Pilot and Feasibility Studies

STUDY PROTOCOL

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It is time to address fear of cancer recurrence in family caregivers: protocol for the feasibility and acceptability of a randomized pilot study of the online version of the Family Caregiver–Fear Of Recurrence Therapy (FC-FORT)

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Abstract

Background Fear of cancer recurrence (FCR) is common, persistent, and is associated with lower quality of life, impaired functioning, and psychological distress in cancer patients. Studies suggest that family caregivers of cancer patients experience equal or greater levels of FCR than patients themselves. In the past 5 years, several interventions have demonstrated their ability to reduce FCR among cancer patients and in patient-caregiver dyads. However, to date, no intervention exists to individually target family caregiver's FCR. The aims of the proposed pilot study are to (1) assess the feasibility and acceptability of the newly adapted Family Caregiver–Fear Of Recurrence Therapy (FC-FORT) intervention to inform a larger randomized control trial study, and (2) estimate the clinical significance of FC-FORT. Initial evaluation of FC-FORT revealed high user satisfaction and usability.

Methods A parallel, two-group, pilot randomized controlled trial comparing FC-FORT to a waitlist control (care as usual) will be conducted. Participant inclusion criteria are (a) women family caregivers taking care of adult cancer patients (no recurrence), (b) experiencing clinical levels of FCR, (c) access to a computer/internet connection, and (d) living in Canada. Participants ($n=36$) will be recruited at Ottawa and Toronto hospitals, previous study participant pools, through social media and community partners across Canada. Participants in the intervention group will complete the FC-FORT intervention (7 consecutive weeks of virtual group therapy and homework). Participants in the control group will be offered the intervention after their participation in the study. All participants will be asked to complete questionnaire packages at baseline (T0), immediately post-intervention (7 weeks; T1) and at 3-months post-intervention (T2). Feasibility (e.g., recruitment, allocation, fidelity), acceptability (e.g., dropout, completion, satisfaction) and clinical significance of secondary outcomes will be evaluated (i.e., FCR illness uncertainty). Participants in the intervention group will be asked to complete measures of group cohesion and therapeutic alliance and take part in a semi-structured exit interview exploring their overall experience with FC-FORT.

Discussion This project will evaluate the acceptability and feasibility of the newly adapted FC-FORT to inform a larger trial.

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Background

Fear of cancer recurrence (FCR), or the fear, worry, or concern that cancer may come back or progress [1], manifests itself on a continuum with 59% of cancer survivors experiencing moderate to severe levels of FCR (also known as clinical FCR) [2]. At the individual level, clinical FCR is associated with impairment in functioning, psychological distress, sleep difficulties, stress response symptoms, and lower quality of life (QoL) [3–9]. Younger age, gender (with women being more susceptible than men), and the existence of somatic symptoms like pain and fatigue are all common risk factors for FCR [10]. Moreover, FCR appears to be prevalent and persistent across various cancer types and stages [10]. According to two meta-analyses published to date [11, 12], clinical FCR can be decreased in cancer survivors by either group or individual therapy with small to moderate effect sizes and evidence of sustained improvements at follow-up (on average 8 months post-therapy). Although there is evidence that interventions created to address FCR in cancer survivors are effective, to date, there have been few attempts to provide these treatments to family caregivers despite their unmet FCR needs.

Family caregivers (herein referred to as caregivers), also defined as family members who provide unpaid support, play an integral role in the treatment and care of cancer survivors [13–15]. According to a recent systematic review [16], approximately 50% of caregivers experience levels of FCR equal or greater than those reported by cancer survivors. FCR in caregivers, similarly to cancer survivors, is persistent, associated with lower QoL, lower functioning, and higher psychological distress [16]. In addition, FCR has been found to be one of the primary unmet need most frequently associated with caregivers reporting depressive symptoms [17]. Furthermore, in couples, FCR experienced by one partner can influence the other partner's FCR [9, 18, 19]. Therefore, treating FCR in caregivers could improve QoL for both caregivers and cancer survivors.

Many interventions have been developed to address the needs of caregivers [20, 21]. Generally, interventions for caregivers include psychoeducation, skills training and counselling in individual, group, and paired settings. Results from two meta-analyses [20, 21] suggest that interventions dedicated to caregivers generally had small to medium effect sizes in reducing caregiver burden, alleviating psychological symptoms, and improving caregivers coping capabilities, self-efficacy and QoL. To date, three studies (two qualitative and one randomized control trial [RCT]) [16] have been developed to address FCR in caregivers. However, while the results from the two-site, parallel-group RCT (1:1 randomization) [22] suggested a significant reduction of FCR in survivors' post-intervention [compared to the control group; F (1, 71) = 8.6, p = 0.005], no significant decline was demonstrated in the FCR of caregivers. In addition, all of them focused specifically on FCR within dyads (survivors and caregivers). Thus, this is the first attempt to develop and evaluate an intervention to individually address FCR in caregivers. In considering the adaptation of the proposed pilot RCT, it is important to account for the consistent evidence that caregivers often cannot access services due to a variety of constraints (e.g., time, finances, travel, patient-focused view, lack of resources, negative perceptions of mental health professionals and services, stigma avoidance) [23–25]. Previous in-person therapy studies for caregivers have reported difficulty in reaching caregivers and had low attendance and high attrition rates [26]. Furthermore, traditional in-person interventions may also not be feasible in the current COVID-19 era [27]. Therefore, an online format may provide a more viable option for this specific population.

When it comes to cancer care, e-Health, or web-based interventions, are becoming increasingly popular as they provide several benefits over traditional in-person interventions such as unrestricted space, accessibility, flexibility, cost-effectiveness, time-efficiency, convenience, and stigma reduction [28, 29]. A systematic review [30] found evidence of small to large effect sizes for web-based dyadic interventions on physical health (d = 0.17–0.75), psychological health (d = 0.04–0.08), overall quality of life (d = 0.20–0.68), and dyadic relationships (d = 0.30–0.95). More specifically, online support groups via videoconferencing are suggested to be comparable to in-person interventions as they enable real-time interactive face-to-face exchange, while drawing participants that may otherwise not be able to access support. Banbury and colleagues [31] conducted a systematic review of telehealth interventions delivering support groups through videoconferencing and found that online support groups were effective (i.e., pre- and post-intervention similar to face-to-face groups and usual care, and significantly better than text-based forums, high levels of cohesion

and perceived social support between participants, and increase accessibility), feasible (i.e., participants were provided with the appropriate tools, usability was high, the majority of studies reported few technical issues), and had high acceptability (i.e., high levels of participant satisfaction, high attendance with few dropouts, convenience was highly valued and privacy was not a concern). Additionally, their implementations were comparable to face-to-face interventions (strong reliability and validity). Moreover, a recent systematic review [32] identified that, compared to care as usual, e-Health interventions effectively reduced symptoms of depression and improved quality of life of caregivers of cancer survivors. Another systematic review [33] found e-Health interventions to be feasible, usable, and acceptable for caregivers of cancer survivors. Finally, there is also evidence from a range of interventions that e-Health interventions can be effective at lowering FCR among cancer survivors. These interventions include a pilot study using videoconferencing [34], a web/text based randomized control trial [35], a pilot study using a single pre-post design [9], and a RCT using an online self-guided format [36]. Given the many constraints experienced by caregivers [13], including accessibility and financial, e-Health interventions represent a suitable alternative and, perhaps, a preferable option to in-person therapies.

