Original Article

A Multi-step Approach to Adapting a Mind-Body Resiliency Intervention for Fear of Cancer Recurrence and Uncertainty in Survivorship (IN FOCUS)

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Abstract

Background: For cancer survivors, there is a paucity of fear of recurrence (FOR) interventions that integrate empirically supported mind-body and psychological skills for managing FOR and are delivered in scalable formats.
Objective: To adapt an evidence-based resiliency intervention to address FOR among cancer survivors.
Methods: A multidisciplinary team of researchers, clinicians, and patient stakeholders followed an iterative intervention adaptation process (ORBIT). In Step 1, we sought to define key FOR management skills through a literature review and feedback from stakeholders. In Step 2, we integrated findings into a treatment manual and refined procedures for in-person delivery to groups of cancer survivors, defined as adults who had completed primary cancer treatment for non-metastatic cancer. In Step 3, we conducted a single arm trial to assess initial acceptability and change in FOR severity with 23 cancer survivors (N=4 intervention groups). In Step 4, we conducted additional qualitative interviews with 28 cancer survivors (N=6 focus groups stratified by FOR severity, N=15 individual interviews) to define adaptive and maladaptive strategies for coping with FOR and to identify preferences for delivery. In Step 5, we refined the treatment manual and procedures for testing in a future pilot randomized feasibility trial.
Results: We identified critical feedback using a combination of qualitative and quantitative methods. The single arm trial suggested preliminary feasibility and sustained reductions in FOR severity, yet need for refinement (i.e., eligibility, delivery modality), prompting additional qualitative interviews for further targeting. The resulting intervention (IN FOCUS) is comprised of virtual, synchronous, group-delivered sessions that offer an integrated approach to FOR management by teaching cognitive-behavioral techniques, meditation, relaxation training, adaptive health behaviors, and positive psychology skills. Sessions are targeted by applying skills to FOR and associated healthcare engagement.
Conclusions: IN FOCUS is a targeted intervention for teaching mind-body resiliency skills to groups of cancer survivors with elevated FOR. Next steps are testing feasibility in a pilot randomized trial.

Keywords

cancer, survivorship, fear of recurrence, mind-body, intervention adaptation, qualitative methods

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Background

For cancer survivors diagnosed with non-metastatic cancer, life after completing cancer treatment is characterized by uncertainty and self-monitoring. Many survivors are faced with the task of managing ongoing somatic concerns and emotional challenges largely on their own.[1] As many as two-thirds of cancer survivors live with fear of recurrence (FOR), a staggering figure considering the growing prevalence of cancer survivors worldwide.[2-5] Observational studies have concluded that FOR accounts for up to 44% of distress in cancer survivors,[6-8] and that FOR severity is independent of cancer site or time since completing treatment.[9-17] FOR can be multidimensional, resulting in symptoms of anxiety, depression, excessive rumination, cognitive biases, functional impairment, and the adoption of negative health behaviors.[2,18,19] Worrying about one's future risk of cancer recurrence may also affect how survivors engage in their healthcare, potentially resulting in delayed diagnoses, unnecessary or ineffective treatments, and ultimately higher rates of morbidity and mortality, as well as greater costs.[3,20-23] If left untreated, FOR can persist for years after treatment ends, and survivors are often ill-equipped to manage their elevated stress and uncertainty.[9-11,13]

There is a need for evidence-based treatments for FOR that address the multidimensional nature of FOR in cancer through teaching multiple skills. Mind-body practices, defined as practices focused on the interactions between the brain, mind, body, and behavior, offer a holistic approach to addressing fear-related cognitions, emotions, behaviors, and physiological responses.[8,24] Two recent systematic reviews and meta-analyses of RCTs testing psychological and mind-body interventions for FOR found similar conclusions: collective effects were statistically significant, yet small-to-moderate, suggesting the need for further intervention development.[25,26] Notably, similar effects were demonstrated by interventions teaching cognitive-behavioral techniques (e.g., cognitive reframing appraisals about the future, modifying behaviors that perpetuate anxiety), meditation (seated and movement-based), relaxation training, or positive psychology practices.[25,26] Although relatively few trials have tested relaxation and positive psychology techniques, these techniques are especially important to study given the high demand for mind-body interventions among cancer survivors [27,28] and particularly among survivors with elevated FOR.[25,27] Mind-body interventions may thus represent an acceptable set of treatments for FOR, with some emerging evidence of their benefits on reducing fear, although further research is needed to develop targeted multimodal interventions. Furthermore, most existing FOR interventions have been developed and tested with homogenous samples of survivors that have been treated for a single cancer site (e.g., breast),[25,26] which limits generalizability to survivors of other non-metastatic cancers who experience FOR at similar levels.[1-3,6,16] Collectively, an integrated intervention comprised of a combination of empirically supported FOR management skills (i.e., cognitive-behavioral techniques, meditation, relaxation, and positive psychology) may be appealing to survivors of various cancers and yield higher effects on reducing FOR than existing FOR interventions that only teach these skills in isolation.

