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Mindfulness and Tai Chi for Sleep, Fatigue, and Pain in Distressed People After Cancer Treatment: A Partially Randomized Patient-Preference Comparative Effectiveness Trial

Yan Ma, MD, MPH[1]; Linda E. Carlson, PhD[2]; Jennifer M. Jones, PhD[3]; Oluwaseyi A. Lawal, PhD[2]; Devesh Oberoi, MD, PhD[2]; Katherine-Ann Piedalue, BSc[2]; Daniel Santa Mina, PhD[3]; Michael Speca, PhD[2]; and Peter M. Wayne, PhD[1]

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ABSTRACT

PURPOSE Sleep, fatigue, and pain are common symptoms in cancer survivors. Mindfulness-based cancer recovery (MBCR) and Tai Chi/Qigong (TCQ) are beneficial for these conditions, but have not been studied together. The Mindfulness and Tai Chi for Cancer Health (MATCH) study was designed to incorporate innovative design features, including patient choice, while evaluating two interventions for distressed cancer survivors with predefined secondary outcomes, including sleep, fatigue, and pain.

METHODS Participants chose one of the two interventions or chose to be randomly assigned into either intervention, then were further randomly assigned into immediate intervention or waitlist groups. We evaluated the efficacy of MBCR and TCQ, whether participants' choices affected intervention effects, and correlations among changes in sleep, fatigue, and pain.

RESULTS Participants (N = 587) were on average 60.7 years, with multiple types and stages of cancer. At postintervention, compared with waitlist controls, the TCQ group had an average improvement of 1.9 points on the sleep quality scale, which remained statistically significant compared with controls after adjustment for age, sex, cancer stage, and preference ($P = .004$). Compared with waitlist controls, both MBCR and TCQ groups had significantly improved fatigue with mean improvements of 3.66 and 3.42 points, respectively (MBCR: $P = .036$. TCQ: $P = .043$) and over 1 point of change on pain interference (MBCR: $P = .029$. TCQ: $P = .002$). MBCR and TCQ did not differ from one another. Preference status did not affect outcomes. Significant correlations were observed among changes in sleep, fatigue, and pain interference, suggesting mild to moderate associations.

CONCLUSION Compared with waitlist controls, MBCR and TCQ both improved fatigue and pain interference at post-intervention, and TCQ also improved sleep quality. Correlations across outcomes highlight the importance of addressing clusters of cancer symptoms within a whole-person health framework.

ACCOMPANYING CONTENT

- Appendix
- Graphical Abstract
- Data Sharing Statement
- Protocol

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INTRODUCTION

The prevalence of people living long term after cancer treatment is high and growing. Unfortunately, many people face chronic morbidities related to disease pathology or cancer treatment side effects, with significant impact on function and quality of life. Among the most common and impactful complaints are sleep disturbances, fatigue, and pain,[1-3] which are also frequently reported as a symptom cluster by people after treatment.[4-6]

Sleep is crucial for people with cancer and is a key bio-behavioral target.[7-9] Up to 95% of people with cancer report sleep disturbances/disorders at some point during diagnosis, treatment, and after 10 years of survivorship.[10-12] Cancer-related fatigue is prevalent and distressing, present in over one third of cancer survivors up to 6 years after treatment, and associated with high levels of disability.[13,14] Pain is another prevalent and debilitating symptom reported by over 70% of cancer survivors,[15] affecting physical health, psychological health, quality of life, and everyday activities.[16-18]

CONTEXT

Key Objective

This study investigated the effects of choosing or being randomly assigned to mindfulness-based cancer recovery (MBCR) or Tai Chi/Qigong (TCQ) programs on sleep, fatigue, and pain in a broad range of distressed people after cancer treatment.

Knowledge Generated

Both MBCR and TCQ were effective for improving this symptom cluster compared with a waitlist control and whether people chose a specific group or were randomly assigned did not affect the magnitude of changes. MBCR significantly improved fatigue and pain interference, and TCQ significantly improved sleep, fatigue, and pain interference.

Relevance *(S.B. Wheeler)*

Equivalent and positive benefits of these two interventions suggest people with cancer may follow their preference and receive similar benefit in terms of sleep, pain, and fatigue, illustrating the promise of mind-body interventions in addressing multiple symptoms impacting cancer survivors.*

*Relevance section written by *JCO* Associate Editor Stephanie B. Wheeler, PhD, MPH.

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Collectively, although sleep disturbances, fatigue, and pain are the most common symptoms in people living with cancer,[19-21] the nature of their interdependence and how the components of this symptom cluster respond to various interventions remain unclear.

Among integrative oncology approaches, mindfulness-based cancer recovery (MBCR) and Tai Chi/Qigong (TCQ) are increasingly popular, endorsed by current guidelines,[22] and show promise for managing multiple symptoms in people with cancer.[10,22-24] MBCR is a modification of mindfulness-based stress reduction (MBSR) and modified by our group for people with cancer.[24-27] Recent clinical trials and reviews support the benefits of MBCR in improving physical, emotional, and spiritual health and well-being for individuals living with cancer.[22,23,28-30] Emerging evidence also supports that Tai Chi and Qigong improve multiple symptoms in cancer survivors.[31,32] Tai Chi and Qigong share a common history, both incorporate elements of slow, gentle movement, awareness and regulation of breathing, intentional direction of attention, imagery, and sensation.[32] Therefore, Tai Chi and Qigong are often grouped together and referred to here as TCQ.[32-35] Despite existing evidence for the benefits of MBCR and TCQ in cancer care, to our knowledge, no studies have evaluated them together in a large and diverse population of cancer survivors.[31,35,36]

Although randomized controlled trials (RCTs) remain the gold standard for determining efficacy in clinical research, there is growing interest in preference-based trials where participants are allowed to choose among intervention options, mirroring the real world. This is especially the case when blinding (or masking) the interventions is challenging and there is a strong chance that participants may prefer a given intervention.[37-39] The use of preference-based methodology has also been hypothesized to increase participant recruitment and retention,[39,40] resulting in improved clinical outcomes.[41-43]

In this study, we report on a subset of predefined secondary outcomes from the Mindfulness and Tai Chi for Cancer Health (MATCH) trial, a preference-based, multisite, randomized, comparative clinical effectiveness trial evaluating MBCR and TCQ for people with cancer after treatment who were suffering from distress. Our approach follows standard practice in clinical trials with multiple end points, by reporting outcomes according to conceptual domains, in this case, a symptom cluster and prespecified hypotheses. This allows for more focused interpretation while avoiding an overly broad and potentially confusing presentation of heterogeneous end points.

The MATCH trial is unique not only in design, but also for its large size (N = 587), and in screening for elevated distress as an inclusion criterion. This is significant methodologically as only approximately 30% of interested participants would likely meet this criterion, but they would also be more likely to improve over time (not suffering from a floor effect as seen in other mind-body therapy trials). We also included all types and most stages of cancer, and both men and women to enhance generalizability. These design elements are rarely included in mind-body therapy studies, marking MATCH as a step forward in advanced methodology. To our knowledge, MATCH is also the first to investigate the benefits of these interventions for sleep, fatigue, and pain symptom clusters in people after treatment with various cancer diagnoses.

