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Efficacy and cost-effectiveness of an online mindfulness program (MindOnLine) to reduce fear of recurrence among people with cancer: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Fear of cancer recurrence (FCR) is a common condition among cancer survivors that can lead to significant levels of distress, anxiety and depression. Online mindfulness programmes may provide the mechanism to support cancer survivors manage FCR and distress, and improve people's well-being over the short, medium and long term. The primary aim of this study is to determine the potential efficacy of MindOnLine, a 9 session mindfulness-based programme for survivors of breast, prostate and colorectal cancer. A formal economic programme will also be conducted.

Methods and analysis A single-blind randomised controlled trial to determine the efficacy and cost-efficacy of a MindOnLine programme for cancer survivors. A total of 400 people living with cancer will be recruited via online advertisements on social media platforms, peak consumer advocacy groups or through outpatient services at healthcare providers across Victoria, Australia. People will be randomly allocated to either the MindOnLine programme (n=200) or waitlist control (n=200). Participant assessments will occur at baseline, at 9 weeks and 9-month follow-up. The primary outcome is change in Fear of Recurrence Index Score total score between baseline and 9 weeks; secondary outcomes are changes in depression and anxiety, quality of life and mindfulness. The economic analysis comprises a cost-consequences analysis where all outcomes will be compared with costs.

Ethics and dissemination Ethics approval was obtained from the Peter MacCallum Cancer Centre (20-53) and Deakin University (2020-284). All participants will be required to provide written informed consent. Findings will be disseminated in peer reviewed journals and among key stakeholder organisations including hospitals, cancer and community organisations and Government. If successful the project will be rolled out nationally with a formal implementation plan.

Trial registration number Australian New Zealand Clinical Trials Registry (12620000645954); Pre-results. Registered 6 June 2020, https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=379520&isReview=true.

Strengths and limitations of this study

- Strengths of our randomised controlled trial include the assessment of both the efficacy and cost-effectiveness of the MindOnLine programme, and the involvement of consumer advocacy groups to support recruitment, interpretation of results, dissemination and translation.
- Incorporating an economic evaluation into the study design will complement clinical findings and support decision-making processes for potential scaling.
- Advances in social platforms, smartphone technology and web-based programming can change substantially in a short period and, while this may affect the actual online platform used, measures are in place to maintain the same intervention during the study period, so we do not believe that this will influence the programme content or delivery mechanisms.
- Recruitment primarily through social media platforms means we cannot accurately assess reach of the intervention, as we will not be able to identify the number of eligible people exposed to our advertisements.
- Participants will need access to the internet, which will result in some people unable to take part in the study.

INTRODUCTION

Over one million Australians are cancer survivors, and this population is expected to grow substantially due to an ageing population and improved community-based screening programmes and treatments.[1] A cancer diagnosis can cause people to confront their own mortality, often for the first time,[2] so it may be unsurprising that three-quarters of cancer survivors experience fear of cancer recurrence (FCR) and 49% report moderate to high levels of fear,[3] as well as high levels of clinical depression[3] and anxiety.[4]

FCR is a highly prevalent and persistent condition that can result in significant levels of anxiety and depression across the disease trajectory.[5] It is imperative to address this issue and our recent work into early psychosocial support indicates it may be possible to significantly reduce FCR through an online mindfulness programme.[6] Mindfulness is a state of mind in which one pays attention to the present experience in a nonjudgmental, curious and accepting way. Some studies have shown mindfulness is associated with improved mental health outcomes and management of the emotional consequences of cancer,[7 8] while other have found no effect.[9]

Mindfulness-based interventions consist of regular informal and formal mindfulness meditation practices and are supported by educational principles that are person and relationship-centred.[10] Research into the use of mindfulness has mostly evaluated face-to-face programmes which are time-intensive, of limited accessibility and costly.[11] Online mindfulness programmes represent a potentially cost-effective mechanism to help people with physical health conditions.[12] For cancer survivors, there is evidence that online mindfulness programmes may help manage FCR and distress, and improve mental well-being over the short, medium and long term.[2]

There is also some evidence that online mindfulness-based cognitive therapy (MBCT) can improve psychological outcomes. A recent study compared an online programme to face-to-face MBCT which showed improved outcomes;[13] however, the sample comprised of mainly breast cancer survivors and it is unclear whether the programme would asist with other cancer types.[13] Although this intervention was found to be as effective as a face-to-face MBCT in reducing psychological distress and FCR in patients with cancer,[13] there is a lack of robust evidence assessing the effectiveness of a general online mindfulness programme for cancer survivors, limiting capacity for implementation and dissemination.[14 15]

The aim of this study is to conduct a randomised controlled trial of *MindOnLine,* an online 9 session mindfulness-based intervention, for survivors of breast, prostate and colorectal cancer (CRC), the most common solid tumours among men and women in Australia,[1] to determine the effectiveness and cost-effectiveness of the programme.

Preliminary work

To inform the development of *MindOnLine*, we undertook a systematic review of methodologies for internet-based mindfulness interventions.[16] This review showed a dearth of studies with long-term follow-up periods. Our team also conducted an exploratory study on the knowledge of, attitudes toward and behaviours regarding meditation among patients with melanoma.[17] Our study of 291 cancer survivors recruited at a single tertiary cancer hospital found that a key barrier to engaging with meditation was a lack of knowledge about its practice. Findings also indicated interest in an online meditation-based intervention once informed about possible benefits of meditation for people with cancer. Those interested in an online meditation-based programme reported higher perceived stress, indicating a need for such a programme.

