Evaluation of a stepped-care approach (*Fear-Less*) to treat fear of cancer recurrence in cancer survivors

Short title: Evaluation of the *Fear-Less* Program in cancer survivors

Project Leads and Contact:	Dr Maria Ftanou Lead Clinical Psychologist
Mailing Address:	Locked Bag 1, A'Beckett Street
Suburb/City:	Melbourne
Postcode:	8006
State, Country:	VIC, Australia
Organisation:	Peter MacCallum Cancer Center
Department:	Psychosocial Oncology Program
Email:	Maria.Ftanou@petermac.org
Phone (BH):	03 8559 7174
Phone (mobile):	0402 463 898

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PROJECT STAFF

Project Lead

Name	Organisation	Department	Role
Dr Maria Ftanou	Peter MacCallum Cancer Centre (Peter Mac)	Psychosocial Oncology Program	Project oversight: design, model of care implementation, evaluation, dissemination.

Project Team

Name	Organisation	Department	Role
Ms Mei Jun Tran	Peter Mac	Psychosocial Oncology Program	Project Manager
Dr Fiona Lynch	Peter Mac	Psychosocial Oncology Program	Expert advice – input and advice on all aspects of the project, including guidance with the self-management resource and providing individual therapy.
Ms Lynda Katona	Alfred Health	Manager of Psychology	Expert advice and governance support – guidance with development of the self-management resource, psychological intervention and educational resources.
Dr Jo Phipps-Nelson	Peter Mac	Cancer Experiences Research	Expert advice and governance support.
Prof. Steve Ellen	Peter Mac	Psychosocial Oncology Program	Expert advice and governance support – input into design and implementation of the model of care and clinical pathways.
A/Prof. David Weisenfeld	Peter Mac / Royal Melbourne Hospital (RMH)	Head and Neck	Principal Investigator at RMH site. Expert advice and governance support.
A/Prof. Orla McNally	Royal Women's Hospital (RWH)	Gynaecology	Principal Investigator at RWH site. Expert advice and governance support.
Tumour stream nurses and leads	TBC		Input and advice on all aspects of the project within their tumour stream units
Research assistant	TBC		Support project manager with day-to-day running of the project

Steering Committee

Name	Position, Organisation
Prof. Michael Jefford	Medical Oncologist, Peter Mac Director of the Australian Cancer Survivorship Centre
A/Prof. Joanne Shaw	Director of the Psycho-Oncology Co-operative Research Group
Dr Ben Smith	Translational research fellow, University of New South Wales
A/Prof. Haryana Dhillon	Research fellow, University of Sydney
Dr Lachlan McDowell	Radiation Oncologist, Peter Mac
Alan White	Consumer Representative
Clare Halloran	Consumer Representative

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PROJECT SPONSOR AND COLLABORATING PARTNERS

Peter Mac is the project sponsor: Peter Mac, Royal Melbourne Hospital, and Royal Women's Hospital are collaborating partners.

BACKGROUND

Fear of cancer recurrence (FCR) describes the fear, worry, or concern that cancer will come back or progress [1] and affects up to 70% of all cancer survivors [2, 3]. FCR involves intrusive thoughts, worries, hypervigilance to physical symptoms and either avoidance of, or excessive levels of symptom checking [1]. It is often particularly heightened in the days or weeks before receiving scan results or attending medical reviews [4]. At clinical levels, FCR has been associated with poor day-to-day functioning, reduced quality of life and increased rates of depression, anxiety and worry about the future [5]. Untreated FCR has been related to the avoidance of or excessive requests for medical reviews, examinations or follow-ups, potentially risking adverse health outcomes for survivors and increased health costs to survivors and health services [5-7].

Over the past decade, a number of psychological interventions have been developed and trialled to better address FCR in cancer survivors [6, 8-14]. These interventions tend to target attitudes, beliefs and behaviours that may exacerbate or maintain FCR. In addition to

significantly reducing levels of FCR, these interventions have led to improvement in emotional wellbeing [8, 9] and quality of life [8].

One such intervention is ConquerFear, a five-session manualised treatment [8] developed based on a cognitive processing model of FCR [15]. The intervention targets key processes proposed to contribute to FCR, including worry and excessive threat monitoring, unhelpful beliefs about worry, inappropriate monitoring and screening behaviours, and existential issues [8]. Compared to a manualised relaxation intervention, ConquerFear was shown to reduce FCR in survivors with early stage disease, with gains maintained at six months. Furthermore, ConquerFear was considered by clinicians to be a sustainable intervention in routine practice [16].

Unfortunately, these promising results have yet to be translated into clinical practice. Barriers have included lack of routine screening for FCR [17] and limited availability of therapists with specialised training to deliver FCR interventions [18]. Questions also remain regarding how efficacious interventions can be integrated into a cohesive model, such as a stepped-care approach. This is particularly relevant for ConquerFear, which appears to be more efficacious amongst survivors with high FCR scores [19]. Low-intensity interventions may therefore be more appropriate for survivors with mild-to-moderate levels of FCR.

To address this service gap, a stepped-care intervention (*Fear-Less*) was developed at Peter MacCallum Cancer Centre (PMCC), which aimed to efficiently reduce FCR in survivors with stage IV melanoma treated with immunotherapies and targeted therapies (see previously approved project 18/213L). For this project, survivors with subthreshold levels of FCR were stratified to a self-management booklet while those with clinical levels of FCR were treated with ConquerFear. The findings from the project indicated that the stepped-care intervention was acceptable to survivors and was feasible to implement [20].