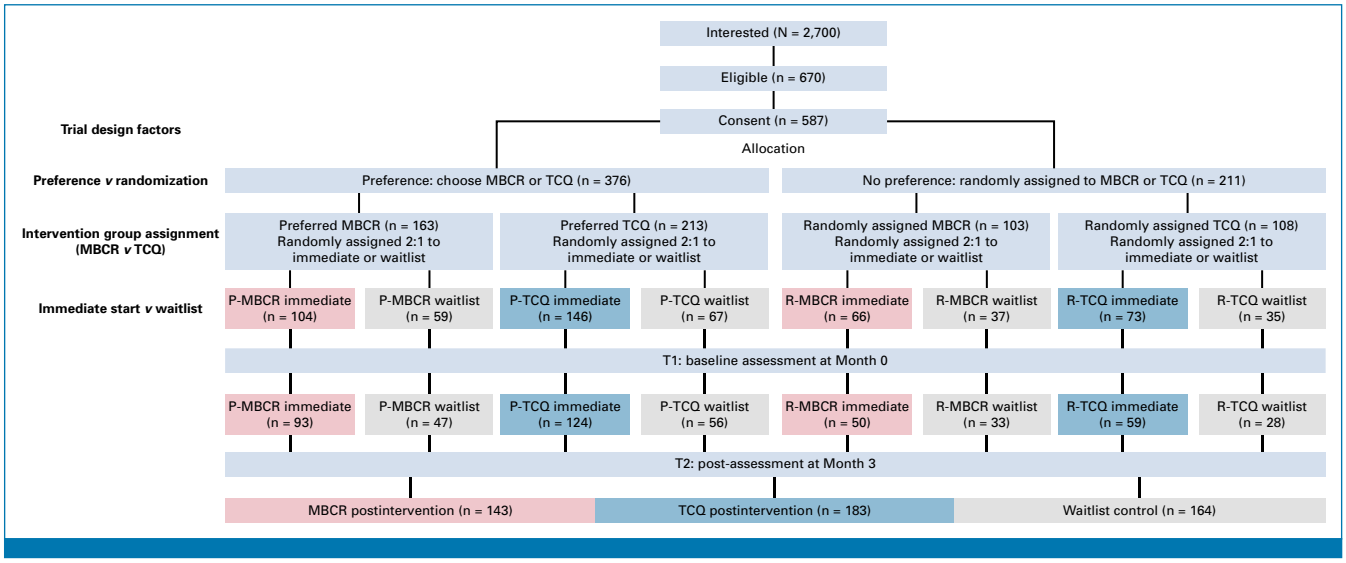


FIG 1. Flowchart of the study design and data collection at baseline (Month 0) and Month 3. MBCR, mindfulness-based cancer recovery; P-, participants preferred to the group; R-, participants were randomly assigned to the group; TCQ, Tai Chi/Qigong.

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METHODS

MATCH Trial Design

Details of the MATCH trial (ClinicalTrials.gov identifier: NCT02801123) have been reported elsewhere[44-46] and in Appendix 1 (online only). Institutional review board approvals were obtained from both study sites, and all participants provided written consent before enrollment.

Here, we present findings for the following aims and hypotheses.

1. Aim 1 evaluated the overall efficacy of interventions—regardless of whether interventions were chosen or randomly assigned—compared with the waitlist control group in improving sleep, fatigue, and pain outcomes at postintervention after MBCR or TCQ or waiting with usual care.[44] We hypothesized that compared with the waitlist control group, those who received MBCR or TCQ would exhibit greater improvement regardless of preference or randomization.
2. Aim 2 evaluated whether effects differed between chosen interventions or randomly assigned interventions. We hypothesized that compared with participants who were randomly assigned, those who expressed a preference and chose their interventions would exhibit greater clinical improvements for all outcomes across interventions.
3. Exploratory Aim 3 evaluated whether changes across our three secondary outcomes were independent or interdependent. We hypothesized that changes in sleep, fatigue, and pain in response to both interventions would be significantly correlated.

Participants with a preference for either MBCR or TCQ received their preferred intervention, while those without a preference underwent block randomization into either the MBCR or TCQ program. Furthermore, within all groups, participants were randomly assigned into immediate intervention or waitlist control in a 2:1 ratio (Fig 1). The waitlist group was used to test whether MBCR/TCQ produced improvements beyond natural recovery or passage of time, and their eventual postintervention data are not included in this report.

Interventions

MBCR was adapted from MBSR to address the specific needs of people with cancer.[25,27,47,48] The 9-week program consisted of weekly in-person group meetings of 105 minutes and assigned home practice of 45 minutes per day (15 minutes of yoga; 30 minutes of meditation). A 6-hour weekend retreat was offered on a Saturday between weeks 6 and 7. Different forms of meditation were introduced (body scan sensory awareness experience progressing to sitting and walking meditations) as the program progressed. Hatha yoga was incorporated throughout using a series of gentle postures, as a form of moving meditation. Didactic instruction, group discussion and reflection, problem solving, and skillful inquiry were commonly applied teaching tools during group meetings.

TCQ training followed the structure and content of protocols used in studies based at the Harvard Medical School,[49-54] and incorporated simple training elements common to both Tai Chi and Qigong.[36,55] The intervention integrated flowing rhythmic movements, along with breath awareness and a variety of cognitive skills, including focused attention, heightened body awareness, and imagery. The TCQ intervention had equal contact time as MBCR but was structured as an 11-week in-person program consisting of a 90-minute weekly group meeting, a 4-hour

weekend retreat, and daily home practice supported with digital training videos.

Both MBCR and TCQ were delivered in-person, except in our final cohort, which was delivered via Zoom videoconferencing from January to April 2020 due to the COVID-19 pandemic.

Outcome Measures

Outcomes were selected based on a predefined clinical symptom cluster, with no post hoc selection based on strength of signal.

Sleep quality was assessed with the Pittsburgh Sleep Quality Index (PSQI), which has seven subscales and a global score ranging from 0 to 21, with higher scores indicating poorer sleep quality.[56] PSQI is a validated tool for sleep dysfunction in clinical and nonclinical samples, including cancer populations.[57-60] In the data set, sleep efficiency scores were unusable so we proportionally adjusted total PSQI score, where we summed the available six subscales, then multiplied by seven and divided by the number of nonmissing subscales. This approach makes the adjusted total score comparable with the standard PSQI metrics. Recent methodological discussions support similar normalization techniques when certain PSQI components are incomplete.[61]

Fatigue was assessed using the Functional Assessment of Chronic Illness Therapy—fatigue (FACIT-F), which has been validated to assess the level of fatigue symptoms and the degree to which fatigue interferes with overall function in both cancer and noncancer populations.[62-64] The FACIT-F is a 13-item questionnaire with a score range of 0-52. Higher scores indicate better quality of life and less fatigue.[62,65,66]

Pain was assessed with the Brief Pain Inventory (BPI). The BPI includes 10 questions for pain intensity and pain interference.[67] Each item on the BPI is scored individually on a scale of 0-10, with higher scores indicating more pain severity or greater interference. The BPI has been shown to be valid and reliable across multiple cancer populations.[67-69]

Statistical Analysis

We included all participants according to their assignment. Statistical analyses were performed using SPSS Statistics version 25 (IBM Corp, Armonk, NY). Demographic characteristics recorded at enrollment included age, sex, education, employment status, marital status, cancer types, and stages. Categorical variables were tested using chi-square tests. Continuous variables with normal distributions were reported as mean ± standard deviation in tables and presented as mean ± SE in figures. Group differences on the pre-post changes of scores (scores from Month 3 minus scores from Month 0) were tested by analysis of variance (Aim 1). If significant differences were found among groups, post hoc tests were conducted using Bonferroni as a correction method for Type I error inflation. Linear regression models were conducted on the outcome measures to explore effects of the three trial design factors (Aim 2), intervention group assignment (MBCR or TCQ), how they were assigned to the group (preferred or randomly assigned), and when intervention was received (immediate start or waitlist). For longitudinal analysis (Aim 1 and Aim 2), we conducted linear mixed-effects models for outcome measures for the effects on time, intervention, and their interactions. We report coefficients (β) and their 95% CI from unadjusted models and adjusted models controlling for age, sex, cancer stage, and randomly assigned/preferred. To explore correlations among outcomes related to sleep, fatigue, and pain, Pearson's correlation analysis was conducted using the pre-post changes of scores—either unadjusted or adjusted for age, sex, and cancer stages (Aim 3). For all the above-mentioned analyses, a P value < .05 was used to indicate significant difference, and Bonferroni corrections were also tested to control for false positives.

