

A Metacognitive Strategy Intervention for People With Parkinson's Disease: Pilot and Feasibility Trial

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Importance: Cognitive impairment is a common and disabling feature of Parkinson's disease (PD), and interventions to mitigate its negative functional consequences are in high demand. Metacognitive strategy interventions, such as the Multicontext (MC) Approach, may support daily function among people with PD (PwPD).

Objective: To determine feasibility, participant acceptance, and preliminary estimates of the MC Approach's treatment effect for PwPD.

Design: Quasi-randomized controlled pilot trial. Participants underwent pretreatment assessment, allocation to treatment group (MC, $n = 29$; control, $n = 28$), 10 treatment sessions, 1-wk posttreatment assessment, and 3-mo questionnaire follow-up.

Setting: Participants' homes.

Participants: PwPD without dementia but with subjective cognitive concerns.

Intervention: Ten weekly sessions of the MC Approach, which aimed to develop awareness and strategies to control cognitive performance across activities via therapist mediation, functional activity performance, and homework. The control intervention used the same structure and treatment activities but did not address awareness or strategy use or use mediated learning.

Outcomes and Measures: Indicators of trial feasibility (recruitment, retention, study duration), participant acceptance (satisfaction, homework completion), and treatment effect (self-rated functional cognitive goal performance).

Results: We enrolled 3 participants/mo and had 87% retention. Both groups' satisfaction and homework completion were high. Compared with control participants, MC participants reported greater improvement in functional cognitive goal performance from preintervention to postintervention that was maintained at follow-up.

Conclusions and Relevance: The MC Approach is a feasible, acceptable, and potentially efficacious intervention to address the functional cognitive goals of PwPD without dementia. A larger, fully randomized trial is required to provide definitive efficacy data.

Plain-Language Summary: Cognitive impairment is one of the most common and disabling features of Parkinson's disease. As such, cognitive interventions that support daily function for this population are in high demand. The purpose of this study was to establish the feasibility of one such potential intervention, the Multicontext (MC) Approach, among people with Parkinson's disease (PwPD) without dementia. We also wanted to generate preliminary estimates of its effect on everyday cognitive function to inform future definitive trials. In a pilot quasi-randomized controlled trial, we found that the MC Approach is feasible, safe, and acceptable for people with PwPD. We also found that it may improve self-rated performance of daily cognitive goals. We can now proceed with a full-scale randomized controlled trial to determine its efficacy. Ultimately, this work will meet the pressing need for evidence-based cognitive interventions that improve or maintain occupational performance and participation among PwPD.

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Cognitive impairment is common among people with Parkinson's disease (PwPD) and is an area of unmet need in terms of clinical management

(Burn et al., 2014). About one-third of PwPD in the earliest stages demonstrate mild cognitive deficits, most commonly in executive or attentional control

functions (Foltynie et al., 2004; Muslimovic et al., 2005; Yarnall et al., 2014). These deficits cause disability, reduced quality of life, and restricted participation, often to a larger extent than motor impairment (Cahn et al., 1998; Foster & Hershey, 2011; Lawson et al., 2016). Medical treatments for PwPD do not address cognitive impairment, so cognitive rehabilitation interventions to attenuate its negative functional consequences are in high demand (Deane et al., 2014; Goldman & Weintraub, 2015; Walton et al., 2017).

Most cognitive interventions for PwPD use a restorative cognitive training approach, attempting to improve specific cognitive processes (e.g., working memory) through practice of tasks that demand those processes. Meta-analyses demonstrate that this approach produces small to medium short-term improvements on neuropsychological tests ($g_s = 0.23$ to 0.55); however, these benefits do not translate to improved daily activity function or quality of life ($g_s = -0.07$ to 0.10 ; Lawrence et al., 2017; Leung et al., 2015; Orgeta et al., 2020; Sanchez-Luengos et al., 2021). There is a need for cognitive interventions that address everyday function among PwPD.

In contrast to cognitive training, strategy training more directly addresses everyday function by teaching people to use metacognitive, compensatory, or adaptive techniques to optimize information processing or bypass information processing limitations to achieve task-related goals (Mowszowski et al., 2016). Strategy training is recommended for those with mild (vs. more severe) cognitive decline because it requires learning, capitalizes on existing cognitive resources, and aims to prevent or delay functional decline (Mowszowski et al., 2016). Metacognitive strategy training to facilitate awareness and self-regulation of functional activity performance is recommended as a practice standard for treatment of executive and attention deficits after acquired brain injury (Cicerone et al., 2019). PwPD without dementia share similar cognitive profiles and rehabilitation goals with these populations (Vlagsma et al., 2016), so metacognitive strategy training may also benefit them.

