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TITLE:

Protocol for the Implementation of a Stepped-Care Model to Address Fear of Cancer Recurrence in Patients Previously Diagnosed With Early-Stage (0-II) Melanoma

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Abbreviations:

AQOL-8D – Assessment of Quality of Life 8 Dimensions Questionnaire; DASS-21 – Depression, Anxiety and Stress Scales 21-item Short Form; FCR – fear of cancer recurrence; FCRI-SF – Fear of Cancer Recurrence Inventory 9-item Short Form; FCRI – Fear of Cancer Recurrence Inventory 42-item Form; MCP – Melanoma Care Program; MIA – Melanoma Institute Australia; MQA – Melanoma: Questions and Answers; REDCap – Research Electronic Data Capture.

ABSTRACT

Introduction

Fear of cancer recurrence (FCR) is commonly reported by patients diagnosed with early-stage (0-II) melanoma and can have a significant impact on daily functioning. This study will pilot the implementation of the Melanoma Care Program, an evidence-based, psychological intervention to reduce FCR into routine practice utilising a stepped-care model.

Methods and Analysis

Intervention effectiveness and level of implementation will be investigated using a hybrid type-I design. Four weeks before their next dermatological appointment, melanoma patients will be invited to complete the Fear of Cancer Recurrence Inventory Short-Form, measuring self-reported FCR severity. Using a stepped-care model, clinical cut-off points will guide the level of support offered to patients. This includes: (1) usual care, (2) *Melanoma: Questions and Answers* psycho-educational resource, and (3) three or five psychotherapeutic telehealth sessions. This longitudinal, mixed-method pilot implementation study aims to recruit 108 patients previously diagnosed with Stage 0-II melanoma at Melanoma Institute Australia affiliated sites: the Poche Centre and Sydney Melanoma Diagnostic Centre. The primary effectiveness outcome is change in FCR severity over time. Secondary outcomes include anxiety, depression, stress, health-related quality of life and melanoma-related knowledge. All outcomes are measured at baseline, within one week of the final telehealth session, and 6 and 12 months post-intervention. Implementation stakeholders at each study site and interested patients will provide feedback on intervention acceptability and appropriateness. Implementation stakeholders will also provide feedback on intervention cost, feasibility, fidelity, and sustainability. These outcomes will be measured throughout implementation, using questionnaires and semi-structured interviews/expert group discussions. Descriptive statistics, linear mixed-effect regression and content analysis will be used to analyse study data.

Ethics and Dissemination

Ethics approval was granted by the Sydney Local Health District – Royal Prince Alfred Zone (2020/ETH02518). Results will be disseminated through peer-reviewed journals, conference presentations, social media and result summaries distributed to interested participants.

Registration Details

Australia and New Zealand Clinical Trials Register (http://www.anzctr.org.au) (ACTRN12621000145808).

Keywords

Fear of cancer recurrence, stepped-care, intervention, psychological stress, implementation, melanoma, psycho-oncology.

ARTICLE SUMMARY

Strengths and Limitations of the Study

- This study aims to evaluate the pilot implementation of the evidence-based Melanoma Care Program into the routine clinical care of patients previously diagnosed with early-stage (0-II) melanoma.
- It is the first study to implement a stepped-care model to routinely screen for fear of cancer recurrence (FCR) in patients previously diagnosed with early-stage melanoma and tailor the intensity of intervention to reported FCR severity.
- Consumer representatives, practice managers, directors and clinicians have been involved throughout the study design process.
- The hybrid type-I design allows for the simultaneous evaluation of clinical and implementation outcomes.
- The primary limitation of this pilot implementation study is the absence of a comparison group, as withholding this intervention from patients who may benefit from it could not be justified, given prior evidence of its effectiveness.[1]

INTRODUCTION

Background and rationale

The global incidence of melanoma has steadily increased in the past several decades,[2] with an estimated 324,635 individuals receiving a diagnosis of melanoma in 2020.[3] Australia and New Zealand have the highest melanoma incidence rate in the world,[4] where it is the third most common cancer in Australian men and women.[5] In 2016, the Australian age-standardised incidence and mortality rate of melanoma was 53.5 cases per 100,000 and 4.5 deaths per 100,000, respectively.[5] Considering the average five-year survival rate of Australians with Stage I and II melanoma being 99.2% and 73.6% respectively,[5] there is growing attention to patient's psychosocial adjustment and quality of life. Among the most frequently reported challenges of this population is the fear of cancer recurrence (FCR),[6] defined as the fear, worry or concern that cancer may return or progress.[7] FCR is associated with lower emotional, physical, role and social functioning; poorer health care satisfaction; lower overall health-related quality of life; increased reassurance seeking behaviour; and increased fatigue, pain, distress, anxiety and depressive symptoms.[8]

The Melanoma Care Program (MCP) is a brief, evidence-based psychological intervention developed to address FCR in patients with a previous diagnosis of early-stage melanoma at risk of developing new primary disease.[1 9] The intervention consists of two components: (1) a psycho-educational resource entitled, *Melanoma: Questions and Answers* (MQA),[10] and (2) three psychotherapeutic telehealth sessions scheduled around patients' dermatological visits and delivered over a one-month period.[9] This is the first intervention specifically developed for patients with a previous diagnosis of early-stage melanoma who are at high risk of developing another primary melanoma. When investigated in a randomised controlled trial, intervention participants reported significantly lower FCR severity compared to a control group immediately post-intervention and at 6 months follow-up,[1] with effects sustained at 12 months

follow-up.[11] In addition, the intervention was well-accepted by patients,[1] and evidence suggests good value for money.[12] While the efficacy of this intervention was established, the randomised controlled trial did not assess patients' FCR severity prior to trial enrolment which would allow for tailoring intervention intensity to each patient's need. The present protocol outlines a pilot implementation study to translate and apply this evidence-based intervention into real-world clinical settings, using a stepped-care approach. Patients with a previous diagnosis of early-stage melanoma attending routine dermatological appointments will be screened for FCR and its severity assessed, allowing for the intensity of support to match the severity of the patients' FCR.

Study aims and hypotheses

The primary aim of this study is to examine the effectiveness of a stepped-care model offering a psychological intervention (henceforth referred to as 'stepped-care intervention') in reducing FCR severity in patients with a previous diagnosis of early-stage melanoma who are identified as having elevated FCR.

Secondary aims include:

- Evaluation of the effects of the stepped-care intervention on patient-reported depression, anxiety, stress, melanoma-related knowledge, health-related quality of life and the following aspects of FCR: triggers, psychological distress, coping strategies, functional impairments, insight, and reassurance.
- Evaluation of the sustainability of routine implementation of the stepped-care intervention in real-world clinical settings by documenting barriers (e.g. low screening uptake, time and cost of screening) and facilitators (e.g. participant engagement and screening adherence) to implementation and assessing the usefulness of strategies to address barriers.

It is hypothesised that:

I. Patients who report elevated FCR and receive the psycho-educational resource and psychotherapeutic telehealth counselling sessions will report immediately, and at 6 and 12 months' follow-up:
   a. A significant reduction in FCR severity;
   b. A decrease in FCR-related triggers, psychological distress, functional impairments, reassurance seeking behaviour and patient-reported levels of depression, anxiety and stress;
   c. An increase in FCR-related coping strategies and insight, melanoma-related knowledge and health-related quality of life compared with baseline scores.

II. The implementation of the stepped-care intervention will be considered:
   a. Acceptable and appropriate by patients who receive the intervention;
   b. Acceptable, appropriate, feasible and sustainable by implementation stakeholders.

III. The stepped-care intervention will be delivered with high fidelity and adherence to the therapist manual.

METHODS

Study design

Translational research investigates the degree to which an evidence-based practice retains its effectiveness when implemented into 'real-world' settings.[13] The hybrid effectiveness-implementation design, which takes a dual focus of assessing both the effectiveness and the implementation of an evidence-based practice, is commonly used in translational research studies.[14] Three variations of this design exist, based on the relative focus that is placed *a priori* on effectiveness and implementation outcomes. Type-I designs primarily evaluate the health

and well-being impact of an evidence-based practice, whilst also gathering contextual information on the implementation process to guide future implementation efforts.[14] Thus, a type-I design was selected for this study as it will be implemented in settings where its effectiveness is unknown, while evidence concerning its long-term sustainability is gathered to guide more extensive implementation efforts in the future.

Setting

This pilot implementation study will be conducted in two dermatology clinics specialising in the diagnosis and treatment of melanoma in Sydney, Australia: (1) Melanoma Dermatology, located at the Poche Centre, North Sydney; and (2) Sydney Melanoma Diagnostic Centre, located at Royal Prince Alfred Hospital, both affiliated with Melanoma Institute Australia (MIA) and the University of Sydney.

Participant selection

Two groups of participants will be included: (1) patients with a previous diagnosis of early-stage melanoma who have an upcoming appointment at either of the study sites, and (2) implementation stakeholders, including investigators of the original MCP randomised controlled trial, and individuals who are involved in the implementation of the intervention at one of the study sites (i.e. dermatologists, nurses, practice managers, administration staff). Table 1 outlines the study inclusion and exclusion criteria.

[Insert Table 1 here]

Participant recruitment

Patients

Four weeks prior to their routine scheduled dermatology appointment, patients will be invited to participate via an automated text message. This timeframe allows for individuals with high FCR to be identified and offered the intervention prior to the week of their appointment, when

anxiety is likely to be greatest.[15] The text message invitation contains a brief introduction to the study and a link to MIA's Research Electronic Data Capture (REDCap) webpage, which includes a landing page describing the study, the participant information statement, consent form, Fear of Cancer Recurrence Inventory Short Form (FCRI-SF)[16] and relevant questionnaires. During an eligible patient's next appointment, their clinician will check that the text message was received, answer any questions about the study, and, if interested, provide patients with a printed advertisement containing the link to MIA's REDCap or offer a paper information packet containing study materials.

Implementation stakeholders

The chief investigator at each study site will approach potential implementation stakeholders via email or in person. Additionally, members of the investigative team of the MCP randomised controlled trial will be invited via email to participate as implementation stakeholders, as these individuals have first-hand experience with the MCP intervention and may foresee possible implementation issues. A research assistant will email a participant information sheet and consent form to the implementation stakeholders who express interest in participation, with a reminder sent two weeks' following the initial email if no response is received.

Intervention description

Melanoma: Questions and Answers resource

The *Melanoma: Questions and Answers* (MQA) psycho-educational resource was originally developed by a multidisciplinary team to provide comprehensive information on a range of melanoma-related topics.[10] As part of standard care at MIA, patients diagnosed with early-stage melanoma are provided with the *Your Guide to Early Melanoma* (3rd Edition) booklet,[17] which contains similar information on melanoma diagnosis, treatment and risk factors as the MQA resource.

In an effort to reduce costs and increase the long-term sustainability of the MQA resource, the first two chapters of the MQA resource which focus on melanoma diagnosis, treatment and risk factors will be reviewed and consolidated into one chapter. The MQA resource will also encourage patients who want more information to speak to their medical practitioner, and to refer to the MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet. The revision of the MQA resource will be completed by a consumer representative, melanoma clinicians and researchers.

Psychotherapeutic telehealth sessions

The content of the psychotherapeutic telehealth sessions is outlined in the MCP psychologist manual, which will not be altered for the present study. The content of these telehealth sessions is outlined in Table 2. To maximise fidelity to the treatment protocol, in addition to the psychologist manual, the lead psychologist (NK) involved in the MCP randomised controlled trial will train the psychologist(s) delivering the stepped-care intervention as a part of the present study.

[Insert Table 2 here]

Stepped-care model of intervention delivery

Patients who participate in this pilot implementation study will be placed into a stepped-care model.[18] This will allow the intervention to be tailored to each patients' severity of FCR, potentially maximising overall benefit and service provision efficiency whilst conserving resources.[18]

Patients will be invited to complete FCR screening using the FCRI-SF approximately four weeks before their scheduled dermatological appointment. The FCRI-SF is measured using a nine item, five-point Likert scale with scores ranging from 0 to 36, with higher scores indicating greater FCR severity.[16] Cut-off scores of 13/36[19] and 22/36[20] have been suggested in the

literature, which will be used to guide the placement of patients into different levels of the stepped-care model (Table 3).

[Insert Table 3 here]

Patients triaged to Step 1 (low FCR) will receive usual care, consisting of clinical follow-up and MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet. Patients triaged to Step 2 (moderate FCR) and Step 3 (severe FCR) will continue to receive usual care, as well as the MQA resource and their contact details being provided to the psychologist responsible for facilitating the psychotherapeutic telehealth sessions. The psychologist will contact patients to schedule their first session as soon as possible, ideally conducting the first session before the patients' upcoming dermatology appointment. Subsequent telehealth sessions will be conducted on a flexible two-week basis.

Data collection

Patients

In addition to completing the FCRI-SF, patients triaged to Step 1 (low FCR) will complete a demographic questionnaire. Patients triaged to Step 2 (moderate FCR) and Step 3 (severe FCR) will complete the demographic questionnaire plus a baseline questionnaire collecting data relating to the outcome measures of interest. Patients triaged to Step 2 or 3 will also complete three questionnaires within one-week of completing their final telehealth session and at 6 and 12 months' follow-up. Furthermore, patients will be invited to participate in a semi-structured interview to explore their perceptions and experiences of the stepped-care intervention within one-week of completing their final telehealth session. The Theoretical Framework of Acceptability[21] will be used to guide these semi-structured interviews. This framework consists of seven component constructs relevant to intervention acceptability: affective

attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Patients will choose whether to complete questionnaires electronically (MIA's REDCap) or in paper format. A reminder email/letter will be sent to patients who do not provide a response after two weeks, with a telephone reminder after four weeks.