MindOnline was initially developed as a 6-week online mindfulness-based intervention and follows the Framework for mindfulness-based programme described by Crane *et al*.[10] The programme promoted awareness and acceptance of thoughts and emotions, and empowered participants to address their distressing thoughts and emotions in more adaptive ways. Through this action, participants learn to manage anxious and depressive moods. These moods are triggered by unhelpful and intrusive thoughts, which are strongly associated with moderate to high levels of FCR.[18] A pilot study was conducted to assess the potential impact of a 6-week mindfulness programme and explore whether the intervention impacted on FCR, worry and perceived stress compared with usual care. Details of the pilot study are published elsewhere.[6] Briefly, 69 melanoma survivors agreed to participate, and 46 participants were randomised into the intervention group (2:1). Scores on all FCR Inventory (FCRI) subscales reduced in the intervention group, with the severity subscale decreasing significantly compared with the control group (−2.6, 95% CI −4.4 to −0.7; p=0.008) after 6 weeks. The total FCRI score also showed a decrease although non-significant (−6.2, 95% CI −13.12 to 0.68, p=0.07). Previous studies have indicated that a 4.1 point decrease on the severity scale is a clinically important change.[19]

Based on participant feedback from the pilot study[6] regarding the benefits of mindfulness practice and the suggestion of a maintenance period to enhance sustainability of the effects, *MindOnLine* was expanded to a 9-week programme with the last 3 weeks revisiting concepts already explored in the programme and supporting regular practice. The structure of MindOnLine reflects the mindfulness-based stress reduction approach by incorporating characteristics typical of mindfulness-based programmes, namely educational component, and formal and informal mindfulness practices. Keeping in line with Crane *et al*'s,[10] Framework for adaptation of mindfulness-based programmes, MindOnLine adapted the delivery of the programme to an online version to facilitate access and convenience of use.

METHODS AND ANALYSIS

Aims and hypotheses

The aims of this study are to determine the effect of *MindOnLine* on FCR, anxiety and depression in cancer survivors. The specific aims are:

Aim 1

To evaluate the impact of the *MindOnLine* intervention on the primary outcome (FCR), measured using the FCRI total score[20] at the end of the 9-week intervention period. *Hypothesis 1:* participants receiving the intervention will report lower average FCRI total scores at 9 weeks, compared with the waitlist group.

Aim 2

To evaluate the impact of *MindOnLine* on secondary outcomes at 9 weeks: (1) anxiety and depression, using the Patient Health Questionnaire (PHQ-9)[21] and Generalised Anxiety Disorder (GAD-7) Scale;[22] (2) Quality of Life (QoL) measured by Assessment of Quality of Life (AQOL-4D);[23] and (3) mindfulness, using Cognitive and Affective Mindfulness Scale-Revised (CAMS-R).[24] *Hypothesis 2*: compared with the waitlist group, participants in the intervention group will report improvement in all of the secondary outcomes at 9 weeks.

Aim 3

To assess if the effect of the intervention on the primary and secondary outcomes, relative to usual care, is sustained at the 9-month follow-up. *Hypothesis 3*: compared with the waitlist group, participants in the intervention group will report sustained improvement in primary and secondary outcomes at 9 months.

Aim 4

To assess, from a health sector and broader societal perspective, the cost-effectiveness of *MindOnLine*. *Hypothesis 4*: compared with the waitlist group, *MindOnLine* will be cost-effective with an incremental cost-effectiveness ratio likely to fall below the commonly used threshold of US$28 000–US$50 000/QoL Year.

Study design

This study is a randomised controlled trial, to test the effectiveness and cost-effectiveness of MindOnLine compared with usual care on FCR, anxiety, depression and QoL among people diagnosed with breast, prostate or CRC. Overall, 400 patients will be recruited with 200 patients randomly allocated to the intervention group and 200 to the waitlist group (usual care only). The intervention group will receive usual care and the online mindfulness programme. Primary and secondary outcomes will be collected at baseline, 9 weeks and 9 months post randomisation. Nine months corresponds to approximately 6 months following the end of the intervention period. Following completion of the study (9 months), participants in the waitlist group will be offered the *MindOnLine* intervention (figure 1).

Participants

People with a diagnosis of breast, prostate or CRC will be recruited via online advertisements on social media platforms, peak consumer advocacy groups for each cancer Breast Cancer Network Australia (BCNA), or Prostate Cancer Foundation Australia (PCFA), Bowel Cancer Australia social media platforms and CRC support groups or through outpatient services at healthcare providers across Victoria; see figure 1.

Inclusion criteria

Adults, aged 18 years of older, living in Australia, who completed active treatment for stage 1–3 breast, prostate or CRC, (trastuzumab/similar and hormone treatment exempt) within the past 5 years and have no evidence of disease; have internet access and an FCRI severity score ≥13, indicating clinically significant FCR.[19] Our pilot study showed 74% of participants with melanoma were identified as having clinically significant FCR.[6]

Exclusion criteria

Insufficient English language skills to understand videos presented in English, complete surveys in English or living with advanced cancer (stage IV disease with less than a 12-month prognosis of survival).

Recruitment procedures

Multiple methods will be applied to recruit people to the study:

1. Online through *MindOnLine* social media pages including Facebook, Instagram, Twitter, Reddit and LinkedIn.
2. Sharing recruitment flyers through BCNA and PCFA social media platforms, and Australian-based cancer groups.
3. Email invitations sent to BCNA and PCFA supporters (and CRC support groups) and cancer registries.
4. Paid Facebook and Instagram advertising.
5. Through outpatient clinics, chemotherapy and radiotherapy units and rooms of oncologists and surgeons at cancer treatment centres.