On the basis of these outcomes, the current project aims to replicate the above project with survivors of early stage cancers. This is important given FCR research has primarily been conducted in survivors with early stage disease, yet barriers to routine implementation of FCR interventions remain. Additionally, most FCR research has been conducted in women with breast cancer, yet there is a diverse population of people with cancer for whom FCR interventions would be relevant [18]. The present project aims to address a significant unmet need of cancer survivors with early stage disease.

AIMS

The overall aim of the current project is to evaluate the feasibility of a multisite, stepped-care intervention that identifies and treats FCR in cancer survivors with early stage disease using an established treatment protocol, ConquerFear. For this project, survivors with early stage disease will be defined as individuals who have been treated with curative intent, who have no evidence of metastatic disease.

The specific objectives of this project are to:

- Improve identification of FCR in cancer survivors through developing a screening process and exploring sustainable screening models
- Adapt the original *Fear-Less* self-management booklet for the early stage disease setting

- Improve access to self-management interventions for cancer survivors with moderate levels of FCR
- Improve access for survivors with clinical levels of FCR to evidenced based interventions (ConquerFear)
- Assess the feasibility and acceptability of an FCR stepped-care intervention that includes both low- and high-intensity interventions

PROJECT DESIGN / METHODOLOGY

The current project design is based on the original *Fear-Less* project (see previously approved projects 18/175L and 18/213L) and involves three phases:

1. Adaption of the original *Fear-Less* booklet for a general early stage cancer population
2. Implementation and evaluation of a stepped-care approach to identify and treat FCR in early stage disease
3. Dissemination of the *Fear-Less* resources

The methodology for each of these phases will be described in more detail in the sections below.

PHASE 1: ADAPTION OF THE ORIGINAL *FEAR-LESS* BOOKLET FOR A GENERAL CANCER POPULATION

As the original *Fear-Less* booklet was tailored to survivors with stage IV melanoma, the initial phase of the current project will adapt the existing booklet for a general, early stage cancer population. We expect the content of the updated self-management booklet will be similar to the original *Fear-Less* booklet, and will include information about FCR, wellbeing, and key cognitive behavioural strategies (such as relaxation, cognitive strategies and pleasant activity scheduling) to help change thoughts and behaviours that trigger and maintain FCR.

To adapt the booklet, the current project will follow a similar methodology to that used in the development of the original *Fear-Less* booklet (see previously approved project 18/175L). This process will likely involve four steps, as outlined below.

1. Removing sections of the booklet specific to melanoma or advanced disease
2. Conducting a consumer workshop to seek feedback regarding the content and design of the booklet
3. Amending the booklet in accordance with consumer and project team feedback
4. Quality review process as per Peter Mac policy to ensure acceptability

1. Removing sections of the booklet specific to melanoma

The content of the original *Fear-Less* booklet will be reviewed by the project team and steering committee, comprising clinicians and researchers with expertise in FCR. Sections of the booklet specific to melanoma and inappropriate for early stage disease will be removed.

2. Conducting a consumer workshop for feedback

Following the initial edit of the booklet, a consumer workshop will be conducted to seek feedback on the content of the booklet, any necessary adaptations or modifications required, and any editing and design adjustments. For example, feedback from the original *Fear-Less* project indicated the self-management booklet provided was pitched at a high literacy level. As such, one proposed adaption will be to simplify the original booklet to be more accessible to a general population.

The consumer workshop will be held in person and/or via teleconference, in accordance with COVID-19 restrictions. Consumers unable to attend the workshop in person will be offered the option of taking part via teleconference or participating in a one-on-one audio-recorded phone discussion with a member of the project team. The workshop and phone discussions will be audio-recorded for later reference and one facilitator will take notes throughout the workshop to broadly capture issues discussed and consensus reached regarding content to include in the final booklet.

2.1 Workshop participants

Consumer representatives from different tumour streams will be invited to participate in the consumer workshops. The eligibility criteria are:

- Survivor of early stage disease from any tumour stream, who has completed curative treatment
- Aged 18 years or older
- Able to read, write and speak English

2.2. Recruitment

The aim is to recruit a sample of 6 to 8 consumers for the workshop. Consumer representatives will be invited to take part through consumer organisations and PMCC's research consumer engagement coordinator. We anticipate consumers will be informed of the workshop via each consumer organisation's regular communications with survivors. This may include newsletters, email, or social media.

Consumers who indicate interest will be sent an invitation email (Appendix A) and the Participant Information and Consent Form (PICF) for Workshop Participation (Appendix B). Consumers who respond to the invitation email will be contacted via phone or email and asked three screening questions to confirm they meet the eligibility criteria:

- Have you been diagnosed with early stage cancer and completed your treatment?
- Are you 18 or over?
- Can you attend a one-off Zoom or in-person workshop at Peter MacCallum Cancer Centre?

A record of the consumers who are eligible will be kept to invite these participants to the workshop.

Consumers who do not meet the eligibility criteria or are unsure of their stage of disease or treatment will be thanked for their interest in the study and advised the study is not suitable for them to take part in. No record of these participants will be kept.

Should the workshop be held in-person, consumers who attend will complete a signed consent form at the commencement of the workshop. Participants who are participating via teleconference or one-on-one phone call will have the option of returning a signed and scanned/emailed consent form to the researchers, or completing consent over the phone. Participants completing telephone consent will be reminded of the key details of the project in the PICF, confirmed they have received and had an opportunity to read the PICF, will be reminded that their participation is voluntary, and will be asked if they consent to taking part in the interview or teleconference workshop.

2.3. Procedure

Participants involved in the workshop will be sent the draft self-management booklet in advance of the workshop. Should the workshop be held in person, consumers will be reimbursed for transport expenses.