A treatment framework well-suited for adaptations for managing FOR is the Stress Management and Resiliency Training—Relaxation Response Resiliency Program (SMART-3RP).[29] SMART-3RP is an evidence-based, multimodal mind-body program that was designed to promote stress coping and resilience. It is rooted in eliciting the relaxation response (RR), which has well-established positive implications on physiological, psychological, and functional health outcomes.[30-32] The SMART-3RP is traditionally delivered as an 8-week in-person program with 90-minute weekly sessions. In each session, patients learn to incorporate RR elicitation practices, cognitive-behavioral techniques, and growth enhancement strategies. This intervention has been successfully adapted and employed to reduce stress in a number of diverse populations, such as patients with monoclonal gammopathy of undetermined significance and multiple myeloma, palliative care clinicians, and women coping with infertility.[29,33,34] The SMART-3RP provides participants with multiple options and educational materials to promote an adaptive response to stress management. Although the SMART-3RP has been delivered to cancer survivors in clinical settings, the intervention content and procedures have not been specifically targeted to address fears and worry about cancer recurring.

Stakeholder feedback using qualitative methods is critical when designing acceptable and feasible FOR interventions.[35] For instance, survivors with elevated FOR could shed light on coping strategies and behaviors that are not effective or potentially maladaptive (e.g., avoidance of follow-up cancer screening). Similarly, survivors with non-elevated FOR could provide insight on successful coping strategies and behaviors that are helpful and adaptive when they experience uncertainty about cancer recurrence. Feedback from oncologists and other clinicians treating cancer survivors could be used to refine screening and recruitment procedures and identify suitable content on adaptive healthcare engagement. Taken together, a FOR intervention developed by integrating these stakeholder perspectives could address limitations of currently available FOR interventions and optimize the adaptation of an existing intervention (i.e., SMART-3RP) to target FOR. Guided by an established treatment adaptation framework,[36] this paper describes the systematic, stepwise approach taken to adapt a multimodal, mind-body resiliency program to address FOR.

Methods

Overview: Steps 1 through 5. Our stepwise approach followed the ORBIT model, a systematic framework for developing behavioral treatments for preventing and treating chronic diseases developed by the National Institutes of Health Office of Behavioral and Social Sciences Research,

which allows for iterative refinement of behavioral interventions guided by feedback obtained at each step.[36] Given the need for adaptation, we chose the ORBIT framework[37] versus other intervention frameworks that include relatively less guidance on adaptation and greater emphasis on steps to evaluate effectiveness and implementation of efficacious interventions (e.g., NIH Stage Model for Behavioral Intervention Development). (Table 1)

All procedures were approved by the local institutional review boards. All cancer survivors provided written informed consent before participating in the steps detailed below. Survivors in Step 3 were compensated up to $100 for completing all assessments including exit interviews and up to $40 for travel-related costs to sessions. In Step 4, survivors were compensated $30 for participating in a focus group and an additional $25 for completing an individual interview. Parking vouchers were offered for those attending in-person.

Step 1: Data Collection (ORBIT Phase Ia: Define). We began by reviewing the literature for examples and strategies of skills used by cancer survivors for coping with FOR.[25] Guided by our findings and our team's clinical expertise in psycho-oncology, potential FOR-specific modifications to the treatment manual were identified. We then collected feedback from a series of expert panels. First, we presented the proposed changes to a panel of SMART-3RP clinicians and investigators at the Massachusetts General Hospital (MGH) Benson-Henry Institute for Mind Body Medicine. They reviewed our proposed changes to ensure the targeted content was consistent with the general principles and structure of the core SMART-3RP intervention. Next, we presented our modifications to oncologists and cancer clinicians in the MGH Cancer Survivorship Program to solicit feedback about targeting the core SMART-3RP health behavior content to cancer survivors who have completed treatments for early stage (i.e., non-metastatic) cancer. Finally, we held a panel with Beth Israel Deaconess Medical Center oncologists and cancer clinicians for feedback on the feasibility of our proposed intervention and recruitment plans. A feedback form was administered to these same providers to elicit constructive feedback on the proposed intervention.

Step 2: Integration (ORBIT Phase Ib: Refine). Utilizing the findings from Step 1, the study investigators refined the SMART-3RP intervention content and procedures to target cancer survivors with elevated FOR. The original SMART-3RP manual was integrated with the specific modifications identified in the data collection phase, resulting in the initial adaptation of the treatment manual (see Table 2).

Step 3: Single Arm Trial (ORBIT Phase IIa: Proof of Concept). After finalizing the first iteration of the adapted intervention, we conducted a proof of concept pilot study with 4 groups among a sample of 23 cancer survivors who had completed primary cancer treatment (Clinical Trials # NCT03695406). The procedures and primary results from this pilot study have been previously reported.[38] In this initial testing of the adapted intervention content and procedures, survivors were offered the program over 8 weekly sessions (90 minutes per session) in-person at Beth Israel Deaconess Medical Center. Survivors completed a validated FOR severity measure (Fear of Cancer Recurrence Inventory-Severity subscale; elevated FOR ≥16)[18,39] at 4 assessments (baseline, post-intervention, 1 month follow-up, 3 month follow-up) and acceptability ratings after each session. Survivors also completed individual exit interviews with an independent assessor using a semi-structured interview guide that were recorded, transcribed, and evaluated using thematic content analysis. Rather than review our previously reported methods and results,[38] we highlight adaptation benchmarks and lessons learned.