Implementation stakeholders

Three expert groups will be formed to explore the perceptions of implementation stakeholders, with the intent to gather information about barriers and facilitators to implementation at the study sites. The first expert group, consisting of investigators of the MCP randomised controlled trial, will meet pre-implementation to discuss barriers and facilitators experienced during the trial and any foreseeable barriers during implementation in routine clinical practice. The second and third expert groups, consisting of implementation stakeholders at the two study sites, will meet three months prior to, and quarterly throughout implementation to discuss key barriers affecting implementation and strategies to address them, meeting a final time three months post-implementation to discuss long-term sustainability of the intervention. These expert group discussions will be guided by the Consolidated Framework for Implementation Research.[22]

Formative evaluation will be used to assess the effectiveness of any strategies put in place to address barriers that are identified during the implementation process.[13] To do so, information collected before, during and after implementation will be shared amongst investigators and stakeholders, allowing the implementation process to adapt to any identified barriers.[13] This method will allow investigators to evaluate the effects of strategies used to address barriers to implementation.

At the conclusion of each expert group, implementation stakeholders will be offered questionnaires to quantitatively explore the acceptability, appropriateness, and feasibility of the intervention. These questionnaires will be offered electronically or in paper format. Reminder emails/letters will be sent within two weeks if a response has not been received, with a telephone call made at four weeks.

Outcomes

The hybrid type-I design will allow this pilot implementation study to evaluate both effectiveness and implementation outcomes, with the primary focus being on the effectiveness of the stepped-care intervention in reducing patient FCR severity. The summary of the outcome assessment methods is presented in Table 4.

[Insert Table 4 here]

Primary effectiveness outcome

The primary outcome of this study is self-reported levels of FCR severity using the validated severity subscale (i.e. FCRI-SF) of the Fear of Cancer Recurrence Inventory 42-item Form (FCRI).[16]

Secondary effectiveness outcomes

All other subscales of the FCRI (triggers, psychological distress, coping strategies, functional impairments, insight, and reassurance) will be measured and reported as secondary outcomes. The FCRI consists of 42 items that patients answer using a five-point Likert scale. Higher scores indicate higher levels of FCR. The FCRI has demonstrated psychometric properties (Table 4) and has been validated in Australians with a history of early-stage melanoma.[23]

Melanoma-related knowledge will be measured using a purpose-designed questionnaire, adapted from the MCP. This questionnaire will be updated in tandem with the MQA resource,

to ensure the questions and answers continue to reflect the information provided in the booklet. Higher scores on this scale correspond to higher levels of melanoma-related knowledge, which is measured using multiple choice, true/false and yes/no style questions.

Depression, anxiety and stress will be measured using the Depression, Anxiety and Stress Scales 21-item Short Form (DASS-21).[24] The DASS-21 is measured using a four-point Likert scale, with higher scores indicating more severe symptoms of depression, anxiety or stress. The DASS-21 has demonstrated psychometric properties (see Table 4) and has clinical cut-off[24] and clinically meaningful[25] scores defined.

Health-related quality of life will be measured using the Assessment of Quality of Life – 8 Dimensions (AQOL-8D).[26] The AQOL-8D contains 35 questions to which patients respond using Likert scales ranging from four-to-six points. The AQOL-8D has demonstrated psychometric properties (see Table 4). The AQOL-8D scores comprise two super dimensions (physical and psychosocial) consisting of eight smaller dimensions (independent living, pain, senses, mental health, happiness, coping, relationships, and self-worth). Higher scores indicate worse quality of life.

Implementation outcomes

Acceptability, appropriateness and *feasibility* of the stepped-care intervention will be quantitatively measured using the Acceptability of Intervention Measure, Intervention Appropriateness Measure and Feasibility of Intervention Measure respectively.[27] Each of these measures consist of four positively worded items, which are measured on a five-point Likert scale, with higher scores indicating greater acceptability, appropriateness and feasibility. As no cut-off scores for these measures exist, scores of 4/5 (agree) and 5/5 (strongly agree) will be used to indicate that the stepped-care intervention is considered acceptable, appropriate and feasible by participants. In addition, semi-structured interviews with patients and expert group

discussions with implementation stakeholders will be used to further explore the perceptions of participants. Acceptability will also be measured using intervention adherence rates (i.e. number of patients who consent to participate, complete the stepped-care intervention and follow-up questionnaires).

The *cost* of this implementation will be reported using process data, which will include costs associated with the MQA resource (i.e. time to review and update, graphic designing, printing), training, salary of a psychologist, text messaging, online screening and survey development, stationary, transcribing interviews and any other incidental expenses. These expenditures will be categorised into costs associated with research, initiating implementation and ongoing implementation.

Fidelity of the telehealth sessions to the psychologist manual will be assessed using a purpose-designed fidelity checklist adapted from the MCP.[1] This checklist includes items specifically designed to review the content of each session, including the items from the Comparative Psychotherapy Process Scale,[28] Revised Cognitive Therapy Scale[29] and Interpretive and Supportive Technique Scale.[30] To ensure the psychologist manual is adequately followed, 10% of conducted telehealth sessions will be randomly reviewed and assessed using this checklist.

Finally, *sustainability* will be assessed through the degree to which the intervention has been incorporated into routine clinical care at the study sites. The sustainability of the stepped-care intervention will be discussed with implementation stakeholders through expert group discussions.

Sample size

At 12 months post-intervention, the MCP randomised controlled trial demonstrated a reduction in FCR severity of -1.41.[11] Based on this value, a sample size of 86 will provide 90% power to detect an overall before/after difference of -1.41 in FCR severity between baseline and 12

months post-intervention. This sample size calculation is based on a paired mean difference design with a standard deviation of 4.0 and type-1 (alpha) error rate set to 0.05.[31] Assuming a conservative lost-to-follow-up rate of 20%, a final sample of 108 patients across both study sites will be recruited and offered the stepped-care intervention. As it is anticipated that approximately 63% of patients who complete screening will be offered the intervention,[32] an estimated 172 patients will complete screening. However, recruitment and screening will continue until the required sample of 108 patients is achieved.

Data analysis plan

Descriptive statistics will be used to describe demographic trends within the study sample. Linear mixed-effect regression will be used to analyse the effect of the intervention on patient psychosocial outcomes, as it can robustly deal with missing data and perform hypothesis testing on longitudinal data.[33] Moderation analysis will also be used to examine the effects of covariates on the relationship between all outcomes and independent variables through linear regression.[34] Thematic analysis will be used to analyse the semi-structured interviews and expert group discussions conducted throughout the study for common themes regarding facilitators and barriers.[35] Quantitative analysis will be completed in IBM SPSS Statistics 26 (Armonk, NY: IBM Corp) and RStudio (RStudio Team 2019, version 1.2.5033); qualitative analysis will be conducted using NVivo 12 Plus (QSR International Pty Ltd.) to assist in data management.

Ethics

This pilot implementation study has received ethical approval from the Sydney Local Health District – Royal Prince Alfred Zone (2020/ETH02518). Based on the MCP randomised controlled trial, it is unlikely that the participants will experience adverse effects from the stepped-care intervention, as only three participants (4%) found discussing their melanoma

experiences with a psychologist confronting.[36] The psychologist delivering the telehealth sessions will address this discomfort, and provide additional information and resources as needed. Furthermore, any participants identified to have a significant co-morbid mental health condition will be referred for community mental health support to better address their needs.

Dissemination plans

Results will be shared with academics, researchers, clinicians, interested patients and other key stakeholders. The investigative team has agreed that the results will be disseminated to academic and clinical audiences through peer-reviewed journals, scientific meetings, and conferences. The results of the study will be reported according to the Standards for Reporting Implementation Studies statement.[37] The associated checklist[38] will be used to ensure all relevant aspects of the intervention study are included in analysis and reporting.

Additionally, lay summaries of results will be shared with interested patients, consumers, implementation stakeholders and posted on the MIA website and social media. Participants may elect to receive this lay summary during the consent process.

Data availability

To facilitate research transparency, reproducibility and accuracy, de-identified data will be available for sharing. Interested researchers can contact the corresponding investigator following the publication of the 12-month follow-up data. Data access will be granted to the projects that are considered by the investigative team to be methodologically sound and Human Research Ethics Committee-approved. The investigative team will create a project-specific workspace within MIA's secure server, which will house the de-identified data and technical appendices.

Patient and public involvement statement

The investigative team included a consumer representative since conception. This team member has provided feedback and guidance on the aims, design, and outcomes of the study. This included substantial input in the development of materials provided to patients (including review of the MQA resource), providing their approval of the intervention and the time commitment required to participate in the study. Furthermore, the original MQA psycho-educational booklet used in the MCP randomised controlled trial was pilot tested with 19 melanoma patients with content revised based on their feedback.[10] Finally, consumer representatives will be involved in results interpretation and development of lay summaries of the results.

DISCUSSION

Strengths

This pilot implementation study represents the next logical step in the translation of an evidence-based psychotherapeutic intervention to reduce FCR in patients with a previous diagnosis of early-stage melanoma into routine clinical practice. The study design will allow for concurrent assessment of effectiveness and implementation variables using a mixed-methods design which includes quantitative data obtained through use of validated and accepted outcome measures, with contextual information obtained from interviews and expert groups. Screening will be used to identify patients experiencing elevated FCR and to ensure each patient is offered the appropriate level of support to address their needs. This screening will take place approximately four weeks before a scheduled appointment in an attempt to capture the background levels of FCR experienced by the patient, as fear often increases in the week before an appointment.[15] Consumer representatives, practice managers, directors and clinicians were included in the study design process, ensuring the intervention has the utmost relevance to patient needs and will suit the organisational structure of the study sites.

Limitations

The MQA resource will be changed from the resource used in the MCP randomised controlled trial. Furthermore, the study design precludes determination of the relative contribution of the educational resources and psychotherapeutic sessions in achieving outcomes. A comparison group would address this limitation; however, the inclusion of a comparison group would withhold evidence-based intervention from patients who may benefit from it, and thus is considered unethical. Available epidemiological evidence will act as an *ad hoc* comparison, as cancer patient FCR levels often remain stable over time.[8]

Significance

Information on the implementation of evidence-based psychosocial interventions into routine melanoma practice is sparse. Only one study was identified that evaluated the implementation of a FCR intervention into routine practice. The Fear-Less[39] study evaluated a stepped-care model on metastatic (Stage IV) melanoma patients, utilising the ConquerFear[40] intervention, which, in a clinical trial was found to be effective in reducing FCR in breast and colorectal cancer and melanoma patients.[41] Fear-Less was found to be both acceptable and feasible. The small sample size precluded determination whether the observed reduction in FCR was statistically significant or clinically meaningful. This study: will be the first to provide a stepped-care intervention for patients with a previous diagnosis of early-stage melanoma reporting elevated FCR in routine clinical practice, using an intervention that has been specifically created for and evaluated with melanoma patients; addresses both the international[42] and Australian[43] research agenda for FCR, specifically as it utilises a stepped-care model, facilitates routine implementation of an evidence-based intervention, and provides access to telehealth interventions to patients outside of clinical trials; is sufficiently powered to assess the impact of the intervention on FCR severity; and will be the first to investigate the acceptability, appropriateness, feasibility, fidelity and sustainability of a psychosocial

intervention implemented into routine practice to address FCR in patients previously diagnosed with early-stage melanoma, from both the consumer and service-provider perspective. The implementation information obtained may be used in future implementation efforts as research moves from the strict confines of clinical trials into real-world settings.

Authors Contributions:

NAK, RS, MD, JRT, IB, and AEC were responsible for the concept of this study. JRT, IB, ALS, LS, LM, PG, NAK, RS, MD, HS, AEC and DM contributed to study design, and intervention and materials development. JRT, IB, LM, PG and ALS will be responsible for overseeing the implementation process. JRT, IB and AS will be responsible for data collection. JRT, IB, ALS, MD and SL will conduct the statistical analysis of results. All authors will be involved in results interpretation. All authors contributed and approved this manuscript.

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Competing interests:

Robyn Saw has received honoraria for advisory board participation from MSD, Novartis and QBiotics and speaking honoraria from BMS. Donna Milne has received honoraria for advisory board participation from MSD, BMS and Novartis and speaking honoraria from BMS and MSD.

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TABLES

Table 1. Participant inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Melanoma Patients	• Previous diagnosis of Stage 0, I or II melanoma. • Sufficient English language skills and cognitive ability to understand study materials and provide informed consent. • Sufficient hearing to participate in telehealth consultations. • Aged 18 years or older.	• Previous diagnosis of Stage III or IV melanoma. • At high risk of, but no previous diagnosis of melanoma. • Significant cognitive impairment that would prevent understanding of the study materials and ability to provide informed consent. • Significant hearing impairment preventing participation in telehealth consultations. • Current diagnosis of severe depression, psychotic illness or other serious psychiatric condition. • Below 18 years of age.
Implementation Stakeholders	• Member of the MCP randomised controlled trial investigative team, OR Current employee of Melanoma Institute Australia or Sydney Melanoma Diagnostic Centre and directly involved in the implementation of the intervention. • Sufficient English language skills and cognitive ability to understand study materials and provide informed consent. • Aged 18 years or older.	• Significant cognitive impairment that would prevent understanding of the study materials and ability to provide informed consent. • Employed by Melanoma Institute Australia or Sydney Melanoma Diagnostic Centre but not directly involved in implementation of the stepped-care intervention. • Below 18 years of age.