A metacognitive strategy intervention that may support everyday cognitive function for PwPD without dementia is the Multicontext (MC) Approach (Toglia & Foster, 2021). The MC Approach focuses on improving functional cognitive performance by enhancing awareness and strategy use across activities and contexts. Through repeated experiences with cognitively challenging functional activities, participants develop personalized general strategies (e.g., planning before initiating multistep activities, checklists for keeping track, alarms as reminders) that they can apply in a variety of situations to prevent or correct cognitive performance errors. The therapist facilitates this process using mediated learning techniques (e.g., guiding prompts, questions) and a metacognitive framework to support anticipation of challenges, self-generation of strategies to mitigate said challenges,

self-monitoring and adjustment during performance, and evaluation of performance and strategy effectiveness. The therapist–client interaction within the MC Approach aims to increase self-efficacy by creating a supportive environment and providing mastery experiences in which the person is empowered to recognize their performance challenges and generate their own solutions. The goal is to enable the person to manage everyday cognitive challenges so they can perform and participate in meaningful daily activities and roles.

The MC approach targets the functional cognitive difficulties of PwPD. PwPD without dementia demonstrate ineffective or inefficient strategy use and awareness in cognitively complex functional activities (Best et al., 2024; Foster et al., 2022; Sturkenboom et al., 2019). Additionally, they have low self-efficacy for recognizing and managing cognitive errors during functional activities (Jethani et al., 2024). These findings underscore the potential of the MC Approach for addressing cognitive performance problems among PwPD because it focuses on developing awareness of performance, using strategies to support performance, and bolstering cognitive self-efficacy.

In a development and proof-of-concept case series study (Stage IA of the National Institutes of Health [NIH] stage model; Onken et al., 2014), PwPD had high satisfaction, credibility, expectancy, adherence, enjoyment, and engagement with the MC Approach (Foster et al., 2018). Furthermore, they reported consistent improvements in performance of and satisfaction with personalized functional cognitive goals on the Canadian Occupational Performance Measure (COPM; Law et al., 2014), with group change scores and almost all individual change scores surpassing the minimal clinically important difference (MCID). These findings provide preliminary evidence that the MC Approach is acceptable and has promise for producing clinically significant improvements in everyday cognitive function among PwPD. They justify moving forward with more rigorous pilot testing using a randomized design with a larger sample.

