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Effect of acceptance and commitment therapy on fear of falling and physical activity in Parkinson's disease: a randomised controlled trial

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ABSTRACT

Introduction This study aimed to evaluate the efficacy of acceptance and commitment therapy (ACT) in reducing the fear of falling (FOF) and promoting physical activity in individuals diagnosed with Parkinson's disease (PD).
Methods and analysis This is a prospective, multicentre, rater-blinded and randomised controlled trial. Patients with PD and a history of falls will be randomly assigned to either an 8-week ACT intervention group or a control group receiving standard care. The primary outcomes measured will include FOF assessment using the Falls Efficacy Scale-International and physical activity levels measured via wearable sensor devices. Secondary outcomes will encompass the assessment of motor function, balance and fall frequency using the Movement Disorder Society Unified Parkinson's Disease Rating Scale, Berg Balance Scale and Timed Up and Go test. Objective measures of balance and physical activity will be obtained through static posturography and wearable sensors over a 3-day period, both before and after the intervention. Data will be analysed using mixed-effects models to evaluate the impact of ACT on FOF and physical activity.
Ethics and dissemination We hypothesised that ACT would lead to a significant reduction in FOF and an increase in physical activity levels compared with standard care. Additionally, this study will also examine the relationship between reduced FOF and improvements in balance and motor function. Our results will provide valuable evidence to support the effectiveness of ACT in reducing FOF and promoting physical activity among patients with PD, and if validated, ACT could be recommended as a beneficial intervention to enhance the quality of life and reduce fall-related morbidity in patients with PD.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Fear of falling (FOF) significantly impacts the risk of falls and reduction of physical activity in patients with Parkinson's disease (PD). It has been reported the effect of cognitive–behavioural therapy (CBT) in reducing FOF.

WHAT THIS STUDY ADDS

⇒ This study aims to investigate the impact of a novel CBT technique, acceptance and commitment therapy (ACT) on FOF. We will also investigate whether the reduction of FOF affects actual physical activity levels subsequently using wearable sensors.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results of this study will establish medical evidence for ACT as a non-pharmacological treatment of falls, thus providing new clinical guidelines for the management of PD. Additionally, by demonstrating the correlation between reduced FOF and actual physical activity, this research will serve as a valuable model for future fall study design.

INTRODUCTION

Parkinson's disease (PD) is the second most prevalent neurodegenerative disorder globally. While dopaminergic medications and surgical interventions have significantly ameliorated both motor and nonmotor symptoms of PD, there remains a lack of disease-modifying therapies.[1] Notably, postural instability, including frequent falls, has proven to be a refractory symptom resistant to conventional medical and surgical interventions.[2] Recent research has revealed that dopaminergic treatments can exacerbate postural instability.[3] Conversely, non-pharmacological interventions, such as exercise, mindfulness yoga and brain stimulation, have demonstrated beneficial effects on gait and balance in patients with PD.[4]

Falls represent a significant complication in the advanced stages of PD, substantially impacting the quality of life of affected individuals.[5] Although defining falls is crucial for identifying high-risk patients and implementing preventive measures, the definition of frequent falls is challenging. Recurrent fallers have a higher risk of falling compared with single fallers. Recurrent falling has been defined as experiencing two or more falls within a specific period.[6]

Various factors, including motor symptoms, depression, cognitive impairments, medication side effects, environmental conditions and fear of falling (FOF), contribute to the occurrence of falls.[7] Falls in PD are intricately linked to cognitive impairment, with various studies highlighting different aspects of this relationship. Cognitive deficits, especially in executive and visuospatial functions, are prevalent in advanced PD and can exacerbate the risk of falls by impairing patients' ability to navigate their environment safety.[8]

