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ORIGINAL ARTICLE

A pilot randomised controlled trial of an online mindfulness-based program for people diagnosed with melanoma

Lahiru Russell[1] · Anna Ugalde[1] · Liliana Orellana[2] · Donna Milne[3] · Meinir Krishnasamy[4,5] · Richard Chambers[6] · David W. Austin[7] · Patricia M. Livingston[1]

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Abstract

Purpose This study assessed the feasibility and acceptability of an online mindfulness-based intervention (MBI) for people diagnosed with melanoma. The potential benefit of the MBI on fear of cancer recurrence (FCR), worry, rumination, perceived stress and trait mindfulness was also explored.

Methods Participants who have completed treatment for stage 2c or 3 melanoma were recruited from an outpatient clinic and randomly allocated to either the online MBI (intervention) or usual care (control). The 6-week online MBI comprised short videos, daily guided meditations and automated email reminders. Participants were asked to complete questionnaires at baseline and at 6-week post-randomisation. Study feasibility and acceptability were assessed through recruitment rates, retention and participant feedback. Clinical and psychosocial outcomes were compared between groups using linear mixed models.

Results Sixty-nine (58%) eligible participants were randomised (46 in the intervention; 23 in the control group); mean age was 53.4 (SD 13.1); 54% were female. Study completion rate across both arms was 80%. The intervention was found helpful by 72% of the 32 respondents. The intervention significantly reduced the severity of FCR compared to the control group (mean difference = − 2.55; 95% CI − 4.43, − 0.67; $p = 0.008$). There was no difference between the intervention and control groups on any of the outcome measures.

Conclusions This online MBI was feasible and acceptable by people at high risk of melanoma recurrence. It significantly reduced FCR severity in this sample. Patients valued accessing the program at their own pace and convenience. This self-guided intervention has the potential to help survivors cope with emotional difficulties. An adequately powered randomised controlled trial to test study findings is warranted.

Keywords Mindfulness · Online · Fear · Cancer · Oncology · Melanoma · Feasibility

Introduction

People with a melanoma diagnosis experience fear and concerns about their cancer recurring [1–5]. A normal level of fear of cancer recurrence (FCR) can ensure a person remains alert and aware of signs and symptoms of recurrence [6], but if the fear persists, it may lead to psychological distress such as anxiety or depression [1]. Among people with melanoma, high FCR can cause delays in seeking medical care and reduced participation in recommended cancer surveillance

✉ Lahiru Russell
l.russell@deakin.edu.au

[1] School of Nursing and Midwifery, Faculty of Health, Deakin University, Geelong, Victoria, Australia

[2] Biostatistics Unit, Faculty of Health, Deakin University, Geelong, Australia

[3] Skin and Melanoma Services/Department of Cancer Experiences Research, Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia

[4] Department of Nursing, School of Health Sciences, University of Melbourne, Melbourne, Victoria, Australia

[5] Victorian Comprehensive Cancer Centre, Melbourne, Victoria, Australia

[6] Campus Community Division, Monash University, 40 Exhibition Walk, Clayton, Victoria 3800, Australia

[7] School of Psychology, Faculty of Health, Deakin University, Geelong, Victoria, Australia

programs [4, 7]. Persistent FCR involves frequent and chronic intrusive thoughts, anxiety and excessive worry about a possible recurrence [8]. FCR is also positively correlated with ruminating over cancer-related information [9].

Psycho-educational interventions targeted at people with melanoma can decrease anxiety and health-related distress, and prompt positive change in coping with illness [3]. More specifically, a theoretical framework for FCR presenting the multidimensional nature of FCR highlighted the importance of cognitive processing and metacognitions in the development and maintenance of FCR. This framework proposed that improving awareness of thoughts may be a therapeutic approach to reduce worrisome and unhelpful thoughts, which underlie FCR [10]. This awareness is an essential component of mindfulness-based interventions (MBIs) [11].

Mindfulness is a state of mind in which one is aware of any thoughts, feelings, bodily sensations and surrounding environment occurring moment-by-moment [12]. In this state of awareness, thoughts and feelings are experienced as passing events in the mind, instead of a reflection of oneself or reality. This detached self-observation allows individuals to reflect on situations and respond in more adaptive ways, instead of reacting in an automatic, habitual pattern [11].

