

# Mindfulness Training Enhances Self-Regulation and Facilitates Health Behavior Change for Primary Care Patients: a Randomized Controlled Trial

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**BACKGROUND:** Self-management of health is important for improving health outcomes among primary care patients with chronic disease. Anxiety and depressive disorders are common and interfere with self-regulation, which is required for disease self-management. An insurance-reimbursable mindfulness intervention integrated within primary care may be effective for enhancing chronic disease self-management behaviors among primary care patients with anxiety, depression, trauma, and stress-related and adjustment disorders compared with the increasingly standard practice of referring patients to outside mindfulness resources.

**OBJECTIVE:** Mindfulness Training for Primary Care (MTPC) is an 8-week, referral-based, insurance-reimbursable program integrated into safety-net health system patient-centered medical homes. We hypothesized that MTPC would be more effective for catalyzing chronic disease self-management action plan initiation within 2 weeks, versus a low-dose comparator (LDC) consisting of a 60-min mindfulness introduction, referral to community and digital resources, and addition to a 6-month waitlist for MTPC.

**PARTICIPANTS:** Primary care providers (PCPs) and mental health clinicians referred 465 patients over 12 months. All participants had a DSM-V diagnosis.

**DESIGN AND INTERVENTIONS:** Participants ( $N=136$ ) were randomized in a 2:1 allocation to MTPC ( $n=92$ ) or LDC ( $n=44$ ) in a randomized controlled comparative effectiveness trial. MTPC incorporates mindfulness, self-compassion, and mindfulness-oriented behavior change skills and is delivered as insurance-reimbursable visits within primary care. Participants took part in a chronic disease self-management action planning protocol at week 7.

**MAIN MEASURES:** Level of self-reported action plan initiation on the action plan initiation survey by week 9.

**KEY RESULTS:** Participants randomized to MTPC, relative to LDC, had significantly higher adjusted odds of self-

management action plan initiation in an intention-to-treat analysis (OR = 2.28; 95% CI = 1.02 to 5.06,  $p=0.025$ ).

**CONCLUSIONS:** An 8-week dose of mindfulness training is more effective than a low-dose mindfulness comparator in facilitating chronic disease self-management behavior change among primary care patients.

**KEY WORDS:** primary care; mindfulness; self-management; health behavior; self-regulation; patient-centered.

J Gen Intern Med 34(2):293–302

DOI: 10.1007/s11606-018-4739-5

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## INTRODUCTION

Primary care treats the majority of patients with anxiety, depression, trauma, and stress,<sup>1–5</sup> which are frequently comorbid with chronic physical illness (e.g., diabetes, arthritis).<sup>6–9</sup> These mental illnesses often impair self-regulation skills,<sup>10</sup> such as emotion regulation (e.g., impulse control), self-related processing (e.g., self-critical rumination, self-efficacy), and cognitive control (e.g., attention, executive function).<sup>11–15</sup> Hence, mental illness combined with chronic physical illness predicts poor health outcomes,<sup>16</sup> prompting integration of mental health treatment into patient-centered medical homes (PCMHs). Programs that enhance primary care patients' self-regulation skills have been shown to improve health outcomes through enhancing chronic illness self-management.<sup>17–20</sup> Self-management, a core focus within both the PCMH health care reform movement and the Chronic Care Model,<sup>18, 20–23</sup> is commonly encouraged through a process of engaged goal setting using the SMART framework<sup>24</sup> and accessible to a diversity of patient populations.<sup>25, 26</sup>

Mindfulness meditation may enhance self-regulation<sup>27–29</sup> (e.g., attention, emotion regulation processes<sup>30, 31</sup>) by increasing cognitive resources<sup>28</sup> (e.g., reappraisal, exposure) and modifying self-related processing<sup>32</sup> (e.g., reduced rumination, enhanced body awareness). Mindfulness-based programs (MBPs)<sup>33</sup>, derived from mindfulness-based stress reduction (MBSR),<sup>34, 35</sup> are evidence-based treatments that seem to harness self-regulatory mechanisms and could help people with

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**Electronic supplementary material** The online version of this article (<https://doi.org/10.1007/s11606-018-4739-5>) contains supplementary material, which is available to authorized users.

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Received November 4, 2017

Revised June 8, 2018

Accepted October 26, 2018

Published online December 3, 2018

self-regulation challenges catalyze behavior change related to managing chronic disease.<sup>36</sup> Meta-analyses demonstrate moderate effects of 8-week MBPs on anxiety, depression, and quality of life during chronic disease.<sup>37, 38</sup>

Implementation of mindfulness training programs within primary care holds promise as a sustainable, large-scale model for enhancing chronic illness self-management, improving patient symptoms,<sup>39</sup> and reducing health care service utilization.<sup>40–42</sup> This study replicates a pilot study of Mindfulness Training for Primary Care (MTPC), an insurance-reimbursable MBP adapted for primary care PCMHs, which suggested MTPC might facilitate medical regimen adherence related to chronic disease self-management action plan initiation.<sup>43</sup>

To determine MTPC's impact on catalyzing health behavior change, we compared health behavior self-management action plan initiation rates for primary care patients randomized to MTPC versus a low-dose comparator (LDC), consisting of 60-min introduction to mindfulness with referral to community and digital mindfulness resources.