FOF is characterised by a phobic response to standing and walking due to past falling experiences and anticipatory anxiety about future falls.[9] This psychological disorder affects approximately 26%–73% of fall-prone individuals, with about half of those experiencing falls.[10] Furthermore, approximately two-thirds of individuals with FOF exhibit activity avoidance due to fear, and the prevalence of FOF increases with age and is more common in women.[11] Consequently, FOF in the elderly leads to reduced physical activity and subsequent loss of independence.[12] Given the importance of education and management of falls in monitoring PD symptoms, FOF has emerged as a critical area for intervention and treatment. Cognitive–behavioural therapy (CBT) has been proposed as an effective method for reducing FOF and improving postural instability.[13] Recently, acceptance and commitment therapy (ACT), known as the 'third wave' of CBT, has garnered attention.[14] Patients with PD experiencing FOF often avoid physical activity due to their fear, leading to a detrimental cycle of reduced mobility and disease progression.[15] For these patients, ACT techniques that promote acceptance of anxiety and reduction of movement-related fear can be highly effective in encouraging them to engage in activities.

ACT is a form of psychotherapy that focuses on aiding patients in recognising and accepting their anxiety, thereby facilitating the avoidance of escape and fostering change from their fears.[16] This therapeutic approach assists patients in making better physical activity choices and overcoming anxiety and fear, ultimately enhancing their quality of life. In particular, it emphasises aligning therapy with patients' values and goals, thereby helping them identify effective coping mechanisms for anxiety and fear. Therefore, it is crucial to support patients with PD by applying ACT to mitigate their anxiety and increase their physical activity levels. We posit that by overcoming anxiety and fear, patients can delay disease progression and improve their overall quality of life.

One notable limitation of FOF studies is the accuracy of measurement of physical activity and fall frequency in real-world settings following a reduction in FOF. To date, only a few clinical trials have focused on FOF treatment in patients with PD. While traditional studies often rely on self-report surveys to assess FOF, physical activity, and fall incidence, our study aimed to employ a quantitative method to estimate physical activity and fall severity. To achieve this, we will use gait analysis devices, such as posturography, to measure balance ability and wearable sensors to monitor physical activity in real-world conditions.

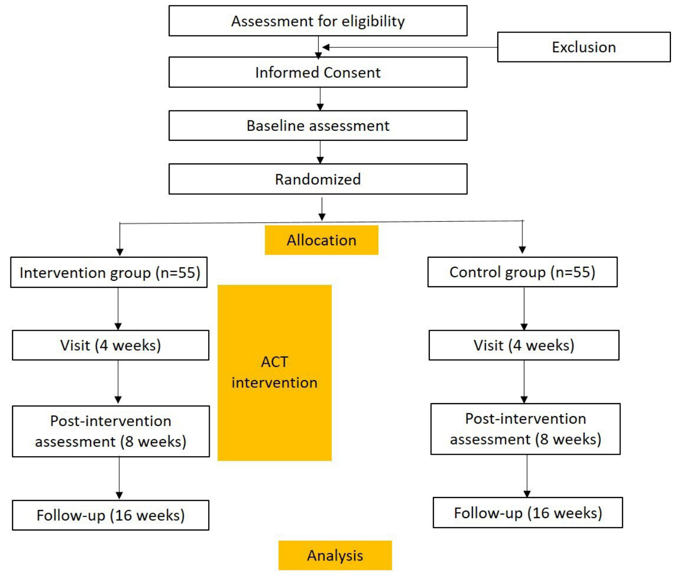

Figure 1 Flow diagram of acceptance and commitment therapy (ACT) for Parkinson's disease patients with fear of falling.

This study aimed to develop a detailed protocol with an appropriate sample size to investigate the effect of ACT on FOF and subsequent physical activity in patients with PD. It is worth noting that this research necessitates a multidisciplinary team, including physicians, counsellors, gait analysis technicians, engineers and coordinators.

METHODS AND ANALYSIS

Study design

This is a prospective, multicentre, rater-blinded, randomised controlled trial. The study flow, including participant allocation, intervention and assessment, is depicted in figure 1. The intervention schedule comprises weekly sessions over an 8-week period. Randomisation will be conducted via simple randomisation using a computer programme. All outcome assessments will be performed by blinded raters. The study will be conducted across three hospitals equipped with three-dimensional gait analysis systems to measure static posturography via a force plate.