The workshop will be facilitated by at least two project team members and will take approximately 2 hours. The workshop will include the following components:

- Presenting the self-management booklet
- Discussing the content of the booklet
- Discussing design and layout options
- Discussing options for introducing booklet to survivors

For participants taking part via an individual phone call, the presentation of the booklet will be completed verbally and participants will have received the written information prior to the workshop as stated above.

The workshop will be unstructured and driven by participant input. However, a summary of prompts that may be used to facilitate discussion during the workshop is included in Appendix C. These prompts may also be used in the individual interviews to prompt discussion.

2. 4. Data collection

Basic demographic data will be collected at the start of the workshop using a project-specific questionnaire (Appendix D). Demographic data will be used for descriptive purposes only to describe the sample that participated in the workshops and reviewed the resource (e.g., in manuscript publications for the broader project).

Should the workshop be held in person, participants will be handed a paper-based version of the questionnaire at the start of the workshop and asked to fill in their information. Alternatively, participants attending via teleconference will be asked to provide these details via an online survey emailed to each participant prior to the workshop. The questionnaire will take no more than 2 – 3 minutes to complete. Any participants who are providing input via phone will provide these details over the phone.

The following data will be collected:

- Gender
- Age
- Diagnosis
- Date of diagnosis
- Treatment received
- Experience with fear of cancer recurrence
- Past use of psychosocial support resources

2.5. Data analysis

Demographic data will be summarized using descriptive statistics. Microsoft Office Excel 2010 will be used for data entry and statistical analysis. Participant anonymity will be ensured when presenting final data aggregates.

Recorded audio from the workshop and individual interviews will be transcribed. Transcriptions will be anonymous, with any identifiable information removed (e.g., names). Workshop and interview transcriptions will be reviewed by the project manager when developing the self-management resource to ensure that participant views were captured accurately to inform the development of this resource. No specific qualitative analysis of the transcriptions is required.

2.6. Additional use of data

Direct quotes from the transcriptions of consumers may be published in the self-management booklet with participant consent. Prior to anonymising transcriptions by removing participant names, relevant quotes from each participant that are appropriate for publishing in the resource will be obtained.

Each participant will receive an individual email (Appendix E) requesting the use of this data with attached quotes from their transcription. In this email, participants will be advised that the use of their quotes is optional and reminded that they are not obliged to consent. If participants are wishing to consent to the additional use of this data, they will be asked if they would like to make any edits to their quote, and to advise the project manager if they would like to be acknowledged using their first name, a pseudonym, or ‘anonymous’.

Participants will be requested to sign a Communications Consent Form and return a scanned copy via email. Participants will not be asked to sign a project specific consent form again in addition to the Communications Consent Form in order to reduce participant burden as a PICF has already been signed or verbal consent obtained.

3. Amending the booklet in accordance with consumer and project team feedback

Based on the input provided during the consumer workshop, the project team will make further changes to the self-management booklet. Once a draft is finalised, the booklet will be circulated to the project team, the steering committee and to all workshop participants for feedback and review of its content and design.

Once feedback is received, the project team will revise and finalize the booklet according to Peter Mac's Patient Information framework [21], which will ensure:

- Any literature used to develop the content is cited appropriately
- Adherence to the style guide as indicated in Peter Mac's 'Patient Information Writing Guide'
- Review from the Quality and Safety Unit is sought to ensure meeting health literacy criteria
- Alignment with one of the three templates as sourced and managed by Peter Mac's Communications and Branding department

4. Quality review process

Once a final copy is produced, the self-management booklet will undergo a quality review process. This will be conducted collaboratively with the Health Communications Manager (HCM) from the Quality and Safety Unit (QSU) and the Consumer Literacy Education & Evaluation Working Group (CLEEG) as required by Peter Mac Patient Information Content Development policy:

- Forward 'draft' to HCM for review, health literacy compliance check and editing if required
- HCM to table draft to CLEEG for participation & feedback
- CLEEG to participate in design, development and provide evaluation using (SCRIPT)
- HCM to return all evaluations, edits and feedback to author
- Author to amend/draft changes to reflect (if applicable) CLEEG evaluation & feedback and submit to stakeholder group for approval
- Stakeholder/Consultation and evaluator(s) teams to review amendment(s) and consider approval
- On stakeholder group approval, submit final and all related paperwork to HCM for electronic storage
- Submit ALL finalised paperwork to HCM

PHASE 2: IMPLEMENTATION AND EVALUATION OF A STEPPED-CARE APPROACH TO IDENTIFY AND TREAT FCR IN EARLY STAGE DISEASE

The second phase of the project aims to use implementation and health services evaluation methodology with a mixed-methods approach to evaluate the feasibility of a stepped-care intervention that identifies and treats FCR in cancer survivors with early stage disease.

1. Study Sites

This project will be conducted in the melanoma, breast, head and neck, genitourinary, lower GI, haematology, and gynaecological oncology outpatient clinics at PMCC, Royal Melbourne Hospital (RMH), and Royal Women's Hospital (RWH).

2. Participants

The current project aims to recruit both patients with early stage disease and clinicians as described below.

2.1. Patients

All patients who have been screened for FCR will be approached to participate in this evaluation project. The current project aims to recruit sixty adults attending outpatient clinics across PMCC, RMH and RWH over 15 weeks.

