Mindfulness-Based Cognitive Therapy Reduces Symptoms of Depression in People With a Traumatic Brain Injury: Results From a Randomized Controlled Trial

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Objective: We sought to determine if we could reduce symptoms of depression in individuals with a traumatic brain injury using mindfulness-based cognitive therapy. **Setting:** The study was conducted in a community setting. **Participants:** We enrolled adults with symptoms of depression after a traumatic brain injury. **Design:** We conducted a randomized controlled trial; participants were randomized to the 10-week mindfulness-based cognitive therapy intervention arm or to the wait-list control arm. **Main Measures:** The primary outcome measure was symptoms of depression using the Beck Depression Inventory-II. **Results:** The parallel group analysis revealed a greater reduction in Beck Depression Inventory-II scores for the intervention group (6.63, $n = 38$,) than the control group (2.13, $n = 38$, $P = .029$). A medium effect size was observed (Cohen $d = 0.56$). The improvement in Beck Depression Inventory-II scores was maintained at the 3-month follow-up. **Conclusion:** These results are consistent with those of other researchers that use mindfulness-based cognitive therapy to reduce symptoms of depression and suggest that further work to replicate these findings and improve upon the efficacy of the intervention is warranted.
Key words: *depression*, *mindfulness*, *randomized controlled trial*, *traumatic brain injury*

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Many individuals with a traumatic brain injury (TBI) have some residual physical and/or psychological impairments,[1–3] even among those believed to have had a good recovery.[4,5] These impairments

may increase the risk of developing symptoms of depression.[6–8] Depression is a significant understudied chronic problem for people with mild TBI[9,10] and is possibly the best predictor of psychosocial adjustment postinjury,[11] even 10 years postinjury.[12]

However, the presence of depression may also not be recognized, especially among people with mild TBI.[9,10] Furthermore, there is a paucity of intervention data based on randomized controlled trials. Research on pharmacological and nonpharmacological treatment of post-TBI depression may lack sufficient rigor to establish best practices.[13–15]

Mindfulness-based cognitive therapy (MBCT), developed by Segal and colleagues,[16] is a relatively new therapeutic approach rooted in cognitive behavioral therapy and mindfulness-based stress reduction.[17] Individuals are taught, by developing a greater awareness of thoughts and feelings, to decenter from problematic thoughts by viewing them as mental events rather than as accurate reflections of reality. The approach has been consistently effective in preventing relapse in individuals with recurrent depression[16,18–20] and is a recommended therapy for relapse prevention in the United Kingdom.[21]

The potential of mindfulness-based interventions in reducing symptoms of depression, preventing relapse, and the relative cost advantage provided by the group format led us to examine the feasibility and potential effect of a modified MBCT program for individuals with a TBI in 2 pilot studies.[22,23] In the first study, we used a 12-week intervention primarily focused on mindfulness-based stress reduction. In the second study, we introduced a cognitive behavioral therapy component and reduced the intervention to 8 weeks. In both studies, we found improvements in health status and depression symptoms,[22,23] which were maintained at 1-year follow-up.[24] The results of the pilot studies were very encouraging but the absence of control groups limit the inferences we can make about the intervention. Hence, the purpose of this study was to examine the efficacy of the intervention using randomized-controlled-trial methodology. We hypothesized that participants who were given the intervention would experience greater reduction in symptoms of depression than participants in the control group. We also expected that the improvements noted after the intervention would be maintained at the 3-month follow-up.

METHODS

Design

We used the first year of the study to train 10 clinicians to deliver the intervention. The training program comprised multiple components including development of personal meditation practice, professional training, and a practice trial with "healthy" participants (eg, family, friends, colleagues). This process has been described elsewhere.[25] One pair of facilitators was selected to provide the intervention at each site.

In year 2, we conducted a multisite, parallel group controlled trial with balanced randomization (1:1) at 3 sites. After initial assessments, participants were randomized to treatment or control groups. Minimization was used to ensure balance between groups on symptoms of depression (ie, Beck Depression Inventory-II [BDI-II] score), age, and sex. The randomization process was done by a statistician, independently of the clinicians and site investigators. Participants in the treatment arm took part in the 10-week intervention while those in the control arm continued as they normally would. At the end of the intervention, assessments were completed by both groups, and then participants in the control arm were offered the intervention. Finally, 3 months after completing their respective mindfulness programs, participants completed a follow-up assessment.