RESULTS

Demographic Characteristics

This clinical trial included 587 participants (75% women, mean age 60.7 ± 11.0 years) with a variety of prior cancer diagnoses, including breast (40.7%), prostate (11.2%), gastrointestinal (9.7%), gynecologic (7.5%), lung (4.6%), skin (4.6%), and many other types of cancer. Approximately half of the participants had early-stage cancer (stage 0 to II). No significant baseline differences were observed among the three groups except for marital status (P = .014; Table 1). Overall, 376 (64.1%) participants chose their intervention, while 211 (35.9%) participants chose to be randomly assigned to either program. There were no significant differences in the number of participants who chose TCQ versus MBCR. There were no significant differences between those who received immediate intervention and the waitlist controls. Detailed demographics and cancer-related data have been reported elsewhere.[45]

Sleep, Fatigue, and Pain

Descriptive results of outcome scores at baseline and postintervention are reported in Appendix Tables A1-A5. Although pre-post changes from all four outcomes showed greater improvement in the intervention groups compared with combined waitlist controls (Appendix Table A2), group differences were only significant on sleep quality (P = .015) and pain interference (P = .013). Post hoc pairwise tests indicated significant differences in the comparisons between TCQ and control on sleep quality and pain interference (Appendix Fig A1).

Effects of Trial Design Factors

Intervention group assignment (MBCR *v* TCQ) or preference (preferred *v* randomly assigned) did not show significant

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TABLE 1. Demographic Characteristics of All Participants at Baseline

Variable	All (N = 587), No. (%)	Control (n = 198), No. (%)	MBCR (n = 170), No. (%)	TCQ (n = 219), No. (%)	*P*
Age, years	60.7 ± 11.0	61.3 ± 11.4	60.4 ± 10.7	60.3 ± 11.0	.646
Sex, women	440 (75.0)	159 (79.5)	118 (69.8)	163 (74.8)	.154
Education, years	15.9 ± 4.8	16.1 ± 4.0	15.9 ± 5.8	15.7 ± 4.7	.689
Employment					
Unemployed	42 (8.3)	14 (8.0)	13 (9.1)	15 (8.1)	.997
Full-time	185 (36.8)	67 (38.5)	50 (35)	68 (36.6)	
Part-time	65 (12.9)	21 (12.1)	21 (14.7)	23 (12.4)	
Retired	182 (36.2)	63 (36.2)	51 (35.7)	68 (36.6)	
Disabled	29 (5.8)	9 (5.2)	8 (5.6)	12 (6.5)	
Marital status					
Single	80 (15.9)	20 (11.6)	16 (11.2)	44 (23.7)	.014
Cohabiting	37 (7.4)	15 (8.7)	6 (4.2)	16 (8.6)	
Married	298 (59.4)	102 (59)	94 (65.7)	102 (54.8)	
Divorced	56 (11.2)	22 (12.7)	18 (12.6)	16 (8.6)	
Widowed	31 (6.2)	14 (8.1)	9 (6.3)	8 (4.3)	
Cancer stage[a]					
Early stage	294 (50.1)	93 (46.5)	87 (51.5)	114 (52.3)	.241
Advanced stage	100 (17.0)	34 (17.0)	23 (13.6)	43 (19.7)	
Unsure/missing	193 (32.9)	73 (36.5)	59 (34.9)	61 (28.0)	
Baseline assignment					
Randomly assigned	211 (35.9)	70 (35.0)	65 (38.5)	76 (34.9)	.721
Preferred	376 (64.1)	130 (65.0)	104 (61.5)	142 (65.1)	

Abbreviations: MBCR, mindfulness-based cancer recovery; TCQ, Tai Chi/Qigong.
[a]Cancer stages 0 to II were grouped as early stage, and stages III to IV were grouped as advanced stage.

impact on the changes of outcomes. The only trial design factor that showed significant effects was assignment to immediate start of an intervention (*v* waitlist; Table 2) for sleep, fatigue, and pain interference. None of the trial design factors showed significant impact on the change of pain severity.

Longitudinal Analysis

Longitudinal regression models revealed significant improvements in sleep, fatigue, and pain interference when comparing those in MBCR or TCQ to those in the control group (Table 3 and Fig 2).

TABLE 2. Effects of the Design Factors on the Pre-Post Changes of Outcome Measures

	Assignment (MBCR/TCQ)		Randomly Assigned/Preferred		Waitlist/Immediate	
Models and Outcome	β (95% CI)	*P*	β (95% CI)	*P*	β (95% CI)	*P*
Unadjusted models						
Sleep quality	−0.11 (−0.92 to 0.71)	.794	−0.10 (−0.95 to 0.75)	.813	−1.15 (−1.98 to −0.32)	.007
Fatigue	−0.28 (−1.76 to 1.21)	.715	0.83 (−0.72 to 2.38)	.295	1.63 (0.11 to 3.15)	.036
Pain severity	−0.33 (−0.86 to 0.19)	.207	−0.09 (−0.65 to 0.48)	.764	−0.14 (−0.67 to 0.39)	.604
Pain interference	−0.20 (−0.74 to 0.34)	.460	0.45 (−0.14 to 1.03)	.132	−0.89 (−1.44 to −0.34)	.002
Adjusted models[a]						
Sleep quality	0.07 (−0.73 to 0.87)	.860	0.16 (−0.68 to 0.99)	.715	−1.4 (−2.22 to −0.58)	.001
Fatigue	−0.11 (−1.67 to 1.45)	.894	0.83 (−0.80 to 2.46)	.319	1.82 (0.22 to 3.43)	.026
Pain severity	−0.46 (−0.99 to 0.06)	.084	0.01 (−0.56 to 0.58)	.979	−0.24 (−0.78 to 0.29)	.369
Pain interference	−0.26 (−0.80 to 0.28)	.346	0.5 (−0.09 to 1.09)	.094	−1.02 (−1.57 to −0.47)	<.001

NOTE. Each model tested the main effects of the trial design factors and the reference variables were underlined.
Abbreviations: BPI, Brief Pain Inventory; MBCR, mindfulness-based cancer recovery; PSQI, Pittsburgh Sleep Quality Index; TCQ, Tai Chi/Qigong.
[a]Models were adjusted for age, sex, and cancer stage. Sleep quality was measured by using PSQI. Fatigue was measured by using Functional Assessment of Chronic Illness Therapy—fatigue (FACIT-F). Pain severity and pain interference were measured by using BPI.