2.1.1. Inclusion criteria

- Aged ≥ 18 years
- Patients with early stage disease who have completed initial curative treatment, including those on maintenance therapy
- Patients able to read and write English
- Patients able to give informed consent

2.1.2. Exclusion criteria

- Patients diagnosed with metastatic disease

2.1.3. Withdrawal criteria

We do not expect that participants will be withdrawn by the research team or therapist involved in delivering the intervention. If participants require referral to other practitioners for complementary care (for example, medication), or care for unrelated morbidity, this will be recorded on the database.

Participants who opt to withdraw from the study will be asked if they would consent to continue completing follow-up measures, evaluation, and for any of their existing data to be included in analyses. If consent is not given for the latter, their data will be erased from the database, and any electronic or paper records pertaining to their involvement will be destroyed at the completion of the study, except medical notes that have been committed to the electronic system. A record of participants who have withdrawn from the study will be maintained in a secure database until the completion of the study, to ensure that these individuals are not approached again by the project team. Participants will be unable to withdraw their data after the completion of the study as their data may have already been used in analyses.

2.2. Clinicians

All clinical staff working in the multidisciplinary tumour streams will be invited to participate in the evaluation component of the project. These clinical staff may include nurses, oncologists, psychosocial oncology staff and allied health staff.

3. Recruitment

3.1. Patient recruitment

Routine FCR screening will be completed in the melanoma, breast, head and neck, genitourinary, lower GI, haematology, and gynaecological oncology outpatient clinics. Members of the project team and/or clinical staff supporting the *Fear-Less* program will complete this screening. Patients who have completed screening and meet the eligibility criteria outlined above will be approached by a member of the project team and invited to take part in the evaluation of the stepped-care approach. The screening will be accompanied by a letter informing survivors about the *Fear-Less* program and that they will be contacted by a member of the project team to follow up (Appendix N).

If the patient is interested in taking part in the study, they will provide formal (signed) informed consent in accordance with Good Clinical Practice (GCP) guidelines. Informed consent involves providing a verbal explanation of the project with an opportunity to ask questions, and providing the patient with a PICF.

For individuals who wish to complete their forms online, an online link will be sent through the secure REDCap survey where they will first complete an online copy of the PICF for Stepped-Care Evaluation (Appendix F), followed by Evaluation Survey A (Appendix G). Participants who request to complete the form and survey in hardcopy will receive the original consent form, Evaluation Survey A and two supplied reply-paid envelopes. Participants will be advised to return the consent form in the separate envelope to the survey to ensure identifiable data remains separated.

Individuals who wish to consider their involvement in the project will be provided with a copy of the PICF to consider. They will be invited to contact the project team should they wish to take part or have any further questions. Individuals who do not return the survey or consent form will be followed up once via email. Those who do not respond to the follow-up email will be considered to have declined involvement and have no further contact with the project team.

A patient screening / approach log will be used to monitor patients who have been approached and will be subsequently entered into the REDCap database (Appendix H). This will ensure that patients are not approached more than once. Once an individual is identified as being eligible, the RA or project manager will review the REDCap database of approached patients to ensure that the patient has not already been approached for the project.

Participation in the project is voluntary; survivors will be assured that a decision to decline participation will not impact on their care or treatment. Individuals who do not wish to be involved in the evaluation will continue with their usual treatment. Should their FCR screening scores indicate a need, this may include referral to a psychiatrist, individual therapy, peer supports or community services. There will be no further contact from the project team.

3.2. Clinician recruitment

Eligible staff will be invited via email to participate. Staff will be sent up to three reminders to complete this survey. Examples of the invitation email and the reminder email are held in

Appendix O. Sampling will be purposive, employing maximum variation to gain a wide range of experiences, perspectives, and needs and preferences. Recruitment will continue until the data generated from the surveys reaches saturation.

Participation is voluntary and consent is implied by completion and return of the data collection measures (outlined in the Evaluation Measures and Data Collection section below).

4. 4. Routine Screening Measures

The following measures (Appendix I) will be administered to survivors at completion of curative treatment or at a follow-up appointment following treatment completion. This is consistent with Cancer Australia's recommendation for routine psychosocial screening [22].

4.1. Fear of Cancer Recurrence One Item Measure (FCR-1)

The FCR-1 is a one-item measure assessing the severity of FCR [23, 24]. Patients are asked to rate their fear of their cancer returning or getting worse on a scale from 0 (no fear) to 10 (worst possible fear).

4.2. Fear of Cancer Recurrent Inventory Short Form (FCRI-SF)

The FCRI-SF [25] is a validated and reliable 9-item instrument that assesses the presence, frequency, intensity, and duration of thoughts associated with FCR. Total scores range from 0-36 with higher scores indicating higher levels of FCR. It is expected that this questionnaire will take approximately 90 seconds to complete.

5. Procedures: Implementation of the stepped-care approach

Implementation of the stepped-care approach will replicate previous successful projects – the original *Fear-Less* project conducted at PMCC and Alfred Health (see previously approved project 18/213L) and the *Can-Sleep* project conducted at PMCC (see previously approved project 17_83L).

Survivors will be stratified into the stepped care approach based on their screening score on the FCRI-SF. The authors of FCRI-SF initially suggested that a cut-off score of ≥ 13 on the FCRI-SF demonstrated optimal sensitivity and specificity [25], although a later study found that a higher FCRI-SF cut-off of ≥22 may be suitable for identifying cancer survivors with clinical levels of FCR with adequate sensitivity and specificity [26]. Scores less than 13 on FCRI-SF are considered low. A score of 13-21 will therefore be used to identify patients with moderate FCR who will be offered self-management, while a score of ≥22 will be used to identify patients with high levels of FCR who may be appropriate for a one-to-one intervention.

The steps for the intervention are described below and are illustrated in Figure 1.

