Pilot and Feasibility Studies

STUDY PROTOCOL

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

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Abstract

Background People with Parkinson's disease can experience psychological distress and have difficulties accessing face-to-face psychological support due to symptom burden and limited availability of psychological services. Digital options for psychological support can bridge this gap. We have developed an app based on acceptance and commitment therapy (ACT) to support people with Parkinson's to improve psychological wellbeing.

Aim To assess the acceptability of the app and the feasibility of conducting a randomised controlled trial (RCT) to evaluate the effectiveness of using the app to improve wellbeing for people with Parkinson's.

Methods We will conduct a parallel-group randomised controlled feasibility trial comparing a digital app based on ACT (intervention group) to usual care (waitlist control group). We will recruit 60 people with Parkinson's, 40 to the intervention group and 20 to the control group. Primary feasibility outcomes include recruitment and retention rate, intervention engagement and satisfaction. Secondary outcomes include measures of clinical effectiveness (anxiety and depression), quality of life and cost-effectiveness. Interviews will be conducted to assess acceptability of the app. Primary feasibility outcome data will be analysed descriptively and compared against pre-defined feasibility criteria. Secondary outcomes will be analysed based on an intention-to-treat principle, and a cost-consequence analysis will be used to estimate cost-effectiveness. Interviews will be analysed using a deductive thematic analysis based on the Theoretical Framework of Acceptability.

Discussion This trial will provide data on the feasibility of conducting a full-scale RCT of the effectiveness and cost-effectiveness of the app to improve psychological wellbeing for people with Parkinson's disease.

Keywords Parkinson's disease, Psychological intervention, App, Randomised controlled trial, Acceptance and commitment therapy

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Introduction

Parkinson's disease is a neurodegenerative disease that can lead to a wide range of motor and 'non-motor' symptoms. People with Parkinson's (PwP) frequently experience a range of psychological issues including anxiety, depression and apathy [1]. Receiving a diagnosis of Parkinson's and having to cope with the unpredictable and debilitating symptoms can also have a psychological impact on individuals [2]. The prevalence of anxiety among PwP can be as high as 50–55% [3, 4] and 50–56% for depression [2, 4].

A number of psychological interventions have been developed to support PwP. Cognitive behavioural therapy (CBT) has been most frequently used in research and has shown to be effective in treating depression and sleep problems in PwP [5]. Some research has also been conducted using other therapeutic approaches. For example, there is some evidence to suggest that interventions using mindfulness and acceptance and commitment therapy (ACT) may be beneficial to improve wellbeing [6, 7]. However, research is limited, and there is a clear need to understand more about how these approaches can be used to support PwP [5]. Acceptance and commitment therapy (ACT) is an empirically based psychological intervention that focuses on personal growth and the cultivation of wellbeing through enhanced psychological flexibility [8]. A recent review revealed that participants' wellbeing was significantly higher in ACT intervention groups than in control groups in all but one study in adult clinical and non-clinical populations [9]. Most of these studies revealed moderate effect sizes in favour of ACT. There is some evidence that ACT interventions effectively support mental health even when delivered online as microlearning [10], but there is limited research on the use of ACT with PwP.

Despite promising research evidence, few psychological therapies have been implemented in clinical practice, and the current provision for mental health support for PwP is not adequate [11]. Most PwP have little access to psychological support because support is time- and resource-intensive. Additionally, mobility limitations, travel burden and cost can make psychological therapy inaccessible for many PwP, and this lack of access intensified during the COVID pandemic [12]. 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 [13]. With Parkinson's, there has been some research using remotely delivered interventions such as CBT and mindfulness, and this was found to be suitable and acceptable to PwP [6, 14–17]. Therefore, digital interventions could be a promising approach for psychological support for PwP.

There has not yet been any research using digital applications known as 'apps' to deliver psychological support for PwP [18]. Although this can be a feasible format, it may also come with certain challenges. Parkinson's symptoms such as tremors and hand/finger dexterity can make it difficult for PwP to access and use electronic devices and programmes that are not designed with accessibility in mind. Similarly, symptoms such as speech difficulties and difficulties with facial expressions may also limit the use of certain features like voice and facial recognition. The design of any digital solution for PwP needs to be made with these accessibility issues in mind. The activities or suggestions within the intervention or app also need to consider this variability in Parkinson's symptoms and levels of ability. The need for digital psychological interventions to be sensitive to physical symptoms and accessibility has been previously highlighted in other similar neurodegenerative conditions [19–21].