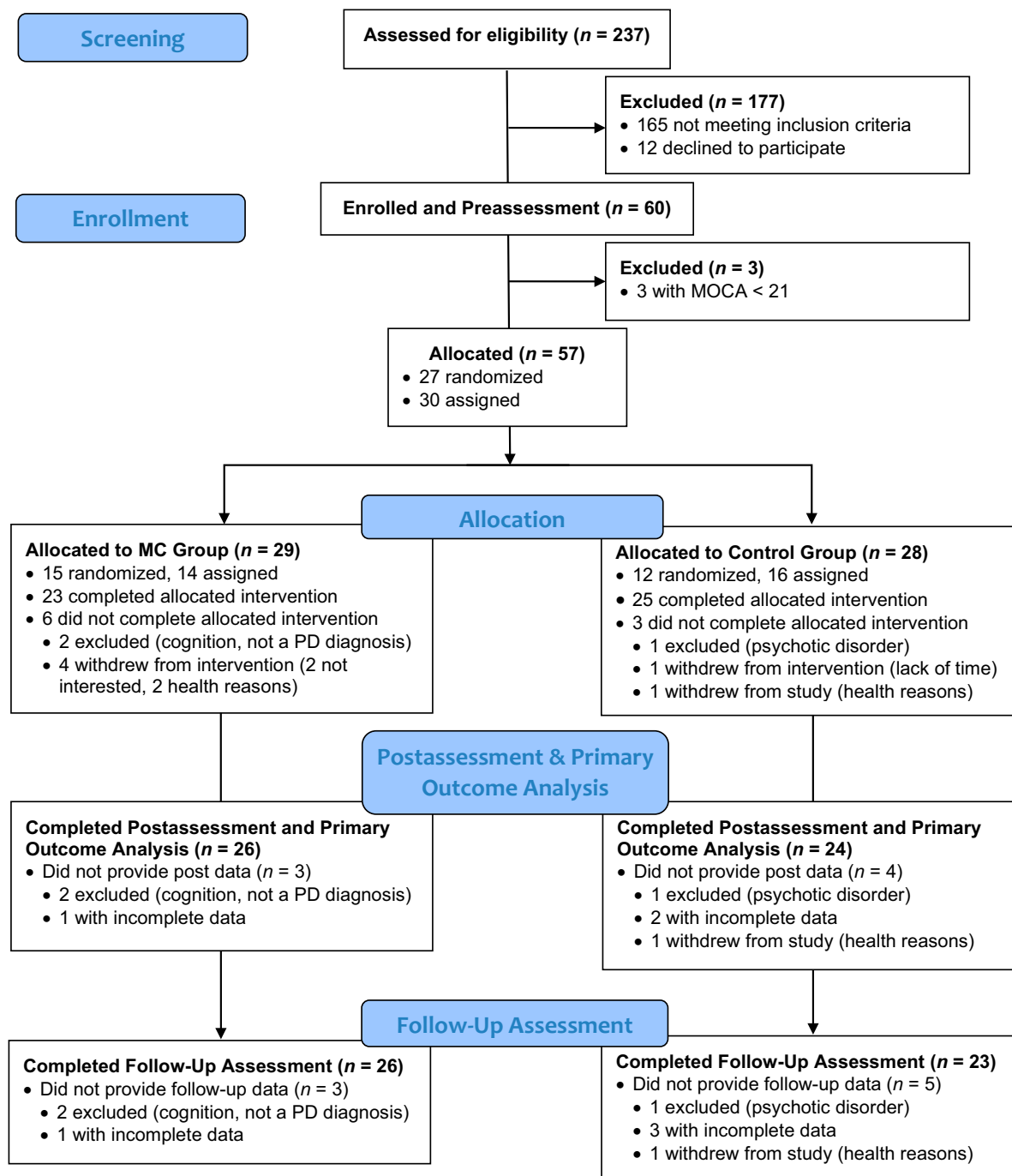
The purpose of this study was to conduct a feasibility pilot trial (NIH Stage IB; Onken et al., 2014) of the MC Approach for PwPD to lay the foundation for future efficacy testing. Our aims were to determine (1) feasibility of the trial protocol, (2) participants' acceptance of the MC Approach, and (3) preliminary estimates of treatment effect on self-rated functional cognitive goal performance.

Method

Design and Procedures

This was a quasi-randomized controlled trial (ClinicalTrials.gov ID NCT040418122). Participants underwent in-person pretreatment assessment, allocation to treatment group, 10 treatment sessions, in-person 1-wk posttreatment assessment, and 3-mo questionnaire follow-up (Figure 1). Data were collected in the

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of participants from the initial screening through the 3-mo follow-up assessment.



Note. The primary outcome was Bangor Goal Setting Interview self-ratings at postassessment. Format from Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., & Lancaster, G. A.; PAFS Consensus Group. (2016). CONSORT 2010 statement: Extension to randomized pilot and feasibility trials. *BMJ*, 355, i5239. MC = multicontext; MOCA = Montreal Cognitive Assessment; PD = Parkinson's disease.

participants' homes and via Research Electronic Data Capture (REDCap) Web-based survey (Harris et al., 2009) or mailed paper questionnaire (2 participants). The study was approved by the Washington University in St. Louis's review board, and written informed consent was obtained from all participants before data collection.

We initially proposed a randomized controlled trial. Because of the coronavirus disease 2019 (COVID-19) pandemic and associated staffing and scheduling restrictions, we were unable to randomize all participants and instead had to assign some ($n = 30$) to a treatment group on the basis of therapist availability. Participants who were randomized ($n = 27$) were

randomized in a 1:1 ratio stratified by Montreal Cognitive Assessment (MOCA) score (≤ 25 or ≥ 26) and sex. The study biostatistician (Ken Schechtman) generated the random allocation sequence and implemented it using the randomization module in REDCap. A co-investigator (Meghan C. Campbell) conducted randomization and allocation to group and communicated with the study therapists, who then scheduled treatment with the participants. The study participants, assessor (Tasha Doty), and primary investigators (Erin R. Foster and Joan Toglia) were masked to treatment group allocation. Additionally, participants were masked to differences in treatment, and assessors were masked to study purpose and treatment. The therapists were masked to details of the treatment they did not administer. Foster and Toglia remained masked to treatment group until all analyses reported in this article were complete.