## METHODS

### Study Design

This was a randomized controlled comparative effectiveness trial<sup>44, 45</sup> evaluating the impact of 8-week MTPC versus LDC on action plan initiation within 2 weeks of setting a health behavior self-management SMART goal (primary outcome). Baseline, 8-week, and 24-week within-group and between-group intervention effects were assessed for health and self-regulation outcomes.

### Participants

We recruited participants from 11 metro-north Boston primary care PCMHs via print and digital flyers, as well as referrals from primary and mental health care settings confirmed by a primary care provider. Individuals were eligible if  $\geq 18$  years old, had a DSM-V diagnosis, and received primary care within a participating PCMH site. Individuals were excluded if they presented with psychosis symptoms, thought disorder, active substance use disorder, cognitive impairment, severe mental illness, high risk for hospitalization, insurance coverage not including group psychotherapy, English reading proficiency below 7th grade (using REALM-SF Health Literacy Assessment<sup>46</sup>), or third trimester pregnancy. Participants were required to have an evaluation with a mental health clinician who completed a 9-item checklist to confirm eligibility and DSM-V diagnosis. A board-certified psychiatrist reviewed diagnosis and eligibility if unclear.

**Informed Consent.** Eligible individuals were invited to an informed consent group session which communicated they could continue receiving standard mental health treatment, including psychopharmacology and psychotherapy

consistent with the IMPACT stepped care model<sup>47–50</sup> regardless of their randomization status. There were 10 recruitment cycles, each with an average of 2 different date options for a consent session (total 20 group consent sessions), between January and October 2017.

**60-min Mindfulness Introduction.** After consenting, participants received a 60-min mindfulness introduction from a MTPC group leader before randomization. The session introduced basic mindfulness principles, brief guided mindfulness practices, inquiry,<sup>51</sup> and review of mindfulness resources. After mindfulness introduction session, participants could decline continuation before randomization.

**Randomization and Allocation.** A blinded study staff member employed a computer-based forced block randomization algorithm in Stata with a 2:1 allocation ratio placing enrolled individuals who completed baseline surveys ( $N=136$ ) into MTPC ( $n=92$ ) or LDC ( $n=44$ ) arms (Fig. 1). The algorithm stratified across four PCMH regions offering MTPC and also by PCP mindfulness training level to prevent confounding by differences in PCP mindfulness expertise.

### Interventions

**Intervention: Mindfulness Training for Primary Care.** MTPC incorporates elements from MBSR and mindfulness-based cognitive therapy<sup>52</sup> (MBCT) with evidence-based elements from other mindfulness-oriented behavior change approaches.<sup>43, 52–55</sup> MTPC is also designed to be trauma-informed.<sup>56–59</sup> MTPC offers 8 weekly 2-h sessions, a 7-h all-day session, and 30–45 min of recommended daily home practice with guided recordings. Sessions cover awareness of body sensations and breathing, autopilot, and stress responses, relating to discomfort, integration of core practices from MBCT and mindful self-compassion,<sup>53</sup> and novel components related to health behavior, communication, chronic illness self-management,<sup>60</sup> values clarification,<sup>61</sup> and mindful orientation towards action planning.<sup>62</sup> Weekly session curricula were designed to be adaptable to different primary care treatment contexts, allowing mental health and primary care providers to adapt session format to meet criteria for insurance billing as group psychotherapy or group medical visit, respectively.<sup>43</sup>

MTPC groups were co-led by two of 13 trained providers, including 12 licensed mental health clinicians (e.g., psychology, social-work, psychiatry) and one primary care provider, who all completed 35 h of 8-week MBSR plus practicum and 40 h of MTPC specific training.<sup>43</sup> MTPC curriculum adherence was tracked through weekly supervision and session-specific fidelity checklists.<sup>63</sup> Adherence to curriculum was rated as 0–1–2 (absent–partial–complete), with a mean of 1.91 (SD=0.31) over 10 MTPC cycles (80 total sessions). Sessions were audio-recorded, and 10% were reviewed by trained observers for adherence and competency, preventing drift.<sup>64–66</sup>