Aims of the current study

The primary aim of this pilot RCT is to examine the feasibility (defined by the rates of recruitment, retention, and questionnaire completion) and the acceptability (including satisfaction, adherence, perceived usefulness, and attrition) of FC-FORT.

The secondary aim is to estimate the potential clinical significance (i.e., whether changes can be observed) of FC-FORT on FCR, cancer-specific distress, perceived risk of cancer recurrence, illness uncertainty, intolerance of uncertainty, positive beliefs about worrying, coping, group cohesion, therapeutic alliance, and QoL as established by comparing improvements between and within groups [FC-FORT, waitlist control group (WLCG)].

Methods

Design

The proposed project is a pilot, mixed-method, parallel, two-group, unblinded RCT where caregivers are randomized to receive either (1) FC-FORT or (2) care as usual (WLCG). The study design was guided by the adapted CONSORT checklist for pilot trials [37, 38]. The reporting of this protocol is in line with the SPIRIT guidelines [39].

Eligibility

Inclusion criteria include (1) women adult caregivers caring for an adult cancer survivor of any type of cancer, stages I-III, who has completed treatments and has not had a recurrence of their cancer; (2) a score of 13 or greater on the Caregiver Version of the Fear of Cancer Recurrence Inventory–Short Form (range 0–36), suggesting clinical levels of FCR [5, 40]; (3) access to a computer and stable internet connection; and (4) living in Canada. Exclusion criteria include (1) caregivers who do not identify as women; (2) caregivers of a pediatric cancer survivor; (3) non-English speaking; (4) caregivers currently participating in another therapist-led psychosocial support group or a peer-led support group; and (5) caregivers with unmanaged/undermanaged mental health disorder judged to be clinically contra-indicated and/or likely to affect the group work. This study will focus on women caregivers specifically as research consistently indicates that women carry a heavier caregiver burden than men [41]. Additionally, the original Fear Of Recurrence Therapy (FORT) intervention has only been validated with women and studies on FCR in caregivers include mostly women caregivers [4, 9, 42].

Sample size justification

Sample size for the present pilot study was calculated based on the estimated sample size needed in a future RCT with a two-arm design (intervention vs. waitlist control) and three measurement occasions (pre-, post-, and 3-month follow-up). Sensitivity power analyses were performed with G*Power 3.1 using a two-sided, type 1 error rate of 0.05 and 95% power, of an independent sample size of fifty-seven participants per arm, and with a three-time assessment. Under these conditions, an effect size of 0.40 (Cohen's *d*) would detect a difference between FC-FORT and a WLCG. Based on FORT's observed dropout rate and loss to follow-up [43, 44], an additional 20% participants per treatment group would be needed, thus requiring sixty-eight participants per arm for a total of 136 study participants. This would mean conducting sixteen groups of nine caregivers (eight interventions and eight WLCG who would get the intervention after 3 months). Assuming a 4-year recruitment rate for the RCT, we need to be able to recruit four groups (i.e., thirty-six caregivers) in a period of 15 months during the present study to demonstrate feasibility of this future RCT.

Recruitment

Thirty-six women caregivers will be recruited to participate in the study. Participants will be recruited using advertisement at the Princess Margaret Survivorship Clinic and the Princess Margaret Caregiver Clinic, The Ottawa Hospital, previous study participant pools, with cancer societies (e.g., Prostate Cancer Canada and Ovarian Cancer Canada), through social media, and with community support partners across Canada. Interested caregivers will contact the research coordinator via email to be screened for eligibility and to complete the consent form.

Allocation, randomization, and concealment

Eligible participants will attend a one-on-one pre-therapy meeting with the research coordinator or assistant to prepare them for the group work (i.e., review expectations and assess whether group work is appropriate for the participant) [45]. For most participants, this will be done during their initial eligibility meeting. These pre-therapy meetings will occur prior to randomization to reduce potential bias.

Before randomization, all eligible participants will complete (a) the consent form, (b) the sociodemographic questionnaire, and (c) the baseline measures. A list of four group allocations with equal numbers of intervention (I) and WLCG groups (e.g., I-I-WLCG-WLCG; I-WLCG-WLCG-I) will be randomly generated by the research coordinator. To limit bias, we will have each of the four allocations in separate sealed envelopes that will be opened one by one by an independent research assistant not associated with the project each time nine participants are deemed eligible (minimizing attrition). Overall, four groups (two intervention and two WLCG) of nine participants each will be created. Study therapists will be blinded to participant allocation as well as feasibility and acceptability outcomes. All participants will be assigned a participation ID at the onset of the study (prior to randomization) which will be used to complete questionnaire packages and data analysis.

Fear Of Recurrence Therapy intervention

The Fear Of Recurrence Therapy (FORT) is a standardized and manualized intervention that consists of six consecutive weekly sessions [43–45]. It was first pilot tested as a group intervention using a single-arm pre-post study design and 56 breast or ovarian cancer survivors. Results of the pilot study showed reductions of FCR and other secondary outcomes, such as cancer-specific distress, perceived risk of cancer recurrence, illness uncertainty, intolerance of uncertainty, positive beliefs about worrying, coping, and QoL, which resulted in medium effect sizes of pre to post (within group) change that were sustained at a 3 months follow-up [43]. A large multisite RCT of FORT was subsequently completed with 136 women cancer survivors who were either randomized to FORT or a structurally equivalent support group. Cancer survivors in the experimental arm experienced FCR reductions five times greater than those in the control group (moderate effect size; $d = -0.53$) [44]. In addition, compared to the control group, the experimental arm experienced significant decreases in secondary outcomes [triggers, ($d = -0.415$), coping ($d = -0.244$), cognitive avoidance ($d = -0.424$), QoL mental health ($d = 0.165$)], with sustained improvements at the 3-month follow up. Moreover, FORT was also adapted to an individual format in a pilot study RCT [46]. Results also demonstrated that survivors in the experimental arm experienced significant decreases, over time, in both FCR [primary outcome; $F(2, 27.87) = 15.82$, $p < 0.001^*$] and secondary outcomes such as cancer-specific distress [$F(2, 28.68) = 10.58$, $p < 0.001^*$], uncertainty in illness [$F(2, 30.24) = 21.46$, $p < 0.001^*$], reassurance seeking [$F(2, 29.63) = 3.92$, $p = 0.031^*$], cognitive avoidance [$F(2, 29.01) = 6.22$, $p = 0.006^*$], and intolerance of uncertainty [$F(2,24.71) = 5.43$, $p = 0.011^*$] with sustained improvements at the 3-month follow up [46]. Finally, a series of case studies of cancer survivors receiving the individual FORT intervention via videoconference [34] suggested acceptability and usability.

