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Addressing fear of cancer recurrence among women with cancer: a feasibility and preliminary outcome study

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Abstract
Background Evidence suggests that fear of cancer recurrence (FCR) is one of the most frequently cited unmet needs among cancer survivors and is associated with psychological distress, stress-response symptoms, and lower quality of life, as well as increased use of health care resources. Despite these factors, few manualized interventions exist to address FCR among cancer survivors.
Purpose To develop, manualize, and pilot test the feasibility and preliminary efficacy of a 6-week cognitive-existential (CE) group intervention designed to address FCR in women with breast or ovarian cancer.
Methods This study was a single-arm multi-site study with pre-, post-, and 3-month follow-up measurement occasions.
Results A total of 56 breast or ovarian cancer survivors enrolled in the study; 44 completed the CE group intervention. Following the intervention, women experienced a reduction in the primary study outcome measure of FCR and secondary study outcome measures of cancer-specific distress and uncertainty. They also reported improvements in secondary study outcome measures of quality of life and coping. The effect sizes of the observed changes were for the most part in the medium to large effect range; furthermore, almost all changes were sustained at 3-month follow-up.
Conclusion This brief intervention appears feasible and has shown promising results in addressing FCR and related secondary outcomes of cancer-specific distress, uncertainty, quality of life, and coping; however, it should be further tested using a randomized controlled study design to more definitively assess its efficacy.
Implications for Cancer Survivors FCR is a near-universal worry for cancer survivors that, when left unaddressed, tends to remain stable over time. This study has important

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implications for all cancer survivors as it is the first published intervention that provides preliminary evidence of its efficacy in decreasing fear of cancer recurrence.

Keywords Fear of cancer recurrence · Pilot study · Cognitive-existential intervention · Breast cancer · Ovarian cancer

Fear of cancer recurrence (FCR) has been described as the sword of Damocles that hangs over patients for the rest of their lives [1, 2]. FCR is defined as "the fear or worry that the cancer will return or progress in the same organ or in another part of the body" [3, 4]. FCR is the first or second most commonly reported problem by patients with breast, ovarian, colon, lung, or prostate cancer [1, 5, 6]. More specifically, the proportion of cancer survivors reporting FCR ranges from as high as 74 % in lung cancer survivors to 49 % in prostate cancer survivors [7]. There is a wide variability in patients' severity of their FCR [3]. The current literature suggests that moderate to high levels of FCR affect 22 to 87 % of cancer patients [3, 8–12]. Being female, of younger age, and having children have been found to reliably predict more severe FCR [4, 6, 9–11, 13–16]. FCR is consistently associated with psychological distress, stress-response symptoms, and lower quality of life [3, 10, 11, 13, 17]. FCR is also associated with greater utilization of health care resources such as number of visits to an emergency room and number of medications taken [16], unscheduled visits to one's family physician, and use of complementary and alternative medicines [18], thus suggesting that unattended FCR is likely to increase cost to the health care system.

Despite clear evidence that cancer patients with higher FCR have poorer psychological adjustment and may incur additional medical costs, there is a paucity of literature on psychosocial interventions that address FCR. To date, there has been only one published group intervention study that has addressed fear of disease progression, a concept related to FCR, in people with cancer or chronic arthritis [19]. In this partially randomized controlled study, participants were offered either a generic cognitive behavioral therapy (CBT) group intervention or a generic supportive expressive therapy (SET) group intervention. Both interventions consisted of four 90-min sessions, followed by two booster telephone calls at 6 and 9 months. According to the authors of the study, the SET group intervention (which did not directly address how to manage FCR) was meant to serve as the control condition and was expected to be less effective in reducing fear of disease progression than the CBT group intervention. However, both were successful in decreasing fear of disease progression compared to a control group subsequently recruited, but only for cancer patients. The effects were maintained at 3- and 12-month follow-ups. Two important limitations of this study are that neither intervention was based on FCR theories, and their mechanisms of action are unknown. The authors speculated that the observed changes were due to therapeutic agents common to both approaches such as focusing on fears and the acquisition of coping strategies. However, this hypothesis remains to be tested. One potentially important confound is that participants were inpatients attending rehabilitation clinics who were thus obtaining close support from health care professionals. This limits the external validity of the findings.