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TABLE 3. Unadjusted and Adjusted Longitudinal Analyses

Models and Outcome	Model 1		Model 2		Model 3	
	β (95% CI)	*P*	β (95% CI)	*P*	β (95% CI)	*P*
Outcome: sleep quality						
MBCR	−0.361 (−1.190 to 0.469)	.393	−0.326 (−1.178 to 0.527)	.453	−0.324 (−1.176 to 0.529)	.456
TCQ	0.408 (−0.368 to 1.184)	.302	0.510 (−0.298 to 1.318)	.216	0.509 (−0.300 to 1.317)	.217
Time	−0.145 (−0.999 to 0.708)	.739	−0.079 (−0.960 to 0.801)	.860	−0.078 (−0.959 to 0.802)	.861
MBCR × time	−1.003 (−2.293 to 0.287)	.127	−1.215 (−2.537 to 0.108)	.072	−1.212 (−2.535 to 0.111)	.072
TCQ × time	−1.793 (−3.026 to −0.56)	.004	−1.898 (−3.18 to −0.616)	.004	−1.900 (−3.182 to −0.617)	.004
Outcome: fatigue						
MBCR	−0.329 (−2.561 to 1.904)	.773	−0.442 (−2.757 to 1.873)	.708	−0.453 (−2.761 to 1.854)	.700
TCQ	−1.303 (−3.39 to 0.784)	.221	−1.596 (−3.79 to 0.598)	.154	−1.584 (−3.772 to 0.603)	.155
Time	1.37 (−0.814 to 3.555)	.219	1.188 (−1.09 to 3.466)	.306	1.189 (−1.086 to 3.464)	.305
MBCR × time	3.04 (−0.26 to 6.341)	.071	3.696 (0.276 to 7.116)	.034	3.662 (0.247 to 7.078)	.036
TCQ × time	3.125 (−0.029 to 6.279)	.052	3.411 (0.096 to 6.727)	.044	3.415 (0.104 to 6.726)	.043
Outcome: pain severity						
MBCR	−0.232 (−0.803 to 0.339)	.425	−0.286 (−0.863 to 0.291)	.330	−0.292 (−0.868 to 0.285)	.320
TCQ	0.304 (−0.245 to 0.853)	.277	0.383 (−0.174 to 0.94)	.177	0.389 (−0.167 to 0.945)	.169
Time	0.119 (−0.444 to 0.681)	.679	0.1 (−0.48 to 0.68)	.734	0.083 (−0.497 to 0.663)	.779
MBCR × time	−0.221 (−1.089 to 0.646)	.616	−0.095 (−0.984 to 0.794)	.834	−0.072 (−0.961 to 0.816)	.873
TCQ × time	−0.668 (−1.509 to 0.173)	.119	−0.802 (−1.675 to 0.071)	.072	−0.796 (−1.669 to 0.076)	.073
Outcome: pain interference						
MBCR	0.421 (−0.193 to 1.035)	.178	0.452 (−0.175 to 1.079)	.157	0.447 (−0.18 to 1.075)	.162
TCQ	0.786 (0.196 to 1.376)	.009	0.814 (0.209 to 1.419)	.009	0.817 (0.211 to 1.422)	.008
Time	0.631 (0.011 to 1.251)	.046	0.652 (0.006 to 1.298)	.048	0.639 (−0.008 to 1.287)	.053
MBCR × time	−1.196 (−2.15 to −0.242)	.014	−1.116 (−2.102 to −0.131)	.027	−1.100 (−2.088 to −0.113)	.029
TCQ × time	−1.403 (−2.327 to −0.479)	.003	−1.527 (−2.497 to −0.558)	.002	−1.522 (−2.492 to −0.552)	.002

NOTE. Model 1 was unadjusted for effects of intervention, time, and intervention × time interaction term. Model 2 was built upon Model 1 with adjustment for stratification factors (age, sex, and cancer stage). Model 3 was fully adjusted for stratification factors (age, sex, and cancer stage) and whether participants were randomly assigned or preferred to the group. In these models, waitlist control, baseline, and preferred enrollment were used as references, respectively.
Abbreviations: MBCR, mindfulness-based cancer recovery; TCQ, Tai Chi/Qigong.

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For sleep quality, in the unadjusted model, TCQ significantly reduced the PSQI total score (β = −1.79 [95% CI, −3.03 to −0.56]; *P* = .004). The effects of TCQ remained significant after adjustment for age, sex, cancer stage, and whether participants were randomly assigned or preferred the group (β = −1.90 [95% CI, −3.18 to −0.62]; *P* = .004). Compared with the controls, MBCR also reduced PSQI scores in unadjusted and adjusted models, but the effects did not reach the significance level.

For fatigue, both MBCR and TCQ improved fatigue, but the effects were only significant in adjusted models. In the fully adjusted model, both MBCR (β = 3.66 [95% CI, 0.25 to 7.08]; *P* = .036) and TCQ significantly improved fatigue (β = 3.42 [95% CI, 0.10 to 6.73]; *P* = .043).

For pain, TCQ showed trends of reducing pain severity, with effects not significant in unadjusted models, but approaching significance in adjusted models. MBCR and TCQ significantly reduced pain interference in unadjusted and adjusted models. In the fully adjusted model, MBCR (β = −1.10 [95% CI, −2.09 to −0.11]; *P* = .029) and TCQ (β = −1.52 [95% CI, −2.49 to −0.55]; *P* = .002) significantly reduced pain interference. Although the magnitude of improvement was greater in the TCQ group, the difference was not significant when comparing TCQ and MBCR.

The differences between TCQ and MBCR were not statistically significant on any of these outcomes. Inclusion of marital status in fully adjusted models did not materially change the intervention effects (Appendix Table A6).

Correlations Among Symptom Outcome Responses

Correlations were observed in the change scores among sleep, fatigue, and pain interference. Correlations among each pair of outcomes were significant, even after controlling for age, sex, and cancer stage. The significant correlation coefficients |r| ranged from 0.2 to 0.4, suggesting mild to moderate associations (Table 4). Most of