Table 2. Outline of psychotherapeutic telehealth sessions

Session	**Content** (Dieng et al.[9])
Introduction	The psychologist introduces themselves to the patient, checks all materials have been received, re-confirms consent and schedules the first session.
Session 1	The psychologist assesses patient needs, referring to the MQA resource where appropriate when discussing any concerns or unmet needs the patient has.
Sessions 2-4	The psychologist reviews previous session(s) with the patient and discusses any difficulties that have arisen since. The psychologist will continue to address the unmet needs of patients utilising the MQA resource where possible.
Final Session	The psychologist reviews all previous sessions and addresses any new difficulties. The psychologist discusses the degree to which patient unmet needs have been addressed, new strategies to address possible future concerns and referral for further support if required.

Table 3. Stepped-care model

Steps of Intervention	FCRI-SF Clinical Cut Off Score	Usual Care*	MQA resource	Number of psychotherapeutic telehealth sessions
Step 1 Low FCR	<13	✓	-	0
Step 2 Moderate FCR	13-21	✓	✓	3
Step 3 Severe FCR	>21	✓	✓	5
Step 4 Significant co-morbid mental health condition	N/A†	✓	✓	Referral‡

MQA, Melanoma Questions and Answers

* Patient education and support as per usual clinical practice, including the provision of MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet.

† Identified through baseline questionnaire and clinical judgement during telehealth sessions.

‡ Referred to community mental health specialist or general practitioner.

Table 4. Outcome variables, measures, psychometric properties, and timeline of data collection

Primary Effectiveness Outcome

Variable	Measures	Participants	Reliability	Validity	E0	E1	E2	E3
Fear of cancer recurrence	FCRI	Patients	Internal consistency, test-retest[16 44]	Concurrent, convergent, discriminant[16 44]	✓	✓	✓	✓

Secondary Effectiveness Outcomes

Variable	Measures	Participants	Reliability	Validity	E0	E1	E2	E3
Demographic information	Demographic questionnaire	Patients	N/A	N/A	✓	-	-	-
Melanoma-related knowledge	Purpose-designed questionnaire	Patients	N/A	N/A	✓	✓	✓	✓
Depression, anxiety and stress	DASS-21	Patients	Internal consistency[45-49]	Concurrent, convergent, discriminant[45-47]	✓	✓	✓	✓
Health-related quality of life	AQOL-8D	Patients	Internal consistency, test-retest[50-52]	Concurrent, convergent, discriminant[50 52-54]	✓	✓	✓	✓

Implementation Outcomes

Variable	Measures	Participants	I1	I2	I3
Acceptability	Acceptability of Intervention Measure	Patients*, Implementation Stakeholders	✓	✓	✓
	Semi-structured interviews	Patients†	-	-	-
	Expert group discussions	Implementation Stakeholders	✓	✓	✓
	Process data	N/A	✓	✓	✓
Appropriateness	Intervention Appropriateness Measure	Patients*, Implementation Stakeholders	✓	✓	✓
	Semi-structured interviews	Patients†	-	-	-

	Expert group discussions	Implementation Stakeholders	✓	✓	✓
Feasibility	Feasibility of Intervention Measures	Implementation Stakeholders	✓	✓	✓
	Expert group discussions	Implementation Stakeholders	✓	✓	✓
Cost	Process data	N/A	✓	✓	✓
Fidelity	Review of telehealth sessions	Implementation Stakeholders	-	-	✓
Sustainability	Expert group discussions	Implementation Stakeholders	-	✓	✓

E0, baseline; E1, one week follow-up; E2, 6 months' follow-up; E3, 12 months' follow-up.
I1, three months pre implementation; I2, quarterly throughout implementation; I3, three months post implementation.
* Patients will complete the Acceptability of Intervention Measure and Intervention Appropriateness measure within one week of completing their final telehealth session, 6 and 12 months' follow-up.
† Patients will be invited to participate in semi-structured interviews within one week of completing their final telehealth session.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	6-7	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	9-10	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	9-12	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	9-10	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	10-11	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	11-17	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	N/A	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	12	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	12-13	The population targeted by the intervention and any eligibility criteria.
Description	**9**	14-15	A description of the implementation strategy	14	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	18-19	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	17-18	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	18-19	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	19	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	19	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	20	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	20	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		
Results					

Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	18-19	Primary and other outcome(s) of the implementation strategy	17-18	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	21	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	22-24	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	23-24	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	23-24	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	4, 7, 21-22	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

BMJ Open

Protocol for the Implementation of a Stepped-Care Model to Address Fear of Cancer Recurrence in Patients Previously Diagnosed With Early-Stage (0-II) Melanoma

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Protocol for the Implementation of a Stepped-Care Model to Address Fear of Cancer Recurrence in Patients Previously Diagnosed With Early-Stage (0-II) Melanoma

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Abbreviations:

AQOL-8D – Assessment of Quality of Life 8 Dimensions Questionnaire; DASS-21 – Depression, Anxiety and Stress Scales 21-item Short Form; FCR – fear of cancer recurrence; FCRI-SF – Fear of Cancer Recurrence Inventory 9-item Short Form; FCRI – Fear of Cancer Recurrence Inventory 42-item Form; HRQOL – Health-related Quality of Life; MCP – Melanoma Care Program; MCP-SCI – Melanoma Care Program Stepped Care Intervention; MIA – Melanoma Institute Australia; MQA – Melanoma: Questions and Answers.

ABSTRACT

Introduction

Fear of cancer recurrence (FCR) is commonly reported by patients diagnosed with early-stage (0-II) melanoma and can have a significant impact on daily functioning. This study will pilot the implementation of the Melanoma Care Program, an evidence-based, psychological intervention to reduce FCR into routine practice utilising a stepped-care model.

Methods and Analysis

Intervention effectiveness and level of implementation will be investigated using a hybrid type-I design. Between four weeks before and one week after their next dermatological appointment, melanoma patients will be invited to complete the Fear of Cancer Recurrence Inventory Short-Form, measuring self-reported FCR severity. Using a stepped-care model, clinical cut-off points will guide the level of support offered to patients. This includes: (1) usual care, (2) *Melanoma: Questions and Answers* psycho-educational booklet, and (3) three or five psychotherapeutic telehealth sessions. This longitudinal, mixed-method pilot implementation study aims to recruit 108 patients previously diagnosed with Stage 0-II melanoma. The primary effectiveness outcome is change in FCR severity over time. Secondary effectiveness outcomes include anxiety, depression, stress, health-related quality of life and melanoma-related knowledge. All outcomes are measured at baseline, within one week of the final telehealth session, and 6 and 12 months post-intervention. Implementation stakeholders at each study site and interested patients will provide feedback on intervention acceptability and appropriateness. Implementation stakeholders will also provide feedback on intervention cost, feasibility, fidelity, and sustainability. These outcomes will be measured throughout implementation, using questionnaires and semi-structured interviews/expert group discussions. Descriptive statistics, linear mixed-effect regression and thematic analysis will be used to analyse study data.

Ethics and Dissemination

Ethics approval was granted by the Sydney Local Health District – Royal Prince Alfred Zone (2020/ETH02518), protocol number: X20-0495. Results will be disseminated through peer-reviewed journals, conference presentations, social media and result summaries distributed to interested participants.

Registration Details

This pilot implementation study was registered with the Australia and New Zealand Clinical Trials Register on the 12th February 2021 (http://www.anzctr.org.au) (ACTRN12621000145808). All details of the World Health Organisation's Trial Registration Data Set can be found within this article and the corresponding trial registry on the Australia and New Zealand Clinical Trials Register webpage.

Keywords

Fear of cancer recurrence, stepped-care, intervention, psychological stress, implementation, melanoma, psycho-oncology.

ARTICLE SUMMARY

Strengths and Limitations of the Study

- This study aims to evaluate the pilot implementation of the evidence-based Melanoma Care Program into the routine clinical care of patients previously diagnosed with early-stage (0-II) melanoma.
- It is the first study to implement a stepped-care model to routinely screen for fear of cancer recurrence (FCR) in patients previously diagnosed with early-stage melanoma and tailor the intensity of intervention to reported FCR severity.
- Consumer representatives, practice managers, directors and clinicians have been involved throughout the study design process.
- The hybrid type-I design allows for the simultaneous evaluation of clinical and implementation outcomes.
- The primary limitation of this pilot implementation study is the absence of a recruited control group, however control group data from the Melanoma Care Program randomised controlled trial will be used as an *ad hoc* comparison group.[1]

INTRODUCTION

Background and rationale

The global incidence of melanoma is increasing,[2] with an estimated 324,635 individuals receiving a diagnosis of melanoma in 2020.[3] Australia and New Zealand have the highest melanoma incidence rate in the world.[4] In 2016, the Australian age-standardised incidence and mortality rate of melanoma were 53.5 cases per 100,000 and 4.5 deaths per 100,000, respectively.[5] The average five-year survival rate of stage I and II melanoma patients is 99.2% and 73.6% respectively,[5] increasing the importance of their psychosocial adjustment and quality of life. Fear of cancer recurrence (FCR), defined as the fear, worry or concern that cancer may return or progress,[6] is the most frequently reported challenge of this population.[7] FCR is associated with: lower emotional, physical, role and social functioning, and health-related quality of life (HRQOL); poorer health care satisfaction; and increased reassurance seeking behaviour, fatigue, pain, distress, anxiety and depressive symptoms.[8]

A meta-analysis of 23 psychological interventions targeting FCR found them to be effective; however, only one intervention, The Melanoma Care Program (MCP), focused on Australian melanoma patients.[9] The MCP is a brief, evidence-based psychological intervention developed to address FCR in patients with a previous diagnosis of early-stage melanoma at risk of developing new primary disease.[1,10] The intervention consists of two components: (1) a *Melanoma: Questions and Answers* (MQA) psycho-educational booklet,[10,11] and (2) three psychotherapeutic telehealth sessions scheduled around patients' dermatological visits and delivered over a one-month period.[10] This is the first intervention specifically developed for patients with a previous diagnosis of early-stage melanoma. When investigated in a randomised controlled trial, intervention participants reported significantly lower FCR severity compared to a control group immediately post-intervention and at 6 months follow-up,[1] with effects sustained at 12 months follow-up.[12] The intervention was also well-accepted by patients[1] and

cost-effective.[13] While the efficacy of this intervention was established, the randomised controlled trial did not assess patients' FCR severity prior to trial enrolment to tailor intervention intensity to patient need. The present protocol outlines a pilot implementation study to translate this evidence-based intervention into real-world clinical settings, using a stepped-care approach. Patients with a previous diagnosis of early-stage melanoma attending routine dermatological appointments will be screened for FCR, allowing the intensity of support to match the severity of the patients' FCR.

Study aims and hypotheses

The primary aim of this study is to examine the effectiveness of a stepped-care model offering the MCP (henceforth referred to as the 'Melanoma Care Program – stepped-care intervention' or MCP-SCI) in reducing FCR severity in patients with a previous diagnosis of early-stage melanoma who are identified as having elevated FCR in routine clinical practice.

Secondary aims include:

- Evaluation of the effects of the MCP-SCI on patient-reported depression, anxiety, stress, melanoma-related knowledge, HRQOL and further aspects of FCR: triggers, psychological distress, coping strategies, functional impairments, insight, and reassurance.
- Evaluation of the sustainability of routine implementation of the MCP-SCI in real-world clinical settings by documenting barriers (e.g. low screening uptake, time and cost of screening) and facilitators (e.g. participant engagement and screening adherence) and assessing the usefulness of strategies to address barriers.

It is hypothesised that:

I. Patients who report elevated FCR and receive the MCP-SCI will report immediately, and at 6 and 12 months' follow-up:
   a. A significant reduction in FCR severity;
   b. A decrease in FCR-related triggers, psychological distress, functional impairments, reassurance seeking behaviour and patient-reported levels of depression, anxiety and stress;
   c. An increase in FCR-related coping strategies and insight, melanoma-related knowledge and HRQOL compared with baseline scores.

II. The implementation of the MCP-SCI will be considered:
   a. Acceptable and appropriate by patients who receive the intervention;
   b. Acceptable, appropriate, feasible and sustainable by implementation stakeholders.

III. The MCP-SCI will be delivered with high fidelity and adherence to the therapist manual.

METHODS

Study design

Translational research investigates the degree to which an evidence-based practice retains its effectiveness when implemented into 'real-world' settings.[14] The hybrid effectiveness-implementation design, which takes a dual focus of assessing both the effectiveness and the implementation of an evidence-based practice, is commonly used in translational research studies.[15] Three variations of this design exist, based on the relative focus that is placed *a priori* on effectiveness and implementation outcomes. Type-I designs primarily evaluate the health and well-being impact of an evidence-based practice in real-world settings, whilst also gathering contextual information on the implementation process to guide future implementation efforts.[15] Thus, a type-I design was selected for this study to investigate the

effects of the MCP-SCI in routine practice, while evidence concerning its long-term sustainability is gathered to guide more extensive implementation efforts in the future.

