# A Randomized Wait-List Controlled Trial of Feasibility and Efficacy of an Online Mindfulness–Based Cancer Recovery Program: The eTherapy for Cancer AppLying Mindfulness Trial

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**Objective:** A treatment-as-usual randomized wait-list controlled trial was conducted to investigate the feasibility and impact of an online synchronous Mindfulness-Based Cancer Recovery (MBCR) group program for underserved distressed cancer survivors. **Methods:** Sixty-two men and women exhibiting moderate to high distress within 3 years of completing primary cancer treatment without access to in-person MBCR were randomized to either immediate online MBCR ($n$ = 30) or to wait for the next available program ($n$ = 32). Participants completed questionnaires preintervention and postintervention or wait period online. Program evaluations were completed after MBCR. Feasibility was tracked through monitoring eligibility and participation through the protocol. Intent-to-treat mixed-model analyses for repeated measures were conducted. **Results:** Feasibility targets for recruitment and retention were achieved, and participants were satisfied and would recommend online MBCR. There were significant improvements and moderate Cohen $d$ effect sizes in the online MBCR group relative to controls after MBCR for total scores of mood disturbance ($d$ = 0.44, $p$ = .049), stress symptoms ($d$ = 0.49, $p$ = .021), spirituality ($d$ = 0.37, $p$ = .040), and mindfully acting with awareness ($d$ = 0.50, $p$ = .026). Main effects of time were observed for posttraumatic growth and remaining mindfulness facets. **Conclusions:** Results provide evidence for the feasibility and efficacy of an online adaptation of MBCR for the reduction of mood disturbance and stress symptoms, as well as an increase in spirituality and mindfully acting with awareness compared with a treatment-as-usual wait-list. Future study using larger active control RCT designs is warranted. **Trial Registration:** Clinical Trials.gov: NCT01476891.
**Key words:** mindfulness meditation, cancer, oncology, randomized wait-list controlled trial, online, synchronous.

**CSOSI** = Calgary Symptoms of Stress Inventory; **F2F** = face-to-face; **FFMQ** = Five Facet Mindfulness Questionnaire; **FACIT-sp** = Functional Assessment of Chronic Illness Therapy–Spiritual Well-being; **ITT** = intent-to-treat; **LMM** = linear mixed models; **MBCR** = Mindfulness-Based Cancer Recovery; **MBSR** = Mindfulness-Based Stress Reduction; **PTG** = posttraumatic growth; **POMS** = Profile of Mood States; **TMD** = Total Mood Disturbance; **TAU** = treatment as usual.

## INTRODUCTION

A wide range of effective psychosocial interventions have been developed to assist individuals in overcoming life challenges posed by cancer and in management of cancer-related distress and symptoms (1). Clinical distress is reported by approximately 35% to 45% of people diagnosed as having cancer, and psychosocial interventions are in high demand (2–6). Within all stages and types of cancer, people commonly present with anxiety and mood disturbance, highlighting the importance of testing accessible psychosocial interventions intended to mitigate such disease and treatment-related effects. One program that has received considerable research attention in the oncology field to treat these symptoms is Mindfulness-Based Stress Reduction (MBSR) and the cancer-specific adaptation of Mindfulness-Based Cancer Recovery (MBCR).

### MBSR and MBCR

MBSR, modeled after the program developed by Kabat-Zinn (7), cultivates the practice of present-moment awareness with an open, accepting, and nonjudgemental attitude through formal and informal mindfulness practice. The 8-week intervention consists of training in mindfulness meditation and Hatha yoga originally intended to treat symptoms of chronic illness, pain, and stress (7). MBCR is an adaptation of MBSR for an oncology population. MBSR and MBCR programs within oncology have now been extensively studied (6,8), and Lengacher and colleagues (9) in 2011 reported that MBSR was one of the most frequently researched interventions for individuals diagnosed as having cancer between the years 2000 and 2009. For people living with cancer, MBSR results in decreased mood disturbance, symptoms of stress, fatigue, and anger, with concurrent increases in spirituality, health-related quality of life, posttraumatic growth (PTG), sleep quality, and general well-being (10–23). Meta-analytic and comprehensive reviews of the effects of face-to-face (F2F) MBSR and MBCR within oncology concluded that it is a clinically valuable evidence-based intervention for individuals living with cancer (24–29).

### Benefit Finding

Although much research within psychosocial oncology has focused on the amelioration of negative symptoms consequent to a cancer diagnosis, there has been a more recent shift toward investigating the possible benefits resulting from the experience of cancer. Despite the struggle to adjust to living with cancer and a potential decrease in physical functioning, many people living with cancer identify positive changes including greater appreciation for life, personal growth, and increased spirituality (30,31).

Two of these specific benefits identified after a cancer diagnosis are the development of spirituality and PTG, also known as "benefit finding." Although consensus is lacking regarding a definition, spirituality generally refers to the experience and feelings associated with the search for connection to others and to something larger than oneself, and the subjective sense that a

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person's life has purpose, value, and meaning (32–34). PTG refers to the experience of searching for or discovering positive benefits through adversity such as cancer (35,36). In the cancer context, PTG specifically refers to benefits perceived after a diagnosis that exceed precancer adjustment levels (36). Spirituality and PTG have been linked to other positive outcomes such as increased positive affect, psychological adjustment, and quality of life, as well as decreased physical discomfort and dysfunction after a diagnosis of cancer (37–40).

Psychosocial interventions that increase perceived benefits for people living with cancer may support adaptation and coping for successful long-term survivorship. Thus, there is a need to investigate interventions that have the potential to not only treat distressing symptoms but also encourage a spectrum of positive changes after a potentially traumatic event such as a diagnosis and subsequent treatment of cancer. Research has only begun to investigate the impact of F2F MBCR on positive outcomes, but it may also be the case that online adaptations may provide this benefit as well.