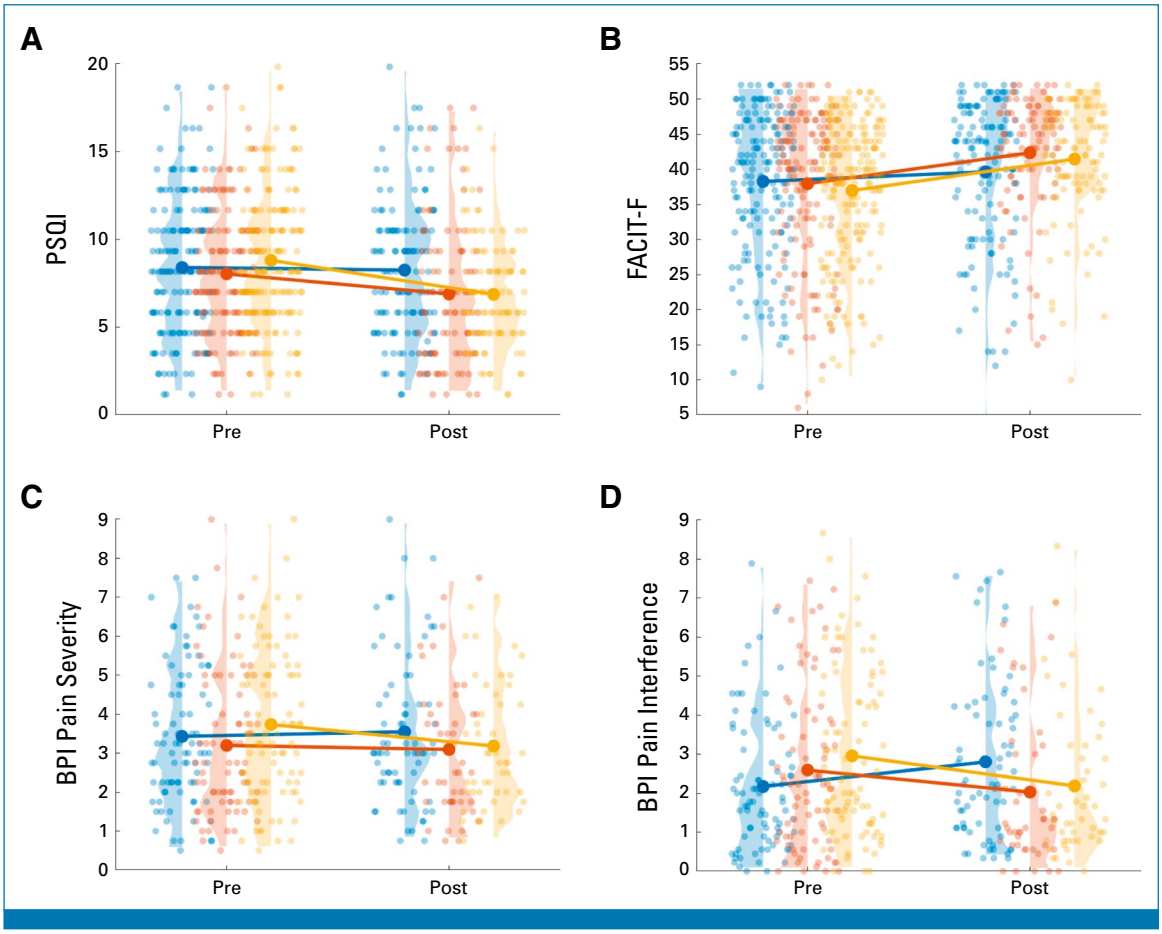


FIG 2. Longitudinal changes in sleep, fatigue, and pain. Raincloud plots show the distribution of outcome scores at baseline (pre) and postintervention (post) for waitlist, MBCR, and TCQ groups: (A) PSQI, (B) FACIT-F, (C) BPI pain severity, and (D) BPI pain interference. Jittered points represent individual participants. Half-violin plots show score distributions. Connected points indicate group means, with error bars representing 95% CIs. BPI, Brief Pain Inventory; FACIT-F, Functional Assessment of Chronic Illness Therapy—fatigue; MBCR, mindfulness-based cancer recovery; PSQI, Pittsburgh Sleep Quality Index; TCQ, Tai Chi/Qigong.

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the correlations remained significant after Bonferroni adjustment.

DISCUSSION

This study reports findings for prespecified secondary outcomes assessed in the MATCH trial evaluating the impact of self-selected or randomly assigned MBCR or TCQ on sleep, fatigue, and pain in people with cancer who had completed primary treatments but were still experiencing at least moderate distress. As hypothesized, compared with the waitlist control group, both interventions improved sleep quality, fatigue, and pain interference postintervention. Outcomes for participants who received interventions they explicitly preferred did not differ from outcomes in participants who were randomly assigned interventions. Finally, we observed significant correlations among the improvement of sleep, fatigue, and pain interference, suggesting that changes of the three outcomes were interdependent, and supporting future research evaluating the impact of interventions on interdependent symptom clusters and an integrated whole-person framework.[70] Findings from our study confirm the benefits of mind-body interventions in addressing multiple symptoms affecting cancer survivors of all types and stages, and extend our knowledge of the potential of MBCR and TCQ in addressing these challenges.

Our longitudinal analyses revealed trends of improvement on fatigue in both MBCR and TCQ groups, and the effects were both significant after adjustment for age, sex, and cancer stage, regardless of participants being randomly assigned or choosing the interventions. For the assessment of fatigue, a change of 3-4 points on FACIT-fatigue is considered a minimal clinically important difference (MCID).[71-73] We observed roughly 4 points of change from both MBCR and TCQ, indicating improvement on fatigue that is likely to affect participants' day-to-day function. These findings are in line with current evidence that mindfulness-based interventions and TCQ both have significant effects in reducing cancer-related fatigue.[31,32,35,74-76]

TABLE 4. Correlations Among the Changes of Sleep, Fatigue, and Pain Interference

Correlation	Sleep	Fatigue	Pain Interference
Pearson correlation			
Sleep			
r	1	−0.219**	0.367**
P		<.001	<.001
Fatigue			
r	−0.219**	1	−0.263**
P	<.001		.005
Pain interference			
r	0.367**	−0.263*	1
P	<.001	.005	
Partial correlation controlling for age, sex, and cancer stage			
Sleep			
r	1	−0.201	0.355**
P		.042	<.001
Fatigue			
r	−0.201	1	−0.236
P	.042		.017
Pain interference			
r	0.355**	−0.236	1
P	<.001	.017	

NOTE. Sleep quality was measured by using PSQI. Fatigue was measured by using FACIT-F. Pain interference was measured by using BPI. Pain severity was not included here because it was not significantly correlated with sleep or fatigue measures. In the tables, r indicates the correlation coefficient and *P* indicates raw original *P* values from correlation analysis.
Abbreviations: BPI, Brief Pain Inventory; FACIT-F, Functional Assessment of Chronic Illness Therapy—fatigue; PSQI, Pittsburgh Sleep Quality Index.
*$P < .05$ after Bonferroni adjustment.
**$P < .01$ after Bonferroni adjustment.

Significant improvement in pain interference in both MBCR and TCQ groups was also observed. For pain measured by BPI, a change of 1 point is considered clinically meaningful, and a change of 2 points is considered moderate and clinically significant.[77,78] We only observed nonsignificant changes of 1 point on pain severity after TCQ and smaller changes in MBCR. For pain interference, we observed significant changes of 1 point from MBCR and significant changes of 1.5 points from TCQ, indicating small-to-moderate clinically meaningful improvement.

This differential effect on pain severity versus pain interference tracks with the rationale and pedagogy of mind-body therapies (MBTs), where emphasis is often on managing increases in the overall experience of suffering from pain caused by mental and physical resistance to existing pain sensations. Indeed, in MBCR, we use the formula S = P × R (overall suffering = pain x resistance) with the explanation that although MBTs can help to ease physical and psychological resistance to pain, the initial pain sensation or severity itself may not change. Seeing self-reported decreases in pain interference suggests that the overall suffering from pain has decreased for participants across both programs, although in some cases, similar pain intensity remains, suggesting participants were using appraisal skills from the programs to manage pain interference.

The MCID for PSQI is a change of 2.5-3 points.[79,80] We observed a change of score of about 2 points after TCQ and about 1 point after MBCR. Some studies suggest a PSQI global score of 8 or higher as an indicator of poor sleep quality in people living with cancer.[59,81] Our participants' baseline PSQI scores were around 8, indicating mildly poor sleep at baseline. They were not selected for high levels of sleep disturbance and would not be expected to improve as much as those in studies of people selected to have high levels of sleep disturbance or clinical insomnia at baseline. Also, application of the proportionally adjusted total PSQI score could affect the interpretability and comparability of MCID results. Overall, TCQ performed better in terms of the improvement on sleep quality based on the MCID scores, but the differences between TCQ and MBCR were not statistically significant. Other emerging evidence also supports the benefits of MBTs for sleep disturbance among people with cancer with small effect sizes.[31,82]

To our knowledge, the MATCH trial is the first of its kind to incorporate a preference-based, nonrandomized effectiveness design alongside a fully randomized efficacy trial comparing MBCR and TCQ, with randomized waitlist controls included in both cases.[44] Among the three trial design factors (ie, initial intervention group assignment, preferred or randomly assigned, and immediate start or waitlist), participants' choices of intervention groups did not affect the magnitude of changes at the end of intervention. The only factor that significantly affected outcomes of interest was the immediate start of interventions, that is, getting either program versus usual care/waitlist. From longitudinal analyses, the effects of randomized enrollment versus preferred enrollment were included in fully adjusted models for all four secondary outcomes focused on in this paper, and the effects were only significant on fatigue, favoring randomized enrollment rather than preferred enrollment. Therefore, our results suggest that the improvement of sleep, fatigue, and pain did not rely on whether participants were randomly assigned or chose the group based on preference.

