



Pilot Randomized Controlled Trial in Women With Non-Small Cell Lung Cancer to Assess the Feasibility of Delivering Group-Based Psychosocial Care via Videoconference

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Abstract

Background: The goal of this pilot randomized controlled trial was to examine the feasibility and acceptability of delivering group-based psychosocial care via videoconference (ie, Zoom) to women with lung cancer undergoing treatment. **Methods:** At baseline, women indicated their typical computer and internet use and were then randomized to a group-based intervention that either focused on mindfulness training or psychoeducation. Participants completed 1 Zoom “practice run” prior to starting the 5 group sessions (1 per week). After the last session, they evaluated their experiences with the intervention and its delivery. **Results:** With a consent rate of 68%, 54 women (mean age = 66 years; 69% non-Hispanic White; 48% with stage IV disease) were equally randomized. Attendance was high in both arms (session mean, mindfulness = 4.38; education = 4.75; 85% attended all sessions). Across arms, all women rated the program as useful; most preferred group-based delivery (67%) and remote delivery (50%) or had no preference. Although the sample’s typical computer use was relatively low (eg, 19% said that they rarely or never use a computer), most women (76%) indicated that Zoom was “very easy” or “easy” to use. After only 0 to 1 attempts, 56% felt comfortable but 26% stated that they never felt comfortable with the technology. **Conclusions:** It seems to be feasible to deliver group-based psychosocial interventions via videoconference in women with lung cancer undergoing treatment. Challenges regarding scheduling the group sessions and familiarizing older rather than infrequent computer users with the technology were encountered but resolved over the course of the trial.

Keywords

NSCLC, women, online-groups, mindfulness, feasibility, psychosocial care

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Introduction

Forty years ago, men were 3 times more likely to be diagnosed with lung cancer (LC) than women.¹ Since then, incidence has more than doubled in women, and LC is the number 1 cancer killer for women in the United States. While the increase in LC incidence rates for women plateaued around 2007 and are now on a downward trend, rates for women have decreased more slowly than for men.² In addition to these differences, accumulating evidence identifies clear sex differences in disease presentation, etiology,

carcinogenesis factors, and survival rates.^{3–5} Although disease burden due to symptom severity (eg, fatigue, pain, dyspnea) tends to be high in lung cancer patients in general,

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some studies suggest that women show an increased vulnerability to psychological distress relative to men.⁶⁻⁸ An underlying issue may be related to the stigmatization of the disease given the link between tobacco use and LC. In fact, LC patients including those *without* a smoking history report high rates of stigmatization and blame.⁹ Moreover, despite lower smoking rates, women with LC are more likely than men to be stigmatized and blame themselves for having LC.^{6,10-12}

To mitigate social isolation and disease-related stigma, group-based psychosocial care may be a promising supportive care strategy as it provides opportunities for women to engage with others who have the same disease sharing their experiences. However, while a rather large body of literature has revealed the positive effects of group-based interventions for women with breast cancer, the intervention literature for women with LC is sparse at best.¹³⁻¹⁶ Additionally, because most previous group-based programs have been conducted in person, the delivery of remote (ie, online) psychosocial groups has become of increasing interest. In fact, since the onset of the Coronavirus Disease 2019 (COVID-19) pandemic restricting in-person contact, telemedicine has become highly relevant to clinical operations and research efforts. With a few exceptions, the existing knowledge is based on adolescents and young adults (AYAs) with cancer, survivors, or parents of pediatric cancer patients.¹⁷⁻²⁰ Because LC patients tend to be older, frailer, and more symptomatic than many other cancer populations, it is currently unclear if videoconference delivery of psychosocial programs could serve as a facilitator to intervention access and adherence or if it might be considered a barrier to feasibility. Considering LC patients' generally low performance status, it is important to examine videoconferenced sessions beyond reasons related to the recent social distance requirements. In fact, the success of group-based psychosocial care research may hinge on determining feasibility and acceptability of remote delivery for this vulnerable patient population. To address these knowledge gaps, the goal of this randomized controlled trial (RCT) is to examine the feasibility and acceptability of 2 group-based psychosocial interventions delivered via videoconference.