Step 4: Stratified Focus Groups and Individual Interviews (ORBIT Phase Ia: Define). In line with the ORBIT model's emphasis on flexibility and optimization, we continued to systematically obtain feedback from cancer survivors on our adapted intervention, in order to define areas for further adaptation. Pilot study exit interviews had highlighted the importance of learning from survivors with elevated FOR as well as survivors with non-elevated FOR to explicate helpful coping skills, needs, and protective factors.

To delineate the needs of cancer survivors with FOR, and learn from those without FOR, the Fear of Cancer Recurrence Inventory-Severity subscale[18,39] was used to stratify cancer survivors into groups with elevated FOR (score ≥16) and groups with non-elevated FOR. An initial cohort of 6 focus groups (3–8 survivors per group) included survivors of non-metastatic solid or blood malignancies who had completed primary cancer treatment: 3 groups with elevated FOR and 3 groups with non-elevated FOR. Focus groups were approximately 60 minutes each. Survivors of all cancer sites (e.g., colon) were invited to participate, and eligibility was not restricted by time since treatment completion. A purposive sampling technique was used to ensure that survivors of multiple cancers were represented and consulted.[40] Survivors had their choice of attending an in-person focus group or 1 held remotely via secure video conferencing technology.

Focus groups were led by a member of the study team (DH) using a semi-structured interview guide with open-ended questions and response probes. Survivors were asked about their experiences managing FOR and coping with cancer-related uncertainty (i.e., *"Currently, if you ever worry about getting cancer again, what helps you to worry less?"*; "*Would anyone be willing to share something they do to try and stop worrying that may be more harmful than helpful?"*) and their experiences engaging in healthcare (i.e., *"After completing your treatment, what are reasons why you have contacted your oncologist?"*; "*In terms of scheduling medical visits and tests, what advice do you have for cancer survivors who feel very afraid about the possibility of getting cancer again?"*).[41] Focus groups were audio recorded and

Table 1. Overview of Sequential Intervention Adaptation Process.

Step	Description	Resulting Takeaways
Step 1: Data Collection (ORBIT Phase Ia: Define)	- Examined literature on FOR interventions - Convened experts in (a) the SMART-3RP intervention, (b) cancer survivorship, and (c) clinician stakeholders at recruitment site	- *Identified* skills to address FOR (Hall et al., 2018) - *Mapped* FOR skills onto SMART-3RP treatment manual - *Identified* NCCN Survivorship Health Behavior Guidelines to target health behavior content to cancer survivors - *Defined* eligibility for Step 3 (e.g., survivors 3-30 months post-treatment)
Step 2: Integration (ORBIT Phase Ib: Refine)	- Synthesized findings from Step 1 into initial adaptation of treatment manual	- *Refined* content of treatment manual to target FOR - *Refined* procedures for single arm trial (e.g., in-person delivery)
	- 23 survivors participated in the in-person intervention (4 cohorts of 3-8 survivors)	- *Tested* proof of concept pilot (Hall et al., 2020)
	- Assessed acceptability after each session and patient-reported outcomes at baseline, post-intervention, +1 month, and +3 months	- Preliminary acceptability: 87% of post-session ratings were "High" or "Very High" in enjoyability
	- Exit interviews assessed survivors' feedback about multimodal nature of intervention	- Preliminary feasibility: 96% retention baseline to 3-month follow-up; 77% session attendance, feasibility of skills practice (16% at baseline, 76% post-intervention) - Reductions in FOR post-intervention (d = 0.87) and 3-month follow-up - *Identified* areas for further refinement: - Eligibility: Expand to include long-term survivors and restrict to elevated FOR. *Chief reason for ineligibility was cap on time since treatment; Limited benefits for survivors with low FOR at baseline.* - Content: For all skill modalities, provide guidance on when to apply techniques when engaging in healthcare. *Strong preference for learning a variety of skills; Desired tips for applying skills before, during, and after healthcare visits and cancer testing.* - Delivery: Offer remote, group sessions. *Strong preference for group delivery. Chief reasons for eligible survivors not enrolling were distance and time constraints. Chief reasons for missed sessions were late effects of treatments and travel logistics for attending in-person.*
Step 4: Stratified Focus Groups and Individual Interviews (ORBIT Phase Ia: Define)	- 28 survivors participated in focus groups to identify FOR-related coping skills and healthcare engagement (3 focus groups w/ elevated FOR, 3 focus groups w/ non-elevated FOR)	- *Identified* maladaptive coping skills and maladaptive healthcare engagement skills from elevated FOR groups
	- Survivors with elevated FOR (n = 15) were interviewed individually to identify preferences for intervention delivery	- *Identified* adaptive coping skills and adaptive healthcare engagement skills from non-elevated FOR groups
	- *Identified* adaptive coping skills and adaptive healthcare engagement skills from non-elevated FOR groups	- *Refined* treatment model to integrate themes about tolerance of uncertainty, coping skills, and healthcare engagement
	- *Refined* treatment model to integrate themes about tolerance of uncertainty, coping skills, and healthcare engagement	- *Identified* willingness and preferences for synchronous virtual delivery
	- *Identified* willingness and preferences for synchronous virtual delivery	- *Integrated* tips for adaptive healthcare engagement into content