Another intervention, the AFTER intervention, has been developed to address FCR among head and neck cancer patients [20] but results of this trial are not yet available. Three additional studies have evaluated group therapies designed to improve generic emotional outcomes for breast cancer survivors and have reported on FCR as a secondary outcome. One evaluated the impact of a six-session mindfulness-based stress reduction (MBSR) group and found a significant decrease in FCR immediately following completion of the therapy but no long-term follow-up was conducted [21]. The second reported similar findings with an eight-session MBSR group [22]. The third reported significant reductions in FCR immediately following a 12-week emotion regulation group [23]. However, improvements in FCR were not sustained at 6 and 12 months post-intervention. Lastly, a telephone intervention designed to improve communication between breast cancer survivors and their physicians was not successful at decreasing the secondary outcome of FCR, although it did lead to improvements in the primary outcome of self-efficacy [24]. An important limitation of the aforementioned interventions that evaluated FCR as a secondary outcome is that they did not describe the strategies that were offered to participants to increase their ability to cope with FCR nor did they specifically target possible mechanisms that could lead to a reduction in FCR. In summary, the previously published interventions leave clinicians ill-equipped in knowing exactly which tools to use and which processes to focus on to help patients deal with FCR.

In order to address the needs of patients with moderate to high FCR, we designed a group intervention based on Leventhal's common sense model [25], Mishel's uncertainty in illness theory [26], and cognitive models of worry [27]. We also adapted components of the cognitive-existential (CE) group intervention developed by Kissane and colleagues [28–30] designed to address some of the existential issues related to living

with cancer. The theoretical underpinnings of our intervention were deemed appropriate for several reasons. First, we know that patients with elevated FCR tend to use maladaptive coping strategies [10, 11] and engage in catastrophic thinking [31], making it likely that the cognitive component of the CE group therapy will be particularly helpful in reducing FCR. Second, existential therapies aim to improve quality of life by helping participants increase awareness of their existential defenses and by providing guidance towards finding meaning and purpose in life. In the CE group therapy, this translates into helping patients directly confront topics they may have been previously avoiding such as the threat of death, living with uncertainty, and lifestyle and future goals. A group format was chosen because it is as efficacious as individual therapy in managing distress in cancer populations [32, 33], and in addition to being relatively cost-effective, it allows patients to realize that others have the same struggles they do, to learn from each other, and to feel valued when they are able to help each other.

The purpose of the present study was to develop, standardize, and pilot test the feasibility and the preliminary efficacy of a cognitive-existential group intervention designed to address the primary outcome of FCR among women with breast or ovarian cancer. Secondary outcomes of the intervention included cancer-specific distress, uncertainty, coping, and quality of life. We hypothesized that the intervention would be feasible and that women would experience improvements in (a) FCR and (b) cancer-specific distress, uncertainty, coping, and quality of life as measured pre- and immediately post-intervention. We also hypothesized that improvements would be maintained at a 3-month follow-up.

Method

Study design

This study was a single-arm multi-site pre-post pilot study to address feasibility and preliminary efficacy with a 3-month follow-up to assess for maintenance of improvements.

Participants

Breast or ovarian cancer patients were recruited from two participating sites: the Cancer Survivorship Program at Princess Margaret Cancer Centre in Toronto and the Division of Gynecologic Oncology at The Ottawa Hospital in Ottawa. Research Ethics Boards of both recruitment sites approved the study. Inclusion criteria were the following: (a) first time occurrence of breast or ovarian cancer stages I–III, (b) FCR endorsed as a 4 or more on 50 % of the 22 items (ranging from 1 to 5) of the fear of recurrence questionnaire[1] [34], (c) total score of 26 or greater on the impact of event scale (IES), indicating a score in the clinical range (possible range is 0–75)[1] [35], and (d) completion of first-line treatment (i.e., surgery, radiation, or chemotherapy), with the exception of maintenance therapy or hormonal therapy (e.g., tamoxifen). Women recruited had elevated levels of FCR and cancer-related intrusive thoughts (inclusion criteria b and c) as it has been suggested that cognitive behavioral and stress management interventions that aim to reduce general distress are most successful with patients who have elevated levels of such cancer-related intrusive thoughts [36, 37]. Exclusion criteria were the following: (a) a current untreated self-reported major psychiatric disorder (e.g., severe major depressive episode, psychotic episode, dementia, etc.) that would make group participation difficult and (b) inability to converse in English.

Power calculation

Given that there are no published interventions specifically addressing FCR, we based our sample size calculations on change in intrusion scores (IES) [35] observed in another group intervention study for women at risk for breast cancer, which demonstrated >0.5 standard deviation change in the intrusion scale (this change was associated with clinically meaningful differences) [38]. For a specified power of 80 % with type one error of 0.05, we calculated a sample size for a repeated measure analysis at 37 for a 0.5 standard deviation effect size between pre- and post-intervention outcome measure (IES). Participants were recruited until we reached the required sample size at the 3-month follow-up.