FORT is based on a blended theoretical model of FCR (Fig. 1) [47] that aims to address key vulnerability factors such as internal and external triggers, exaggerated perceived risk of recurrence, hyper-focus on ambiguous physical sensations, maladaptive coping, uncertainty around cancer and its treatments or care, intolerance of uncertainty, and beliefs about the benefits of worrying about one's health. This model is guided by Leventhal's Common Sense Model [48, 49], Mishel's Uncertainty in Illness Theory [50] and the cognitive model of worry [51].

It was developed using principles of Kissane's Cognitive-Existential approach [52, 53] where themes such as death anxiety, living with uncertainty, and future goals are put forward. FORT integrates principles of group therapy to facilitate cancer survivors to identify and express shared struggles, to connect and support others with similar life experiences, but also to feel understood and supported by others [45].

The key goals of FORT include helping women (1) distinguish worrisome symptoms from benign ones; (2) identify FCR triggers and inappropriate coping strategies; (3) facilitate the learning and use of new coping strategies, such as relaxation techniques and cognitive restructuring; (4) increase tolerance for uncertainty; (5) promote emotional expression of specific fears that underlie FCR; and (6) re-examine life priorities and set realistic goals for

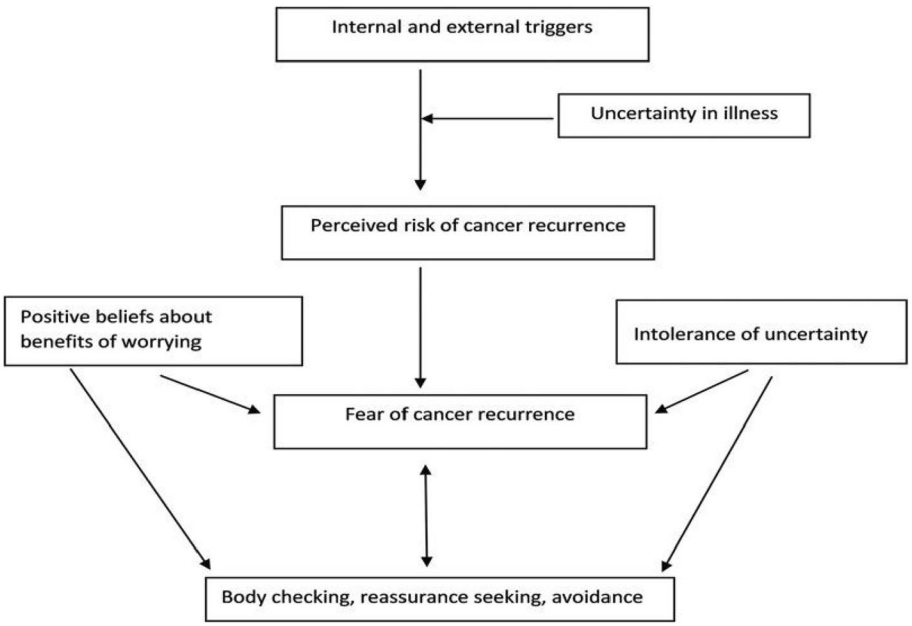

Fig. 1 Model of fear of cancer recurrence (Lebel and al., 2018; adapted from Lee-Jones and al., 1997)

the future. Key components of this intervention include (a) principles of group therapy (e.g., promoting group cohesion by facilitating participants' self-disclosure of their FCR); (b) cognitive behavioural therapy-based techniques (e.g., cognitive restructuring); and (c) elements of existential therapy (e.g., outlining fears related to death and dying).

To adapt FORT to FC-FORT a multidisciplinary advisory board, comprised of the research team, two therapists with experience in online support group formats and psychosocial oncology, and four women caregivers, was created. This advisory board met online to oversee the adaptation of the FORT manuals and provide feedback on recruitment strategies and the study's questionnaire package. The following modifications were made to the original FORT intervention to better represent caregivers' experiences: (a) additional exercises aimed at addressing caregivers' self-care, overcoming protective buffering (i.e., the tendency to withhold sharing painful feelings to not burden others); (b) additional suggestions that support difficult conversations with loved ones regarding FCR, with the focus more on facilitating discussions that support optimizing use of loved ones' health care teams; (c) softening the overall language of the workbooks to represent caregivers' realities; and (d) the addition of a seventh session to incorporate the additional content. A usability study of FC-FORT then ensued [54]. Overall, ten caregivers and three therapists, recruited through social media, community support partners across Canada, and the Princess Margaret Cancer Centre, took part in the usability study. Therapists and participants were asked to complete a short session feedback questionnaire [55] to assess the usefulness, usability, desirability, value, accessibility, and credibility of each session, as well as provide impressions of the online format and features and the general readiness of the session for end users. Brief videoconference or telephone exit interviews post-intervention were conducted with both the participating caregivers and therapists. Combined session participation rate for caregivers was 85%. Response rates for the session feedback questionnaire were 72% for caregivers and 78% for therapists. Average fidelity rating for therapist administration of FC-FORT was 87%. All participants ($n=10$) and the group facilitators took part in the exit interviews. Overall, caregivers and therapists found FC-FORT to be acceptable (i.e., useful, usable, desirable, valuable, etc.). The mean satisfaction rating for caregivers and therapists combined was "Very Satisfied." FC-FORT was rated as "Very Ready" by caregivers and "Extremely Ready" by therapists. Generally, exercises were well received by participants. Following the initial round of the usability study, key changes were made to FC-FORT including increasing length of sessions to 2h, removing and reorganizing exercises (i.e., removing the health care professional's visit, changing order of exercises within sessions), and modifying some of the online features (i.e., break out rooms, chat; see details in Lamarche and al., 2023

[54]). In addition, all caregivers indicated that they had appreciated FC-FORT's virtual format (i.e., convenient, felt safer/more comfortable in their own spaces, ability to meet other women from across Canada, could not meet in person due to personal or loved one's health conditions). All caregivers expressed good group cohesion with other group members and therapists. However, one participant indicated that the virtual format had occasionally impacted their connection to others.