### Online Interventions

Despite efficacy of F2F MBCR and other specialized psychosocial interventions, many people remain unable to access programs because of practical barriers such as geographical distance, transportation issues, cancer-related illness, and limited mobility (41–43). As one predictor of improved psychological functioning over time is referral to psychosocial care and accessing available services, supports, and interventions (44), the Internet represents a promising alternative method of delivering empirically supported psychosocial interventions to underserved people diagnosed as having cancer. In 2013, CancerChat Canada reported that increased access to professionally led support groups via real-time Internet-based chat groups increased cancer-related support to underserved individuals. High level of participation and satisfaction showcased an acceptance and need for additional Internet-based interventions for cancer survivors (45).

The present investigation expands the evidence base of MBCR by assessing the feasibility of an online "real-time" synchronous adaptation of an MBCR program through the evaluation of recruitment, retention, attendance, and participant satisfaction in a sample of moderately to highly distressed people diagnosed as having cancer. Participants were considered underserved if they did not have access to any MBCR program resources. This trial also examines the impact the 8-week online MBCR program on mood and stress, as well as several other positive participant-reported psychological aspects of well-being including spirituality, PTG, and mindfulness immediately after the intervention through a randomized treatment-as-usual (TAU) controlled trial design. It was hypothesized that a) participants would be willing to enroll in and complete the 8-week online intervention and b) people who participated in the online MBCR treatment condition would experience a greater reduction in symptoms of stress and mood disturbance over the course of the intervention compared with a TAU wait-list control and a greater increase in mindfulness, spirituality, and PTG over the course of the 8-week intervention compared with the TAU wait-list condition.

## METHODS

The trial design and detailed procedures for this study have been described elsewhere and will therefore only be briefly reviewed (46). Ethical approval from the Conjoint Health Research Ethics Board of the University of Calgary/Alberta Health Services was obtained before commencement of the trial.

### Participants

Participants were recruited in Alberta through media outreach, promotional pamphlets, community-based networks, and mailing of study invitation letters to potentially eligible people living with cancer from Alberta Cancer Registry case records.

Inclusion criteria were as follows: a) age 18 years or older, b) ability to speak and read English to sufficiently complete questionnaires, c) diagnosis of any type/stage of cancer, d) completed primary cancer treatment within the last 3 years, e) exhibited at least moderate distress as established by Distress Thermometer score of 4 or greater (out of 10), f) no access to an F2F MBCR program, g) access to high-speed Internet, and h) resident of Alberta.

Exclusion criteria were as follows: a) concurrent self-reported diagnosis by medical professional of psychosis, bipolar disorder, substance abuse, or suicidality (however, self-reported diagnosis of a depressive, anxiety, or adjustment disorder did not prevent enrollment) and b) previous participation in F2F MBSR.

### Interventions

#### *Online Mindfulness–Based Cancer Recovery*

Components of the online MBCR program were modeled after the F2F MBCR program at the Tom Baker Cancer Centre in Calgary, Alberta, Canada (see Carlson and Speca (47) for a step-by-step program description). S.F. (coauthor) led all MBCR intervention groups and is a licensed clinician specializing in behavioral medicine with 15 years of experience in teaching online MBSR. S.F. was trained in the cancer-adapted MBSR for this trial by study authors (L.E.C. and M.S.). The programs consisted of weekly 2-hour sessions for 8 weeks. Didactic instruction, experiential practice, and group process were emphasized components of the group, as well as opportunity for extended practice during an online 6-hour retreat between weeks 6 and 7 of the MBCR course. Guided meditation recordings and videos were distributed to support the home practice of 45 minutes of Hatha yoga and mindfulness mediation daily. During the online class sessions, the instructor guided experiential activities of Hatha yoga intended as "mindful movement," qigong mindful movement, and various meditations such as sitting, walking, and loving-kindness meditations. The instructor encouraged communication and support within the online environment to enhance group process.

Headsets, webcameras and MBCR program manuals were provided to all participants via post before beginning the course. In collaboration with the online education company eMindful Inc (www.emindful.com), participants were able to see, hear, and interact in real time with other group members and the instructor during the online synchronous intervention. The virtual classroom allowed multiple webcameras to be viewed by all participants and the instructor simultaneously. Technical support was continuously provided by eMindful during all online sessions to address any technical issues, whereas all other study questions were directed to research coordinators. Before the intervention started, participants were able to set up an individual orientation to the equipment.

#### *TAU Wait-List Control Condition*

In parallel with the online MBCR intervention group, the TAU condition group completed preassessment (T1) and postassessment (T2) online measures before and after their wait period. After the wait period, the TAU control group completed the online MBCR intervention as described above and completed a post-MBCR intervention assessment (T3).

### Objectives

Primary aim: *feasibility*—to determine whether distressed people living with cancer would be willing to participate and complete the online MBCR

intervention. Secondary aim: to examine the efficacy of an online synchronous adaptation of MBCR compared with a TAU wait-list control condition on a range of participant-reported outcomes including mood, symptoms of stress, spirituality, mindfulness, and PTG.

### Primary Outcome: Feasibility

Feasibility was assessed through the following measures: a) proportion "interested" in the program, as estimated through the response rate after study invitation letters sent through the Alberta Cancer Registry (although this number may have underestimated the denominator because we also used other recruitment methods, most eligible participants would have been targeted with the letters); b) proportion "eligible" as estimated by the number of interested participants who met study eligibility; c) proportion "consented" as estimated by the number of eligible people who consented to participate; and d) proportion "completed" as estimated by the number of consenting participants who completed the study protocol (see Fig. 1).