We hypothesized that at least 50% of eligible women would consent to participate, 75% would attend all 5 intervention sessions, and at least 75% would indicate that the programs are useful and enjoyable. Because feasibility rates vary widely in the existing online group-based intervention literature, these a priori benchmarks were informed by our previous trial in LC patient-caregiver dyads participating in a videoconferenced intervention study.²¹ We also explored whether typical computer and internet use and participant characteristics (eg, age, disease stage, education) would be associated with technology-related feasibility indicators.

Methods

Participants

Eligible patients met the following criteria: (1) female gender diagnosed within the last 12 months with stage I to IV non-small cell lung cancer on active cancer treatment; (2) an Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 ; (3) access to the internet; (4) able to read, write, and speak English; and (5) at least 18 years of age. Patients were excluded if they had (1) cognitive deficits (as determined by the clinical team) that would impede the completion of the study and (2) regular participation (self-defined) in psychotherapy or a formal cancer support group. Participants who discontinued cancer treatment due to disease progression and transition to hospice care became study ineligible.

Procedures

Potential participants were identified via electronic medical records and approached at their routine clinic appointments or contacted by phone to ascertain eligibility and introduce the study. If eligible and interested, participants provided written informed consent and then completed the National Comprehensive Cancer Network (NCCN) distress thermometer (in person or over the phone). Prior to randomization, participants completed an electronic survey to collect their demographic information and assess their typical computer and internet use. Videoconferencing procedures were explained to participants in detail. Moreover, all participants received 1 individual Zoom practice session prior to starting the group-based intervention. Electronic follow-up surveys to assess participants' evaluations of the intervention including their experiences with the videoconference and group-based delivery format were administered via REDcap within 1 week following the last intervention session. Study staff was not blinded to group assignment. The trial was conducted between January 2019 and April 2020.

Randomization

We used covariate-adaptive randomization called minimization allowing for balanced groups.²² Factors used for randomization included age, stage at diagnosis, smoking history, and NCCN distress thermometer score.

Intervention Groups

We tested 2 group-based interventions. One program focused on mindfulness training and cultivating positive emotions via guided imagery/meditation exercises. The other program involved a psychoeducational support group often found in the psycho-oncology literature.^{23,24} In both

arms, participants attended one 60-minute group session per week for 5 weeks (total of 300 minutes) delivered via the Zoom videoconferencing application. Each closed group consisted of 3 to 5 women, and each woman was required to attend the first session to participate in the group. Sessions for both arms were scheduled and led by master-level mind-body specialists certified in mindfulness-based stress reduction. All participants used their own device although they could have borrowed a device from the research team if needed.

Mindfulness-based group. The intervention was developed based on pilot work with lung cancer patients and evidence-based positive psychology.²¹ Session 1 included a short program introduction and mindfulness training. Session 2 focused on compassion training and emotional processing. Session 3 concentrated on cultivating gratitude and social support skills. Session 4 focused on meaning making and value-based living. Session 5 reviewed and integrated content from the previous 4 sessions. Women were encouraged to share their experiences particularly emotions that surfaced during these exercises.

Psychoeducation group. Participants received educational material on lung cancer and coping with their diagnosis (as outlined by the American Cancer Society), including an overview of their diagnosis and treatment, communicating with their healthcare team, communicating with their family and friends, symptom management, and coping skills. Women were encouraged to share their experiences as they related to the discussion topics.

Measures

Demographic/medical factors: Demographic factors were collected prior to group assignment. Medical data were extracted via the patient's electronic medical record.

Feasibility data: Consent rates (including reasons for ineligibility and refusal) and attendance were documented.

Acceptability. To assess intervention and delivery acceptability, after completing the program, participants completed items pertaining to their perception of the intervention's usefulness and benefit; delivery preferences regarding online or in-person delivery and group-based or individual delivery ("no preference" was included as an option); and likelihood to recommend this intervention to other patients on a Likert type scale (1 = strongly disagree to 4 = strongly agree). These items were developed for the purpose of this study.

Computer use and zoom evaluation. Prior to randomization, participants were asked how often they typically use a computer/laptop and access the internet (never to daily). After

the last session, participants indicated the type of device they used for the sessions (desktop, laptop, tablet, and/or smartphone) and completed Likert-Scale items evaluating their Zoom experience. These items were developed for the purpose of this study.

Data Analysis Strategy

To evaluate feasibility, we calculated descriptive statistics for accrual, attendance, and acceptability. We compared baseline characteristics between intervention groups and across remote-delivery acceptability ratings using chi-squared or Fisher's exact tests for categorical variables or *t*-tests or analysis of variance for continuous variables.

