graham et al., 2016). For example, if a PwP values being part of a loving family and social network, the goal would be to 're-engage' in activities that they can still do (despite their motor and non-motor symptoms) with their family members and close friends, and which enable them to be loving and caring towards people who are important to them.

Some evidence suggest that ACT interventions may be beneficial to improve well-being in people with neurological conditions (Han et al., 2023), but perhaps not for all neurological conditions, as for example there was little evidence of potential effectiveness of ACT for people with multiple sclerosis

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(Thompson et al., 2022). In Parkinson's, only one pilot randomised control trial on an ACT-based programme delivered in groups and face-to-face was conducted that showed an improvement in standing balance and emotional well-being (Ghielen et al., 2017). There is also some evidence that ACT interventions effectively support mental health even when delivered online as microlearning (Rickardsson et al., 2021), but there is limited research on the use of ACT with PwP. There is a clear need to understand more about how these approaches can be used to support PwP (Zarotti et al., 2021).

Despite promising research evidence, most PwP have little access to psychological support because support is time- and resource-intensive. Additionally, mobility limitations, travel burden and cost can make face-to-face psychological therapy inaccessible for many PwP and this lack of access intensified during the COVID pandemic (Mucci et al., 2020). As a response to the need for accessible, less resource intensive interventions, the use of digital applications to provide mental health support has grown in recent years (Himle et al., 2022). With Parkinson's, there has been some research on interventions such as CBT and mindfulness delivered *via* telephone or video-conference and this was found to be suitable and acceptable to PwP (Bogosian et al., 2022; Dobkin et al., 2020; Swalwell et al., 2018; Wuthrich & Rapee, 2019). Digital cognitive training programmes have also been a positive addition to current treatment and appear acceptable for PwP (Santini et al., 2022). Digital interventions could be a promising approach for psychological support for PwP. We co-designed a web-based health application (PACT app) with PwP and carers to be delivered *via* smartphones and tablets. We combined elements from two user-centred design approaches: we followed the PERsona CEntred Participatory Technology (PERCEPT) co-design approach (Bourazeri & Stumpf, 2018) and the person-based approach (Yardley et al., 2015). The PERCEPT methods uses co-design workshops to identify users' needs for technology, co-created personas (Neate et al., 2019; Pruitt & Grudin, 2003) and then evaluates the technology designs. This method has been used successfully in co-designing smart home technology with people with Parkinson's and dementia (Bourazeri & Stumpf, 2018). We combined this with a person-based approach (Yardley et al., 2015) to integrate findings from workshop discussions into intervention planning and optimisation. The aim of this approach is to understand the context of target users and use these insights to maximise engagement with the intervention through a systematic framework that can guide intervention developers to identify key features that can make the intervention meaningful, useful, and engaging.

The PACT app delivers a self-guided program of ACT with evidence-based elements tailored for improving wellbeing for PwP. Our app uses microlearning - short bursts (5–10 min) of content for individuals to go through as and when they need it. Microlearning can be easily integrated into PwP's daily lives and routines, and it does not require the assistance of a therapist. The PACT app covers themes such as increasing motivation, behaviour change, acceptance, mindfulness and being present, goal setting, learning about challenges, behaviours and consequences, the cost of avoidance, clarifying values and doing what matters, learning to open up, and changing behaviours. The sessions are delivered *via* audio, video and text content, and encourage reflection and practice from participants. Reflections could be inputted as text or voice-recording (see Figure 1). At the end of each session, participants are asked to rate the session they have completed. After every 6 sessions, participants are asked to review their progress and practice in relation to the processes of being open, aware, and engaged through a 6-item progress questionnaire. The PACT app also sent email reminders to participants to use it. Participants were able to set the frequency of those reminders.