(continued)

Table 1. (continued)

Step	Description	Resulting Takeaways
Step 5: Finalized Treatment Manual (ORBIT Phase Ib: Refine)	- Adapted content of existing treatment manual based on Step 4 - Finalized treatment manual - Planned pilot feasibility RCT (ORBIT Phase IIb: Pilot)	- *Optimized* treatment manual and procedures for synchronous virtual delivery

transcripts underwent directed content analysis by 2 primary coders (DH, HM) and a third coder (EP) who reviewed discrepancies. Codes were developed using by a hybrid approach, combining inductive and deductive coding, in order to capture overarching themes.[42] Deductive coding was guided by constructs in the SMART-3RP resiliency model[43] and Uncertainty in Illness Theory.[44] Emergent themes were added inductively, which were then crystalized into final themes and exemplary quotes that were reviewed for consensus with the investigative team. NVivo 12 software[45] was used to guide iterative refinement of codes until reaching acceptable inter-rater reliability (Kappa index ≥.80). Thematic saturation was determined by consensus among coders (DH, HM, EP) after conducting the initial 6 focus groups, and no additional focus groups were scheduled.

Upon enrollment in focus groups, survivors with elevated FOR were also invited to participate in individual interviews (approximately 30 minutes) either in-person or via remote videoconferencing at their discretion. Survivors were presented with an overview of the proposed session-by-session content (Table 2), then asked about their preferences for mind-body intervention delivery (e.g., in-person vs remote, considerations for optimizing synchronous delivery). Interviews were audio recorded, and transcripts underwent directed content analysis by tabulating frequencies of responses to yes/no questions about virtual delivery and by summarizing considerations for synchronous delivery.

Step 5: Finalized Treatment Manual (ORBIT Phase Ib: Refine). Findings from the focus groups and individual interviews in Steps 4 and 5 informed final adaptation of treatment manual content and delivery medium, in preparation for a future randomized feasibility trial (ORBIT Phase IIb: Pilot).

Results

Step 1: (ORBIT Phase Ia: Define) and Step 2 (ORBIT Phase Ib: Refine).

Adaptations to the content of the treatment manual are summarized in Table 2. After defining skills to address FOR, the main refinements to the SMART-3RP treatment manual consisted of adding new content and modifying examples to target FOR.

Clinicians who deliver the SMART-3RP as a clinical service confirmed that the proposed adaptations were consistent with the spirit and structure of the core SMART-3RP intervention. Recognizing that learning skills for attending to the present moment (i.e., mindfulness meditation) can be challenging for survivors with high levels of anxiety, they suggested adding scheduled worry time practice[46] to Session 3 for minimizing interference from rumination about the past or future. Additionally, incorporating gratitude journaling as a positive psychology skill for managing FOR[47,48] was suggested as a between-session exercise.

Clinicians in the MGH Cancer Center Survivorship Program suggested aligning the health behavior information with the National Comprehensive Cancer Network Cancer (NCCN) survivorship lifestyle behavior guidelines[49] for the health behaviors in the core SMART-3RP (i.e., sleep, physical activity, nutrition). They also suggested making an explicit connection between FOR and changes in health behaviors.

Beth Israel Deaconess Medical Center oncologists and cancer clinicians confirmed that the study procedures were feasible and suggested an onsite location for holding the groups. They also suggested restricting the eligibility criteria for the single arm pilot trial to cancer survivors within 3–30 months post-treatment, as they considered this time window to represent a vulnerable transition period in which survivors are re-integrating into their roles and may be most likely to benefit from a skills-based program. Providers welcomed the idea of a group-based support setting and believed that patients would benefit from exposure to a variety of empirically supported skills to manage FOR.

Step 3: (ORBIT Phase IIa: Proof of Concept).

We conducted a proof of concept trial with 23 cancer survivors and observed moderate-to-large, within-subjects changes in FOR severity from baseline to post-intervention (d = .87), sustained at 3-month follow-up.[38] On average, FOR severity scores fell from the elevated range (16 or higher) to non-elevated levels (15 or lower) across the trial assessments. At baseline, FOR severity scores were on average elevated ($M = 19.4$, $SD = 7.0$), reduced to non-elevated by post-intervention ($M = 15.0$, $SD = 5.7$), and were sustained 1 month ($M = 15.0$, $SD = 5.7$) and 3 months later ($M = 15.0$, $SD = 5.7$).[38] At baseline, 70% of survivors (16/23) had elevated FOR. By post-intervention, this prevalence was cut in half (36%; 8/22), a reduction that was sustained at the 3-month follow-up.

Although a priori feasibility and acceptability benchmarks were met,[38] and themes from exit interviews revealed

Table 2. Summary of Adapted Session Content.