Results

Participant Characteristics

Baseline characteristics of randomized patients are shown by group in Table 1. Overall, women had a mean age of 65.65 years (SD=12.78, range=32-92); over two-thirds (69%) identified as non-Hispanic Whites; were well-educated with 37% having at least a college degree; half (50%) of women were married or cohabitating for >6 months; and the other half were living alone (7% unpartnered; 19% separated/divorced; 15% widowed; and 1.8% declined to answer). Half (50%) of participants were retired with the remainder being full-time (15%), part-time (7%), unemployed (9%); on medical leave (11%); or refused to answer (8%). About a quarter (26%) of patients reported that they never smoked and 13% currently smoked. Participants were approximately 2 months post their initial diagnosis (mean = 1.84 months, SD = 1.40) and almost half (48%) had stage IV disease; and an NCCN distress mean score of 3.43 (SD = 2.61; range: 0-10) with 43.5% scoring at or above the cut-off of 4.

Regarding technology, 7 women (13%) indicated that they never; 3 (6%) rarely; 4 (7%) sometimes; 8 (15%) often; and 19 (35%) daily use a computer/laptop with 14 (26%) women omitting the item. Over half of the sample (n=32) indicated daily/often internet access; 14 (26%) indicated rare/occasional access; and only 1 woman indicated that she never accesses the internet with 14 (26%) women omitting the item.

Feasibility

Recruitment and retention. We screened 782 patients of which 693 were ineligible to due sex (62%), diagnosis date (33%), language (4%), and performance status (1%). We approached 108 women of which 5 were ineligible upon further screening (3 had no internet access, 1 only spoke Chinese, and 1 due to concomitant therapies) and 33 refused

Table 1. Participant Demographics and Characteristics.

	Mindfulness (n=27) mean (SD) min-max	Psychoeducation (n=27) mean (SD) min-max	P-value [†]
Age (years)	66.70 (13.28) 37-92	64.59 (12.42) 32-80	.53
Sex (% female)	100	100	—
Race %	—	—	.80
Asian	4.0	0.0	—
Black or African American	15.0	7.7	—
Native Hawaiian or Pacific Islander	0.0	3.8	—
White	70.4	84.6	—
More than 1 race	4.0	0.0	—
Unknown or not reported	7.4	3.8	—
Ethnicity %	—	—	.63
Hispanic or Latino	11.1	12.0	—
Non-Hispanic or Latino	82.0	84.0	—
Unknown or not reported	7.4	4.0	—
Education %	—	—	.36
High school or less	12.0	15.3	—
Technical school	4.0	19.2	—
Some college	28.0	26.9	—
Bachelor's or associates degree	32.0	30.7	—
Graduate degree	24.0	7.7	—
Household income %	—	—	.50
<\$30 000	0.0	26.8	—
\$30 000-\$50 000	20.8	26.9	—
\$50 000-\$75 000	16.7	7.7	—
\$75 000-\$100 000	20.8	15.4	—
>\$100 000	16.7	7.7	—
Declined to answer	25.0	15.4	—
Employment %	—	—	.19
Full time, outside of the home	24.0	7.7	—
Part time, outside of the home	0.0	15.4	—
Full time, inside the home	4.0	3.8	—
Disability/on leave for treatment	12.0	11.5	—
Job seeking	4.0	3.8	—
Retired	56.0	53.8	—
Declined to answer	0.0	3.8	—
Marital status %	—	—	.44
Married/partnered	68.0	41.3	—
Separated/divorced	12.0	26.9	—
Widowed	8.0	23.1	—
Never married	8.0	7.7	—
Declined to answer	4.0	1.0	—
Stage of disease %	—	—	.71
Stage I-II	29.6	25.9	—
Stage III	18.5	29.6	—
Stage IV	51.9	44.4	—
Time since diagnosis (months)	2.20 (1.35) 0-5	1.42 (1.33) 0-5	.66
NCCN distress thermometer	3.29 (2.76) 0-9	3.56 (2.53) 0-10	.86
NCCN distress thermometer % ≥ 4	42.9	40.0	—
Smoking history %	—	—	.99
Never smoked	28.0	26.9	—
Past smoker	60.0	57.7	—
Current smoker	12.0	15.4	—

Fisher's exact test was used to compare groups on categorical variables as all variables had at least some cells with $n \leq 5$ per cell count; independent samples t-test was used to compare groups on continuous variables.