Due to the promising evidence in support of digital approaches to provide psychological support for PwP, we developed a self-guided digital app based on ACT for PwP. To take into account potential issues with acceptability and accessibility, we developed the app through a co-design process that integrated users' views and feedback in the development and optimisation of the app. In this study, we will assess the acceptability of the app and the feasibility of a trial to evaluate this digital app to improve psychological wellbeing in PwP. We aim 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 app usage and engagement in terms of (a) frequency and duration of app use overall and (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 app for improving psychological wellbeing in people with Parkinson's

Method

Design

We will conduct a parallel-group, non-blinded, randomised controlled feasibility trial comparing a digital app based on ACT (intervention group) to usual

care (waitlist control group). The trial was registered on the ISRCTN clinical trials registry, number ISRCTN65177345.

Participants

Sample size

We will aim for a total sample size of 60 PwP (40 PwP in the intervention group and 20 PwP in the control group). As this is a feasibility trial, the sample size is based on precision of the key variables informing the feasibility decision (objective 1), rather than a formal power calculation. A target sample size will 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 [22], and higher precision (i.e. narrower 95% CI) if the rate is lower than anticipated. Furthermore, we will be able to estimate retention rates with a 95% CI (binomial exact) with a precision (maximum width) of ± 12%. Rates of contamination and adherence in the intervention group will be estimated with a 95% CI (binomial exact) with a precision (maximum width) of ± 16%.

Inclusion and exclusion criteria

Participants will be screened for inclusion based on the following criteria:

Inclusion criteria:

- Age: 18 years and above
- Self-reported diagnosis of Parkinson's
- Lives in the UK
- Has access to computer/tablet/smartphone and the internet
- Is able to read and communicate in English
- Be stable on anti-depressants or anxiolytics if taken—stable dose for a minimum of 1 month
- Mild-to-moderate levels of distress determined by a score between 3 and 8 on the PHQ4 [23]

Exclusion criteria:

- Severe cognitive impairment as determined by a score of 20 or above on the 6-item Cognitive Impairment Test [24].
- Psychiatric conditions (e.g. psychosis, drug/ alcohol addiction) that can potentially risk failure in the treatment or limit participation in the course

Procedure

Recruitment and screening

We will recruit participants through the Parkinson's UK research support network via newsletters, social media and local groups. The study advert through Parkinson's UK will direct potential participants to contact a member of the research team who will then arrange a phone call with potential participants. During this call, the researcher will ask participants some screening questions based on the eligibility criteria and answer any questions participants may have about taking part. Participants will then be informed of their eligibility to take part. Those who are not eligible will be provided with additional information and resources where appropriate.

Randomisation and blinding

Following completion of the baseline questionnaire, participants will be randomly allocated to two groups—40 participants to the intervention group and 20 to the control group (see Fig. 1). Randomisation will follow a 2:1 ratio stratified by disease impact and baseline levels of psychological distress, using variable block sizes. This will be undertaken using an online system called Sealed Envelope (sealedenvelope.com). The participants will be blind to their group allocation at the time of randomisation. Once participants are allocated to either the intervention or waiting list, both participants and the research team (except for the statistician) will be aware of group allocations.

The control group will be sent an email with links for continuing to take part in the trial. Should they indicate high levels of distress, the study team will follow up with further signposting and links to information about mental health from the Parkinson's UK website (https://www.parkinsons.org.uk/information-and-support/parkinsons-and-mental-health) and instructions for continuing to take part in the trial.

At the end of 4 weeks, both intervention and control groups will be sent an email with instructions to fill in the endpoint questionnaire. Participants from the intervention group will also be invited to take part in an interview.

Intervention group

After completing the baseline questionnaire, intervention group participants will be sent a link to access the app along with instructions and log in details by a member of the research team via email. Participants will be requested to use the app regularly for a 4-week period. At the end of 4 weeks, participants will fill in an endpoint questionnaire measuring outcomes and satisfaction with the app. They will also fill in a healthcare utilisation questionnaire and be offered the opportunity to take part in an interview. Participants in the intervention group will

