Protocol

Comparative Effects of Mindful Yoga and Expressive Arts on Perceived Stress and Whole-Person Health in Individuals With Mild-to-Moderate Parkinson Disease: Protocol for a Randomized Controlled Trial

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Abstract

Background: People with Parkinson disease (PD) experience substantial motor, nonmotor, and psychosocial burdens that are often inadequately addressed by pharmacological treatments alone. Mind-body interventions (MBIs), including mindful yoga and expressive arts therapy (EXAT), have shown promise in alleviating stress, increasing quality of life, and improving whole-person health. However, evidence of their comparative effectiveness and underlying mechanisms remains limited, leaving clinicians and patients with little guidance when selecting between these interventions. This study aims to fill this gap.

Objective: This trial aims to compare the effectiveness of mindful yoga and EXAT in reducing perceived stress, increasing quality of life, and improving whole-person health in people with PD. A secondary aim is to examine potential mechanisms of action, including functional, psychosocial, and gut microbiome–related pathways.

Methods: We are conducting a 2-arm, parallel-group, active-comparator randomized controlled trial. People with PD are randomly assigned to receive either mindful yoga or EXAT, delivered in six 90-minute sessions every 2 weeks. The primary outcomes are perceived stress and PD-related quality of life. Secondary outcomes include PD-related symptoms and broader quality of life. Potential mediators will cover biopsychosocial domains, including biological and physical factors (gut microbiota, constipation severity and bowel habits, and physical activity) and psychosocial factors (self-compassion, self-efficacy, and perceived social support). Motor assessments are conducted using Mon4t and BooGuu Aspire Fall Risk Management mobile apps. Fecal samples are collected to generate reproducible taxonomic and functional profiles of the gut microbiota. Outcomes are assessed at baseline and 3 months, 9 months, and 12 months after baseline assessment. Comparative effectiveness will be evaluated using linear mixed models, and potential mechanisms, including psychosocial and microbiome features, will be examined through path analysis. We hypothesize that both interventions will reduce stress, increase quality of life, and improve whole-person health, but they will demonstrate different pathways across biopsychosocial domains.

Results: This study was funded in April 2023, and ethics approval was granted in May 2024. Participant recruitment and data collection began in May 2024 and are ongoing. As of the submission of the manuscript, 144 participants had finished pre- and postintervention assessments (72 in each arm). Final follow-ups are still ongoing. Data analysis has not yet started, and primary findings are expected to be published in December 2026.

Conclusions: By directly comparing 2 active MBIs and integrating biopsychosocial-spiritual domains, this trial will provide comparative evidence on the effectiveness of MBIs. The findings are intended to guide the selection of mind-body approaches in PD, supporting preference-sensitive, whole-person care and informing integrative models that address the complex needs of this population.

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Introduction

Background

Parkinson disease (PD), the second most prevalent neurodegenerative disorder, affects approximately 10 million people globally, with prevalence expected to double by 2040 because of population aging [1-3]. Meanwhile, by the 2030s, Asia is expected to account for more than 60% of the global population aged 65 years and older. Within this demographic shift, China alone is projected to have approximately 5 million individuals living with PD by 2030, representing roughly one-half of all PD cases worldwide [4,5]. The disease is characterized by a constellation of motor symptoms, including resting tremor, rigidity, bradykinesia, and postural instability [6], and a wide range of nonmotor symptoms, including cognitive impairment, constipation, and psychological distress [7]. Nonmotor symptoms are highly prevalent and heterogeneous, and their presentation varies by sex and age at onset [8]. These symptoms substantially impair daily functioning, independence, and health-related quality of life (HRQOL) of people with PD [9]. Compared with the general population, people with PD experience considerably higher stress levels, and their perceived stress has been linked to increased rumination and reduced self-compassion and HRQOL [10-12]. Elevated stress not only diminishes psychological well-being but also exacerbates motor and nonmotor symptoms, contributing to greater disability, potentially accelerated disease progression [13], and increased caregiver burden [14]. Despite these effects, stress and broad psychosocial distress remain relatively underaddressed in routine PD care.

Pharmacological treatments, particularly dopamine replacement therapies, remain central to the management of PD and are effective in alleviating many motor symptoms [15]. Some nonmotor symptoms may also respond to dopaminergic therapy, and additional symptom-targeted medications are available for common manifestations such as depression, anxiety, and sleep disturbance. Nevertheless, nonmotor symptoms and broader psychosocial challenges often remain incompletely controlled, while long-term pharmacological management may be associated with adverse effects, treatment burden, and potential drug-drug interactions [16,17]. Therefore, complementary approaches that address the broader impact of PD are increasingly needed. In this context, mind-body interventions (MBIs) have attracted growing attention as low-risk adjunctive strategies with the potential to support whole-person health, including physical, psychological, social, and spiritual well-being, in people with PD [18].

MBIs, such as meditation, yoga, tai chi, and expressive arts–based practices, are increasingly recognized as whole-person approaches that can be understood within the biopsychosocial-spiritual (BPSS) framework [19,20]. Rather than targeting symptoms solely at the biological level, MBIs may influence interconnected dimensions of health, including physiological functioning, psychological well-being, social experience, and spiritual well-being [21]. Across populations with chronic conditions, including psychiatric disorders [22], cancer [23], and cardiovascular diseases [24], MBIs have been associated with improved stress management and favorable physiological changes, such as modulation of the hypothalamic-pituitary-adrenal axis, reduced cortisol levels, and lower levels of proinflammatory cytokines, such as interleukin-6 and tumor necrosis factor-α [25,26]. Within the BPSS framework, these biological effects may occur alongside improvements in emotional regulation, coping, social connectedness, and meaning-making [27]. This multidimensional perspective is particularly relevant for people with PD, whose motor and nonmotor symptoms affect not only physical functioning but also emotional well-being, social participation, and daily sense of meaning [21].

Among MBIs, mindful yoga and expressive arts therapy (EXAT) may be especially relevant to PD, although they are likely to operate through partially distinct pathways. Mindful yoga integrates movement, breathing, and focused attention and may support stress regulation, body awareness, balance, and physical functioning [28] while also addressing psychological well-being [29]. EXAT, by contrast, uses modalities such as guided drawing, movement, music, drama, and creative writing to facilitate emotional expression, interpersonal engagement, and meaning-making [30,31]. These creative processes may be particularly valuable in PD, where communication difficulties, emotional blunting, apathy, and social withdrawal are common [32]. Thus, although both interventions are used as adjunctive mind-body approaches to improve stress and overall well-being, mindful yoga may place greater emphasis on movement-based self-regulation, whereas EXAT may more strongly engage expressive, relational, and existential dimensions of health.

Prior systematic reviews and meta-analyses suggest that MBIs can improve motor symptoms and selected psychosocial outcomes in people with PD [33-35]; however, the current evidence provides limited guidance on how to choose between different MBIs. Most prior studies have evaluated a single intervention in small samples, relied predominantly on self-reported outcomes, and rarely examined broader whole-person health or underlying biological pathways. This gap is especially important in PD, where stress, psychosocial well-being, physical function, and nonmotor symptoms interact in complex ways. Emerging evidence further suggests that alterations in the gut microbiota may contribute to PD onset, progression, and symptom expression through the microbiota-gut-brain axis rather than serving merely as a passive correlate [36]. However, biological mechanisms such as these have seldom been incorporated into MBI research in PD.