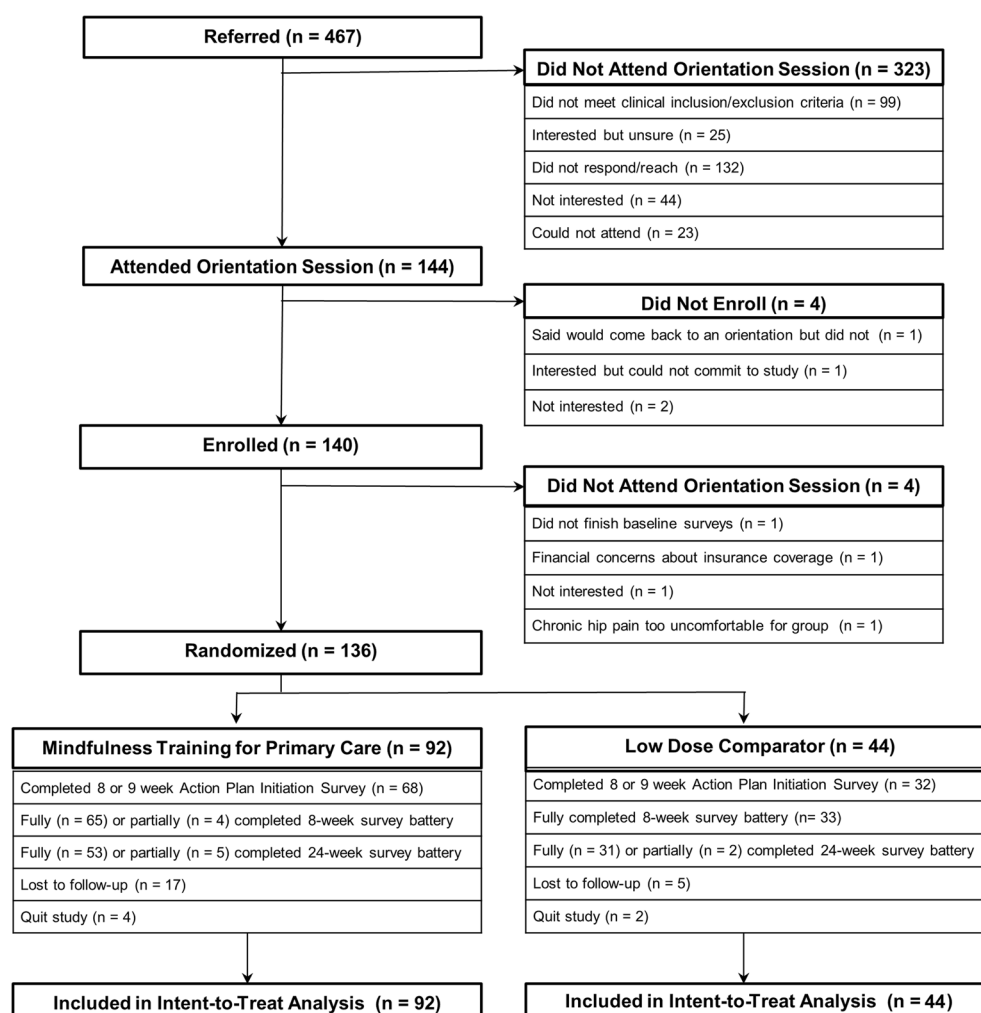


Figure 1 Consort Diagram.

**Low-Dose Comparator.** Participants randomized to LDC were encouraged to practice mindfulness skills learned during 60-min introductions and use digital<sup>67</sup> and community resources<sup>43</sup> while continuing standard mental health care described earlier. Participants were guaranteed an 8-week MBP spot 6 months later contingent on survey completion.

**Participant Outreach.** Participants in both arms received engagement calls (~10 min) every other week for 8 weeks to provide attention-matched study staff support (e.g., logistics, mindfulness practice encouragement), minimize attrition,<sup>68</sup> and facilitate survey completion.<sup>69</sup> Participants unresponsive to a survey were contacted by phone, e-mail, and/or text message up to five times within the 14-day completion window.<sup>70</sup>

## Measures

We collected and managed data using REDCap data capture tools.<sup>71</sup> Participants completed baseline surveys for sociodemographic and meditation experience variables (Table 1).

## Primary Outcome

During study week 7, participants created a short-term action plan focused on behavior change related to self-management of chronic disease and/or health maintenance using video and written materials outlining the well-established SMART goal framework.<sup>25, 62</sup> Participants then reported their level of action plan initiation in the action plan initiation (API) survey,<sup>72</sup> from 1 (not at all) to 7 (completely) at weeks 8 and 9, a 2-week time window consistent with previously published studies.<sup>26, 72, 73</sup> Evidence of plan initiation was defined as API score  $\geq 5$ . Primary outcome was the highest score on either API survey by the end of week 9.

## Secondary Outcomes

Secondary outcomes were assessed at baseline and 8 and 24 weeks.

**Health Outcomes.** Anxiety and depression were assessed using Patient-Reported Outcomes Measurement Information System (PROMIS) Anxiety Short Form 8a (Cronbach's  $\alpha = 0.92$ )<sup>74, 75</sup> and PROMIS Depression Short Form 8a ( $\alpha = 0.97$ ).<sup>76, 77</sup> Both were scored from 1 (never) to 5 (always).<sup>76</sup>

Table 1 Baseline Demographic and Clinical Characteristics of Participants by Study Arm