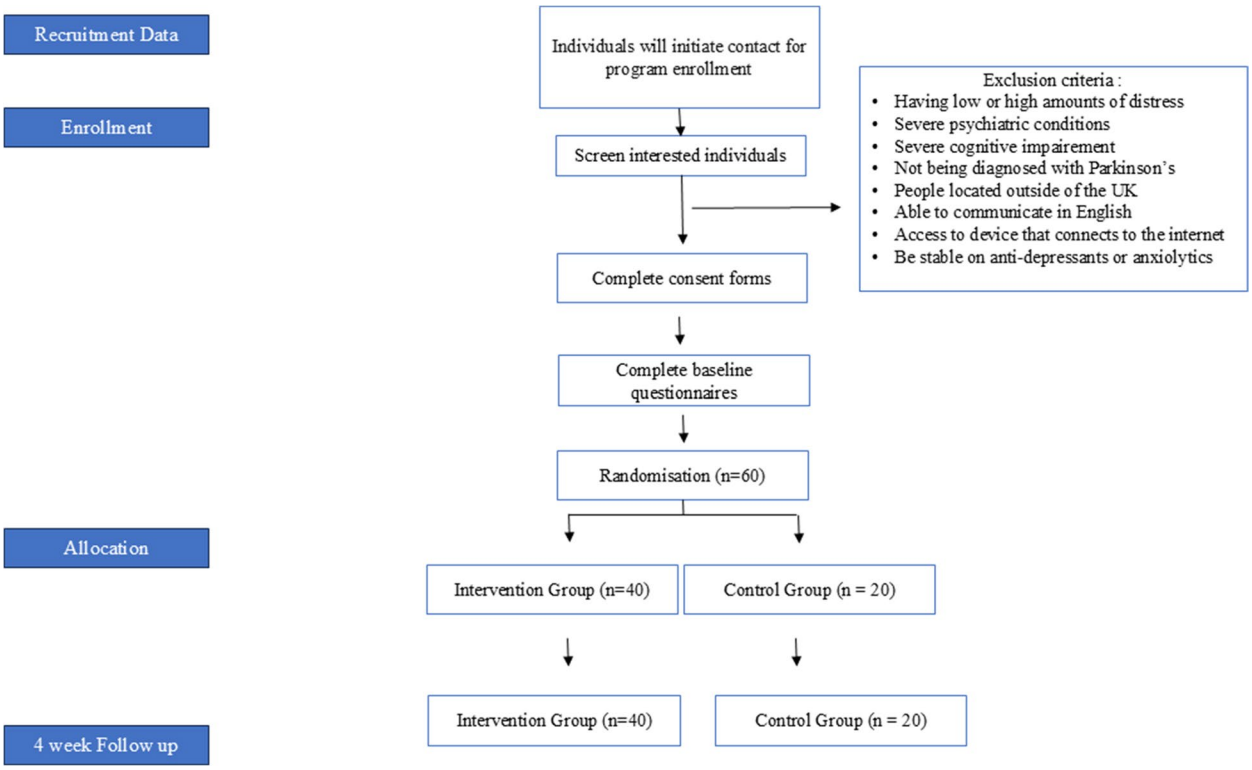

Fig. 1 Diagram of the intervention group and the control group: CONSORT Diagram

be able to contact a member of the research team if they experience any technical difficulties using the app during the trial period.

Waitlist control group

Participants allocated to the control group will receive 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 National Health Service (NHS) by a multidisciplinary team including neurologists, physiotherapists, occupational therapists, speech and language therapists and Parkinson's specialist nurses. The patient and carer may also be offered or introduced to support from a charity called Parkinson's UK. In addition, as these were participants who had some level of psychological distress, they will be sent a link with information about mental health from Parkinson's UK website (https://www.parkinsons.org.uk/information-and-support/parkinsons-and-mental-health). After 4 weeks, they will be sent an endpoint questionnaire (measuring outcomes only) and a healthcare utilisation questionnaire. Control group participants will be offered a chance to use the app after the 4-week trial period and the endpoint questionnaire has been completed.

Intervention

The intervention group will be emailed a link (along with a username and password) that gives them access to the app and an informational video demonstrating how to use the app. On first use, they can change the password and set up their profile. Except for participant first names, all other personal details are kept separate from any application data for security and privacy purposes. Reminders are sent to participants to prompt session completion and encourage regular app use. Participants are also asked to set their main reason for using the app and are reminded of this to motivate continued app use.

The app contains a toolkit of sessions based on ACT. The aim of the intervention is to improve psychological wellbeing by increasing psychological flexibility in PwP so that they are open and accepting of their thoughts and feelings, struggle less with these thoughts and feelings, learn to connect with the present moment and engage in more value-based activities. The aim is for the app to be used as a stand-alone intervention without any therapist support or facilitation.