Baseline assessments will be performed following the screening phase, and the ACT programme will commence 1 week after the baseline assessment. Postintervention assessments are scheduled to occur immediately after the 8-week intervention period, specifically within 5 days before to 1 week after the final ACT session. The control group will be advised to continue their usual care routine while the waitlist controls will continue receiving the ACT programme after the completion of the intervention phase. Subsequently, a follow-up assessment will be performed at 8 weeks after intervention to evaluate the sustained effect of the ACT intervention. The overall study process is shown in table 1.

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Table 1 Study protocol

Timeline	Screening	Baseline 0 week	Intervention 4 weeks	Post-intervention 8 weeks	Follow-up 16 weeks
Enrollment					
Informed consent	V				
Allocation		V			
Intervention					
Intervention group			Intervention		
Control group					
Asssessment					
Interview & Examination	V	V	V	V	V
MMSE	V				
H&Y stage	V		V		
FES-I		V		V	V
BAI		V		V	V
BDI-II	V	V		V	V
PDF-Q		V		V	V
MDS-UPDRS Part III		V		V	V
Timed up and go test		V		V	V
Berg balance scale		V		V	V
Static posturography		V		V	V
Gait analysis		V		V	V
wearable sensor		V		V	V

BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory-II; FES-I, Falls Efficacy Scale-International; MDS-UPDRS Part III, Movement Disorder Society Unified Parkinson's Disease Rating Scale Part III; MMSE, Mini-Mental State Examination; PDF-Q, Parkinson's Disease-specific Fall Questionnaire; H&Y stage, Hoehn and Yahr stage.

Patient and public involvement

Patients and their caregivers were involved in extensive discussions, significantly influencing the necessity and design of this study. Feedback was obtained from the patients regarding the design and schedule of the ACT programme. The results of this study will be disseminated to patients and the public to gather feedback from their perspectives.

Sample size calculation

The Fall Efficacy Scale-International (FES-I) is the most widely used instrument for assessing FOF.[17] In a previous study using the FES-I, the minimal clinically important difference was determined to be an effect size of 4.[18] For this study, assuming an SD of 7, a power of 80% and a significance level set at 0.05, 49 participants are needed per group. However, considering a 10% drop-out rate, 55 participants will be recruited per group.

Participants recruitment

Participants meeting the following eligibility criteria will be selected for inclusion in this study: (1) Patients diagnosed with PD according to the Movement Disorder Society (MDS) criteria[19] and (2) Those categorised as having Hoehn and Yahr stages 2–3[20], having experienced one or more falls in the past year from the time of enrolment. Falling was defined as experiencing more than one fall within 1 year. The exclusion criteria will encompass (1) patients with dementia (Mini-Mental State Examination (MMSE) score <24), (2) those experiencing major depressive disorders, (3) those having other neurological disorders affecting gait and falls, (4) those with orthopaedic conditions causing pain and (5) those undergoing other non-pharmacological interventions such as physical therapy, occupational therapy or music therapy. The drop-out criteria will comprise (1) failure to complete all eight sessions of the ACT programme, (2) changes in dopaminergic medication dosage during the intervention period and (3) the occurrence of events affecting gait, such as fractures or other medical conditions as determined by the investigator.