Recruitment began in November 2019 and ended in January 2022 when the target of 60 enrolled participants was reached. Recruitment was suspended twice during this period: mid-March through mid-July 2020 because of the COVID-19 pandemic and July through September 2021 while waiting for approval for COVID-related supplemental funding. The trial ended in July 2022 when all eligible retained participants completed follow-up. Other than our inability to randomize all participants, there were no changes to the proposed study methods or outcomes after the trial commenced.

Participants

Participants were men and women older than age 40 who met the criteria for typical idiopathic PD (Hughes et al., 1992), were at Hoehn and Yahr scale Stages 1 to 4 (Hoehn & Yahr, 1967), had subjective cognitive decline (Jessen et al., 2014), and could list at least one daily cognitive challenge they wanted to address.

Exclusion criteria were possible dementia or moderate to severe cognitive impairment (according to Movement Disorders Society criteria [Emre et al., 2007], a MOCA score of < 21 [Dalrymple-Alford et al., 2010], medical records, or physician or informant report), another neurological disorder (e.g., stroke), brain surgery (e.g., deep brain stimulation), history of psychotic disorder or significant current psychiatric disorder, or any other condition that would interfere with participation (e.g., non-English speaking, lives more than 1 hr away). Participants were identified through the Washington University Movement Disorder Center, Missouri Chapter of the American Parkinson Disease Association, word of mouth, and snowball sampling.

Interventions

Common Features

Each intervention consisted of ten 1- to 1.5-hr weekly treatment sessions delivered in an individual, face-to-face format in the participants' home, community, or

both by a trained, licensed occupational therapist. To avoid treatment contamination, different therapists administered the MC and control interventions (two therapists per intervention). The initial two sessions of both interventions involved a review of preassessment data, explanation of the treatment and what to expect, administration of secondary outcome or process measures (not reported here), administration of the Bangor Goal Setting Interview (BGSi; Clare et al., 2016) to identify functional cognitive problems and develop treatment goals (see description in the "Treatment Effect" section), and one treatment activity (in Session 2). Subsequent treatment sessions (3–10) involved review of prior session learning and homework, two treatment activities, and a homework assignment. Treatment activities were simulated functional activities that provided a functionally relevant and optimal level of cognitive challenge for the participant. For standardization across treatment group, the first five treatment activities (Sessions 2–4) were selected from a pre-designed menu of published activities developed for use in cognitive interventions (Toglia, 2017, 2018, 2019). For Sessions 5 to 10, the occupational therapist and participant had the option to continue using the published activities or to develop their own treatment activities on the basis of the participant's cognitive performance, goals, and interests. Examples of treatment activities included scheduling a month of recreational activities based on several criteria, planning a trip within a budget, developing a weekly meal plan and shopping list, comparing Bible passages, constructing a birdhouse, and creating an online birthday party invitation. All treatment sessions in both interventions were audio recorded, and Foster and Toglia reviewed a random selection of recordings (initially 50%, tapering to 20%) and met regularly with the occupational therapists to reinforce training, correct problems, and ensure high treatment fidelity.

MC Intervention

As described earlier and published in detail elsewhere (Toglia & Foster, 2021), the MC intervention involved a metacognitive framework and therapist mediation regarding activity performance to enhance awareness, guide strategy generation, and support practice and optimization of strategy use across functional activities. Treatment activities followed a horizontal continuum with increasing demand on transfer distance (i.e., a gradual change in surface features while maintaining the same demands) and a range of strategy applications. The therapist asked guiding questions or provided prompts before, during, and after the activities to help the participant (1) anticipate potential challenges and self-generate strategies to manage them, (2) self-monitor and adjust performance, and (3) evaluate performance and strategy effectiveness and generate possible enhancements for future activities. The presence of two treatment activities provided the opportunity for immediate transfer of learning,

awareness, and strategy use across activities. Additionally, the MC intervention incorporated a strategy bridging discussion after the two treatment activities to summarize and reinforce session learning and explicitly connect it to the participant's daily life activities and goals. This was followed by completion of an action plan that required the participant to apply what they learned from the session to their real-life activities as homework (homework varied across sessions as treatment progressed). Action plan results were then reviewed in the next treatment session.