To date, no head-to-head evidence has compared different MBIs used for PD care, leaving clinicians and patients without guidance on which approaches best match specific needs and preferences. Decisions about psychosocial interventions are inherently preference sensitive. Some individuals may prefer structured and movement-based practices, such as mindful yoga, whereas others may resonate more with creative and relational approaches, such as EXAT. In real-world settings, limited resources often constrain services to implement only one primary group-based MBI. Therefore, comparative effectiveness research that directly evaluates the relative benefits and mechanisms of credible and feasible MBIs for PD is needed. In addition to quantitative trial outcomes, qualitative inquiry is needed to capture participants' lived experiences, perceived mechanisms, acceptability, and preferences, thereby providing contextual insights that cannot be obtained from outcome measures alone and supporting interpretation of comparative-effectiveness findings.

This randomized controlled trial (RCT) addresses these gaps through a 2-arm, active-comparator design comparing mindful yoga and EXAT as adjuncts to usual care for people with PD. An active comparator was chosen over a passive control because passive (no-treatment) controls can inflate effect estimates through expectancy and attention effects, as highlighted in critiques of earlier intervention trials [37]. An active comparator better accounts for nonspecific therapeutic effects, such as instructor attention, group interaction, and participation in structured activity, while also reflecting real-world clinical decision-making, in which patients typically choose between active treatment options rather than between treatment and no treatment. Both interventions have shown benefits relative to control conditions in prior studies [38-41], making a comparative-effectiveness approach both clinically relevant and methodologically appropriate. By focusing on perceived stress while also evaluating psychosocial, functional, clinical, and microbiome outcomes, this trial is designed to generate comparative and mechanistic evidence to inform preference-sensitive, whole-person, integrative care in PD. The intervention protocols were informed by prior formative work, including the research teams' previous work on mindful yoga for people with PD, which supported the acceptability and relevance of these approaches for this population [28,29,33,42].

Aims

The first aim is to compare the effects of mindful yoga and EXAT delivered as adjuncts to usual care on changes over time in the coprimary outcomes of perceived stress and PD-related quality of life (QOL), as well as in secondary outcomes reflecting whole-person health, in people with PD.

The second aim is to examine whether between-group differences in primary and secondary outcomes are mediated by between-group differences in changes in biological/physical, psychological, and social variables.

Finally, aim 3 is to explore participants' experiences of mindful yoga and EXAT, including perceived benefits, barriers, and mechanisms of change across biopsychosocial-spiritual domains, in order to complement and contextualize the quantitative findings.

Hypotheses

Hypothesis 1 is that the EXAT and mindful yoga groups will differ in their changes in the primary and secondary outcomes over time.

Hypothesis 2 is that the between-group differences in primary and secondary outcomes will be partially mediated by between-group differences in changes in biological/physical, psychological, and social variables.

Hypothesis 3 is that qualitative findings will provide convergent and complementary evidence regarding participants' perceived benefits, barriers, and mechanisms of change, thereby contextualizing the quantitative results.

Methods

Design

This study is an assessor-blinded, 2-arm, randomized, active-comparator trial with a sequential mixed methods design and evaluates the effects and acceptability of 2 distinct group-based MBIs (EXAT and mindful yoga), which are delivered as adjuncts to usual care for people with PD. Figure 1 shows the CONSORT (Consolidated Standards of Reporting Trials) flow diagram. Repeated outcome measures are collected at 4 time points across a 12-month study period for the quantitative evaluation of the immediate and sustained effects of each intervention on the perceived stress, PD-related QOL, and whole-person health outcomes (biological, clinical/functional, psychosocial, and generic QOL) of people with PD. The assessment time points are as follows: baseline (T0: prior to randomization) and 3 months (T1: immediately after intervention), 9 months (T2), and 12 months (T3) after the baseline assessment. Qualitative focus group interviews will be conducted at 1 month after the intervention (ie, 4 months after baseline) with a subsample of participants from each intervention group to explore their experiences, perceived mechanisms of change, and views on the feasibility

and acceptability of the 2 MBIs. The qualitative findings will be integrated with quantitative results to provide a comprehensive, mixed methods evaluation of the interventions. Table 1 provides the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) figure, and the SPIRIT 2025 checklist is included in Checklist 1 .

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram. The target sample size is 77 participants per group; as of manuscript submission, 144 participants had completed both the pre- and postintervention assessments (72 in each arm). EXAT: expressive arts therapy.

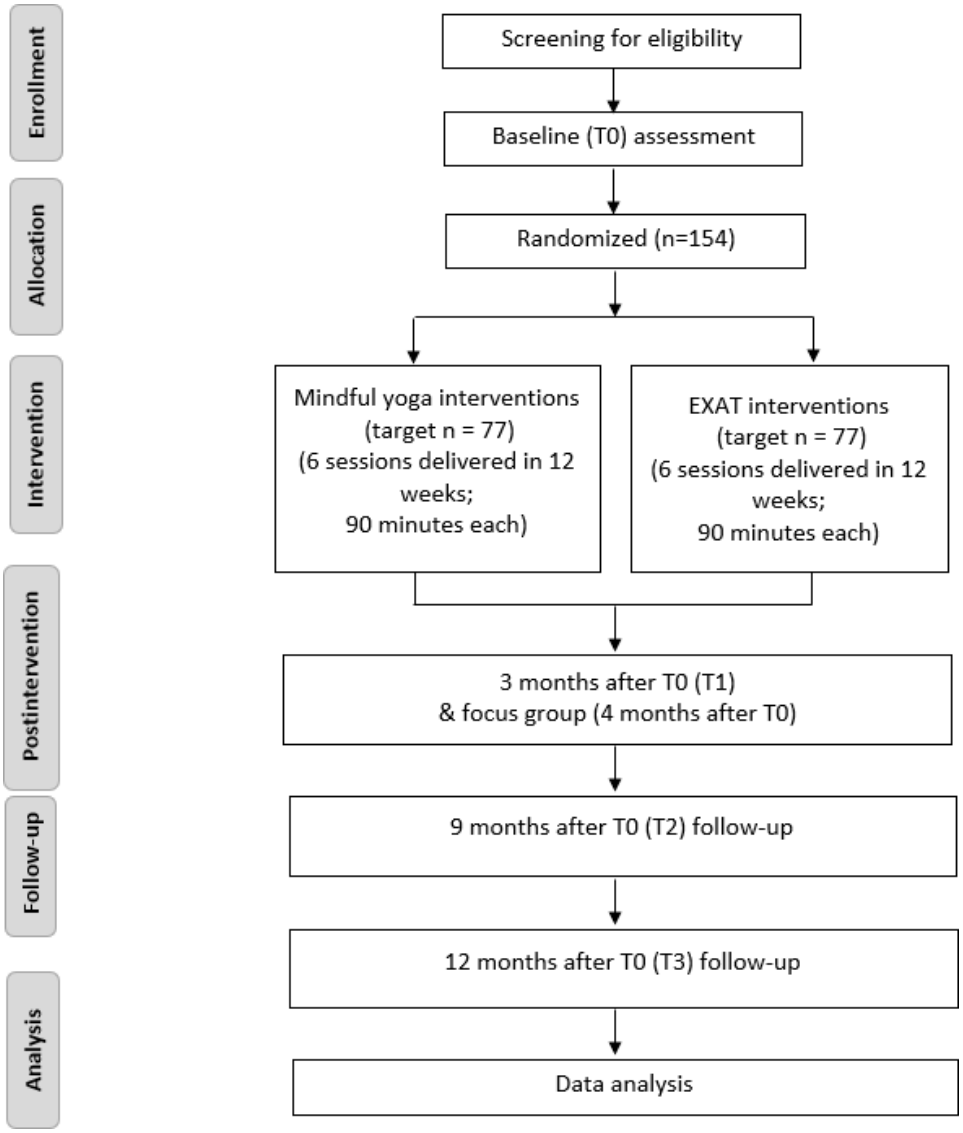


Table 1. SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) schedule of enrollment, interventions, and assessments at baseline (T0), completion of the intervention (T1), 9 months after baseline (T2), and 12 months after baseline (T3).