Intervention of ACT

To achieve the study's objectives, participants in the experimental group will receive weekly 60 min ACT sessions over an 8-week period. The duration of CBT interventions related to FOF varies across studies, ranging from 4 to 20 weeks.[21] In one study involving stroke survivors, interventions lasted for 8 weeks with sessions conducted

Table 2 Acceptance and commitment therapy (ACT) programme for participants

Session	Topic	Content
1	Introduction to the programme	► Introduction and structuring of counselling for rapport building. ► Psychological model of fear of falling and introduction of ACT perspective. ► Review of ineffective fear of falling control strategies used so far.
2	Values clarification	► Identifying activities where most time and energy are invested. ► Finding values in key areas of life.
3	Cognitive defusion	► Observing negative (catastrophic) thoughts related to falling without trying to evaluate or change them. ► Practising separating thoughts, emotions and fearful mind.
4	Acceptance and contact with present experience	► 'Being present' mindfulness. ► Creating space for fear of falling.
5	Committed action	► Connecting values, goals, obstacles and strategies
6	Starting a values-based life	► Planning a specific values-based life.
7	Experiencing a values-based life	► Sharing experiences and stories (practical strategies, obstacles)
8	Conclusion of the programme	► Grasping the core of the treatment process. ► Reviewing and evaluating programme content. ► Sharing impressions

twice a week,[22] and the effectiveness of CBT interventions in reducing FOF and improving balance has been observed immediately after the interventions and up to 12 months postintervention.[23] These findings suggest that CBT interventions can have both immediate and lasting effects on reducing FOF, typically over durations ranging from weeks to a few months. Thus, for this study, an 8-week ACT intervention for patients with PD with FOF was deemed appropriate.

Generally, when conducting a programme at multiple centres, ensuring the consistency of programme delivery is crucial. As a result, therapists will be educated on the importance of maintaining consistency in each session of the predeveloped programme. Feedback sessions will also be conducted after each session through online meetings to ensure uniform counselling and address any issues.

The ACT programme implemented in this study was adapted for patients with FOF based on the protocol developed by Wetherell *et al* for patients experiencing chronic pain in a group format.[24] The content of the ACT sessions conducted in this study is as follows and is depicted in table 2:

(a) Session 1 (Introduction to the programme): Introduction and structuring of counselling for rapport building; psychological model of FOF and introduction of the ACT perspective; review of ineffective FOF control strategies used so far. (b) Session 2 (Value clarification): Identifying activities where most time and energy are invested; finding value in key areas of life. (c) Session 3 (Cognitive defusion): Observing negative (catastrophic) thoughts related to falling without trying to evaluate or change them; practising separating thoughts, emotions and fearful mindsets. (d) Session 4 (Acceptance and contact with present experience): Practising 'being present' mindfulness; creating space for FOF. (e) Session 5 (Committed action): Connecting values, goals, obstacles and strategies. (f) Session 6 (Starting a values-based life): Planning a specific values-based life. (g) Session 7 (Experiencing a value-based life): Sharing experiences and stories; discussing practical strategies and obstacles. (h) Session 8 (Conclusion of the programme): Summarising the core treatment process; reviewing and evaluating the programme content; sharing impressions and feedback.

Outcome measurement

This study aimed to determine whether reducing the FOF can subsequently decrease the incidence of falls and increase physical activity in real-world settings. The primary outcome will include both assessments of FOF and estimations of physical activity. Secondary outcomes will encompass motor function, balance function and fall frequency. Notably, while previous studies have frequently employed self-report questionnaires, we aim to use objective measurements, including posturography and wearable sensors, in addition to self-reporting to assess balance and physical activity,[25] as depicted in table 3.

Clinical scales for FOF and falls

There are numerous scales available for measuring FOF. The most commonly used and validated scale is the FES-I, which comprises 16 items, each scored from 1 to 4. Higher scores indicate greater concern about falling,[26] demonstrating good psychometric quality and making it suitable for clinical and research purposes. FOF is significantly associated not only with motor functions, such as balance but also with non-motor symptoms, including anxiety and depression. Consequently, anxiety and depression can be measured using the Beck Anxiety Inventory and the Beck Depression Inventory-II, respectively.[27 28] Assessing falls is challenging because they are episodic symptoms