Control Intervention

The control intervention had the same structure within and across treatment sessions and used the same treatment activities as the MC intervention. However, the occupational therapist did not use mediated learning techniques or explicitly address strategies, metacognition, or transfer and generalization. Rather, the intervention was a task-oriented training approach, whereby the participant received functional task practice with cueing by the occupational therapist focused on improving task performance or outcome (rather than awareness of performance and strategy use). Homework assignments were to practice specific cognitively challenging everyday life activities (assignments also varied across sessions), but there was no action plan component.

Outcomes

The outcome measures for each objective, along with prespecified benchmarks for success (targets) and criteria for failure, if applicable, were as follows: trial feasibility, participant acceptance, and treatment effect.

Trial Feasibility

Primary measures of feasibility included total enrollment (target, $N = 60$), enrollment rate (target, 4 participants/mo), retention (target, $\geq 85\%$; criteria for failure, $\leq 60\%$ retention in intervention, $\leq 75\%$ retention in study), and intervention duration (target, $\geq 85\%$ completing within 12 wk). Additional indicators of feasibility included the success of masking and participant safety. Safety was assessed via an adverse events interview conducted at each treatment session and at postintervention. The adverse events interview asked about falls and medical events as well as psychological effects, because frustration and discomfort were stated risks of study participation. The safety assessment also included a question at postintervention regarding perception of protection of privacy because breach of confidentiality was a stated risk of study participation. Safety data were reviewed in person every 6 mo by a standing Data Safety and Monitoring Board. Success of study participant masking was assessed at postintervention by asking participants whether they thought they received the active cognitive treatment (unsure, yes, no).

Participant Acceptance

Indicators of participant acceptance were satisfaction and homework adherence. Satisfaction was assessed with the 8-item Client Satisfaction Questionnaire (CSQ-8; [Attkisson & Zwick, 1982](#)) at postintervention (target, $\geq 24/32$, indicating all positive responses). Homework adherence was rated by the occupational therapist at each treatment session as *did not do* (0), *partial* (0.5), or *complete* (1), according to prespecified descriptors; session scores were summed and divided by the total number of homework assignments (9) to yield a homework completion rate for each participant (target, ≥ 0.8).

Treatment Effect

The primary outcome measure of treatment effect was self-rated performance on individualized functional cognitive goals as measured with the BGSI ([Clare et al., 2016](#)), which has been validated and used in PD cognitive rehabilitation trials ([Hindle et al., 2018](#); [Watermeyer et al., 2016](#)). We chose this measure over the COPM because it does not constrain goals to the areas of productivity, self-care, and leisure ([Tenison et al., 2025](#)). The BGSI is a semistructured interview that was used to identify functional cognitive problems or challenges and develop related treatment goals, and it was conducted by the occupational therapist in the initial treatment sessions. Examples of participants' goals included the following: "Take my afternoon meds within the half-hour every day," "complete my home cleaning tasks weekly," "actively participate in my book club," "get better at using my iPhone," and "exercise regularly" (see [Kang et al., 2023](#), for a detailed analysis). Participants rated each goal on a 10-point scale (1 = *cannot do or am not doing successfully*, 10 = *can do and am doing very successfully*) at preintervention, postintervention, and follow-up, and ratings were averaged across goals at each time point for analysis. There is no established MCID for the BGSI, but 2 points is typically used, based on the COPM ([Tenison et al., 2025](#)). Pretreatment goal ratings occurred in the presence of the occupational therapist, but postintervention and follow-up goal ratings were collected via REDCap Web-based survey or mailed paper questionnaire.

Sample Size

We aimed to enroll 30 participants per group. This sample size was feasible to accomplish within the study time frame and funding; would permit reasonable confidence bounds around our feasibility and acceptance outcomes, assuming 15% attrition; and would allow us to detect mean differences in change in goal attainment of 0.85 (two-tailed, $\alpha = .05$, 90% power).

Analyses

We conducted an intention-to-treat analysis with IBM SPSS Statistics (Version 28) using all available data.

Descriptive statistics were calculated for all variables and used to assess most of the feasibility data. Independent-samples t tests and χ^2 tests were used for group comparisons of participant characteristics and acceptance data. One-sample t tests with one-sided hypotheses were used to compare each group's acceptance data with the prespecified benchmarks for success. Mixed-model repeated-measures analyses of variance with planned pairwise comparisons were used to assess change in self-rated functional cognitive goal performance between groups and across time. Statistical significance was set at $p < .05$.