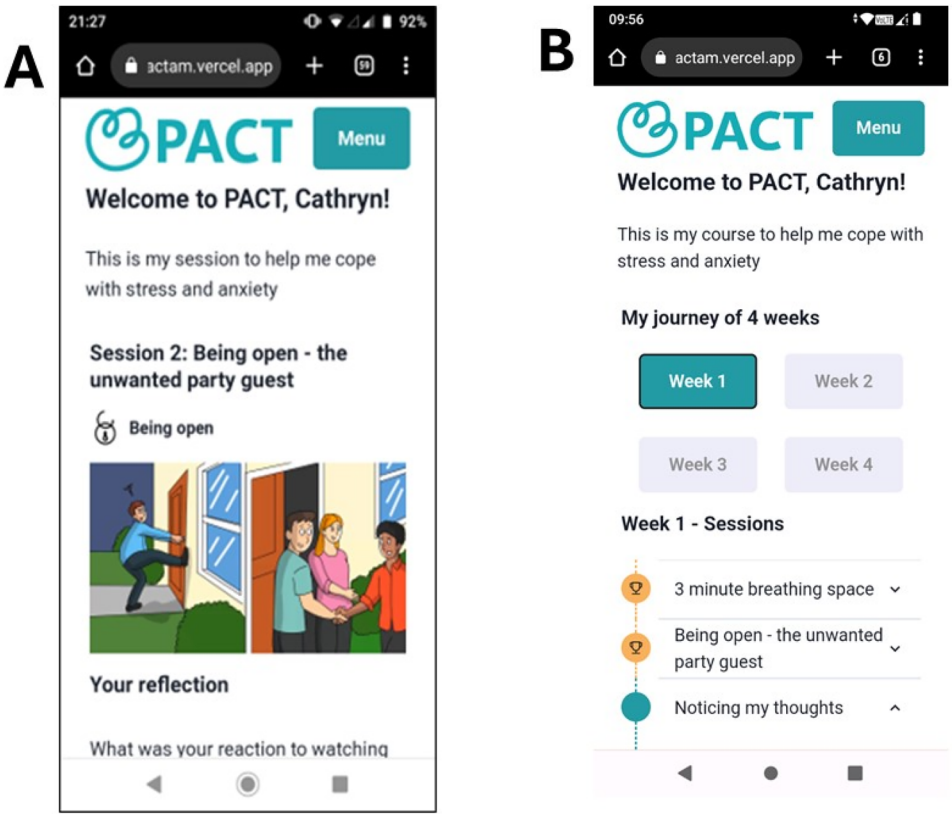

Figure 1. The PACT app (A) screenshot of overview of the PACT four sessions (B) Screenshot of a session showing introduction, video explanation and reflection space.

In this study, we assessed the acceptability of the web application and the feasibility of a trial to evaluate this digital app to improve metal health in PwP. We aimed to determine whether a larger RCT examining clinical- and cost-effectiveness is warranted.

Research objectives:

1. To assess the feasibility of trial procedures and methods, based on a) recruitment rate, b) retention rate, c) contamination rate, and d) adherence rate.
2. To describe patterns of PACT usage and engagement in terms of a) frequency and duration of PACT use overall b) rates of engagement with individual elements.
3. To provide preliminary assessments of the treatment effect on primary and secondary outcomes
4. To provide a preliminary assessment of the cost-effectiveness of the intervention
5. To assess satisfaction with and acceptability of the web application.

Materials and methods

Design

This was a two-armed parallel-group, randomised controlled feasibility trial comparing a digital app based on ACT (intervention group) to usual care (waitlist control group). Randomisation followed a 2:1 ratio stratified by, disease duration, and baseline levels of psychological distress, using fixed block sizes to maintain an equal allocation ratio throughout recruitment. A randomisation list was generated using Sealed Envelop the online service. This was administered by AB to maintain allocation concealment at the point of randomisation. Given the nature of the study it was not possible to blind participants or researchers to group allocation. All participants were asked to complete online questionnaires at baseline and at 4 wk post-randomisation when those in the control group were expected to have completed the intervention.

The study received ethical approval from the Senate Research Ethics Committee, City, University of London (ref: ETH2324-1065). All participants provided written informed consent. Data were collected between October 2023 to February 2024. Study was registered with the ISRCTN register (ISRCTN65177345) on 01/09/2023. The study has followed the plan as set out in the registry and full protocol (Pinto et al., 2025) with no changes.

Participants

Sample size

As this was a feasibility trial the sample size was based on precision of the key variables informing the feasibility decision (objective 1), rather than a formal power calculation. A target sample size of 60 participants would allow us to estimate the recruitment rate out of all of those assessed for eligibility with a 95% CI (binomial exact) with precision (i.e. width) of ±10%, assuming a 60% rate based on previous studies with similar recruitment (Bogosian et al., 2022), and higher precision (i.e. narrower 95% CI) if the rate is lower than anticipated.