Sessions are designed to be delivered as micro-content (i.e. 5–10 min bursts of content) that participants can complete in a short time period and at their own pace and convenience. The sessions are delivered via audio,

video and text format, and encourages reflection and practice from participants. Reflections can be input as text or voice-recorded. 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 first 12 sessions are guided, standardised sessions for all participants. The purpose of these sessions is to introduce participants to the key processes of ACT—open, aware and engage through providing information, metaphors and experiential activities. After 12 sessions, participants can use the app in two ways—one path provides session recommendations and the other path allows participants to 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 has been designed through four of co-production workshops with 10 participants (3 carers and 7 people with Parkinson's). Participants were purposively selected to represent different symptoms and familiarity with using technology. Researchers used a combination of the PERCEPT method and the person-based approach to inform the development process [25, 26]. The PERCEPT method guided the content and discussions of the co-production workshops and used personas to inform the design of the app. The person-based approach was used to keep users' needs and context at the heart of intervention development. Literature reviews and experiences of workshop participants were used to develop the plan for the intervention and guiding principles. Drafts of the app content and design were presented to participants, changed iteratively and recorded using a table of changes. The app prototype was presented to participants during the workshop, and feedback was incorporated into the final version. This app was also beta-tested with six users before developing the final version for the trial. Key themes that informed intervention planning included the struggle with acceptance of Parkinson's disease, finding a balance with Parkinson's care, and accessibility and consideration of different Parkinson's symptoms. Table 1 shows the guiding principles on how each of these themes shaped intervention design.

Assessments and outcome measures

Several assessments and outcome measures will be collected at each stage of the study from screening to baseline, during the trial and post-intervention (see Figs. 2 and 3 for a summary).

At baseline, the following demographic and clinical data will be 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 include 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 completed the baseline and end-point assessments), adherence rates (number of times logged on to the app and number of sessions completed), contamination rates (proportion of people in the control who receive an intervention expected to impact the primary outcome) and data completeness (missing data from baseline and endpoint questionnaires).

App usage and engagement

In order to capture app usage and engagement, we will describe the sessions completed (number and type), the session ratings the pattern of engagement (i.e. frequency, time of day), and describe the different app features used by the participants (for example, session reflections, motivations, progress questionnaires). This data will be logged automatically as participants use the app.

Secondary outcomes

Effectiveness

To inform the selection of outcome measures for a full RCT, the following measures will be administered to all participants at baseline and endpoints:

1. Depression—Patient Health Questionnaire (PHQ-9). The PHQ-9 [27] is a 9-item measure of depression symptoms based on the Diagnostic and Statistical Manual (DSM-IV) criteria for depression. Participants rate each item on a 4-point scale between 0 (not at all) and 3 (nearly every day). The PHQ-9 is sensitive to change and has demonstrated reliability and validity as a measure of depression symptoms [27].
2. Anxiety—General Anxiety Disorder (GAD-7). This is a self-administered patient questionnaire used to measure the severity of anxiety. It is a 7-item scale and has good reliability, as well as criterion, construct, factorial and procedural validity, and has been

Table 1 Guiding principles

Design objective	Design features
To be appealing and engaging for people who may struggle with acceptance of PD and may be resistant to mental health support	• App content to be framed in a gentle way, normalising negative emotions • Order of sessions—start with sessions that are easier and don't bring up negative experiences or emotions, without teaching tools to help with these emotions • User interface and graphics need to be engaging and uplifting • Introduction to app: provide reassurance that the investment in time and effort is worthwhile, explain how ACT can help with Parkinson's
Needs to fit around users' different needs and preferences (e.g. how often they can use the app, the types of activities)	• Flexibility in terms of how often the sessions are done • Allow people to have different options for notifications • Do not have mandatory/everyday practice, but encourage people to practice in their own time and at their own pace • Sessions should not exceed 5–10 min for users to complete • Audio and text/subtitle options, allow going back and forth between sessions and reviewing reflections
To motivate people to try out new activities and persist with using the app	• Explain why these activities are important, what's the point of them • Ask people what their goal for using the app is. Highlight and remind people of this goal as they complete sessions in the app • Use notifications to remind and motivate people to continue using the app. Notifications can use ACT-based messages • Within the activity description and instructions, emphasise the benefit of doing these activities for wellbeing
To be accessible and sensitive to people who may have different PD symptoms	• Offer options to input via voice recording or typing for the reflections feature • Wherever possible, have options to either click or select options from a dropdown list • Explain concepts in plain English and keep instructions short and clear for people with mild cognitive impairment to be able to follow • Minimal reading, use audio and video features wherever possible • Phrase session content so it is sensitive to differences in ability and PD symptoms • Acknowledge that some people with certain symptoms might find these activities difficult, empathise and offer tips and strategies to overcome this • Incentivise practise, some of the benefit may be experienced only when activities are repeated regularly
To be easy for people to use if they are upset or feeling down or anxious	• Appealing visuals and graphics to draw people in and motivate engagement • Foster a sense of achievement from completing app sessions, visually depict progression through the app • Use notifications and messages within the sessions to reward people for different types of engagement—logging in, completing a session or a week's sessions, practicing things they've learned • If people don't engage, try and encourage engagement rather than focus on what was not achieved, frame notification messages accordingly • Begin with more guidance—set order for the app sessions, and then once users have had a taste, give them the option to choose app sessions
People will want to know what to expect: before they start each session, or before they decide they want to use the app	• When introducing the app and the trial, explain clearly how long will the app be available for, what's the structure guided v/s not guided, what kind of activities or support is on offer, level of time and commitment required • Brief descriptions/overviews of the app sessions can help orient people to what's coming • Say how long the session may take, whether it is an audio/video session, and whether they need privacy or a quiet space for the particular session