Results

Participant Characteristics

Data from 50 participants were analyzed for the primary outcome (MC group, $n = 26$, control group, $n = 24$; Figure 1). Demographic and clinical characteristics for the participants are presented in Table 1. The only significant group difference was in education distribution, $\chi^2(50) = 8.5$, $p = .04$. The MC group tended to have lower Unified Parkinson's Disease Rating Scale Part III (UPDRS III; Fahn et al., 1987) scores, $t(48) = -1.99$, $p = .06$. For self-identified race, the MC group had 25 White participants and 1 Asian

participant, and the control group had 23 White participants and 1 Asian participant. All participants identified as not Hispanic or Latino, except 1 participant in the MC group, who declined to state their ethnicity.

Trial Feasibility

The flow of participants through the phases of the study, including numbers and reasons for attrition, is depicted in Figure 1. There was no difference in the proportion of participants randomized or assigned to each group, $\chi^2(57) = 0.50$, $p = .60$. We enrolled the targeted 60 participants over 20 mo of active recruitment, yielding an enrollment rate of 3 participants/mo. Retention data are displayed in Table A.1 of the Supplemental Material (available online with this article at <https://research.aota.org/ajot>). By the most conservative calculation (the denominator is the total number enrolled; $N = 60$), overall retention for the primary study outcome was 83%. Retention per treatment arm (the denominator is the number allocated) was 90% for the MC group and 86% for the control group. The intervention duration ranged from 9 to 19 wk ($M = 11.8$, $SD = 2.1$), with 87.5% of participants completing the intervention within 12 wk.

Adverse events data are provided in Table A.2 in the Supplemental Material. Thirty-seven participants experienced 148 total adverse events, with no concerns regarding group membership. Other than 25 of the psychological effects (no between-groups difference), no adverse events were related to study participation.

Forty-nine participants (MC group, $n = 26$; control group, $n = 23$) answered the questions about treatment masking and protection of privacy at postintervention. All participants felt the study team protected their privacy. When asked whether they thought they received the active cognitive treatment, 26 (MC group, $n = 12$; control group, $n = 14$) were unsure, 16 (MC group, $n = 10$; control group, $n = 6$) answered yes, and 7 (MC group, $n = 4$; control group, $n = 3$) answered no, and there were no group differences in this distribution, $\chi^2(49) = 1.12$, $p = .57$.

Table 1. Participant Characteristics ($N = 50$)

| Characteristic | <i>n</i> | |
|---|-----------------|----------------------|
| | MC ($n = 26$) | Control ($n = 24$) |
| Age, yr, <i>M</i> (<i>SD</i>) | 71.1 (7.0) | 70.3 (7.4) |
| Gender | | |
| Male | 13 | 12 |
| Female | 13 | 12 |
| Education level* | | |
| High school graduate | 1 | 2 |
| Some college | 11 | 2 |
| Undergraduate degree | 6 | 12 |
| Postgraduate degree | 8 | 8 |
| Duration of PD diagnosis, yr, <i>M</i> (<i>SD</i>) | 5.7 (5.6) | 6.3 (4.8) |
| UPDRS III score while on medication, <i>M</i> (<i>SD</i>) | 22.0 (7.2) | 27.5 (11.8) |
| Hoehn & Yahr stage | | |
| 2 | 14 | 11 |
| 2.5 | 8 | 7 |
| 3 | 4 | 4 |
| 4 | 0 | 2 |
| MOCA, <i>M</i> (<i>SD</i>) | 25.9 (2.2) | 25.0 (2.8) |

Note. MC = multicontext; MOCA = Montreal Cognitive Assessment; UPDRS III = Unified Parkinson Disease Rating Scale Motor Subscale.

* $p = .04$.

Table 2. Group Scores on Indicators of Participant Acceptance ($N = 50$)

| Measure and Group | <i>M</i> (<i>SD</i>) | Range | 95% CI |
|--------------------|------------------------|-----------|--------------|
| CSQ-8 | | | |
| MC | 29.3 (3.1) | 21–32 | [28.1, 30.5] |
| Control | 28.8 (3.0) | 22–32 | [27.6, 30.0] |
| Homework adherence | | | |
| MC | .89 (.14) | 0.63–1.00 | [.83, .95] |
| Control | .83 (.13) | 0.63–1.00 | [.77, .89] |

Note. MC group, $n = 26$; control group, $n = 24$. CI = confidence interval; CSQ-8 = 8-item Client Satisfaction Questionnaire; MC = multicontext.