Inclusion and exclusion criteria

Participants were included if they were over 18 years of age, self-reported a diagnosis of Parkinson's, lived in the UK, had access to computer/tablet/smartphone and the internet, were able to read and communicate in English, were stable on anti-depressants or anxiolytics if taken- stable dose for a minimum of 1 month and had mild-to-moderate levels of distress determined by a score between 3–8 on the PHQ-4. Participants with severe cognitive impairment as determined by a score of 20 or above on the 6-item Cognitive Impairment Test (Katzman et al., 1983) or psychiatric conditions (e.g. psychosis, drug/alcohol addiction) that can potentially risk failure in the treatment or limit engagement with the treatment methods, were excluded.

Recruitment and screening

We recruited participants through the Parkinson's UK research support network *via* newsletters, social media, and local groups. Interested PwP were then contacted by a member of the research team who answered any questions and screened potential participants over the phone. Those who were not eligible were provided with additional information and resources where appropriate. Eligible participants were emailed the participant information sheet and links to complete the consent form and baseline questionnaire.

Waitlist control group

Participants allocated to the control group received the care they would usually expect within the NHS. This is typically in secondary care with a specialist neurology team according to individual health needs. The individual may be supported in the NHS by a multidisciplinary team including neurologists, physiotherapists, occupational therapists, speech and language therapists and Parkinson's specialist nurses. The PwP and carer may also be offered or introduced to support from the charity Parkinson's UK. In addition, as these were participants who had some level of psychological distress, they were sent a link with information about mental health from the Parkinson's UK website (https://www.parkinsons.org.uk/information-and-support/parkinsons-and-mental-health). Control group participants were offered a chance to use the PACT app after the 4-week trial period and endpoint questionnaire had been completed.

Intervention

Participants in the intervention group were asked to use the PACT app for 4 weeks. The first 12 sessions (2 weeks) were guided, standardised sessions for all participants. The purpose of these sessions was to introduce participants to the key processes of ACT—open, aware, engage - through providing information, metaphors and experiential activities. After 12 sessions, participants could follow session recommendations or choose sessions based on their own judgement of needs and preferences. Session recommendations are made using a combination of results from participants' session ratings and the responses to the 6-item progress questionnaire. Visuals are used to display and reward session completion and progress. The intervention was designed through a series of co-design workshops. The PACT app was also beta-tested with six users before developing the final version for the trial.

Assessments and outcome measures

At baseline, the following demographic and clinical data were collected from both intervention and control groups: age, gender, ethnicity, education, work status, diagnosis, medications, Parkinson's duration, symptoms and severity, familiarity and comfort with using technology.

Primary feasibility outcomes

Primary feasibility outcomes for the trial included the recruitment rate (proportion of people identified as eligible after screening, and proportion of eligible people randomised/consented to the study) and retention rates (proportion of people who began the follow-up survey), adherence rates (number of times people logged on to the app and number of sessions completed), contamination rates (proportion of people in the control who received an intervention expected to impact the primary outcome) and data completeness (missing data from baseline and endpoint questionnaires).

App usage and engagement

Description of the sessions completed (number and type), session ratings, pattern of engagement (i.e. frequency, time of day), and a description of the different PACT app features used (for example, reflections, motivations, progress questionnaires) was logged as participants used the web application.

Potential effectiveness outcomes

Signal for efficacy in terms of effectiveness was determined based on the following six outcomes. Each scale is calculated as a total score by summing the response to items within the scale. Total scores were calculated pro-rata across all completed items in instances where participants miss items, up to 50% of the scale being completed. This is equivalent to mean imputation.

- Depression (PHQ-9): The PHQ-9 is a 9-item measure of the frequency of depression symptoms over the past two-weeks based on the DSM-IV criteria for depression (Kroenke et al., 2001). Participants rate each item on a 4- point scale between 0 (not at all) and 3 (nearly every day). Total scores range from 0 to 27, where higher scores indicate greater levels of distress.
- Anxiety (GAD-7): The GAD-7 is a 7-item measure of the frequency of anxiety symptoms over the past two-weeks based on the DSM-IV criteria for anxiety (Spitzer et al., 2006). As with the PHQ-9, participants rate each item on a 4- point scale between 0 (not at all) and 3 (nearly every day). Total scores range from 0 to 21, where higher scores indicate greater levels of distress.
- Quality of life (PDQ-8): The PDQ-8 is an 8-item Parkinson's-specific measure of health-related quality of life of the last month, assessing mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort (Jenkinson et al., 1997). Each item is rated on a 4-points scale between 0 (Never) and 4 (Always or cannot do). Total scores range between 0 and 32, where higher scores indicate greater impact of disease on quality of life.
- Committed action (CAQ-8): The CAQ-8 is an 8-item measure of the degree to which individuals flexibly pursue valued goals in the presence of challenges, a key treatment process of ACT (McCracken et al., 2015). Items are rated on a 7-point scale based on the extent to which each item applies to them on a scale from 0 (never true) to 6 (always true). Half of the items (items 5, 6, 7, 8) are reverse coded. Total scores range from 0 to 56 where higher scores reflect greater committed action.
- Experiential avoidance (AAQ-II): The AAQ-II is a 7-item measure of acceptance and experiential avoidance, which is a key treatment process in ACT (Bond et al., 2011). Each item is rated on a 7-point scale from 1 (never true) to 7 (always true). Total scores range from 7 to 49, where higher scores indicate greater avoidance.
- Decentering (EQ-14): The EQ is a 14-item scale to measure decentering, defined as the ability to observe one's thoughts and feelings in a detached manner as temporary objective events in the mind (Fresco et al., 2007). Participants rate statements on a scale from 1 (never) to 5 (all the time). Total scores range from 14 to 70, where higher scores represent greater decentering.