Smart-3RP Content	Adapted Content Targeting FOR
Session 1: Stress Management and Resiliency Training The science of mind-body medicine, breath awareness, single-pointed meditation, energy battery	•*Targeted* opening quotes to managing uncertainty[a] •*Added* information about cancer-related uncertainty, FOR, and healthcare engagement as they relate to stress and resiliency in cancer survivorship •*Targeted* relaxation practice (i.e., preface encouraging survivors to make adjustments as needed to accommodate late effects of cancer treatments, discussion question about applying relaxation practice before, during, or after a healthcare visit)[a] •*Targeted* energy battery to FOR and healthcare engagement behaviors
Session 2: Relaxation Response (RR) Body scan, sleep hygiene, stress signals, MINI RR, autogenic feedback	•*Added* information about FOR and cancer-related insomnia •*Incorporated* NCCN Survivorship guidelines for sleep •*Targeted* "stress signals" exercise to "Signs of FOR and stress" •*Condensed* between-session practice (e.g., removed biodot activity)
Session 3: Stress Awareness Mindfulness, mindful eating, identifying positive emotions and sensations, social support	•*Targeted* mindfulness to FOR and certainty of present experiences •*Added* "worry time" to limit interference of rumination on daily activities and to reduce fear avoidance •*Targeted* positive emotions/sensations exercise to identify changes before vs. after cancer treatment •*Targeted* social support needs to cancer survivorship (e.g., cancer-related information, insurance)
Session 4: Mending Mind and Body Yoga, automatic thoughts, cognitive distortions, walking meditation	•*Targeted* rationale for applying meditative movement to manage FOR (i.e., certainty of present experience, nonjudgment of change moment-to-moment) •*Targeted* examples of negative automatic thoughts to FOR
Session 5: Creating an Adaptive Perspective Guided imagery, coping log, adaptive perspectives, acceptance, nutrition, stop breathe reflect and choose	•*Targeted* guided imagery exercise to FOR •*Incorporated* NCCN Survivorship guidelines for nutrition •*Targeted* adaptive perspectives and acceptance strategies to FOR (e.g., self-compassion, patience, acceptance about survivorship involving tolerating uncertainty) •*Condensed* by moving Stop, Breath, Reflect, and Choose to between-session practice
Session 6: Promoting Positivity Contemplation, physical activity, optimism, relaxation signals, good bad and routine, gratitude letter	•*Added* information about FOR and physical activity •*Incorporated* NCCN Survivorship guidelines for physical activity •*Targeted* optimism exercise to FOR •*Added* gratitude letter to experiences with cancer survivorship
Session 7: Healing States of Mind Loving kindness, problem-solving vs. acceptance, root fear, creativity, empathy	•*Targeted* loving kindness exercise to self-compassion when feeling afraid of cancer recurrence •*Condensed* acceptance vs. problem-solving •*Added* worksheet on managing controllable vs. uncontrollable cancer-related uncertainties •*Targeted* root fear exercise to cancer-related fear •*Targeted* creative expression to expressing FOR creatively
Session 8: Humor, Empathy and Staying Resilient Idealized self, humor, energy battery part 2, staying resilient	•*Targeted* education about humor as a tool for coping with FOR •*Targeted* review of skills to include plans to apply skills before, during, and after healthcare visits

Note: Sessions are delivered weekly and last approximately 90 minutes each.
[a]Applied throughout Sessions 1-8.

behavioral, cognitive, emotional, and existential benefits,[38] we identified the need for further refinement with respect to eligibility, content, and delivery format, as summarized below.

(1) Eligibility. We learned to expand eligibility to include long-term cancer survivors and to restrict eligibility to cancer survivors with elevated FOR. The chief reason for ineligibility among those screened was having completed cancer treatments longer than 30 months before the intervention (19/25 = 76%). Given previous research demonstrating that FOR severity is independent of time since treatment,[9-17] and the high interest in our program among long-term survivors,

we learned it would be prudent to expand eligibility to include long-term survivors. Additionally, sensitivity analyses of within-subjects changes in FOR severity revealed that survivors with non-elevated levels at baseline were less likely to benefit, suggesting the need for restricting eligibility to survivors with elevated FOR.[38]

(2) Content. When asked about aspects of the intervention that were most helpful, survivors most often described the diversity and range in coping skills provided (21/22 survivors). Survivors explained this was helpful because sessions increased their exposure to a variety of mind-body practices. The skills most commonly identified as helpful included relaxation and meditation training, identifying and reframing negative automatic thoughts, scheduled worry time, visualization and imagery, practicing gratitude and appreciations, and learning adaptive health behaviors. When asked how content in the program could be more helpful, survivors suggested including discussion about how relaxation skills could be applied before, during, or after cancer-related visits, such as setting a reminder to practice visual imagery the morning of a mammogram.

(3) Delivery. Overall attendance was high, and most survivors (74%) attended at least 75% (6/8) of sessions. Retention was also high across study assessments, with 96% of survivors completing surveys at baseline, post-intervention, 1 month follow-up, and 3-month follow-up.[38] The chief reasons why eligible survivors declined to enroll were distance and time constraints (71%), as the program required survivors to travel to in-person sessions. Among those enrolled, 3 survivors (13%) attended just 2 out of 8 sessions. When asked about reasons for missed sessions, they cited difficulty traveling to sessions due to medical or psychiatric comorbidities, including pain, fatigue, and episodic depression. Exit interviews identified a preference that future versions of the program be designed to minimize travel and allow access from home. Traffic, parking, and session start times were the most common examples provided when asked about any aspect of the program that was inconvenient. Collectively, this feedback suggested that a remotely delivered program might be an appealing delivery modality for enhancing access to cancer survivors experiencing FOR, among whom lasting late effects of cancer treatments may be present. Finally, when asked whether they would have preferred an individual format (versus group), nearly all survivors preferred group, citing the ability to learn from peers while developing a peer support network.