There is evidence suggesting interdependent relationships among sleep, fatigue, and pain, for example, through bidirectional relationships whereby poor sleep can lead to increased fatigue and pain sensitivity, and pain itself can

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disrupt sleep.[6,83-86] There is evidence indicating that poor sleep can affect pain intensity via multiple putative mediators including affect/mood, depression and/or anxiety, attention to pain, pain helplessness, stress, fatigue, and physical activity.[87] Data from the MATCH study offered an opportunity to understand how changes in one symptom affected outcomes in other symptoms in people with cancer. Our results revealed that the correlations among changes in sleep, fatigue, and pain were mild to moderate, indicating that associations among improvements in reported outcomes were significant. Shared underlying factors that may influence this symptom cluster could include inflammation.[88-90] Other possible mechanisms by which MBCR and TCQ improve sleep, fatigue, and pain may include effects on emotion regulation and cognitive processes such as decreases in rumination and worry[91,92] and pain catastrophizing.[93,94] Theoretical models hypothesize that less pain and worry lead to better sleep, which together lead to less fatigue.[6,95] Our results extend the knowledge of multimodal interventions, particularly highlighting the potential value of MBCR and TCQ, and fill important gaps in translational research that might inform better whole-person cancer care. Clinically, approaching these symptoms from the perspective of whole-person health in future trials or clinical health management would help to avoid a vicious cycle whereby each factor exacerbates the others.

There are several strengths and limitations of the MATCH study. Specifically relevant to this secondary analysis, retention and missing data, which have been discussed elsewhere,[44,46] may reduce the precision of the study's estimates. However, our analyses with mixed-effects models provide generalizable and realistic results by reflecting real-world clinical effectiveness and offering a more conservative estimate of treatment effects.[96,97] Evaluation of the health economic benefits of MBCR and TCQ, including health care costs, cost-effectiveness, and cost-utility, will be presented in a subsequent publication. In this work, we focus on a subset of prespecified secondary symptoms from the original MATCH protocol, and our analyses include multiple hypothesis tests across four symptom measures (sleep quality, fatigue, pain severity, and pain interference), several trial-design factors, and longitudinal intervention-by-time comparisons. Only a subset of these comparisons yielded statistically significant findings, and the outcomes are correlated rather than independent. These outcomes were not selected based on observed statistical signals, rather they were chosen because they represent a clinically related cluster of prespecified cancer-symptom outcomes from the MATCH protocol. Other prespecified secondary outcomes from distinct domains will be reported separately. In the present manuscript, based on the preliminary finding that there were no differences between randomized and preference-based groups on these outcomes, we chose to present a pooled analysis of sleep, fatigue, and pain while accounting for preference status in adjusted models, to allow for ease of interpretation and improve power in the analyses by having fewer larger groups. Pooling across preference and randomized groups may mask heterogeneity and should therefore be interpreted cautiously. Also, given the number of related outcomes, time points, and models examined, our analyses involve substantial multiple testing. This increases the risk of type I error, which means that some statistically significant findings, particularly those with *P* values close to .05, may represent chance results. Accordingly, these secondary and exploratory results should be interpreted cautiously, with primary emphasis on effect sizes, CIs, the overall pattern of results, and their consistency with the prespecified MATCH protocol and primary outcomes. Strengths of our study include the unique trial design with the consideration of participants' preferences, sample size, broad inclusion criteria to enhance generalizability, and the variety of outcomes measured from multiple health domains. More specifically, to our knowledge, this is the first RCT that involves MBCR, TCQ, and waitlist control, and is the first to investigate the benefits of these interventions for sleep, fatigue, and pain symptom clusters in people after treatment with various cancer diagnoses. Our results highlight the value of multimodal interventions for targeting whole-person health. Advice to involve patients and consider their preferences in decision making is included in many clinical cancer treatment recommendations.[98] Equivalent and positive benefits of these two interventions suggest people with cancer may follow their preference and receive similar benefit in terms of sleep, pain, and fatigue. We also measured treatment expectancy and treatment credibility in the trial, as we hypothesized that they would be higher in those who chose their intervention over those who were randomly assigned, and may be associated with outcomes. These data will be reported in future publications.

In conclusion, compared with waitlist controls, MBCR and TCQ significantly improved fatigue and pain interference postintervention, and TCQ significantly improved sleep quality. Treatment effects of the two interventions did not differ between one another. Participants' choices of intervention groups did not affect health improvement at the end of intervention. There were significant correlations among the improvement of sleep, fatigue, and pain interference, which highlights the importance of a whole-person health framework and the promise of multimodal interventions.

AFFILIATIONS

[1]Osher Center for Integrative Health, Harvard Medical School and Brigham and Women's Hospital, Boston, MA
[2]Department of Oncology, University of Calgary, Calgary, AB, Canada
[3]Department of Supportive Care, Princess Margaret Cancer Centre, Toronto, ON, Canada

CORRESPONDING AUTHOR

Linda E. Carlson, PhD; e-mail: l.carlson@ucalgary.ca.

EQUAL CONTRIBUTION

Y.M. and L.E.C. contributed equally to this work.

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AUTHOR CONTRIBUTIONS

Conception and design: Yan Ma, Linda E. Carlson, Jennifer M. Jones, Devesh Oberoi, Michael Speca, Peter M. Wayne
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Provision of study materials or patients: Linda E. Carlson, Jennifer M. Jones, Oluwaseyi A. Lawal, Michael Speca, Peter M. Wayne
Collection and assembly of data: Yan Ma, Linda E. Carlson, Jennifer M. Jones, Oluwaseyi A. Lawal, Devesh Oberoi, Katherine-Ann Piedalue, Daniel Santa Mina, Peter M. Wayne
Data analysis and interpretation: Yan Ma, Linda E. Carlson, Jennifer M. Jones, Oluwaseyi A. Lawal, Devesh Oberoi, Peter M. Wayne
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Mindfulness and Tai Chi for Sleep, Fatigue, and Pain in Distressed People After Cancer Treatment: A Partially Randomized Patient-Preference Comparative Effectiveness Trial

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Uncompensated Relationships: Mobio Interactive

Daniel Santa Mina
Employment: Shoppers Drug Mart
Stock and Other Ownership Interests: PrehabRx
Honoraria: AstraZeneca, Fresenius Kabi, Merck, Novartis
Travel, Accommodations, Expenses: Novartis

Peter M. Wayne
Other Relationship: Tree of Life Tai Chi Center

No other potential conflicts of interest were reported.