The PHQ-9, GAD-7 and PDQ-8 are patient reported outcome measures. The CAQ-8, AAQ-II and EQ-14 questionnaires are ACT treatment process measures designed to capture the mechanism of impact of treatment on the outcomes.

Treatment satisfaction and acceptability. Acceptability of the intervention was assessed *via* a short 8-item questionnaire that was adapted based on the Theoretical Framework of Acceptability (TFA) (Sekhon et al., 2017), along with space for open-ended responses if participants wanted to give further feedback. TFA consists of seven constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy.

Healthcare resource utilisation. This Client Service Receipt Inventory (CSRI) was administered to participants in the intervention and control groups at both baseline and endpoints. This questionnaire measured variables such as medication used, healthcare professional consultations or visits, psychological support services accessed one month before and during the trial period and results will inform the economic evaluation of the intervention.

Progression criteria

We decided to proceed with a full-scale efficacy RCT if the criteria outlined in Table 1 are met. These indicators were developed through consensus among the research team, who have experience in conducting trials. They were agreed upon before conducting the feasibility trial and after reviewing criteria used in other feasibility trials with similar populations.

Table 1. Progression criteria.

Criteria	Green	Amber	Red
1a) Recruitment rate: Against target sample size of 60	≥60 participants (i.e. ≥100% target)	≥50 participants	<50 participants
1b) Retention rate: % randomised participants retained at end of the trial	>66%	>50 and ≤66%	≤50%
2) Intervention use: % of intervention group that log into app and complete at least one session	>70%	>50 and ≤70%	≤50%
3a) Acceptability (overall): % of the intervention group rating 'agree'/'strongly agree' for overall acceptability	>50%	>30 and ≤50%	≤30%
3b) Acceptability (effectiveness): % of the intervention group rating 'agree'/'strongly agree' for perceived effectiveness	>50%	>30 and ≤50%	≤30%

A decision to progress was made based on progression criteria (see Table 1) using the following rules:

1. Where all green criteria are met, we considered the progression criteria met and that a full-scale trial is feasible without the need for amendment.
2. Where a mixture of green and amber criteria are met, we considered the progression criteria partially met and that a full-scale trial is feasible following amendment to relevant intervention or trial procedures.
3. Where any red criteria are met, we considered the progression criteria not met and that a full-scale trial is not feasible and will not proceed without substantial amendment and a further feasibility trial.

Data analysis

Primary and secondary outcomes

The feasibility outcomes were described as percentages with 95% CIs estimated using the binomial-exact method—proportions of people screened, recruited, retention and dropouts, number of people who engaged with the PACT app at different levels, and proportion of missing data. Analysis of secondary outcomes was conducted following the intention-to-treat (ITT) principle by a statistician. We describe the approach as a modified ITT analysis as it was only possible to include people providing outcome data at the post-randomisation assessment. Treatment effects on the secondary outcomes were estimated using linear regression with robust standard errors to account for potential heteroskedasticity of residuals. Covariates included dummy coded treatment group indicator, the baseline level of outcome, and variables included as stratification factors in the randomisation procedure (Parkinson's impact & baseline GAD score). Contrasts based on the model estimates were used to compute point estimates with 95% CIs relating to treatments effects for the intervention arm versus the control arm. These were converted to Hedge's g effect sizes by dividing these by the pooled standard deviation with small sample adjustment (White & Thomas, 2005). Given the study aim and that it was therefore not powered to detect significant between groups differences formal significant testing was not applied. Instead, signal for efficacy is based on the range of plausible effect sizes supported by the data as indicated by the 95% confidence interval. Sensitivity analyses were undertaken to explore the impact of assumptions around missing data on the treatment effect for the secondary outcomes using a baseline observation carried forward approach. Analyses were conducted in R (4.2.2).