The adapted Family Caregiver—Fear Of Recurrence Therapy intervention

Like the original FORT, FC-FORT is a standardized and manualized therapist led intervention. It consists of seven consecutive weekly group sessions of 120 min each, offered via videoconference, and weekly assigned homework. It is built upon FORT's original blended theoretical model of FCR (Fig. 1) [47] with some adaptations made to represent caregivers' realities. It also includes principles of Kissane's Cognitive-Existential therapy [52, 53],

Table 1 Overview of sessions

Sessions	Session Content
Session 1: Introduction to the group, learning new skills to deal with FCR (120 min)	• Introduction by each participant with a focus on their experience with fear of cancer recurrence (FCR) • Introduce ABC model of therapy, FCR model, cognitive restructuring and identify triggers • Teach cognitive restructuring and self-care • **Homework:** Complete thought record and practice self-care
Session 2: Identifying knowledge gaps on FCR (120 min)	• Discuss uncertainty and ways of regaining a sense of control • Discuss the patient's health care team • Teach progressive muscle relaxation • **Homework:** Complete thought log and practice daily progressive muscle relaxation
Session 3: Increasing tolerance for uncertainty (120 min)	• Discuss acceptable level of worry • Challenge faulty beliefs about benefits of worry • Discuss uncertainty and ways of regaining a sense of control • Teach the use of calming self-talk and listening to relaxation files • **Homework**: Challenge faulty beliefs about benefits of worry Practice calming self-talk and progressive muscle relaxation daily
Session 4: Building your coping skills (120 min)	• Discuss maladaptive coping strategies • Address communication difficulties and teach new coping skills to address your fear of cancer recurrence • Teach guided imagery • **Homework**: Having a conversation about FCR. Practice guided imagery daily; challenge faulty beliefs about benefits of worry; complete thought record with behaviour
Session 5: Getting deeper into underlying fears (120 min)	• Provide psychoeducation about worry and the need for exposure to worse fears • Promote emotion expression and confront specific fears that underlie FCR by writing down worse fear scenario • Teach mindfulness exercise • **Homework:** Read worst case scenario daily. Practice self-care and mindfulness exercise daily
Session 6: Moving beyond specific fears (120 min)	• Review exposure to worst case scenario exercise • Discuss ways of coping with some of the feared outcomes • Encourage participants to become re-engaged with important life goals, people, or activities • Discuss what meaning the future and planning now have for them • Teach mindfulness exercise • **Homework:** Write down goals and priorities for the future, practice mindfulness exercise
Session 7: Review and conclusion (120 minutes)	• Review all content covered • Discuss future goals and setting new priorities • Promote the expression of saying good-bye to the group and provide closure

principles of group therapy, and cognitive behavioural therapy-based techniques.

Intervention groups

Participants in the intervention group will complete the seven-week FC-FORT intervention (see Table 1). Membership will be closed once groups are formed and the sessions have started to enhance group cohesiveness and consistency [56]. Before starting the intervention, participants will receive a standardized electronic or paper manual describing each session's activities and assignments. Participants will be asked to complete questionnaire packages and measures as per the data collection schedule detailed below.

Waitlist control groups

Participants in the WLCG will not receive any interventions initially. They will be asked to complete questionnaire packages as per the data collection schedule detailed below. Once the 3-month questionnaire returned, caregivers in the WLCG will be offered FC-FORT.

Therapist recruitment, training, and supervision

Three therapists (two co-facilitators and one back up therapist) will be recruited to conduct the FC-FORT videoconference therapy sessions. Therapist competency to administer FC-FORT will be determined by the following criteria: (1) registered allied health professionals with experience in counselling/psychotherapy and psychosocial oncology, (2) ability to offer virtual services across Canada, (3) at least 5 years of experience in psychosocial oncology, and (4) having led at least one support group.

To enhance therapist adherence to treatment, therapists recruited for the study will be provided with a standardized FC-FORT manual and will be trained by the team of research psycho-oncologist specialists through an online training. The study psychologists will provide weekly 30-min supervision to the study therapists. Furthermore, the study will use an updated version of the fidelity checklist that was used to evaluate adherence during the previous FORT studies [45, 46]. Some examples of items on the fidelity checklist include "The therapists refer back to the theoretical framework" and "The therapists initiated problem-solving skills." The research coordinator and assistant will check the videos of all sessions from every group. If adherence is less than 80% on any session, the research team will provide additional feedback and supervision to the therapists running the group. This approach to monitoring treatment integrity and fidelity has been successful in previous FORT studies [45, 46].

Minimizing dropouts and attrition

Based on prior research of FORT [43, 45], to maximize attendance, participants will be told during informed consent procedures about the importance of attending all seven sessions to ensure that they benefit from the intervention. Participants will receive an email reminder about each upcoming session along with the videoconference invitation information, as well as reminders to complete session measures. They will be asked to inform group therapists if they are to be absent. Participants who miss more than two sessions will be asked to stop the intervention and restart with the next available group. This approach was successfully tested in previous FORT studies [43, 46]. To maximize the completion of the questionnaire package, participants in the intervention and WLCG will be compensated 20$ for each of the three packages they will complete (pre-intervention, immediately after the intervention and 3 months post-intervention). To minimize differential attrition from the WLCG participants, we will email them monthly with an update about the wait time. All WLCG participants will be offered FC-FORT after study completion regardless of their questionnaire completion.

Data collection

Participants will be asked to complete questionnaire packages (approximately 20 min each) pre and immediately post-intervention (7 weeks), and at 3-month post-intervention. All measures and questionnaires will be administered online via Qualtrics. Participants in the intervention groups will also be asked to complete measures after sessions one, four and seven, and take part in a semi-structured exit interview. Additionally, data will be logged throughout the recruitment (all steps until consent) and course of the study (follow-up of enrolled and randomized caregivers).

Questionnaire package

The questionnaire package will be available in English and includes the following self-administered measures to evaluate this project's primary and secondary outcomes. Measure selection is based on the original FORT intervention (REF), theoretically guided by Leventhal's Common Sense Model [49], Mishel's Uncertainty in Illness Theory [50], and cognitive model of worry [51]. FORT's pilot [43] and RCT [44, 46] studies demonstrated good questionnaire completion rates. Some modifications were made to the original measure selection to reflect caregiver realities and themes (i.e., protective buffering). All measures evaluate a distinct part of the FCR experience or of the content/processes

of the intervention. Whenever possible, the short form of instruments was used to reduce respondent burden.