### Secondary Outcomes

*Profile of Mood States* (*POMS*) (48). This scale scores six dimensions: anxiety, depression, anger, vigor, fatigue, and confusion. The Total Mood Disturbance (TMD) score is calculated by summing the six subscale scores. This scale has been used within medical populations, including cancer, and lower scores indicate less mood disturbance. Kuder-Richardson internal consistency of the six subscales ranged from .84 (Confusion) to .95 (Depression) in two studies, with test-retest reliability of 0.65 (vigor) to 0.74 (depression) during approximately a 3-week a period. This is consistent for a measure of mood states, which are expected to vary over time, and supports its construct validity.

*Calgary Symptoms of Stress Inventory* (*CSOSI*) (49). This scale measures behavioral, psychological, and physical responses to situations deemed stressful. The CSOSI has been validated in a Canadian study of patients with cancer at our center, where the depression scale showed satisfactory internal consistency ($\alpha$ = .90) and strong correlations with the emotional functioning scale of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) (−0.76) and depression-dejection

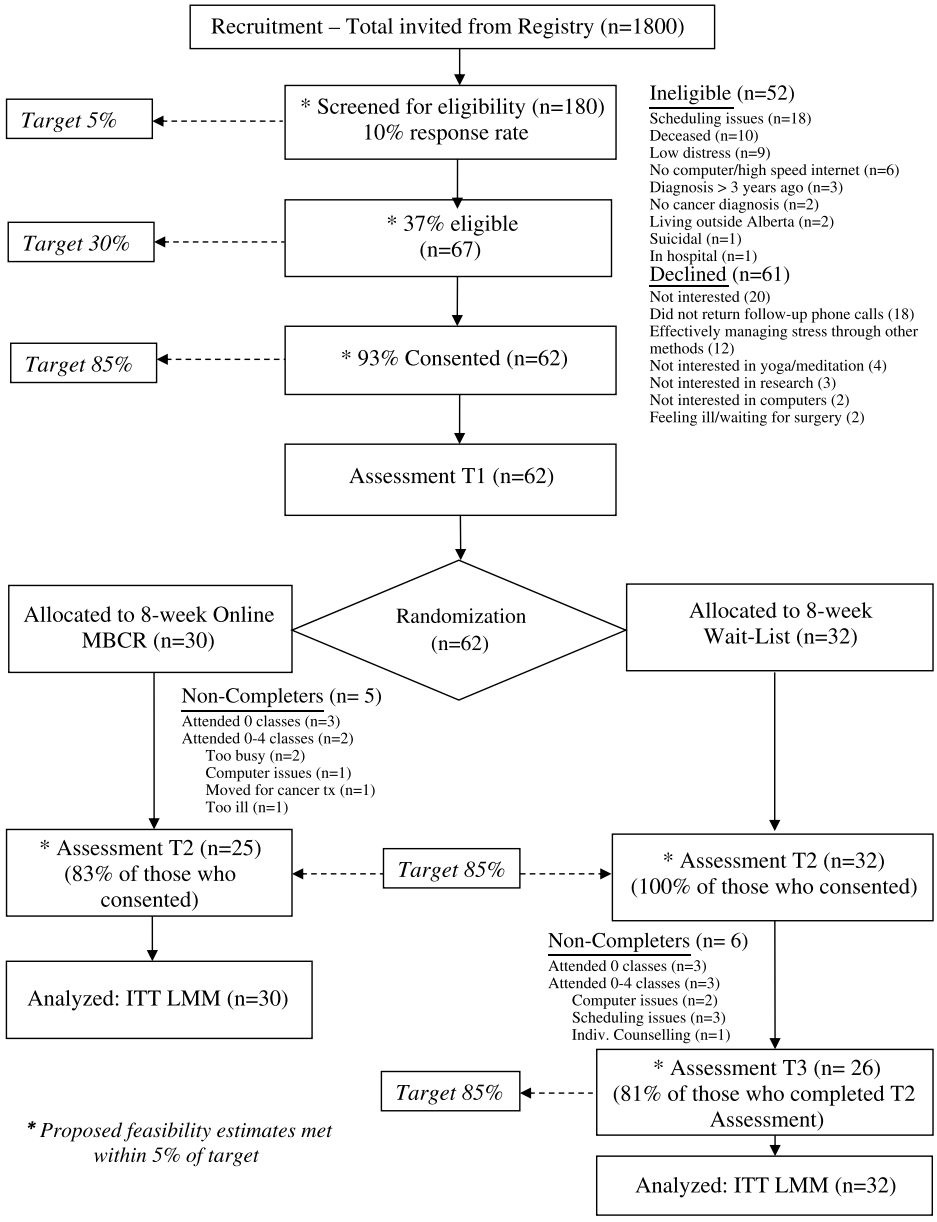


Figure 1. eCALM CONSORT flow diagram. eCALM = eTherapy for Cancer AppLying Mindfulness; MBCR = Mindfulness-Based Cancer Recovery; ITT = intent-to-treat; LMM = linear mixed models.

scale of the POMS-65 (0.87). Eight subscales are calculated from 56 items, and the total scale is obtained from summing subscale scores (49).

*Posttraumatic Growth Inventory* (50). This self-report 21-item inventory measures an individual's subjective perception of positive changes after adversity, and the total scale score was calculated for analysis. The normative sample internal consistency was .90 and .95 in a sample of patients with cancer. Test-retest reliability, measured in the normative sample 8 weeks later, was within acceptable standards (0.71).

*Functional Assessment of Chronic Illness Therapy–Spiritual Well-being* (*FACIT-sp*) (51). This scale is designed to measure spirituality in people with life-threatening or chronic illnesses, with 12 questions summing to the total score, which was used in the trial analysis. Internal reliability of the subscales was reported as good ($\alpha$ = .81–.88).

*Five Facet Mindfulness Questionnaire* (*FFMQ*) (52). The five facets included in this measure of mindfulness are as follows: attending to sensations, perceptions, thoughts, and feelings (observe facet); describing experience with words (describe facet); acting with awareness (acting with awareness facet); nonjudging of experience (nonjudge facet); and nonreactivity to inner experience (nonreact facet). As recommended, these five facets were calculated separately and used in the analysis. The FFMQ showed incremental validity in predicting psychological symptoms and correlated strongly with conceptually related variables (52).