Cost-effectiveness

We conducted a cost-consequences analysis of the PACT app, following the guidelines outlined in the NICE Evidence Standard Framework for digital health technologies (Brassel et al., 2022). This process involved collecting the costs of healthcare utilisation (using the CSRI) for both trial arms, before and after the intervention, for a difference-in-difference (DiD) analysis. We also used these cost estimates to perform an initial cost-utility analysis of the PACT app. The incremental utility was derived by converting the PDQ-8 responses into EQ-5D utility tariffs (Cheung et al., 2008) and applying a similar DiD analysis to calculate the incremental cost-utility ratio.

Patient and public involvement (PPI)

The intervention was co-designed with 7 PwP and 3 carers. Additionally, three PwP were actively involved right from the conception of the project and the intervention idea to the web application development process, and the design and conduct of the trial to evaluate the PACT app, including providing advice on recruitment procedures, study materials, questionnaires, interview topic guides, piloting procedures, trial progress, interpretation of findings, lay summaries, and dissemination activities.

Results

As shown in Figure 2, Fifty-seven PwP were included in the feasibility trial; 38 allocated to the intervention group and 19 to the wating-list control group.

Feasibility

Of the 76 people who responded to the advert, 61 (80%; 95% CI 70–89%) were eligible, and of those eligible, 57 (93%; 95% CI 84–98%) consented, completed the baseline survey, and were randomised. This met the amber progression criteria for recruitment. The average rate of recruitment was 19 per-month.

Overall, 44 out of 57 randomised participants (77%; 95% CI = 64–87%) provided data at the 4-week post-randomisation assessment, meeting the green progression criteria for retention. However, due to differential retention rates between groups – 100% (95% CI = 82–100%) for the control group versus 66% (95% CI = 49–80%) for the intervention group—we decided to consider the amber criteria as met.

App usage and engagement

Of the 39 participants assigned to the intervention, 33 (84%; 95% CI: 69–94%) logged into the app at least once, and 32 (82%; 95% CI = 66–92%) completed at least one session. Of the 33 participants who logged into the PACT app, the mean number of sessions completed was 21.1 (SD 10.7) out of a possible 24. Out of 732 sessions started, 695 were completed (95%; 95% CI = 93–97%), with 17 individuals having at least one incomplete session. Additional information on engagement with the intervention is provided in Supplementary material 1.

Contamination was low, with no participants in the control group receiving any dose of the PACT app intervention. However, four participants (one from the control group and three from the intervention group) reported receiving concomitant psychotherapy during the intervention period. In terms of recruitment, most participants were recruited through Parkinson's UK research newsletter, whereas contacting individual support groups and Facebook pages were not effective strategies. Conducting screening over the phone worked well and was useful to also discuss the web application and people's expectations. As shown in Figure 2, people were mostly eligible, and those that were not had low distress. There were varying levels of cognitive impairment, but no one was excluded after the screening call.

Potential effectiveness outcomes

The analysis of secondary outcomes followed a modified intention-to-treat approach including all participants retained at the