Procedures

Posters describing the study were placed in waiting areas of both recruitment sites. Letters were also mailed to potentially

[1] At the time we started the study, there were only 4 longer (i.e. 10+ items) FCR instruments that were available: the concerns about recurrence scale (CARS) [3], the fear of recurrence questionnaire (FRQ) [31], the fear of cancer recurrence inventory (FCRI) [56], and the fear of disease progression questionnaire (FoP-Q) [57]. However, the CARS has been validated with women with breast cancer only. The FCRI and the FoP-Q have been validated with French and German cancer patients, respectively, and while English translations are available for both instruments, empirical validations of these translated versions have yet to be published. This left the FRQ as the most suitable longer measure of FCR because it is applicable to both breast and ovarian cancer patients and because it is validated in English. However, the FRQ does not have a clinical cut-off score. We attempted to select participants with moderate to high FCF by using a score of 4 or more on 50 % of the 22 items of the FRQ as an inclusion criterion. Recognizing that this method had limitations, we also used the validated cut-off score of the Impact of Events Scale (IES) to reliably identify participants who could be considered to have elevated cancer-specific distress.

eligible participants, and health care professionals were encouraged to tell their patients about the study. Interested participants contacted a research assistant who informed them about the study and assessed their eligibility. After assessment of eligibility and agreement to participate in the study, each individual attended a pre-intervention individual session with one of the CE group intervention therapists to document consent and provide an overview of the goals of the group and counseling regarding participation in a group process. Level of readiness, commitment to completing the six weekly sessions, and identification of any concerns regarding untreated major psychiatric disorders that could result in inability to fully participate in the group process were also explored during this pre-intervention individual session. In an attempt to limit dropouts, we emphasized in this individual meeting that the intervention might elicit difficult emotions but that the group leaders would help participants process and manage these. We also informed participants that we had stringent adherence criteria and that if they were to miss a session, they were expected to redo it either in person or by telephone before the next occurring session; should they miss more than one session, they would be asked to join the next group.

The intervention

Theoretical framework The intervention was theoretically guided by Leventhal's common sense model [25], Mishel's uncertainty in illness theory [26], and cognitive models of worry [27]. Existential psychotherapy [28] was used to guide the interventions by focusing on the subjective experiences of each woman, encouraging women to authentically face existential anxiety, and helping women explore how to live a meaningful life.

Figure 1 summarizes the theoretical framework of the intervention. According to Leventhal's common sense model, FCR is best viewed as a multidimensional construct in which internal and external cues increase perceived risk of recurrence, which in turn heightens FCR [39–41]. Common internal triggers are pain, fatigue, and aches while common external triggers include medical appointments, anniversary day of diagnosis, conversations with friends about cancer, and media exposure to cancer [3]. The misinterpretation of benign physical symptoms is hypothesized to be one of the main contributing factors to FCR [6, 25] and health anxiety in general [42]. The activation of perceived risk of recurrence tends to lead to even more focus on physical sensations, noticing previously benign symptoms and interpreting them as further evidence of recurrence. In cases of high FCR, this is likely to result in anxious preoccupation, personal checking behavior, and over seeking reassurance from doctors, other health practitioners, or family members [25, 43]. While suboptimal coping strategies such as avoidance, checking behaviors, and over seeking reassurance can provide temporary relief from FCR by giving immediate reassuring feedback, such relief is usually short-lived, and in the long-run increases FCR [8, 25, 43, 44].

According to the uncertainty in illness theory [26], uncertainty is generated when components of illness, treatment-related stimuli, and illness-related events possess the characteristics of inconsistency, randomness, complexity, unpredictability, and lack of information in situations of importance to

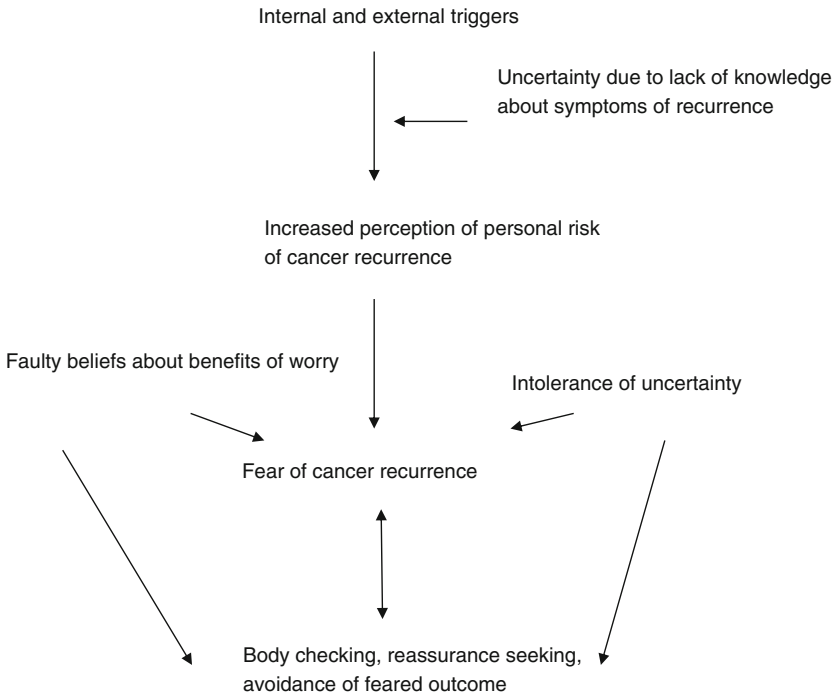

Fig. 1 Theoretical framework of the intervention. Experiencing internal and external triggers increases the perception that cancer survivors are at risk of recurrence, which in turn heightens their FCR. Survivors then engage in personal checking behaviors, avoidance, and over seeking reassurance. Survivors who possess better knowledge of the signs and symptoms of recurrence experience less uncertainty and therefore less FCR. Finally, those who hold faulty beliefs about the benefits of worry and have lower tolerance for uncertainty experience greater FCR and have an increased use of maladaptive coping strategies