Participants and setting

Participants were sought from local sources including: outpatient programs/clinics for individuals with neurological injury and rehabilitation, newspaper and television advertisements, a brain injury association, social events related to treatment of brain injury, as well as through appeals to family physicians, psychologists, chiropractors, and nurse practitioners at 3 sites (Ottawa, Toronto, Thunder Bay) in Ontario, Canada.

Inclusion criteria were: evidence of depression (BDI-II score of 16 or higher), ability to speak and read English, age 18 or over, and having completed all standard treatments for the injury. A TBI was operationalized as

> damage to living brain tissue caused by an external, mechanical force. TBI is usually characterized by a period of altered consciousness (amnesia or coma) that can be very brief (minutes) or very long (months/indefinitely)... . The term does not include brain injuries that are caused by insufficient blood supply, toxic substances, malignancy, disease-producing organisms, congenital disorders, birth trauma or degenerative processes.[26]

Given the variety of recruitment sources, and time since the TBI, confirmation through medical records was achieved in all but 12 participants. Exclusion criteria included: presence of unusual psychological processes such as psychosis, suicidal ideation, and substance abuse, or major concurrent mental illness. These exclusion criteria were examined by the study Research Coordinator using baseline data, and cutoff points provided in advance by the study clinicians; none of the participants met the exclusion criteria. Anxiety is frequently found in people with TBI and was not an exclusion criterion. Participants on antidepressants were allowed to participate in the trial and were not required to make

changes to their usage patterns but none were receiving other forms of treatment.

Intervention

The curriculum of the intervention uses elements from the mindfulness-based stress reduction program,[17] and the manual for MBCT by Segal and colleagues[16] and was standardized across sites. Topics included meditation techniques, breathing exercises, gentle yoga, awareness of thoughts and feelings, acceptance, and staying in the present. We customized the intervention to address issues associated with TBI (eg, problems with attention, concentration, memory, fatigue). We increased the duration of the intervention to 10 weeks (as opposed to the usual 8-week MBCT), with 1½-hour weekly sessions and a recommended daily meditation home practice for 20 to 30 minutes. We shortened the duration of the meditation sessions and included frequent reviews. Further adaptations included simplified language, the use of repetition and visual aids to help reinforce concepts. More attention was paid to fostering learning conditions to encourage an environment of trust and nonjudgment. Connections between learning activities were made more explicit. For example, participants recorded their observations and questions on "new learning" forms to encourage deeper reflection on usual modes of behavior and habits of mind in day-to-day activities. Participants were supplied with handouts from each session and received the book The Mindful Way through Depression: Freeing Yourself from Chronic Unhappiness.[27] Participants were not required to read it but were instructed to use the accompanying CD to guide meditations.

Measures

Demographic information included: age, sex, marital status, employment status, education, and medications. Depression symptoms were measured with the BDI-II, a 21-item tool to assess depression intensity,[28] the Patient Health Questionnaire-9 (PHQ-9), which is based on the PRIME-MD diagnostic instrument for common mental disorders,[29,30] and the SCL-90-R, a 90 item self-report questionnaire designed to measure 9 primary symptom dimensions including depression.[31] Higher scores on all scales indicate more symptoms of depression. Participants' mindfulness was determined with the Philadelphia Mindfulness Scale (PHLMS)[32] and the Toronto Mindfulness Scale (TMS).[33] The PHLMS assesses present-moment awareness and acceptance.[32] The TMS is a self-reported mindfulness measure with 2 subscales (Curiosity and Decentering).[33] The TMS was only collected for those in the intervention arm at pre- and postassessments.