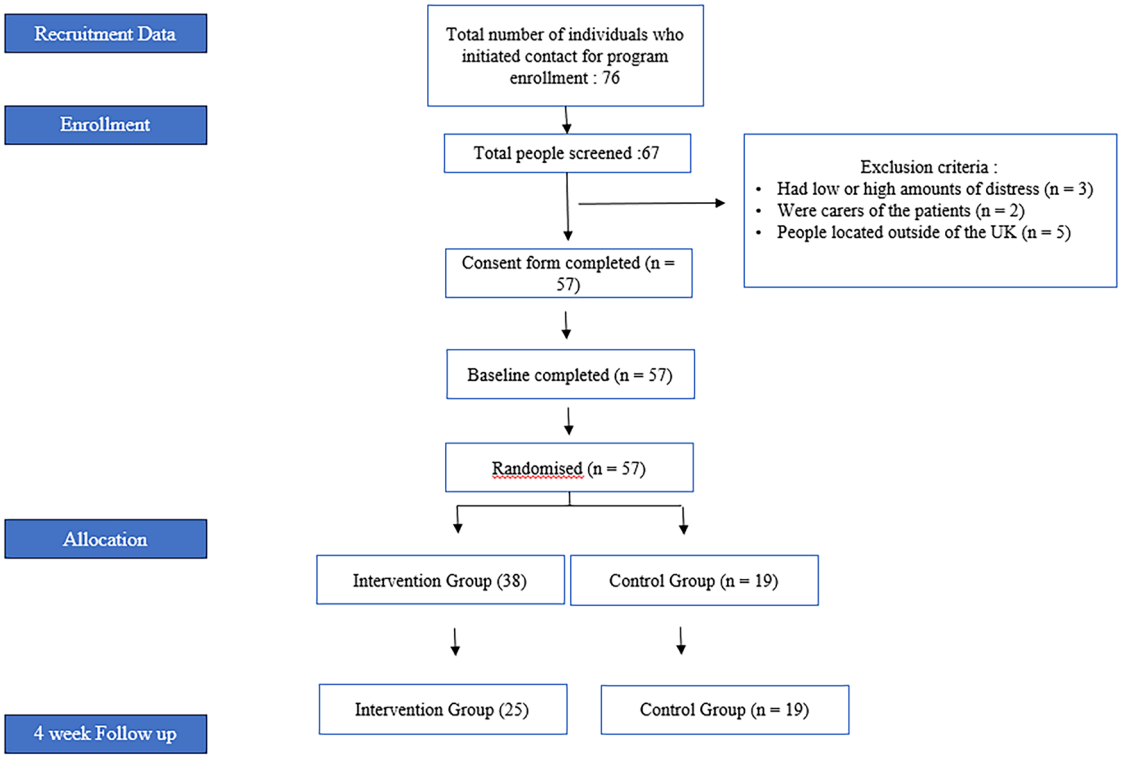

Figure 2. CONSORT Flowchart.

follow-up assessment ($n = 44$). Treatment effects, mean differences between groups adjusted for baseline outcome level and stratification factors, were estimated using linear regression with robust standard errors to account for potential heteroskedasticity. Among mental health and quality of life outcomes, the effect size was largest for depression (g =-0.96; 95% CI = −1.47 to −0.46) and smallest for quality of life (g = −0.14 95% CI = −0.50 to 0.21). Among ACT process variables, effect size was largest for committed action ($g = 0.87$ 95% CI = 0.38 to 1.35) and smallest for avoidance (g = −0.35 95% CI = −0.74 to 0.04) (Figure 3, Supplementary table 1). This interpretation was substantively the same following sensitivity analyses where baseline values for outcome measures were carried forward for 13 individuals who did not complete a follow-up survey (see supplementary material 2 for details). Due to the study's nature, *p* values are not reported. Taken together these findings demonstrate an efficacy signal for the PACT app but with a high degree of uncertainty concerning the magnitude of the treatment effect.

Economic evaluation

The simple DiD analysis of costs conducted on participants with complete data ($n = 44$, 17 in the control group, and 25 in the intervention group) revealed an average increase in costs of £71 (95% CI = −£1516 to £1657) in the control group, and an average decrease in costs for the intervention arm of £54 (95% CI = −£201 to £94). These findings suggest that the PACT app may be cost-saving (mainly triggered by a reduction in general practice visits). The average utility in the intervention arm increased by 0.04 (95% CI = 0.006 to 0.06) points, compared to a 0.02 (95% CI = −0.02 to 0.06) point increase in the control group, indicating a greater improvement of health-related quality of life in the intervention arm. Our analysis suggests that the PACT app has the potential to be cost-effective.

Acceptability outcomes

Twenty participants from the intervention arm completed questions on the acceptability of the PACT app. Twenty (80%; 95% CI = 59–93%) participants said the PACT app was acceptable/completely acceptable, which met the green progression criteria. Nineteen out of 25 (76%; 95% CI = 55–91%) agreed/strongly agreed that the PACT app improved their well-being.

Discussion

The PACT app was designed to address current mental health support challenges and make psychological support more widely available to PwP by providing a completely self-guided ACT program in micro doses *via* smartphones and tablets. Results of this feasibility randomised waiting-list control trial indicate that a full trial of the PACT app is feasible in terms of recruitment and engagement with the app, and that PACT could potentially be clinically effective and cost-effective.