Online recruitment procedure

(1) The *MindOnLine* social media pages will be shared among social networks and will allow people to post questions about the project. (2) A recruitment flyer will be distributed by BCNA, PCFA, Bowel Cancer Australia and CRC Facebook support groups using their existing social media platforms. (3) Study invitations will be sent to supporters registered with BCNA and PCFA who have indicated an interest in learning about research projects. (4) Paid advertisements will run throughout the recruitment period on Facebook, Instagram and Twitter to distribute the project details to a wider audience. The use of paid advertisements in health research is becoming popular and a systematic review has shown this to be an effective recruitment strategy.[25]

In all online recruitment methods, people will have access to the recruitment flyer, which will provide a brief

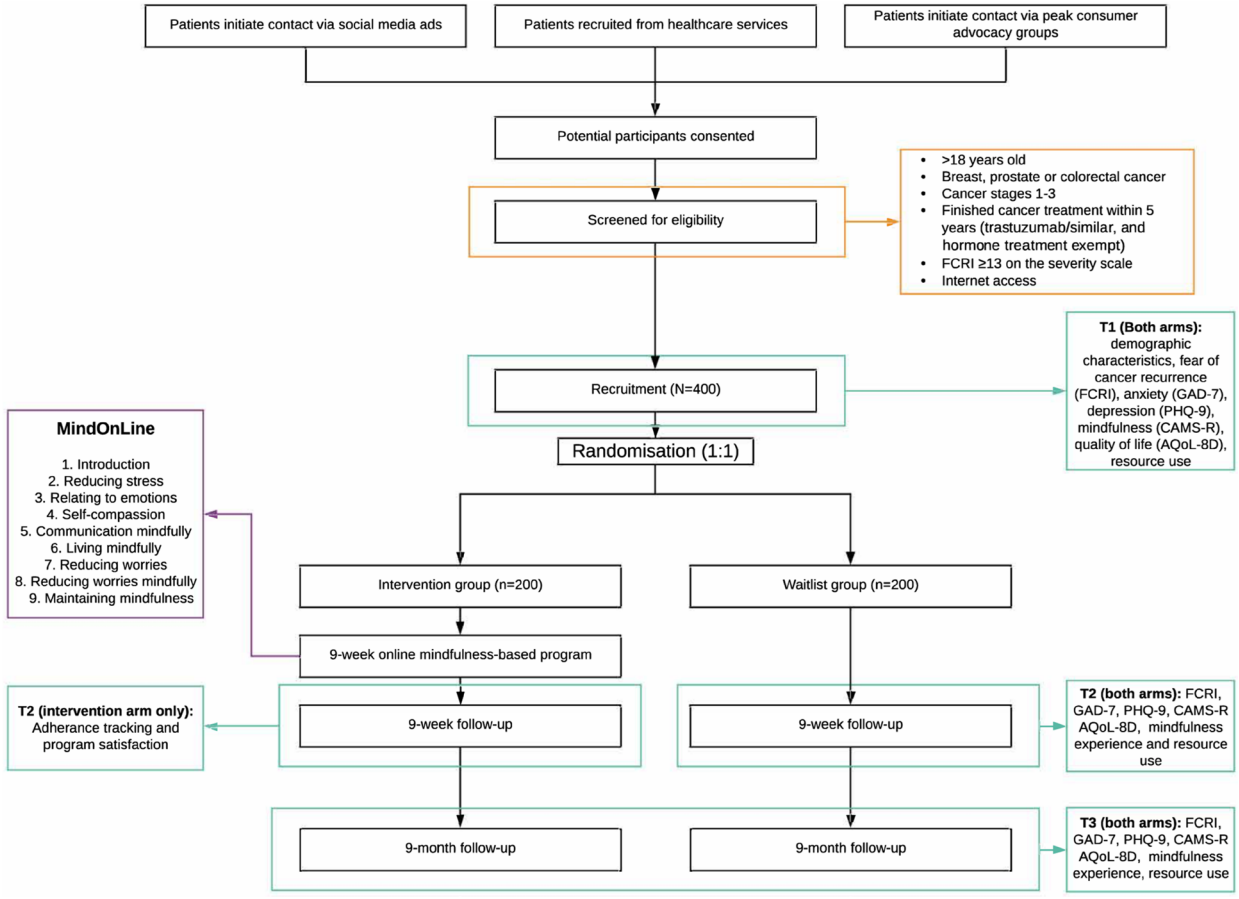

Figure 1 Study flow chart. AQoL-4D, Assessment of Quality of Life-4 Dimensions; CAMS-R, Cognitive and Affective Mindfulness Scale-Revised; FCRI, Fear of Cancer Recurrence Inventory; GAD-7, General Anxiety and Distress Scale; PHQ-9, Patient Health Questionnaire.

overview of the study, the link to the *MindOnLine* registration page and the contact number of the project manager.

Health service recruitment procedures

If recruitment across social media platforms, advertisements and peak consumer advocacy groups does not generate sufficient participation levels, participating health services oncologists or surgeons involved in the project, will support the recruitment process. The research assistant (RA) at each site will screen patients and confirm eligibility of patients with treating clinicians or with nurses working in the outpatient units. RAs will then contact patients by phone and interested patients will be emailed the study details with a link to the study webpage and registration page. If there is no response from patients, a message will be left on their phone. Two further attempts to reach patients will be made (a week apart), and after a third unsuccessful attempt no further contact will be made. If patients have not enrolled in the study within 2 weeks, one follow-up phone call will be made to answer any queries patients may have about the study and to assist with registration. We have used similar screening and recruitment approaches in previous studies and they were found to be acceptable and successful.[6] We anticipate a recruitment period of 18 months.

Consent and screening

Once directed to the *MindOnLine* registration page, participants will be presented with the plain language statement and then asked to provide consent (online supplemental file 1). Potential participants will be asked to provide basic demographic and disease information allowing screening to ensure they meet study eligibility criteria. Potential participants will also complete the severity subscale of the FCRI to allow those with scores ≥13 to be screening into the study. Those screened into the study will provide their email address and contact number, and directed to the baseline questionnaires. People who are not eligible will receive an online message thanking them for their interest in the study and referring them to local support services provided by leading cancer charities should they require support.