Systematic reviews of studies conducted among various cancer populations have shown that MBIs can improve quality of life, trait mindfulness, acceptance of one's cancer situation, and reduce depression and anxiety [13–15]. Although there is a growing body of evidence on the benefits of MBI for individuals living with cancer, practical barriers exist that may limit access to, and participation in, face-to-face programs. Generally, online interventions are more easily accessible, available at any time to people in their own environment, enable people to work at their own pace, and to remain anonymous [16]. In a study of 291 melanoma survivors, 44% reported an interest in participating in an online meditation-based program [17]. Furthermore, a systematic review of online MBIs for people with a medical condition such as cancer reported that online MBIs can have positive effects on patients' general health and psychological well-being [18], and a systematic review of MBIs on chronic conditions found self-guided MBIs can be as effective as therapist guided MBIs [19].

Our study assessed the feasibility and acceptability of conducting an online mindfulness-based program for people at high risk of melanoma recurrence. The potential benefit of the intervention to impact on FCR, worry, rumination, perceived stress and trait mindfulness was also assessed.

Methods

A published protocol details study procedures [20].

This study is registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12617000081314) and follows guidelines from the CONSORT statement for reporting randomised controlled trials [21]. The study was approved by the Human Research Ethics Committees of the recruitment centre (HREC/16/PMCC/139) and Deakin University (DUHREC 2017-036).

Participants

Potential participants attended a comprehensive cancer centre in Melbourne, Australia. Recommended follow-up for patients who have completed treatment for stage 2c or 3 melanoma consists of quarterly follow-up consultations with multidisciplinary oncology specialists and includes physical examination and PET (positron emission tomography) scanning to monitor potential recurrence, new primaries or metastatic disease.

People were eligible for our study if they had a melanoma diagnosis of stage 2c, 3a, 3b or 3c, completed their last treatment within the past 5 years, were 18 years or older, had sufficient understanding of English to consent and complete English-based questionnaires, and had regular access to a digital device (laptop, tablet, smartphone) and the internet.

Patients were excluded if they had a severe cognitive impairment or intellectual disability (as reported in their medical records or determined by the treating clinician or oncology nurse), were due to commence treatment or were currently receiving treatment for a melanoma recurrence.

Study procedure

The study was a pilot randomised (2:1) controlled trial conducted at a single site. Participants in both groups continued to receive the usual care offered by the centre, while participants in the intervention group also received access to a 6-week online mindfulness program.

Patients were identified through the health service database, and clinical eligibility determined using electronic medical records and in consultation with the clinical nurse coordinator. Recruitment took place in the melanoma outpatient clinics over a period of eight months, from February to September 2017.

Clinicians were notified of their patients' eligibility and were asked to inform patients about the study during their consultation. Patients interested to learn more about the study met with the researcher at the end of the consultation. Those having access to the internet and an electronic device were invited to participate. Interested patients were provided with an information package to take home and were contacted by telephone at an agreed time to answer any questions related to the project.

Participants were provided with a URL address, which comprised the study information and a checkbox to provide online consent. Following consent, participants were automatically assigned to a unique study identification number

generated by a Secure Sockets Layer (SSL) certified server to ensure privacy and integrity of the data. Participants were then directed to the baseline online questionnaire and upon completion were randomly allocated (2:1) into either the intervention or the control arm. Randomisation was stratified by sex, time since treatment completion (≤ 12 months, > 12 months), and meditation experience (yes/no), and was embedded in the online system, ensuring allocation concealment. Study personnel did not have access to the sequences and were blinded to group assignment. After randomisation, participants were unblinded to group assignment, as the intervention did not allow for blinding.

An email confirming which group participants were allocated to was sent to each participant. The email for the intervention group also comprised a URL address including the unique study identification number to access the MBI.

Intervention

The development of the intervention was informed be a systematic review of MBIs [19], a survey to understand the knowledge, attitudes and practices associated with meditation among people with melanoma [17], and followed recommendations for adapting mindfulness-based programs [22].

The intervention was a 6-week online mindfulness-based program [23] delivered through a website, which included embedded short videos, and downloadable PDF transcript of the videos. MP3 audio files of guided meditations were available in a separate tab, as well as general information about meditation. In addition to the website, automatically generated email reminders encouraging participants to meditate were sent twice daily.