### Sample Size

Target sample size was based on achieving adequate power for the secondary analysis (because the primary analyses were proportions based on feasibility). The goal was to have 80% power at .05 significance level, to test the efficacy of online MBCR in reducing POMS TMD, compared with the TAU control group. On the basis of observed means and standard deviations in three F2F comparable trials conducted at the Tom Baker Cancer Centre, the estimated effect sizes for group differences in preintervention to postintervention change on the POMS TMD score varied between 0.51 and 0.72. Following Dattalo (53) estimation recommendations, 26 participants were estimated to be required for each group to detect a significant difference between the groups.

### Randomization and Blinding

Participants were randomly allocated to either the immediate MBCR or TAU wait-list condition using a computer-based random number generation program on a cohort-by-cohort basis and remained blind to group allocation until after completion of baseline T1 assessments. The nature of the group assignment and intervention did not allow for masking of participants. However, research tasks were assigned to separate members of the team to ensure that primary investigators remained blind to participant status, and all questionnaires were completed online to attenuate the influence of bias on the part of research assistants.

### Data Analysis

All data provided by participants were included in the analyses. Data were tested for normality and homogeneity of variance. To verify that the intervention and control groups were comparable on continuous and categorical demographic variables and psychological variables at preintervention, a series of independent-samples $t$ tests and $\chi^2$ tests were conducted. Results of baseline comparisons were reported if groups differed.

To evaluate the impact of the online MBCR intervention on the secondary outcome measures of mood disturbance, stress symptoms, mindfulness, spirituality, and PTG, linear mixed models (LMMs) for repeated-measures analyses were performed using an intent-to-treat (ITT) principle, so that all participants who provided baseline data were included in the analyses (54,55). LMM is an appropriate statistical method for longitudinal designs with missing data in clinical trials due to sophisticated statistical imputation of missing at random data. Mixed-effects methods with a random intercept model can also account for the variances between participants and within participants. For each dependent measure, a 2 (group) × 2 (time) LMM for repeated measures with maximum likelihood estimation of parameters was conducted, followed by pairwise contrasts for the two groups.

For each of the models, the random effect was the intercept and the fixed effects were baseline scores, group (online MBCR or TAU control), time, and the time by group interaction. Time was also set as a repeated measure. The restricted maximum likelihood estimate method was used to estimate the model parameters and standard errors of missing parameters with an identity covariance structure and is more conservative than an unstructured covariance structure (54,55). Type III fixed effects were used and set statistical significance of $p$ values as less than .05. The least significant difference method was used for multiple comparisons. Between-group Cohen $d$ effect sizes were calculated using the T2–T1 change scores and pooled standard deviations to measure the impact of the online MBCR intervention (Table 3), as recommended by Cohen (56). Program evaluation, satisfaction, and recommendation ratings were calculated, as well as retention rates for the clinical trial feasibility assessment. All data analyses were conducted with IBM SPSS v. 19.

## RESULTS

### Participant Characteristics

The flow diagram of participants including screening, eligibility, consent, and retention is provided in Figure 1. Recruitment spanned from March 2011 to August 2012, and participants were randomized in four cohorts in spring, fall, or winter. Within each class, there was a range of 4 to 11 participants. Most people were women (73%), in a coupled relationship (82%), and white (92%). The most common cancer type was breast (34%). Participants ranged in age from 29 to 79 years, with a mean age of 58 years. Twenty-one participants (34%) were retired or employed full time (24%), and the majority had completed some type of postsecondary training (77%). Table 1 provides participant characteristics separated by treatment condition.

#### *Attrition and Compliance*

Dropout rates for the intervention and control groups differed significantly (online MBCR, $n$ = 5 [16.66%]; TAU, $n$ = 0 [0%]; $p$ = .016). Of the 30 immediate MBCR participants, 25 completed at least five or more classes (more than half the sessions), and all 32 people waiting to take the program completed the wait period and second questionnaire (Fig. 1). The mean (standard deviation) number of MBCR classes attended was 6 (3.0) of 9 (range, 0–9), including the 6-hour online silent retreat. The mean amount of home meditation and yoga practice reported, which did not include the weekly class practice or retreat time, was 150 min/wk. All online MBCR and control group baseline and postintervention estimated marginal means and standard errors for total scales are presented in Table 2. All online MBCR and control group baseline and postintervention unadjusted means and standard deviations, as well as standardized mean differences between treatment and control conditions (Cohen $d$ effect sizes), are presented in Table 3.

### Primary Outcome

#### *Feasibility*

All target feasibility estimates and actual trial percentages are presented in Figure 1.

Feasibility was considered achieved if actual percentages were within 5% of target estimate. Targets were estimated based on previous recruitment and retention numbers from in-person MBCR trials conducted by the senior author (L.E.C.), taking into account the broad and diverse group of survivors invited, and approved in advance in our study protocols.