Setting

Implementation will take place at two of the three dermatology clinics specialising in the diagnosis and treatment of melanoma that participated in the MCP randomised controlled trial.[1,10] The first study site, Melanoma Dermatology, is located within the Poche Centre at Melanoma Institute Australia (MIA), the world's largest melanoma research and treatment facility. The second study site, Sydney Melanoma Diagnostic Centre, is also associated with MIA but is located at Royal Prince Alfred Hospital. Both study sites: are located in metropolitan Sydney, Australia; are mixed public and private practices that have extensive experience in conducting melanoma-related research and implementation studies; have a strong organisational emphasis on multidisciplinary collaboration, research and clinician training; consist of roughly a dozen clinicians and administration staff; and primarily see melanoma patients at high risk of recurrence.

Participant selection

Two groups of participants will be included: (1) patients with a current or previous diagnosis of early-stage melanoma who have an upcoming follow-up appointment at either of the study sites, and (2) implementation stakeholders, including investigators of the MCP randomised controlled trial, and individuals who are involved in the implementation of the MCP-SCI at one of the study sites (i.e. dermatologists, nurses, practice managers, administration staff). Table 1 outlines the study inclusion and exclusion criteria.

[Insert Table 1 here]

Participant recruitment

Patients

Four weeks prior to their routine scheduled appointment, patients will be invited to participate via an automated text message. This timeframe allows for individuals with high FCR to be identified and offered the intervention prior to the week of their appointment, when anxiety is likely to be greatest.[16] The text message invitation contains a brief introduction to the study and a link to MIA's Research Electronic Data Capture webpage, which includes a landing page describing the study, the participant information statement, consent form, Fear of Cancer Recurrence Inventory Short Form (FCRI-SF)[17] and relevant questionnaires. During an eligible patient's appointment, their clinician will check that the text message was received and answer any questions about the study. If the patient did not receive the text message, the clinician can discuss the study with the patient and collect their contact details if interested. A research assistant will then call the patient within 48 hours of the appointment to discuss the study.

Implementation stakeholders

The chief investigator at each study site will approach potential implementation stakeholders via email or in person. Additionally, members of the investigative team of the MCP randomised controlled trial will be invited to participate as implementation stakeholders, as these individuals have first-hand experience with the intervention and may foresee possible implementation issues. A reminder invitation will be sent two weeks' following initial contact if no response is received.

The recruitment of implementation stakeholders began in June 2021. Patient recruitment is scheduled for January 2022. Study completion is expected by October 2023.

Intervention description

Melanoma: Questions and Answers booklet and psychotherapeutic telehealth sessions

The MCP intervention consists of the MQA booklet and psychotherapeutic telehealth sessions. These two components have not been substantially altered for the present pilot implementation study. Table 2 provides a brief description of the MCP intervention provided to patients in the randomised controlled trial and outlines the justification for any modifications made for the present implementation study.

[Insert Table 2 here]

The content of the psychotherapeutic telehealth sessions is provided in Table 3.

[Insert Table 3 here]

Stepped-care model of intervention delivery

The addition of a stepped-care model of care will allow the intervention to be tailored to each patient's severity of FCR, potentially maximising overall benefit and service provision efficiency whilst conserving resources.[20]

Patients will be invited to complete FCR screening using the FCRI-SF. The FCRI-SF is measured using a nine item, five-point Likert scale with scores ranging from 0 to 36, with higher scores indicating greater FCR severity.[17] Multiple cut-off scores have been suggested in the literature. For the purpose of this pilot implementation study, a cut-off score of ≥ 13[21] will be used to identify patients with clinically indicative levels of FCR to receive the MCP-SCI, with a second cut-off core of ≥ 22[22] used to identify patients with more severe levels of FCR at baseline (Table 4). These cut-off scores were chosen as a preference was placed on sensitivity over specificity to ensure patients experiencing FCR are captured, and the MCP randomised controlled trial sub-group analysis finding participants scoring ≥ 13 at baseline experienced a

significant decrease in FCR severity at 6-months follow-up,[1] whereas participants scoring ≥ 22 at baseline experienced no significant decrease,[12] which investigators attributed to potential dose effect. Hence it was decided to offer an additional two sessions to those who score ≥ 22 at baseline to investigate its effects.

[Insert Table 4 here]

Patients triaged to Step 1 (no/low FCR) will receive usual care, consisting of clinical follow-up and MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet. Patients triaged to Step 2 (moderate FCR) and Step 3 (severe FCR) will continue to receive usual care as well as being offered the MCP intervention, with the difference between these Steps being the number of telehealth sessions offered to the patient (Table 3). The psychologist(s) will contact patients to schedule their first session as soon as possible, ideally conducting the first session before the patients' upcoming appointment. Subsequent telehealth sessions will be conducted on a flexible two-week basis.

Data collection

Patients

In addition to completing the FCRI-SF, patients triaged to Step 1 (no/low FCR) will complete a demographic questionnaire. Patients triaged to Step 2 (moderate FCR) and Step 3 (severe FCR) will complete the demographic questionnaire plus a baseline questionnaire collecting data relating to the outcome measures of interest. Patients triaged to Step 2 or 3 will also complete questionnaires within one-week of completing their final telehealth session and at 6 and 12 months' follow-up. All patients who receive the intervention will be invited to participate in a semi-structured interview during their first follow-up questionnaire to explore their experiences of the MCP-SCI. Recruitment will continue until thematic saturation is reached, and purposeful sampling used to ensure a range of experiences are captured. The

Theoretical Framework of Acceptability[23] will be used to guide these semi-structured interviews. This framework consists of seven component constructs relevant to intervention acceptability: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Patients will choose whether to complete questionnaires electronically or in paper format. A reminder email/letter will be sent to patients who do not provide a response after two weeks, with a telephone reminder after four weeks.

Implementation stakeholders

Three expert groups will be formed to explore the perceptions of implementation stakeholders to gather information about barriers and facilitators to implementation. The first group, consisting of investigators of the MCP randomised controlled trial, will meet pre-implementation to discuss barriers and facilitators experienced during the trial and any foreseeable barriers during implementation in routine clinical practice. The second and third groups, consisting of implementation stakeholders at the two study sites, will meet three months prior to, and quarterly throughout implementation to discuss key barriers and strategies to address them, meeting a final time three months post-implementation to discuss long-term sustainability of the intervention. These expert group discussions will be guided by the Consolidated Framework for Implementation Research and will be audio-recorded and transcribed for thematic analysis.[24]

Formative evaluation will be used to assess the effectiveness of any strategies put in place to address barriers that are identified during the implementation process,[14] with information collected shared with investigators and stakeholders allowing the implementation process to adapt to any identified barriers. Summaries of each expert group and agreed upon modifications will be provided to the study sites within a week of each expert group discussion, allowing

implementation stakeholders to enact any changes. This will allow investigators to evaluate the effects of strategies used to address barriers to implementation.

At the conclusion of each expert group, implementation stakeholders will be offered questionnaires to quantitatively explore the acceptability, appropriateness, and feasibility of the intervention.

Outcomes

Consistent with the hybrid type-I design the primary outcome is the effectiveness of the MCP-SCI in reducing patient FCR severity. The summary of the outcome assessment methods is presented in Table 5.

[Insert Table 5 here]

Primary outcome

The primary outcome of this study is patient self-reported levels of FCR severity using the FCRI-SF, the severity subscale of the Fear of Cancer Recurrence Inventory 42-item Form (FCRI).[17]

Secondary effectiveness outcomes

All other subscales of the FCRI (triggers, psychological distress, coping strategies, functional impairments, insight, and reassurance) will be measured and reported as secondary outcomes. The FCRI consists of 42 items that patients answer using a five-point Likert scale. Higher scores indicate higher levels of FCR. The FCRI has demonstrated psychometric properties (Table 4) and has been validated in Australians with a history of early-stage melanoma.[36]

Melanoma-related knowledge will be measured using a purpose-designed questionnaire, adapted from the MCP randomised controlled trial. This questionnaire was updated in tandem with the MQA booklet, to ensure the questions and answers continue to reflect the information

provided in the booklet. Higher scores on this scale correspond to higher levels of melanoma-related knowledge, which is measured using multiple choice, true/false and yes/no style questions.

Depression, anxiety and stress will be measured using the Depression, Anxiety and Stress Scales 21-item Short Form (DASS-21).[37] The DASS-21 is measured using a four-point Likert scale, with higher scores indicating more severe symptoms of depression, anxiety or stress. The DASS-21 has demonstrated psychometric properties (see Table 5) and has clinical cut-off[37] and clinically meaningful[38] scores defined.

HRQOL will be measured using the Assessment of Quality of Life – 8 Dimensions (AQOL-8D).[39] The AQOL-8D contains 35 questions to which patients respond using Likert scales ranging from four-to-six points. The AQOL-8D has demonstrated psychometric properties (see Table 4). The AQOL-8D scores comprise two super dimensions (physical and psychosocial) consisting of eight smaller dimensions (independent living, pain, senses, mental health, happiness, coping, relationships, and self-worth). Higher scores indicate worse quality of life.

Secondary implementation outcomes

The *acceptability* and *appropriateness* of the MCP-SCI from a patient's perspective will be quantitatively measured using the Acceptability of Intervention Measure and Intervention Appropriateness Measure respectively.[40] Each of these measures consist of four positively worded items, measured on a five-point Likert scale, with higher scores indicating greater acceptability and appropriateness. As no cut-off scores exist, scores of 4/5 (agree) and 5/5 (strongly agree) will be used to indicate that the MCP-SCI is considered acceptable and appropriate by patients. Furthermore, semi-structured interviews with patients will be used to further explore the perceptions of patients. Acceptability will also be measured using

intervention adherence rates (i.e. number of patients who consent to participate, complete the intervention and follow-up questionnaires).

Implementation stakeholders will provide further feedback regarding the *acceptability* and *appropriateness* of the MCP-SCI. This will be quantitatively measured using the Acceptability of Intervention and Intervention Appropriateness measures. Furthermore, implementation stakeholders will also provide feedback regarding the *feasibility* or the MCP-SCI, quantitatively measured using the Feasibility of Intervention Measure.[40] Lastly, expert group discussions with implementation stakeholders will be used to further explore their perceptions of the MCP-SCI.

The *cost* of implementation will be reported using process data, which will include costs associated with the MQA booklet (i.e. time to update, graphic design, and printing), training, salary of a psychologist, text messaging, online screening and survey development, stationary, transcribing interviews and any other incidental expenses. These expenditures will be categorised into costs associated with research, initiating implementation and ongoing implementation.

Fidelity of the telehealth sessions to the psychologist manual will be assessed using a purpose-designed fidelity checklist adapted from the MCP.[1] This checklist includes items specifically designed to review the content of each session, including the items from the Comparative Psychotherapy Process Scale,[41] Revised Cognitive Therapy Scale[42] and Interpretive and Supportive Technique Scale.[43] To ensure the psychologist manual is adequately followed, 10% of conducted telehealth sessions will be randomly reviewed and assessed using this checklist.

Finally, *sustainability* will be assessed through the degree to which the intervention has been incorporated into routine clinical care at the study sites. The sustainability of the MCP-SCI will be discussed with implementation stakeholders through expert group discussions.

Sample size

At 12 months post-intervention, the MCP randomised controlled trial demonstrated a reduction in FCR severity of -1.41.[12] Based on this value, a sample size of 86 will provide 90% power to detect an overall before/after difference of -1.41 in FCR severity between baseline and 12 months post-intervention. This sample size calculation is based on a paired mean difference design with a standard deviation of 4.0 and type-1 (alpha) error rate set to 0.05.[44] Assuming a conservative lost-to-follow-up rate of 20%, a final sample of 108 patients across both study sites will be recruited and offered the MCP-SCI. As it is anticipated that approximately 63% of patients who complete screening will be offered the intervention,[45] an estimated 172 patients will complete screening, with recruitment continuing until the required sample of 108 patients is achieved.

Data analysis plan

All patients who receive the intervention will be analysed as one group with the number of psychotherapeutic telehealth sessions received and baseline FCR scores threated as covariates, with their FCR trajectory compared to that of the control group recruited in the MCP randomised controlled trial.[12] Descriptive statistics will be used to describe demographic trends within the study sample. Linear mixed-effect regression will be used to analyse the effect of the intervention on patient psychosocial outcomes, as it can robustly deal with missing data and perform hypothesis testing on longitudinal data.[46] Moderation analysis will also be used to examine the effects of covariates on the relationship between all outcomes and independent variables through linear regression.[47] Thematic analysis will be used to analyse the semi-structured interviews and expert group discussions conducted throughout the study for common themes regarding facilitators and barriers.[48] Quantitative analysis will be completed in IBM SPSS Statistics 26 (Armonk, NY: IBM Corp) and RStudio (RStudio Team 2019,

version 1.2.5033); qualitative analysis will be conducted using NVivo 12 Plus (QSR International Pty Ltd.).

Ethics

Ethical approval was received from the Sydney Local Health District – Royal Prince Alfred Zone (2020/ETH02518). Any future amendments to the protocol will be approved by the Steering Committee, Human Research Ethics Council, site approval boards and the corresponding clinical trial registry updated. Participants enrolled in the study will be informed by JRT. Based on the MCP randomised controlled trial, it is unlikely that patient participants will experience adverse effects from the stepped-care intervention, as only three participants (4%) found discussing their melanoma experiences with a psychologist confronting.[18] Any discomfort will be addressed during the telehealth sessions. Furthermore, any participants identified to have a significant co-morbid mental health condition will be referred for community mental health support to better address their needs.