The intervention was designed to (1) help participants understand the potential benefits of using mindfulness in their day-to-day life and (2) support the establishment of daily meditation practice. Each week of the program explored a different topic, and built on topics explored in previous weeks. The program was composed of three main components: (1) an educational component delivered through short videos, (2) formal meditation practices and (3) an informal practice encouraging mindfulness behaviours in daily activities (e.g. "During next week, notice when you are stressed. How is your body responding? What happens to your breathing? What sort of thought activate your stress?").

The program was designed to be self-managed without any staff or teacher interactions with participants, and allowed for flexible navigation of the website where the content could be accessed according to the user's preferred order. The design speaks to the sustainability of the intervention and intent to enable self-management.

Participants in the control group received usual care. After completing the 6-week post-randomisation assessments, they were offered access to the online mindfulness program.

Measures

Psychosocial outcomes were collected at baseline, immediately before randomisation, and at the end of the study period (6 weeks after randomisation). Baseline measures also included participants' demographic information (i.e. sex, age, education, marital status and current employment status), previous meditation experience and clinical information (i.e. stage of melanoma, dates of diagnosis and treatment, types of treatment received and time since end of treatment).

Intervention acceptability and engagement

Content relevance of the program was recorded weekly through three open-ended questions inquiring about the benefits experienced and aspects of the program liked and disliked. An additional three questions about the overall helpfulness of the program were also asked at the end of the study period.

Meditation practice was recorded weekly through self-reported questionnaires capturing the use of any other type of meditation unrelated to the intervention, the frequency and duration of the practice, and, if applicable, reasons for not meditating as recommended. The expected weekly meditation time was 70 min for weeks 1 and 2, and 140 min for weeks 3 to 6.

Informal mindfulness practice was recorded weekly through three questions inquiring about the frequency of the practice (e.g. "How often did you notice you were paying attention to the present?") on a 5-point Likert scale (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = most of the time).

Monitoring for the potential influence of external mind-body programs in the control group Participants in the control group were asked at the end of the 6-week study period whether they had enrolled in a mindfulness-based program during the past 6 weeks.

Psychosocial outcomes

For each measure described below, a higher score indicated higher levels of the variable under investigation.

Fear of cancer recurrence Inventory (FCRI) This 42-item questionnaire comprises seven domains: triggers, severity, psychological distress, functional impairment, insight, reassurance, coping strategies [24].