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APPENDIX 1

Eligibility Criteria

The trial was conducted in Canada (Tom Baker Cancer Centre and Princess Margaret Cancer Centre) between 2016 and 2020. Institutional Review Board approvals were obtained from both sites, and all participants provided written consent before enrollment. Eligibility criteria were purposely broad with the intention to generalize across adults with cancer suffering from significant post-treatment distress. Key inclusion criteria were (1) age older than 18 years, (2) diagnosed with any cancer type excluding brain, (3) completed primary treatment (ie, surgery, chemotherapy, radiation therapy), at least 4 months previously, (4) experiencing significant distress (4 or greater) on the distress thermometer, (5) able to attend mindfulness-based cancer recovery (MBCR) or Tai Chi/Qigong (TCQ) classes at scheduled times, (6) sufficient functional capacity to participate in intervention groups, and (7) the ability to speak and write English sufficiently to complete questionnaires and participate in groups. Key exclusion criteria were (1) people with metastatic disease and those with ongoing chemotherapy or radiation therapy, (2) suffering from current major depressive disorder, bipolar disorder, or other psychiatric disorder that would interfere with the ability to participate, (3) currently engaging in meditation or TCQ one or more times per week or having done so within the previous year, (4) participation in an MBCR or mindfulness-based stress reduction program in the past 5 years, and (5) cognitive impairment that would interfere with completing questionnaires or the intervention (<25 on the Mini Mental Status Examination).

Randomization

Permuted blocks were used to help conceal the allocation. Randomization results were concealed from all study team members except the study coordinator, who informed patients of their group assignments.

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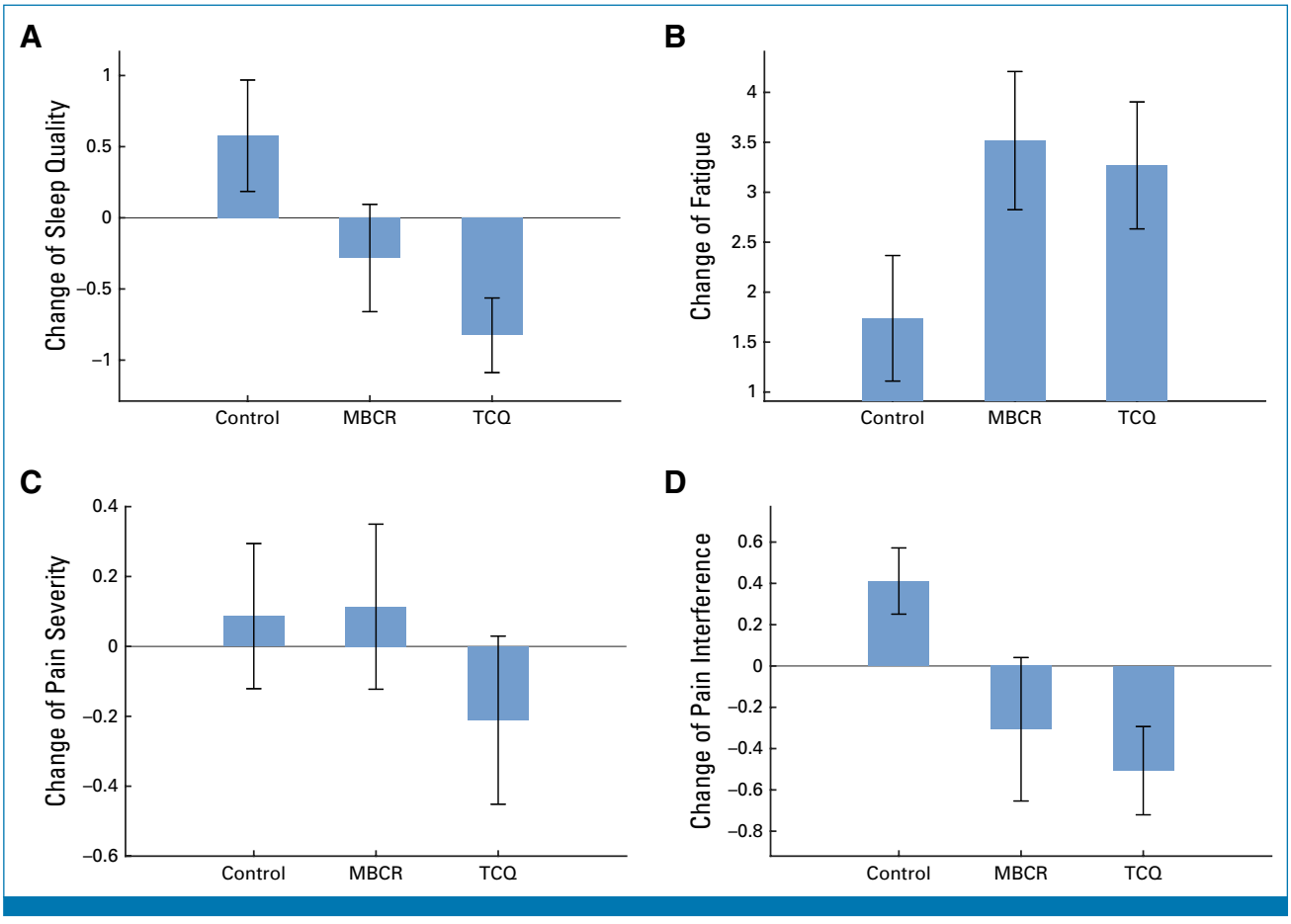


FIG A1. The changes of scores on (A) sleep quality, (B) fatigue, and (C and D) pain for the three groups. MBCR, mindfulness-based cancer recovery; TCQ, Tai Chi/Qigong.

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TABLE A1. Descriptive Results of the Outcomes at Baseline and Postintervention for the Three Groups

Outcome	Control	MBCR	TCQ
Sleep quality			
Baseline	8.5 ± 3.9	7.6 ± 3.4	8.1 ± 3.5
Postintervention	8.0 ± 3.8	6.8 ± 4.0	7.0 ± 3.0
Fatigue			
Baseline	38.5 ± 10.2	39.1 ± 9.8	37.9 ± 9
Postintervention	40.3 ± 9.9	42.6 ± 8	41.2 ± 8.4
Pain severity			
Baseline	3.6 ± 1.8	3.2 ± 1.7	3.5 ± 1.5
Postintervention	3.7 ± 1.9	3.3 ± 1.8	3.3 ± 1.7
Pain interference			
Baseline	2.3 ± 1.8	2.6 ± 2.2	3.0 ± 1.8
Postintervention	2.7 ± 1.9	2.3 ± 2.0	2.5 ± 1.7

NOTE. The reported outcome measures at baseline were from baseline assessments before any interventions started. Sleep quality was measured by using PSQI. Fatigue was measured by using FACIT-F. Pain severity and pain interference were measured by using BPI.
Abbreviations: BPI, Brief Pain Inventory; FACIT-F, Functional Assessment of Chronic Illness Therapy—fatigue; MBCR, mindfulness-based cancer recovery; PSQI, Pittsburgh Sleep Quality Index; TCQ, Tai Chi/Qigong.

TABLE A2. Comparisons of the Score Changes Among the Three Groups

Outcome	Control	MBCR	TCQ	*P*
Sleep quality	0.58 ± 4.45	−0.28 ± 3.68	−0.83 ± 2.70	.015
Fatigue	1.74 ± 6.83	3.52 ± 6.60	3.27 ± 6.38	.102
Pain severity	0.09 ± 1.45	0.11 ± 1.36	−0.21 ± 1.36	.572
Pain interference	0.41 ± 1.10	−0.31 ± 2.0	−0.51 ± 1.21	.013

NOTE. Sleep quality was measured by using PSQI. Fatigue was measured by using FACIT-F. Pain severity and pain interference were measured by using BPI.
Abbreviations: BPI, Brief Pain Inventory; FACIT-F, Functional Assessment of Chronic Illness Therapy—fatigue; MBCR, mindfulness-based cancer recovery; PSQI, Pittsburgh Sleep Quality Index; TCQ, Tai Chi/Qigong.