Participants engaged with the PACT app and found it acceptable. Our target sample size was 60 and we identified 61 eligible participants, 57 were consented, and 44 retained, which was an 'amber' signal in terms of recruitment and retention. The recruitment was completed between November 2023 and January 2024. This meant we had to recruit and ask people to use the app over the Christmas and New Year period, that further reduced the available time to recruit and made engagement with the app more difficult due to conflicting priorities. Even with these constraints we manage to recruit an average of 19 participants per month, a much higher recruitment rate compared to other digital mental health apps (e.g. Strauss et al., 2021). We believe if in the larger trial we allow more time to recruit, we will avoid the pitfalls of this study and we will be able to achieve higher recruitment and retention rates.

Most participants (85%) assigned to the PACT group logged into the app at least once, and those who logged into

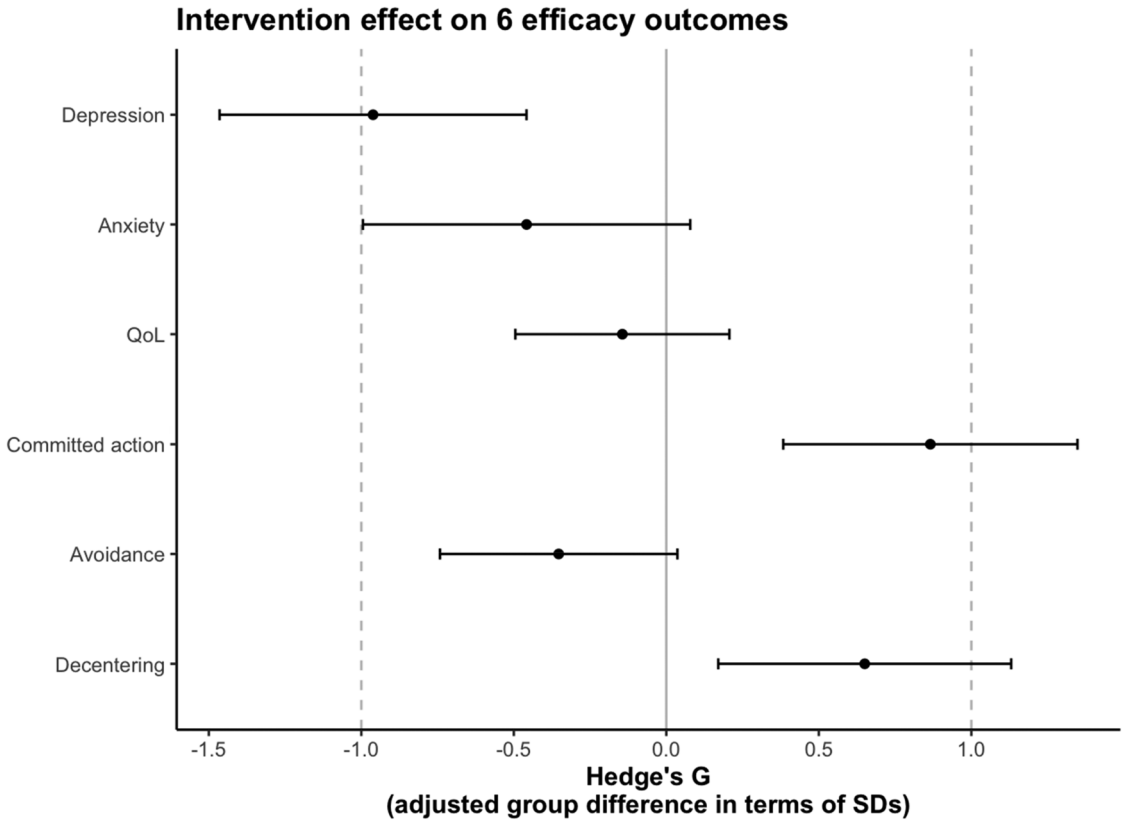

Figure 3. Forest Plot of hedges g's with 95% CIs.

completed the majority of the daily sessions, with a mean of 21.1 mean sessions completed out of 24 potential sessions to be completed. This suggests that the PACT app achieved high engagement levels similar to other digital ACT interventions (Catella et al., 2024). Furthermore, of the participants who completed the acceptability questionnaire, the majority (80%) said the PACT app was acceptable/completely acceptable, and 76% agreed or strongly agreed that the app improved their well-being. However, 25 out of the 38 participants (66%) who were randomised in the intervention group completed the end of study questionnaires and 20 out of those 25 provided acceptability data. Therefore, it is unclear whether the participants did not complete the follow-up questionnaires because they were unable to complete the 4-week course or because they did not find the app acceptable.