Time point	Study period						
	Enrollment	Allocation	Postallocation				
	-T1	0 (after recruitment)	T0 (baseline)	Intervention	T1 (at completion of the intervention)	T2 (9 months after T0)	T3 (12 months after T0)
Enrollment							
Eligibility screen	✓	—[a]	—	—	—	—	—
Oral informed consent	✓	—	—	—	—	—	—
Written informed consent	✓	—	—	—	—	—	—
Allocation	—	✓	—	—	—	—	—
Interventions							
Expressive arts	—	—	—	✓	—	—	—

Time point	Study period						
	Enrollment	Allocation	Postallocation				
	-T1	0 (after recruitment)	T0 (baseline)	Intervention	T1 (at completion of the intervention)	T2 (9 months after T0)	T3 (12 months after T0)
Mindful yoga	—	—	—	✓	—	—	—
Assessments							
Baseline information and sociodemographic characteristics	—	—	✓	—	—	—	—
Outcome measures	—	—	✓	—	✓	✓	✓
Treatment-related information: adverse events, adherence to assigned treatment, including home practice	—	—	✓	—	✓	✓	✓
Potential confounders: medications	—	—	✓	—	✓	✓	✓

[a]Not included at this time point.

Study Participants

The inclusion criteria are as follows: (1) a clinical diagnosis of idiopathic mild-to-moderate PD, defined as Hoehn and Yahr Scale stages I–III (rated 1-5, with higher stages indicating more severe disease); (2) age of 18 years or older; (3) ability to provide written informed consent; (4) ability to access the internet and use smartphones, tablets, or laptops; and (5) ability to comprehend Chinese. The exclusion criteria are as follows: (1) notable cognitive impairment, indicated by an Abbreviated Mental Test score less than 6; (2) participation in regular instructor-led MBIs (eg, tai chi) or arts-based therapies (more than 2 times per week) in the past 3 months; (3) current participation in any other behavioral or pharmacological trial; and (4) other contraindications that may limit their full participation (eg, severe hearing or vision impairment).

The inclusion criteria are designed to optimize the recruitment of suitable participants, and the exclusion criteria are intended to exclude patients who (1) exhibit secondary parkinsonism, in which symptoms are triggered by specific medications, a distinct nervous system disorder, or another underlying condition and (2) have severe medical conditions that contraindicate yoga or exercise, pose safety risks, impede ability to provide fully informed consent, or interfere with adherence to the interventions (eg, dementia). Exclusion criteria 2 and 3 reduce potential bias from current or recent use of other behavioral or pharmacological treatments.

Sampling and Recruitment Strategies

This study is part of the Hong Kong Jockey Club Movin'Care Project for Parkinson's Disease. Convenience sampling is used, and potential participants are recruited from PD support groups, neurological outpatient clinics, and social media platforms. The PD support groups are the (1) Hong Kong Society for Rehabilitation, which is a nonprofit organization serving more than 100,000 members through its primary care and community facilities; (2) the Hong Kong Parkinson's Disease Association, which is a PD patient support association with more than 1200 active members; and (3) the Hong Kong Parkinson's Disease Foundation, which is a PD support foundation that provides accessible, up-to-date public education and funding support to PD self-help groups for activities that enhance patient well-being and disease self-management. A combination of recruitment strategies previously shown to be effective in PD trials are implemented, including distributing printed flyers in patient support centers and neurological clinics and disseminating study information through the newsletters of patient support organizations, which are expected to reach approximately 100,000 members [28,29]. Recruitment is further supported through collaboration with outpatient neurology clinics at Queen Mary Hospital and Tung Wah Hospital in Hong Kong, where neurologists introduce the study and refer interested patients during routine follow-up visits. Traditional promotional approaches, such as advertisements on busses, bus-stop shelters, and tramcars, are used to broaden outreach, and digital recruitment is conducted via social media platforms (eg, Facebook and Instagram). All study information and registration procedures are available online, and research assistants provide additional support in person or by telephone as needed.

Sample Size

Perceived stress and QOL were prespecified as coprimary outcomes. To control the family-wise type I error rate across the 2 primary outcomes, the sample size calculation used a Bonferroni-adjusted 2-sided α of .025 for each outcome. Because no prior head-to-head trial has compared EXAT with mindful yoga in people with PD, no directly applicable estimate of the between-group difference in change over time was available. Meta-analytic effects from intervention-versus-control studies were therefore considered only as contextual evidence [43-46], as such effects may overestimate the differential effect expected in an active-comparator trial. In addition, the available literature does not provide a sufficient basis to determine whether perceived stress or QOL would be expected to show the smaller interaction effect [47]. We therefore adopted a conservative approach and powered the trial to detect the same small-to-moderate group-by-time interaction effect for both coprimary outcomes. The power calculation was aligned with the primary analysis, namely the group-by-time interaction from baseline to posttest, and was performed in G*Power 3.1 using *F* tests and repeated

measures ANOVA with a within-between interaction as the closest approximation to the planned repeated-measures analysis. The effect size metric used was Cohen f for the interaction term. Assuming 2 groups, 2 measurement occasions (baseline and posttest), a correlation of 0.50 among repeated measures, nonsphericity correction of 1, 90% power, and a 2-sided α=.025, a total of 116 completers would allow detection of a small-to-moderate interaction effect (Cohen f=0.166). Allowing for approximately 25% attrition, the target recruitment was set at 154 participants (77 per group).

Randomization, Allocation Concealment, and Blinding

After the baseline assessment, participants are randomly assigned to 1 of the 2 intervention groups in a 1:1 ratio through permuted block randomization. The variable block sizes are 4 and 8. The allocation sequence was generated by an independent researcher who is not involved in any outcome assessment and is concealed from other research personnel and participants until the point of assignment. The same independent researcher is responsible for informing participants of their group allocation.

This trial uses a single-blind RCT design. The outcome assessor, who is independent of the randomization and intervention delivery, will remain blind to the participants' group allocation and is responsible for all outcome measurements. Owing to the nature of behavioral interventions, blinding participants to their assigned group is infeasible and may introduce risks of performance, attrition, and evaluation biases if participants' expectations differ between the groups. These risks are minimized by not informing participants about the specific study hypotheses or detailed contents of the intervention manuals. The informed consent forms adhere to the principle of equipoise, emphasizing uncertainty regarding the superiority of either intervention. The mindful yoga and EXAT groups are described in the information sheet as potentially beneficial for general well-being, and all participants will receive an equal number of intervention sessions and assessments. In addition, the participants are instructed to avoid disclosing their group allocation to the outcome assessor at any time. This approach, consistent with the recommendations of the Evidence-Based Behavioral Medicine Committee [48], is intended to preserve assessor blinding and reduce bias in outcome evaluation.

Study Intervention

Mindful Yoga Group

The mindful yoga intervention is adapted from our previously tested mindfulness yoga program for people with PD [28] and delivered by a certified mindful yoga instructor in a face-to-face group format. The intervention consists of six 90-minute sessions delivered every 2 weeks. Each session follows a universal Hatha yoga framework and includes 3 core components: (1) mindfulness practice of a structured yoga sequence, (2) breathing exercises, and (3) guided meditation. Center- and home-based practice is used. The participants attend in-person sessions in one week and undertake home practice in the alternate week, supported by audio instructions and enlarged visual guides that summarize key exercises and provide prompts for self-practice. A detailed session plan for the mindful yoga group is presented in Table 2.

Table 2. Overview of the mindful yoga intervention.