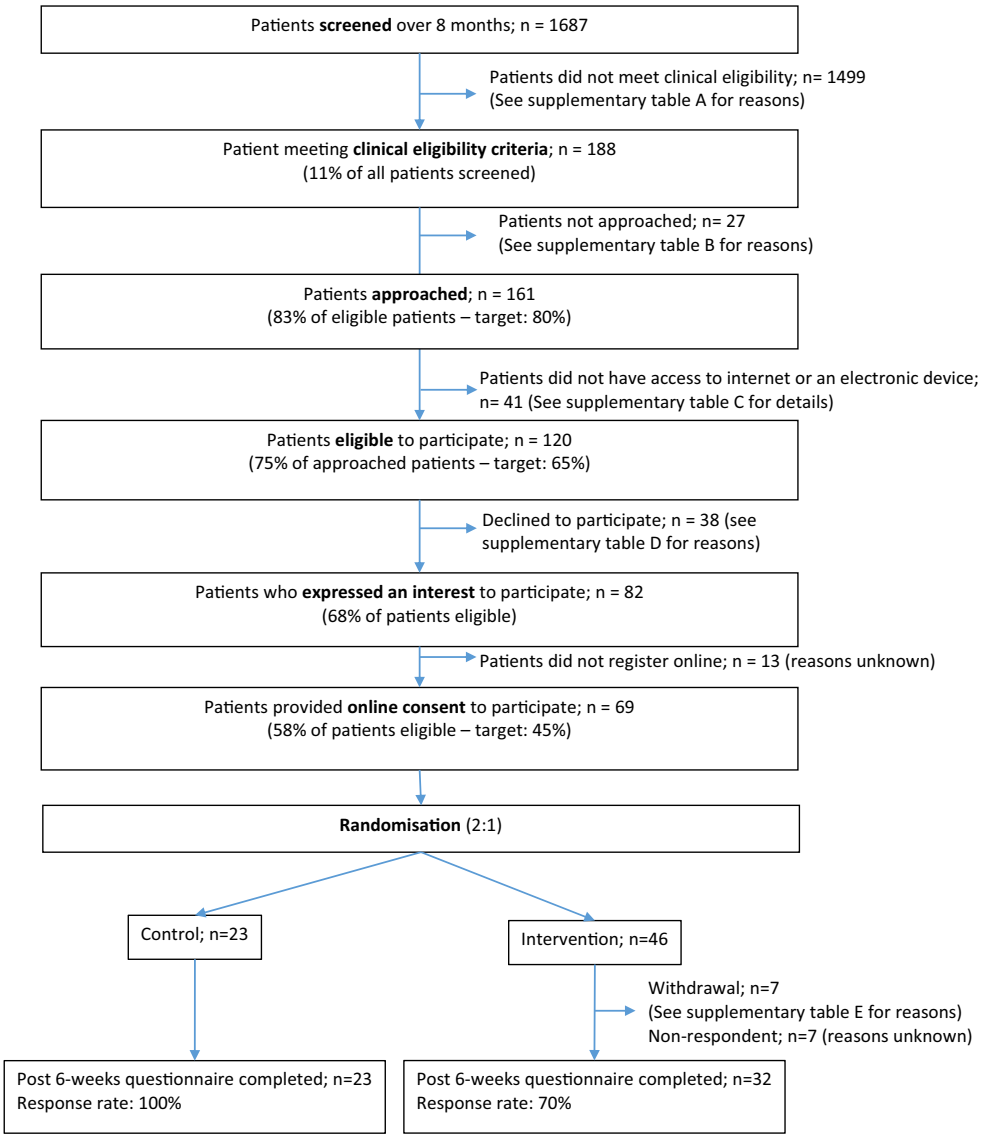

Fig. 1 Study CONSORT diagram

Rumination/Reflection Questionnaire-rumination subscale (RRQ-Rum) This 12-item subscale measures the tendency to dwell on, rehash, or re-evaluate events or experiences [25].

Penn State Worry Questionnaire-Abbreviated (PSQW-A) The 8-item measure of worry severity assesses the excessiveness, prevalence and uncontrollability of clinically worry [26].

Cognitive and Affective Mindfulness Scale-Revised (CAMS-R) The 10-item questionnaire captures mindfulness as a general daily experience [27].

Perceived Stress Scale (PSS10) The 10-item questionnaire measures how unpredictable, uncontrollable and overloaded respondents find their lives [28].

Data and statistical analysis

Descriptive statistics were used to report participant characteristics. Demographic and clinical characteristics, and experience with meditation were compared between intervention and control groups using *t* tests (for continuous variables) and chi-square test, or Fisher's exact test (for categorical variables). Statistical analysis was conducted using SPSS v.23 and SAS v.9.4.

Feasibility

Feasibility criteria metrics were set at the number of people approached as a proportion of those meeting full eligibility criteria (target 80%), the proportion of people interested to participate (target 65%), the proportion of

Table 1 Reasons for ineligibility, non-participation and withdrawal

A—Did not meet clinical eligibility criteria			
Reasons	*n*	Reasons	*n*
Stage 4	324	Treatment completed over 5 years	54
Non-melanoma skin cancers	264	Treatment scheduled	32
Stage 1a	190	Psychological condition	13
Stage 1b	167	Disease recurrence	11
Other cancers	128	Insufficient English	10
Stage 2a	114	Too distressed	3
Stage 0 (in situ)	110	Too unwell	3
Stage 2b	76		
B—Not approached in waiting area			
Reasons			*n*
Unable to approach			17
Patients did not want to learn more about the study			10
C—Did not meet final eligibility criteria			
Reasons			*n*
Do not use a computer			25
Insufficient internet access			9
Do not have an email address			7
D—Non-participation			
Reasons			*n*
Not interested			13
No time			20
Dislike completing questionnaires			3
Going on holidays for extend period			2
E—Withdrawal			
Reasons			*n*
The program required too much time commitment			2
Did not like the guided meditations and felt anxious about completing the weekly surveys			1
Partner did not approved of study participation			1
Brought back memories of treatment period and felt unsettled			1
"I have decided it's not for me it hasn't helped, I feel listening to music makes me feel more at ease and calm"			1
Technical difficulties			1

people enrolled in the study (target 45%) and end-of-study questionnaire completion rate (target 70%).