Variable	MTPC (n = 92)	Comparator (n = 44)	Total (n = 136)
Female, N (%)	63 (68.5)	26 (59.1)	89 (65.4)
Age (years), mean (SD)	40.6 (12.7)	40.3 (12.2)	40.5 (12.5)
Race, N (%)			
White	73 (79.3)	32 (72.3)	105 (77.2)
Black	3 (3.3)	4 (9.1)	7 (5.1)
Other	16 (17.3)	8 (18.2)	24 (17.6)
Ethnicity Hispanic, N (%)	17 (18.5)	4 (9.1)	21 (15.4)
English as second language, N (%)	19 (20.1)	5 (11.4)	24 (17.7)
Annual income < \$20,000, N (%)	31 (33.7)	9 (20.5)	40 (29.4)
Marital status, N (%) <sup>+</sup>			
Single	44 (48.4)	23 (54.8)	67 (49.3)
Married/cohabitating	32 (35.1)	17 (40.5)	49 (36.0)
Divorced	13 (14.2)	2 (4.8)	15 (11.0)
Education (years), mean (SD)	16.6 (3.1)	15.5 (4.1)	16.2 (3.4)
Insurance, N (%)			
Medicaid or Medicare	12 (13.0)	8 (18.2)	20 (14.7)
Subsidized	39 (42.4)	12 (27.3)	51 (37.5)
Private	39 (42.4)	22 (50.0)	61 (44.9)
Other	2 (2.2)	2 (4.6)	4 (2.9)
Have practiced meditation before, N (%)	56 (60.1)	22 (50.0)	78 (57.3)
Baseline meditation practice, mean min/day (SD)	6.8 (10.5)	4.1 (6.5)	5.9 (9.4)
DSM-V diagnosis, N (%)			
Single DSM-V diagnosis	59 (64.1)	30 (68.2)	89 (65.4)
2+ DSM-V diagnoses	33 (35.9)	14 (31.8)	47 (34.6)
Primary DSM-V diagnosis, N (%)			
Major depressive disorder*	27 (29.3)	10 (22.7)	37 (27.2)
Generalized anxiety disorder (300.02)	16 (17.4)	7 (15.9)	23 (16.9)
Anxiety NOS (300)	14 (15.2)	6 (13.6)	20 (14.7)
Adjustment disorder**	11 (12.0)	10 (22.7)	21 (15.4)
Other depressive disorder <sup>^</sup>	9 (9.8)	6 (13.6)	15 (11.0)
Other***	15 (16.3)	5 (11.4)	20 (14.7)
Any PTSD diagnosis, N (%)	11 (12.0)	1 (2.3)	12 (8.8)
Any depression diagnosis, N (%)	48 (52.2)	19 (43.2)	67 (49.3)

<sup>+</sup> Not shown: widowed (MTPC n = 1; LDC n = 1)

\*Includes DSM-V codes: major depressive disorder (MDD), single (296.20), MDD, recurrent (296.31–296.35)

\*\*Includes adjustment disorder, with depressed mood (309.0); adjustment disorder, with anxiety (309.24); adjustment disorder, with mixed anxiety and depressed mood (309.28)

<sup>^</sup>Includes depression NOS (311), persistent depressive disorder/dysthymia (300.4)

\*\*\*Includes post-traumatic stress disorder (PTSD) (309.81), mood disorder NOS (296.89), somatic disorder (300.82), attention-deficit disorders (314.01), psychological factors affecting medical (316), panic disorder with or without agoraphobia (300.01/300.21), social anxiety disorder (300.23), obsessive compulsive disorder (300.3)

T test and  $\chi^2$  test conducted; there were no significant differences between groups. DSM-V, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; PROMIS, Patient-Reported Outcomes Measures

T scores were generated using PROMIS scoring conversion tables.<sup>78</sup>

Stress was assessed by the 10-item Perceived Stress Scale (PSS),<sup>79</sup> with items scored from 0 (never) to 4 (very often) ( $\alpha = 0.83$ ).<sup>80</sup>

**Self-regulation Outcomes.** Emotional regulation challenges were assessed by the 36-item Difficulties in Emotion Regulation Scale (DERS),<sup>81</sup> with items scored from 1 (almost

never) to 5 (almost always). Higher scores indicated greater levels of difficulty with emotion regulation ( $\alpha = 0.94$ ).<sup>82</sup>

Interoceptive awareness was assessed by the 32-item Multidimensional Assessment of Interoceptive Awareness (MAIA),<sup>83</sup> with items scored from 0 (never) to 5 (always). Higher scores indicated higher levels of positive awareness ( $\alpha = 0.69$ – $0.83$ ).<sup>84</sup>

Mindfulness was assessed by the 39-item Five-Facet Mindfulness Questionnaire (FFMQ),<sup>85, 86</sup> with items scored from 1 (never or very rarely true) to 5 (very often or always true) ( $\alpha = 0.75$ – $0.92$ ).<sup>86</sup>

Self-compassion was assessed by the 12-item Self-Compassion Scale Short Form (SCS-SF),<sup>87</sup> with items scored from 1 (almost never) to 5 (almost always). Higher scores indicated higher experience of self-compassion ( $\alpha = 0.87$ ).<sup>87</sup>

The 6-item Self-Efficacy for Chronic Disease (SECD-6) scale<sup>60</sup> measured participant confidence in the ability to do activities related to managing their chronic disease from 1 (not at all confident) to 10 (totally confident) ( $\alpha = 0.90$ ).<sup>88</sup>

Table 2 Multivariate Analysis of Predictors of Action Plan Initiation (N = 136)

	Odds ratio	95% CI	Z	p
MTPC arm	2.28	1.02–5.06	2.24	0.025*
Education (years)	1.17	1.03–1.33	2.47	0.013*
Any PTSD Dx	11.00	1.35–89.48	2.24	0.025*

