

A randomized trial comparing live and telemedicine deliveries of an imagery-based behavioral intervention for breast cancer survivors: reducing symptoms and barriers to care

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Abstract

Objective: This multi-site randomized trial evaluates the quality of life (QOL) benefits of an imagery-based group intervention titled ‘Envision the Rhythms of Life’(ERL).

Methods: Breast cancer survivors >6 weeks post-treatment were randomized to attend five weekly 4-h group sessions at a community center with therapist present (live delivery (LD), $n = 48$), therapist streamed via telemedicine (telemedicine delivery (TD), $n = 23$), or to a waitlist control (WL) group ($n = 47$). Weekly individual phone calls to encourage at-home practice began at session one and continued until the 3-month follow-up. Seven self-report measures of QOL were examined at baseline, 1-month and 3-month post-treatments including health-related and breast cancer-specific QOL, fatigue, cognitive function, spirituality, distress, and sleep.

Results: The Bonferroni method was used to correct for multiple comparisons, and alpha was adjusted to 0.01. Linear multilevel modeling analyses revealed less fatigue, cognitive dysfunction, and sleep disturbance for LD and TD compared with WL across the follow-up (p 's < 0.01). Changes in fatigue, cognitive dysfunction, sleep disturbance, and health-related and breast cancer-related QOL were clinically significant. There were no differences between LD and TD.

Conclusions: Both the live and telemedicine delivered ERL intervention resulted in improvements in multiple QOL domains for breast cancer survivors compared with WL. Further, there were no significant differences between LD and TD, suggesting telemedicine delivered ERL intervention may represent an effective and viable option for cancer survivors in remote areas.

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Introduction

Growing evidence suggests that psychosocial interventions improve quality of life (QOL) in cancer survivors [1]. Among the efficacious approaches, interventions emphasizing guided imagery have been associated with improved QOL, reduced treatment-related side effects, and improved immune function in cancer survivors [2–4] although not all studies have found this association [5]. A single arm pretest/post-test study using the present imagery-based intervention indicated that 30 post-treatment breast cancer survivors living in rural Alaska experienced increased post-treatment general and breast cancer-specific QOL, improved spiritual well-being, and decreased distress [6].

Thus, a randomized controlled trial is the necessary next step to determine whether such changes can be attributed to the intervention rather than simply the passage of time.

Many cancer survivors face significant barriers to care (e.g., living in remote locations, work schedule, family responsibilities, poor health, and psychological distress) that can preclude them from participating in post-treatment care requiring travel to distant medical facilities [7]. Telemedicine is one approach to improving survivor access to care and has been demonstrated to be an effective and accepted method of providing medical consultations, managing post-treatment symptoms, and delivering psychological counseling or mind–body interventions for cancer survivors [8–10].

In addition to the traditional telemedicine delivered in-home via telephone or Internet, effective telecare is also being provided to patients at community health centers. For example, oncology patients unable to travel to a major hospital reported reduced pain and depression symptoms following telecare at community-based oncology clinics [11]. Importantly, a direct comparison of face-to-face versus videoconference-delivered cognitive intervention for community dwelling older persons revealed no differences in cognitive improvement [12]. Thus, telemedicine delivered at community centers may be a powerful avenue to ensure that quality healthcare is available to patients unable to commute to major medical centers. Additionally, group therapy at a community center led by a remote provider (via videoconferencing) can provide patients with important non-specific social support inherent in group therapy experiences and reduce the time required of providers. However, to the best of our knowledge, no published studies have examined the effects of such an intervention.

Despite its utility, telemedicine is estimated to be used by only 4% of psychosocial cancer care providers [13]. Although some suggest that this discrepancy is due to a lack of education about telemedicine modalities [13], only 23% of mental health providers at community-based outpatient clinics indicated that they do not know enough about telemedicine, whereas 79% believed that more research is needed on the effectiveness of telemedicine [14]. Thus, additional research on the potential effectiveness of telemedicine for delivering psychosocial cancer care is warranted.

The primary aim of the current study was to compare the effects of an intervention entitled 'Envision the Rhythms of Life' (ERL) delivered live or via telemedicine compared with a waitlist control (WL) on QOL for breast cancer survivors. Specifically, we hypothesized that participants in the LD and TD groups would report improved QOL across the follow-up compared with the participants in the WL group. Additionally, although the present study was not designed to test for equivalence, we hypothesized that the LD and TD groups would not significantly differ on any outcome.

Methods

Participants

Breast cancer survivors, at least 6 weeks after completing their major cancer treatments, were recruited from 2008 to 2010. Eligibility included confirmed diagnosis of breast cancer, 18 years of age or older, and with no major psychiatric illness. Participants were required to be visual and hearing capable, able to read, write and speak English, and demonstrate an orientation to person, place, and time. Medical release forms were provided to allow all medical records to be reviewed by the research nurse.