Sample size

Power estimates were obtained using the method of D'Amico, Neilands, and Zambarano.[34] Our estimates of the pre- and posttest means and standard deviations as well as the correlations between pre- and posttest scores were taken from the two pilot studies with individuals who had a TBI.[22,23] Using those figures and assuming 44 participants per group, we obtained the following estimates of power to detect a 5-point difference in change scores between the groups: BDI-II Overall, 0.80; BDI-II Cognitive-Affective: 0.99; BDI-II Somatic: 0.99. Given a potential dropout rate of up to 30% a target of 18 to 21 individuals with TBI per arm (ie, 36 to 42 per site) was estimated to provide sufficient statistical power.

Statistical analyses

Descriptive statistics are presented for participants' characteristics. The primary endpoint was reduction in symptoms of depression post-10-week intervention as measured with the BDI-II. One difficult (a priori) decision was to decide on an "intent-to-treat" approach or a "per protocol" approach. We selected a compromise, which was to do a complete case analysis that included all participants who provided outcome data regardless of their attendance to the weekly sessions. We believe this provides a realistic estimate of the actual effect of the intervention, if it were offered in a typical clinical setting. Using a parallel group approach at the postintervention stage, before control participants crossed-over to the intervention arm, we performed analyses of covariance with the postscore as the outcome and the preintervention score as the covariate. Given the potential for site differences, we examined the site-by-group interaction to determine if the treatment effect varied by site.

To quantify the effect size, we calculated Cohen *d* on change scores (ie, mean change in treatment group minus mean change in control group divided by the pooled standard deviation of the change scores). For all participants completing the intervention (including controls who crossed over), secondary analyses employed repeated design analysis of variance (2 groups × 3 time points) to examine if reductions in depression symptoms were maintained at the follow-up assessment. Note that for follow-up analyses, the control groups' original postscores (before crossing over) were used as baseline scores; 2 other sets of data were collected: postintervention and follow-up.

RESULTS

CONSORT statement

The study flow diagram based on the CONSORT statement[35] is presented in Figure 1. One hundred nineteen participants were assessed (between May 2010 and

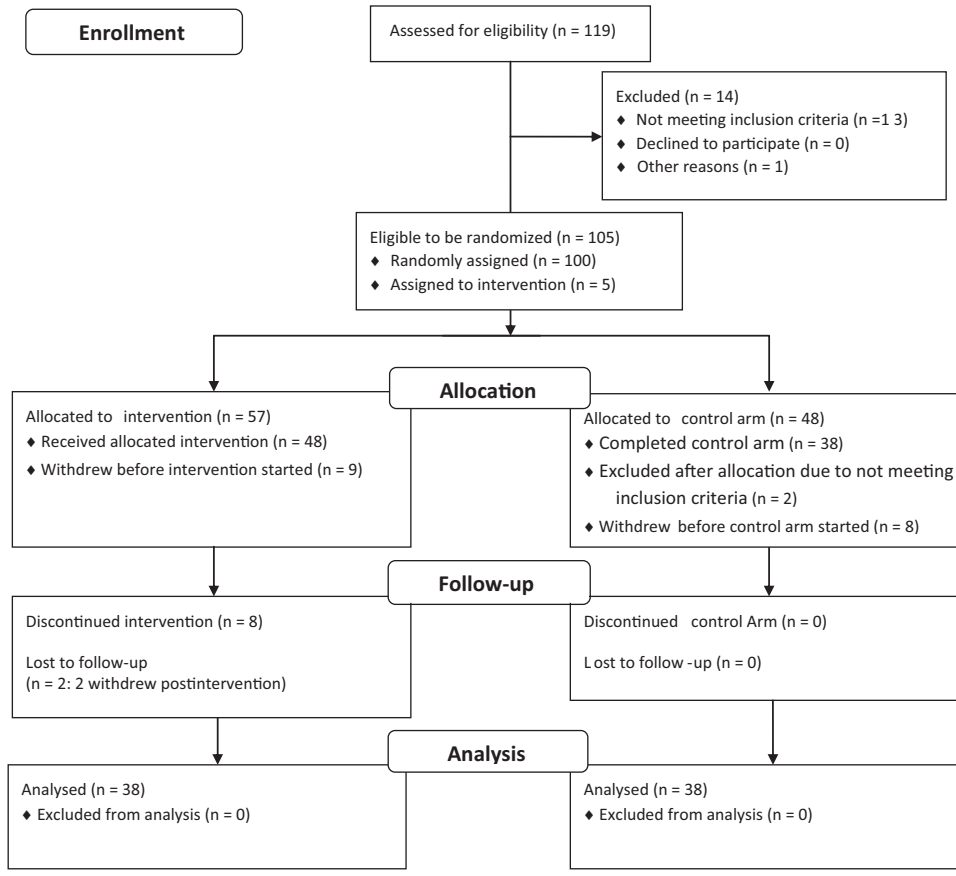

Figure 1. MBCT CONSORT flow diagram–parallel analysis.