[†]P values based on Fisher's exact test or t-test.

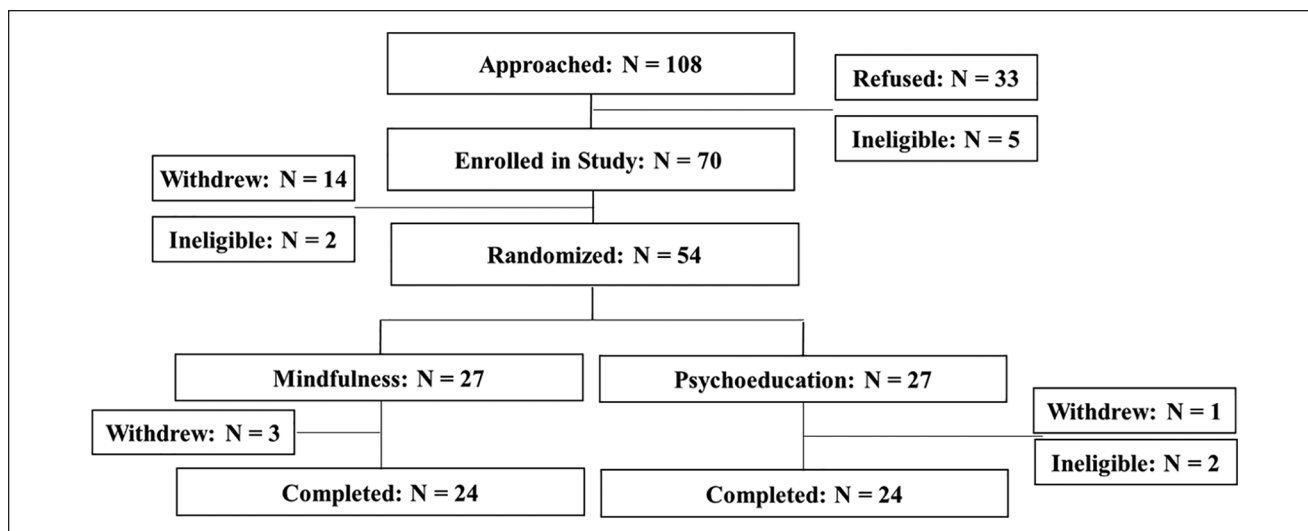


Figure 1. Consort chart.

participation. Refusal reasons included: lack of interest ($n=9$); feeling too distressed/not well enough ($n=8$); scheduling difficulties ($n=7$); unwilling to learn computer skills ($n=7$); and privacy concerns ($n=2$). Of the 70 who consented (68% consent rate), prior to randomization, 14 women withdrew due to scheduling challenges ($n=10$) or high physical symptom burden ($n=4$), and 2 women became ineligible due to transfer to hospice care. Consequently, 54 participants were randomized (meditation arm: $n=27$ [9 groups]; education arm: $n=27$ [8 groups]). Each closed group included 3 to 4 women. Of those randomized, 6 women did not start the sessions (3 in each arm) with 4 women withdrawing due to high symptom burden and 2 becoming ineligible due to transfer to hospice care so that 48 women (73% of eligible participants) started the intervention. There were no significant differences regarding relevant medical and demographic variables between eligible women who started and those who did not ($P < .1$). See Figure 1 for the consort chart.

Session attendance and acceptability. Of those who started the intervention, attendance was high in the mindfulness (mean attendance = 4.38; SD = 1.31; range = 1-5) and education (mean attendance = 4.75; SD = 0.85; range = 2-5) groups. Overall, 85% ($n=41$) of women attended all 5 sessions. Session attendance did not differ as a function of group ($t = -1.18$; $P = .25$). Acceptability ratings regarding overall program usefulness and perceived benefit were also high in both arms. More specifically, all women rated the program as “useful” or “very useful” (1-4 scale; mindfulness mean = 3.50, SD = 0.52, range: 3-4; education mean = 3.32, SD = 0.72, range 2-4; $P = .42$) and only 1 woman in the education arm indicated not having benefited

from the program (1-4 scale; mindfulness mean = 3.21, SD = 0.58, range: 3-4; education mean = 3.18, SD = 0.91, range 1-4; $P = .91$). Across arms, women preferred a group-based delivery (67%) with 22% indicating no preference and 11% preferring individual sessions, and 85% would recommend the intervention to a friend with cancer.