Procedure

Participants were recruited through newspaper ads, cancer support group websites, public presentations, medical referral, posting of flyers, and via TV news and radio coverage. One live delivery (LD), ($n=25$) and one telemedicine delivery (TD) group ($n=23$) were conducted in Anchorage, Alaska; and one LD group ($n=23$) was conducted in Seattle, Washington. Therapy groups consisting of up to 25 participants are routinely conducted at these sites to maximize limited staff and cost effectiveness. Although the authors originally intended for a telemedicine group to also be conducted in Seattle, unforeseen staffing limitations prevented this group from taking place. Seattle was chosen as the secondary location because it was the city in the continental USA for which travel from the therapists' primary location (in Alaska) was most feasible.

After informed consent was obtained, participants were randomized to one of the three groups: LD group sessions, therapist present via audiovisual technology during group sessions (TD), or WL. Assignment by adaptive randomization (minimization) was balanced by age, gender, stage, chemotherapy, surgery, radiation, and hormone use. Participants in LD and TD had five 4-h weekly group sessions and received brief (<10 min) weekly phone calls to encourage at-home practice that began at the start of treatment and continued for 3-month post-treatment. All self-report questionnaires were completed in the presence of a research assistant and were collected at baseline and 1-month and 3-month post-treatment. The study was approved by the Alaska Regional Hospital institutional review board.

ERL intervention

Live delivery and TD groups met in a community center, with either the therapist present (LD) or a research assistant present to set up the videoconferencing software (TD). The videoconferencing software enabled the therapist, who was not physically present, and participants to view and interact with one another. Additionally, the therapist was able to control the camera direction, enabling her to interact with small groups and individuals during the interactive portion of the sessions.

The intervention was delivered by the first and second authors, a licensed professional counselor, and a family medicine physician, respectively. The format followed a manual developed by the first author, and was identical for both delivery types. The first four sessions were separated into three modules each comprised of 25 min of didactic education followed by 25 min of interaction with fellow group members (in triads) to discuss and practice the material presented in the didactic portion (Supplement 1). During the fifth session, each participant presented her long-term plan for continuing to practice the activities taught during the group, and the participants provided feedback and suggestions to enrich each plan.

The didactic portion of sessions provided education on the mind–body connection and presented research on the impact of mental imagery and the sensate experience (e.g., sounds, scent, taste, and touch) on physiological processes (e.g., psychoneuroimmunology processes, heart rate variability (HRV), temperature, and circadian rhythms) [15–18]. The interactive portion of sessions enabled participants to apply what they just learned and receive feedback from their small group and the therapist, who briefly visited with each triad during the interactive group time. Briefly, throughout the intervention, participants identified maladaptive ‘passive imagery’ (e.g., automatic thoughts focused on fear/loss of control), created adaptive ‘active imagery’ (e.g., thoughts focused on empowering, meaning-making themes), and practiced ‘targeted imagery’ (e.g., imagining healthy physiological processes such as HRV, circadian rhythms, and immune function). Participants were instructed to engage all five senses during active and targeted imagery and to monitor the effects of imagery on their own mind–body health. For example, during the interactive portion of Session 3, participants monitored the effects of targeted imagery on their own HRV using an HRV monitoring device (EmWave PRO; HeartMath LCC; Boulder Creek, CA, USA).

Each week, participants received a 20–30 min guided imagery compact disc related to that week’s topic. During intervention delivery and for 3-month post-treatment, participants were instructed to engage in daily formal (using compact discs) and informal (using brief targeted imagery when under stress) practice. Participants received weekly phone calls from their group therapist (approximately 10 min) during intervention delivery and for 3-month post-treatment. These phone calls were designed to encourage participants to engage in practice and troubleshoot barriers to practice. All sessions were videotaped, and 10% was randomly chosen for evaluation of ongoing treatment fidelity. Participants who missed a session were encouraged to attend a one-on-one make-up session with the group therapist, who presented the didactic lessons using the same materials and format as were used in the group session.

Participants in the WL group were offered the ERL intervention delivered with a therapist present after they completed the 3-month follow-up.

Measures

General health-related QOL was measured using the Medical Outcomes Study 36-item short form survey (SF-36) [19]. The Research and Development Health Corporation scoring method was used (score range 0–100) to compute physical component summary (PCS) and mental component summary (MCS) scores, with higher scores representing better QOL.

The 13-item breast cancer-specific subscale of the Functional Assessment of Cancer Therapy-Breast (FACT-B)

[20] assessed breast cancer-specific QOL, using a 0–4 Likert scale with higher scores representing better QOL (score range 0–52).

Fatigue was assessed using the 13-item FACIT-Fatigue Scale (FACIT-F, version 4), on which participants rate their tiredness during usual daily activities over the past week using a 0–4 Likert scale (score range 0–52), with higher scores indicating less fatigue. A score of <36 is associated with clinically significant fatigue [21].

Perceived cognitive function was assessed with the 37-item FACT-Cog (version 2), which uses a 0–4 Likert scale to assess perceived cognitive impairment (PCI), perceived cognitive abilities (PCA), and impact of perceived cognitive impairments on quality of life [24]. A total score was calculated by adding the PCI and PCA subscales [22], with higher scores indicating less perceived impairment (score range 0–116).