Acceptability

Intervention acceptability was determined by participant feedback on the content of the program (benefits experienced, aspects of the program most liked and disliked, and overall helpfulness of the program) and self-reported meditation duration and frequency of informal practice.

Feedback for all 6 weeks from MBI participants were read and coded by first author LR. An iterative process was utilised to identify key concepts from each feedback. The coding consisted of allocating labels to each feedback and then developing categories with themes representing similar groups of labels. The analysis process aimed to be critical and reflective. To enhance rigour, findings were discussed with second author AU, and agreement with coding was established. The overall helpfulness of the program was assessed in a similar way using responses from MBI participants' rating of the program as "not helpful", "can't say" or "helpful" at the end of the 6-week program.

Psychosocial outcomes

The potential efficacy of the intervention on FCR, worry, rumination, perceived stress and trait mindfulness was assessed in an exploratory fashion as the study was not powered to detect small differences between groups. A linear mixed model was fitted including group (intervention, control), time (pre, post) and the interaction group by time as fixed effects, and participant as a

Table 2 Participants demographic and clinical characteristics ($n = 69$)

	Intervention ($n = 46$)	Control ($n = 23$)	p value[&]
Demographic characteristics			
Sex, *n* (%)			
Female	25 (54)	12 (52)	0.533
Male	21 (46)	11 (48)	
Age, mean (SD)	53.5 (12.1)	53.1 (15.2)	0.902[#]
Marital status, *n* (%)			
Married or with a partner	35 (76)	17 (74)	0.532
Living without a partner	11 (24)	6 (26)	
Education level, *n* (%)			
VET[†], high school or less	28 (61)	15 (65)	0.796
University degree	18 (39)	8 (35)	
Occupation, *n* (%)			
Paid	31 (67)	14 (61)	0.800[≠]
Student/homemaker/unemployed	5 (17)	3 (13)	
Retired	10 (22)	6 (26)	
Clinical characteristics			
Number of primary melanoma diagnosis, *n* (%)			
1	41 (91)	21 (91)	1.00[≠]
2 or more	4 (9)	2 (9)	
Number of recurrences, *n* (%)			
None	32 (70)	14 (61)	0.736[≠]
1	9 (20)	6 (26)	
2 or more	5 (11)	3 (13)	
Time since treatment completion, *n* (%)			
Less than 1 year	18 (39)	12 (52)	0.552
1 to < 3 years	16 (35)	7 (30)	
3 to 5 years	12 (26)	4 (17)	
Last type of treatment received, *n* (%)			
Surgery	39 (85)	16 (70)	0.116[≠]
Radiotherapy	6 (13)	3 (13)	
Adjuvant anti-PD1	0	2 (9)	
Adjuvant BRAF-inhibitor	1 (2)	1 (4)	
Adjuvant interferon therapy	0	1 (4)	
Meditation experience, *n* (%)			
Never meditated	26 (57)	14 (61)	0.935[≠]
Currently meditate	14 (30)	6(26)	
Meditated in the past	6 (13)	3 (13)	

[†] *VET* vocational education and training

[#] *T* test

[≠] Fisher's exact test

[&] Chi-squared test unless otherwise specified

random effect. Estimated effects along with 95% confidence intervals and p values are reported. All analyses were undertaken on an intention-to-treat (ITT) basis.

Results

Of the 1687 patients screened, 120 were eligible to participate (Fig. 1). The mean age of eligible patients was 54.2 (SD = 14.9) years. Among the 51 people who declined to participate or did not register online, 73% were men ($p = 0.003$). Participants and non-participants did not differ with regard to age, time since treatment completion and disease stage (Table 1).

Participants

Of the 120 eligible, 69 people aged between 22 and 78 years old provided online consent and enrolled in the study (Table 2).

Nineteen participants reported having had some experience with meditation. Of the nine who had stopped their practice, seven (78%) reported to have ceased as they no longer made it a priority. The most common form of

Table 3 Self-reported weekly mediation times

	n	Average time (minutes)	Range (minutes)
Week 1	14	76	21–140
Week 2	14	64	15–105
Week 3	15	108	4–220
Week 4	12	87	6–188
Week 5	11	129	10–282
Week 6	15	113	10–260

meditation practiced among those who meditated in the past and currently meditate was breathing meditation ($n = 20$; 70%).