Step 1: Treatment as usual

Survivors who score below 13 on FCRI-SF will be offered treatment as usual. FCR will be managed through medical/nursing teams and they will be provided details about how to access psychological intervention should they need services.

Step 2: Self-management intervention

Survivors scoring between 13 to 21 on FCRI-SF will be identified as having subclinical FCR. These individuals will be provided with a brief discussion by a project team member either in person or over the phone to determine their eligibility for the self-management intervention. This discussion aims to confirm that the survivor is concerned about their FCR, would like support for it, and would like to receive treatment. Participants who agree to proceed with the self-management intervention will be provided with education on how to use the self-management booklet, and provided with an opportunity to ask any questions. The self-management resource will then be provided to the patient.

The self-management resource will be posted to participants or provided at their next appointment, depending on patient preference. The self-management resource will be a colour printed booklet consisting of strategies to manage FCR. The development of this resource is described in Phase 1.

The project team will contact participants over the phone after approximately three weeks of receipt of the self-management booklet to provide phone support and further education as needed to support participants in using the self-management resource.

Participants will also be contacted via phone five weeks after receipt of the self-management resource. During this call, the survivor's current treatment needs and options for follow-up clinical support will be discussed. This may include no further treatment, or referrals to services such as a psychiatrist, individual therapy, peer supports or community services GP.

Participants will also be asked during this phone call to complete the follow-up FCR-1, FCRI-SF, and Evaluation Survey B – Self-Management Intervention (Appendix J). If participants prefer not to complete these measures over the phone, they will receive an email link to complete online via REDCap or will be mailed a hardcopy of the forms which they can complete a return to the project team using a supplied reply-paid envelope. Non-returned questionnaires will be followed up using a standard schedule of phone, mail/email reminder to minimise missing data. Participants who do not return the surveys within 2 weeks of receipt will be called up to three times (at 2 week intervals) to remind them to return the survey.

Step 3: Individual intervention

Survivors who score 22 or higher on the FCRI-SF will be identified as having clinical levels of FCR. These participants will be provided with a brief discussion by the project team member either in person or over the phone to determine their eligibility for the ConquerFear. This discussion will take approximately 10 minutes, and will be focused on assessing if their fear of cancer recurrence appears to be clinically significant and a discussion with the patient about the ConquerFear therapy to ensure this is the most appropriate treatment approach. Factors that will be assessed during this discussion will include the frequency, emotional impact, functional impact, and avoidance of their fear of cancer recurrence. Participants who are considered to have less than significant fear of cancer recurrence, or who do not wish to take part in the ConquerFear therapy, will be offered the self-management intervention.

The ConquerFear therapy consists of five individual sessions based on the established ConquerFear protocol [8]. These sessions will teach survivors strategies to manage worry and excessive FCR, and promote value-based goal setting. Each session will be approximately 60 minutes every 1-2 weeks and will be facilitated by a provisional or clinical psychologist face-to-face or via telehealth. Telehealth sessions will be offered as needed. Each session is accompanied by home-based practice of skills learned in session and home reading to consolidate skill acquisition.

The key goals of the Conquer Fear therapy are to:

a) Teach strategies for managing worry and excessive threat monitoring
b) Modify underlying unhelpful beliefs about worry
c) Develop appropriate monitoring and screening behaviours
d) Educate about follow-up care and empirically-supported behavioural change (e.g., weight loss, exercise etc.) to reduce the risk of cancer recurrence
e) Address existential changes brought about by a cancer diagnosis
f) Promote goal-setting

In Session 1, a FCR-specific assessment will be conducted and the model of FCR on which the treatment program is based will be introduced. Discussion of existential changes brought about by cancer will be introduced as well as values clarification and goal setting tasks to be completed for homework.

In Session 2, the impact of vulnerability factors (e.g., past traumatic life events) on the interpretation and meaning of FCR will be discussed. The rationale for the practice of Attention Training Technique (ATT) will be discussed, which aims to help patients reduce their rumination and shift their attention more flexibly when thoughts of recurrence occur. Clients will be asked to practice ATT on a daily basis throughout the remainder of the intervention.

In Session 3, Detached Mindfulness will be introduced. This is designed to enhance meta-cognition awareness and the ability to become an objective observer of thought content without evaluating or reacting to cognitions.

In Session 4, information about possible symptom recurrence will be provided and guidelines to help participants distinguish those from benign physical complaints. Self-examination practices and medical surveillance will be reviewed. Avoidant or excessive behaviours will be identified and a behavioural contract help clients engage in recommended levels of self-examination and follow-up tests will be developed. Beliefs that may underpin FCR will also be explored through Socratic dialogue.

In Session 5, the goal setting task will be reviewed, as well as skills learned during the intervention. A relapse prevention plan will be developed.

After the fifth session, survivors will complete follow-up FCR-1, FCRI-SF, and Evaluation Survey B – ConquerFear (Appendix K). Options for follow-up clinical support will also be discussed depending on the survivor's needs. This may include no further treatment, or referrals to services such as a psychiatrist, additional individual therapy, peer supports or community services GP.