Spiritual well-being was measured with the 23-item Functional Assessment of Chronic Illness Therapy Spiritual Well-Being Expanded Scale (FACIT-Sp-Ex; version 4), which uses a 0–4 Likert scale to assess meaning, peace, and faith, with higher scores indicating greater spiritual well-being (score range 0–92) [23].

Psychological distress was assessed using the 18-item Brief Symptom Inventory-Global Severity Index (BSI-GSI) [24]. BSI-GSI scores have been standardized and are represented as *T*-scores in the present paper with higher scores representing worse distress (score range 30–75).

Sleep disturbances were assessed using the nine-item Pittsburgh Sleep Quality Index (PSQI), which assesses quality of sleep and sleep disturbances over a 1-month period [25]. A total score is derived with a score of 5 or greater associated with being a ‘poor’ sleeper (score range 1–21) [25].

Demographic factors were included in the baseline questionnaires, and medical data were extracted from patients’ medical records. Tracking data were kept regarding class attendance, completion of questionnaires, and attrition.

Data management and analysis

Data were scored and analyzed using SAS (version 9.2; SAS, Cary, NC, USA). Descriptive statistics were computed. The PROC MIXED procedure in SAS was used to conduct linear multilevel modeling (LMM) analyses [26] to estimate the effects of group, time, and the group × time effects on each of the eight primary QOL outcomes (SF-36 (PCS, MCS), FACIT scales (FACT-B, FACIT-F, FACT-Cog, FACIT-Sp-Ex), BSI-GSI, and PSQI) covarying for the respective QOL baseline measure, and covariates determined a priori (age, months since diagnosis, stage, chemotherapy, surgery, radiation, and hormone therapy). LMM efficiently handles unbalanced designs and missing data without excluding participants or imputing values [27]. The Bonferroni method was used to correct for the eight primary QOL outcome measures, taking into account the

average correlation between outcome variables (mean $r=0.27$), and alpha was adjusted to 0.011 [28]. The t -test was used for all post hoc group comparisons. Additionally, exploratory analyses were conducted using χ^2 -tests to examine group differences in the proportion of participants reporting clinically significant sleep disturbances (PSQI 5) [25] and fatigue (FACIT-F < 36) [21] at each time point. A priori power analyses determined that with 45 patients per each group in this study and a 15% dropout rate (i.e., with 38 evaluable participants per group), we would be able to declare as statistically significant differences between two groups that are at least 0.65 standard deviations assuming a two-sided significance level of 0.05 and 80% power.

Preliminary analyses revealed no differences between cities (Anchorage vs. Seattle) in demographic or medical characteristics. Further, with the exception of baseline FACIT-Sp-Ex, there were no baseline (demographic, medical, or psychosocial) or follow-up differences between the Anchorage and Seattle LD groups (p 's > 0.3). There was a trend for LD participants in Anchorage to report higher baseline FACIT-Sp-Ex than those in Seattle ($p=0.07$). Thus, the LD groups were combined for all analyses, and the city was entered as a covariate in analyses examining FACIT-Sp-Ex.

Results

Sample characteristics

Among the 121 participants consented to the study, 118 (97.5%) were randomized and provided baseline data (LD=48, TD=23, and WL=47), 104 (LD=41, TD=19, and WL=44) completed the intervention and 1-month

follow-up, and 102 (LD=40, TD=19, and WL=43) completed the 3-month follow-up. Reasons for attrition can be seen in the CONSORT diagram (Figure 1). There were no significant group differences in loss to follow-up. The demographic, medical, and baseline psychosocial variables did not differ between participants who did and did not drop out of the study by T2 or T3 follow-ups. There were no group differences in demographic or medical characteristics (Table 1) or in baseline psychosocial measures (Table 2). Additionally, the average class size did not differ between LD and TD.

Adherence

Five of the 48 participants randomized to LD withdrew from the study prior to attending any classes; two participants attended some classes before dropping out because of deaths in the family. Thirty-five of the remaining 41 LD participants attended all sessions as scheduled, six missed one session but attended a make-up session, and one missed the final session and did not perform a make-up. One of the 23 participants randomized to TD withdrew without attending any classes and three attended some classes before dropping out because of personal reasons. Eighteen of the remaining 19 TD participants attended all sessions as scheduled and one participant missed one session but received a make-up session.