Table 3 Outcome measurement

Psychological assessment	Purpose	Measure
FES-I	Fear of falling	Self-report
BAI	Anxiety	Self-report
BDI-II	Depression	Self-report
Assessment of motor function		
PDF-Q	Fall frequency	Self-report
MDS-UPDRS Part III	Motor symptom of PD	Evaluation by rater
Timed Up and Go test	Gait	Evaluation by rater
Berg Balance Scale	Balance function	Evaluation by rater
Objective measurement		
COP diameter	Balance function	Diameter, area, velocity
Spatiotemporal parameters from gait analysis	Gait	Walking speed, stride length
Physical activity from wearable sensor	Physical activity	Activity level during 3 days

BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory-II; COP, centre of pressure; FES-I, Falls Efficacy Scale-International; MDS-UPDRS, Movement Disorder Society Unified Parkinson's Disease Rating Scale; PD, Parkinson's disease; PDF-Q, Parkinson's Disease-specific Falls Questionnaire.

influenced by various environments. Therefore, the PD-specific Fall Questionnaire will be used to estimate fall frequency.[29]

Measurement of fall, balance and physical activity

The MDS-Unified Parkinson's Disease Rating Scale parts I–IV will be used to assess balance and gait function in all participants before and after the ACT intervention.[30] To evaluate balance and gait function, the Berg Balance Scale and the Timed Up and Go test will be applied to all participants.[31]

We will employ objective tools, including static posturography and wearable sensors, to measure balance and physical activity. Posturography is a diagnostic technique used to assess balance and stability by recording the centre of pressure (COP) while participants stand on a specially designed mechanical force platform.[32] All data will be processed using Nexus software (V.1.7, Oxford, UK) as the force plate is synchronised with the motion analysis system at all centres (figure 2). COP will be measured while participants stand on an unmoving platform with their eyes open and closed to eliminate visual compensation. Subsequently, COP data will be filtered using second-order Butterworth filters with a 20 Hz low-pass filter. 20 s of signal data, excluding the first and last 5 s of a 30 s trial, will be used for analysis. COP parameters to be analysed include length, area and velocity in the anteroposterior and mediolateral directions. Additionally, spatiotemporal

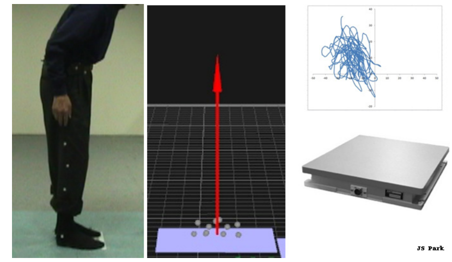

Figure 2 Force plate for estimating centre of pressure.

parameters, such as stride length, walking speed, cadence, step width, stance phase and swing phase, will be evaluated using three-dimensional motion analysis.

Commercially available wearable sensors will be used to objectively measure physical activity in real-world environments. Physical activity in the real world refers to engaging in physical movements and exercise in everyday life settings outside controlled environments like the laboratory. Physical activity in daily life can be categorised into occupational, sports, conditioning, household or other activities.[33] Given the characteristics of the participants, physical activity will be measured in their home environment. Wearable sensors will be worn on the wrist, and activity levels will be recorded over a period of 3 days before and after the intervention during normal daily activities. Participants will be instructed to maintain their usual daily activities during the 3-day physical activity measurement period.

Statistical analysis

Variables will be summarised as frequencies and percentages for categorical data and mean±SD for numeric data. Group differences will be tested using the χ^2 test or Fisher's exact test for categorical data and the independent t-test or Mann-Whitney U test for numeric data, as appropriate. Differences between two time points will be compared using the paired t-test or Wilcoxon signed-rank test for numerical variables, depending on the data distribution. The Shapiro-Wilk test will be used to assess the normality of the data distribution.

To compare the changes in clinical scales, COP and physical activity between the experimental and control groups, mixed-effects models will be applied, incorporating both fixed and random effects. The model will be fitted using the restricted maximum likelihood (REML) approach to estimate each parameter, as REML reduces bias in the variance component estimation. We will also investigate the interaction between the treatment group and time to assess whether the changes in FOF and physical activity levels differ significantly between the groups over time. We plan to include MMSE as a covariate in the fixed effect of the mixed-effect model to adjust for the impact of cognitive function on falls.