the individual [45]. The fact that cancer could recur anytime, that reminders of the cancer experience are unpredictable, and that survivors often report vague and complex physical complaints contribute to the experience of uncertainty among cancer survivors. Lack of knowledge about symptoms that indicate a recurrence (vs. benign symptoms) heightens FCR by increasing the chance that benign physical symptoms will be interpreted as signs of recurrence [31]. According to this model, providing cancer patients with accurate information about symptoms of recurrence should decrease uncertainty, which in turn should decrease FCR. While uncertainty cannot be completely eliminated, patients can learn to manage the accompanying distress by developing new coping strategies (e.g., cognitive reframing and using relaxation techniques) [31].

Lastly, our intervention was informed by cognitive models of worry that suggest that one of the functions of worry is to avoid feared outcomes by interfering with emotional processing [27, 46, 47]. Previous studies show that FCR is multidimensional: When probed about specific fears, patients report that their main concerns are fear of dying, fear of further treatment, especially chemotherapy, and fear of further suffering [3]. By identifying and confronting their specific fears and developing coping strategies around them, the hypothesis was that cancer survivors would increase their belief that they could cope with these feared outcomes, should they ever happen, which would then reduce their FCR. Cognitive models of worry suggest that worriers tend to have faulty beliefs about the benefits of worry such as, "worry is useful because it helps prevent negative outcomes from occurring."

Cognitive models of worry also suggest that worriers have lower tolerance for uncertainty than non-worriers [27]. Patients with elevated FCR may consider anything less than complete certainty that they are cancer-free as inadequate, which may explain their increased need for medical reassurance.

The goals of the CE group therapy were as follow:

- Help each woman identify her own triggers of FCR.
- Teach women about possible signs of cancer recurrence through psychoeducation provided by a breast or ovarian health care specialist.
- Introduce cognitive restructuring techniques and help women use them to reduce catastrophic interpretations of their physical symptoms.
- Decrease women's reliance on maladaptive coping strategies (e.g., excessive body checking) that can maintain FCR.
- Practice alternative adaptive coping strategies (e.g., relaxation techniques, processing existential concerns).
- Engage women in exploration of their worst case scenario and encourage additional exposure to it to reduce cognitive avoidance of specific feared outcomes and existential concerns.
- Challenge beliefs about the benefits of worrying.
- Promote the idea that uncertainty is part of daily life and help women identify and act on what is within their control while living meaningfully and better tolerating the uncertainty that remains.

Content of the six sessions The complete intervention consisted of six consecutive weekly group sessions of 90 min each (see Table 1 for content of the six sessions). There were at-home exercises assigned between each session.

Table 1 Content of each of the six group cognitive-existential sessions

Session no.	Session description
1	- Introduction by each participant with a focus on their experience with FCR
	- Introduce FCR model
	- Identification of internal and external triggers
	- Introduce notion of cognitive restructuring and triggers
	- Coping skills teaching: progressive muscular relaxation
2	- 30-min visit from a health care professional to provide information about signs of recurrence and follow-up care
	- Discuss ways of regaining sense of control
	- Coping skills teaching: calming self-talk phrases and use of relaxation CD
3	- Explore reasonable levels of worry
	- Challenge faulty beliefs about benefits of worry
	-Review maladaptive coping strategies like reassurance seeking and avoidance
	- Coping skills teaching: guided imagery
4	- Provide psychoeducation about worry and the need for exposure to underlying fears
	- Promote emotional expression and confront specific fears that underlie each participant's FCR
	- Write down worst case fear scenario
	- Coping skill teaching: mindfulness exercises
5	- Review exposure to worst case scenario
	- Discuss ways of coping with some of the feared outcomes
	- Encourage expression of feelings of demoralization
	- Encourage participants to become re-engaged with important life goals, people, or activities they may have given up
	- Discuss what the future and planning now means for each participant
6	- Review all content covered to date
	- Discuss future goals
	- Set new priorities
	- Promote the expression of saying goodbye to the group and provide closure

Administration of the therapy We developed two manuals, one for therapists and one for participants to ensure standardization of the intervention. All group leaders were health care professionals who were formally trained in psychotherapy (psychologists, social workers, and nurses; $n=8$). All group leaders participated in a 1-day training session provided by authors S.L. and C.C. All sessions were videotaped to ensure uniformity of delivery, reviewed weekly for adherence to the manual by authors C.M and S.L, and feedback was provided to the therapists weekly in person or over the phone.