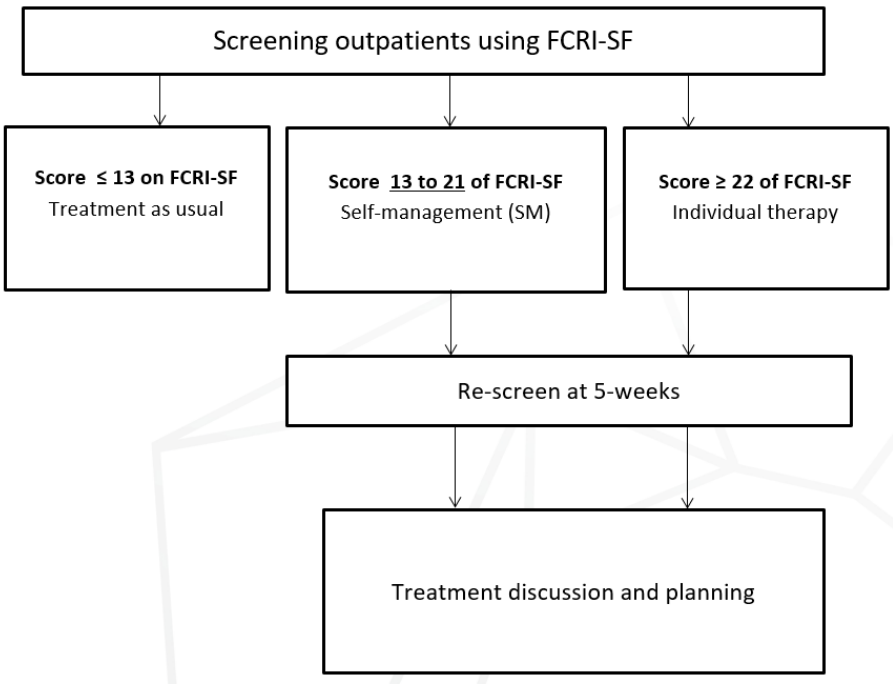

Figure 1. Stepped-Care Approach

6. Evaluation

The evaluation plan for the current project will be based on the previous *Fear-Less* project. The measures and data collected will identify how the program can be improved (a formative evaluation), and the impact and outcomes for survivors and clinicians (a summative evaluation).

The evaluation aims to answer the following questions:

1) Is screening for FCR feasible and acceptable to survivors and staff?
2) Is the FCR self-management booklet relevant and useful to survivors?
3) What is the uptake of the stepped-care interventions?
4) Is stepped-care a feasible and acceptable model of care to deliver in cancer centres?
5) How well have the tumour streams and teams engaged with the stepped interventions?
6) How can this initiative be sustained?

6.1. Evaluation Part A (Formative evaluation)

Evaluation Part A aims to evaluate the feasibility and acceptability of the implementation of routine FCR screening. Little is known about FCR screening given it has not been routinely implemented thus far. Outcomes from the original *Fear-Less* project indicated FCR screening was feasible and acceptable to Stage IV melanoma survivors and clinicians. Evaluation Part A therefore aims to evaluate whether these outcomes are generalisable to early stage disease in other tumour streams, and whether there are differences across tumour stream units.

Eligible patients who have completed screening and agreed to be contacted by the project team will have been identified as part of the recruitment process. This will include survivors with and without significant FCR. Survivors with low FCR and have consented to the project will be administered Evaluation Survey A and will complete involvement in the project at completion of this survey.

Other data collected at this time for the evaluation project includes demographic and medical information (from the medical record), number of patients who completed screening, number of patients referred to self-management intervention (and number that take up this referral), number of patients referred to ConquerFear (and number of patients that take up this referral), time taken by clinicians and project staff to screen patients and complete referrals, and the number of patients that complete the evaluation project.

6.2. Evaluation Part B (Summative evaluation)

Evaluation Part B aims to evaluate the feasibility, acceptability, and impact of the interventions. Participants will complete Evaluation Survey B after their follow-up care (i.e., after five weeks of self-management intervention or five sessions of ConquerFear). This survey collects data about the patient's experiences of follow-up care, and also enquires about ways of improving this care. Data from the FCRI-SF and FCR-1 will be used to evaluate the impact of the *Fear-Less* Program.

Other data collected includes; the number of patients rescreened, number of ConquerFear sessions attended, the number of patients that complete the evaluation project, and time taken by clinicians and project staff to re-screen and provide follow-up care. Feasibility of delivering ConquerFear to patients will be assessed using a review of the session checklist, recording 10% of therapy sessions, and qualitative data from interviews conducting via focus groups or individual.

At the end of the evaluation project, clinicians in participating clinics will be sent a link to the Staff Engagement Survey via email (Appendix L) to assess their experiences with screening and the *Fear-Less* Program.

7. Evaluation Measures and Data Collection

The measures, data collection and time/place of data collection, according to the project aims are described below.

During the data collection period, regular quality assurance will be undertaken to ensure accuracy, precision and completeness of study data.

7.1. Patient demographic and medical record data

Patient demographic and clinical characteristics will be collected from the patient's medical record after the patient has consented to the project and from liaison with the treating team. Data collected will include:

- Age
- Sex
- Cancer type
- Treatment received

Identifying information of the patient's name and contact details will be obtained from the medical record and/or consent form to maintain contact with the patient only. This information will not be used in data analysis, and will be removed from the database at the conclusion of the project.

7.2. Appropriateness and acceptability

7.2.1. Patient Experiences: Evaluation - Survey

Patient reported appropriateness and acceptability will be collected by two surveys designated Evaluation Survey A and Evaluation Survey B.

Evaluation Survey A (titled: Patient Experience Survey – Screening Questionnaires):

Every patient who completes routine screening and consents to participate in the stepped-care evaluation will be asked to complete this ten-item survey (Appendix G). This survey will be completed following the initial screening; each survivor will complete this survey only once.

This survey consists of ten questions and is expected to take approximately ten minutes to complete.

The survey has been purpose built to assess how well the reasons and procedure for completing the *Fear-Less* Program screening questionnaires were explained, how easy the screening questionnaires were to understand and complete, and whether the completion time was acceptable or too long.