Characteristics (duration)	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6
Theme (N/A[a])	Body Encounter & Awareness	Sensations & Pleasures	Emotional Awareness & Expressions	Nonjudgmental Presence	Self-Compassion & Common Humanity	Ongoing Attunement in Uncertainties & Celebration
Introductions (20 minutes)	• Greetings and introduction of Namaste • Introduction of mindful yoga through brief experiential and small group sharing about group expectations • Introduction of mindfulness attitudes	• Greetings and recapitulation of group norms (eg, muting phones) and content in last session • Small group sharing about home practice experiences • Recapitulation and further introductions of mindfulness attitudes	• Greetings and recapitulation of group norms (eg, muting phones) and content in last session • Small group sharing about home practice experiences • Recapitulation and further introductions of mindfulness attitudes	• Greetings and recapitulation of group norms (eg, muting phones) and content in last session • Small-group sharing about home practice experiences • Sing songs to recapitulate mindfulness attitudes	• Greetings and recapitulation of group norms (eg, muting phones) and content in last session • 3-minute breathing space • Small group sharing about home practice experiences	• Greetings and recapitulation of content in previous sessions • Small group sharing about home practice experiences
First segment (20 minutes)	• Body-breath connection exercise	Metaphoric yoga postures • Mountain • Half moon • Bird • Lotus mudra • Ox/cow • Weeping willow • Rock-paper-scissors with feet • Coconut tree	Recap of metaphoric yoga postures with 1-2 new exercises • Mountain • Half moon • Lion • Rock-paper-scissors with feet • Coconut tree	Warm-up exercises • Mountain • Moon • Ox • Lion	• Acroyoga exercises	• Warm-up exercises
Second segment (15 minutes)	• Abdominal breathing	• Mindful walking	• Supine movement • Aware of breathing movements while lying down	• Tapah exercises	• Excerpt of inside yoga exercises	• Dharana yoga – simplified sun salutation
Third segment (15 minutes)	Yoga nidra	Ocean breath	Mountain meditation	Meditation: naming breaths, bodily sensations, emotions, thoughts	Om meditation	Mindful walking exercise
Fourth segment (10 minutes)	Sharing and mini psychoeducation	Sharing and mini psychoeducation	Sharing	Sharing	Sharing	Sharing
Closure (10 minutes)	✓	✓	✓	✓	✓	✓

Characteristics (duration)	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6
Home practice (N/A)	• Crane soaring • Yoga Nidra	• Standing • Ocean breathing • Mindful walking	• Lying • Mountain • Mindful walking	• Standing • Sitting • Mindful walking	• Dyadic practicing • Om meditation • Mindful walking	• Self-selection of practice

[a]N/A: not applicable.

EXAT Group

The EXAT intervention was developed as a multimodal expressive arts program grounded in EXAT principles and tailored to the needs of people with PD. Its design was informed by prior literature, clinical experience, and the recognition that PD affects not only motor function but also emotional expression, communication, self-concept, and social engagement. The intervention comprises six 90-minute sessions delivered every 2 weeks and integrating multiple art modalities, such as visual arts, dance or movement, music, and calligraphy to support nonverbal expression, embodied awareness, symbolic meaning-making, and interpersonal connection. Each session is structured according to a 5-phase framework [49]: (1) filling-in (greeting and check-in), (2) bridging (warm-up), (3) decentering (art-making and art appreciation), (4) harvesting (sharing and response), and (5) closure. The sequencing of activities was designed to provide a gradual progression from sensory and body-based engagement to emotional exploration, reflection, and group sharing (detailed objectives of each activity are reported in Multimedia Appendix 1). As in the mindful yoga group, a combination of face-to-face and home-based practices are used, and the participants attend in-person sessions one week and engage in guided home activities the following week. Picture-based educational booklets are provided to all participants to support and guide their home-based EXAT practice. The detailed session plan for the expressive arts group is shown in Table 3.

Table 3. Overview of the expressive arts therapy (EXAT) intervention.

Characteristics (duration)	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6
Theme (N/A[a])	Body Encounter & Awareness	Sensations & Pleasures/ Playfulness	Emotional Awareness & Expressions	Nonjudgmental Presence	Self-Compassion & Common Humanity	Ongoing Attunement in Uncertainties & Celebration
Welcome and introduction (5 minutes)	✓	N/A	N/A	N/A	N/A	N/A
Greetings and check-in (15 minutes)	✓[b]	✓	✓	✓	✓	✓
Warm-up (15 minutes)	Move with rhythm	5 senses	Body movement	Body movement	Body movement	Body movement
Core 1 (15 minutes)	Body movement	Artmaking: spiritual rhythm bottle	Music and movement	Calligraphy and doodle	Artmaking: clay work	Artmaking: marble painting
Core 2 (20 minutes)	Artmaking	N/A[c]	Artmaking	Ink painting	Cocreation: presenting gifts to others	Group dance: dance and celebrate
Final segment (15 minutes)	Sharing and response	Sharing and response	Harvesting: sharing and response	Harvesting: sharing and response	Harvesting: sharing and response	Harvesting: sharing and response
Closure (10 minutes)	✓	✓	✓	✓	✓	✓
Home practice (N/A	Practice of using music to find own rhythm	Observe: spiritual rhythm bottle	Practice self-compassion by observing bodily sensations	Practice self-compassion by observing bodily sensations	Awareness of one's current condition; cultivate nonjudgmental and self-compassionate attitudes and comprehend common humanity	Awareness of one's current condition; cultivate nonjudgmental and self-compassionate attitudes and comprehend common humanity
Purpose (N/A)	Establish group rules and relationships; perceive different body parts and cultivate awareness of the mind-body connection.	Focus on information received through the 5 senses to experience the "present moment." Enhance confidence in finding joy.	Explore and become aware of emotions stored in the body; express emotions in a safe way.	Explore the body's window of tolerance; practice nonattachment to bodily sensations.	Learn to care for oneself in the face of adversity; encourage mutual support among group members.	Practice adapting to the unknown; review and consolidate group practices and experiences.
PD-related needs addressed (N/A)	Balance and stability, posture and proprioception, coordination, sleep	Fatigue, loss of smell, neurological and psychological symptoms	Facial expressions, emotions related to physical symptoms (eg, tremors)	Gradual loss of mobility, stiffness and pain, slowness of movement	Speech and voice, grief over gradual loss of mobility, stiffness and pain, slowness of movement, relationships	Endurance, cognitive function (memory for sequential movements), mind-body integration, self-efficacy

[a]N/A: not applicable.

[b]Only 10 minutes due to the 5-minute welcome and introduction.

[c]Core 1 lasts 35 minutes.

(page number not for citation purposes)

Adherence

Participants are advised to maintain their regular medication routines and physical activity levels and to avoid starting any new instructor-led intervention or program during the study period. Sessions are conducted at local community facilities. To support home-based practice, picture-based educational booklets are provided to the EXAT groups, and audio instructions featuring enlarged visual guides are provided to the mindful yoga groups. Additionally, in both groups, participants attend face-to-face sessions every other week and are instructed to complete home-based practice during the alternating weeks between sessions. Adherence to home-based practice is tracked using a self-reported activity log. Session attendance is recorded by the instructor, and any instance of absenteeism is documented and verified by the research coordinator. Because EXAT and mindful yoga pose minimal risk, participation may be discontinued at the participant's request. In the event of discontinuation, the reason is documented. Any adverse events related to EXAT and mindful yoga are documented and reported to the ethics review board and the study's supervisory team.

Measurements

Guided by the BPSS model, the quantitative component operationalizes whole-person health as the integrated biological, psychological, and social domains through standardized measures, whereas the qualitative interviews are designed to capture participants' lived experiences across all biological, psychological, social, and spiritual dimensions of health and well-being. As the spiritual domain is highly personal, culturally shaped, and context-dependent, it will be explored mainly during the focus group interviews.

For the quantitative component, the following instruments are administered online or offline (based on participants' preferences) for outcome evaluation at baseline (T0: prior to randomization) and 3 months (T1: immediately after the intervention), 9 months (T2), and 12 months (T3) after the baseline assessment.