**TABLE 1. Participant Demographics**

| | Mindfulness Group ($n$ = 30) | Wait-List Group ($n$ = 32) |
|---|---|---|
| Sex | | |
| Female | 22 (73.3%) | 23 (71.9%) |
| Male | 8 (26.7%) | 9 (28.1%) |
| Age, mean (SD), y | 58 (8.2) | 58 (13.0) |
| Cancer stage | | |
| Stage 1 | 10 (33.3%) | 11 (34.4%) |
| Stage 2 | 8 (26.7%) | 7 (21.9%) |
| Stage 3 | 7 (23.3%) | 2 (6.3%) |
| Stage 4 | 4 (13.3%) | 5 (15.6%) |
| Not available[a] | 1 (3.3%) | 7 (21.9%) |
| Cancer type | | |
| Breast | 14 (46.7%) | 7 (21.9%) |
| Blood/Lymph | 1 (3.3%) | 6 (18.8%) |
| Colon/Gastrointestinal | 5 (16.7%) | 2 (6.3%) |
| Prostate | 2 (6.7%) | 2 (6.3%) |
| Female genitourinary | 1 (3.3%) | 5 (15.6%) |
| Thyroid | 3 (10.0%) | 1 (3.1%) |
| Other[b] | 4 (13.3%) | 9 (28.1%) |
| Relationship status | | |
| Married/Living with partner | 25 (83.3%) | 26 (81.3%) |
| Divorced or separated | 3 (10.0%) | 5 (15.6%) |
| Widowed | 2 (6.7%) | 1 (3.1%) |
| Employment status | | |
| Full-time | 8 (26.7%) | 7 (21.9%) |
| Part-time | 5 (16.7%) | 3 (9.4%) |
| Unemployed | 1 (3.3%) | 2 (6.3%) |
| Retired | 10 (33.3%) | 11 (34.4%) |
| Disability | 6 (20.0%) | 9 (28.1%) |
| Education | | |
| Primary/Secondary school | 3 (10.0%) | 4 (12.5%) |
| High school graduate | 5 (16.7%) | 2 (6.3%) |
| College/Associate/ Technical degree | 9 (30.0%) | 15 (46.9%) |
| University degree | 5 (16.7%) | 7 (21.9%) |
| Masters/Postgraduate degree | 7 (23.3%) | 4 (12.5%) |
| Doctoral degree | 1 (3.3%) | — |

SD = standard deviation.
Percentages may not equal 100% due of rounding.
[a] Cancer stage not specified or available in medical chart review.
[b] Other cancer types include bone, brain, esophageal, kidney, liver, lung, and testicular.

Feasibility was assessed through the following measures. a) Proportion interested was estimated at 5%. One thousand eight hundred people were invited to participate with mailed invitation letters through the Alberta Cancer Registry, with 180 responding (10% response rate). b) Proportion eligible was estimated at 30% because of the strict distress score eligibility criteria. This target was met with 67 participants (37%) eligible and interested to participate. c) Proportion consented was targeted at 85%. Sixty-two participants (93%) completed the required consent forms, enrolled in the study, completed baseline T1 assessment, and were subsequently randomized into the treatment conditions (online MBCR: $n$ = 30; TAU wait-list: $n$ = 32). d) Proportion completed accounted for dropout during MBCR or wait (85% target). At T2, 83% (MBCR) and 100% (wait-list) completed, and at T3, 81% of the original wait-list group completed the online MBCR program after their wait condition.

### *Program Evaluation and Satisfaction*

Online MBCR program satisfaction and program recommendation ($n$ = 51) data from all participants who completed the intervention (intervention plus wait-list participants) revealed that 100% of the participants were satisfied with the program (49% satisfied that the program met their expectations, and 51% positively surprised by the online program, which exceeded expectations). Of the 51 participants who completed program recommendation data, 48 would recommend the program to other cancer survivors with no hesitation, whereas 3 participants indicated that they would recommend the program with reservation. Reservations were a) requirement of adequate space around the computer for yoga and meditation, b) requirement of quiet space to meditate, and c) an interest in exploring mindfulness.

## Secondary Outcomes—Psychological Participant-Reported Outcomes

The statistical details of the ITT linear mixed-model analysis are presented in Table 2.

### *Profile of Mood States*

POMS TMD scores revealed a time by group interaction ($F(1,113) = 3.95$, $p = .049$), which indicated that the group effect varied with time and vice versa (Fig. 2). Testing of simple effects indicated that TMD scores were reduced from preintervention to postintervention for the MBCR treatment group ($p$ = .002; Fig. 2). Effect size was 0.44, indicating a medium-sized effect.

### *Symptoms of Stress*

ITT analyses of the CSOSI total score revealed a time by group interaction ($F(1,1113) = 5.48$, $p = .021$). Testing of simple effects indicated that overall symptoms of stress were reduced from preintervention to postintervention for the MBCR treatment group ($p$ = .001; Fig. 2). Cohen $d$ effect size was 0.49 (medium).

### *Spirituality*

ITT analyses of the FACIT-Sp total score revealed a time by group interaction ($F(1,1113) = 4.31$, $p$ = .040). Compared with the control condition, simple effect testing indicated that spirituality scores increased from preintervention to postintervention for the MBCR treatment group ($p$ = .002; Fig. 2). Cohen $d$ effect size was 0.37 (small).

### *Posttraumatic Growth*

Results of the LMM analyses on the Posttraumatic Growth Inventory total scores revealed main effects of time ($F(1,113)$

**TABLE 2. Statistical Details of Linear Mixed-Model Analyses Assessing Psychological Outcome Total Scale Scores for ITT Sample (MBCR *n* = 30; TAU Control *n* = 32)**