\*Significance defined by  $p < 0.05$

Multicollinearity was assessed using variance inflation factor (VIF) and was not found among variables



Table 3 Mixed Effects Intention-to-Treat Analysis (N = 136)

Outcome	Arm	Baseline mean score (SD)	8-week vs. baseline				24-week vs. baseline			
			Week 8 mean score (SD)	<i>d</i> (within-group)	Difference-in-differences MTPC vs. LDC		Week 24 mean score (SD)	<i>d</i> (within-group)	Difference-in-differences MTPC vs. LDC	
					<i>B</i> (SE)	<i>d</i>			<i>B</i> (SE)	<i>d</i>
PROMIS-Anx	MTPC	63.9 (6.9)	58.5 (6.6)	−0.80 ( <i>p</i> < 0.001*)	−2.44 (1.58)	—	58.1 (6.4)	−0.87 ( <i>p</i> < 0.001*)	−2.02 (1.63)	—
	LDC	61.9 (6.6)	58.9 (6.9)	−0.45 ( <i>p</i> = 0.02*)	<i>p</i> = 0.12		58.0 (6.7)	−0.59 ( <i>p</i> = 0.004*)	<i>p</i> = 0.22	0.30
PROMIS-Dep	MTPC	59.2 (8.6)	53.9 (7.9)	−0.59 ( <i>p</i> < 0.001*)	−2.94 (1.68)	—	54.4 (7.3)	−0.59 ( <i>p</i> < 0.001*)	0.20 (1.4)	0.02
	LDC	58.0 (8.6)	55.6 (8.0)	−0.29 ( <i>p</i> = 0.08)	<i>p</i> = 0.08		52.9 (7.8)	−0.62 ( <i>p</i> < 0.001*)	<i>p</i> = 0.91	
PSS	MTPC	25.0 (6.7)	19.9 (6.3)	−0.77 ( <i>p</i> < 0.001*)	−1.69 (1.28)	—	19.7 (6.0)	−0.81 ( <i>p</i> < 0.001*)	−1.15 (1.32)	—
	LDC	24.3 (6.6)	20.9 (6.3)	−0.53 ( <i>p</i> = 0.001*)	<i>p</i> = 0.19		20.2 (6.1)	−0.64 ( <i>p</i> < 0.001*)	<i>p</i> = 0.39	0.17
SECD	MTPC	6.1 (1.9)	6.7 (1.6)	0.30 ( <i>p</i> = 0.001*)	0.34 (0.34)	0.15	6.7 (1.5)	0.30 ( <i>p</i> = 0.002*)	0.40 (0.35)	0.21
	LDC	6.2 (2.0)	6.5 (1.7)	0.16 ( <i>p</i> = 0.32)	<i>p</i> = 0.31		6.4 (1.7)	0.11 ( <i>p</i> = 0.39)	<i>p</i> = 0.25	
FFMQ	MTPC	115.8 (18.2)	132.0 (16.9)	0.92 ( <i>p</i> < 0.001*)	12.46 (3.49)	0.57	135.2 (16.0)	1.11 ( <i>p</i> < 0.001*)	8.95 (3.53)	0.41
	LDC	115.6 (24.5)	119.4 (26.4)	0.15 ( <i>p</i> = 0.19)	<i>p</i> < 0.001*		126.0 (25.6)	0.42 ( <i>p</i> < 0.001*)	<i>p</i> = 0.01*	
SCS-SF	MTPC	2.6 (0.67)	3.1 (0.65)	0.85 ( <i>p</i> < 0.001*)	0.29 (0.13)	0.41	3.2 (0.62)	0.98 ( <i>p</i> < 0.001*)	0.25 (0.13)	0.36
	LDC	2.6 (0.73)	2.8 (0.69)	0.52 ( <i>p</i> = 0.01)	<i>p</i> = 0.03*		3.0 (0.67)	0.52 ( <i>p</i> < 0.001*)	<i>p</i> = 0.06	
PCQ	MTPC	23.5 (4.4)	25.3 (4.2)	0.41 ( <i>p</i> = 0.001*)	1.04 (0.92)	0.22	24.3 (4.0)	0.19 ( <i>p</i> = 0.14)	−0.76 (0.95)	—
	LDC	23.0 (4.4)	23.8 (4.3)	0.19 ( <i>p</i> = 0.29)	<i>p</i> = 0.26		24.6 (4.2)	0.38 ( <i>p</i> = 0.38)	<i>p</i> = 0.42	0.19
DERS	MTPC	76.1 (23.0)	60.2 (21.8)	−0.71 ( <i>p</i> < 0.001*)	−13.42 (4.28)	—	58.5 (20.4)	−0.80 ( <i>p</i> < 0.001*)	−7.73 (4.45)	—
	LDC	72.2 (23.2)	68.8 (21.8)	−0.15 ( <i>p</i> = 0.48)	<i>p</i> < 0.00*	0.58	61.4 (21.7)	−0.48 ( <i>p</i> = 0.006*)	<i>p</i> = 0.08	0.34
MAIA	MTPC	2.4 (0.73)	3.1 (0.64)	1.00 ( <i>p</i> < 0.001*)	0.55 (0.13)	0.75	3.1 (0.63)	1.00 ( <i>p</i> < 0.001*)	0.55 (0.14)	0.71
	LDC	2.5 (0.73)	2.6 (0.69)	0.14 ( <i>p</i> = 0.42)	<i>p</i> < 0.001*		2.6 (0.67)	0.28 ( <i>p</i> = 0.14)	<i>p</i> = 0.001*	