Primary Outcomes

Perceived Stress Level

Perceived stress level is measured using the Perceived Stress Scale [50]. It uses a 5-point Likert scale to measure perceived stress level. The 10 items in the scale constitute 2 subscales: perceived helplessness and perceived self-efficacy (reverse-scored). A high score indicates a high perceived stress level. The Cronbach α value of the validated Chinese version of the scale is 0.85 [51].

PD-Related QOL

The validated Parkinson disease Questionnaire-8 (PDQ-8, [52]) is used to measure participants' PD-related HRQOL. The scale consists of 8 items, and it includes 8 domains, namely, mobility, activities of daily living, emotional well-being, social support, communication, cognition, body discomfort, and stigma. A high score indicates poor HRQOL. The Cronbach α value is 0.80. The internal consistency of the Chinese version of PDQ-8 has been validated with a Cronbach α of 0.87, and construct validity has been demonstrated against the Hoehn and Yahr Scale and Unified Parkinson Disease Rating Scale (UPDRS) motor scores [53].

Secondary Outcomes

PD-Related Symptoms

PD-related motor and nonmotor symptoms are evaluated using the Movement Disorder Society-UPDRS [54]. The scale assesses 4 domains: (1) nonmotor experiences of daily living, (2) motor experiences of daily living, (3) motor examination severity, and (4) motor complications. Symptom severity increases with score. The subscales have shown good reliability in prior research, with Cronbach α values ranging from 0.79 to 0.94 [54].

The assessment of PD-related motor symptoms is conducted using 2 mobile apps: Mon4t (Montfort Brain Monitor) and BooGuu Aspire Fall Risk Management (Booguu Company Limited). These apps are designed to evaluate various PD-associated motor symptoms by conducting tasks, such as the timed-up-and-go test, finger tapping, and measuring resting and postural tremors. The motor assessments are video-recorded for subsequent analysis and validation.

Generic QOL

QOL is measured using the brief World Health Organization Quality-of-Life Scale [55]. It measures the 4 dimensions of QOL: physical health, psychological health, social relationships, and environment. The scale consists of 26 items and uses a 5-point Likert scale. Higher scores indicate better QOL. The Cronbach α value of the subscales ranges from 0.73 to 0.82 [55].

Mediators

Biological and Physical Well-Being

Gut microbiota composition in fresh stool samples will be analyzed. The samples are preserved in sterile collection tubes containing a stabilizing agent and maintained at room temperature. Fecal sample collection follows standardized protocols guided by an instructional leaflet and a YouTube video, which were pilot-tested before data collection. At assessment timepoints T0, T1, and T2, the research team collects and aliquots samples into 5 separate 2.0 mL microcentrifuge tubes. These aliquots are stored at −80 °C in accordance with the manufacturer's protocol until subsequent processing. The samples are then sent to the laboratory, and DNA will be extracted from the fecal samples with a QIAamp PowerFecal Pro DNA kit in accordance with the manufacturer's guidelines. Shotgun metagenomic sequencing will be conducted on the DNBseq platform at BGI (Hong Kong) with 150 bp paired-end sequencing to generate comprehensive genomic data.

Constipation severity is assessed using the 16-item Chinese version of the Constipation Severity Instrument [56]. The instrument consists of 3 subscales: obstructive defecation, colonic inertia, and pain. Total scores range from 0 to

78, and high scores indicate increased constipation severity. The scale has demonstrated high internal consistency in previous studies, and Cronbach α values range from 0.93 to 0.95 [56].

Bowel habits are measured using a self-reported 7-day bowel diary. The participants document (1) the time and number of bowel movements, (2) the sensation of complete bowel emptying, (3) stool consistency (rated on the Bristol Stool Form Scale [57]), and (4) the use of laxatives (including type and frequency). The Bristol Stool Form Scale classifies stool form into 7 pictorial types, from type 1 (separate hard lumps, indicating slow transit) to type 7 (entirely liquid, indicating rapid transit). This scale has been validated in a Chinese population [58].

Physical activity levels are assessed using the International Physical Activity Questionnaire (IPAQ) Short Form [59], which has been shown to be reliable and valid within a Chinese population [60]. This questionnaire evaluates 3 types of activities: walking, moderate-intensity activities, and vigorous-intensity activities. For each participant, the total metabolic equivalent of task (MET)-minutes/week will be calculated, where MET represents the energy cost of physical activities. On the basis of the criteria outlined in the IPAQ guidelines, physical activity levels will be categorized as low, moderate, or high. Total MET and physical activity levels will be determined using the participants' responses to all questions concerning the number of days per week and the daily time spent performing walking, moderate, and vigorous activities in the past 7 days. Those who are unable or unwilling to answer all these questions will be excluded from the analysis, as indicated in the IPAQ guidelines.

Psychosocial Well-Being

Self-compassion is measured using the 12-item Chinese version of Self-compassion Scale [61]. Using a 5-point Likert scale, it explores the 6 dimensions of self-compassion: self-kindness, self-judgment, common humanity, isolation, mindfulness, and over-identification. A high capacity for self-compassion is reflected by a high score. The Cronbach α value is 0.64 for the Chinese version [62].

Self-efficacy is measured using the Chinese version of Self-efficacy to Manage Chronic Disease Scale [63]. The 6-item scale measures confidence in performing specific activities by people with chronic diseases on a 10-point Likert scale. A high score indicates high self-efficacy. The Cronbach α value for the Chinese population is 0.88 [63].

Perceived social support is measured using the adapted version of the Duke-UNC Functional Social Support Questionnaire [64]. On a 5-point Likert scale, it measures the perceived supportiveness of other people (eg, family members, friends, relatives, and coworkers) from the respondent's point of view. The 8 items reflect 3 types of social support: emotional, instrumental, and informational. A high score indicates greater social support.

Control Variables

Sociodemographic characteristics, dietary habits, and clinical data comprise the participants' profiles (age, gender, education level, financial status, religiosity, employment status, and marital status), probiotics and medication taken in the past 3 days, anthropometric parameters (weight, height, waist, and hip circumference), clinical data (year of PD diagnosis, motor subtype, psychiatric history, disease comorbidity, history of social or rehabilitation service utilization, and medical service utilization), and daily dietary fiber intake. These collected data will be considered as control variables in data analysis.

Focus Group Interview

Qualitative focus group interviews are conducted (1 month after the intervention, which is 4 months after baseline) to explore participants' narratives about their overall experiences and perceptions of the MBIs and their impact on well-being across biopsychosocial-spiritual domains guided by the BPSS model. Moreover, the qualitative findings will be used to gather insights regarding the participants' experience, intervention process, and mechanism of change of MBIs, as potentially reflected in the quantitative data. For each intervention group, 1 or 2 focus group interviews will be conducted based on data saturation. Each focus group consists of 5 to 8 participants who attend all intervention sessions and are willing to join the focus group interview. The interviews are held at a convenient location where all participants feel comfortable. If participants prefer, the interview may be conducted via Zoom. The interviews are facilitated by a member of the research team who is not involved in the group facilitation or administration of the interventions to ensure objectivity. Each focus group interview is expected to last between 30 minutes and 60 minutes. The topic guide of the focus group interview can be found in Multimedia Appendix 2.

Attrition and Missing Data

To address potential attrition and missing data, an attrition rate of approximately 25% has been anticipated for this trial, and the trial's progress is closely monitored against this benchmark. To minimize attrition and missing data, the study team and participants are informed of the importance of full and consistent participation, regardless of treatment assignment. Follow-up sessions are scheduled at times convenient for participants to reduce the burden of data collection. Follow-ups are arranged by contacting participants via phone, and reminders are sent via phone call or WhatsApp messages 2 weeks and 1 day before a scheduled follow-up. Attentive follow-up is provided to support a positive study experience. Study procedures are clearly explained to participants, and the assessor provides individualized feedback on performance assessments and their health implications at the end of each follow-up. Participants' contact information is regularly updated, and reasons for dropout will be documented.