| Outcome | Assessment Time, Estimated Marginal Group Mean (SE) | | | Type III Tests of Fixed Effects, LMM Statistical Tests: *F* (*df*) [*p*] | | |
|---|---|---|---|---|---|---|
| | Group | Baseline (T1) | Post (T2; 8 wk) | Group Effect | Time Effect | Group * Time Interaction |
| POMS[a] | Online MBCR | 39.57 (3.67) | 18.31 (4.10) | 5.25 (1,113) [.024] | 13.89 (1,113) [.000] | 3.95 (1,113) [.049] |
| | TAU control | 40.72 (3.55) | 37.21 (3.55) | | | |
| CSOSI[a] | Online MBCR | 62.49 (3.12) | 40.29 (3.49) | 7.00 (1,113) [.009] | 21.83 (1,113) [.000] | 5.48 (1,113) [.021] |
| | TAU control | 63.49 (3.02) | 56.12 (3.02) | | | |
| FACIT-sp[a] | Online MBCR | 26.32 (0.81) | 31.78 (0.90) | 6.85 (1,113) [.010] | 21.19 (1,113) [.000] | 4.32 (1,113) [.040] |
| | TAU control | 25.86 (0.78) | 27.92 (0.87) | | | |
| PTGI[b] | Online MBCR | 50.77 (2.18) | 61.84 (2.44) | 0.56 (1,113) [.456] | 19.69 (1,113) [.000] | 0.31 (1,113) [.578] |
| | TAU control | 50.35 (2.11) | 58.95 (2.11) | | | |
| FFMQ-awa[a] | Online MBCR | 27.53 (0.57) | 30.10 (0.64) | 4.17 (1,113) [.044] | 4.87 (1,113) [.029] | 5.11 (1,113) [.026] |
| | TAU control | 27.65 (0.55) | 27.62 (0.55) | | | |
| FFMQ-obs[b] | Online MBCR | 24.65 (0.62) | 26.56 (0.70) | 0.06 (1,113) [.816] | 7.18 (1,113) [.008] | 1.13 (1,113) [.725] |
| | TAU control | 24.72 (0.60) | 26.19 (0.60) | | | |
| FFMQ-des[b] | Online MBCR | 25.17 (0.50) | 26.45 (0.56) | 0.01 (1,113) [.936] | 8.93 (1,113) [.003] | 0.18 (1,113) [.671] |
| | TAU control | 24.91 (0.48) | 26.67 (0.48) | | | |
| FFMQ-nrea[b] | Online MBCR | 19.31 (0.50) | 21.72 (0.56) | 0.51 (1,113) [.478] | 19.95 (1,113) [.000] | 0.10 (1,113) [.753] |
| | TAU control | 19.10 (0.48) | 21.20 (0.48) | | | |
| FFMQ-njud[b] | Online MBCR | 27.28 (0.60) | 30.09 (0.67) | 1.59 (1,113) [.210] | 8.77 (1,113) [.004] | 2.66 (1,113) [.106] |
| | TAU control | 27.51 (0.58) | 28.32 (0.58) | | | |

ITT = intent-to-treat; MBCR = Mindfulness-Based Cancer Recovery; TAU = treatment as usual; SE = standard error; POMS = Profile of Mood States; CSOSI = Calgary Symptoms of Stress Inventory; FACIT-sp = Functional Assessment of Chronic Illness Therapy–Spiritual Well-being; PTGI = Posttraumatic Growth Inventory; FFMQ-awa = Five Facet Mindfulness Questionnaire Acting with Awareness total scale score; FFMQ-obs = Five Facet Mindfulness Questionnaire Observe total scale score; FFMQ-des = Five Facet Mindfulness Questionnaire Describe total scale score; FFMQ-nrea = Five Facet Mindfulness Questionnaire Nonreact total scale score; FFMQ-njud = Five Facet Mindfulness Questionnaire Nonjudge total scale score.

[a] Significant interaction effect.

[b] Significant time effect.

= .19.69, $p < .001$). Results of follow-up analyses indicated that, regardless of group assignment, total scores for PTG increased at the 8-week assessment compared with baseline scores.

### *Mindfulness*

ITT analyses of the FFMQ Acting with Awareness facet total score revealed a time by group interaction ($F(1,113) = 5.11$, $p = .026$). Testing of simple effects indicated that the mindfulness facet of acting with awareness increased from preintervention to postintervention for the MBCR treatment group ($p = .004$; Fig. 2). Effect size was medium (0.50). A main effect of time was observed for all four of the other FFMQ subscale total scores: Observing ($F(1,113) = 1.13$, $p = .73$), Describing ($F(1,113) = .18$, $p = .67$), Nonjudging of Inner Experience ($F(1,113) = 2.66$, $p = .12$), and Nonreacting to Inner Experience ($F(1,113) = 0.10$, $p = .75$). Post hoc analyses revealed higher total scores at 8-week assessment when compared with baseline, regardless of group assignment for the Nonjudge ($p = .050$); however, the Observe, Describe, and Nonreact facet simple effect testing did not reveal significant differences over time.

## DISCUSSION

This trial is the first to assess the feasibility of providing an online synchronous MBCR program to underserved people living with cancer. The eTherapy for Cancer AppLying Mindfulness (eCALM) trial is also the first to compare an online synchronous MBCR intervention to a TAU wait-list control condition for distressed cancer survivors. As predicted, feasibility estimates were met. Given that psychosocial interventions in general are taken up by a minority of cancer survivors and because this is a very specialized intervention requiring interest in learning meditation and yoga online over a period of 8 weeks, we did not expect more that 5% to 10% of those broadly targeted in a mailed invitation letter based only on geographic location to be interested. Hence, we were pleased to have met this target. Participants not only were willing to enroll and complete the online MBCR program, but were satisfied with the online format of MBCR—which either met or exceeded all participants' expectations. All participants also indicated that they would recommend the online program, to other people living with cancer.

Consistent with our hypotheses, there were statistically significant improvements and medium effect sizes for the