Dissemination plans

Results will be shared with academics, researchers, clinicians, interested patients and other key stakeholders. Results will be disseminated to peer-reviewed journals, scientific meetings and conferences and reported according to the Standards for Reporting Implementation Studies statement.[49] The associated checklist[50] will be used to ensure all relevant aspects of the intervention study are included in analysis and reporting. Authorship will be determined by the criteria outlined in the International Committee for Medical Journal Editors.[51] Lay summaries of results will be shared with interested patients and implementation stakeholders and posted on the MIA website.

Data availability

To facilitate research transparency, reproducibility and accuracy, de-identified data will be available for sharing. Interested researchers can contact the corresponding investigator following the publication of the 12-month follow-up data. Data access will be granted to the projects that are considered by the investigative team to be methodologically sound and Human Research Ethics Committee-approved. The investigative team will create a project-specific workspace within MIA's secure server, which will house the de-identified data and technical appendices.

Patient and public involvement statement

The investigative team included a consumer representative since conception. This team member has provided feedback and guidance on the aims, design, and outcomes of the study with substantial input in the development of materials provided to patients (including review of the updated MQA booklet) and providing their approval of the intervention and the time commitment required to participate in the study. Furthermore, the original MQA psycho-educational booklet used in the MCP randomised controlled trial was pilot tested with 19 melanoma patients with content revised based on their feedback.[11] Finally, consumer representatives will be involved in results interpretation and development of lay summaries of the results.

DISCUSSION

Strengths

This pilot implementation study represents the next logical step in the translation of an evidence-based psychotherapeutic intervention to reduce FCR in patients with a previous diagnosis of early-stage melanoma into routine clinical practice. The study design will allow for concurrent assessment of effectiveness and implementation variables using a mixed-

methods design which includes quantitative data obtained through use of validated and accepted outcome measures, with contextual information obtained from interviews and expert groups. Screening will be used to identify patients experiencing elevated FCR and ensure patients are offered the appropriate level of support to address their needs. This screening will take place between four weeks before and one week after a scheduled appointment in an attempt to capture the background levels of FCR experienced by the patient, as fear often increases in the week before an appointment.[16] Consumer representatives, practice managers, directors and clinicians were included in the study design process, ensuring the intervention has the utmost relevance to patient needs and will suit the organisational structure of the study sites.

Limitations

Similar to the MCP, the study design precludes determination of the relative contribution of the MQA booklet and psychotherapeutic telehealth sessions in achieving outcomes. Further studies may be designed to systematically investigate this. Furthermore, a control group will not be recruited, as withholding evidence-based intervention from patients who may screen high on FCR in the control group was not considered ethical. Available control group data from the MCP randomised controlled trial will act as a comparison group to estimate 12-month FCR trajectories without an intervention. Furthermore, there is a risk of recruitment bias as patients with severe FCR may avoid participating in this study. The extent of this recruitment bias will be estimated by comparing recruitment rates to other interventional studies in the melanoma literature.

Significance

Information on the implementation of evidence-based psychosocial interventions into routine melanoma practice is sparse. Only one study was identified that evaluated the implementation

of a FCR intervention into routine practice. The Fear-Less[52] study evaluated a stepped-care model on metastatic (Stage IV) melanoma patients, utilising the ConquerFear[53] intervention, which, in a clinical trial was found to be effective in reducing FCR in breast and colorectal cancer and melanoma patients.[54] Fear-Less was found to be both acceptable and feasible. The small sample size precluded determination whether the observed reduction in FCR was statistically significant or clinically meaningful. This study will be the first to provide a stepped-care intervention for patients with a previous diagnosis of early-stage melanoma reporting elevated FCR in routine clinical practice, using an intervention that has been specifically created for melanoma patients; addresses both the international[55] and Australian[56] research agenda for FCR, specifically as it utilises a stepped-care model, facilitates routine implementation of an evidence-based intervention, and provides access to telehealth interventions to patients outside of clinical trials; is sufficiently powered to assess the impact of the intervention on FCR severity; and will be the first to investigate the acceptability, appropriateness, feasibility, fidelity and sustainability of a psychosocial intervention implemented into routine practice to address FCR in patients previously diagnosed with early-stage melanoma, from both the consumer and service-provider perspective. The implementation information obtained may be used in future implementation efforts as research moves from the strict confines of clinical trials into real-world settings.

Authors Contributions:

NAK, RPMS, MD, JRT, IB, and AEC were responsible for the concept of this study. A Steering Committee comprising of JRT, IB, ALS, LS, LM, PG, NAK, RPMS, MD, HS, AEC, SL and DM contributed to study design, intervention and materials development. JRT, IB, LM, PG and ALS will be responsible for overseeing the implementation process. JRT, IB and ALS will be responsible for data collection and management. JRT, IB, ALS, MD and SL will conduct the statistical analysis of results. All authors will be involved in results interpretation. All authors contributed and approved this manuscript.

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Competing interests:

RS has received honoraria for advisory board participation from MSD, Novartis and QBiotics and speaking honoraria from BMS. DM has received honoraria for advisory board participation from MSD, BMS and Novartis and speaking honoraria from BMS and MSD.

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TABLES

Table 1. Participant inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Melanoma Patients	• Current or previous diagnosis of Stage 0, I or II melanoma and currently completing follow-up at one of the study sites. • Sufficient English language skills and cognitive ability to understand study materials and provide informed consent. • Sufficient hearing to participate in telehealth consultations. • Aged 18 years or older.	• Current or previous diagnosis of Stage III or IV melanoma, irrespective of current disease status. • At high risk of, but no previous diagnosis of melanoma. • Significant cognitive impairment that would prevent understanding of the study materials and ability to provide informed consent. • Significant hearing impairment preventing participation in telehealth consultations. • Current diagnosis of severe depression, psychotic illness or other serious psychiatric condition. • Below 18 years of age.
Implementation Stakeholders	• Member of the MCP randomised controlled trial investigative team, OR Current employee of Melanoma Institute Australia or Sydney Melanoma Diagnostic Centre and directly involved in the implementation of the intervention. • Sufficient English language skills and cognitive ability to understand study materials and provide informed consent. • Aged 18 years or older.	• Significant cognitive impairment that would prevent understanding of the study materials and ability to provide informed consent. • Employed by Melanoma Institute Australia or Sydney Melanoma Diagnostic Centre but not directly involved in implementation of the stepped-care intervention. • Below 18 years of age.

Table 2. Description of the MCP intervention

	MCP Randomised Controlled Trial[10]	Pilot Implementation Study
Study Sites	1. Sydney Melanoma Diagnostic Centre; 2. Poche Centre, MIA; 3. Newcastle Skin Check Clinic.	1. Sydney Melanoma Diagnostic Centre; 2. Poche Centre, MIA.
Screening	N/A	Conducted using the FCRI-SF.
Melanoma: Questions and Answers booklet	A purpose-designed, psycho-educational booklet developed by a multidisciplinary team and published in March 2014 featuring comprehensive information on a range of topics identified as important to melanoma patients:[11] melanoma diagnosis, treatment, recurrence rates, prevention and strategies to address and cope with FCR. Patients have found this booklet both satisfactory and beneficial, with responses being overwhelmingly positive.[11,18]	The MQA booklet's design and information was updated and made complimentary to MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet,[19] which is offered to early-stage melanoma patients as a part of standard care at MIA. As both booklets contain similar information on melanoma diagnosis and treatments, information in the MQA booklet on these topics were summarised to reduce patient burden. This review was completed by a consumer representative, melanoma clinicians and researchers to ensure it contains up-to-date information as of publishing in December 2021. All patients who participate in this study will be offered a copy of MIA's booklet as a part of their standard care, with patients who receive the intervention also offered a copy of the MQA booklet.
Psycho-therapeutic Telehealth Sessions	Three telephone-based sessions with a trained psychologist based on the principles of brief, psychodynamically-oriented psychotherapy, aiming to provide melanoma patients with effective emotional and behavioural coping strategies. These sessions were guided by a psychologist manual, outlining the different features and discussion topics of the first, middle and final sessions.	Based on the results of the MCP randomised controlled trial and discussion with its lead investigators, patients with significantly elevated FCR at baseline would have likely benefitted from more than three telehealth sessions.[12] Thus, this study will offer these patients a total of five sessions rather than three. It is important to note that although a patient will be offered a number of telehealth sessions, the number of sessions received will be dependent on the clinical opinion of the psychologist(s) and patient need. The psychologist manual has not been altered for this study

		(patients offered five sessions will receive one 'first', three 'middle' and one 'final' session) and these sessions will take place via telephone or video-conferencing software.
Timing of Telehealth Sessions	The first session was held one week before the melanoma patient's upcoming dermatology appointment. All subsequent sessions were held on a fortnightly basis.	The first session will be held as soon as possible after FCR screening, which can take place between four weeks before to one week after the melanoma patient's upcoming dermatology appointment. All subsequent sessions will be held on a fortnightly basis.
Primary Study Outcome	FCR Severity measured using the FCRI-SF.	FCR Severity measured using the FCRI-SF.
Primary Outcome Collection Timeline	• Baseline: four-to-six weeks before upcoming dermatology appointment; • Follow-up 1: one week after final telehealth session; • Follow-up 2: six months after final telehealth session; • Follow-up 3: 12 months after final telehealth session.	• Baseline: ranging from 4 weeks before to 1 week after upcoming dermatology appointment • Follow-up 1: one week after final telehealth session; • Follow-up 2: six months after final telehealth session; • Follow-up 3: 12 months after final telehealth session.

FCR, Fear of Cancer Recurrence; FCRI-SF, Fear of Cancer Recurrence Inventory 9-item Short Form; MCP, Melanoma Care Program; MIA, Melanoma Institute Australia; MQA, Melanoma: Questions and Answers.

Table 3. Outline of psychotherapeutic telehealth sessions

Session	Content[10]
Introduction	The psychologist introduces themselves to the patient, checks all materials have been received, re-confirms consent and schedules the first session.
Session 1	The psychologist assesses patient needs, referring to the MQA booklet where appropriate when discussing any concerns or unmet needs the patient has.
Sessions 2-4	The psychologist reviews previous session(s) with the patient and discusses any difficulties that have arisen since. The psychologist will continue to address the unmet needs of patients utilising the MQA booklet where possible.
Final Session	The psychologist reviews all previous sessions and addresses any new difficulties. The psychologist discusses the degree to which patient unmet needs have been addressed, new strategies to address possible future concerns and referral for further support if required.

MQA, Melanoma Questions and Answers.

Table 4. Stepped-care model

Steps of Intervention	FCRI-SF Clinical Cut Off Score	Usual Care*	MQA Booklet	Number of offered psychotherapeutic telehealth sessions
Step 1 No/Low FCR	<13	✓	-	0
Step 2 Moderate FCR	13-21	✓	✓	3
Step 3 Severe FCR	≥ 22	✓	✓	5
Step 4 Significant co-morbid mental health condition	N/A†	✓	✓	Referral‡

FCR, Fear of Cancer Recurrence; FCRI-SF, Fear of Cancer Recurrence Inventory 9-item Short Form; MQA, Melanoma Questions and Answers.

* Patient education and support as per usual clinical practice, including the provision of MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet.

† Identified through baseline questionnaire and clinical judgement during telehealth sessions.

‡ Referred to community mental health specialist or general practitioner.

Table 5. Outcome variables, measures, psychometric properties, and timeline of data collection

Primary Outcome

Variable	Measures	Participants	Reliability	Validity	E0	E1	E2	E3
Fear of cancer recurrence severity	FCRI-SF	Patients	Internal consistency, test-retest[17,25]	Concurrent, convergent, discriminant[17,25]	✓	✓	✓	✓

Secondary Effectiveness Outcomes

Variable	Measures	Participants	Reliability	Validity	E0	E1	E2	E3
Demographic information	Demographic questionnaire	Patients	N/A	N/A	✓	-	-	-
Fear of cancer recurrence subscales	FCRI	Patients	Internal consistency, test-retest[17,25]	Concurrent, convergent, discriminant[17,25]	✓	✓	✓	✓
Melanoma-related knowledge	Purpose-designed questionnaire	Patients	N/A	N/A	✓	✓	✓	✓
Depression, anxiety and stress	DASS-21	Patients	Internal consistency[26-30]	Concurrent, convergent, discriminant[26-28]	✓	✓	✓	✓
Health-related quality of life	AQOL-8D	Patients	Internal consistency, test-retest[31-33]	Concurrent, convergent, discriminant[31, 33-35]	✓	✓	✓	✓

Secondary Implementation Outcomes

Variable	Measures	Participants	I1	I2	I3
Acceptability	Acceptability of Intervention Measure	Patients*	-	-	-
		Implementation Stakeholders	✓	✓	✓
	Semi-structured interviews	Patients†	-	-	-
	Expert group discussions	Implementation Stakeholders	✓	✓	✓

	Process data	N/A	✓	✓	✓
Appropriateness	Intervention Appropriateness Measure	Patients*	-	-	-
		Implementation Stakeholders	✓	✓	✓
	Semi-structured interviews	Patients†	-	-	-
	Expert group discussions	Implementation Stakeholders	✓	✓	✓
Feasibility	Feasibility of Intervention Measures	Implementation Stakeholders	✓	✓	✓
	Expert group discussions	Implementation Stakeholders	✓	✓	✓
Cost	Process data	N/A	✓	✓	✓
Fidelity	Review of telehealth sessions	Implementation Stakeholders	-	-	✓
Sustainability	Expert group discussions	Implementation Stakeholders	-	✓	✓

AQOL-8D, Assessment of Quality of Life 8 Dimensions; DASS-21, Depression, Anxiety and Stress 21-item Short Form; FCRI, Fear of Cancer Recurrence Inventory; FCRI-SF, Fear of Cancer Recurrence Inventory 9-item Short Form.
E0, baseline; E1, one week follow-up; E2, 6 months' follow-up; E3, 12 months' follow-up.
I1, three months pre implementation; I2, quarterly throughout implementation; I3, three months post implementation.
* Patients will complete the Acceptability of Intervention Measure and Intervention Appropriateness measure within one week of completing their final telehealth session, 6 and 12 months' follow-up.
† Patients will be invited to participate in semi-structured interviews within one week of completing their final telehealth session.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	4	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	7-8	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	8-10, 12-13, 29-30	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	7-8, 12-13, 29-30	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	8-9	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	9-13, 29-30	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	10	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	10	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	10, 28	The population targeted by the intervention and any eligibility criteria.
Description	**9**	14-15	A description of the implementation strategy	12-13, 29-30	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	16-17	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	15-16	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	14-15, 16-18	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	17	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	17	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	18	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	18-19	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		
Results					

Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	20-21	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	21-22	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	21-22	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	3, 5, 23	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5
	2b	All items from the World Health Organization Trial Registration Data Set	5
Protocol version	3	Date and version identifier	5
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	23
	5b	Name and contact information for the trial sponsor	23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	23
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	7-8
	6b	Explanation for choice of comparators	21
Objectives	7	Specific objectives or hypotheses	8-9

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9-10
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10, 28
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12-13, 29-32
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	32
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14-15, 17
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	15-18, 33-34
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	29-30
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	18
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11-12
Methods: Assignment of interventions (for controlled trials)			
This trial is not a controlled trial, thus items 16a-17b do not apply.			