Caregiver version of the Fear of Cancer Recurrence Inventory–Short Form (FCRI-SF) [5, 40] FCR will be measured using the adapted version of the Fear of Cancer Recurrence Inventory–Short Form (FCRI-SF). The FCRI-SF has been validated with both cancer survivors [5] and caregivers [40]. A score of 13 or greater on this 9-item instrument (range 0–36) indicates clinical level of FCR [5]. The original FCRI-SF has been shown to have adequate reliability and validity (construct validity; $r=0.68$ to 0.77; and reliability scores; $\alpha=0.95$) [5]. The caregiver version of the FCRI has also demonstrated good internal consistency ($\alpha=0.95$) [40] and test–retest reliability ($\alpha=0.88$) [40].

Perceived risk of cancer recurrence [57] Perceived risk of cancer recurrence will be assessed using a one-item question rated on a 5-point Likert scale from "Much less likely" to "Much more likely" [57]: "Compared to persons of their age, how do you rate your family member's perceived risk of cancer recurrence?".

Intolerance of Uncertainty Scale–Short Form [58] Intolerance of uncertainty will be measured with the Intolerance of Uncertainty Scale–Short Form (IUS-12) which measures reactions to uncertainty, ambiguous situations and the future and is comprised of two factors, prospective anxiety (seven items) and inhibitory anxiety (five items). Both factors have good internal consistencies ($\alpha=0.85$) [58].

Mishel Uncertainty in Illness Scale-ShortForm [59] Uncertainty in illness will be measured by the Mishel Uncertainty in Illness Scale-Short Form (MUIS-SF). It consists of five items rated on a 5-point Likert scale. The MUIS-SF has adequate internal consistency ($\alpha=0.70$) [59].

Why People Worry About Health Questionnaire [60] Positive beliefs about worrying will be measured using the Why People Worry About Health Questionnaire. It has excellent internal consistency ($\alpha=0.90$), and satisfactory temporal stability ($r=0.71$) [60].

Cognitive Avoidance Questionnaire [61] Coping will be measured with the Cognitive Avoidance Questionnaire (CAQ) that contains twenty-five items that measure avoidance coping. The CAQ has excellent internal consistency ($\alpha=0.95$), and good test–retest reliability ($r=0.85$) [61].

Protective Buffering Scale [62] Protective buffering will be measured with the Protective Buffering Scale. This scale consists of ten items rated on a 5-point Likert scale. Internal reliability for this scale is good in both partners and cancer survivors ($\alpha=0.80$–0.89) [62].

Satisfaction Participant opinions regarding satisfaction with FC-FORT will be assessed using a one-item question rated a 5-point Likert scale from "Very satisfied" to "Very unsatisfied": "How satisfied are you with the Family Caregiver–Fear of Recurrence Therapy?".

Sociodemographic information Variables such as age, gender, ethnicity, marital status, family member role (e.g., spouse, partner, child, sibling), education level, medical history of their loved one, and more will be collected through a demographic questionnaire pre-intervention.

After session measures (sessions 1, 4, and 7)

Group Cohesiveness Scale [63] Group cohesion will be measured using the Group Cohesiveness Scale (CGS) which consists of seven items rated on a 5-point Likert scale. The Group Cohesiveness Scale GCS has good internal consistency ($\alpha=0.87$) [63].

Working Alliance Inventory–Revised Short Form [64] Therapeutic alliance will be measured using the Working Alliance Inventory–Revised Short Form (WAI-SR). It is composed of twelve items (compared to its original thirty-six) rated on a 7-point Likert scale. The WAI-SR has corresponding versions for therapist and clients. The WAI-SR has good internal consistency ($\alpha=0.91$–0.92) [64].

Participant exit interviews

To gain further insights about the feasibility, acceptability, and potential clinical significance of the FC-FORT, participants in the intervention groups will be asked to participate in a one-on-one semi structured interview with the research coordinator or assistant (who is not involved in the clinical administration of FC-FORT) after completing the intervention. These interviews will enable a holistic understanding of their experience of FC-FORT, elucidate key intervention processes, and identify additional secondary outcomes. The interview guide contains questions regarding participant expectations, general impact of FC-FORT, helpful/unhelpful segments, group cohesion and therapeutic alliance, timing and length, homework practice, usability of learned material, and participant suggestions. These interviews will be

conducted via videoconferencing, are anticipated to last between 30 and 60 min, will be recorded and transcribed verbatim. Lastly, the research coordinator will attempt to interview participants who dropped out of the intervention to understand any hindering factors. They will do so by emailing participants once to invite them to take part in the exit interview process.

Study log

The research coordinator will collect the number of individuals approached, number of individuals self-referred to the study, the number of individuals eligible and ineligible, the number of participants consented and randomized, the number of participants who declined, withdrew, and dropped out (and why).

Data analysis

SPSS version 28 and NVivo version 12 software will be used for data analysis.

Quantitative analysis

Descriptive statistics with 95% confidence intervals will be used to report on the primary outcomes.

Feasibility data

Recruitment and refusal rates will be reported descriptively. Rates for completed measures, questionnaire packages, and missing data will be calculated using similar methods. Therapist adherence to FC-FORT will be calculated based on fidelity rating of each session (aiming for above 80% on 75% of sessions).

Acceptability data Dropout rates will be calculated. Participant adherence to FC-FORT will be calculated based on the number of sessions missed (aiming for 80% completion). FC-FORT will be considered satisfactory based on a score of ≥ 4 for 80% of participants on the satisfaction measure.

Clinical significance Descriptive statistics will be used to report on FCR outcomes. Variability of the main and interaction effects will be examined for secondary outcomes using separate mixed ANOVA models, with Bonferroni corrections applied. Partial eta squared (η_p^2) and associated confidence intervals will be calculated as an estimate of the effect size both over time (within groups) and between groups. Missingness will be evaluated on a case-by-case basis such that drop-outs will be excluded. Data will be analyzed when all recruitment and data collection has been performed.