**TABLE 3. Unadjusted Means and SDs and Standardized Mean Difference Between Treatment and Control Group Effect Sizes for Outcome Total Scores for MBCR and TAU Groups**

| | Online MBCR Group ($n$ = 30), Mean (SD) | TAU Wait-List Group ($n$ = 32), Mean (SD) | Cohen $d^a$ |
|---|---|---|---|
| POMS | | | |
| Baseline (T1) | 37.43 (35.69) | 42.16 (27.40) | |
| Posttreatment (T2) | 17.16 (30.72) | 35.69 (31.52) | 0.44 |
| CSOSI | | | |
| Baseline (T1) | 59.70 (32.52) | 66.10 (33.77) | |
| Posttreatment (T2) | 36.83 (21.87) | 58.72 (37.38) | 0.49 |
| FACIT-sp | | | |
| Baseline (T1) | 27.60 (9.95) | 24.78 (9.05) | |
| Posttreatment (T2) | 33.04 (8.08) | 26.84 (8.66) | 0.37 |
| PTGI | | | |
| Baseline (T1) | 51.97 (22.29) | 49.38 (22.43) | |
| Posttreatment (T2) | 62.96 (17.57) | 57.97 (23.02) | 0.11 |
| FFMQ-observe | | | |
| Baseline (T1) | 24.53 (6.29) | 24.88 (7.23) | |
| Posttreatment (T2) | 26.29 (5.02) | 26.34 (6.06) | 0.05 |
| FFMQ-describe | | | |
| Baseline (T1) | 26.17 (6.20) | 23.81 (7.28) | |
| Posttreatment (T2) | 28.13 (6.03) | 25.53 (6.73) | 0.06 |
| FFMQ–act with awareness | | | |
| Baseline (T1) | 27.17 (7.67) | 27.78 (6.05) | |
| Posttreatment (T2) | 30.21 (5.00) | 27.80 (5.64) | 0.50 |
| FFMQ-nonjudge | | | |
| Baseline (T1) | 26.63 (7.06) | 28.03 (7.12) | |
| Posttreatment (T2) | 29.50 (5.68) | 28.84 (5.86) | 0.32 |
| FFMQ-nonreact | | | |
| Baseline (T1) | 19.73 (4.68) | 18.75 (4.07) | |
| Posttreatment (T2) | 22.13 (3.71) | 20.84 (4.81) | 0.07 |

MBCR = Mindfulness-Based Cancer Recovery; TAU = treatment as usual; SD = standard deviation; POMS = Profile of Mood States; CSOSI = Calgary Symptoms of Stress Inventory; FACIT-sp = Functional Assessment of Chronic Illness Therapy–Spiritual Well-being; PTGI = Posttraumatic Growth Inventory; FFMQ = Five Facet Mindfulness Questionnaire.

[a] Cohen $d$ formula used = difference between two mean changes between groups (T2–T1 change scores) divided by the pooled SDs.

online MBCR group relative to controls after the 8-week MBCR for total mood and stress symptom scores. Compared with Ledesma and Kumano's (27) F2F MBSR meta-analysis of a medium effect size for mental health factors ($d$ = 0.48) and Musial and colleagues (29), who calculated effect size for mood ($d$ = 0.42) or distress ($d$ = 0.58), the current online synchronous program results are comparable with medium effect sizes for both TMD ($d$ = 0.44) and overall symptoms of stress ($d$ = 0.49). Effect sizes on mood were also similar to those reported by our group in studies of F2F MBSR (12,16,57). The POMS minimally important difference is a half standard deviation, or 18.40 points; the intervention group exceeded this cutoff with an average change of 20.53, compared with the TAU wait-list change of 6.47. In addition, 22 participants in the treatment group achieved significant change versus 8 in the waiting group. Hence, the changes seen are likely meaningful in the day-to-day lives of participants. With improvements over and above a TAU wait-list in reduction of both mood disturbance and stress symptoms in the distressed sample, additional research into the online synchronous format to reach underserved cancer survivors is warranted.

Regarding positive outcomes, we found an increase in spiritual well-being. This is consistent with findings from Garland et al. (14) and Henderson et al. (21) with F2F MBSR. However, a recent review by Cramer and colleagues (58) did not report a significant effect on spirituality after F2F MBSR. These discrepancies could be explained by the use of differing spirituality measures or differences between F2F and online MBSR formats. Although differing measures and modalities make comparisons challenging, the encouraging results from our trial echo the increases in spirituality in F2F MBCR observed in a previous trial from our research group (14). However, contrary to hypotheses, we did not see an effect of the intervention on PTG—instead, both the intervention and control groups increased over time. Although we do not know why there was not a significant interaction effect for PTG, a potential reason for the time effect may have to do with the effects of repeatedly

