ISRCTN65177345 https://doi.org/10.1186/ISRCTN65177345

Personalised Acceptance and Commitment Therapy (PACT) for Parkinson's Disease

Submission date
02/08/2023

Recruitment status
No longer recruiting

Registration date
21/08/2023

Overall study status
Completed

Last Edited
27/03/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Living with Parkinson's disease presents daily challenges, which can affect a person's wellbeing. Face-to-face talking therapies are effective at improving wellbeing but can be time-consuming and difficult to access. The COVID-19 pandemic has reduced access to face-to-face support and expanded our digital world. Digital applications on smartphones and tablets are an effective way of delivering psychological support.
The aim of this study is to develop and test a digital application which provides brief daily support for psychological wellbeing based on the talking therapy Acceptance and Commitment Therapy (ACT). The application or app will provide 5-10 minute 'bite-sized' sessions. Using technology, the content will be tailored to meet each person's needs. The application will teach coping skills that can be used long-term to support psychological wellbeing.

Who can participate?
Patients aged 18 years and over with Parkinson's disease who need psychological support

What does the study involve?
Participants will be randomly allocated to be given access to the app for 4 weeks or to receive care and support as they usually would (they will receive the app at the end of the trial). The researchers will then compare the two groups on several aspects of wellbeing to see if using the app made a difference. They also want to know if the app is acceptable and may make further refinements based on people's experience using it. All the questionnaires and interviews can be completed through online surveys or videocall.

What are the possible benefits and risks of participating?
It is unlikely that participants will experience any harm by taking part in the study and using the app. If using the app causes any discomfort, distress or concern, participants are free to stop or withdraw at any time. The researchers can also help share some resources or contact the neurology team for any further assistance.
It is hoped that using the app and learning some of the tools and activities can help participants manage any emotional struggles they may have and help with their wellbeing. If this app is

effective, the researchers hope to roll it out so that other people with Parkinson's may also benefit from it. They also hope that participants will find it interesting to take part and learn of the results.

Where is the study run from?
City, University of London (UK)

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

Who is funding the study?
Parkinson's UK

Who is the main contact?
Cathryn Pinto, cathryn.pinto@city.ac.uk

Study website
https://blogs.city.ac.uk/pact-am

Contact information

Type(s)
Public

Contact name
Dr Cathryn Pinto

ORCID ID
http://orcid.org/0000-0001-7607-7192

Contact details
School of Health and Psychological Sciences
City, University of London
1 Myddelton Street
London
United Kingdom
EC1R 1UW
+44 (0)20 7040 4041
cathryn.pinto@city.ac.uk

Type(s)
Scientific

Contact name
Dr Angeliki Bogosian

Contact details
School of Health and Psychological Sciences
City, University of London
Northampton Square
London

United Kingdom
EC1V 0HB
+44 (0)20 7040 8532
Angeliki.Bogosian.1@city.ac.uk

Type(s)
Principal Investigator

Contact name
Dr Angeliki Bogosian

Contact details
School of Health and Psychological Sciences
City, University of London
Northampton Square
London
United Kingdom
EC1V 0HB
+44 (0)20 7040 8532
Angeliki.bogosian.1@city.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
City, University of London ethics committee ETH2223-1570

Study information

Scientific Title
Acceptability and feasibility randomized controlled trial of a digital psychological support intervention for people with Parkinson’s disease

Acronym
PACT-am

Study objectives
A psychological support app based on Acceptance and Commitment Therapy (ACT) is acceptable to people with Parkinson's disease. It is feasible to conduct a randomized controlled trial to assess the effectiveness and cost-effectiveness of a psychological support app for Parkinson's disease.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 15/08/2023, City Research Ethics Online, City University of London (Northampton Square, London, EC1V 0HB, United Kingdom; Not available; SenateREC@city.ac.uk), ref: ETH2223-1570

Study design
Parallel-group randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
See study outputs table

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

Interventions
The intervention is a digital app that contains sessions based on Acceptance and Commitment Therapy (ACT). Randomisation will follow a 2:1 ratio stratified by disease duration and baseline levels of psychological distress, using fixed block sizes. Participants will be randomized into two groups (2:1 - 40 participants in the intervention group and 20 participants in the control group). The intervention group will be able to access this app online where it will be available for 4 weeks. The control group is a waitlist control group who will receive usual care for 4 weeks followed by the offer to use the app if they choose to.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment and retention rate: proportion of people identified as eligible after screening, proportion of eligible people randomized and consented to the study, proportion of people who completed the baseline and end-point assessments
2. Intervention engagement: number of times logged on to the app and number of sessions completed during the 4-week trial period
3. Intervention acceptability measured by a questionnaire and interviews based on the Theoretical Framework of Acceptability domains at the end of the trial period

Secondary outcome measures

1. Depression measured using the PHQ-9 at 4 weeks
2. Anxiety measured using the GAD-7 at 4 weeks
3. Quality of life measured by the PDQ-8 at 4 weeks
4. Acceptance and commitment therapy processes measured by the AAQ-2, Experiences questionnaire and CAQ-8 at 4 weeks
5. Healthcare utilisation measured by the Client service receipt inventory (CSRI) at baseline and 4 weeks

Overall study start date
01/06/2023

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Self-reported diagnosis of Parkinson's
3. Lives in the UK
4. Has access to computer/tablet/smartphone and the internet
5. Is able to read and communicate in English
6. Be stable on anti-depressants or anxiolytics if taken- stable dose for a minimum of 1 month
7. Mild-to-moderate levels of distress determined by a score between 3-8 on the PHQ4

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Severe cognitive impairment as determined by a score of 20 or above on the 6-item Cognitive Impairment Test (Katzman, Brown & Fuld, 1983)
2. Psychiatric conditions (e.g., psychosis, drug/ alcohol addiction) that can potentially risk failure in the treatment or limit participation in the course

Date of first enrolment
01/09/2023

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
PARKINSON'S DISEASE SOCIETY OF THE UNITED KINGDOM (Parkinson's UK)
Parkinson's UK
215 Vauxhall Bridge Road
London
United Kingdom
SW1V 1EJ

Sponsor information

Organisation
City, University of London

Sponsor details
Northampton Square
London
England
United Kingdom
EC1V 0HB
+44 (0)20 7040 5060
SenateREC@city.ac.uk

Sponsor type
University/education

Website
http://www.city.ac.uk

ROR

https://ror.org/04489at23

Funder(s)

Funder type
Charity

Funder Name
Parkinson's UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high impact journal

Intention to publish date
01/04/2025

Individual participant data (IPD) sharing plan
The anonymised datasets generated during/or analysed during the current study will be stored in a publicly available repository (Open Science Framework https://osf.io/ or Health Open Research https://healthopenresearch.org/parkinsonsuk)

The type of data stored is datasheets with anonymised quantitative data about trial outcomes, acceptability and satisfaction, and anonymised interview transcripts around intervention experience and acceptability. These data will be available after the publication of papers using this data, with no expiration date. Consent from participants was required and obtained.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	01/08/2023	09/08/2023	No	Yes

Results article	26/03/2025	27/03/2025	Yes	No