All statistical analyses will be performed by using IBM SPSS Statistics for Windows, V.29.0.2.0 (IBM). A $p<0.05$ will be considered statistically significant.

DISCUSSION

This study was designed to investigate the effect of ACT in reducing FOF and to determine whether this reduction subsequently decreases actual falls and increases physical activity in patients with PD. Given the 8-week intervention period of ACT, objectively assessing its effectiveness through fall questionnaires in participants who infrequently experience falls can be challenging. Therefore, this study aimed not only to use questionnaires but also to measure physical activity levels over a 3-day period using wearable sensors to observe whether a reduction in FOF genuinely correlates with an increase in physical activity.

The design of this study incorporated several novel aspects. First, we investigated the effect of ACT on FOF in patients with PD. Unlike traditional CBT, which focuses on symptom control or reduction, ACT emphasises acceptance and awareness of present experiences without judgement, aiming to enhance psychological flexibility and improve functioning. A meta-analysis has demonstrated the efficacy of acceptance-based interventions in patients with chronic pain. Compared with CBT, ACT has been shown to significantly improve depression, anxiety and pain, with higher levels of treatment satisfaction reported. We anticipate the following effects in patients undergoing ACT therapy: ACT teaches patients to accept and manage their anxiety, thereby reducing the high levels of anxiety associated with FOF.[34] Patients learn to recognise and accept their anxiety, leading to a reduction in FOF. Subsequently, ACT helps patients overcome their fear of movement and engage in more activities, enabling them to increase their physical activity levels, improve physical function and enhance their overall well-being. ACT provides participants with greater freedom to cope with anxiety and fear, increasing their adaptability to FOF and enhancing their ability to cope with challenging situations. Therefore, ACT is expected to be a highly beneficial treatment option for patients experiencing FOF.

Second, we focused not only on reducing FOF but also on determining whether this reduction translates into an overall increase in physical activity. To achieve this outcome, objective measurement and quantification of physical activity in real-world settings are essential, extending beyond the assessment of FOF decline alone. Wearable sensors for measuring physical activity have become widespread in both clinical and research settings.[35] In recent years, advancements in data processing technology have enabled highly accurate measurement of physical activity in real-world environments through wearable sensors. Hence, we designated physical activity levels measured by wearable sensors as the primary outcome of our study. Additionally, we used an objective tool to assess balance function. Although dynamic posturography is considered the most accurate tool for assessing balance function, static posturography with vision control has also been validated.

In this study, it is imperative to consider whether patients with advanced PD possess the requisite cognitive function to adequately perform the ACT intervention. Advanced PD is closely associated with a high prevalence of dementia, with 83% of 20-year survivors affected.[36] We will exclude participants with PD dementia and use the MMSE to detect cognitive impairment when screening potential study participants. Furthermore, we will include MMSE as a covariate in the mixed-effect model when conducting the statistical analysis.

However, this study protocol has some limitations that should be acknowledged. First, although falls will be evaluated using a fall questionnaire, the 8-week observation period may be too short to assess the severity of falls. Given the definition of falls, a longer study period may be necessary, restricting our evaluation within the study timeframe. Second, while exercise is commonly recommended as a non-pharmacological treatment for PD, our study will not incorporate any specific exercise programme beyond individual physical activity. As this study primarily will focus on reducing FOF and increasing physical activity through ACT, no exercise intervention will be implemented. Consequently, the potential synergistic effects of combining exercise with ACT remain uncertain.

In conclusion, our study will aim to assess the effectiveness of ACT in reducing FOF and measuring changes in physical activity among patients with PD. The findings will be expected to provide evidence and guidance for interventional treatments aimed at increasing physical activity in patients with PD experiencing FOF.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study was approved by the Institutional Review Board of the Heaundae Paik Hospital (IRB No: HP2024-05-037). All participants provided informed consent.

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