Qualitative analysis

A conventional content analysis method in which codes are directly derived from the data rather than starting with a theory or research findings as an initial guide will be used [65]. Interviews will be audiotaped, transcribed verbatim, and managed using the qualitative software program NVivo. Members of the research team will undergo multiple readings of a single text to systematically identify units of meaning and will assign codes, words, or short phrases, to these units [66]. They will then come to consensus on the grouping of related codes into categories and/or subcategories that will be inserted in the coding framework to facilitate their description and interpretation to uncover trends and patterns in the data. Transcripts will be systematically coded into anticipated (e.g., motivations to participate, benefits of participation) and emergent themes using thematic analysis. This is an iterative process whereby an initial set of themes are coded, applied to new transcripts, and revised to adjust for new information, until no new codes emerge. Data analysis will consist of three phases: (1) data disassembling into codes, (2) congregation of codes that are related or share some common characteristics into categories, and (3) identify patterns and relationships between the codes and categories [67]. Further along the analytic process, categories can often be further analyzed to develop themes. Themes are recurring concepts that emerge from analysis that typically represent underlying meaning between categories in content analysis and require a higher level of abstraction [66, 68]. Coding will be conducted by a trained research assistant under the close supervision of the research team. To facilitate trustworthiness, each transcript will be read by the qualitative team and 20% will be coded independently by the study coordinator. The qualitative team will meet on a weekly basis to discuss the coding structure in the coding framework and assess for agreement and consensus. Trustworthiness in the validity of our findings will be addressed by (1) weekly debriefing sessions with the research team members to reduce the risk of biased decisions; (2) the use of appropriate quotations; and (3) keeping an audit trail of self-reflexivity [65, 69]. Throughout the analysis, categories will be examined with an explicit gender and intersectionality lens [70] to allow us to understand how identity factors (e.g., gender, sexual orientation, minority, rural vs. urban context, or socioeconomic status) simultaneously shape our participants' experiences with FC-FORT.

Pilot outcomes justifying a larger trial

The protocol of this pilot project will be deemed feasible based on the (1) ability to recruit thirty-six caregivers in

15 months; (2) ability to randomize these thirty-six caregivers; (3) complete questionnaire packages and measures for 90% of participants; and (4) ability to deliver FC-FORT as intended as measured by a fidelity rating of above 80% on 75% of reviewed sessions.

FC-FORT will be deemed acceptable based on (1) ability to deliver FC-FORT to twenty-seven caregivers in 15 months (25% dropout rate); (2) 80% completion of five out of the seven sessions; and (3) caregivers' satisfactory ratings > than 80% in terms of its content, therapists, and mode of delivery.

The clinical significance of the FC-FORT pilot study will be measured with effect sizes (CONSORT guidelines for pilot studies) [37] with 95% confidence intervals. Based on a systematic review of caregiver interventions [20], an ES $\geq$ 0.3 for the intervention group will be considered a clinically meaningful finding for the primary and secondary outcomes at 3 months post-intervention compared to those in the waitlist control group (WLCG).

Discussion

Caregivers experience similar or greater levels of FCR than cancer patients themselves. In addition, FCR in caregivers is persistent and associated with negative outcomes (i.e., quality of life, psychological distress, etc.). Although some interventions exist to address FCR in dyads (caregivers and cancer patients), this is the first study to offer an intervention to caregivers individually. Studies also suggest that levels of FCR in caregivers significantly impact levels of FCR experienced by cancer patients. Therefore, by addressing FCR in caregivers, this study could also potentially contribute to reducing overall levels of FCR in cancer patients.

The present study primarily aims to test the feasibility and acceptability of the newly adapted FC-FORT intervention among caregivers living with clinical levels of FCR. Given the efficacy and acceptability of FORT (the original intervention) with cancer patients, the similarities between FCR in caregivers and cancer patients, as well as the rigorous approach to adaptations made to FORT prior to the RCT, we posit that FC-FORT could have significant impact on potential clinical outcomes. In fact, if this pilot study's protocol is deemed feasible and acceptable, we will proceed towards the development of a larger multi-site RCT designated to evaluate FC-FORT.

Finally, this study will contribute to the literature on caregivers' unmet needs and further underscore the importance of well-designed, standardized psychological interventions targeting the emotional well-being of caregivers. Further, by supporting caregivers' needs, they will be better equipped to carry out the challenging caregiving role in supporting their loved one in their cancer journey. Thus, overall, increasing supports for caregivers contributes to a better experience and outcomes for caregivers, cancer survivors, healthcare providers, and optimizes the use of the health care system.

Abbreviations

FCR	Fear of cancer recurrence
QoL	Quality of life
FORT	Fear Of Recurrence Therapy
FC-FORT	Family Caregiver–Fear Of Recurrence Therapy
RCT	Randomized control trial
WLCG	Waitlist control group
FCRI-SF	Fear of Cancer Recurrence Inventory–Short Form
IUS-12	Intolerance of Uncertainty Scale–Short Form
MUIS-SF	Mishel Uncertainty in Illness Scale-Short Form
CAQ	Cognitive Avoidance Questionnaire
WAI-SR	Working Alliance Inventory–Revised Short For
GCS	Group Cohesiveness Scale

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-024-01567-4.

Supplementary Material 1.

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Authors' contributions

JL, RN, JA, JW, CM, SDL, AML, JJ, MJE, and SL all contributed to the adaptation of the FC-FORT intervention, conceptualized this study and helped obtain funding. JL and SL were responsible for the trial registration, continue to lead recruitment of participants, and are responsible for the administration of FC-FORT and data management. JL drafted the manuscript. All authors critically reviewed the manuscript and approved the final version.

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Data availability

The study manuals (therapists and patients) are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval was granted from the University of Ottawa Ethics Committee (Reference Number H-05–20-5584), The Ottawa Hospital Research Institute's Ottawa Health Science Network Research Ethics Board (Reference Number 20230147-01H) and The University Health Network's Research Ethics Board (Reference Number 21–5060.3). All participants will provide informed consent by acknowledging that they have read and understood the Consent Form before beginning the group intervention. Any amendments to the study protocol will be communicated to the University's Ethics Committee for formal approval.

Consent for publication

Not applicable.

Competing interests
The authors declare no competing interests.