Measures

Demographic information including age, ethnicity, marital status, working status, education, and family income was collected at baseline on all study participants. Similarly, self-reported medical data was collected at baseline on all study participants including date of diagnosis, stage, and previous history of cancer.

Feasibility was assessed by examining time to reach desired sample size, number of participants screened for eligibility and enrolled, and dropout rates.

Prior to the start of the CE group therapy (T1), at the end of the therapy (T2), and at follow-up (3 months; T3), women completed a battery of self-administered standardized questionnaires which included the following:

Primary outcome The primary outcome measure for the study was FCR, measured with the fear of recurrence questionnaire [34]. This 22-item questionnaire evaluates worry about health status and illness returning, triggers which influence worry, uncertainty, and the concerns of significant others. Measured on a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5), scores range from 22 to 110. Rating was summed to yield a total score with higher score indicating higher FCR. Cronbach's α in the current sample was 0.83.

Secondary outcomes Cancer-specific distress was measured using the impact of event scale (IES) [35]. The IES measures the frequency of intrusive and avoidant thoughts associated with cancer. The total IES score was used in the study by summing all the items. Scores range from 0 to 75. Cronbach's α in the current sample was 0.79. Quality of life was measured using the impact of cancer scale [48]. This 81-item, ten-subscale, and quality of life measure assesses specific aspects of the cancer survivorship experience ranging from concerns with employment, life outlook, body and health, feelings about cancer, meaning of cancer, and social activities and relationships. Cronbach's α of the subscales ranged from 0.61 to 0.85 in the present study. Scores are produced by summing the ten specific subscales ranging from strongly disagree (1) to strongly agree (5) into positive and negative quality of life scores. Uncertainty was measured using the Mishel uncertainty in illness scale [26]. The 33-item questionnaire ranges from strongly disagree (1) to strongly agree (5) on items representing areas of uncertainty. Cronbach's α in the current sample was 0.91. Coping was measured using the Brief COPE that contains 28 items and 14 coping subscales, consisting of two items each. Its psychometric proprieties are adequate [49]. Cronbach's α of the subscales in the current sample ranged from 0.43 to 0.96 with nine of the subscales having good internal consistency (i.e., $\alpha>0.70$).

Statistical analyses

Statistical analyses were performed using SPSS Statistics version 20. Pairwise deletion was used to exclude missing data. Descriptive statistics including mean, standard deviations, and effect sizes were generated for the psychological variables at the three measurement occasions. Repeated measures analyses of variance were carried out on the primary (FCR) and secondary (cancer-specific distress, coping, uncertainty, and quality of life) outcome measures pre- and post-intervention and at the 3-month follow-up. The reliable change index (RCI) [50] was used to determine the frequency of reliable change in FCR from T1 to T2. The index is derived from the standard error of measurement of a test, and it represents the 95 % confidence interval for the difference in scores between two assessments that is expected if no real change has occurred. Because the test-retest reliability is unknown for the fear of recurrence questionnaire, we set this value at $r_{T1-T2}=0.80$. Values $>\pm1.96$ are classified either as reliably changed or reliably deteriorated while values $<\pm1.96$ are classified as unchanged [50].

Results

Participants

A total of 56 women enrolled in the study forming 9 groups of 5–8 women with either breast (7 groups) or ovarian cancer (2 groups). Of these, 46 had breast cancer and 10 had ovarian cancer. Sociodemographic and medical characteristics of the sample are presented in Table 2. The average participant was 55 years of age (range was 36–71 years), university educated, married, and working for pay. The majority of participants had stage II cancer and were diagnosed on average 2.3 years earlier.

Table 2 Demographic and medical characteristics of the intervention participants (n=56)

Characteristics	M (SD)
Age	54.8 (9.0)
Time since diagnosis (years)	2.3 (1.8)
	%
Marital status	
Single	19.6
Married/common Law	58.9
Separated/divorced	17.9
Widowed	3.6
Ethnic background	
Caucasian	80.8
African-Canadian	–
Asian	10.6
Hispanic	4.3
Other	4.3
Working status	
Working	50.9
Not working	49.1
Education	
≤High school	5.4
College/some university	14.3
University degree	55.4
Graduate degree	25.0
Family income ($)	
<$20,000	6.1
$21,000–40,000	12.2
$41,000–60,000	14.3
$61,000–80,000	16.3
$81,000–100,000	18.4
>$100,000	32.7
Cancer diagnosis	
Breast	82.1
Ovarian	17.9
Cancer stage	
I	28.6
II	39.3
III	32.2

Feasibility

From October 2010 to October 2012, a total of 97 women were screened for eligibility. Of these, 41 women were not enrolled in the study for the following reasons: not meeting eligibility criteria, n=15; could not commit to the timeline, n=6; declined participation upon receiving further information, n=16; did not return the T1 questionnaire, n=2; or the intervention was deemed by the group leaders not to be the right resource for their current need, n=2.