\*Significant after Hochberg FDR procedure, family-wise *p* < 0.05

^Significant before Hochberg FDR procedure

PROMIS-Anx, anxiety; PROMIS-Dep, depression; PSS, perceived stress; SECD, self-efficacy; FFMQ, mindfulness; SCS-SF, self-compassion; PCQ, perceived control; DERS, emotion regulation difficulty; MAIA, interoceptive awareness

Baseline: *n* = 92 (MTPC), *n* = 44 (LDC); week 8: *n* = 65 (MTPC), *n* = 33 (LDC); week 24: *n* = 53 (MTPC), *n* = 31 (LDC)

The 5-item Perceived Control Questionnaire (PCQ)<sup>89, 90</sup> asked participants to rate their sense of control over chronic disease from 1 (none) to 7 (total) ( $\alpha = 0.74$ ).<sup>89</sup>

## Home Practice and Resource Use

Participants recorded 18 daily practice/resource variables weekly until week 8 using either hand-delivered scantron (MTPC) or link to REDCap (LDC), including formal practice (e.g., body scan), informal practice (e.g., breathing space), and use of mindfulness resources (e.g., guided recordings) (Table 4).

## Adverse Events

We collected adverse event reports (AERs) during engagement phone calls, week 8, and week 24, using a combination of checklist and open-ended questions. Research staff

documented any AERs occurring during group sessions. We categorized AERs as serious or non-serious. An independent reviewer monitored AERs quarterly.

## Statistical Analysis

To evaluate randomization, we compared sociodemographic and baseline variables using *t* test, Fisher's exact, or  $\chi^2$  test.

To evaluate comparative effectiveness of MTPC versus LDC on action plan initiation, we used unadjusted bivariate logistic regression (*logit*) in a cross-sectional analysis to assess between-group changes in frequency of initiation. In intent-to-treat (ITT) analysis, we defined non-initiator status as participants who never endorsed greater than 4 or who did not complete the API survey at all by week 9. We powered the study based on expected differences in action plan initiation between study arms. Assuming  $\alpha = 0.05$ , a sample of 136 participants randomized 2:1 would have 80% power to detect

Table 4 Weekly Mindfulness Practice and Resource Use (Weeks 2–8) by Study Arm

Practice	MTPC		LDC		<i>t</i>	<i>p</i>
	<i>N</i>	Mean (SD)	<i>N</i>	Mean (SD)		
Formal practice (mean min/week)	78	190.9 (121.5)	36	53.0 (79.4)	6.2	<0.001*
Informal practice (mean count/week)	78	15.4 (11.5)	36	6.2 (8.2)	4.3	<0.001*
Formal (mean min/week)						
Body scan	78	87.6 (60.0)	36	18.4 (46.9)	6.1	<0.001*
Mindful sitting	77	38.4 (34.8)	36	13.5 (21.8)	3.9	<0.001*
Mindful movement	77	40.5 (46.1)	36	16.1 (26.2)	3.0	<0.005*
Kindness/compassion	76	26.0 (30.8)	36	5.1 (9.8)	4.0	<0.001*
Informal (mean count/week)						
Gratitude	77	2.3 (2.4)	36	1.0 (2.0)	2.8	<0.01*
Mindful eating	78	2.1 (1.9)	36	0.9 (1.7)	3.4	<0.005*
Body awareness	78	3.8 (2.3)	36	1.7 (2.4)	4.5	<0.001*
Informal kindness	77	2.2 (2.5)	36	0.5 (1.2)	3.8	<0.001*
Mindful walking	78	1.8 (1.8)	36	0.96 (1.7)	2.4	<0.05*
Breathing space	78	1.8 (2.1)	36	0.7 (1.6)	2.9	<0.01*
Self-compassion break	78	1.4 (1.8)	36	0.4 (0.9)	3.2	<0.01*
Resource use (mean count/week)						
Mindfulness/wellness centers	80	0.42 (0.5)	36	0.1 (0.26)	3.4	<0.001*
Online recordings	80	1.3 (1.8)	36	0.4 (0.77)	3.1	<0.005*
Mobile apps	80	0.9 (1.6)	36	0.7 (1.3)	0.7	0.50
MTPC recordings	80	2.8 (2.2)	36	0.1 (0.3)	7.5	<0.001*
Mindfulness books/articles	80	1.2 (1.7)	36	0.6 (1.1)	1.9	0.059
Spiritual centers	80	0.3 (1.0)	36	0.3 (0.97)	−0.1	0.96
Yoga centers	80	0.3 (1.0)	36	0.1 (0.28)	1.2	0.22

\*Significant after Hochberg FDR procedure, family-wise  $p < 0.05$

a 20% difference in API rates between arms. We used adjusted multivariable logistic regression models to determine other API predictors, in addition to study arm, using covariates where  $p < 0.05$  in bivariate analyses.