Data Analysis

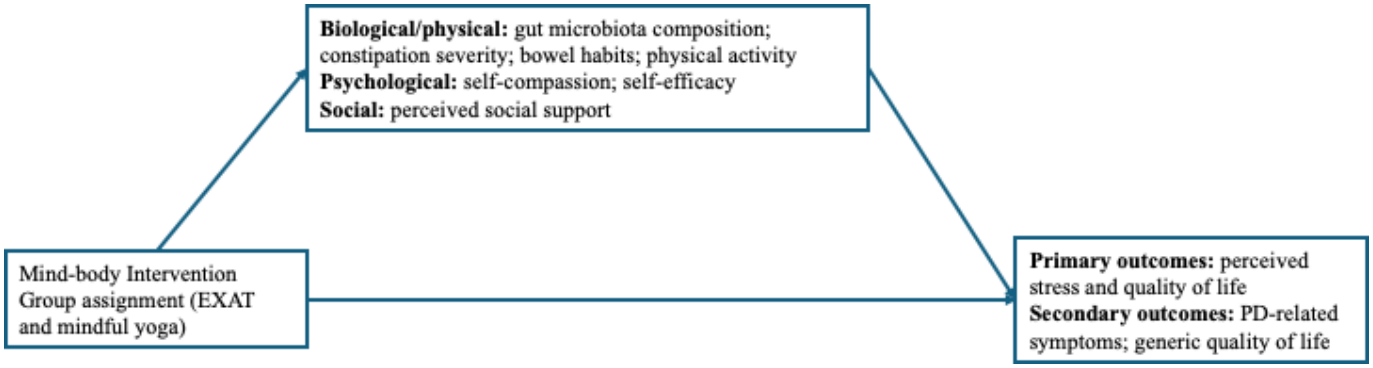
Data analyses will be based on the intention-to-treat principle, including all randomized participants in their assigned groups regardless of adherence. All statistical tests will be 2-sided, with α=.025 for each coprimary outcome and .05 for all other tests, and analyses will be performed using Stata 19.0 [65]. Baseline demographic and clinical characteristics and pretest outcome scores will be summarized using means and standard deviations for continuous variables and frequencies with percentages for categorical variables for the assessment of comparability between the EXAT and mindful yoga groups. To analyze the effect of the intervention on the primary and secondary continuous outcomes over the 3 time points, we will use linear mixed effects models (LMMs; [66]). This longitudinal approach is advantageous because it effectively handles the correlated nature of repeated measures within individuals and is robust to data that are missing at random. The LMMs will specify the outcome variable as the dependent variable, with fixed effects for treatment group (EXAT vs mindful yoga, with mindful yoga as the reference group), time (as a categorical factor), and group-by-time interaction. To improve statistical power and account for potential baseline differences, the baseline value of the relevant outcome will be entered as a covariate, and outcome measurements at T1, T2, and T3 will be modeled longitudinally. Furthermore, the model will incorporate random intercepts for each participant to account for individual-level variability in baseline scores, and a random slope for time may be included to account for changes in individual differences over time, with model fit compared using information criteria (eg, Akaike information criterion and Bayesian information criterion). The primary test of the intervention's efficacy will be the statistical significance of the group-by-time interaction term, which indicates whether the trajectory of change in the outcome differs significantly between the 2 groups. A similar LMM approach will be used for all secondary continuous outcomes. Sensitivity analysis will be performed to compare the results of complete and noncomplete cases. This analysis will test hypothesis 1.

Adherence to home practice will be monitored using participant practice logs and summarized descriptively, including which activities were practiced at home and the frequency and duration of practice during the intervention period. As secondary analyses, sensitivity analyses will examine whether treatment effects are robust after adjustment for home-practice adherence. Video-recorded motor tasks will be independently rated in a blinded manner as an additional sensitivity analysis.

For fecal sample data analysis, low-quality reads and sequences aligning to the *Homo sapiens* reference genome will be removed prior to downstream analyses. High-quality paired-end reads will then be used for taxonomic profiling with MetaPhlAn [67] and functional pathway profiling with HUMAnN [68]. The bioinformatics workflow will be automated using the metapi pipeline [69]. Gut-brain interaction and metabolic module profiles will be generated using omixer-rpmR [70], which leverages manually curated reference modules for gut metabolic and gut-brain functions. Alpha diversity (within-sample diversity) and beta diversity (between-sample variation) will be calculated from species-level profiles. To minimize technical bias, fecal samples will be randomized across DNA extraction batches and sequencing runs, with intervention arm and collection time point balanced across batches where feasible. Extraction batch and sequencing run will be recorded for all samples and assessed as potential sources of technical variation using ordination-based visualization and permutational multivariate analysis of variance (PERMANOVA) [71]. In downstream analyses, batch variables will be included as covariates where appropriate; if substantial residual batch effects are detected, sensitivity analyses will be conducted using batch-correction methods such as empirical Bayes adjustment applied to appropriately transformed abundance data. Because gut microbiota composition may be influenced by clinical and lifestyle factors, information on prespecified potential confounders, including dietary factors, constipation severity, laxative use, probiotic use, recent antibiotic exposure, antiparkinsonian medication changes, physical activity, and disease severity, is collected and will be considered in the analysis. Associations between prespecified covariates and gut microbiota composition will be assessed using canonical correspondence analysis [72] and PERMANOVA [71]. For unadjusted comparisons between the 2 intervention groups, the Wilcoxon rank-sum test will be used for continuous microbiome features, including alpha diversity and individual taxa or pathway abundances, as appropriate. Correlations between 2 variables, including alpha diversity and abundances of species or pathways, will be assessed using Spearman rank correlation [73]. To control for false-positive findings arising from multiple comparisons, *P* values from feature-level analyses, including tests of taxa, pathways, gut-brain/metabolic modules, and correlation analyses, will be adjusted using the Benjamini-Hochberg false discovery rate (FDR) procedure, with FDR-adjusted q values <0.05 considered statistically significant [74].

To examine potential mechanisms of intervention effects, mediation analyses will be conducted using a path analysis framework guided by the BPSS model. The analyses will evaluate whether changes in selected biological/physical, psychological, and social variables mediate the between-group difference (EXAT vs mindful yoga, with mindful yoga as the reference group) in primary and secondary outcomes (Figure 2). The biological/physical mediators will include gut microbiota composition, constipation severity, bowel habits, and physical activity. The psychological mediators will include self-compassion and self-efficacy. In addition, social mediators will include perceived social support.

Figure 2. Mediating process of mind-body interventions on primary and secondary outcomes. EXAT: expressive arts therapy; PD: Parkinson disease.



The analysis will be conducted in the full sample, with intervention assignment (EXAT vs mindful yoga) modeled as a binary exogenous variable. For each proposed mediator, the posttest (T1) mediator value will be regressed on intervention assignment while controlling for the corresponding baseline (T0) mediator value. The posttest (T1) outcome value will then be regressed on intervention assignment and the posttest mediator value while controlling for the corresponding baseline (T0) outcome value. This approach evaluates whether between-group differences in change in the mediator are associated with between-group differences in change in the outcome. This analysis will test hypothesis 2.

The indirect effect for each mediation pathway will be estimated as the product of the path from intervention assignment to the mediator and the path from the mediator to the outcome. Because the distribution of indirect effects may deviate from normality, nonparametric bootstrapping with 5000 resamples will be used to estimate robust standard errors and bias-corrected 95% confidence intervals [75]. A mediation effect will be considered statistically significant if the confidence interval does not include zero. All analyses will be conducted using Stata 19.0 [65].