QOL outcomes for live delivery versus telemedicine delivery versus waitlist

Unadjusted group means and standard deviations at baseline, 1-month and 3-month follow-ups and adjusted group

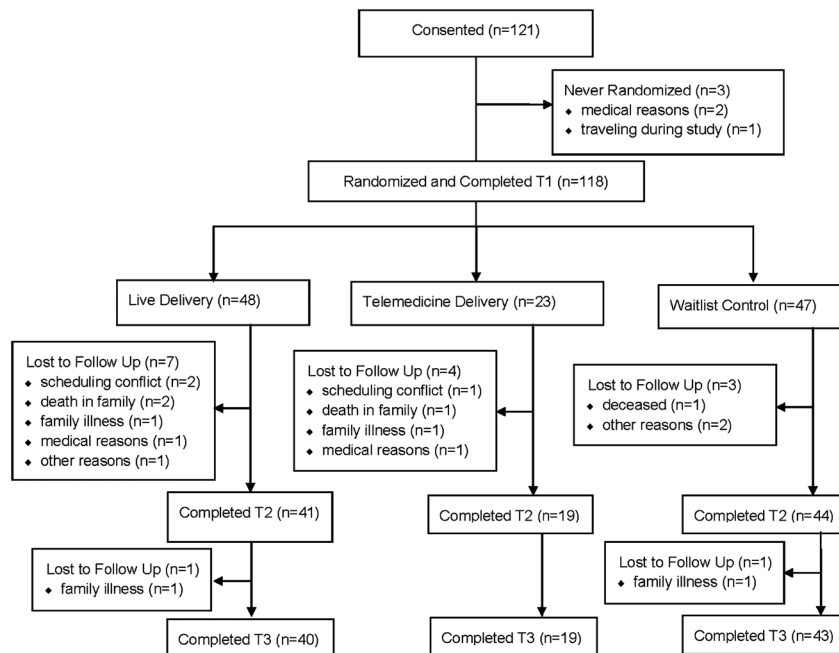


Figure 1. Consort diagram

Table 1. Demographic and medical characteristics by study group.

Characteristic	Live delivery <i>n</i> = 48	Telemedicine delivery <i>n</i> = 23	Waitlist control <i>n</i> = 47
Mean age (SD)	55.44 (8.08)	55.57 (9.88)	55.28 (7.90)
Ethnicity <i>N</i> (%)			
White	40 (83.33)	20 (86.96)	43 (91.49)
African American	0 (0)	0 (0)	1 (2.23)
Hispanic/Latino	0 (0)	1 (4.35)	0 (0)
American Indian/Alaska native	8 (16.67)	2 (8.70)	3 (6.38)
Marriage status <i>N</i> (%)			
Married/cohabitating	30 (62.50)	17 (73.91)	26 (55.32)
Divorced/separated	13 (27.08)	4 (17.39)	13 (27.66)
Never married	5 (10.42)	2 (8.70)	5 (10.64)
Education <i>N</i> (%)			
High school diploma	2 (4.17)	1 (4.35)	2 (4.26)
Some college	11 (22.92)	4 (17.39)	11 (23.40)
College degree	23 (47.92)	11 (47.83)	16 (34.04)
Graduate degree	11 (22.92)	7 (30.43)	18 (38.30)
City <i>N</i> (%)			
Anchorage	25 (52.08)	23 (100)	24 (51.06)
Seattle	23 (47.92)	0 (0)	23 (48.94)
Months since diagnosis (SD)	50.48 (41.72)	62.65 (61.60)	45.53 (36.68)
Stage of disease <i>N</i> (%)			
0	6 (13.33)	4 (19.05)	3 (7.32)
I	16 (35.56)	6 (28.57)	16 (39.02)
II	15 (33.33)	4 (19.05)	15 (36.59)
III	7 (15.56)	6 (28.57)	5 (12.20)
IV	1 (2.22)	1 (4.76)	2 (4.88)
Surgery <i>N</i> (%)			
Lumpectomy	15 (31.91)	12 (52.17)	19 (42.22)
Mastectomy only	26 (55.32)	11 (47.83)	23 (51.11)
Mastectomy with reconstruction	6 (12.77)	0 (0)	3 (6.67)
Chemotherapy <i>N</i> (%)			
Yes	31 (64.58)	13 (56.52)	33 (70.21)
Radiation <i>N</i> (%)			
Yes	34 (70.83)	17 (73.91)	36 (76.60)
Hormone therapy <i>N</i> (%)			
Yes	31 (64.58)	13 (59.09)	27 (57.45)

SD, standard deviation.

means collapsed across time can be seen in Table 2. Using a Bonferroni correction for multiple QOL comparisons ($\alpha=0.011$), there was a significant effect of group on FACIT-F, FACT-Cog, and PSQI (p 's ≤ 0.002). A priori pairwise comparisons indicated that individuals in LD and TD reported higher FACIT-F and FACT-Cog and lower PSQI scores compared with individuals in the WL group (p 's < 0.01). Using the adjusted alpha, there was no group effect on PCS, MCS, FACT-B, FACIT-Sp-Ex, or BSI-GSI, although means were in the expected direction. Exploratory pairwise comparisons following up on group effects that reached $p \leq 0.05$ revealed that women in LD and TD reported higher MCS and FACIT-Sp-Ex and lower BSI-GSI scores compared with women in the WL group (p 's < 0.05). Additionally, pairwise comparisons revealed no differences between LD and TD groups on any outcome measure.

There was an effect of time on FACT-B ($p=0.003$), with scores increasing over time. There was no effect of time on any other outcome.