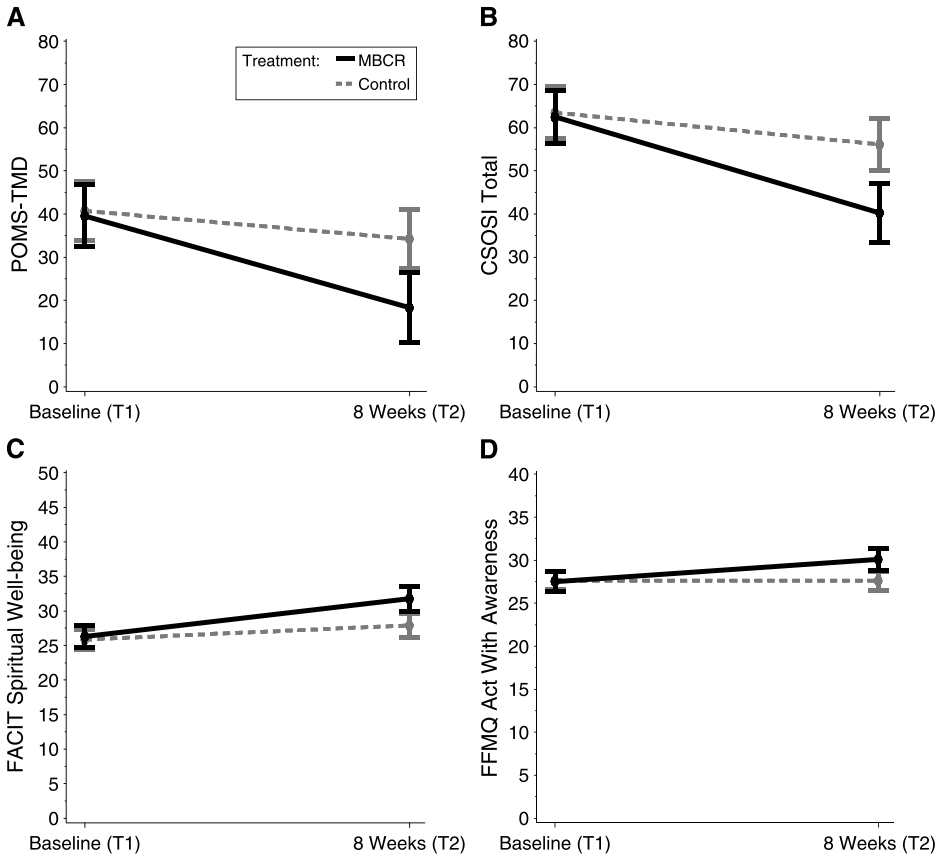


Figure 2. Estimated group means and 95% CI on POMS TMD (A), CSOSI (B), FACIT-sp (C), and FFMQ Act with Awareness Total Scores (D) from baseline to immediately postintervention. CI = confidence interval; POMS = Profile of Mood States; TMD = Total Mood Disturbance; CSOSI = Calgary Symptoms of Stress Inventory; FACIT-sp = Functional Assessment of Chronic Illness Therapy–Spiritual Well-being; FFMQ = Five Facet Mindfulness Questionnaire; MBCR = Mindfulness-Based Cancer Recovery.

completing questionnaires on PTG, a form of self-monitoring, or perhaps at the second time point, wait-list participants were anticipating imminently starting the program and may have been feeling more hopeful as a result. Previous research has demonstrated increases in PTG after F2F MBCR (14); however, this research did not include a wait-list comparison, highlighting the importance of including a control group and the need for future MBCR trials to use active control conditions to help determine the specificity of the interventions.

Previous research indicates that increases in mindfulness after participation in mindfulness-based interventions are correlated with improved psychological outcomes in cancer populations (22,59,60) and within the general population (61–64). This is the first study to examine mindfulness facets after an online synchronous MBCR intervention. Our trial did not demonstrate a statistically significant interaction effect of MBCR participation on mindfulness facets, apart from acting with awareness ($d = 0.50$). The mindfulness facet acting with awareness, viewed as a key component of mindfulness, can be described as the opposite of automatically acting while attention is focused elsewhere (11). Increased awareness of internal experiences is hypothesized to be a foundational aspect of mindfulness and required before modification of subsequent cognitions or actions can occur. Within the online MBCR program, people are first encouraged to pay attention to emotions, cognitions, and behaviors in a nonevaluative manner. This practice is hypothesized to create space for reperceiving, or fostering alternative ways to respond to negative emotional experiences (65). Consistent with a dissertation examining effect sizes for each of the mindfulness facets as mediators, increased present-focused attention/awareness was the strongest mediator of the effect of the in-person MBCR program on mood disturbance and stress symptoms (11,66).

Consistent with the eCALM results, Garland and colleagues (59) reported a medium effect size evaluating an F2F MBCR intervention for acting with awareness; however, in contrast to our results, they also indicated medium effects for describing and nonjudging scales as well, and large effect sizes for observing and nonreacting to inner experience scales. Computation of the FFMQ total score is not recommended by the scale authors and therefore was not calculated (52), preventing comparison to trials that reported this result. Investigation into the mechanisms of action in F2F MBCR and determining whether increases in mindfulness contribute to better mental health or if other mechanisms mediate these benefits will help inform future research of this online format. Preliminary investigations of decreases in rumination (8,67) and, more recently, experiential avoidance (68) are possible areas of future research.

This study is characterized by several strengths. Participants were randomized to a manualized MBCR program or to wait,

and only people with moderate to high levels of distress were recruited to mitigate floor effects seen in other psychosocial intervention trials. The generalizability of these results is maximized by the inclusion of men and women with heterogeneous cancer types and stages.

There are also limitations to this trial. All data collected were self-report, which may be influenced by social desirability bias. To partially mitigate this bias, we actively reassured participants regarding the confidentially of their responses to the online questionnaires. The pre/post wait-list trial design limited long-term follow-up, preventing conclusions about the efficacy of the online treatment to maintain effects after the intervention. As an initial step, a wait-list design can control for the influences of pretreatment and posttreatment assessment, symptom self-monitoring, natural recovery from cancer treatments, and spontaneous remission or deterioration of symptoms, as well as regression to the mean over time in this moderately to highly distressed sample. Future research will benefit from using a control group matched for attention and time across the entire 8-week online MBCR period and extended follow-up. Although our intent in choosing a synchronous online group format was to mimic as closely as possible in-person group interactions, a limitation of this format is that it does not alleviate the scheduling issues inherent in group programming that asynchronous interventions ameliorate. Because several different components are included in the online MBCR program, such as mindfulness meditation, Hatha yoga, psychoeducation, and group discussion, the MBCR intervention is typically evaluated as a treatment package rather than identifying specific components that produce benefits. Future dismantling studies could be helpful in elaborating more reductionistic research questions for F2F mindfulness research as well as online adaptations. Time since cancer diagnosis was not recorded for this sample and could be an interesting factor to consider in future investigations. To generalize our results to a broader group of patients with cancer and further explore the positive psychological outcomes associated with MBCR, inclusion of both distressed and nondistressed patients may increase accessibility to patients with cancer who, although not initially distressed, may still benefit from enhancement of spiritually, PTG, and other positive outcomes.

In summary, the eCALM trial incorporated sophisticated real-time technology to reach underserved people diagnosed as having cancer who are currently excluded from F2F MBCR programs, with the goal of improving access to psychosocial interventions for a difficult-to-reach population, while simultaneously reducing mood disturbance and stress symptoms, and increasing spirituality and some aspects of mindfulness. Programs using similar synchronous technology could potentially improve access to highly specialized evidence-based psychosocial programs in oncology and extend reach to other illness populations. We hope the results of this study will encourage further research into the integration of mind-body medicine and technology for underserved populations.

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