Randomisation

Eligible participants will be allocated to treatment groups using random sequences embedded in the online survey platform Qualtrics, ensuring allocation concealment. Randomisation (using stratified random permuted blocks) will be conducted in blocks of size 2, stratified by cancer type (breast, prostate, CRC) and age (<60; ≥60 years old). Participants will be unblinded to group

Table 1 Weekly content of the *MindOnLine* programme

Week	Theme	Meditation	Daily practice
1	Introduction to mindfulness	Breath	Being present with the experience
2	Reducing stress	Body scan	Notice how the body responds to stress
3	Relating to emotions	Working mindfully with emotions	Noticing the cycle of emotions
4	Self-compassion	Self-compassion	Notice self-criticism
5	Communicating mindfully	Listening/sound meditations	Bringing attention back to the conversation
6	Living mindfully	Practising with gentleness and patience	Pause throughout the day
7	Reducing worries	Mindfully working with worries and fears	Notice when caught up overthinking
8	Reducing worries mindfully	Loving kindness meditation	Notice acts of kindness
9	Maintaining mindfulness	Silence with bells	Notice when distracted from being present

assignment, while researchers and data analysts will be blinded to the group condition.

Waitlist control group

Participants allocated to the waitlist group will receive usual care. Following randomisation, they will receive an email with a list of services they may contact for information and support. They will be informed that they will be granted access to *MindOnLine* intervention in 9-month's time, when intervention participants have completed the final survey.

Intervention group—MindOnLine program

Participants allocated to the intervention will be provided with the link to *MindOnLine,* which comprises three main components:

1. an educational component to increase participants' knowledge about the science and practice of mindfulness and how it may benefit them in everyday life;
2. a formal mindfulness meditation practice to improve awareness and emotion regulation; and
3. an informal practice to teach participants how to bring mindfulness to daily activities.

A new theme is introduced each week, with a new meditation practice which participants will be encouraged to undertake every day *The MindOnLine* programme is detailed in table 1.

Each module's theme will be explained through a short 5–10 min video. At the end of each week, participants will receive an email with a link to the video introducing the theme for the upcoming week. The transcripts for the videos will be available for downloading and saving or printing in a pdf format so that participants can keep a copy for later reference. At the end of each module, participants will receive an automatically generated email reminding them to continue daily meditation practice (formal practice) and given specific everyday mindfulness exercises to apply during daily activities (informal practice).

To enhance adherence and retention to the 9-week programme and deepen their mindfulness experience, participants will have access to additional programme features. The features are guided by a framework proposed by Abraham and Michie[26] to facilitate behaviour change in interventions:

1. Two times per day reminders to complete mindfulness practice. Adapted from the pilot study, emails containing a link to a short, guided meditation audio file will be sent to participants two times per day. These emails will serve as reminders to meditate and will provide easy access to the meditation practice of the week.
2. Progress tracking. Participants will be able to monitor their own mindfulness practice each day by reviewing how many times they have used each section of the programme, and the duration of use. Embedded usage data tracking systems records each login and provides real time representation of programme use.
3. Goal setting. When enrolled in the programme, participants will have the opportunity to set goals for their mindfulness practice (figure 2). Goals are linked to usage data tracking to provide participants with feedback about whether they are reaching their goals. Goals may be practice orientated, for example, to practise mindfulness for 5 min each day, or may be specific to each person's situation for example, I would like to manage my worries leading up to my oncologist appointment.
4. Reflective journaling. Participants will have the opportunity to journal their experiences during the mindfulness programme by using the 'My Journal' functionality (figure 3). Each week's content will have a journal section, which will include prompts related to mindfulness programme content, participants will be able to enter and save their responses within the programme for future review. Prompts will be developed specifically for the study.

The mindfulness programme can be accessed at any time via direct login to the website or via the hyperlink sent to participants in the daily emails.

Data collection

Table 2 illustrates the overall schedule for trial participants in both groups. All assessments will be performed online. The questionnaires at baseline, at 9 weeks including the satisfaction survey for those in the intervention group and at 9 months, will be sent via Qualtrics through an

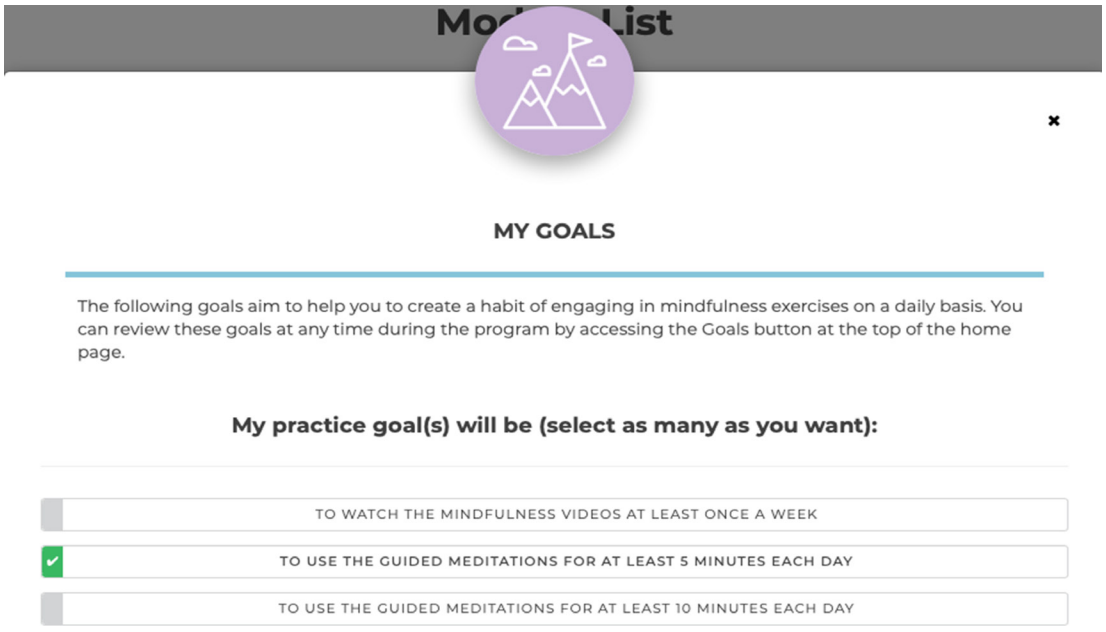

Figure 2 My Goal functionality in MindOnLine.