Evaluation Survey B (titled: Patient Experience Survey – Post Follow-Up Care):

Participants who receive follow-up care will complete this survey within 2 weeks of completing the follow-up care they receive, i.e., either the self-management resource (Appendix J), or five-session ConquerFear treatment (Appendix K).

The survey has been purpose built to determine what barriers prohibited seeking help for fear of cancer recurrence in the past, what the most useful/helpful and least useful/helpful aspects of their follow-up care were, and whether participants experienced any changes in their fear following the intervention they received. This survey is expected to take approximately 10 minutes to complete.

7.2.2. Clinician: Evaluation - Survey

Clinician reported appropriateness and acceptability data are collected through an online survey using REDCap. The aim of the survey is to elicit information about positive and negative experiences with the *Fear-Less* Program, to identify any improvements that may be required. This survey will be sent to clinicians towards the end of the evaluation period allowing enough time to collect and analyse data prior to project completion. This survey consists of 10 questions and is anticipated to take no more than 20 minutes to complete (Appendix L).

7.3. Fidelity and utility of ConquerFear

7.3.1. Session checklists

The fidelity of the ConquerFear treatment protocol will be assessed through a review of each session by the psychologists administering the treatment. This will be completed using session checklists usually included in the ConquerFear protocol. The checklist will be completed at the end of each session.

7.3.2. Impact

The impact of the *Fear-Less* Program on participants will be evaluated based on the number of survivors who exhibit clinically significant change in severity of FCR, where a clinically significant change is defined as a reduction of 10% or more of the scale range. This is consistent with accepted rules of thumb for interpreting clinically significant changes in patient-reported outcomes [27] and, for the FCRI-SF, is consistent with the mean within-group change observed in the original randomised trial that demonstrated efficacy of ConquerFear compared with attention control [8]. Data collected from screening tools will be examined.

7.4. Assessment of processes and procedures in the clinical setting

A number of measures outlined in the table below will be used to evaluate appropriateness and acceptability of the *Fear-Less* Program. Similar to the previous Fear-Less project (see previously approved project 18/213L), calculation of the rates of screening, referral uptake, and treatment adherence from the data below will provide information regarding survivor engagement with the *Fear-Less* program.

A Case Report Form (CRF; Appendix M) will be used by the project team and/or psychology clinician to assess follow-up. The CRF information will be entered directly into REDCap database for the self-management intervention at some sites, and others will complete a hardcopy CRF that will be subsequently entered into the REDCap database (e.g., treatment sessions). The project team, using the Screening / Approach Log and CRF will collect the following:

Data	Variables	Collection method	Collection place / time
Screening	# pts initially screened	Patient Screening / Approach Log	Collected in clinics during screening
	# pts rescreened after receiving follow-up care	Project specific CRF	Collected during rescreening
	# pts who declined screening	Patient Screening / Approach Log	Collected during screening.
Referral rates/uptake	# pts referred to each component of follow-up care (self-management/Conquer Fear)	Project specific CRF	Collected during the referral process
	# pts that accepted referrals for follow-up care	Project specific CRF	Collected from the referral/intervention processes.
Patient adherence to therapy	# weeks completed self-management intervention # sessions of Conquer Fear attended.	Project specific CRF	Collected during self-management follow up phone calls or Conquer Fear sessions by clinicians
Evaluation participation	# pts who completed evaluation # clinicians who completed surveys	Project specific CRF Clinician survey data extracted from REDCap.	Collected at screening and at subsequent end of follow-up care.

7.4.1. Clinicians and project team time

Time and costing data for implementing new program and delivery of intervention will be based on the number of minutes or hours spent per task costed according to role of the staff member (clinician or project team member). An outline of the variables collected is below, and this data will be collected on the Screening / Approach Log and CRF.

Activity	Variables	Data collected
Screening	Clinician/Project team member time including explaining screening tools to patient, scoring tools, triaging patients.	Role (e.g. psychologist, clinician) Time in minutes
Intervention delivery: Self-management intervention	Clinician/Project team member time: • Delivery of one-on-one introductory session (patient's receipt of resource). • Follow-up at three weeks • Rescreening • Follow-up care discussion at end of intervention, including referrals • Other: free text*	Role (e.g. psychologist, administrator) Time in minutes
Intervention delivery: Conquer Fear	Clinician/Project team member time: • Time for follow-up care discussion • Time additionally to intervention (e.g., follow up phone calls etc.) • Rescreening • Follow-up care discussion at end of intervention, including referrals	Role (e.g. psychologist, administrator) Time in minutes

8. Data Analysis

8.1. Quantitative data

Descriptive statistics will be used to summarise demographic, clinical and operational data, initial responses to the FCRI-SF and FCR-1, and responses to relevant questions from the evaluation surveys. Initial responses to the FCRI-SF will also be recoded to discrete variables comprising three ordered categories (categories will correspond to those described in Figure 1); then relative frequencies will be computed for each variable.

Change scores will be calculated for all participants who accept the self-management resource and all participants who agree to participate in the ConquerFear intervention. For each group, participants who report a reduction of 10% or more on the FCRI-SF and FCR-1 will be summarised with a proportion and 95% confidence interval; the latter will be estimated using the Wilson method [28]. As appropriate, paired samples t-tests will be used to compare FCRI-SF and FCR-1 before and after intervention. Tests will be performed separately for participants who accepted the self-management resource and those that agree to participate in the

ConquerFear intervention. Tests will be performed for both the full sample for each intervention, and separately for those who completed an acceptable level of the intervention; defined as reading 75% or more of the self-management booklet according to self-report (Q4 added to Patient Experiences Survey), or completing four or more sessions of the Conquer Fear intervention. These analyses are contingent on the project obtaining an appropriate sample size that may not be reached.