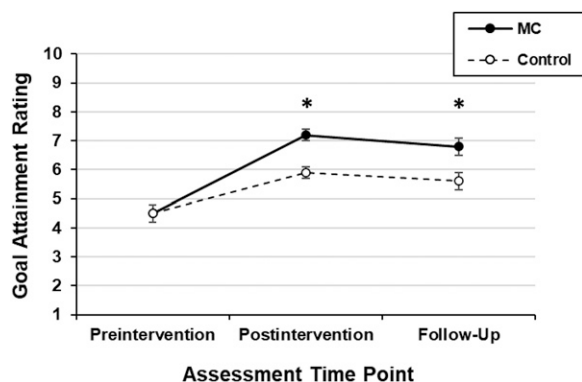
Participant Acceptance

Participant acceptance data are provided in Table 2. CSQ-8 scores in both groups were very high and did not differ from each other, $t(48) = 0.56$, $p = .58$. Both groups' mean CSQ-8 scores were higher than 24 out of 32 (the prespecified benchmark for success; $p < .001$). Mean homework completion rates in both groups were above the prespecified benchmark for success (.80) and did not differ from each other, $t(48) = 1.68$, $p = .10$. The MC group's homework completion was higher than the benchmark, $t(25) = 3.20$, $p = .002$, but the control group's was not, $t(23) = 1.00$, $p = .16$.

Preliminary Treatment Effect

BGSI data are shown in Figure 2. On average, participants developed five goals ($SD = 1.4$, $Mdn = 5$, modes = 4 and 5, range = 3–8). For the primary comparison (preintervention to postintervention), there were effects of time, $F(1, 48) = 132.14$, $p < .001$, and group, $F(1, 48) = 6.05$, $p = .02$, as well as a Group \times Time interaction, $F(1, 48) = 8.19$, $p = .006$. Both groups improved from preintervention to postintervention, but the MC group's improvement was larger; thus, the MC group had higher scores at postintervention compared with the control group, $F(1, 48) = 17.08$, $p < .001$. The pattern of results is similar when including all three time points. Both groups improved from preintervention to postintervention, with the MC group experiencing a larger improvement that was maintained at follow-up, resulting in the MC group having higher scores at postintervention and follow-up compared with the control group, $F_s(1, 46) \geq 7.30$, $p_s \leq .01$. Of note, the MC group's mean improvement from preintervention to postintervention (mean change = 2.7) and follow-up (mean change = 2.3) surpassed the previously cited MCID, whereas the control group's did not (mean change = 1.4 and 1.1).

Figure 2. Self-rated functional cognitive goal performance (Bangor Goal Setting Interview) at preassessment, postassessment, and 3-mo follow-up for each treatment group.



Note. MC group, $n = 50$; control group, $n = 24$. Error bars represent ± 1 standard error of the mean. Asterisks indicate significant group differences ($p < .05$). MC = multicontext.

All results remained the same when including randomization status, education level, and UPDRS III scores as covariates in the models and after stratifying by randomization status.

Discussion

Our purpose was to establish the feasibility and acceptance of the MC Approach among PwPD without dementia and to determine preliminary estimates of its effect on everyday cognitive function. We conducted a feasibility pilot trial in which PwPD were allocated to receive the MC Approach or a task-oriented control intervention. We used prespecified criteria to establish aspects of trial feasibility and acceptance and compared the groups' self-rated functional cognitive goal performance from before to after treatment to assess treatment effect. We found that the trial was feasible and safe, the interventions were acceptable, and the MC Approach has promise as an efficacious intervention to address everyday cognitive function among PwPD.

Despite the challenge of conducting a clinical trial during the COVID-19 pandemic, we were successful in enrolling and retaining participants and completing the intervention in a reasonable time frame. We were slightly below our ideal targets for enrollment and retention (depending on the denominator), but well above our prespecified criteria for failure. Participant privacy and masking were preserved. All participant-reported psychological events (e.g., frustration, discomfort, stress) were mild, and there were no safety concerns or group differences; however, further investigation into the nature and cause of such effects and measures to reduce them in future work are warranted. Our results demonstrate that it is feasible to conduct a controlled clinical trial of the MC Approach among PwPD without dementia, and we now have the data necessary for efficacy trial planning.