Although there were no group \times time effects that reached the adjusted alpha level of 0.011, there was a group \times time effect on BSI-GSI scores at the $p < 0.05$ level ($p=0.032$). Pairwise comparisons of groups at each time point revealed that while neither TD nor LD differed from WL at the 1-month follow-up (p 's > 0.3), both LD ($p=0.011$) and TD ($p=0.004$) reported lower BSI-GSI than WL at the 3-month follow-up, and TD and LD did not differ from one another at either time point (p 's > 0.7). No other group \times time effects reached significance.

Exploratory χ^2 analyses indicated no group differences in the percentage of participants reporting clinically significant sleep disturbances (PSQI ≥ 5) at baseline ($p=0.77$). However, significantly fewer individuals in the LD and TD reported clinically significant sleep disturbance compared with the WL at the 1-month and 3-month follow-ups (p 's < 0.01 ; Figure 2(a)). Similarly, groups did not differ in the percentage of participants reporting clinically significant fatigue (FACIT-F < 36) at baseline, but fewer individuals in the LD and TD reported clinically

Table 2. Unadjusted group means

	Live delivery <i>n</i> = 48		Telemedicine delivery <i>n</i> = 23		Waitlist control <i>n</i> = 47		Group effect <i>p</i> -value	Time effect <i>p</i> -value	Group × time effect <i>p</i> -value
	M	SD	M	SD	M	SD			
SF-36 PCS							0.154	0.529	0.111
Baseline	47.20	8.60	46.54	8.48	45.24	10.23			
1 month	48.81	9.84	48.64	9.05	43.49	11.34			
3 months	50.54	8.49	46.95	8.04	45.44	10.24			
Group LSM, SE ^a	48.32	0.91	49.93	1.36	46.81	0.91			
SF-36 MCS							0.020	0.612	0.661
Baseline	42.45	10.50	43.45	8.03	42.41	10.04			
1 month	48.51	8.72	49.25	7.97	46.50	10.40			
3 months	49.80	8.04	50.84	7.58	43.29	12.75			
Group LSM, SE ^a	48.77	1.24	49.40	1.86	44.30	1.25			
FACT-B							0.076	0.003	0.208
Baseline	22.63	5.98	22.09	4.03	20.32	6.06			
1 month	25.32	5.97	24.84	5.29	22.32	6.08			
3 months	26.18	5.83	27.21	4.22	22.72	5.20			
Group LSM, SE ^a	24.66	0.57	26.03	0.85	23.66	0.58			
FACIT-F							0.002	0.084	0.321
Baseline	29.75	10.08	29.78	10.19	29.21	11.01			
1 month	38.44	12.02	36.74	10.68	31.05	12.15			
3 months	39.78	8.05	41.53	12.36	31.51	11.23			
Group LSM, SE ^a	38.16	1.34	39.62	2.00	32.26	1.34			
FACT-Cog							0.001	0.154	0.687
Baseline	47.48	20.01	50.30	21.13	50.66	18.54			
1 month	64.20	19.46	65.42	16.69	51.41	18.93			
3 months	64.85	21.15	68.79	15.22	54.23	18.86			
Group LSM, SE ^a	63.75	2.18	67.69	3.24	54.48	2.17			
FACIT-Sp-Ex ^b							0.049	0.657	0.462
Baseline	67.68	13.70	68.87	14.81	67.64	14.22			
1 month	75.73	14.44	74.42	11.49	68.64	14.44			
3 months	74.10	14.21	75.74	12.24	69.54	16.12			
Group LSM, SE ^a	74.60	1.36	76.08	2.24	70.61	1.37			
BSI-GSI							0.051	0.120	0.032
Baseline	53.98	7.75	51.77	7.81	55.51	7.26			
1 month	48.88	8.31	49.32	8.58	52.20	8.44			
3 months	46.80	7.82	49.26	7.34	53.02	8.95			
Group LSM, SE ^a	48.24	1.02	47.81	1.59	51.51	1.03			
PSQI							<0.001	0.346	0.303
Baseline	8.79	4.11	8.30	3.74	9.96	4.74			
1 month	6.12	3.74	5.95	3.47	9.18	4.61			
3 months	6.70	3.83	5.53	2.46	9.74	4.32			
Group LSM, SE ^a	7.09	0.36	6.04	0.54	8.74	0.37			

Higher SF-36 and FACIT subscales indicate better QOL. Higher BSI-GSI and PSQI indicate more distress and sleep disturbance, respectively. Group, time, and group × time *p*-values are based on linear multilevel models (LMM) covarying for age, time since diagnoses, stage, and medical treatments (chemotherapy, surgery, radiation, hormone therapy), and baseline level of the outcome variable.

^aGroup least squared means (LSM) and standard errors (SE) are associated with the group effect (collapsed across time) in the LMMs described above.

^bCity is entered as a covariate in the LLM predicting FACT-Sp-Ex.