During the course of the study, 12 women dropped out, resulting in a 21 % dropout rate. Reasons for dropout were the following: (1) patients felt their FCR was getting worse following the educational session on possible signs of recurrence (n=3); others felt it was difficult to think about their cancer (n=3); (2) difficulties with scheduling or personal illness (not cancer-related) resulting in more than one session missed (n=5); and (3) did not provide a reason for dropping out of the study (n=1). All participants who dropped out were provided with the contact information of an appropriate resource (i.e., the psychosocial oncology program or the program psychologist) should they feel the need for additional help with their FCR. There were no significant sociodemographic, medical, or baseline outcome measurement differences between the women who completed the study (n=44) and the women who dropped out (n=12) except that women who dropped out had greater self-blame coping scores at baseline (M=4.6, SD=1.4) than women who completed the study (M=3.5, SD=1.5), F=5.34, p<0.05. A total of 41/44 (93 %) participants returned their T2 packages and 37/44 (84 %) returned their T3 packages.

Changes in outcome measures

The means and standard deviations of the primary and secondary outcomes at baseline, post-completion of the intervention, and at the 3-month follow-up are presented in Table 3.[2] Repeated measures ANOVAs revealed significant time effects for FCR, cancer-specific distress, uncertainty, negative quality of life, and for the following coping subscales: use of emotional and instrumental support, positive reframing, and acceptance (see Table 3). The effect sizes of the observed changes ranged from 0.16 to 0.73.

As shown in Table 3, pairwise comparisons revealed that immediately following the intervention, women reported significantly lower levels of FCR, cancer-specific distress, uncertainty, and negative quality of life and increased use of emotional and instrumental support coping, positive reframing coping, and acceptance coping. Furthermore, all of the changes were maintained at the 3-month follow-up, with the exception of emotional and instrumental support coping which decreased and

[2] We compared the effects of the intervention by cancer diagnosis (breast vs. ovarian) using repeated measures ANOVAs with cancer diagnosis as a between factor. Results revealed few differences among the two groups of participants. There was a TimeXDiagnosis difference in the use of active coping ($F_{(2, 34)}$=3.31, p<0.05). Univariate analyses revealed that the use of active coping increased over time only among women with ovarian cancer. There were also main effects of diagnosis on the use of instrumental support ($F_{(1, 36)}$=5.35, p<0.05) and planning coping ($F_{(1, 36)}$=5.66, p<0.05). For both coping strategies, women with breast cancer reported more use of these strategies than women with ovarian cancer but neither group showed changes over time on either strategy.

Table 3 Psychological outcomes at baseline (T1), post-intervention (T2), and 3-month follow-up (T3): means, standard deviations, and effect size

	Mean (SD)				*F* and *p* values	Effect size partial Eta square
	T1	T2	T3	*N*	Time	
Fear of cancer recurrence	92.97 (8.08)a	82.00 (7.33)b	80.35 (10.07)b	38	$F_{(2, 36)}$=48.65, p<0.001	0.73
Cancer-specific distress	35.04 (13.24)a	28.95 (9.78)b	25.84 (10.73)c	38	$F_{(2, 36)}$=10.99, p<0.001	0.38
Uncertainty	91.16 (19.43)a	83.97 (16.38)b	81.49 (18.92)b	36	$F_{(2, 34)}$=11.68, p<0.001	0.41
Self-distraction	5.66 (1.56)a	5.97 (1.44)a	5.66 (1.53)a	38	$F_{(2, 36)}$=0.98, p=0.39	0.05
Active coping	6.30 (1.29)a	6.43 (1.19)a	6.27 (1.26)a	37	$F_{(2, 35)}$=0.42, p=0.66	0.02
Denial	2.84 (1.34)a	2.57 (0.96)a	2.54 (0.90)a	37	$F_{(2, 35)}$=1.62, p=0.21	0.08
Substance use	2.39 (1.13)a	2.29 (0.84)a	2.40 (0.92)a	38	$F_{(2, 36)}$=0.76, p=0.48	0.04
Use of emotional support	5.89 (1.43)a	6.24 (1.61)b	5.54 (1.61)a	37	$F_{(2, 28)}$=4.88, p<0.05	0.22
Use of instrumental support	5.71 (1.51)a	5.87 (1.61)a,b	5.21 (1.73)a	38	$F_{(2, 36)}$=3.39, p<0.05	0.16
Behavioral disengagement	2.50 (0.91)a	2.22 (0.54)a	2.39 (0.73)a	36	$F_{(2, 34)}$=2.81, p=0.08	0.14
Venting	4.69 (1.59)a	4.89 (1.59)a	4.51 (1.65)a	35	$F_{(2, 33)}$=1.05, p=0.36	0.06
Positive reframing	4.54 (1.76)a	5.57 (1.30)b	5.43 (1.80)b	37	$F_{(2, 35)}$=9.11, p<0.001	0.34
Planning	5.66 (1.42)a	6.13 (1.38)a	5.47 (1.69)a	38	$F_{(2, 36)}$=3.16, p=0.54	0.15
Humor	4.05 (2.03)a	4.05 (1.80)a	3.82 (1.81)a	38	$F_{(2, 36)}$=0.51, p=0.61	0.03
Acceptance	6.17 (1.61)a	7.14 (1.02)b	6.89 (1.26)b	36	$F_{(2, 34)}$=6.37, p<0.01	0.27
Religion	4.68 (2.08)a	5.08 (1.71)a	4.86 (2.06)a	37	$F_{(2, 35)}$=2.02, p=0.15	0.21
Self-blame	3.53 (1.43)a	3.21 (0.91)a	3.29 (1.58)a	38	$F_{(2, 36)}$=1.65, p=0.21	0.08
Positive QOL	4.38 (0.57)a	4.42 (0.56)a	4.40 (0.62)a	36	$F_{(2, 34)}$=0.16, p=0.86	0.01
Negative QOL	3.53 (0.59)a	3.19 (0.55)b	3.09 (0.50)b	35	$F_{(2, 33)}$=19.28, p<0.001	0.54