automatically generated schedule. Participants who do not complete questionnaires will be followed up by telephone at each data collection point. At baseline, participants' demographic information (ie, gender, age, marital status, current employment status, highest level of education, postcode, type of cancer, date of diagnosis, time since end of last treatment, type of treatment and previous meditation experience) will be collected.

Outcome measures

Primary outcome

Fear of Cancer Recurrence Inventory

The 42-item FCRI is a multidimensional FCR scale intended for use with all patients with cancer. Items were developed on the basis of a cognitive–behavioural formulation of FCR (range: 0–168).[19] The FCRI consists of seven domains: triggers, severity, psychological distress, functional impairment, reassurance, insight and coping strategies (scoring range: 0–36). It has shown high internal consistency, good construct and criterion validity in adults with different cancer types.[20]

Secondary outcomes

Anxiety and depression

The *GAD-7 Scale*[22] is a valid and efficient tool for assessing generalised anxiety symptoms and assessing severity in clinical practice and research. The seven items assess the frequency of core symptoms of GAD within the past 2 weeks (scoring range: 0–21).[22]

The *PHQ-9*[20] parallels the nine diagnostic symptom criteria that define the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) major depressive disorders (fourth edition). At only 9 items (scoring range: 0–27), the PHQ-9 is shorter than most depression tools. Unlike most other measures of depression, the PHQ-9 was developed, tested and refined for use with medical patients.[21]

The PHQ-9 and GAD-7 are recommended for use among cancer survivors in the American Society of Clinical Oncology Guidelines.[27]

Mindfulness

Trait mindfulness is measured using the CAMS-R,[24] a 10-item self-report questionnaire. This scale uses everyday

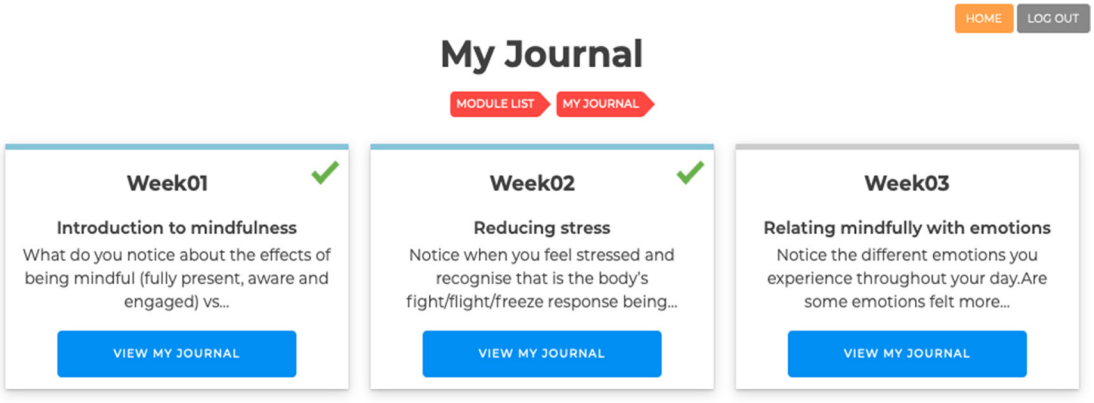

Figure 3 My Journal-guided self-reflection practise in MindOnLine.

Table 2 Schedule of enrolment, interventions and assessments

	Study period											
			Post allocation									Post intervention
Timepoint	**Enrolment**	**Allocation**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Week 8**	**Week 9**	**9 months**
Enrolment												
Eligibility screen	X											
Informed consent	X											
Allocation		X										
Interventions												
Immediate access to MindOnLine				◆	———	———	———	———	———	———	———	◆
Waitlist group												
Assessments (both groups)												
Demographic characteristics	X											
FCRI[18]	X										X	X
GAD-7[20]	X										X	X
PHQ-9[19]	X										X	X
CAMS-R[22]	X										X	X
AQoL-4D[21]	X										X	X
Mindfulness experience	X										X	X
Resource use	X										X	X
COVID-19 measures	X										X	X
Assessments (intervention group only)												
Adherence tracking and meditation log			X	X	X	X	X	X	X	X	X	X
Programme satisfaction											X	X

AQOL-4D, Assessment of Quality of Life; CAMS-R, Cognitive and Affective Mindfulness Scale-Revised; FCRI, Fear of Cancer Recurrence Inventory; GAD-7, Generalised Anxiety Disorder; PHQ-9, Patient Health Questionnaire.

language appropriate for those with little meditation experience and is designed to capture mindfulness as a general daily experience. The questionnaire comprises four domains of mindfulness (attention, present-focus, awareness and acceptance/non-judgement). Participants are asked to rate on a 4-point Likert scale how much they relate to each statement (scoring range: 4–40). Compared with other measures of mindfulness, the CAMS-R is unique in that it is related to psychological distress,[28] which is highly relevant to the current study population.[29]

Other outcome measures

Mindfulness experience

In order to control for access to external mindfulness-based programmes particularly in the waitlist group, all participants will be asked whether they have enrolled in a mindfulness-based programme in the period between surveys and/or used other supportive care services (eg, peer support, psychologists, psychotherapy, counsellors, yoga and meditation).