8.2. Qualitative data

Free text items from the patient and clinician surveys will be analysed using summarising content analysis using NVivo software. A deductive content analysis approach will be used for coding data. Pre-defined categories will be formulated based on the research questions informing the study. Additional inductive codes will be identified from the survey responses.

PHASE 3: DISSEMINATION OF RESOURCES

The outcomes of this project may be published or presented at seminars and conferences. No identifying information will be made available during the publications or presentations.

Additionally, the resources developed as part of this project may be made publicly available to other hospitals and organisations (e.g., various Cancer Councils). This aims to broaden the reach and accessibility of resources for cancer survivors experiencing FCR.

OVERALL ETHICAL CONSIDERATIONS

The study will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research (2007 and updates) and the World Medical Association Declaration of Helsinki (2013 and updates).

1. Informed consent

To ensure participants do not feel obligated to participate, the study team will assure invitees that participation is entirely voluntary and that they may stop their involvement in the project at any time. The study team will explain that their decision will not impact on their care or their relationship with the hospital. This will be reinforced in each of the Phase 1 and Phase 2 PICFs.

2. Data storage and privacy

All electronic data will be stored securely in password-protected folders on Peter Mac's secure servers. Only members of the project team will have access to this data, in accordance with the National Statement on Ethical Conduct in Human Research 2007 and the Australian Code for Responsible Conduct of Research 2018. Hard-copy data will be stored in locked filing cabinets within Peter Mac Department of Psychosocial Oncology. Five years after publication or dissemination of project outcomes, hard-copy and electronic data will be destroyed.

2.1. Phase 1: Adaption of the original *Fear-Less* booklet for a general cancer population

Demographic data from this phase of the project will be anonymous and kept separate from identifiable information such as consent forms. Participants' identifiable information will be kept in one digital master file only.

At the completion of the consumer workshop, the workshop audio-recording will be downloaded and transcribed onto the Peter Mac shared drive. The recording on the portable device will then be immediately deleted.

Consumer participants who consent to the use of their transcribed data as quotes in the self-management resource may choose to be acknowledged by first name, a pseudonym, or using 'anonymous'. Participants will be identifiable by first name only, and no other identifiable information will be included in quotes.

All participants may choose to have their full name acknowledged at the back of the booklet as contributors to the development of the resource. Participants will advise if they would like their name acknowledged via email.

2.2. Phase 2: Implementation and evaluation of a stepped-care approach to identify and treat FCR in early stage disease

A unique study identification number system will be used for data collected for this phase of the project. This system involves keeping a 'key' that specifies and links the patient's personal identifying information (e.g. names, URNs) with the patient's corresponding study identification number (e.g. PT01/ PT02 etc.). The key will be kept electronically (in a password protected excel spread sheet) separate from all hardcopy and softcopy data collected on a Peter Mac server. Any identifying information will be entered into the REDCap database to maintain contact with patients only, and will not be used in data analysis. Any identifying information will be permanently deleted from the REDCap database at the conclusion of the project and will not be disclosed during any analysis, publications, or dissemination. At the conclusion of data analysis, the REDCap project will be archived on the REDCap platform.

Similar to the previous *Fear-Less* project (project number 18/213L), anonymous data from the FCRI-SF and FCR-1 may be shared with each measure's author to assist in their ongoing validation of these measures. For example, this may include validating the use of the FCRI-SF across cultures or settings. The data shared may also include anonymous demographic and medical information to describe the population from which the data is drawn. This data will be anonymised in a separate password protected file, the password will be provided to the author separately to the emailed data file. A data sharing agreement will be developed and submitted to a Governance Review. The data will be shared with the author of the FCRI-SF, Professor Sébastian Simard (Université du Québec à Chicoutimi), and the author of the FCR-1, Dr Ben Smith (Centre for Oncology Education and Research Translation).

3. Distressed participants

Participants may become upset during the consumer workshop in Phase 1 when recounting negative experiences. The project team is trained in group facilitation and has extensive work experience dealing with distressed patients. Any participants who feel distressed will be

referred to various support options as appropriate, including: support services at Peter Mac, Employment Assistance Program and the Cancer Council Victoria 13 11 20 telephone support service.

4. Confidentiality

It is not expected that participating in this project will pose any risks of harm to participants. If any disclosures of risks to safety (e.g., suicidal ideation) occur during any stages of the project, standard clinical processes will be followed including safety planning with the participant, and when needed advising an appropriate support person such as a member of the participant's treating team and/or a family member. This limit to confidentiality is included in the PICF.

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APPENDICES

Appendix A: Consumer Workshop Invitation Email

Appendix B: Participant Information and Consent Form (PICF) for Workshop Participation

Appendix C: Consumer Workshop Prompts

Appendix D: Demographic Questionnaire for Consumer Workshop

Appendix E: Consumer Workshop Email Requesting Use of Quotes

Appendix F: Participant Information and Consent Form (PICF) for Stepped-Care Evaluation

Appendix G: Evaluation Survey A

Appendix H: Patient Screening / Approach Log

Approach I: Routine Screening Measures

Appendix J: Evaluation Survey B – Self-Management Intervention

Appendix K: Evaluation Survey B – ConquerFear

Appendix L: Staff Engagement Survey

Appendix M: Case Report Form

Appendix N: Letter Accompanying FCR Screening

Appendix O: Invitation and Reminder Emails to Clinicians for the Staff Engagement Survey