January 2011) and 14 were excluded (13 did not meet eligibility criteria). Of the 105 eligible participants, 100 were randomized into either treatment ($N = 52$) or control arms ($N = 48$). Given low recruitment numbers for the last wave at 1 of the 3 sites, 5 eligible participants were placed directly into the treatment arm. However, neither the site investigator nor the group facilitators had met these participants, presumably lowering the risk of bias.

Therefore, the treatment and control arms began with 57 and 48 participants respectively. A total of 29 participants (28%) did not complete the study–17 prior to their respective arm starting (treatment = 9, control = 8) and 8 participants during the mindfulness program. Reasons for not completing the study included moving, other commitments, scheduling issues, or not enjoying the program. Two control arm participants were excluded after allocation due to not meeting inclusion criteria. An additional 2 treatment participants were lost to follow-up and did not complete the postassessment and 3-month assessment. Thus, for our analysis, we had 38 participants in the treatment arm and 38 participants in the control arm. We formally compared participant age, sex, and baseline BDI-II scores by completion status; none of the group differences achieved statistical significance (see Table 1). The characteristics of participants for whom we had outcome data are presented in Table 2. Regarding medication use, 13 participants (34%) of the intervention group were taking antidepressants at baseline, and this number remained unchanged postintervention. Fourteen control participants (37%) were taking antidepressants at baseline; 6 of them discontinued antidepressant usage during the trial.

Change in symptoms of depression

On the basis of the parallel group analysis the reduction in BDI-II scores was found to be greater for the intervention group than the control group (see Table 3). A medium-effect size was observed for the BDI-II overall and subscales. However, we did not find such an improvement on the PHQ-9 and SCL-90R Depression scales. The effect of the intervention on depression measures was not dependent on the site (none of the group by site interactions approached statistical significance).

Change in mindfulness

The direction of the change in mindfulness was in the hypothesized direction but did not achieve

TABLE 1 *Comparison of key screening characteristics for participants and noncompleters*[a]

	Participants		Noncompleters		Comparison	
	N		*N*		t/χ^2 (*df*)[b]	*P*
Age, y	75	46.77 (13.37)	27	49.57 (12.55)	− 0.95 (100)	.346
Sex (male)	76	42 (55%)	29	13 (45%)	0.91 (1)	.338
BDI-II (baseline)	76	26.3 (9.42)	29	29.45 (10.39)	− 1.49 (103)	.140

[a]Data are means (SD) or numbers (%).
[b]*t*-test comparison of group means; χ^2 comparison for proportions.
Abbreviation: BDI-II, Beck Depression Inventory-II.

TABLE 2 *Baseline characteristics by group assignment*[a]

	Treatment (*n* = 38)	Control (*n* = 38)
Age, mean (SD)	47.10 (12.03)	45.81 (14.80)
Male sex	19 (50)	23 (60)
Years since TBI, mean (SD)	4.50 (4.14)	4.00 (3.47)
Marital status		
Married or common law	22 (58)	17 (45)
Single	10 (26)	12 (31)
Separated/ divorced/ widowed	5 (13)	9 (24)
Unknown	1 (3)	0 (0)
Employment status		
Full-time	8 (21)	8 (21)
Part-time	6 (16)	1 (3)
Unemployed	8 (21)	10 (26)
Home maker/ volunteer	4 (11)	0 (0)
Retired	4 (11)	6 (16)
Other	8 (21)	13 (34)
Living situation		
Family	25 (66)	24 (63)
Alone	9 (24)	10 (26)
Friends or other	4 (10)	4 (11)
Education		
Elementary	1 (3)	2 (5)
Some secondary	4 (11)	4 (11)
Completed secondary	12 (32)	7 (18)
Some postsecondary	4 (11)	6 (16)
Completed postsecondary	17 (45)	19 (50)
Any antidepressant medication	13 (34)	14 (37)

Abbreviation: TBI, traumatic brain injury.
[a]Data are number (%) unless otherwise stated.

statistical significance for either the PHLMS or TMS scales. Small effect sizes were observed for both the PHLMS-Acceptance and TMS-Decentering subscales. The results did not vary by site (see Table 4).