Study feasibility

Targets to establish study feasibility were met (Fig. 1). The average recruitment rate was two participants per week, ranging between zero and eight participants a week. The study completion differed significantly between the groups (32 in intervention: 70%, and 23 controls: 100%; $p = 0.003$).

Of the 46 participants in the intervention group, 34 (74%) completed at least one weekly questionnaire. The median number of weekly questionnaires returned per participant was 2.5 (range 0 to 6).

Meditation times

Depending on the week, the proportion of people reporting to have either meditated twice a day as proposed by the program, used another guided meditation, or meditated in silence ranged between 61% (week2, $n = 23$) and 80% (week 4 $n = 15$). Self-reported weekly meditation times are presented in Table 3.

Twenty-seven participants provided a reason for not meditating; 24 (89%) reported that they did not make it a priority; 17 (63%) did not have enough time; 12 (44%) kept forgetting; 3 (6%) had too many medical appointments; 2 (1%) encountered technical difficulties.

Participants' weekly feedback

Four categories that best reflected participants' responses resulted from the analysis: (1) "Benefits" reflect aspects reported as enhancing wellbeing or quality of like (e.g. feeling calm or relaxed); (2) "positive feedback" relate to aspects of the intervention participants enjoyed engaging with (e.g. clarity and educational aspect of videos); (3) "negative feedback" relate to aspects of the intervention that was disliked (e.g. meditation session being too long or repetitive); (4) "Challenges" comprised aspects of the intervention that participants found difficult to engage with, but were not reported as a dislike (e.g. prioritising the mindfulness practice due to lack of time or difficulty creating a habit). These categories are described in further detail in Table 4.

Overall helpfulness of the program

Of the 32 participants who completed the end of study questionnaire, 23 (72%) found the program helpful; 8 were not sure if the program was helpful; one did not find the program helpful, but reported that she had found some of the information in the program interesting.

Monitoring for the potential influence of external mind-body programs in the control group

Two participants in the control group reported having started a mind-body program within the past six week.

Clinical/psychosocial outcomes

At baseline, the two groups did not differ on any of the outcome measures, but at follow-up, participants in the intervention group reported significantly less severity of FCR compared to the control group (Table 5). The two groups did not differ on the other FCRI subscales nor on the rumination worry perceived stress or mindfulness outcomes.

Discussion

This study assessed the feasibility and acceptability of conducting an online MBI for people at high risk of melanoma recurrence. The potential for the intervention to positively impact FCR, worry, rumination and mindfulness compared to a usual care group was also explored. Participants who had provided data found the intervention beneficial and helpful. The intervention significantly reduced the severity of FCR when compared to usual care.

The feasibility of the intervention was confirmed with 70% response rate to the end-of-study questionnaire, and most participants reported beneficial effects from the intervention. Feeling relaxed, calm or peaceful are common consequences of mindfulness practices and regular meditation exercises, as people stop agitating their mind and activating the stress response. Exercises like breathing and body awareness are also typically used in techniques whose main purpose is to promote relaxation, such as breath counting or progressive muscle relaxation techniques [29]. As a result, some people may have perceived the program (or elements of it) as a relaxation exercise, which commonly happens when people start learning mindfulness [17]. However, a key concept of MBIs was the adaptation to the present moment by cultivating awareness