To evaluate health and self-regulation outcomes, we conducted a difference-in-differences, ITT, repeated measures analysis using linear mixed effects models<sup>91</sup> (*mixed*) to evaluate time  $\times$  treatment interaction from baseline to 8 weeks and from baseline to 24 weeks. Mixed effects models accounted for clustering of multiple observations within participants and handled missing data with maximum likelihood estimation. We computed contrasts of predictive margins<sup>92</sup> to test for significant within-group changes and difference-in-differences (between-group) estimates over time and to ease interpretation of results. Between-group and within-group effect size (Cohen's  $d$ ) was computed based on the predictive margins generated from the mixed models.

MTPC practice diaries were scanned and scored using Remark.<sup>93</sup> Average weekly practice was calculated by summing daily minutes/counts of all weekly diaries and dividing by the number of diaries completed. Missing diaries were recorded but not included in averages. We used  $t$  tests to compare MTPC with LDC.

## Multiple Comparisons Testing

The Benjamini-Hochberg false discovery rate (FDR) procedure,<sup>94</sup> which accounts for multiple comparisons, was implemented according to Cao et al.<sup>95</sup> in which a cutoff  $p$  value is determined for a family of similar variables and analyses (family-wise error rate = 0.05).<sup>96, 97</sup> Statistical significance was determined for the following analysis families: within- and

between-group health (family size  $n = 3$ ) and self-regulation ( $n = 6$ ) outcomes at both time points, formal practices ( $n = 4$ ), informal practices ( $n = 7$ ), and resource use ( $n = 7$ ).

Adverse events were analyzed using descriptive statistics and  $\chi^2$  test.

To prevent bias during analysis, an external statistical consultant (T.C.) oversaw the analysis plan and conduct and reviewed Stata MP 14.2<sup>98</sup> results and syntax. This study had a NIH-approved data safety monitoring plan with an independent monitor and was approved by the Cambridge Health Alliance (CHA) Institutional Review Board.

## RESULTS

### Participant Flow and Characteristics

Over 12 months, providers ( $n = 142$ ) referred 465 patients, 140 of whom attended an orientation and provided informed consent (Fig. 1). Randomized participants ( $N = 136$ ) were 65% female, 40.5 years old (SD = 12.5) on average, and 23% identified as non-white or mixed race. Participants most commonly had a type of anxiety disorder (36.0%) or depressive disorder (37.5%). Baseline characteristics, diagnoses, and scores on outcomes were similar between intervention and LDC arms (Table 1).

### Completion Rates

All randomized participants completed baseline surveys ( $n = 92$  [MTPC],  $n = 44$  [LDC]). Survey completion rates were similar across study arms: API survey by 9 weeks: MTPC = 74%, LDC = 75% ( $p = 0.89$ ); 8-week surveys: MTPC = 75%,

LDC = 75% ( $p = 1.0$ ); 24-week surveys: MTPC = 63%, LDC = 75% ( $p = 0.17$ ). Individuals with private insurance were overrepresented among completers of 8-week (51% vs. 27%,  $p = 0.01$ ) and API surveys (51.5% vs. 25.7%,  $p = 0.008$ ) versus non-completers.

## Attendance

Participants in the MTPC arm ( $n = 92$ ) attended an average of 6.3 of 9 (SD = 2.7) sessions: 74% ( $n = 68$ ) attended  $\geq 6$  sessions and 59% ( $n = 54$ ) attended the all-day session. PTSD diagnosis was overrepresented among participants who attended  $\geq 6$  sessions (15% vs. 3%,  $p = 0.016$ ).

## Action Plan Initiation

Of all randomized participants, 75% ( $n = 101$ ) made an action plan goal and reported level of initiation by week 9. The action plans related to mindfulness or self-care (45%), physical activity (31%), diet (8%), or other aspects impacting health or capacity for self-management of health condition (18%). There were no significant differences in action plan category between arms.

MTPC participants reported a higher rate of action plan initiation (API) compared with LDC (57.6% [ $n = 53$ ] vs. 31.8% [ $n = 14$ ], OR = 2.91,  $p = 0.006$ ). Baseline variables such as education and diagnosis were individually associated with API (Supplementary Fig. 1); however, the association between MTPC and API remained significant when holding these variables constant (Table 2).

Of participants who responded to the API survey ( $n = 101$ ), MTPC remained associated with higher API rates (77.9% [ $n = 53$  of 68] vs. 42.4% [ $n = 14$  of 33], OR = 4.8,  $p = 0.001$ ).

Dose of formal or informal practice was not significantly different for individuals with API versus non-initiators, but online mindfulness recording use was ( $n = 116$ , OR = 1.39 [1.03–1.88],  $p = 0.029$ ). Other practice and resource variables were not significantly associated with API.

## Health and Self-regulation Outcomes Analysis

MTPC was more effective than LDC for improving emotion regulation, interoceptive awareness, self-compassion, and mindfulness between baseline and 8 weeks and between baseline and 24 weeks (Table 3). There were no significant between-group changes in the scores for health outcomes at either time point.