Within a row, values with different lowercase letters indicate significant differences at p<0.05. For negative QOL, higher scores indicate worse quality of life. For positive QOL, higher scores indicate better quality of life

were no longer significantly different from pre-intervention levels. Cancer-specific distress showed an additional significant decrease from post-intervention to 3-month follow-up.[3]

According to the RCI analysis on the 41 participants who provided complete data on the measure of FCR before and immediately after the intervention, 29 patients (71 %) could be classified as reliably improved, 12 patients (29 %) as unchanged, and none as deteriorated.

Discussion

This is one of the first published interventions that specifically targets FCR in cancer survivors. Strengths include an intervention grounded in theory and explicating the processes and tools that clinicians can use to address FCR (see Fig. 1 and Table 1). Findings from our pilot study suggest that this brief, 6-week, group intervention may be successful in decreasing FCR among women with breast and ovarian cancer. It may also improve secondary outcomes of cancer-specific distress, uncertainty surrounding cancer, quality of life, and coping. Improvements also appear to be maintained at 3 months. These results are encouraging given that, left untreated, FCR usually does not decrease over time [10–12]. The preliminary effect sizes of the observed changes were, for the most part, in the medium to large effect range [51].

The intervention also appears to be feasible. Despite the challenges of having two recruitment sites as well as two different target populations (breast and ovarian cancer), we were able to successfully recruit 56 participants over 2 years. Of these 56 participants, 44 completed the intervention. The number of participants who dropped out (21 %) is in line with the 22 % overall dropout rates from outpatient mental health care in the USA [52] and is very similar to the rate reported by Hershbach et al. [19] (an overall 20–24 % dropout rate across

[3] At the suggestion of one of the reviewers, we performed additional analyses to see if time since diagnosis had any impact on our results. First, we ran bivariate correlations between time since diagnosis and the variables that were significantly impacted by the intervention (FCR, cancer-specific distress, uncertainty, use of emotional and instrumental support coping, positive reframing coping, acceptance coping, and negative quality of life) for each of the three time points. Of possible 24 comparisons, only two were significant (greater time since diagnosis was associated with greater use of acceptance coping at T1 and higher levels of cancer-specific distress at T3). We also recalculated the repeated measures ANOVAs to examine the time effects for FCR, cancer-specific distress, uncertainty, use of emotional and instrumental support coping, positive reframing coping, acceptance coping, and negative quality of life controlling for time since diagnosis as a covariate. Time since diagnosis was not a significant covariate in any of these analyses and the significance of the results remained unchanged. It thus appears that the intervention is equally effective for cancer survivors who have finished treatment, regardless of time since diagnosis.

their 1-year follow-up). Dropouts tended to occur early in the intervention, usually after the first or second session, which is also typical of patients seeking mental health services [52]. The second session of the intervention included a presentation by a nurse on possible symptoms of cancer recurrence. Three participants from the first two groups reported that the information session delivered by the oncology nurse was overwhelming and that they had decided to stop attending the group. In the remaining seven groups, we decreased the amount of information that was delivered in that session: we focused more on specific questions that the women brought to the session for the breast or ovarian cancer nurse, rather than on all possible complications women may experience as a result of their cancer or its treatment. In our experience, participants' questions focused mainly on symptoms of recurrence and monitoring issues. Following this modification, no further participants indicated that the information session by the nurse was their main reason for dropping out.