efficient at assessing generalised anxiety disorder in clinical practice and research [28].

3. Quality of life—Parkinson's Disease Questionnaire (PDQ-8). This is a patient-reported outcome measure widely used to quantify quality of life in people with Parkinson's disease [29]. It has 8 items and measures 8 dimensions—mobility, activities of daily living, emotional wellbeing, stigma, social support, cognition, communication and bodily discomfort—that have been psychometrically tested for PwP [28]. PDQ-8 has been proven to be a very strong predictor of the full version PDQ-39 scores [30].

	STUDY PERIOD			
	Enrolment	**Allocation**	**Post-allocation**	**Close-out**
TIMEPOINT	t_1	0	t_2	t_3
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Baseline questionnaire	X			
Allocation		X		
INTERVENTIONS:				
Intervention group			—	
Waitlist control group				—
ASSESSMENTS:				
Baseline demographic and clinical data	X			
Outcomes (anxiety, depression, quality of life, ACT process variables)	X		X	
Healthcare resource use	X		X	
Acceptability and intervention satisfaction			X	
Post-intervention interviews				X
App usage data			X	

Fig. 2 Summary of assessments and outcome measures collected at each stage of the study

4. ACT variables:

    a. Acceptance and avoidance questionnaire AAQ-2—This is a short 7-item, general measure of experiential avoidance [31, 32].

    b. Experiences questionnaire [33]—This is a 14-item scale to measure decentering or the ability to observe one's thoughts and feelings in a detached manner. Participants rate statements on a scale from 1 (never) to 5 (all the time). Higher scores represent greater decentering.