For the qualitative component, audio and video recordings of the focus groups will be reviewed, transcribed verbatim, and managed using NVivo software [76]. The data will be analyzed using an inductive thematic analysis approach, guided by a 6-phase framework [77]. This rigorous process will begin with the research team immersing themselves in the data through repeated, active reading of the transcripts to achieve familiarization. The researchers will then systematically generate initial codes from the data that capture interesting features relevant to the research questions. These codes will then be collated into potential themes, which will be subsequently reviewed and refined by checking them against the coded extracts and entire dataset. To enhance analytical rigor and ensure the credibility of the findings, at least two researchers will independently code a subset of transcripts before meeting to compare codes; resolve any discrepancy through discussion; and develop a final, consensus-based coding framework. The clearly defined and finalized themes will then be integrated with the quantitative findings in a triangulation process. This mixed methods approach will allow us to examine points of convergence, complementarity, or divergence between the 2 data types, ultimately providing a rich and nuanced understanding of the trial outcomes and contributing to the elucidation of mechanisms underlying changes from the participants' own perspectives.

Qualitative and quantitative data will first be analyzed separately then integrated at the interpretation stage using triangulation and joint displays. Specifically, themes derived from the focus groups will be mapped onto major quantitative outcome domains and compared across intervention groups to identify areas of convergence, complementarity, or divergence. This approach will help explain observed outcome patterns, clarify how participants experienced each intervention, and inform interpretation of comparative effectiveness in relation to individual needs and preferences.

Ethical Considerations

Autonomy, Privacy, and Confidentiality

Ethics approval was obtained from the institutional review board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (reference number UW 23-565). The study was registered at ClinicalTrials.gov under the identifier NCT06078046. Written informed consent is obtained from eligible participants before any assessment or intervention. Participation is voluntary, and the participants are allowed to withdraw from the study at any time. Confidentiality is maintained using unique identification numbers for participants. To compensate participants for their time, they will receive a HK $100 (US $12.80) supermarket voucher upon completion of each follow-up assessment, up to a maximum of HK $300 (US $38.2) for completing all three follow-up assessments. All data are kept in a locked and secured cabinet, and access is restricted to the research staff. The study is conducted in accordance with the Declaration of Helsinki and relevant local regulations.

Risks and Safety

Both study interventions are nonpharmacological and are generally considered low risk for individuals with mild-to-moderate PD [78]. The primary potential physical risks are musculoskeletal strain, overexertion, or minor injuries associated with movement-based activities. To mitigate these risks in the mindful yoga group, all sessions include structured warm-up and cool-down components, and postures are carefully adapted to the participants' functional levels. Props, such as towels, chairs, and walls, are used to provide

additional support and stability, particularly for challenging poses or balance-related movements. Similarly, movement components within the expressive arts sessions (eg, dance or movement) are tailored to PD-related motor limitations and delivered at a pace and intensity assessed to be safe and tolerable by the therapist. For both interventions, all movement sequences are developed and reviewed by an expert panel to ensure that they are introduced in a progressive and safe manner for individuals with mild-to-moderate PD.

The EXAT groups will be led by registered expressive arts therapists, and the mindful yoga groups will be conducted by certified mindful yoga instructors with experience working with clinical populations. Participants are instructed to report unexpected, unusual, or worsening symptoms immediately to the principal investigator or intervention facilitators. All adverse events are documented in a project adverse event log, and any serious adverse event will be reported promptly to the ethics committee in accordance with institutional guidelines. No formal stopping rules for efficacy are prespecified. However, the trial will be discontinued if an unacceptable risk of serious adverse events is identified in one or both intervention groups, and the investigators will recommend the early termination of the affected arm or the entire study.

Consent for Publication

No individual identifying personal data (including names, images, or videos) are included in this manuscript.

Compensation

To compensate participants for their time, they receive a HK$100 (US $12.80) supermarket voucher upon completion of each follow-up assessment, up to a maximum of HK$300 for completing all 3 follow-up assessments.

Plans for Communicating Important Protocol Amendments to Relevant Parties (eg, Trial Participants and Ethical Committees)

In the event of any protocol amendments, the institutional review board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster will be notified, and approval will be sought from the IRB. Amendments will be reported to the trial registration platform on ClinicalTrials.gov.

Oversight and Monitoring

Composition of the Coordinating Center and Trial Steering Committee

The study is overseen by a supervisory team composed of registered nurses, expressive arts therapists, mindful yoga instructors, social workers, statisticians, and the principal investigator. The team holds monthly meetings to monitor the trial's progress, ensure adherence to the study protocol, review potential risks or ethical challenges, and make strategic decisions regarding trial implementation.

Composition, Role, and Reporting Structure of the Data Monitoring Committee

In this trial, the program steering committee, represented by the supervisory team, determined that an independent data monitoring committee was not necessary. This decision was based on the absence of planned interim analyses, which typically require independent data review and decision-making. However, the supervisory team will continue to monitor any major study discontinuation event or instance of trial misconduct.

Dissemination Plans

The findings will be published in peer-reviewed journals and presented at international and local conferences. In addition, the results will be shared and discussed with relevant stakeholders.

Results

This study is being conducted in accordance with protocol version 1.0, dated January 23, 2024. Participant recruitment commenced in May 2024. As of June 30, 2026, 144 participants had completed the pre- and postintervention assessments (72 in each arm). Study implementation has followed the planned timeline, including participant screening, enrollment, and baseline data collection. Follow-up assessments and study procedures have been conducted according to the protocol schedule. No major deviations from the original protocol have been identified. Recruitment and follow-up will continue until the target sample size and all prespecified study procedures have been completed.

Discussion

Overview

To the best of our knowledge, this RCT is the first head-to-head, active comparator study of 2 MBIs in PD. Rather than asking whether a single modality is superior to usual care, we address a question that is highly relevant for services and patients. Given limited resources and diverse patient preferences, this trial evaluates whether 2 credible, feasible mind-body options, namely mindful yoga and EXAT, differ in their effects on stress, QOL, and whole-person health and explores the mechanisms through which they operate. By incorporating assessments of comparative effectiveness into a whole-person framework and integrating biological, psychological, and social outcomes, the study will provide evidence that can directly support preference-sensitive, integrative care in PD.

Furthermore, this study represents the first rigorously designed RCT that directly compares the standardized protocols of mindful yoga and EXAT in a PD population. The study's methodological strengths are as follows: (1) use of manualized, standardized intervention protocols that ensure scientific rigor and facilitate implementation in clinical and community settings; (2) implementation

of multidimensional assessment incorporating validated patient-reported outcomes, objective motor measures, and stool-based biological markers; and (3) incorporation of high-throughput microbiome profiling to explore potential gut-brain pathways. The microbiome component is particularly innovative, given the increasing evidence for gut-brain interactions in PD [79] and the potential of MBIs to modulate stress-related physiological systems [80]. By using contemporary sequencing and analytic frameworks, such as metapi, to structure metagenomic workflows, the study aims to generate robust, transparent microbiome data that can be interrogated alongside clinical and psychosocial outcomes.

Clinically, both interventions are inherently patient-centered and emphasize active self-management. Guided by the BPSS model, this trial conceptualizes whole-person health in PD as arising from the interaction of biological/physical, psychological, social, and spiritual dimensions, rather than as a collection of isolated outcomes. From this perspective, the inclusion of biological, psychosocial, and clinical outcomes within a single framework is warranted because changes in one domain may influence functioning in others [81]. For example, improvement in motor symptoms, constipation, or physical activity may reduce distress and enhance daily functioning; improved self-compassion, self-efficacy, or stress regulation may strengthen coping and support better symptom management; and greater social support or interpersonal connection may promote emotional well-being, participation, and QOL. The spiritual dimension, including meaning-making, acceptance, hope, and sense of connection, is also relevant to adaptation in PD and will be explored primarily through the qualitative component.