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References

1. Lebel S, Ozakinci G, Humphris G, et al. From normal response to clinical problem: definition and clinical features of fear of cancer recurrence. Support Care Cancer. 2016;24(8):3265–8.
2. Luigjes-Huizer YL, Tauber NM, Humphris G, et al. What is the prevalence of fear of cancer recurrence in cancer survivors and patients? A systematic review and individual participant data meta-analysis. Psychooncology. 2022;31(6):879–92.
3. Moschopoulou E, Hutchison I, Bhui K, Korszun A. Post-traumatic stress in head and neck cancer survivors and their partners. Support Care Cancer. 2018;26(9):3003–11.
4. Kim Y, Carver CS, Spillers RL, Love-Ghaffari M, Kaw CK. Dyadic effects of fear of recurrence on the quality of life of cancer survivors and their caregivers. Qual Life Res. 2012;21(1):517–25.
5. Simard S, Savard J. Screening and comorbidity of clinical levels of fear of cancer recurrence. J Cancer Surviv. 2015;9(3):481–91.
6. Berrett-Abebe J, Cadet T, Pirl W, Lennes I. Exploring the relationship between fear of cancer recurrence and sleep quality in cancer survivors. J Psychosoc Oncol. 2015;33(3):297–309.
7. Hanprasertpong J, Geater A, Jiamset I, et al. Fear of cancer recurrence and its predictors among cervical cancer survivors. J Gynecol Oncol. 2017;28(6):e72–e72.
8. Sarkar S, Scherwath A, Schirmer L, et al. Fear of recurrence and its impact on quality of life in patients with hematological cancers in the course of allogeneic hematopoietic SCT. Bone Marrow Transplant. 2014;49(9):1217–22.
9. van de Wal M, Langenberg S, Gielissen M, Thewes B, van Oort I, Prins J. Fear of cancer recurrence: a significant concern among partners of prostate cancer survivors. Psychooncology. 2017;26(12):2079–85.
10. Simard S, Thewes B, Humphris G, et al. Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. J Cancer Surviv. 2013;7(3):300–22.
11. Hall D, Luberto C, Philpotts L, Song R, Park E, Yeh G. Mind-body interventions for fear of cancer recurrence: a systematic review and meta-analysis. Psychooncology. 2018;27(11):2546–58.
12. Tauber N, O'Toole M, Dinkel A, et al. Effect of psychological intervention on fear of cancer recurrence: a systematic review and meta-analysis. J Clin Oncol. 2019;37(31):2899–915.
13. Sinha, M. Portrait of caregivers. Ottawa, Ontario: Statistics Canada/Statistique Canada, Social and Aboriginal Statistics Division; 2012. https://www150.statcan.gc.ca/n1/pub/89-652-x/89-652-x2013001-eng.htm
14. Kim Y, Baker F, Spillers R. Cancer caregivers' quality of life: effects of gender, relationship, and appraisal. J Pain Symptom Manage. 2007;34(3):294–304.
15. Kent E, Rowland J, Northouse L, et al. Caring for caregivers and patients: research and clinical priorities for informal cancer caregiving. Cancer. 2016;122(13):1987–95.
16. Smith A, Wu VS, Lambert S, Lamarche J, Lebel S, Leske S, Girgis A. A systematic mixed studies review of fear of cancer recurrence in families and caregivers of adults diagnosed with cancer. J Cancer Surviv. 2022;16(6):1184–219.
17. Lambert SD, Hulbert-Williams N, Belzile E, Ciampi A, Girgis A. Beyond using composite measures to analyze the effect of unmet supportive care needs on caregivers' anxiety and depression. Psychooncology. 2018;27(6):1572–9.
18. Boehmer U, Tripodis Y, Bazzi AR, Winter M, Clark MA. Fear of cancer recurrence in survivor and caregiver dyads: differences by sexual orientation and how dyad members influence each other. J Cancer Surviv. 2016;10(5):802–13.
19. Mellon S, Kershaw TS, Northouse LL, Freeman-Gibb L. A family-based model to predict fear of recurrence for cancer survivors and their caregivers. Psychooncology. 2007;16(3):214–23.
20. Northouse LL, Katapodi MC, Song L, Zhang L, Mood DW. Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. CA Cancer J. 2010;60(5):317–39.
21. Fu F, Zhao H, Tong F, Chi I. A systematic review of psychosocial interventions to cancer caregivers. Front Psych. 2017;8:834–834.
22. Heinrichs N, Zimmermann T, Huber B, Herschbach P, Russell DW, Baucom DH. Cancer distress reduction with a couple-based skills training: a randomized controlled trial. Ann Behav Med. 2012;43:239–52.
23. Reblin M, Ketcher D, Vadaparampil ST. Care for the cancer caregiver: a qualitative study of facilitators and barriers to caregiver integration and support. J Cancer Educ. 2022;37(6):1634–40.
24. Taylor J, Fradgley EA, Clinton-McHarg T, Byrnes E, Paul CL. Access to support for Australian cancer caregivers: in-depth qualitative interviews exploring barriers and preferences for support. J Psychos Oncol Res Pract. 2021;3(2): e047.
25. Mosher CE, Given BA, Ostroff JS. Barriers to mental health service use among distressed family caregivers of lung cancer patients: barriers to mental health service use. Eur J Cancer Care. 2015;24(1):50–9.
26. Applebaum AJ, Breitbart W. Care for the cancer caregiver: a systematic review. Palliat Support Care. 2013;11(3):231–52.
27. Weinberg H. Online group psychotherapy: challenges and possibilities during COVID-19—A practice review. Group Dyn Theory Res Pract. 2020;24(3):201–11.
28. Griffiths F, Lindenmeyer A, Powell J, Lowe P, Thorogood M. Why are health care interventions delivered over the internet? A systematic review of the published literature. J Med Internet Res. 2006;8(2): e10.
29. Eysenbach G. What is e-health? J Med Internet Res. 2001;3(2):E20.
30. Luo X, Gao L, Li J, Lin Y, Zhao J, Li Q. A critical literature review of dyadic web-based interventions to support cancer patients and their caregivers, and directions for future research. Psychooncology. 2020;29(1):38–48.
31. Banbury A, Nancarrow S, Dart J, Gray L, Parkinson L. Telehealth interventions delivering home-based support group videoconferencing: systematic review. J Med Internet Res. 2018;20(2): e25.
32. Li J, Zhang Y, Ding Y, Hu X. The effectiveness of e-Health interventions on caregiver burden, depression, and quality of life in informal caregivers of patients with cancer: a systematic review and meta-analysis of randomized controlled trials. Int J Nurs Stud. 2022;127: 104179.
33. Heynsbergh N, Heckel L, Botti M, et al. Feasibility, useability, and acceptability of technology-based interventions for informal cancer carers: a systematic review. BMC Cancer. 2018;18(1):244.
34. Lamarche J, Grenier J, Lafontaine M-F, et al. Première étape dans l'utilisation de la thérapie par videoconference auprès de survivants du cancer vivant en contexte linguistique minoritaire : une étude pilote. Psychooncologie. 2019;13(3–4):183–90.
35. Wagner LI, Duffecy J, Penedo F, Mohr DC, Cella D. Coping strategies tailored to the management of fear of recurrence and adaptation for E-health delivery: The FoRtitude intervention. Cancer. 2017;123(6):906–10.
36. van den Berg S, Gielissen M, Custers J, van der Graaf W, Ottevanger P, Prins J. BREATH: web-based self-management for psychological adjustment after primary breast cancer—results of a multicenter randomized controlled trial. J Clin Oncol. 2015;33(25):2763–71.
37. Thabane L, Hopewell S, Lancaster GA, Bond CM, et al. Erratum to: methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials. Pilot Feasibil Stud. 2016;2(1):35.
38. Moher D, Hopewell S, Schulz KF, Montori V, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol. 2010;63(8):e1–37.