M, mean; SD, standard deviation; SF-36, medical outcomes study 36-item short form survey; PCS, physical component summary; MCS, mental component summary; FACT-B, Functional Assessment of Cancer Therapy-Breast; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue Scale; FACT-Cog, Functional Assessment of Cancer Therapy-Cognitive Function Scale; FACIT-Sp-Ex, Functional Assessment of Chronic Illness Therapy Spiritual Well-Being Expanded Scale; BSI-GSI, Brief Symptom Inventory-Global Severity Index; PSQI, Pittsburgh Sleep Quality Index.

significant fatigue compared with the WL at 1-month and 3-month follow-ups (*p*'s < 0.05; Figure 2(b)).

Discussion

Our results are consistent with the other studies that have shown beneficial effects of psychosocial interventions for improving QOL in cancer survivors [1–3]. Although SF-36 scores in the present study are slightly higher than

those reported by oncology patients receiving telecare for pain and depression in rural community centers, pre-treatment to post-treatment change in SF-36 scores was similar [11]. Additionally, the current sample reported baseline PSQI scores similar to women with breast cancer enrolled in Mindfulness Based Stress Reduction but showed greater improvement in PSQI scores following the intervention [29]. Further, a review of exercise interventions for breast cancer survivors indicated baseline

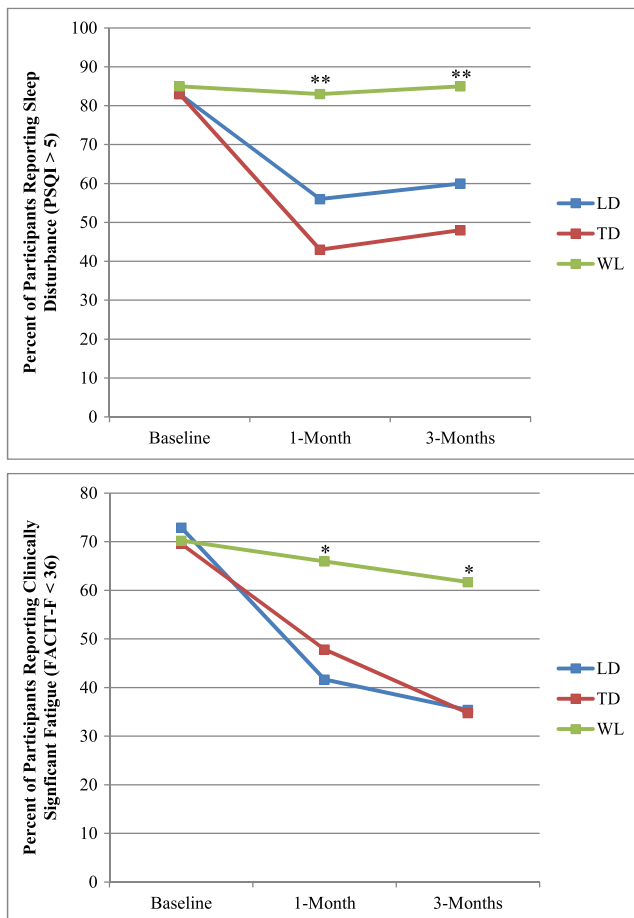


Figure 2. Percentage of participants reporting clinically significant sleep disturbance and fatigue. PSQI, Pittsburgh Sleep Quality Index; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue Scale; ** denotes that WL differed from TD and LD $p < 0.01$; * denotes that WL differed from TD and LD $p < 0.05$

FACIT-F scores almost 10 points higher than the present study; yet, end of intervention FACIT-F scores in the present study are on par with those of exercise interventions [30].

To our knowledge, the present study represents the first randomized trial of a telemedicine mind-body intervention delivered to a group of cancer survivors. Although the study was not powered to test equivalence, participating in the telemedicine delivered intervention did not result in different outcomes compared with the intervention delivered in person. Further, using a conservative Bonferroni adjustment, either form of the intervention resulted in significantly better cognitive function, less fatigue, and less sleep disturbance compared with individuals in the WL group. Although the intervention and control groups did not significantly differ on health-related or breast cancer-specific QOL, distress, or spiritual well-being using the adjusted alpha, means were in the expected directions.

The improvements in cognitive function, fatigue, sleep disturbance, and mental health-related and breast cancer-related QOL were considered clinically significant. The

intervention groups, but not the waitlist group, reported a ≥ 10 points improvement in cognitive function and fatigue from baseline to 3-month follow-up [31,32]. Additionally, there were clinically significant improvements in sleep quality and fatigue in both intervention groups and no changes in the WL group [21,25]. Further, although group differences in mental health-related and breast cancer-specific QOL did not reach statistical significance, means suggest that individuals in the intervention groups, but not in the waitlist group, experienced a clinically significant improvement in mental health-related QOL (≥ 5 points increase in MCS) and in breast cancer-related QOL (≥ 3 points increase in FACT-B subscale) at the 3-month follow-up [36,34]. Thus, the ERL intervention results in clinically significant improvements in many facets of QOL.