Follow-up analyses of depression measures

To examine whether the reduction in symptoms of depression was sustained at follow-up, we examined all cases–both treatment participants and 22 controls who crossed-over and completed the MBCT intervention. Approximately 84% and 73%, respectively, of participants originally allocated to the treatment and control arms completed a follow-up assessment. For both groups, the reduction in pre- and postsymptoms of depression is present across all measures (see Table 5). Furthermore, these reductions appear to be maintained at follow-up. There was no difference by original group assignment (treatment vs control). However, a statistically significant group by time effect was observed for the PHQ-9.

DISCUSSION

To our knowledge, this is the first randomized controlled trial to examine the impact of MBCT on symptoms of depression in people with a TBI. Our results suggest that our mindfulness intervention reduces symptoms of depression as measured by the BDI-II. Furthermore, this reduction was maintained at the 3-month follow-up. These results are consistent with other research using MBCT to prevent depression relapse[16,18–20] and also for other clinical populations such as people with anxiety and cancer.[36,37]

However, we did not find a reduction of symptoms of depression using the 2 secondary scales. This is somewhat puzzling as our previous work always demonstrated good convergence of results on different scales. One possibility is that PHQ scores were lower at baseline for the intervention group (minimization to balance groups was based on BDI-II scores, not PHQ scores), and this may have limited the room for

TABLE 3 *Parallel comparisons—symptoms of depression*

	Descriptive statistics												Parallel analysis comparison		
	Site 1: Ottawa, mean (SD)			Site 2: Thunder Bay, mean (SD)			Site 3: Toronto, mean (SD)			All sites, mean (SD)					
	N	Pre	Post	*N*	Pre	Post	*N*	Pre	Post	*N*	Pre	Post	Group *F* (*P*)	Group × Site *F* (*P*)	Effect size, Cohen *d*
BDI: Overall															
Treatment	16	24.75 (7.94)	17.88 (7.39)	9	21.11 (2.67)	9.56 (7.20)	13	29.38 (9.39)	26.46 (9.63)	38	25.47 (8.12)	18.84 (10.26)	4.99 (.029)	1.39 (.256)	0.56
Control	13	25.92 (9.48)	24.38 (12.07)	3	23.33 (5.86)	20.33 (9.02)	22	28.36 (11.79)	26.00 (14.42)	38	27.13 (10.61)	25.00 (13.12)			
BDI: Cognitive															
Treatment	16	7.50 (4.38)	4.25 (2.65)	9	6.00 (1.94)	3.00 (2.74)	13	9.85 (5.01)	8.54 (4.50)	38	7.95 (4.36)	5.42 (4.06)	3.66 (.060)	1.17 (.315)	0.52
Control	13	7.15 (4.49)	6.00 (5.34)	3	7.33 (2.52)	6.67 (5.03)	22	7.91 (4.77)	7.05 (5.52)	38	7.61 (4.46)	6.66 (5.30)			
BDI: Somatic															
Treatment	16	17.25 (5.20)	13.63 (6.12)	9	15.11 (2.76)	6.56 (4.82)	13	19.54 (5.38)	17.92 (6.81)	38	17.53 (4.99)	13.42 (7.34)	4.42 (.039)	1.22 (.301)	0.49
Control	13	18.77 (5.56)	18.38 (7.81)	3	16.00 (3.46)	13.67 (4.16)	22	20.45 (8.40)	18.95 (9.69)	38	19.53 (7.24)	18.34 (8.72)			
PHQ: Overall															
Treatment	14	10.50 (5.19)	9.79 (5.52)	9	9.44 (4.56)	6.22 (3.53)	13	14.08 (4.39)	13.38 (6.05)	36	11.53 (5.03)	10.19 (5.88)	0.55 (.461)	0.72 (.489)	0.02
Control	13	13.38 (5.87)	12.54 (6.01)	3	13.00 (7.81)	12.00 (7.94)	22	14.64 (6.98)	13.14 (7.29)	38	14.08 (6.52)	12.84 (6.74)			
SCL-90R: Depression subscale															
Treatment	16	1.53 (0.89)	1.18 (0.80)	9	1.22 (0.52)	0.64 (0.45)	13	2.01 (0.72)	2.08 (0.74)	38	1.62 (0.80)	1.36 (0.90)	0.13 (.715)	1.79 (.174)	0.02
Control	13	1.56 (0.86)	1.29 (0.98)	3	1.51 (0.98)	1.30 (1.01)	21	1.88 (1.00)	1.64 (1.10)	37	1.74 (0.94)	1.49 (1.04)			