39. Chan T, J. M., Gøtzsche, P. C., Altman, D. G., & al. SPIRIT,. explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;2013(346): e7586.
40. Lin C-R, Chen S-C, Simard S, Chang JT-C, Lai Y-H. Psychometric testing of the fear of cancer recurrence inventory-caregiver Chinese version in cancer family caregivers in Taiwan. Psychooncology. 2018;27(6):1580–8.
41. Fast J, Duncan K, Dunlop C. Policy brief no. 2-gender differences in family/friend caregiving in Canada. Popul Change Lifecourse Strat Knowl Cluster Research/Policy Brief. 2011;1(2):Article 1.
42. Longacre ML, Ridge JA, Burtness BA, Galloway TJ, Fang CY. Psychological functioning of caregivers for head and neck cancer patients. Oral Oncol. 2012;48(1):18–25.
43. Lebel S, Maheu C, Lefebvre M, Secord S, et al. Addressing fear of cancer recurrence among women with cancer: a feasibility and preliminary outcome study. J Cancer Surviv. 2014;8(3):485–96.
44. Maheu C, Lebel S, Bernstein LJ, Courbasson C, et al. Fear of cancer recurrence therapy (FORT): a randomized controlled trial. Health Psychol. 2023;42(3):182–94.
45. Maheu C, Lebel S, Courbasson C, Lefebvre M, et al. Protocol of a randomized controlled trial of the fear of recurrence therapy (FORT) intervention for women with breast or gynecological cancer. BMC Cancer. 2023;16(289):291.
46. Tomei C, Lebel S, Maheu C, Lefebvre M, Harris C. Examining the preliminary efficacy of an intervention for fear of cancer recurrence in female cancer survivors: a randomized controlled clinical trial pilot study. Support Care Cancer. 2018;26(8):2751–62.
47. Lebel S, Maheu C, Tomei C, et al. Towards the validation of a new, blended theoretical model of fear of cancer recurrence. Psychooncology. 2018;27(11):2594–601.
48. Cameron LD, Leventhal H. The self-regulation of health and illness behavior. The self-regulation of health and illness behavior London: Routledge; 2003.
49. Lee-Jones C, Humphris G, Dixon R, Bebbington Hatcher M. Fear of cancer recurrence—a literature review and proposed cognitive formulation to explain exacerbation of recurrence fears. Psychooncology. 1997;6(2):95–105.
50. Mishel M. Uncertainty in illness. Image J Nurs Sch. 1988;20(4):225–32.
51. Ladouceur R, Dugas MJ, Freeston MH, et al. Efficacy of a cognitive-behavioral treatment for generalized anxiety disorder : evaluation in a controlled clinical trial. J Consult Psychol. 2000;68(6):957–64.
52. Kissane DW, Bloch S, Miach P, et al. Cognitive-existential group therapy for patients with primary breast cancer—techniques and themes. Psychooncology. 1997;6(1):25–33.
53. Kissane DW, Bloch S, Smith GC, et al. Cognitive-existential group psychotherapy for women with primary breast cancer: a randomised controlled trial. Psychooncology. 2003;12(6):532–46.
54. Lamarche J, Cusson A, Nissim R, et al. It's time to address fear of cancer recurrence in family caregivers usability study of a virtual version of the family caregiver fear of recurrence therapy. Front Digit Health 2023 5
55. Orr M, Isaacs J, Godbout R, et al. A usability study of an internet-delivered behavioural intervention tailored for children with residual insomnia symptoms after obstructive sleep apnea treatment. Internet Interv. 2019;18:100265–100265.
56. Badr H, Carmack CL, Diefenbach MA. Psychosocial interventions for patients and caregivers in the age of new communication technologies: opportunities and challenges in cancer care. J Health Commun. 2015;20(3):328–42.
57. Bish A, Sutton S, Jacobs C, et al. Changes in psychological distress after cancer genetic counselling: a comparison of affected and unaffected women. Br J Cancer. 2002;86(1):43–50.
58. Carleton RN, Norton MPJ, Asmundson GJ. Fearing the unknown: a short version of the Intolerance of Uncertainty Scale. J Anxiety Disord. 2007;21(1):105–17.
59. Hagen K, Aas T, Lode K, et al. Illness uncertainty in breast cancer patients: validation of the 5-item short form of the Mishel Uncertainty in Illness Scale. Eur J Oncol Nurs. 2015;19(2):113–9.
60. Pelletier O, Gosselin P, Langlois F, Ladouceur R. Étude des propriétés psychométriques de deux nouveaux instruments évaluant les croyances présentes dans l'hypocondrie auprès d'une population non clinique. L'Encéphale. 2002;28(4):298–309.
61. Sexton KA, Dugas MJ. The Cognitive Avoidance Questionnaire: validation of the English translation. J Anxiety Disord. 2008;22(3):355–70.
62. Manne S, Dougherty J, Veach S, Kless R. Hiding worries from one's spouse: protective buffering among cancer patients and their spouses. Cancer Res Ther and Cont. 1999;8:175–88.
63. Wongpakaran T, Wongpakaran N, Intachote-Sakamoto R, Boripuntakul T. The Group Cohesiveness Scale (GCS) for psychiatric inpatients. Perspect Psychiatr Care. 2013;49(1):58–64.
64. Hatcher RL, Gillaspy JA. Development and validation of a revised short version of the working alliance inventory. Psychother Res. 2006;16(1):12–25.
65. Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res. 2005;15(9):1277–88.
66. Kleinheksel AJ, Rockich-Winston N, Tawfik H, Wyatt TR. Demystifying content analysis. Am J Pharm Educ. 2020;84(1):7113–37.
67. Graneheim UH, Lindgren B-M, Lundman B. Methodological challenges in qualitative content analysis: A discussion paper. Nurse Edu Today. 2017;56:29–34.
68. Polit D, Beck C. Nursing research : generating and assessing evidence for nursing practice. 10th ed. Philadelphia: Wolters Kluwer; 2017.
69. Miles MB, Huberman AM. Qualitative data analysis: an expanded sourcebook. 2nd ed. Thousand Oaks: Sage Publications; 1994.
70. Bowleg L. The problem with the phrase women and minorities: intersectionality—an important theoretical framework for public health. Am J Public Health. 2012;102(7):1267–73.

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