Step 4: (ORBIT Phase Ia: Define).

Twenty-eight cancer survivors participated in 1 of 6 focus groups (3–8 survivors per group). Three focus groups were comprised of survivors with elevated FOR (15 survivors), and 3 groups were held with survivors with non-elevated FOR (13 survivors). Table 3 presents survivors' demographic information, clinical characteristics, and treatment history. Similar to the sample recruited for Step 3, the sample in Step 4 had been treated for a variety of non-metastatic cancers and had completed cancer treatments at least 3 months prior to the start of the intervention. In contrast to Step 3, the Step 4 sample also included long-term survivors, who were on average 3.6 years since treatment completion (range = 3 months–21 years).

Focus Groups. When asked about their experiences managing FOR, coping with cancer-related uncertainty, and accessing healthcare after treatment completion, survivors identified a number of themes and subthemes under the following domains: Relaxation Response Elicitation, Stress Awareness and Cognitive-Behavioral Techniques, Adaptive Strategies, and Healthcare Engagement. Domains, themes, definitions, and exemplary quotes appear in Supplementary Table 1. The final inter-rater reliability of themes was high (Kappa index = .88).

(1) Relaxation Response Elicitation. Survivors with non-elevated FOR told us that when they feel worried or uncertain about their cancer recurring, they find it helpful to use mind-body practices to elicit relaxation. Similarly, survivors with elevated FOR voiced an interest in learning strategies to relax when they feel worried or uncertain about cancer recurring. Survivors in both the clinical and non-clinical FOR groups highlighted using breathing techniques, massage, and various types of meditation (imagery, mantra/personal prayer, meditative movement, mindfulness) as ways to induce relaxation.

(2) Stress Awareness and Cognitive-Behavioral Techniques. When asked about identifying stressors and how to address unhelpful thought patterns, survivors shared a number of cognitive techniques that they had used successfully. First, survivors found that it was important to identify signs and triggers of the stress response (i.e., an unexpected bruise, somatic pain) in order to prevent it from exacerbating stress. Often, they noted, stress was intimiately tied to FOR. Survivors voiced a need for determining aspects of stressors that could be controlled (e.g., making plans for follow-up care) to promote stress awareness. Survivors discussed using the following techniques to help cope with stress: appreciating the small things in life, focusing on the present, and shifting their attention. To shift unwanted thought patterns, survivors felt it was helpful to re-appraise negative assumptions about their future health and to consider uncertainty as something to be tolerated, rather than avoided, especially with regard to engaging in healthcare.

Table 3. Characteristics of Participants in Step 3 Single Arm Pilot Study and Step 4 Stratified Focus Groups and Individual Interviews.

	Step 3 (N = 23)	Step 4 (N = 28)
	N (%)/Mean (Range)	
Age (years)	61.0 (35-88)	53.1 (23-74)
Gender (female)	20 (86.9%)	20 (71.4%)
Race		
Asian	0 (0%)	2 (7.1%)
African American	2 (8.7%)	1 (3.6%)
Multiracial	1 (4.3%)	0 (0%)
White	20 (86.9%)	24 (85.7%)
Ethnicity (Hispanic)	0 (0%)	1 (3.6%)
Cancer site		
Blood/hematologic malignancy	1 (4.3%)	10 (35.7%)
Breast	9 (39.1%)	9 (32.1%)
Colon/gastric	9 (39.1%)	5 (17.9%)
Gynecological	3 (13.0%)	4 (14.3%)
Prostate	0 (0%)	1 (3.6%)
Kidney	0 (0%)	1 (3.6%)
Lung	2 (8.7%)	1 (3.6%)
Melanoma	1 (4.3%)	1 (3.6%)
Retinoblastoma	0 (0%)	1 (3.6%)
Sinus tumor	0 (0%)	1 (3.6%)
Thyroid	0 (0%)	1 (3.6%)
Time since treatment (months)	12.3 (3-30)	43.7 (3-252)
Cancer treatment history		
Chemotherapy	18 (78.3%)	18 (64.3%)
Radioactive iodine	8 (34.8%)	1 (3.6%)
Stem cell transplant	0 (0%)	1 (3.6%)
Surgery	22 (95.6%)	20 (71.4%)

[a]Survivors could have received treatment for more than 1 cancer.