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-17, 33-34
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-15
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	20
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18-19

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18-19
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed A formal DMC was deemed not necessary for this study based on the SPIRIT guidelines, as this pilot study is expected to have a short duration (~6 months) and is minimal risk to patients.	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial Please see response to 21a – this study does not have a DMC.	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	19
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	5
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	19
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	20 and Consent Form
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	20 and Consent Form

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	23 and Consent Form
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	19
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	20
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached to manuscript submission
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Protocol for the Implementation of a Stepped-Care Model to Address Fear of Cancer Recurrence in Patients Previously Diagnosed With Early-Stage (0-II) Melanoma

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Protocol for the Implementation of a Stepped-Care Model to Address Fear of Cancer Recurrence in Patients Previously Diagnosed With Early-Stage (0-II) Melanoma

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Abbreviations:

AQOL-8D – Assessment of Quality of Life 8 Dimensions Questionnaire; DASS-21 – Depression, Anxiety and Stress Scales 21-item Short Form; FCR – fear of cancer recurrence; FCRI-SF – Fear of Cancer Recurrence Inventory 9-item Short Form; FCRI – Fear of Cancer Recurrence Inventory 42-item Form; HRQOL – Health-related Quality of Life; MCP – Melanoma Care Program; MCP-SCI – Melanoma Care Program Stepped Care Intervention; MIA – Melanoma Institute Australia; MQA – Melanoma: Questions and Answers.

ABSTRACT

Introduction

Fear of cancer recurrence (FCR) is commonly reported by patients diagnosed with early-stage (0-II) melanoma and can have a significant impact on daily functioning. This study will pilot the implementation of the Melanoma Care Program, an evidence-based, psychological intervention to reduce FCR into routine practice utilising a stepped-care model.

Methods and Analysis

Intervention effectiveness and level of implementation will be investigated using a hybrid type-I design. Between four weeks before and one week after their next dermatological appointment, melanoma patients will be invited to complete the Fear of Cancer Recurrence Inventory Short-Form, measuring self-reported FCR severity. Using a stepped-care model, clinical cut-off points will guide the level of support offered to patients. This includes: (1) usual care, (2) *Melanoma: Questions and Answers* psycho-educational booklet, and (3) three or five psychotherapeutic telehealth sessions. This longitudinal, mixed-method pilot implementation study aims to recruit 108 patients previously diagnosed with Stage 0-II melanoma. The primary effectiveness outcome is change in FCR severity over time. Secondary effectiveness outcomes include change in anxiety, depression, stress, health-related quality of life and melanoma-related knowledge over time. All outcomes are measured at baseline, within one week of the final telehealth session, and 6 and 12 months post-intervention. Implementation stakeholders at each study site and interested patients will provide feedback on intervention acceptability and appropriateness. Implementation stakeholders will also provide feedback on intervention cost, feasibility, fidelity, and sustainability. These outcomes will be measured throughout implementation, using questionnaires and semi-structured interviews/expert group discussions. Descriptive statistics, linear mixed-effect regression and thematic analysis will be used to analyse study data.

Ethics and Dissemination

Ethics approval was granted by the Sydney Local Health District – Royal Prince Alfred Zone (2020/ETH02518), protocol number: X20-0495. Results will be disseminated through peer-reviewed journals, conference presentations, social media and result summaries distributed to interested participants.

Registration Details

This pilot implementation study was registered with the Australia and New Zealand Clinical Trials Register on the 12th February 2021 (http://www.anzctr.org.au) (ACTRN12621000145808). All details of the World Health Organisation's Trial Registration Data Set can be found within this article and the corresponding trial registry on the Australia and New Zealand Clinical Trials Register webpage.

Keywords

Fear of cancer recurrence, stepped-care, intervention, psychological stress, implementation, melanoma, psycho-oncology.

ARTICLE SUMMARY

Strengths and Limitations of the Study

- This study aims to evaluate the pilot implementation of the evidence-based Melanoma Care Program into the routine clinical care of patients previously diagnosed with early-stage (0-II) melanoma.
- It is the first study to implement a stepped-care model to routinely screen for fear of cancer recurrence (FCR) in patients previously diagnosed with early-stage melanoma and tailor the intensity of intervention to reported FCR severity.
- Consumer representatives, practice managers, directors and clinicians have been involved throughout the study design process.
- The hybrid type-I design allows for the simultaneous evaluation of clinical and implementation outcomes.
- The primary limitation of this pilot implementation study is the absence of a recruited control group, however control group data from the Melanoma Care Program randomised controlled trial will be used as an *ad hoc* comparison group.

INTRODUCTION

Background and rationale

The global incidence of melanoma is increasing,[1] with an estimated 324,635 individuals receiving a diagnosis of melanoma in 2020.[2] Australia and New Zealand have the highest melanoma incidence rate in the world.[3] In 2016, the Australian age-standardised incidence and mortality rate of melanoma were 53.5 cases per 100,000 and 4.5 deaths per 100,000, respectively.[4] The average five-year survival rate of stage I and II melanoma patients is 99.2% and 73.6% respectively,[4] increasing the importance of their psychosocial adjustment and quality of life. Fear of cancer recurrence (FCR), defined as the fear, worry or concern that cancer may return or progress,[5] is the most frequently reported challenge of this population.[6] FCR is associated with: lower emotional, physical, role and social functioning, and health-related quality of life (HRQOL); poorer health care satisfaction; and increased reassurance seeking behaviour, fatigue, pain, distress, anxiety and depressive symptoms.[7]

A meta-analysis of 23 psychological interventions targeting FCR found them to be effective; however, only one intervention, The Melanoma Care Program (MCP), focused on Australian melanoma patients.[8] The MCP is a brief, evidence-based psychological intervention developed to address FCR in patients with a previous diagnosis of early-stage melanoma at risk of developing new primary disease.[9,10] The intervention consists of two components: (1) a *Melanoma: Questions and Answers* (MQA) psycho-educational booklet,[10,11] and (2) three psychotherapeutic telehealth sessions scheduled around patients' dermatological visits.[10] This is the first intervention specifically developed for patients with a previous diagnosis of early-stage melanoma. When investigated in a randomised controlled trial, intervention participants reported significantly lower FCR severity compared to a control group immediately post-intervention and at 6 months follow-up,[9] with effects sustained at 12 months follow-up.[12] The intervention was also well-accepted by patients[9] and cost-effective.[13] While the efficacy of this

intervention was established, the randomised controlled trial did not assess patients' FCR severity prior to trial enrolment to tailor intervention intensity to patient need. The present protocol outlines a pilot implementation study to translate this evidence-based intervention into real-world clinical settings, using a stepped-care approach. Patients with a previous diagnosis of early-stage melanoma attending routine dermatological appointments will be screened for FCR, allowing the intensity of support to match the severity of the patients' FCR.

Study aims and hypotheses

The primary aim of this study is to examine the effectiveness of a stepped-care model offering the MCP (henceforth referred to as the 'Melanoma Care Program – stepped-care intervention' or MCP-SCI) in reducing FCR severity in patients with a previous diagnosis of early-stage melanoma who are identified as having elevated FCR in routine clinical practice.

Secondary aims include:

- Evaluation of the effects of the MCP-SCI on patient-reported depression, anxiety, stress, melanoma-related knowledge, HRQOL and further aspects of FCR: triggers, psychological distress, coping strategies, functional impairments, insight, and reassurance.
- Evaluation of the sustainability of routine implementation of the MCP-SCI in real-world clinical settings by documenting barriers (e.g. low screening uptake, time and cost of screening) and facilitators (e.g. participant engagement and screening adherence) and assessing the usefulness of strategies to address barriers.

It is hypothesised that:

I. Patients who report elevated FCR and receive the MCP-SCI will report immediately, and at 6 and 12 months' follow-up:

a. A significant reduction in FCR severity;
b. A decrease in FCR-related triggers, psychological distress, functional impairments, reassurance seeking behaviour and patient-reported levels of depression, anxiety and stress;
c. An increase in FCR-related coping strategies and insight, melanoma-related knowledge and HRQOL compared with baseline scores.

II. The implementation of the MCP-SCI will be considered:
a. Acceptable and appropriate by patients who receive the intervention;
b. Acceptable, appropriate, feasible and sustainable by implementation stakeholders.

III. The MCP-SCI will be delivered with high fidelity and adherence to the therapist manual.

METHODS

Study design

Translational research investigates the degree to which an evidence-based practice retains its effectiveness when implemented into 'real-world' settings.[14] The hybrid effectiveness-implementation design, which focuses on assessing both the effectiveness and implementation of an evidence-based practice, is commonly used in translational research.[15] Three variations of this design exist, based on the relative focus that is placed *a priori* on effectiveness and implementation outcomes. Type-I designs primarily evaluate the health and well-being impact of an evidence-based practice in real-world settings, whilst also gathering contextual information on the implementation process to guide future implementation efforts.[15] Thus, a type-I design was selected for this study to investigate the effects of the MCP-SCI in routine practice, while evidence concerning its long-term sustainability is gathered to guide more extensive implementation efforts in the future.

Setting

Implementation will take place at two of the three dermatology clinics specialising in the diagnosis and treatment of melanoma that participated in the MCP randomised controlled trial.[9,10] The first study site, Melanoma Dermatology, is located within the Poche Centre at Melanoma Institute Australia (MIA), the world's largest melanoma research and treatment facility. The second study site, Sydney Melanoma Diagnostic Centre, is associated with MIA but is located at Royal Prince Alfred Hospital. Both study sites: are located in metropolitan Sydney, Australia; are mixed public and private practices that have extensive experience in conducting melanoma-related research and implementation studies; have strong organisational emphasis on multidisciplinary collaboration, research and clinician training; consist of roughly a dozen clinicians and administration staff; and primarily see melanoma patients at high risk of recurrence.

Participant selection

Two groups of participants will be included: (1) patients with a current or previous diagnosis of early-stage melanoma who have an upcoming follow-up appointment at either of the study sites, and (2) implementation stakeholders, including investigators of the MCP randomised controlled trial, and individuals who are involved in the implementation of the MCP-SCI at one of the study sites (i.e. dermatologists, nurses, practice managers, administration staff). Table 1 outlines the study inclusion and exclusion criteria.

[Insert Table 1 here]

Participant recruitment

Patients

Four weeks prior to their routine scheduled appointment, patients will be invited to participate via an automated text message. This timeframe allows for individuals with high FCR to be

identified and offered the intervention prior to the week of their appointment, when anxiety is likely to be greatest.[16] The text message invitation contains a brief introduction to the study and a link to MIA's Research Electronic Data Capture webpage, which includes a landing page describing the study, participant information statement, consent form, Fear of Cancer Recurrence Inventory Short Form (FCRI-SF)[17] and relevant questionnaires. During an eligible patient's appointment, their clinician will check that the text message was received and answer any questions about the study. If the patient did not receive the text message, the clinician can discuss the study with the patient and collect their contact details if interested. A research assistant will then call the patient within 48 hours of the appointment to discuss the study.

Implementation stakeholders

The chief investigator at each study site will approach potential implementation stakeholders via email or in person. Additionally, members of the investigative team of the MCP randomised controlled trial will be invited to participate as implementation stakeholders, as these individuals have first-hand experience with the intervention and may foresee possible implementation issues. A reminder invitation will be sent two weeks' following initial contact if no response is received.

The recruitment of implementation stakeholders began in June 2021. Patient recruitment is scheduled for January 2022. Study completion is expected by October 2023.