Abbreviations: BDI, Beck Depression Inventory; PHQ, Patient Health Questionnaire.

TABLE 4 *Parallel comparisons—mindfulness scores*

	Descriptive Statistics												Parallel Analyses Comparison		
	Site 1: Ottawa, mean (SD)			Site 2: Thunder Bay, mean (SD)			Site 3: Toronto, mean (SD)			All sites, mean (SD)					
	N	Pre	Post	*N*	Pre	Post	*N*	Pre	Post	*N*	Pre	Post	Group *F* (*P*)	Group × Site *F* (*P*)	Effect Size, Cohen *d*
Philadelphia Mindfulness Scale															
Awareness															
Treatment	14	34.29 (6.57)	35.29 (6.90)	8	32.13 (7.40)	34.88 (6.77)	9	34.67 (6.52)	35.00 (4.24)	31	33.84 (6.62)	35.10 (6.01)	0.89 (.348)	0.71 (.497)	0.16
Control	12	33.33 (3.42)	35.25 (4.27)	3	38.33 (4.93)	35.00 (4.58)	21	33.71 (7.16)	33.86 (5.82)	36	33.97 (6.02)	34.42 (5.17)			
Acceptance															
Treatment	14	29.07 (7.37)	32.00 (7.34)	8	28.88 (6.24)	32.38 (8.14)	9	26.78 (8.96)	28.78 (6.92)	31	28.35 (7.42)	31.16 (7.35)	0.61 (.439)	0.93 (.401)	0.27
Control	12	29.33 (5.38)	33.50 (6.96)	3	23.00 (3.00)	25.67 (5.86)	21	28.19 (8.68)	27.57 (7.35)	36	28.14 (7.45)	29.39 (7.55)			
													Paired Analyses Comparison		
													Time	Time × Site	
Toronto Mindfulness Scale															
Curiosity															
Treatment	2	19.00 (4.24)	10.50 (3.54)	5	13.40 (5.68)	17.40 (3.91)	8	13.38 (6.86)	12.00 (8.12)	15	14.13 (6.16)	13.60 (6.86)	0.44 (.521)	1.23 (.327)	−0.08
Decentering															
Treatment	2	13.00 (4.24)	10.50 (3.54)	5	15.40 (7.23)	19.20 (2.95)	8	11.25 (4.53)	12.63 (8.18)	15	12.87 (5.50)	14.53 (7.00)	0.16 (.692)	0.55 (.589)	0.26

TABLE 5 *Change over time in symptoms of depression for all participants who completed the intervention (control group data acquired after crossing over to treatment arm)*