Program satisfaction

Participants in the intervention group will be asked to provide feedback about the *MindOnLine* programme. Quantitative and qualitative data using open-ended questions will be collected in relation to satisfaction with programme content, the helpfulness of the programme, usability and areas for improvement. The satisfaction questionnaire has been adapted from the satisfaction questionnaire used in the pilot study.[6]

Economic outcomes

AQoL 4D[23] is a health-related QoL utility measure. It is generally used in economic evaluations. The *Resource Use Questionnaire* covers general healthcare services usage (self-reported), use of other welfare services and impacts on work force participation. The questionnaire has been successfully used in cancer psychosocial intervention studies.[30]

The surveys will take approximately 20 min to complete.

Adherence tracking and meditation log

The software package used to run *MindOnLine* was developed at Deakin University and has inbuilt functionality to collect and clean usage data. Google Analytics has been incorporated into the platform to allow for validation of findings. Both software will track participants' online activity, including login date/times, navigation patterns, page views and duration and features used (video, audio, goals and reflective journaling).

Impact of COVID-19

To control for potential environmental impacts on mental well-being outcomes, participants will be asked whether COVID-19 has had an impact on their mental well-being in the 2 weeks prior to baseline, 9-week and 9-month assessments.

Sample size calculations

Power calculations are conservative, that is, the detectable differences reported below are possibly larger than the true detectable differences, because they are based on two-group comparison of change while the main analysis (see Analysis plan) will adjust for baseline values of the outcome and for factors used in the stratified randomisation.[31] The statistical software PASS V.14.0.9 (NCSS, LLC) was used for all calculations (α=0.05; two-sided tests).

Primary outcome

Change in FCRI total score between baseline and 9 weeks. The target sample size (200 participants per arm) achieves 94% (80%) power to detect a mean difference between arms of 10 points (8 points) change in FCRI score or 80% power to detect a difference of 8 points (SD: 23.5[32]) SD estimate obtained from Butow *et al*,[32] as their study included a heterogenous sample of patients with cancer while our pilot study only included patients with melanoma stage 2–3. The selected effect sizes correspond to Cohen's d of 0.43 (moderate/large) and 0.34 (small/moderate), respectively. Currently, there is no definition of a clinically significant improvement for FCRI score; however, the proposed effect size is comparable to that described in other studies.[32]

Secondary outcomes

The target sample size (200 participants per arm) achieves 80% power to detect an intervention effect of size 0.34 (Cohen's f, small/moderate) at 9 weeks for any of the outcomes. This effect size corresponds to mean differences between groups of: (1) 1.5 point in PHQ-9 depression score (SD=4.5, maximum SD reported in patients with breast, colorectal and prostate cancer;[33] PHQ-9 minimal clinically important difference (MCID) for patients with cancer: 2.6–5);[34] (2) 1.4 point in GAD-7 anxiety score (SD=4.1, maximum SD reported in patients with breast, colorectal and prostate cancer;[35] MCID=1.95);[33] and mean differences between group in change from baseline to 9 weeks of: (3) 1.2 points in FCRI severity score (SD=3.6, pilot study effect: 2.6);[6] (4) 1.1 points in CAMS-R score (SD=3.4); (5) 2.5 points in Worry score (SD=7.3); (6) 3.0 points in PSS score (SD=8.9); the last three reflecting moderate Cohen's d effect sizes (<0.35).

To meet the sample size needs of our desired statistical power, we will recruit 400 participants. In our pilot study, six participants (13%) withdrew in the intervention group and none in the control group. Assuming a conservative 30% attrition rate at 9 months, we expect to have complete data for approximately 280 participants (140 per group).

Analysis plan

All statistical analysis will be conducted on an intention-to-treat basis whereby all randomised participants with at least one postbaseline measurement will be analysed by original treatment assignment regardless of adherence.

Baseline characteristics will be described using summary measures selected based on variable distribution. The main analysis will adjust for baseline values of the outcome and for factors used in the stratified randomisation.[31]

Aims 1 and 2: the effect of the intervention on each of the outcomes, defined as change from baseline to 9 weeks, will be assessed using linear models including group and the stratification factors. *Aim 3*: the effect of the intervention across the three measurement times will be estimated using linear mixed models, including study group, time (categorical: 9 weeks, 9 months) interaction group×time and the stratification factors as fixed effects and participant as a random effect. If there is a positive intervention effect on mental health outcomes, exploratory mediation analyses will be conducted to determine whether improvements are mediated by increases in mindfulness.[36] For outcomes where it is a plausible assumption that missing data are completely at random, we will use complete case analysis; if not plausible, we will use multiple imputation. *Subgroup analysis*: we will explore whether age or gender modify the effect of the intervention on FCR, depression and anxiety at 9 weeks.

Aim 4: this study will also comprise a cost-consequences analysis where incremental costs of the intervention will be compared with the full spectrum of outcomes included in the study. A series of cost-effectiveness ratios can be determined which have been shown to be useful for decision-makers. Inclusion of the AQoL 4D will also enable a cost-utility analysis to be undertaken, thereby allowing practical judgements to be made regarding value for money credentials of the intervention. Nevertheless, the economic analysis will be primarily from the perspective of the healthcare sector and a secondary analysis from the broader societal perspective will also be undertaken. A detailed costing of the intervention will be undertaken and the evaluation will first measure and value any change to the use of healthcare resources over the period of the study between the two arms of the trial and then compare any additional costs to the additional outcomes achieved. Standardised economic evaluation techniques will be used including incremental analysis of mean differences and bootstrapping to determine CIs along with a net monetary analysis to determine the cost-effectiveness of the intervention for different value for money threshold criteria. The costs of routine roll-out will be estimated.