Regarding technological aspects, across arms, 50% of women used a smartphone, 22% a tablet/iPad, 17% a laptop; and 11% a desktop computer to attend the sessions. Women preferred remote delivery (50%) or had no preference (42%); yet, 8% of women stated an in-person preference. Most women (76%) indicated that Zoom was “very easy” or “easy” to use; yet 12% rated the software as “difficult” or “very difficult” to use. Moreover, most participants (56%) felt comfortable with Zoom after 0 to 1 attempts; however, 26% stated that they never felt comfortable with the technology. Most participants (76%) would recommend Zoom to other users; 18% felt ambivalent, and 6% would not recommend Zoom. Figure 2 depicts additional specific components of the Zoom evaluation.

Computer/internet use and feasibility. Baseline computer or internet use (daily vs less frequent use) was not significantly associated with remote delivery preference and ratings on the Zoom evaluations. Among demographic and medical factors including distress, only age was significantly associated with Zoom ratings so that older participants thought the software was more difficult ($F = 10.81$; $P < .02$), required more attempts to feel comfortable ($F = 9.24$; $P < .01$) and were less likely to recommend Zoom ($F = 6.28$, $P < .05$) compared to younger women. Of note, baseline computer or internet use was not associated with age.

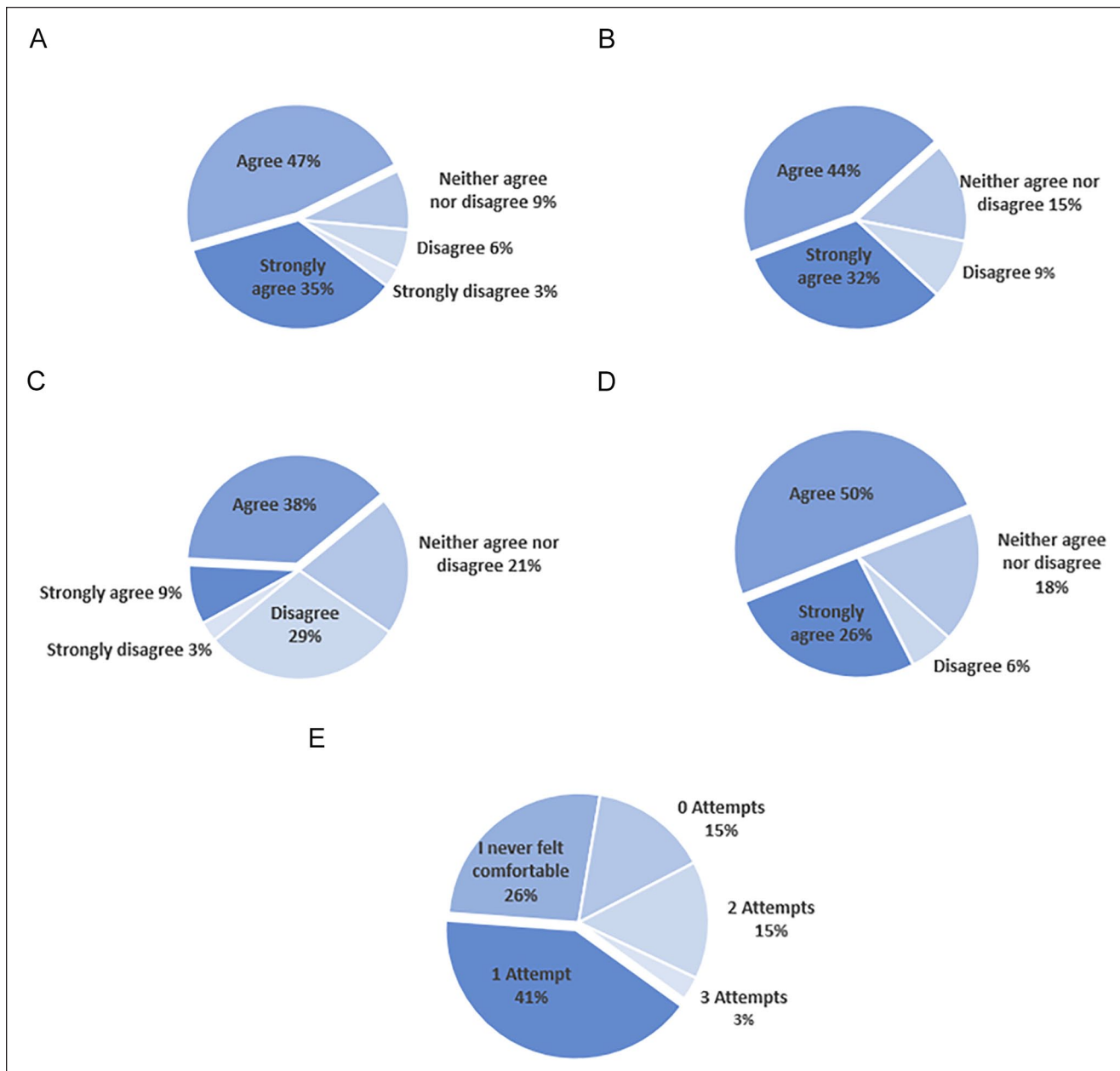


Figure 2. Participant experience with Zoom videoconferencing platform. (A) I could easily talk to the other participants using Zoom. (B) I could clearly hear the other participants using Zoom. (C) I believe Zoom sessions were the same as they would have been in-person. (D) I would recommend Zoom to other people. (E) How many attempts did it take for you to feel comfortable using Zoom?

Discussion

The goal of this pilot RCT was to examine the feasibility and acceptability of Zoom delivered group-based psychosocial care to women with LC undergoing cancer treatment. A priori benchmarks regarding consent, adherence, and acceptability were met or exceeded. More specifically, our consent rate of 68%, adherence rate of 85%, and overall acceptability of 100% regarding intervention utility support

that this delivery format is both feasible and acceptable to women with LC. Despite these overall encouraging findings, we encountered challenges regarding the randomization and the intervention initiation rate, which improved as the trial proceeded. Although 70 women were consented, only 54 (77%) were randomized of which only 48 started the sessions. Lack of randomization and intervention start was mainly due to either scheduling challenges given the

group-based delivery, high disease burden, and hospice transfer rendering participants as study ineligible.