Within this BPSS framework, mindful yoga and EXAT are expected to influence overlapping but potentially distinct pathways. Mindful yoga emphasizes mindful movement, breath regulation, and embodied awareness and may therefore more directly support biological/physical and psychological regulation, including motor function, balance, stress reduction, and self-regulatory capacity [82]. Meanwhile, EXAT engages multimodal creative processes that may more strongly facilitate emotional expression, identity reconstruction, meaning-making, and social connection while also supporting psychological adaptation and well-being [83]. Both modalities may foster psychological resilience, self-compassion, and adaptive coping, enabling individuals to reframe their illness experience and cultivate positive emotional states. Their favorable safety profiles and low risk of serious adverse events render them attractive adjuncts to pharmacological treatment, particularly for addressing nonmotor and psychosocial needs that are not fully met by current standard care.

From a service and public health perspective, this trial addresses critical gaps in PD care by providing comparative effectiveness data on 2 realistic, group-based interventions that can be embedded in outpatient or community settings. If effective and acceptable, these interventions may form the basis for scalable programs that extend psychosocial and rehabilitative support beyond hospital walls. The comparative design is particularly relevant for policymakers and service planners who must select optimal nonpharmacological options in the context of constrained resources. Furthermore, the mechanistic insights gained from linking changes in stress, psychosocial functioning, motor outcomes, and gut microbiota can provide novel avenues for research on neuroprotective strategies and personalization of MBIs based on patients' profiles and preferences.

Ultimately, this investigation contributes to the growing movement toward holistic PD care models that integrate the biological, psychological, and social dimensions of health [84,85]. By clarifying how 2 distinct mind-body modalities perform in a direct comparison and by probing potential pathways of change, the trial aims to support a more nuanced, patient-informed approach for selecting and tailoring psychosocial interventions for comprehensive PD management.

Limitations

Several limitations should be acknowledged. First, despite the use of diverse recruitment strategies across multiple sites and platforms, the sample may overrepresent individuals who are already engaged with community resources or motivated to participate in group-based activities, potentially limiting generalizability to less active or more socially isolated populations. Second, as is common in behavioral intervention trials, participant and instructor blinding is not feasible, which introduces the possibility of performance, expectancy, and attrition biases. Although we sought to minimize these risks by presenting both interventions as credible options, emphasizing equipoise, withholding detailed hypotheses, and standardizing instructor contact time, residual bias cannot be fully excluded, particularly for self-reported outcomes such as perceived stress. The use of video-recorded motor tasks will allow independent blinded rating as a sensitivity analysis, and future studies should incorporate formal measures of treatment expectancy and credibility to better quantify and adjust for these effects. Third, the intervention schedule involves 6 in-person sessions delivered over 12 weeks, along with multiple follow-up assessments and video-recorded motor tasks. This level of engagement may be challenging for some participants, especially those with mobility limitations, caregiving responsibilities, or transportation barriers, and may contribute to selective attrition despite the use of reminder systems, flexible scheduling, and supportive follow-up. Finally, the trial compares 2 active interventions without a usual care or no-intervention control group. Although this active-comparator design is appropriate for a comparative effectiveness question and helps control for nonspecific effects such as attention and group participation, it does not allow estimation of the absolute efficacy of either EXAT or mindful yoga relative to standard care alone. In addition, because EXAT is delivered as a multimodal intervention integrating several artistic modalities, the study cannot isolate the specific contribution of each component to any observed effects. Future studies could incorporate usual care or education-only control groups or use dismantling/factorial designs to clarify both absolute and component-specific effects.

Digital Accessibility and Selection Bias

Although study information and registration will be made accessible online, we will implement multiple offline recruitment and data collection pathways to mitigate the digital divide (such as phone calls from research assistants and instructions for how to use different materials and alternative booklets). Nevertheless, the requirement for some degree of digital engagement (eg, accessing home practice materials that will be uploaded to YouTube or completing online questionnaires) may favor participants with higher digital literacy or access. Although smartphone ownership and internet use among Hong Kong residents aged 65 years and older are high (87.1% internet use and 89.7% smartphone ownership in 2025 [86]) and YouTube reach is substantial (84.4% of the population [87]), individuals with limited digital skills or without smartphone access may still be underrepresented. Future studies should continue to prioritize multimodal recruitment and assessment strategies to ensure inclusivity across varying levels of digital literacy.

Conclusion

Despite substantial theoretical and empirical support for the stress-relieving and health-enhancing effects of MBIs, their therapeutic potential for people with PD has not been examined through a comparative effectiveness, mechanism-oriented approach. This 2-arm, active-comparator randomized trial directly addresses this gap by evaluating mindful yoga and EXAT, 2 distinct, feasible mind-body modalities delivered as adjuncts to usual care for people with PD. By combining validated patient-reported outcomes, objective motor assessments, and gut microbiome profiling, the study will provide comparative and mechanistic insights into how different mind-body approaches may support holistic health and symptom management for PD. The findings are expected to guide the selection and tailoring of psychosocial interventions based on patient needs and preferences, expand the evidence base for mind-body care in PD, and inform integrative models of whole-person care.

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Generative AI Use

The authors declare the use of generative AI (GAI) in the research and writing process. According to the GAIDeT taxonomy 2025 [88], the following tasks were delegated to GAI tools under full human supervision: proofreading and editing.
The GAI tool used was: ChatGPT 5.4.
Responsibility for the final manuscript lies entirely with the authors.
GAI tools are not listed as authors and do not bear responsibility for the final outcomes.
Declaration submitted by: collective responsibility.

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Data Availability

As this manuscript describes a study protocol, no data are available at the time of submission. Because the study data will include patient information, motor assessment data, and medical record data, the data will not be made publicly available in order to protect participant privacy and confidentiality. After study completion, deidentified data may be made available from the corresponding author upon reasonable request, subject to institutional approval, applicable ethical and legal requirements, and any necessary data use agreements.
No individual identifying personal data (including names, images, or videos) are included in this manuscript. No participants reported objection for publication of the protocol.

Authors' Contributions

Conceptualization: JYYK (lead), RTHH (lead), CKPC (co-lead), MHYF (supporting)
Funding acquisition: JYYK (lead), RTHH (co-lead)
Methodology: JYYK (lead), RTHH (lead), CKPC (co-lead), MHYF (supporting)
Project administration: JYYK (lead), QW (supporting), MHYF (supporting), CAL (supporting), SYYC (supporting), RTHH (supporting)
Supervision: JYYK (lead), RTHH (co-lead)
Writing – original draft: JYYK (lead), QW (co-lead), MHYF (supporting), CAL (supporting), SC (supporting)

Writing – review & editing: JYYK (lead), RTHH (co-lead), QW (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1

Session plan for the expressive arts therapy (EXAT) group.
[DOCX File (Microsoft Word File), 55 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Focus group interview prompts.
[DOCX File (Microsoft Word File), 23 KB-Multimedia Appendix 2]

Checklist 1

SPIRIT 2025 checklist.
[PDF File (Adobe File), 286 KB-Checklist 1]

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Abbreviations

BPSS: biopsychosocial-spiritual
CONSORT: Consolidated Standards of Reporting Trials
EXAT: expressive arts therapy
FDR: false discovery rate
HRQOL: health-related quality of life
IPAQ: International Physical Activity Questionnaire
LLM: linear mixed effects model
MBI: mind-body intervention
MET: metabolic equivalent of task
PD: Parkinson disease
PERMANOVA: permutational multivariate analysis of variance
QOL: quality of life
RCT: randomized controlled trial
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
UPDRS: Unified Parkinson's Disease Rating Scale

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