(3) Adaptive Strategies. Survivors mentioned a number of adaptive strategies they use to help cope with stress and worries surrounding cancer recurrence. Distraction and staying busy through various activities (i.e., watching movies) and/or obligations (work, childcare) were noted as stress coping strategies. Certain health behaviors such as focusing on nutrition (i.e., following a healthy diet pattern, avoiding alcohol) and engaging in physical activity were found to be helpful. Maintaining a positive perspective was another adaptive strategy discussed in the focus groups, which was achieved through acceptance of one's cancer diagnosis, gratitude for one's medical care, creative practice, humor, and/or engaging in self-care/pleasant activities. Survivors also noted the importance of social connectedness, including engaging in prosocial behaviors (i.e., volunteering, giving advice to others going through cancer treatment) and enhancing one's social support network to promote adaptive stress coping.

(4) Healthcare Engagement. When asked about how FOR influences their healthcare engagement (i.e., means of interaction with the healthcare system, one's healthcare team, and/or health-related information), survivors described engagement that occurred within a healthcare system (i.e., communicating with one's oncologist, asking questions at appointments) and outside of a healthcare system (i.e., consulting WebMD). The same trend appeared when discussing cancer-specific supportive services; survivors noted accessing these services both inside (i.e., cancer-center sponsored support groups, programs) and outside (i.e., community groups and organizations) of the healthcare system. In terms of scheduling follow-up care, survivors described feeling grateful for their health insurance (e.g., "*I'm very fortunate that my wife has good insurance*"), yet they also noted that navigating the complexities of insurance (e.g., speaking to insurers, determining coverage) can often generate uncertainty and worry about potential financial impacts of cancer recurrence. Finally, the importance of self-advocacy, including getting second opinions to "make sure that you're heard," was also identified by survivors in both groups as a way to gain a sense of control of FOR.

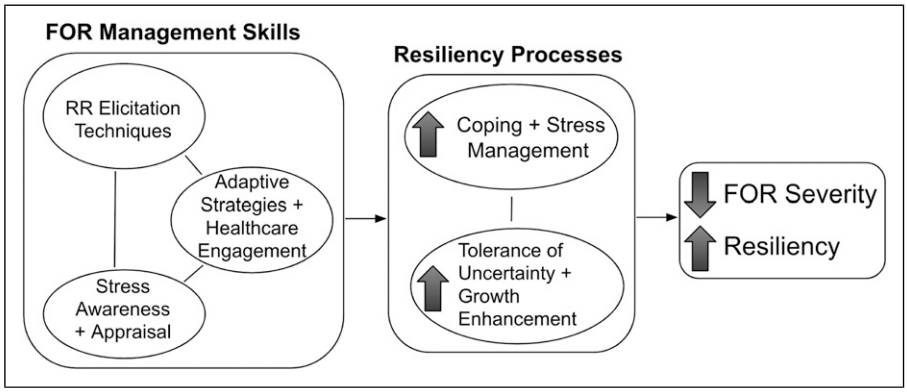

Figure 1. Integrated FOR treatment model adapted from the SMART-3RP model.

To synthesize the integration of core SMART-3RP material with content specific to FOR, we finalized an integrated treatment model (Figure 1). The model was informed by the original SMART-3RP theoretical model[30] and findings from Steps 1–5. As depicted in Figure 1, FOR management skills (i.e., RR Elicitation Techniques, Stress Awareness and Appraisal, and Adaptive Strategies and Healthcare Engagement) can allow survivors to both reduce the severity of FOR and increase their Resiliency. Coping and Stress Management allow survivors to reduce maladaptive and distressing thoughts, emotions, and behaviors associated with FOR. In addition, Tolerance of Uncertainty and Growth Enhancement skills improve the ability of survivors to perceive the future as less threatening and build their capacity for positive and prosocial emotions and behaviors.

Individual Interviews. Fifteen survivors with clinically elevated FOR who participated in focus groups also participated in individual interviews with the study team. After being presented with an overview of the proposed intervention content, 15/15 survivors found the program to be acceptable and relevant to their concerns. When asked to provide feedback on delivery modality, most survivors (12/15) said they were willing to attend a program like this if it were delivered remotely using synchronous, virtual sessions (e.g., live videoconferencing). Nearly half (7/15) said they would prefer remote delivery to in-person, noting that remote delivery would be more convenient and remove unforeseen barriers to attending sessions on time (i.e., weather, traffic) compared to participating in-person. In contrast, in-person programs were appealing to some survivors because they promoted a sense of connectedness that, they indicated, could be more difficult to achieve through a screen. Multiple strategies were identified for enhancing rapport and group cohesion during synchronous, virtual sessions (e.g., minimizing screen sharing during group discussions, establishing ground rules for muting microphones during relaxation exercises).

Step 5: (ORBIT Phase Ib: Refine).

Informed by the qualitative findings in Step 4, we updated the treatment manual content to integrate content on adaptive healthcare engagement (e.g., education about FOR and healthcare seeking vs avoidance; tips to applying mind-body skills before, during, and after oncology visits and tests). Guided by feedback from clinician stakeholders in the MGH Cancer Survivorship Program, the intervention was named INtervention for Fear of Cancer recurrence and Uncertainty in Survivorship (IN FOCUS). Additionally, we finalized plans for synchronous virtual delivery (e.g., selection of platform, refining electronic handouts to include large fonts, finalizing guidelines for group members) for testing in a future randomized feasibility pilot trial (ORBIT Phase IIb: Pilot).