TABLE A3. Descriptive Results of the Outcomes at Baseline and Postintervention for the Four Groups

Outcome	MBCR_WL	MBCR_IM	TCQ_WL	TCQ_IM
Sleep quality				
Baseline	9.2 ± 3.8	8.0 ± 3.5	7.6 ± 3.8	8.8 ± 3.8
Postintervention	8.7 ± 4.0	6.9 ± 4.1	7.9 ± 3.8	6.9 ± 3.0
Fatigue				
Baseline	38.2 ± 10.6	37.9 ± 10.5	38.4 ± 9.6	37 ± 9.7
Postintervention	39.2 ± 11.3	42.3 ± 8.3	40.0 ± 9.7	41.5 ± 8.4
Pain severity				
Baseline	3.3 ± 1.8	3.2 ± 1.8	3.6 ± 1.7	3.7 ± 1.9
Postintervention	3.4 ± 1.9	3.1 ± 1.7	3.7 ± 1.9	3.2 ± 1.6
Pain interference				
Baseline	2.2 ± 1.7	2.6 ± 2.1	2.1 ± 1.6	3.0 ± 2.1
Postintervention	2.9 ± 2.2	2.0 ± 1.9	2.7 ± 1.9	2.2 ± 1.9

NOTE. The reported outcome measures at baseline were from baseline assessments before any interventions started. Sleep quality was measured by using PSQI. Fatigue was measured by using FACIT-F. Pain severity and pain interference were measured by using BPI.
Abbreviations: BPI, Brief Pain Inventory; FACIT-F, Functional Assessment of Chronic Illness Therapy—fatigue; IM, immediate start of intervention; MBCR, mindfulness-based cancer recovery; PSQI, Pittsburgh Sleep Quality Index; TCQ, Tai Chi/Qigong; WL, waitlist.

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TABLE A4. Comparisons of the Score Changes Among the Four Groups

Outcome	MBCR_WL	MBCR_IM	TCQ_WL	TCQ_IM	*P*
Sleep quality	0.27 ± 4.66	−0.28 ± 3.68	0.83 ± 4.28	−0.83 ± 2.7	.028
Fatigue	1.87 ± 7.57	3.52 ± 6.6	1.63 ± 6.21	3.27 ± 6.38	.204
Pain severity	0.28 ± 1.2	0.11 ± 1.36	−0.07 ± 1.64	−0.21 ± 1.36	.592
Pain interference	0.49 ± 1.16	−0.31 ± 2	0.34 ± 1.06	−0.51 ± 1.21	.033

NOTE. Sleep quality was measured by using PSQI. Fatigue was measured by using FACIT-F. Pain severity and pain interference were measured by using BPI.
Abbreviations: BPI, Brief Pain Inventory; FACIT-F, Functional Assessment of Chronic Illness Therapy—fatigue; IM, immediate start of intervention; MBCR, mindfulness-based cancer recovery; PSQI, Pittsburgh Sleep Quality Index; TCQ, Tai Chi/Qigong; WL, waitlist.

TABLE A5. Descriptive Results of the Outcomes at Baseline and Postintervention for the Eight Groups.

Outcome	P_MBCR_IM	P_MBCR_WL	P_TCQ_IM	P_TCQ_WL	R_MBCR_IM	R_MBCR_WL	R_TCQ_IM	R_TCQ_WL
Sleep quality								
Pre	8.2 ± 3.7	9.1 ± 4.0	9.1 ± 3.9	7.3 ± 3.5	7.8 ± 3.3	9.3 ± 3.7	8.2 ± 3.5	8.4 ± 4.2
Post	6.9 ± 4.2	8.4 ± 4.3	7.2 ± 3.0	7.5 ± 3.4	6.9 ± 4.0	9.2 ± 3.5	6.1 ± 2.8	8.6 ± 4.4
Fatigue								
Pre	37.7 ± 10.7	38.0 ± 10.4	36.0 ± 10.2	37.7 ± 10.0	38.3 ± 10.2	38.5 ± 11	38.9 ± 8.3	39.7 ± 8.7
Post	42.7 ± 7.6	39.4 ± 10.5	40.8 ± 8.5	40.0 ± 9.7	41.7 ± 9.4	38.8 ± 12.8	42.8 ± 8.1	40.1 ± 9.9
Pain severity								
Pre	3.3 ± 1.8	3.0 ± 1.7	3.6 ± 2.0	3.4 ± 1.7	3.1 ± 1.9	3.8 ± 2.0	4.1 ± 1.8	3.9 ± 1.6
Post	3.1 ± 1.6	3.2 ± 1.7	3.0 ± 1.5	3.7 ± 1.7	3.1 ± 1.9	3.7 ± 2.1	3.6 ± 1.7	3.6 ± 2.3
Pain interference								
Pre	2.6 ± 2.0	2.1 ± 1.6	2.8 ± 2.1	1.9 ± 1.3	2.5 ± 2.3	2.4 ± 2.0	3.2 ± 2.1	2.7 ± 2.4
Post	2.0 ± 2.0	2.8 ± 2.3	2.0 ± 1.4	2.9 ± 1.7	2.1 ± 1.8	3.2 ± 2.1	2.5 ± 2.5	2.5 ± 2.2

NOTE. The outcome scores were reported as mean and standard deviation at baseline (pre) and postintervention (post). Sleep quality was measured by using PSQI. Fatigue was measured by using FACIT-F. Pain severity and pain interference were measured by using BPI.
Abbreviations: BPI, Brief Pain Inventory; FACIT-F, Functional Assessment of Chronic Illness Therapy—fatigue; IM, participants immediately started the intervention; MBCR, mindfulness-based cancer recovery; P, participants were assigned to a group based on their preference; PSQI, Pittsburgh Sleep Quality Index; R, participants were randomly assigned to a group; TCQ, Tai Chi/Qigong; WL, participants were on the waitlist.

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TABLE A6. Inclusion of Marital Status in the Fully Adjusted Longitudinal Analyses

Outcome	β (95% CI)	*P*
Outcome: sleep quality		
MBCR	−0.300 (−1.159 to 0.558)	.492
TCQ	0.458 (−0.360 to 1.276)	.272
Time	−0.101 (−0.982 to 0.780)	.822
MBCR × time	−1.161 (−2.483 to 0.161)	.085
TCQ × time	−1.877 (−3.158 to −0.596)	.004
Outcome: fatigue		
MBCR	−0.586 (−2.879 to 1.707)	.616
TCQ	−1.350 (−3.533 to 0.833)	.225
Time	1.312 (−0.936 to 3.560)	.252
MBCR × time	3.449 (0.080 to 6.819)	.045
TCQ × time	3.314 (0.049 to 6.579)	.047
Outcome: pain severity		
MBCR	−0.282 (−0.860 to 0.297)	.339
TCQ	0.425 (−0.137 to 0.986)	.138
Time	0.115 (−0.468 to 0.698)	.699
MBCR × time	−0.127 (−1.021 to 0.767)	.780
TCQ × time	−0.838 (−1.714 to 0.039)	.061
Outcome: pain interference		
MBCR	0.420 (−0.206 to 1.046)	.187
TCQ	0.788 (0.179 to 1.396)	.011
Time	0.623 (−0.020 to 1.267)	.058
MBCR × time	−1.116 (−2.098 to −0.133)	.026
TCQ × time	−1.503 (−2.466 to −0.540)	.002

NOTE. Results were fully adjusted for stratification factors (age, sex, and cancer stage), marital status, and whether participants were randomly assigned or preferred to the group. In these models, waitlist control, baseline, and preferred enrollment were used as references, respectively.
Abbreviations: MBCR, mindfulness-based cancer recovery; TCQ, Tai Chi/Qigong.

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