Notably, the PACT app use resulted in between-arm effect sizes that were in the anticipated direction for all potential effectiveness secondary outcome measures. As the study was not powered for significance testing, effects are interpreted based on point estimates and their uncertainty. 95% CIs were consistent with treatment effects for psychological distress and ACT process measures that were small to large benefits, ruling out potential harm. For QoL estimates were consistent with either moderate benefits, no effect or small risk of harm. Specifically, for depression - the primary outcome in a future full-scale trial- the effect size was comparable to those seen with in-person ACT interventions for people with neurological conditions (Han et al., 2023). Consistent with the goals and expectations of ACT, the improvements associated with using the PACT app in this preliminary efficacy analysis may have resulted primarily from an increased in committed action, meaning increased engagement in behaviours aligned with personal core values, and decentring, meaning greater ability to observe thoughts and feelings with a sense of detachment rather than being dominated by them. Revisions to the app content will consider whether it is possible to expand the number of facets of psychological flexibility to successfully enhance it.

Cost-effectiveness results showed healthcare utilisation costs increasing for the control group but decreasing in the intervention group. As this is a feasibility trial, sample sizes were too low for statistical significance; a larger RCT would be necessary to confirm these effects. Although PROM scores generally showed positive changes, the utility tariffs derived from the PDQ-8 did not reflect a significant treatment effect difference. The PDQ-8 is a well-established tool in the literature, and psychometrically tested for PwP. The lack of significant utility estimates may be due to the use of a mapping algorithm for the PDQ-8. Future trials should consider estimating incremental utility directly from the generic utility measure EQ-5D (as recommended in NICE guidelines). With more data, the PACT app has the potential to be cost-saving and could either increase utility or remain effect-neutral, both of which would indicate good value for money.

Many of the previously published randomised trials focused on digital behavioural therapies for neurological conditions have included psychotherapist-delivered guidance in the form of regular feedback, support, clarification, and/or encouragement (Han et al., 2023). Although guidance and healthcare professional involvement was shown to improve outcomes in internet delivered ACT (Thompson et al., 2021), it imposes many of the same limitations to accessibility as traditional in-clinic ACT. Significant effort was expended to make the PACT app engaging to PwP, including extensive co-design workshops and beta testing prior to this study. Further, using AI, to suggest more personalised content for users, unique ACT-based reminders, opportunities for weekly progress monitoring are likely to have helped with increased engagement and acceptability of the app, despite the lack of therapist contact. As this app is not

intended as treatment of clinical distress but an aid to enhance psychological well-being. We would like to retain the app as self-guided as this will provide a more straight forward roll-out of the app if it is proved to be effective as well as ensures the app will be available to all people with Parkinson's without clinical thresholds for inclusion.

Study limitations include the small sample size and a homogenous patient population. As a feasibility study, power calculations were not conducted. Therefore, it is not possible to infer efficacy of the intervention. However, the results obtained from this study provide some indication of signal for efficacy and will be used in power calculations for a larger, multi-site trial. More importantly, the small sample size limited out ability to determine acceptability for key subgroups of patients. The patient population lacked diversity in race, ethnicity, and gender which limits our ability to demonstrate generalizability. This will be further considered as part of a nested qualitative study. An additional limitation of the current study was the short time frame and effects on psychological outcomes may need more time and more practice. Conversely, it might have been the short timeframe that people had access to the PACT app (4 weeks), that has encouraged more intense engagement with the app. In a larger randomised controlled trial, we can modify the treatment duration and length of follow up based on the findings from this study and findings from online ACT interventions that have been conducted that have been mostly conducted over an 8-week period (Trindade et al., 2021; Van de Graaf et al., 2021). We will also measure ACT processes and examine if the intervention has an effect on the treatment mechanisms. The information from this study will also be useful for us to refine and select appropriate outcomes for a larger randomised controlled trial.

In this feasibility study, the PACT app was beneficial, acceptable, and provided preliminary evidence of reductions in the overall impact of Parkinson's on outcomes compared to a waiting-list control who received treatment as usual. PwP sustained high treatment engagement and adherence throughout the study. The potential efficacy and engagement observed with the PACT app, combined with the increased accessibility and scalability, suggests the PACT app may provide a promising addition to the psychological support provisions for PwP. A larger, multicentre study will be able to evaluate further the efficacy of the PACT app in improving the quality of life for PwP.

Disclosure statement

No potential conflict of interest was reported by the authors.

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Data availability statement

The data that support the findings of this study are openly available in ReShare at doi number 10.5255/UKDA-SN-857427.

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