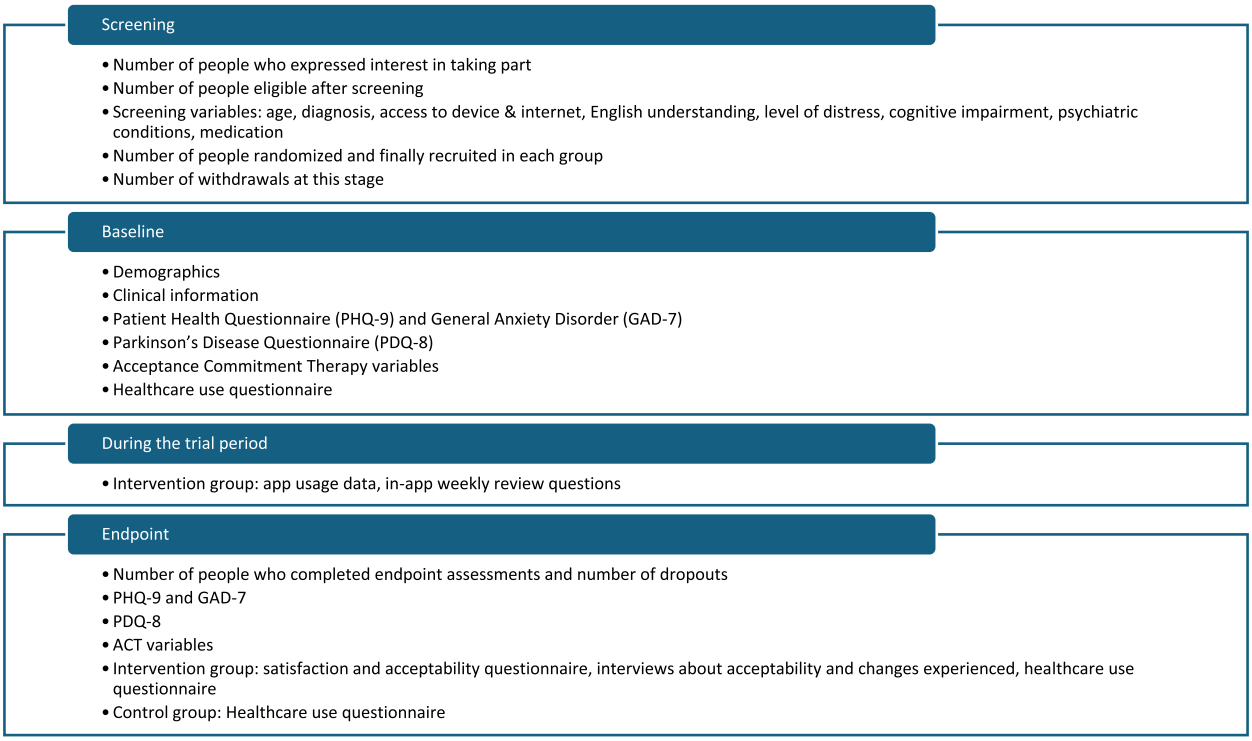

Fig. 3 Summary of variables collected at different stages of the trial

c. Committed actions questionnaire—CAQ-8. The CAQ-8 is a measure of committed action, which describes the degree to which individuals continue to flexibly pursue valued goals in the presence of challenges, a key treatment process of ACT [34, 35].

Treatment satisfaction and acceptability

Acceptability with the intervention will be assessed via a short 8-item questionnaire based on the theoretical framework of acceptability [36], along with space for open-ended responses if participants want to give further feedback.

We will conduct in-depth interviews with up to 20 PwP who used the app to gather feedback on their experiences. At the end of the trial period, a researcher will conduct qualitative interviews over the phone or via videocall to gather feedback about participants' experiences using the app. Participants who have dropped out of the intervention group will also be invited to take part in the interviews. Purposive sampling will be used to identify our sample from the intervention group to ensure we interview participants with a variety of demographic and clinical characteristics such as age, gender, symptoms, illness severity and disease duration, and participants who were highly engaged and minimally engaged with the intervention.

Interviews will take place between weeks 4 and 6. Participants will be asked questions around the acceptability of the app and their experience of using the app and associated ACT activities. The interview schedule and questions will be based on the theoretical framework of acceptability [36]. This framework consists of 7 constructs—affective attitude (attitude towards the intervention), burden (reasons for discontinuation/drop out, amount of effort required), perceived effectiveness (extent to which the intervention can achieve its purpose), ethicality (extent to which the intervention fits with the individual's values), intervention coherence (extent to which the participant understands the intervention and how it works), opportunity costs (extent to which benefits or values are given up to undertake the intervention) and self-efficacy (confidence that they can perform behaviour required for the intervention).

Healthcare resource utilisation

The PD REHAB Healthcare Usage Questionnaire [37] will be administered to participants in the intervention and control groups at both baseline and endpoints. This questionnaire will measure variables such as healthcare professional consultations or visits and health aids and

equipment used one month before and during the trial period. The results will inform the economic evaluation of the intervention.

Feasibility criteria

We will consider it appropriate to proceed with an RCT if:

(1) We can (a) recruit 60 (≥100%) and (b) retain 40 (>66%) participants during the trial period (recruitment and retention).
(2) If more than 70% of the intervention group log in to the app and complete at least one session.
(3) If more than 50% of the intervention group participants rate their overall acceptability with the app and perceived usefulness for health and wellbeing above the midpoint.

We will decide to amend the intervention or trial procedures, and then proceed with an RCT if:

(1) We can recruit 50 participants and retain 50% of those recruited.
(2) If between 50 and 70% of the intervention group log in to the app and complete at least one session.
(3) If 30–50% of the intervention group participants rate the overall acceptability and perceived usefulness for health and wellbeing above the midpoint.

We will not proceed with an RCT if:

(1) We are unable to recruit more than 40 participants and retain 20% of those recruited.
(2) If less than 50% of the intervention group log in and complete one session.
(3) If less than 30% of intervention group participants rate the overall acceptability of the app and perceived usefulness for health and wellbeing above the midpoint.

These indicators were developed based on consensus between the research team who have experience in conducting trials and agreed upon before conducting the feasibility trial and through reviewing criteria used in other feasibility trials with similar populations.