Intervention description

Melanoma: Questions and Answers booklet and psychotherapeutic telehealth sessions

The MCP intervention consists of the MQA booklet and psychotherapeutic telehealth sessions. These two components have not been substantially altered for this pilot implementation study. Table 2 provides a brief description of the MCP intervention provided to patients in the

randomised controlled trial and outlines the justification for any modifications made for the present implementation study.

[Insert Table 2 here]

The content of the psychotherapeutic telehealth sessions is provided in Table 3.

[Insert Table 3 here]

Stepped-care model of intervention delivery

The addition of a stepped-care model of care will allow the intervention to be tailored to each patient's severity of FCR, potentially maximising overall benefit and service provision efficiency whilst conserving resources.[18]

Patients will be invited to complete FCR screening using the FCRI-SF. The FCRI-SF is measured using a nine item, five-point Likert scale with scores ranging from 0 to 36, with higher scores indicating greater FCR severity.[17] Multiple cut-off scores have been suggested in the literature. For the purpose of this pilot implementation study, a cut-off score of ≥ 13[19] will be used to identify patients with clinically indicative levels of FCR to receive the MCP-SCI, with a second cut-off core of ≥ 22[20] used to identify patients with more severe levels of FCR at baseline (Table 4). These cut-off scores were chosen as a preference was placed on sensitivity over specificity to ensure patients experiencing FCR are captured, and the MCP randomised controlled trial sub-group analysis finding participants scoring ≥ 13 at baseline experienced a significant decrease in FCR severity at 6-months follow-up,[9] whereas participants scoring ≥ 22 at baseline experienced no significant decrease,[12] which investigators attributed to potential dose effect. Hence it was decided to offer an additional two sessions to those who score ≥ 22 at baseline to investigate its effects.

[Insert Table 4 here]

Patients triaged to Step 1 (no/low FCR) will receive usual care, consisting of clinical follow-up and MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet. Patients triaged to Step 2 (moderate FCR) and Step 3 (severe FCR) will continue to receive usual care as well as being offered the MCP intervention, with the difference between these Steps being the number of telehealth sessions offered to the patient (Table 3). The psychologist(s) will contact patients to schedule their first session, ideally conducting the first session before the patients' upcoming appointment. Subsequent telehealth sessions will be conducted on a flexible two-week basis.

Data collection

Patients

In addition to completing the FCRI-SF, patients triaged to Step 1 (no/low FCR) will complete a demographic questionnaire. Patients triaged to Step 2 (moderate FCR) and Step 3 (severe FCR) will complete the demographic questionnaire plus a baseline questionnaire collecting data relating to outcome measures of interest. Patients triaged to Step 2 or 3 will also complete questionnaires within one-week of completing their final telehealth session and at 6 and 12 months' follow-up. All patients who receive the intervention will be invited to participate in a semi-structured interview during their first follow-up questionnaire to explore their experiences of the MCP-SCI. Recruitment will continue until thematic saturation is reached, and purposeful sampling used to ensure a range of experiences are captured. The Theoretical Framework of Acceptability[21] will be used to guide these semi-structured interviews. This framework consists of seven constructs relevant to intervention acceptability: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Patients will choose whether to complete questionnaires electronically or in paper format. A reminder email/letter will be sent to patients who do not provide a response after two weeks, with a telephone reminder after four weeks.

Implementation stakeholders

Three expert groups will be formed to explore the perceptions of implementation stakeholders to gather information about barriers and facilitators to implementation. The first group, consisting of investigators of the MCP randomised controlled trial, will meet pre-implementation to discuss barriers and facilitators experienced during the trial and any foreseeable barriers during implementation in routine clinical practice. The second and third groups, consisting of implementation stakeholders at the two study sites, will meet three months prior to, and quarterly throughout implementation to discuss key barriers and strategies to address them, meeting a final time three months post-implementation to discuss long-term sustainability of the intervention. These expert group discussions will be guided by the Consolidated Framework for Implementation Research and will be audio-recorded and transcribed for thematic analysis.[22]

Formative evaluation will be used to assess the effectiveness of any strategies put in place to address barriers that are identified during the implementation process,[14] with information collected shared with investigators and stakeholders allowing the implementation process to adapt to any barriers. Summaries of each expert group and agreed upon modifications will be provided to the study sites within a week of each expert group discussion, allowing implementation stakeholders to enact any changes. This will allow investigators to evaluate the effects of strategies used to address barriers to implementation.

At the conclusion of each expert group, implementation stakeholders will be offered questionnaires to quantitatively explore the acceptability, appropriateness, and feasibility of the intervention.

Outcomes

Consistent with the hybrid type-I design the primary outcome is the effectiveness of the MCP-SCI in reducing patient FCR severity. The summary of the outcome assessment methods is presented in Table 5.

[Insert Table 5 here]

Primary outcome

The primary outcome of this study is change in patient self-reported levels of FCR severity over time, measured using the FCRI-SF, the severity subscale of the Fear of Cancer Recurrence Inventory 42-item Form (FCRI).[17]

Secondary effectiveness outcomes

Changes over time in all other subscales of the FCRI (triggers, psychological distress, coping strategies, functional impairments, insight, and reassurance) will be measured and reported as secondary outcomes. The FCRI consists of 42 items that patients answer using a five-point Likert scale. Higher scores indicate higher levels of FCR. The FCRI has demonstrated psychometric properties (Table 4) and has been validated in Australians with a history of early-stage melanoma.[23]

Change over time in *Melanoma-related knowledge* will be measured using a purpose-designed questionnaire, adapted from the MCP randomised controlled trial. This questionnaire was updated in tandem with the MQA booklet, to ensure the questions and answers continue to reflect the information provided in the booklet. Higher scores on this scale correspond to higher levels of melanoma-related knowledge, which is measured using multiple choice, true/false and yes/no style questions.

Changes over time in *Depression, anxiety and stress* will be measured using the Depression, Anxiety and Stress Scales 21-item Short Form (DASS-21).[24] The DASS-21 is measured using a four-point Likert scale, with higher scores indicating more severe symptoms of depression, anxiety or stress. The DASS-21 has demonstrated psychometric properties (see Table 5) and has clinical cut-off[24] and clinically meaningful[25] scores defined.

Change over time in *HRQOL* will be measured using the Assessment of Quality of Life – 8 Dimensions (AQOL-8D).[26] The AQOL-8D contains 35 questions to which patients respond using Likert scales ranging from four-to-six points. The AQOL-8D has demonstrated psychometric properties (see Table 4). The AQOL-8D scores comprise two super dimensions (physical and psychosocial) consisting of eight smaller dimensions (independent living, pain, senses, mental health, happiness, coping, relationships, and self-worth). Higher scores indicate worse quality of life.

Secondary implementation outcomes

The *acceptability* and *appropriateness* of the MCP-SCI from a patient's perspective will be quantitatively measured using the Acceptability of Intervention Measure and Intervention Appropriateness Measure respectively.[27] Each of these measures consist of four positively worded items, measured on a five-point Likert scale. As no cut-off scores exist, scores of 4/5 (agree) and 5/5 (strongly agree) will be used to indicate that the MCP-SCI is considered acceptable and appropriate by patients. Furthermore, semi-structured interviews with patients will be used to further explore the perceptions of patients. Acceptability will also be measured using intervention adherence rates.

Implementation stakeholders will provide further feedback regarding the *acceptability* and *appropriateness* of the MCP-SCI. This will be quantitatively measured using the Acceptability of Intervention and Intervention Appropriateness measures. Furthermore, implementation

stakeholders will also provide feedback regarding the *feasibility* or the MCP-SCI, quantitatively measured using the Feasibility of Intervention Measure.[27] Lastly, expert group discussions with implementation stakeholders will be used to further explore their perceptions of the MCP-SCI.

The *cost* of implementation will be reported using process data, which will include costs associated with the MQA booklet (i.e. time to update, graphic design, and printing), training, salary of a psychologist, text messaging, online screening and survey development, stationary, transcribing interviews and any other incidental expenses. These expenditures will be categorised into costs associated with research, initiating implementation and ongoing implementation.

Fidelity of the telehealth sessions to the psychologist manual will be assessed using a purpose-designed fidelity checklist adapted from the MCP.[9] This checklist includes items specifically designed to review the content of each session, including the items from the Comparative Psychotherapy Process Scale,[28] Revised Cognitive Therapy Scale[29] and Interpretive and Supportive Technique Scale.[30] To ensure the psychologist manual is adequately followed, 10% of conducted telehealth sessions will be randomly reviewed and assessed.

Finally, *sustainability* will be assessed through the degree to which the intervention has been incorporated into routine clinical care at the study sites. The sustainability of the MCP-SCI will be discussed with implementation stakeholders through expert group discussions.

Sample size

At 12 months post-intervention, the MCP randomised controlled trial demonstrated a reduction in FCR severity of -1.41.[12] Based on this value, a sample size of 86 will provide 90% power to detect an overall before/after difference of -1.41 in FCR severity between baseline and 12 months post-intervention. This sample size calculation is based on a paired mean difference

design with a standard deviation of 4.0 and type-1 (alpha) error rate set to 0.05.[31] Assuming a conservative lost-to-follow-up rate of 20%, a final sample of 108 patients across both study sites will be recruited and offered the MCP-SCI. As it is anticipated that approximately 63% of patients who complete screening will be offered the intervention,[32] an estimated 172 patients will complete screening, with recruitment continuing until the required sample of 108 patients is achieved.

Data analysis plan

All patients who receive the intervention will be analysed as one group with the number of psychotherapeutic telehealth sessions received and baseline FCR scores treated as covariates. Linear mixed-effect regression will be used to analyse the effect of the intervention on patient psychosocial outcomes, as it can robustly deal with missing data and perform hypothesis testing on longitudinal data.[33] Furthermore, the FCR trajectory of both the intervention group and the control group recruited in the MCP randomised controlled trial[12] will be graphically displayed in the same figure using mean scores at baseline, 1-week, 6 and 12 months follow-up with 95% confidence intervals for ad-hoc comparison. No formal statistical inference will be performed to compare the two groups. Moderation analysis will also be used to examine the effects of covariates on the relationship between all outcomes and independent variables through linear regression.[34] Thematic analysis will be used to analyse the semi-structured interviews and expert group discussions conducted throughout the study for common themes regarding facilitators and barriers.[35] Quantitative analysis will be completed in IBM SPSS Statistics 26 (Armonk, NY: IBM Corp) and RStudio (RStudio Team 2019, version 1.2.5033); qualitative analysis will be conducted using NVivo 12 Plus (QSR International Pty Ltd.).

Ethics

Ethical approval was received from the Sydney Local Health District – Royal Prince Alfred Zone (2020/ETH02518). Any future amendments to the protocol will be approved by the Steering Committee, Human Research Ethics Council, site approval boards and the corresponding clinical trial registry updated. Participants enrolled in the study will be informed by JRT. Based on the MCP randomised controlled trial, it is unlikely that patient participants will experience adverse effects from the stepped-care intervention, as only three participants (4%) found discussing their melanoma experiences with a psychologist confronting.[36] Any discomfort will be addressed during the telehealth sessions. Furthermore, any participants identified to have a significant co-morbid mental health condition will be referred for community mental health support to better address their needs.

Dissemination plans

Results will be shared with academics, researchers, clinicians, interested patients and other key stakeholders. Results will be disseminated to peer-reviewed journals, scientific meetings and conferences and reported according to the Standards for Reporting Implementation Studies statement.[37] The associated checklist[38] will be used to ensure all relevant aspects of the intervention study are included in analysis and reporting. Authorship will be determined by the criteria outlined in the International Committee for Medical Journal Editors.[39]

Data availability

To facilitate research transparency, reproducibility and accuracy, de-identified data will be available for sharing. Interested researchers can contact the corresponding investigator following the publication of the 12-month follow-up data. Data access will be granted to the projects that are considered by the investigative team to be methodologically sound and Human Research Ethics Committee-approved. The investigative team will create a project-specific

workspace within MIA's secure server, which will house the de-identified data and technical appendices.

Patient and public involvement statement

The design of this study, its aim and outcome measures are a result of the positive outcomes and satisfaction reported by the participants of the MCP randomised controlled trial,[36] as well as the clinical experiences of the investigative team regarding patients displaying anxiety and FCR. The investigative team also includes a consumer representative who has provided guidance on the design of the study and its materials, approved of the intervention's possible burden on patients, and will continue to provide guidance throughout implementation as barriers are identified. No consumers are directly involved in the recruitment process. A lay summary of results will be provided to any interested patients and posted on the MIA website.

DISCUSSION

Strengths

This pilot implementation study represents the next logical step in the translation of an evidence-based psychotherapeutic intervention to reduce FCR in patients with a previous diagnosis of early-stage melanoma into routine clinical practice. The study design will allow for concurrent assessment of effectiveness and implementation variables using a mixed-methods design which includes quantitative data obtained through use of validated and accepted outcome measures, with contextual information obtained from interviews and expert groups. Screening will be used to identify patients experiencing elevated FCR and ensure patients are offered the appropriate level of support to address their needs. This screening will take place between four weeks before and one week after a scheduled appointment in an attempt to capture the background levels of FCR experienced by the patient, as fear often increases in the week before an appointment.[16] Consumer representatives, practice managers,

directors and clinicians were included in the study design process, ensuring the intervention has the utmost relevance to patient needs and will suit the organisational structure of the study sites.