Large within-group effect sizes ( $d > 0.8$ )<sup>99</sup> for MTPC were observed for anxiety, mindfulness, self-compassion, and interoceptive awareness at both 8 and 24 weeks, and for emotion regulation at 24 weeks. Moderate-to-large within-group effect sizes ( $0.5 < d < 0.79$ ) were observed within MTPC for depression and stress at 8 and 24 weeks and within LDC arm for self-compassion and stress at 8 and 24 weeks, in addition to anxiety and depression at 24 weeks.

## Mindfulness Practice and Community Resources

Most participants recorded practice and resource use: 85% ( $n = 78$ ) of MTPC and 82% ( $n = 36$ ) of LDC completed a weekly practice/resource diary (Table 4).

## Adverse Events

During the study, there were 18 AERs completed (14 [MTPC] vs. 4 [LDC],  $p = 0.32$ ). Of these, 14 were non-serious and two were related to the protocol. Of the two related to the protocol, one MTPC participant experienced a flashback during the day of silent practice, calmed himself, finished the session, and received consultation from group leaders. Another MTPC participant felt anxious during an open awareness practice, consulted with a group leader, and continued participating. There were no serious adverse events in the LDC arm.

Of the 4 serious events, one participant was diagnosed with cancer. Three individuals had psychiatric hospitalizations related to worsening of their underlying conditions (hypomanic episode, increased PTSD symptoms, suicidal ideation), but all took place  $> 2$  months after completing MTPC.

## DISCUSSION

Findings demonstrated MTPC was more effective in catalyzing health behavior action plan initiation (API) than LDC. API survey response rates ( $\sim 75\%$  in both arms) within 2 weeks of goal setting were similar to previous action planning studies.<sup>26, 73</sup>

MTPC was more effective for improving emotion regulation, interoceptive awareness, self-compassion, and mindfulness at 8 weeks compared with LDC. These improvements in self-regulation mechanisms may contribute to the effectiveness of mindfulness meditation.<sup>32</sup> Follow-up studies in an adequately powered sample are needed to answer whether improvements in self-regulation mechanisms mediate the impact of mindfulness training on self-management behavior change in primary care patients.<sup>29</sup>

Trauma is associated with impairment of self-regulation.<sup>100, 101</sup> A trauma-sensitive approach<sup>102, 103</sup> is increasingly recognized as essential for providing MBPs safely in clinical settings.<sup>56, 58, 104, 105</sup> PTSD diagnosis was non-significantly more common among MTPC ( $p = 0.1$ ), and unexpectedly, PTSD was a strong predictor of API, which supports the trauma-informed<sup>106</sup> nature of MTPC.

By combining access to standard mental health (psychopharmacology and psychotherapy) and mindfulness resources with biweekly encouragement calls from staff, LDC participants received a gradual 6-month self-led training in mindfulness. While this LDC program may

not be as effective at catalyzing behavior change or as immediately impactful on mental health as MTPC, the positive changes in LDC at 24 weeks suggest a program offering access to high-quality mental health treatment in conjunction with ongoing encouragement calls for mindfulness practice with digital and community resources, and the potential to join an intensive mindfulness group in the future may moderately reduce stress, depression, and anxiety. The modest positive impact of the LDC program on mental health outcomes at 24 weeks warrants future study of low-dose mindfulness interventions combined with standard mental health care.

This study had several limitations. The use of an enhanced standard care comparator rather than a purely passive or well-defined active control led to variability in the level of mental health care that the LDC received, limiting conclusions about secondary health outcomes. A comparison with MBCT or cognitive-behavioral therapy, which are commonly integrated into clinical settings for depression, might elucidate how MTPC compares with other MBPs and well-defined non-mindfulness interventions in its impact on chronic disease self-management behavior change and mental health. Finally, the API protocol relies on self-report assessment of API. Future studies will compare self-reported behavior changes with experience sampling and ecological activity tracking to objectively verify API and health behavior change.

This study demonstrates that fully integrating MTPC into the health care system as an insurance-reimbursable, referral-based treatment is effective in facilitating health behavior change for primary care patients with a variety of chronic health conditions. MTPC's unique combination of whole-person orientation<sup>107</sup> with a focus on self-regulation and self-management skills within a group-based format makes it a promising treatment that may be associated with less stigma compared with traditional mental health treatment.<sup>108–110</sup>

MTPC facilitates self-management of chronic diseases and represents a compelling model for dissemination within primary care patient-centered medical homes.

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**Funding Information** This study was made possible through grant funding provided by a cooperative agreement supported by the NIH Common Fund Science of Behavior Change Initiative and the National Center for Complementary and Integrative Health: "Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications" (UH2AT009145) (PI: Loucks, Project PI: Schuman-Olivier). Additional funding was provided by the Arthur Vining Davis Foundations (PI: Schuman-Olivier), the Arnold P. Gold Foundation (PI: Schuman-Olivier), as well as with funding from Cambridge Health Alliance.

**Data Availability** The authors will make all data available upon request.

### Compliance with Ethical Standards:

This study had a NIH-approved data safety monitoring plan with an independent monitor and was approved by the Cambridge Health Alliance (CHA) Institutional Review Board and procedures followed all provisions of the Declaration of Helsinki.

**Conflict of Interest:** The authors declare that they do not have a conflict of interest.

**Publisher's Note** Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

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