Metacognitive strategy interventions require effort and engagement from the client to derive full benefits. Our results indicate that PwPD can achieve such engagement, because the participants were highly satisfied with the intervention and had good homework completion. This high acceptance may stem from the functional goal-oriented and person-centered nature of the intervention. PwPD want to be actively involved in care that is personalized to their needs and desires, and such circumstances improve their satisfaction, engagement in treatment, and treatment outcomes (Grosset & Grosset, 2005; Mathur & Mathur, 2024; Vaartio-Rajalin et al., 2019; van der Eijk et al., 2013). Furthermore, with the MC Approach, homework provides an important opportunity to apply treatment session learning to daily cognitive challenges and to use and evaluate strategies in real-world contexts. In this way, it is critical for facilitating generalization of learning to everyday function. Thus, our findings related to participant acceptance suggest that PwPD can engage in the MC Approach at a level that will promote their learning, retention, and transfer of

metacognitive skills and functional cognitive strategies to support functional goal attainment.

Although our aims related to establishing participant acceptance were concerned with the MC Approach, it is worth noting that the intervention groups did not differ in these features, and acceptance was also high in the control group. This finding supports the quality of the control intervention as an active control and will strengthen future conclusions that differences in treatment effect are due to active treatment ingredients (e.g., strategy use, metacognitive framework) rather than adherence or other psychosocial mechanisms.

This pilot trial was not designed to determine efficacy; however, our results support the potential of the MC Approach to produce real-world functional benefits and address the rehabilitation goals of PwPD.

Although preliminary, this is important and encouraging in the context of cognitive rehabilitation research in PD, which so far lacks evidence of benefit for everyday function (Lawrence et al., 2017; Leung et al., 2015; Orgeta et al., 2020; Sanchez-Luengos et al., 2021). We hypothesize that this advantage stems from the strategy training approach, which provides skills to help people manage their daily cognitive function rather than assume improvements in cognitive processes will translate to improved daily function. Furthermore, we hypothesize that the MC Approach has unique attributes that confer an advantage over other strategy training interventions, including using mediated learning (vs. direct instruction), which is known to enhance metacognitive control, carryover of learning, and self-efficacy (Harris et al., 2008; Lebeer, 2016), and explicitly using evidence-based techniques to “train for transfer,” an aspect missing from many typical strategy training approaches (Geusgens et al., 2007). We also posit that the MC Approach is particularly well suited to PwPD, because it directly targets their functional cognitive difficulties, including poor awareness and strategy use in complex tasks and low cognitive self-efficacy (Best et al., 2024; Foster et al., 2022; Jethani et al., 2024; Sturkenboom et al., 2019).

This study was limited by our inability to fully randomize the cohort, which could have led to imbalances in key characteristics across groups (e.g., education, motor impairment). Analyses suggest that our results were robust to these differences and not affected by randomization status; however, future trials will need to be fully randomized to establish efficacy. Additionally, the sample’s ethnographic diversity was limited, a common problem in PD-related research and clinical trials (Gilbert & Standaert, 2020). Future work must make every effort to include samples that are adequately representative of the population with PD.


Implications for Occupational Therapy Practice

This pilot trial established the feasibility of, participants’ satisfaction with, and safety of the MC

Approach for PwPD. Larger, fully randomized trials are required to demonstrate its efficacy and fully evaluate its clinical impact. This study has the following implications for occupational therapy practice:

- PwPD can complete weekly homework assignments designed to promote application of strategy use to everyday life.
- The MC Approach has potential to address the everyday functional cognitive goals of PwPD without dementia.
- If practitioners choose to implement the MC Approach with clients with PD, they should carefully document treatment content, client responses to treatment, and changes in functional outcomes.

Conclusion

Cognitive impairment is one of the most common and disabling features of PD, and there is wide recognition of the need for early initiation of cognitive interventions that support daily function in this population. We have shown that the MC Approach is a feasible, acceptable, and potentially efficacious intervention to address the functional cognitive goals of PwPD without dementia. These findings justify proceeding with its development and testing. Our immediate next step is a definitive, full-scale efficacy randomized controlled trial with longer-term follow-up. Ultimately, this work will meet the pressing need for evidence-based cognitive interventions that improve or maintain occupational performance and participation among PwPD. 

Acknowledgments

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