There are some limitations to the current study. The overall sample size was relatively small, and unforeseen staffing limitations resulted in the telemedicine group being smaller than expected. Thus, it is possible that the present study was underpowered to detect differences between telemedicine compared with live and waitlist groups. However, post hoc power analyses suggested that a sample size of >600 would be required to detect statistically significant differences between the two intervention groups on all outcomes aside from the PSQI. On the PSQI, a sample size of 424 would be required to detect significant intervention group differences, with the means in favor of the TD group [35]. Nonetheless, the relatively small sample size, particularly for the TD group, necessitates caution in interpreting these results and calls for validation of these findings in a larger study. Adherence to at-home practice was not documented, limiting our ability to examine a 'dose effect' of the intervention. Future studies could document this by providing patients with practice logs or devices (such as MP3 players) equipped to document use of audio files, eliminating the bias inherent in self-reported practice. The lack of an active control group with which to compare the ERL program (versus just usual care) limits the ability to know that the effects are directly attributable to the specific content of the program versus non-specific effects such as social support or attention. Additionally, the present study did not specifically assess social support, making it difficult to examine or control for change in social support in the present analyses. In light of this, a subsequent trial should include an attention control group or other active program for comparison. Future research is needed to test the long-term benefits of participating in an imagery-based group intervention after contact with therapists has concluded. Additionally, although the present study provides support for the use of telemedicine delivered at community centers in areas that may not have access to mental healthcare providers, future research is needed to examine home-based or internet-based telemedicine interventions for survivors

unable to travel even to community centers. Further, although the time commitment (five 4-h weekly sessions) of the present intervention is similar to Mindfulness Based Stress Reduction (eight 2.5-h weekly sessions plus a full day retreat), future research altering the modules to fit within the schedule of a workweek is warranted [36]. As is the challenge of all mind–body interventions [37], determining optimal length and essential components of interventions is paramount to the dissemination of evidence-based treatment. There was low minority representation in the study and future research should examine the efficacy of the ERL program for minority groups. Finally, the present findings reflect subjective QOL outcomes and do not include corroborating objective, biological measures of QOL.

The ERL program represents a mind–body program that comprehensively addresses many facets of QOL relevant to breast cancer survivors, including general health-related and cancer-related QOL, spiritual well-being, cognitive

function, fatigue, sleep disturbance, and distress. Further, our results suggest that telemedicine is an effective and viable method to deliver a group intervention aimed at improving QOL in breast cancer survivors.

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Conflict of interest

The authors have declared no conflicts of interest.

References

- Andersen BL, Thornton LM, Shapiro CL, *et al.* Biobehavioral, immune, and health benefits following recurrence for psychological intervention participants. *Clin Cancer Res* 2010; **16**(12):3270–3278.
- Roffe L, Schmidt K, Ernst E. A systematic review of guided imagery as an adjuvant cancer therapy. *Psycho-Oncology* 2005; **14**(8): 607–617.
- Eremin O, Walker MB, Simpson E, *et al.* Immuno-modulatory effects of relaxation training and guided imagery in women with locally advanced breast cancer undergoing multimodality therapy: a randomised controlled trial. *Breast* 2009; **18**(1):17–25.
- Lengacher CA, Bennett MP, Gonzalez L, *et al.* Immune responses to guided imagery during breast cancer treatment. *Biol Res Nurs* 2008; **9**(3):205–214.
- Nunes DF, Rodriguez AL, da Silva Hoffmann F., *et al.* Relaxation and guided imagery program in patients with breast cancer undergoing radiotherapy is not associated with neuroimmunomodulatory effects. *J Psychosom Res* 2007; **63**(6):647–655.
- Freeman L, Cohen L, Stewart M, *et al.* Imagery intervention for recovering breast cancer patients: clinical trial of safety and efficacy. *J Soc Integr Oncol* 2008; **6**(2):67–75.
- Hendren S, Chin N, Fisher S, *et al.* Patients' barriers to receipt of cancer care, and factors associated with needing more assistance from a patient navigator. *J Natl Med Assoc* 2011; **103**(8):701–710.
- Pruthi S, Stange KJ, Malagrino GD Jr., Chawla KS, LaRusso NF, Kaur JS. Successful implementation of a telemedicine-based counseling program for high-risk patients with breast cancer. *Mayo Clin Proc* 2013; **88**(1): 68–73.
- Sherman DW, Haber J, Hoskins CN, *et al.* The effects of psychoeducation and telephone counseling on the adjustment of women with early-stage breast cancer. *Appl Nurs Res* 2012; **25**(1):3–16.
- Zernicke KA, Campbell TS, Specia M, Kelley M-R, Flowers S, Carlson LE. 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. *Psychosom Med* 2014; **76**(4):257–267.
- Kroenke K, Theobald D, Wu J, *et al.* Effect of telecare management on pain and depression in patients with cancer: a randomized trial. *JAMA* 2010; **304**(2):163–171.
- Poon P, Hui E, Dai D, Kwok T, Woo J. Cognitive intervention for community-dwelling older persons with memory problems: telemedicine versus face-to-face treatment. *Int J Geriatr Psychiatry* 2005; **20**(3):285–286.
- Schnur JB, Montgomery GH. E-counseling in psychosocial cancer care: a survey of practice, attitudes, and training among providers. *Telemed J E Health* 2012; **18**(4):305–308.
- Jameson JP, Farmer MS, Head KJ, Fortney J, Teal CR. VA community mental health service providers' utilization of and attitudes toward telemental health care: the gatekeeper's perspective. *J Rural Health* 2011; **27**(4):425–432.
- Freeman LW, Lawlis GF. *Mosby's Complementary & Alternative Medicine*. Mosby, 2004.
- Núñez MaJ, Mañá P, Liñares D, *et al.* Music, immunity and cancer. *Life Sci* 2002; **71**(9): 1047–1057.
- Manyande A, Berg S, Gettins D, *et al.* Preoperative rehearsal of active coping imagery influences subjective and hormonal responses to abdominal surgery. *Psychosom Med* 1995; **57**(2):177–182.
- Kiecolt-Glaser JK, Graham JE, Malarkey WB, Porter K, Lemeshow S, Glaser R. Olfactory influences on mood and autonomic, endocrine, and immune function. *Psychoneuroendocrinology* 2008; **33**(3):328–339.
- Ware J, Sherbourne C. **30**The MOS 36-item shortform health survey. *Med Care* 1992; **47**:473–483.
- Cella DF, Tulskey DS, Gray G, *et al.* The functional assessment of cancer therapy scale: development and validation of the general measure. *J Clin Oncol* 1993; **11**(3): 570–579.
- Alexander S, Minton O, Stone PC. Evaluation of screening instruments for cancer-related fatigue syndrome in breast cancer survivors. *J Clin Oncol* 2009; **27**(8):1197–1201.
- Jacobs SR, Jacobsen PB, Booth-Jones M, Wagner LI, Anasetti C. Evaluation of the functional assessment of cancer therapy cognitive scale with hematopoietic stem cell transplant patients. *J Pain Symptom Manage* 2007; **33**(1):13–23.
- Peterman AH, Min GFD, Brady MJ, Cella D. Measuring spiritual well-being in people with cancer: the functional assessment of chronic illness therapy—Spiritual Well-being Scale (FACIT-Sp). *Ann Behav Med* 2002; **24**(1): 49–58.
- Derogatis LR. *BSI, Brief Symptom Inventory: Administration, Scoring & Procedures Manual*. National Computer Systems: Minneapolis, MN, 1993.
- Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989; **28**(2): 193–213.