MindOnLine usage data by the intervention group will be reported using descriptive statistics. Linear mixed models, with random intercept and slope for each person, will be fitted to estimate time trends in usage.

Data management

Data will be exported from Qualtrics on a monthly basis and crossed checked during exportation to ensure accuracy in results. All identifying participant information will be removed from data sets. Documents containing sensitive information will be saved as password protected files and stored within the Deakin University One Drive.

Monitoring

Data

The adherence data will be monitored by the programme developer. The programme developer does not have any competing interests. Other project data will be monitored by the project steering committee with regular meetings and progress updates. No interim analysis will be performed during the trial.

Patient and public involvement

Representatives from three consumer organisations have been involved in the design and implementation of the project since its inception. Their contribution has included development of the intervention and its content, wording on recruitment material, and provided advice on recruitment strategies. Representatives from each consumer organisation have contributed to project steering meetings.

Ethics and dissemination

Harms

All participants will be required to provide written informed consent. In the event that a participant reports distress to the project manager they will be advised to seek assistance from the regular medical professionals and provided with additional referrals to lifeline.org.au. Ethics approval was obtained from the Peter MacCallum Cancer Centre (20-53) and Deakin University (2020-284). Any adverse events will be reported to the ethics committees.

Auditing

The trial may be audited by the governing Human Research Ethics Committees.

Protocol amendments

Protocol amendments will be approved by the governing Human Research Ethics Committees. Any relevant changes will be submitted as a modification to the Australian and New Zealand Clinical Trial Registry.

Dissemination

The findings of this study will be written by study authors and published in peer reviewed journals project steering committee. All identifying participant information will be removed prior to publication.

DISCUSSION

One of the most significant changes across society is the use of web-based technology. Online mindfulness-based interventions circumvent problems with traditional face-to-face delivery of the programme, impacted by work commitments, caring responsibilities, geographical isolation and pandemics.[37 38]

This study will rigorously evaluate the efficacy of a self-directed online mindfulness programme in reducing FCR in breast, prostate and CRC survivors. The study will advance the literature regarding the benefits of

mindfulness for cancer survivors by representing one of few large well controlled trials of a self-directed mindfulness-based programme, involving smartphone technology, aimed at reducing FCR. Including a health economic evaluation of the programme adds to the utility of the trial with the study providing information that budget holders and policy-makers need when considering recommendations and support for supportive care programmes. This trial will fill a gap in knowledge regarding the potential impact of an online mindfulness programme in supporting cancer survivors.[7] Extensive pilot work in identifying the type of programme cancer survivors is interested in involving consumers in designing the content and length of the programme and providing reminders and practice tips increase the likelihood of participants engaging with the programme and the intervention having a positive impact.

The study is being conducted in partnership with health services and cancer advocacy groups. As partners in the study, they will ensure the intervention can be rolled out to cancer survivors if shown to be effective. In addition to consumer advocacy groups, the study is being conducted in partnership with government. As we expect the *MindOnLine* intervention to improve health outcomes, reduce the fear and distress in cancer survivorship and reduce health service and community costs our partnership with government will ensure that policy-makers are informed of the study's findings particularly cost-effectiveness findings.

The study has a number of strengths and weaknesses. Development of the intervention through a review of the literature, input from consumers and findings from a pilot study and involvement of consumer advocacy groups and government are study strengths ensuring translation of the programme into practice if shown to be effective. For example, consumer advocacy groups have contributed to the design of the intervention programme, recruitment of eligible patients, and will provide advice on the interpretation of results, dissemination and translation. Incorporating an economic evaluation into the study design is a strength as it will complement clinical findings and support decision-making processes for potential implementation.

However, several methodological limitations also need to be acknowledged. Recruitment through social media platforms means we cannot accurately assess uptake of the intervention, as we will not be able to identify the number of eligible people exposed to our advertisements. This may limit our ability to determine reach of the programme. However, recording the time taken for recruitment and accessing google analytic data on internet traffic and page visits may provide some information in this area. Participants will need access to the internet to participate. While this may mean some people will be excluded from the study, we believe this will have minimal impact on the study. We envisage that the study will take approximately 4 years to complete. Advances in social platforms, technology and app-based programming can change substantially in a short period. While this may affect the actual online platform used for the programme, we do not consider this will influence the programme content or delivery mechanisms. As technology advances will likely increase interest in self-directed support programmes for cancer survivors, it is essential that cancer survivors access programmes with demonstrated effectiveness.

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Participant Information Sheet/Consent Form

Title	MindOnLine: a mindfulness program for people with breast, bowel or prostate cancer.
Short Title	MindOnLine
Principal Investigator	Prof Trish Livingston
Location	Deakin University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, because you have received treatment for breast, prostate or bowel cancer. This research project is testing an online mindfulness-based program for people who have completed their treatment.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to provide consent online. By agreeing you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

Following treatment for cancer, many people feel anxious and scared about the cancer coming back. This is one of the most common fears of cancer survivors, and it can affect people's ability to enjoy life

and plan for the future. In some people, this fear can decrease over time, but most people find that they worry at certain times. The mindfulness program aims to help cancer survivors to manage their fears and worries once treatment is completed.

Research has shown that mindfulness-based programs can help people cope with anxious thoughts about their cancer. The internet allows people to use the program from the comfort of their home, and at their most convenient times. We have tested an online mindfulness program for people who received treatment for melanoma, with promising results. This research is to find out whether mindfulness can help people with breast, prostate or bowel cancer.

This research is being conducted across healthcare services and cancer organisations and is led by researchers at the School of Nursing and Midwifery at Deakin University.