Data analysis

Primary and secondary outcomes

The feasibility outcomes will be described—percentages and proportions of people screened, recruited, retention and dropouts, number of people who engaged with the app at different levels and proportion of missing data. Analysis of secondary outcomes will be conducted following the intention-to-treat principle by a statistician. Signal for efficacy in terms of effectiveness will be determined based on the following six outcomes. The PHQ9, GAD7 and PDQ8 are patient-reported outcome measures. The CAQ8, AAQ2 and EQ questionnaires are ACT treatment process measures designed to capture the mechanism of impact of treatment on the outcomes. Each scale is calculated as a total score by summing the response to items within the scale. Total scores will be calculated pro-rata across all completed items in instances where participants miss items, up to 50% of scale being completed. This is equivalent to mean imputation. For anxiety (GAD7) and depression (PHQ9), a change of 4 or more points and 6 or more points, respectively, is considered to be clinically meaningful change. This is a reliable improvement and reliable recovery when combined with caseness cut-offs [38, 39]. The feasibility outcomes will be reported descriptively as number for each criterion, denominator and percentage with a 95% binomial exact confidence interval. Retention and contamination rates will be reported overall and by the treatment group. Adherence rates will be reported only by the intervention group. Where relevant numbers with missing data and impact on denominator will be clearly reported. In addition to the specified feasibility outcomes, rates of potential effectiveness outcome assessment at each time point the reliability of the potential effectiveness outcome at the baseline assessment will be reported for the overall sample. Analysis of secondary outcomes will be conducted following the intention-to-treat principle by a statistician. Treatment effects on the primary and secondary outcomes will be estimated using linear regression, with robust standard errors (Huber-White sandwich estimator) to protect against potential heteroskedasticity of the residuals. Covariates will include dummy-coded treatment group indicator, the baseline level of outcome, and any variables included as stratification factors in the randomisation procedure. Contrasts based on the model estimates will be used to compute point estimates with 95% CIs relating to treatment effects for the intervention arm versus the control arm. Due to the nature of the study, *p*-values will not be reported. Mediation analyses using the product of coefficients approach will help determine whether any changes in process variables mediate the effect of the treatment on the outcomes. This will be reported as indirect effects on standardised (i.e. correlation) metric and the proportion of the total effect explained by the mediators. Again, *p*-values will not be reported. Sensitivity analyses will also be undertaken to explore the impact of assumptions around missing data (i.e. baseline observation carried forward imputation of missing outcome data) and

adherence to the treatment protocol (i.e. using a per-protocol sample) on the treatment effect for the primary outcome.

Treatment satisfaction and acceptability

Treatment satisfaction will be analysed descriptively, and a content analysis will be used for responses to open-ended questions. The interviews assessing intervention acceptability and changes experienced will be audiotaped, transcribed and analysed using a deductive thematic analysis based on the Theoretical Framework of Acceptability (TFA) domains, i.e. affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Cost-effectiveness

This study will aim to run a cost-consequence analysis of the app, informing decision-makers for a potential roll-out of the intervention. The analysis will be carried out using National Institute for Health and Care Excellence (NICE)'s Medical Technologies Evaluation Programme (MTEP) model template, to maximise interpretability for NHS stakeholders and the efficiency of any future submissions. This process involved collecting the costs of healthcare utilisation (using the Client Service Receipt Inventory form (CSRI)) for both trial arms, before and after the intervention, for a difference-in-difference (DiD) analysis. Clinical effects were measured using the Parkinson's Disease Questionnaire short form (PDQ-8) [31], which is the reference instrument to measure the quality of life in PwP [28, 36]. 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 [39, 40] and applying a similar DiD analysis to calculate the incremental cost-utility ratio. This utility measure is an estimate of quality of life regardless of the disease being investigated. This will ensure that the clinical evidence is able to meet potential future requirements for a cost-utility analysis as part of the evolving MTEP appraisal process while allowing flexibility to use the clinical evidence for other purposes.

Data protection and management

Before launching the app, we will conduct a data protection impact assessment and work through issues around data protection and sharing between the research team at the University of Glasgow and City University of London. Data related to the trial and participant data (contact details, demographics, outcome measures) will be retained and managed at City University. The research team at the University of Glasgow will collect data around app usage and engagement, and this will be shared with the research team at City University in a de-identified format.