We were able to mitigate some withdrawals pertaining to scheduling challenges as 75% of all withdrawals occurred in the first half of the trial. Rather than approaching patients by date of clinic visit, we learned that a monthly recruitment blitz, whereby all eligible patients were approached in “batches” was more successful. This method reduced the time from consent to randomization and first session resulting in fewer participants with physical declines, schedule changes, or lost interest. Moreover, this method allowed for starting multiple groups with close temporal proximity to better accommodate participants’ scheduling preferences. Despite these initial challenges, high adherence rates were observed. Of note, the trial was completed right at the onset of the COVID-19 pandemic. As technology use has become more accessible and available than ever, we now anticipate even greater engagement.

In addition to this recruitment strategy, we included basic technology skills training (eg, downloading an application, adjusting volume, closing windows, leaving the Zoom call) as needed in the practice run sessions. Through these practice sessions, we learned not to make any assumptions regarding participants’ existing computer knowledge and provide a thorough orientation to the platform. We used a text-based login strategy, where participants joined the Zoom call with the meeting code rather than navigating a link-based entry to the platform. We additionally learned that groups of 4 participants seem to be an appropriate size for online groups as most women participated with smartphones, where the Zoom platform only displays 4 faces on a screen.

The present sample was relatively diverse, with 31% representing a racial/ethnic minority along with various education and employment backgrounds. Participants’ age ranged from 32 to 92 (30% were over age 75) and almost half had stage IV disease. Although the sample showed variability in baseline computer and internet use, with more than a quarter reporting limited computer use, these factors were not associated with feasibility outcomes. Instead, older participants rated the software as more difficult, required more attempts to feel comfortable and were less likely to recommend Zoom compared to younger women. Consequently, researchers and clinicians are encouraged to allow for more time and provide clear guidance when working with participants over age 75 when delivering interventions remotely.

In conclusion, group-based psychosocial interventions that focus on mindfulness training or psychoeducation seem generally feasible and acceptable when delivered via videoconference to women with LC, including those with advanced disease. Older participants may benefit from additional assistance with technology. Research to evaluate

the efficacy of remote group-based interventions to mitigate psychosocial distress in women with LC is warranted.

Declaration of Conflicting Interests

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Trial Registration

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