26. Littell RC, Milliken GA, Stroup WW, Wolfinger RD, Schabenberger O. *SAS for Mixed Models* (2nd edn). SAS Institute Inc: Cary, NC, 2006.
27. Gibbons RD, Hedeker D, Waternaux C, Davis JM. Random regression models: a comprehensive approach to the analysis of longitudinal psychiatric data. *Psychopharmacol Bull* 1988;**24**:438–443.
28. Sankoh AJ, Huque MF, Dubey SD. Some comments on frequently used multiple endpoint adjustment methods in clinical trials. *Stat Med* 1997;**16**(22):2529–2542.
29. Lengacher CA, Reich RR, Paterson CL, et al. The effects of mindfulness-based stress reduction on objective and subjective sleep parameters in women with breast cancer: a randomized controlled trial. *Psycho-Oncology* 2015;**24**(4):424–432. DOI: 10.1002/pon.3603.
30. Battaglini CL, Mills RC, Phillips BL, et al. Twenty-five years of research on the effects of exercise training in breast cancer survivors: a systematic review of the literature. *World J Clin Oncol* 2014;**5**(2):177–190.
31. Cella D, Eton DT, Lai JS, Peterman AH, Merkel DE. Combining anchor and distribution-based methods to derive minimal clinically important differences on the Functional Assessment of Cancer Therapy (FACT) anemia and fatigue scales. *J Pain Symptom Manage* 2002;**24**(6):547–561.
32. Cheung YT, Foo YL, Shwe M, et al. Minimal clinically important difference (MCID) for the functional assessment of cancer therapy: cognitive function (FACT-Cog) in breast cancer patients. *J Clin Epidemiol* 2014;**67**(7): 811–820.
33. Sloan JA, Frost MH, Berzon R, et al. The clinical significance of quality of life assessments in oncology: a summary for clinicians. *Support Care Cancer* 2006;**14**(10):988–998.
34. Eton DT, Cella D, Yost KJ, et al. A combination of distribution- and anchor-based approaches determined minimally important differences (MIDs) for four endpoints in a breast cancer scale. *J Clin Epidemiol* 2004;**57**(9):898–910.
35. Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;**39**:175–191.
36. Kabat-Zinn J. Mindfulness-based interventions in context: past, present, and future. *Clin Psychol Sci Pract* 2003;**10**(2): 144–156.
37. Carmody J, Baer RA. How long does a mindfulness-based stress reduction program need to be? A review of class contact hours and effect sizes for psychological distress. *J Clin Psychol* 2009;**65**(6):627–638.

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