Participants' email addresses will be retained to inform them of the outcome of the study and will then be deleted. Data regarding participants who have been screened will be stored by the research team at City University and deleted after analysis for feasibility outcomes is complete. Participants who have consented to take part in the study will be given a participant ID. Baseline and endpoint questionnaires will be linked to this ID, collected online via Qualtrics, and stored securely at City University. All anonymised participant data will be held in a repository for future use, in accordance with Parkinson's UK data sharing and preservation policy and guidelines. Data sharing agreements between the universities involved in the project will ensure data is shared in a confidential and secure manner.

Ethics approval and consent to participate

Ethical approval will be obtained from the City, University of London. Eligible participants will be emailed the participant information sheet and links to complete the consent form and baseline questionnaire. The study materials and questionnaires have been developed in collaboration with patient and public involvement members. The research team also has expertise and has previously conducted research with people with Parkinson's and can therefore anticipate potential issues or burden with the questionnaires and trial procedures. We will also measure distress for both intervention and control group participants and respond appropriately if participants indicate high levels of distress. Participants who indicate a high level of distress (in relation to PHQ9 and GAD7) on the baseline and endpoint questionnaires will be contacted and asked if they need any further assistance and would like us to pass on their details to their neurology team. We will also share relevant resources from the Parkinson's UK website if participants would like more information about how to deal with emotional challenges. Participants in the intervention group will be prompted to report any serious adverse events, for example suicidal thoughts, hospitalisations, worsening of mental health issues and life-threatening events to the research team during the trial period. The research team will record this and follow steps from the distress protocol to respond to participants.

Patient and public involvement (PPI)

The intervention was co-designed with 7 PwP and 3 carers. PPI members fed back on the co-production workshop design and recruitment methods, in particular giving suggestions for building rapport and facilitating the workshops as we were dealing with sensitive content

about Parkinson's and people's mental health. PPI members gave us feedback and helped improve the accessibility of the study materials for the co-production phase (for example, the layout and font of the study advert, suggested using bullet points for the participant information leaflet, and not including a lengthy health utilisation questionnaire but a shorter version instead). We provided discussion summaries to PPI members at the end of each co-production workshop. This included involvement in the pilot study planning and recruitment, and user-testing the app. PPI members will also be given regular updates about the project timelines. We have adopted a flexible approach with email updates or reviewing documents via email, and arranging meetings separately with individual PPI members as well as organising group meetings. In addition, we regularly involve 2 PPI members in the research team meetings which helps keep everyone informed about the progress of the project.

Discussion

The trial data will determine if the trial design and procedure are feasible, including the feasibility of recruitment and treatment completion. We will use primary feasibility outcomes in combination with interview data around intervention acceptability and experience to make modifications to either the intervention or the trial design for further evaluation in a randomised controlled trial. Examining the patterns of app usage and understanding changes experienced from using the app will help us make decisions around appropriate/recommended intervention dose and intervention duration. Data on feasibility outcomes and intervention acceptability will help us determine if a full-scale trial of effectiveness and cost-effectiveness is warranted.

ACT interventions delivered via digital formats have shown to have significant effects in improving outcomes for people with chronic pain [10], and we would anticipate that our intervention would also improve psychological outcomes for people with Parkinson's. One limitation of the study is the short time frame and effects on psychological outcomes may need more time and more practice. In a larger randomised controlled trial, we can modify the treatment duration and length of follow-up based on the findings from this study. We will also measure ACT processes and estimate 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.

The app was designed using co-production and user-centred methods with people with Parkinson's. We hope this will improve the relevance and acceptability of the intervention; however, it is still important to test intervention acceptability when participants use the intervention over a period of time. We have adopted a mixed methods approach to understanding participants' views and experiences using the intervention. This is a strength of the study and will provide relevant data to improve the intervention or make recommendations for further intervention development in this area. Recruitment is expected to be completed by February 2024 and the feasibility trial data analysed around April 2024.

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Authors' contributions
AB, CH, PCM, LMC, SN and SS have conceptualised the study and secured funding. AB, CP, JB, CH, PCM, LMC, SN and SS contributed to designing the study protocol. AB, CP and CH were responsible for the recruitment of PPI and co-production members recruitment. AB and CP were responsible for collecting the data. SC, PCM and SN contributed to analysis plans. CP drafted the manuscript. AB, CH, PCM, LMC, SN, SC, JB and SS all reviewed and edited the manuscript.

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Data availability
Not applicable.

Declarations

Consent for publication
All authors have agreed to the publication of this protocol.

Competing interests
The authors declare that they have no competing interests.

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