Discussion

As the prevalence of cancer survivorship continues to increase worldwide, there is growing consensus about the need for accessible, evidence-based FOR interventions. We have developed a novel, synchronous group-based FOR intervention for survivors of various non-metastatic cancers who have completed cancer treatment that can be delivered remotely, incorporates a multitude of empirically supported skills, and addresses several limitations of existing group-delivered FOR interventions. Guided by an established framework for iteratively identifying, integrating, pilot-testing, and optimizing adaptations to intervention content and delivery (ORBIT),[36] the adapted intervention includes mind-body resiliency skills targeted to FOR and its behavioral consequences (e.g., healthcare engagement) and is now ready to be tested in a randomized feasibility trial.

Our approach was strengthened by applying qualitative (focus groups and individual interviews) and experimental (proof of concept single arm trial) methods, triangulating feedback from multiple stakeholders (survivors with elevated and non-elevated FOR, oncologists, cancer clinicians, mind-body clinicians), and an evidence-based resiliency model (i.e., SMART-3RP) as the basis for the adapted FOR intervention. By incorporating feedback from stakeholders across

multiple levels (e.g., patients, clinicians, and clinical investigators), our findings have resulted in a refined FOR intervention model, intervention manual, and delivery plans.

Although the initial face-to-face version of program we tested met a priori benchmarks of acceptability and feasibility (i.e., Step 3),[38] we identified several areas that required further adaptation through additional steps (i.e., Steps 4 and 5). Through focus groups, we learned that FOR management is appealing to survivors who completed treatment recently (i.e., 3 months ago) as well as those with a distal treatment history (i.e., up to 20 years ago). This finding suggests the acceptability and potential reach of our intervention to a broad spectrum of survivors who have completed treatment. However, we acknowledge that cancer survivorship also includes patients who are undergoing active treatment or who are living with metastatic disease; these subgroups have unique psychological needs that may require additional considerations before participating in this program.[1] Exit interviews from our first pilot study identified a need to add content on applying mind-body practices before, during, and after healthcare visits. Our focus groups with cancer survivors with non-elevated FOR suggest this modification may help survivors tolerate uncertainty about cancer recurrence and to engage in healthcare more adaptively (i.e., attending routine cancer testing). Finally, survivors voiced a preference for a delivery modality that maximizes the social connectedness of an in-person, group-based program, citing benefits from peer support and reinforcement of new skills, yet is also accessible, a consideration that was especially important for survivors with comorbid psychological and/or medical concerns. Recognizing that delivering mind-body skills in-person is not feasible for many cancer survivors, particularly since the start of the COVID-19 pandemic, it is possible that survivors' willingness to participate in remotely delivered, synchronous sessions has increased.[50] In light of these considerations, and recent evidence that remotely delivered FOR interventions are appealing and efficacious,[51] the final program is open to short term and long-term survivors of non-metastatic cancer, includes healthcare engagement content, and has been adapted for delivery in virtual, synchronous group sessions.

Our findings also suggest that optimal FOR management likely requires a multitude of topics and skills, teaching not only cognitive-behavioral techniques, but also training in meditation (seated and movement-based), the relaxation response, adaptive health behaviors (including NCCN Survivorship guidelines for optimal sleep, nutrition, and physical activity), and positive psychology skills to foster gratitude and self-compassion. Research by our group and others has demonstrated the promise of resiliency interventions that integrate these practices into a cohesive intervention for addressing other survivorship populations.[38,43,52] Randomized trials are needed to confirm whether cancer survivors with elevated FOR find this integrated approach to be appealing and associated with clinically-meaningful benefits. Optimization designs such as multiphase optimization strategy[53] are complementary with the ORBIT framework and could be used to explicate the efficacy of various combinations of mind-body skills, as has been done with cognitive-behavioral techniques for managing FOR.[51] Optimization is also needed to guide future implementation, including addressing possible barriers at the patient level (e.g., access to internet for remote sessions, awareness that FOR is modifiable), provider level (e.g., screening for FOR, training in intervention protocol), and systems level (e.g., integration within existing hospital-based or community services). Once ready for implementation, remote delivery could follow a stepped-care model, which involves using repeated assessments of FOR severity to tailor referrals to various intervention options starting with the option that is effective but requires the least amount of resources. Lynch et al[54] (2021) recently demonstrated that a stepped-care model for treating FOR was feasible and acceptable among patients with metastatic melanoma, whereby survivors were offered a self-management toolkit or individual psychotherapy as needed based on FOR severity. While our focus groups highlighted the broad interest in learning mind-body skills for managing FOR across survivors with either elevated or non-elevated FOR, our proof of concept trial taught us that survivors with elevated FOR benefitted the most. Thus, this program may be most appropriate for survivors who have persistent concerns about recurrence after completing treatment.

In conclusion, this report summarizes the systematic, multi-step process of developing and adapting a mind-body resiliency intervention to address fear of recurrence. By soliciting feedback from stakeholders at multiple levels, the intervention content, procedures, and delivery plans have been refined. Plans for further testing in a randomized feasibility pilot trial are currently underway (NCCIH K23AT010157; PI: Hall).

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Supplemental Material

Supplemental material for this article is available online.

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