		Descriptive statistics, mean (SD)			Type III tests of fixed effects		
	N	Pre	Post	Follow-up	Group *F* (*P*)	Time *F* (*P*)	Group × Time *F* (*P*)
BDI: Overall							
Treatment	32	25.72 (8.37)	18.16 (10.08)	16.47 (10.68)			
Control	16	22.69 (12.45)	14.69 (12.31)	15.69 (12.74)			
Total	48	24.71 (9.88)	17.00 (10.87)	16.21 (11.28)	0.63 (.430)	37.71 (<.001)	0.93 (.399)
BDI: Cognitive							
Treatment	32	7.81 (4.29)	5.22 (4.25)	5.19 (4.99)			
Control	16	6.19 (5.27)	4.00 (4.24)	4.94 (5.00)			
Total	48	7.27 (4.65)	4.81 (4.24)	5.10 (4.94)	0.60 (.444)	18.71 (<.001)	1.45 (.240)
BDI: Somatic							
Treatment	32	17.91 (5.22)	12.94 (6.93)	11.28 (6.95)			
Control	16	16.50 (8.25)	10.69 (8.39)	10.75 (8.19)			
Total	48	17.44 (6.34)	12.19 (7.44)	11.10 (7.30)	0.51 (.480)	35.71 (<.001)	0.58 (.561)
PHQ: Overall							
Treatment	30	11.47 (5.35)	10.10 (6.10)	8.90 (6.30)			
Control	16	12.00 (6.36)	7.56 (6.35)	8.44 (6.86)			
Total	46	11.65 (5.66)	9.22 (6.24)	8.74 (6.43)	0.21 (.646)	17.08 (<.001)	3.52 (.034)
SCL-90R: Depression subscale							
Treatment	31	1.55 (0.81)	1.24 (0.88)	1.17 (0.93)			
Control	15	1.34 (1.01)	1.01 (0.98)	0.99 (0.99)			
Total	46	1.48 (0.87)	1.16 (0.91)	1.11 (0.94)	0.59 (.446)	10.44 (<.001)	0.04 (.962)

Abbreviations: BDI, Beck Depression Inventory; PHQ, Patient Health Questionnaire.

improvement. The Depression subscale of the SCL-90 may be less responsive than the BDI-II. In our most recent pilot study, we also had a smaller effect size with the SCL-90 than for the BDI-II. The 3-month patterns were, however, similar across groups.

Our results were not dependent on the site where the trial was conducted, suggesting that our efforts to train the facilitators were successful. But, we could not demonstrate an increase in mindfulness. This may indicate that some nonspecific therapist effect was at play, but it is also possible that the scales we used are not as responsive to change as the BDI-II. We are not aware of studies demonstrating responsiveness to change with the PHLMS. For the TMS, Lau and colleagues[33] found that the change in decentering accounted for less than 10% of the change in their outcome variable, and that the change in curiosity was not related to the outcome variables. Similarly, the data we obtained were in the hypothesized direction for the Decentering subscale but the effect size was nearly zero for the Curiosity subscale. Ultimately, this lack in responsiveness may reflect difficulties in capturing the true facets of mindfulness.[38] Another possibility is that the scales measure stable traits rather than states. Given that individuals who focus on their impairments are at greater risk of experiencing symptoms of depression,[39] it is reasonable to surmise that the intervention's goal to help participants decenter from problematic thoughts may have succeeded. Nonetheless, further examination of the issue is warranted.

This study has important limitations. First, it is not possible to generalize our findings to the general population of people with a TBI. Our participants self-selected into the study, 5 were assigned to the intervention without randomization, and many did not complete the intervention. Although we found no statistical differences between completers and dropouts, the dropout rate was considerable but this may not be entirely surprising given that we did not have a "run-in" period. Some participants did not attend all 10 sessions, and we have no clear indication of the participants' adherence to the recommended home exercises. Ultimately, some individuals may have "responded" better to the intervention, and further work to identify if there is such a group of responders would be fruitful. As with any study of this nature, the participants were not blind to the intervention, however the research assistants collecting information were blind to group allocation. Finally, our control group was a "wait-list" control group. Choosing a more comparable control condition (eg, attention control group) would be the logical next step.

Our results await replication and should encourage further research. Specifically, it may be desirable to (1) examine what characteristics may predict a better response to the intervention, (2) investigate further the issue of sensitivity to change across instruments, (3) investigate approaches to reduce the drop-out rate and to increase adherence to the treatment protocol, (4) further investigate options to improve the intervention's efficacy in relation to the individual domains of the BDI-II (affective, cognitive, and somatic), and (5) further test the intervention by contrasting it to more comparable control groups.

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