Limitations

Similar to the MCP, the study design precludes determination of the relative contribution of the MQA booklet and psychotherapeutic telehealth sessions in achieving outcomes. Further studies may be designed to systematically investigate this. Furthermore, a control group will not be recruited, as withholding evidence-based intervention from patients who may screen high on FCR in the control group was not considered ethical. Available control group data from the MCP randomised controlled trial will act as a comparison group to estimate 12-month FCR trajectories without an intervention. Furthermore, there is a risk of recruitment bias as patients with severe FCR may avoid participating in this study. The extent of this recruitment bias will be estimated by comparing recruitment rates to other interventional studies in the melanoma literature.

Significance

Information on the implementation of evidence-based psychosocial interventions into routine melanoma practice is sparse. Only one study was identified that evaluated the implementation of a FCR intervention into routine practice. The Fear-Less[40] study evaluated a stepped-care model on metastatic (Stage IV) melanoma patients, utilising the ConquerFear[41] intervention, which, in a clinical trial was found to be effective in reducing FCR in breast and colorectal cancer and melanoma patients.[42] Fear-Less was found to be both acceptable and feasible. The small sample size precluded determination whether the observed reduction in FCR was statistically significant or clinically meaningful. This study will be the first to provide a stepped-care intervention for patients with a previous diagnosis of early-stage melanoma

reporting elevated FCR in routine clinical practice, using an intervention that has been specifically created for melanoma patients; addresses both the international[43] and Australian[44] research agenda for FCR, specifically as it utilises a stepped-care model, facilitates routine implementation of an evidence-based intervention, and provides access to telehealth interventions to patients outside of clinical trials; is sufficiently powered to assess the impact of the intervention on FCR severity; and will be the first to investigate the acceptability, appropriateness, feasibility, fidelity and sustainability of a psychosocial intervention implemented into routine practice to address FCR in patients previously diagnosed with early-stage melanoma, from both the consumer and service-provider perspective. The implementation information obtained may be used in future implementation efforts as research moves from the strict confines of clinical trials into real-world settings.

Authors Contributions:

NAK, RPMS, MD, JRT, IB, and AEC were responsible for the concept of this study. A Steering Committee comprising of JRT, IB, ALS, LS, LM, PG, NAK, RPMS, MD, HS, AEC, SL and DM contributed to study design, intervention and materials development. JRT, IB, LM, PG and ALS will be responsible for overseeing the implementation process. JRT, IB and ALS will be responsible for data collection and management. JRT, IB, ALS, MD and SL will conduct the statistical analysis of results. All authors will be involved in results interpretation. All authors contributed and approved this manuscript.

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Competing interests:

RS has received honoraria for advisory board participation from MSD, Novartis and QBiotics and speaking honoraria from BMS. DM has received honoraria for advisory board participation from MSD, BMS and Novartis and speaking honoraria from BMS and MSD.

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TABLES

Table 1. Participant inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Melanoma Patients	• Current or previous diagnosis of Stage 0, I or II melanoma and currently completing follow-up at one of the study sites. • Sufficient English language skills and cognitive ability to understand study materials and provide informed consent. • Sufficient hearing to participate in telehealth consultations. • Aged 18 years or older.	• Current or previous diagnosis of Stage III or IV melanoma, irrespective of current disease status. • At high risk of, but no previous diagnosis of melanoma. • Significant cognitive impairment that would prevent understanding of the study materials and ability to provide informed consent. • Significant hearing impairment preventing participation in telehealth consultations. • Current diagnosis of severe depression, psychotic illness or other serious psychiatric condition. • Below 18 years of age.
Implementation Stakeholders	• Member of the MCP randomised controlled trial investigative team, OR Current employee of Melanoma Institute Australia or Sydney Melanoma Diagnostic Centre and directly involved in the implementation of the intervention. • Sufficient English language skills and cognitive ability to understand study materials and provide informed consent. • Aged 18 years or older.	• Significant cognitive impairment that would prevent understanding of the study materials and ability to provide informed consent. • Employed by Melanoma Institute Australia or Sydney Melanoma Diagnostic Centre but not directly involved in implementation of the stepped-care intervention. • Below 18 years of age.

Table 2. Description of the MCP intervention

	MCP Randomised Controlled Trial[10]	Pilot Implementation Study
Study Sites	1. Sydney Melanoma Diagnostic Centre; 2. Poche Centre, MIA; 3. Newcastle Skin Check Clinic.	1. Sydney Melanoma Diagnostic Centre; 2. Poche Centre, MIA.
Screening	N/A	Conducted using the FCRI-SF.
Melanoma: Questions and Answers booklet	A purpose-designed, psycho-educational booklet developed by a multidisciplinary team and published in March 2014 featuring comprehensive information on a range of topics identified as important to melanoma patients:[11] melanoma diagnosis, treatment, recurrence rates, prevention and strategies to address and cope with FCR. Patients have found this booklet both satisfactory and beneficial, with responses being overwhelmingly positive.[11,36]	The MQA booklet's design and information was updated and made complimentary to MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet,[45] which is offered to early-stage melanoma patients as a part of standard care at MIA. As both booklets contain similar information on melanoma diagnosis and treatments, information in the MQA booklet on these topics were summarised to reduce patient burden. This review was completed by a consumer representative, melanoma clinicians and researchers to ensure it contains up-to-date information as of publishing in December 2021. All patients who participate in this study will be offered a copy of MIA's booklet as a part of their standard care, with patients who receive the intervention also offered a copy of the MQA booklet.
Psycho-therapeutic Telehealth Sessions	Three telephone-based sessions with a trained psychologist based on the principles of brief, psychodynamically-oriented psychotherapy, aiming to provide melanoma patients with effective emotional and behavioural coping strategies. These sessions were guided by a psychologist manual, outlining the different features and discussion topics of the first, middle and final sessions.	Based on the results of the MCP randomised controlled trial and discussion with its lead investigators, patients with significantly elevated FCR at baseline would have likely benefitted from more than three telehealth sessions.[12] Thus, this study will offer these patients a total of five sessions rather than three. It is important to note that although a patient will be offered a number of telehealth sessions, the number of sessions received will be dependent on the clinical opinion of the psychologist(s) and patient need. The psychologist manual has not been altered for this study

		(patients offered five sessions will receive one 'first', three 'middle' and one 'final' session) and these sessions will take place via telephone or video-conferencing software.
Timing of Telehealth Sessions	The first session was held one week before the melanoma patient's upcoming dermatology appointment. All subsequent sessions were held on a fortnightly basis.	The first session will be held as soon as possible after FCR screening, which can take place between four weeks before to one week after the melanoma patient's upcoming dermatology appointment. All subsequent sessions will be held on a fortnightly basis.
Primary Study Outcome	Change in FCR Severity over time measured using the FCRI-SF.	Change in FCR Severity over time measured using the FCRI-SF.
Primary Outcome Collection Timeline	• Baseline: four-to-six weeks before upcoming dermatology appointment; • Follow-up 1: one week after final telehealth session; • Follow-up 2: six months after final telehealth session; • Follow-up 3: 12 months after final telehealth session.	• Baseline: ranging from 4 weeks before to 1 week after upcoming dermatology appointment • Follow-up 1: one week after final telehealth session; • Follow-up 2: six months after final telehealth session; • Follow-up 3: 12 months after final telehealth session.

FCR, Fear of Cancer Recurrence; FCRI-SF, Fear of Cancer Recurrence Inventory 9-item Short Form; MCP, Melanoma Care Program; MIA, Melanoma Institute Australia; MQA, Melanoma: Questions and Answers.

Table 3. Outline of psychotherapeutic telehealth sessions

Session	Content[10]
Introduction	The psychologist introduces themselves to the patient, checks all materials have been received, re-confirms consent and schedules the first session.
Session 1	The psychologist assesses patient needs, referring to the MQA booklet where appropriate when discussing any concerns or unmet needs the patient has.
Sessions 2-4	The psychologist reviews previous session(s) with the patient and discusses any difficulties that have arisen since. The psychologist will continue to address the unmet needs of patients utilising the MQA booklet where possible.
Final Session	The psychologist reviews all previous sessions and addresses any new difficulties. The psychologist discusses the degree to which patient unmet needs have been addressed, new strategies to address possible future concerns and referral for further support if required.

MQA, Melanoma Questions and Answers.

Table 4. Stepped-care model

Steps of Intervention	FCRI-SF Clinical Cut Off Score	Usual Care*	MQA Booklet	Number of offered psychotherapeutic telehealth sessions
Step 1 No/Low FCR	<13	✓	-	0
Step 2 Moderate FCR	13-21	✓	✓	3
Step 3 Severe FCR	≥ 22	✓	✓	5
Step 4 Significant co-morbid mental health condition	N/A†	✓	✓	Referral‡

FCR, Fear of Cancer Recurrence; FCRI-SF, Fear of Cancer Recurrence Inventory 9-item Short Form; MQA, Melanoma Questions and Answers.

* Patient education and support as per usual clinical practice, including the provision of MIA's *Your Guide to Early Melanoma* (3rd Edition) booklet.

† Identified through baseline questionnaire and clinical judgement during telehealth sessions.

‡ Referred to community mental health specialist or general practitioner.

Table 5. Outcome variables, measures, psychometric properties, and timeline of data collection

Primary Outcome

Variable	Measures	Participants	Reliability	Validity	E0	E1	E2	E3
Fear of cancer recurrence severity	FCRI-SF	Patients	Internal consistency, test-retest[17,46]	Concurrent, convergent, discriminant[17,46]	✓	✓	✓	✓

Secondary Effectiveness Outcomes

Variable	Measures	Participants	Reliability	Validity	E0	E1	E2	E3
Demographic information	Demographic questionnaire	Patients	N/A	N/A	✓	-	-	-
Fear of cancer recurrence subscales	FCRI	Patients	Internal consistency, test-retest[17,46]	Concurrent, convergent, discriminant[17,46]	✓	✓	✓	✓
Melanoma-related knowledge	Purpose-designed questionnaire	Patients	N/A	N/A	✓	✓	✓	✓
Depression, anxiety and stress	DASS-21	Patients	Internal consistency[47-51]	Concurrent, convergent, discriminant[47-49]	✓	✓	✓	✓
Health-related quality of life	AQOL-8D	Patients	Internal consistency, test-retest[52-54]	Concurrent, convergent, discriminant[52, 54-56]	✓	✓	✓	✓

Secondary Implementation Outcomes

Variable	Measures	Participants	I1	I2	I3
Acceptability	Acceptability of Intervention Measure	Patients*	-	-	-
		Implementation Stakeholders	✓	✓	✓
	Semi-structured interviews	Patients†	-	-	-
	Expert group discussions	Implementation Stakeholders	✓	✓	✓

	Process data	N/A	✓	✓	✓
Appropriateness	Intervention Appropriateness Measure	Patients*	-	-	-
		Implementation Stakeholders	✓	✓	✓
	Semi-structured interviews	Patients†	-	-	-
	Expert group discussions	Implementation Stakeholders	✓	✓	✓
Feasibility	Feasibility of Intervention Measures	Implementation Stakeholders	✓	✓	✓
	Expert group discussions	Implementation Stakeholders	✓	✓	✓
Cost	Process data	N/A	✓	✓	✓
Fidelity	Review of telehealth sessions	Implementation Stakeholders	-	-	✓
Sustainability	Expert group discussions	Implementation Stakeholders	-	✓	✓

AQOL-8D, Assessment of Quality of Life 8 Dimensions; DASS-21, Depression, Anxiety and Stress 21-item Short Form; FCRI, Fear of Cancer Recurrence Inventory; FCRI-SF, Fear of Cancer Recurrence Inventory 9-item Short Form.
E0, baseline; E1, one week follow-up; E2, 6 months' follow-up; E3, 12 months' follow-up.
I1, three months pre implementation; I2, quarterly throughout implementation; I3, three months post implementation.
* Patients will complete the Acceptability of Intervention Measure and Intervention Appropriateness measure within one week of completing their final telehealth session, 6 and 12 months' follow-up.
† Patients will be invited to participate in semi-structured interviews within one week of completing their final telehealth session.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5
	2b	All items from the World Health Organization Trial Registration Data Set	5
Protocol version	3	Date and version identifier	5
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	23
	5b	Name and contact information for the trial sponsor	23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	23
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	7-8
	6b	Explanation for choice of comparators	21
Objectives	7	Specific objectives or hypotheses	8-9

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9-10
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10, 28
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12-13, 29-32
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	32
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14-15, 17
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	15-18, 33-34
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	29-30
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	18
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11-12
Methods: Assignment of interventions (for controlled trials)			
This trial is not a controlled trial, thus items 16a-17b do not apply.			

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-17, 33-34
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-15
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	20
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18-19

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18-19
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed A formal DMC was deemed not necessary for this study based on the SPIRIT guidelines, as this pilot study is expected to have a short duration (~6 months) and is minimal risk to patients.	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial Please see response to 21a – this study does not have a DMC.	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	19
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	5
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	19
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	20 and Consent Form
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	20 and Consent Form

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	23 and Consent Form
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	19
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	20
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached to manuscript submission
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	4	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	7-8	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	8-10, 12-13, 29-30	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	7-8, 12-13, 29-30	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	8-9	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	9-13, 29-30	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	10	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	10	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	10, 28	The population targeted by the intervention and any eligibility criteria.
Description	**9**	14-15	A description of the implementation strategy	12-13, 29-30	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	16-17	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	15-16	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	14-15, 16-18	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	17	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	17	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	18	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	18-19	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		
Results					

Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	20-21	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	21-22	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	21-22	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	3, 5, 23	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		