The pilot study suggests that the intervention does not appeal to all cancer survivors. The acceptability of the intervention is challenged, as nearly half of the interested enrollees self-selected out of the intervention before its outset, and approximately 10 % dropped when the nurse presented anxiety-inducing material or because it was too difficult to think about their cancer. There is a possibility that participants who dropped out had experienced a temporary increase in their FCR, as they started hearing and talking about it and were being encouraged to decrease the use of avoidance coping. Some patients appear to manage their FCR well by the extensive use of suppressive coping strategies [40] and may become temporarily distressed when attempts are made to modify their existing coping strategies. Similar reasons may have motivated some potential enrollees to self-select out of the intervention. However, while confronting fear might challenge the acceptability of the intervention for some patients, several CBT theorists suggest that exposure is a key ingredient in the successful treatment of anxiety disorders [53–55]. Thus, it seems that while the intervention did not appeal to all participants, those who accepted the CBT rationale and continued participation (despite having to tolerate anxiety when contemplating their fears) experienced a great deal of benefit from it.

Study limitations

Women with breast or ovarian cancer who took part in the present study were not randomized so we cannot draw definite conclusions that the intervention is responsible for the changes observed amongst participants. Also, while most psychological outcomes showed improvements, we observed changes on only 4 of the 14 Brief COPE subscales (positive reframing, acceptance, and use of emotional and instrumental support). However, the Brief COPE may not have been specific enough to reflect the coping behaviors we were trying to decrease according to our model of FCR: cognitive avoidance, reassurance seeking, and bodily checking. We also recommend that future intervention studies use a measure of FCR that has a clinical cut-off score; at the present time, there exist only two such measures, the fear of cancer recurrence inventory [56] and the fear of disease progression questionnaire [57]. In the absence of a clinical cut-off, it is difficult to comment on how clinically meaningful the observed FCR changes are in the present study. However, the majority of participants achieved reliable improvements (i.e., greater than 1.96 SD) [58]. The preliminary effectiveness of the intervention may in part be explained by the selection of participants with high levels of FCR and cancer-specific distress, which has been found in other intervention studies of cancer-specific distress to produce greater improvements than interventions that do not screen for such participants [59]. However, we do not currently know if the intervention would be appropriate or effective in reducing FCR for individuals who suffer from low levels of FCR and who, according to a recent review of the literature, represent 51 % of all cancer survivors [11].

Other limitations of the present study include the absence of data on the intervention fidelity check and on the ease of using the intervention from the therapists involved in the study. Finally, we did not rigorously keep track of how many participants were approached due to the multitude of recruitment methods that were used by both centers. This limits our assessment of the feasibility of the study, which only examines time to recruit the desired number of participants. Results from this pilot study should therefore be interpreted with some caution, and future FCR intervention studies should strive to more thoroughly examine feasibility and acceptability.

Future directions

Emerging intervention studies suggest it is possible to help patients deal with the realistic fear of disease recurrence or progression [19, 21, 22, 60]. However, most published interventions were theoretical which led to the development of the present theoretical framework based on Leventhal's common sense model [25], Mishel's uncertainty in illness theory [26], and cognitive models of worry [27]. This framework was useful in providing a common language for patients and therapists throughout all of the six sessions; however, its validity needs to be further established. While it was beyond the scope of this pilot study to test this theoretical framework via regression analyses (i.e., test the influence of changes in uncertainty or coping on changes in FCR), we are encouraged that the intervention showed changes in possible process variables such as uncertainty and coping. Future research

efforts should consider determining which components of the proposed model have the greatest influence on changes in the main outcome of FCR.

Participants in the present study were women with breast or ovarian cancer as there is evidence of a moderate association between female gender and a higher incidence of moderate to elevated levels of FCR [11]. As our intervention was untested, we wanted to establish its preliminary efficacy on individuals most likely to experience the phenomenon we hoped to improve. Future studies should examine the efficacy of the intervention among other cancer populations, including male cancer survivors.

In conclusion, preliminary results of the present pilot study are encouraging and are in line with a successful intervention. We therefore plan to further test our manualized, brief, and cognitive-existential intervention in a randomized controlled trial with breast and gynecological cancer patients (funds awarded: Lebel & Maheu Canadian Cancer Society Research Institute: grant no. 702589).

Implications for cancer survivors

This pilot study suggests it is possible to help cancer survivors who experience moderate to high FCR, a concern that, when left unaddressed, tends not to decrease over time. Future studies are needed to further test the efficacy of this brief, 6-week group cognitive-existential intervention.

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Conflict of interest I, Sophie Lebel, declare that myself or my institution (University of Ottawa) or my co-authors have no relationship, financial or otherwise, with individuals or organizations that could influence the authors' work inappropriately.

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