In this research project we will be testing a mindfulness program among people who meet the following criteria:

- People who are over 18 years of age
- People who speak English well enough to understand videos and surveys presented in English
- People who have access to a computer or device to receive the program
- People who received treatment for breast, bowel or prostate cancer
- People who finished chemotherapy, radiotherapy or surgery treatment within the last five years
- People who experience a high level of fear of cancer recurrence.

You will be asked some questions after providing consent to determine if you meet the eligibility criteria above. To measure your fear of cancer recurrence you will be asked 9 questions about how your thoughts and feelings towards cancer may impact on your everyday living.

3 What does participation involve?

To participate in this study, each participant will need to have access to a computer, a smartphone, or a similar tablet device, and internet. If you agree to take part in this project you will be allocated to either receive the mindfulness program (intervention group) or stay in your usual care (control group). We need to compare responses from people in these two groups to see if the mindfulness program provides any benefits to cancer survivors. In order to make sure the groups are the same, participants are put into one of the two groups by chance (random).

If you decide to take part in this study, you will need to provide your consent to participate by accessing the following website: https://mindonline.org.au Before providing your consent you will be asked a number of questions to make sure you are eligible for the study.

After consenting to take part in the study, you will be asked to complete a survey before being randomly allocated to the intervention or control group. The same survey will be completed again 9 weeks and 9 months later. The survey asks you questions about possible fears of the cancer coming back, how stressful and worrisome you perceive your life to be, and the type of thoughts you generally focus on. We will also collect your email address and contact number. Your email and contact number will be used to send you reminders and other information related to the study.

If you are randomised to the mindfulness program, you will receive an email informing you of your allocation group with instructions on how to access the website. Your participation will involve using the program for 9 weeks. The program is designed to help you understand and experience potential benefits of using mindfulness in your day to day life. You will be invited to:

- Watch short videos at the start of each week. The videos will introduce a new topic about mindfulness.
- Practice short meditations twice a day. We will help you create a meditation routine by emailing you a direct link to guided meditations at times you will have chosen.
- Apply mindfulness skills in your day-to-day life.

If you are assigned to the mindfulness program we will monitor how often the mindfulness program is used. This will be recorded by your study identification number, and no personal information such as your Internet Protocol (IP) address linked to your computer or device will be collected.

If you are randomised to the control group you will receive an email informing you of your allocation group and you will continue to receive your usual care from your healthcare providers. You will receive emails to ask you to complete the questionnaires at 9 weeks and 9 months. After the 9-month survey you will be able to use the mindfulness program.

We will compare the results between those in the mindfulness program and those who are not, to see if there are any differences in wellbeing between the two groups.

There are no additional costs associated with participating in this research project, nor will you be paid.

4 Other relevant information about the research project

This study will show if the mindfulness program is helpful for people with breast, prostate or colorectal cancer. If successful the program we be made open to the wider population.

For this study, approximately 400 people will be invited to participate from online and social media advertisements and from healthcare services.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with those treating you or involved in your follow-up care, or your relationship with Deakin University, Breast Cancer Network Australia, or Prostate Cancer Foundation of Australia.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits for the community may include additional support for people who have completed treatment for cancer.

7 What are the possible risks?

Some people may feel uncomfortable or upset when answering questions in this survey. If you do not wish to answer a question you may skip it and go to the next question, or you may stop immediately. In the event that you become upset or distressed as a result of your participation, the researcher can arrange for counselling or other appropriate support provided by staff who are not members of the research team. In addition, you may want to contact an external support service such as Lifeline services on 13 11 14, or www.mindhealthconnect.org.au or the Cancer Council 13 11 20 telephone service.
If you have any concerns or are unsure whether you should participate in this project, you may wish to speak to your healthcare professional about your feelings.

8 What if I withdraw from this research project?

If you decide to withdraw, please notify a member of the research team about this decision. This notice will ensure that we can remove you from our records and will mean you will not receive any notices about the project.

If you decide to withdraw from the project, we would like to keep the personal and health information about you that has been collected. This is to help us make sure that the results of the research can be measured properly. If you want to withdraw your data from the study as well, please let them know when you tell them about withdrawing from the study.

9 What happens when the research project ends?

If you wish to obtain a final copy of the research report describing the results of this study, please contact the project manager (Dr Natalie Heynsbergh on 03 9246 8225, or email n.heynsbergh@deakin.edu.au) and she will arrange for a copy to be sent to you after completion of the study in December 2022.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

Any information obtained in connection with this research project that can identify you (e.g. email address) will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law.

All the information you provide will be coded so you cannot be identified by name, and only the research team will have access to the list that can link your name to your data. All identifying information will be stored in password-protected electronic files or in a locked filing cabinet in the office of the research staff, and will be disposed of as confidential waste after five years.

You will not be identified in any report or publication from this study. Information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named in the last section below if you would like to access your information.

11 Who is organising and funding the research?

This research project is being managed by Dr Natalie Heynsbergh at Deakin University, and is being funded by a National Health and Medical Research Council (NHMRC) grant.

12 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been

approved by the Peter MacCallum Human Research Ethics Committee (Reference number 20/53) and the Deakin University Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

13 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact:

- The principal investigator: Prof Patricia Livingston on 03 9244 6609, or email trish.livingston@deakin.edu.au
- The project manager: Dr Natalie Heynsbergh on 03 92468225, or email: n.heynsbergh@deakin.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	Peter MacCallum Cancer Centre Ethics Committee
Project reference number	20/53
HREC Executive Officer	Ethics Coordinator
Telephone	03 8559 7540
Email	ethics@petermac.org

14 What do I do if I want to participate?

If you would like to participate in this study, please log on to https://mindonline.org.au, to answer the eligibility questions and provide your consent to participate.