Table 4 Frequency of benefits, challenges and feedback reported over 6 weeks

Participants' feedback Categories and themes	Examples of participants' quotes	*n* participants /times reported
Benefits		
Calmness (relaxed, peaceful)	• "I felt calmer and more at ease" (P22, week 1) "I felt a sense of peace" (P22, week 5)	16 participants/38 times reported
Application in daily life (as a regular practice, technique or coping strategy)	• "I could do it waiting in the car at school pickup time or while on a work break" (P34, week 2) "I was able to change the feelings of anxiety into a sense of being tired and then go to sleep" (P16, week 3) • "It's made a real difference to my life and my ability to cope with cancer" (P17, week 6)--	12/27
Focused (being in the moment, centred, clarity)	• "I have found some improvements in my ability to focus on tasks" (P7, week 2) • "My concentration improved greatly last week, I seem to have experienced a greater clarity of thinking" (P30, week5)	9/22
Awareness/acceptance	• "[The program] helped me realise what I have been doing during conversations at work and home i.e. not always listening and then getting the scope of the discussion wrong" (P35, week 5) • "Accepting my feelings as being neither right or wrong" (P14, week 5)	18/21
Familiarising with meditation practices	• "I enjoyed getting more familiar with the techniques" (P2, week 2)	8/16
Reduce anxiety/stress	"Continued ability to reduce stress" (P29, week 5)	5/8
Challenges		
Prioritising mindfulness practices due to: • lack of time	• "I find it hard to make time" (P24, week 5) "Working fulltime, with a young family, I must admit I struggled to prioritise the sessions" (P39, week 6)	15/25
• life events or commitments • difficulty in creating a habit	• "I have not got myself into the daily habit of stopping to meditate" (P1, week 2)	
Difficulty to focus during meditations	• "Found it difficult to focus, mind wandering" (P2, week 1) • "I found it hard to be focused especially for a longer period of time" (P25, week 3)	6/8
Relating to emotions mindfully	• "It took me a long time to get into this topic and identify emotion to use although I practiced every day" (P16, week 3) • "The concepts of being in the present and being mindful of emotions is not familiar practice and some of the terms went over my head in the beginning" (P41, week 3)	5/5
Positive feedback		
Videos presentations were: • Clear	• "The presentations were clear and relatively easy to follow for someone who has not meditated previously" (P35, week 1)	15/28
• Simple	• "Keeping it simple and not information overload" (P40, week 2)	
• Instructive	• "The videos are good coaching and help me to be more self-aware" (P41, week 3)	
Enabling "time out"	• "This program has given me an insight into making time for me" (P16, week 1)	13/23
Meditation sessions were enjoyed for being: • short	• "Short meditations are beneficial" (P41, week 6) • "Very easy to do and often did it without guidance" (P8, week 5)	14/19
• easy to follow		
• provided good guidance • suited personal preferences	• "The voice made me focus on the topic rather than drifting off to sleep or my mind wondering"(P34, week 1)	
	• "I liked practicing not reacting to emotions and breathing into emotions" (P16, week 3)	
	"I liked listening the surroundings" (P44, week 5)	
	"The mindful pause approach does seem to help in day to day tasks" (P35, week 6)	
Program structure for:	• "Consistency allowing to become more familiar with the technique" (P41, week 2)	9/19

Table 4 (continued)

Participants' feedback Categories and themes	Examples of participants' quotes	*n* participants /times reported
• the regularity and consistency of the sessions	"The program was simple and not time consuming" (P40, week 1)	
• its simplicity • its continuity	• "It felt like an extensions of what we had already worked on" (P25, week 5)	
Negative feedback		
Meditation sessions were disliked for being: • too long	• "I also found doing that for 10mins a little bit long so my mind would just wander or I'd fall asleep" (P34, week 3)	5/7
• too repetitive		
• too quite	• "Once you did the practice a few times it became a bit mundane" (P8, week 4)	
	"I would have like some soft music in the background" (P28, week 2)	
Technical difficulties	• "I was away and did not have access to the online program therefore I was trying to work offline and found that hard" (P35, week 4) • "My hot spot 4 g data gets chewed up fairly quickly" (P15, week 4)	5/6
Program structure/navigation	• "I tended to lose track as to where I was with the program. You can jump ahead for the respective weeks. Might be better to only getting to the next week as that week is completed" (P8, week 2)	4/6
"it's not for me"	• "Not really into meditation" (P37, week 1) • "I felt for me personally that music is what calms me when I'm feeling anxious or stressed… being positive gets me thru the day" (P46, week 6)	3/4
Lack of feedback option	• "Not sure if I was doing it correctly" (P2, week 1)	2/3

and acceptance of internal and external experiences through regular training of the mind [22]. Acceptance and awareness coupled with a sense of being more focused were also frequently reported by participants, supporting this key underlying concept.

Meditation times varied greatly, an issue recognised as complicating the understanding of what "dose" of meditation is needed to deliver a beneficial outcome [30]. The dose recommendation will depend on the aim of the practice (e.g. reduce anxiety or maintain general well-being) [30]. But the actual practice is likely to depend on individual needs, background and personality [31]. For example, in our study, some participants found the 10-min meditation period too long, while others liked how it enabled them to take some time for themselves. Some participants reported practising for only 5 min throughout the 6 weeks indicating that some people may require more time to familiarise themselves with meditation. Understanding what impacts one's ability to undertake meditation and whether duration of meditation is important to confer benefits are key issues. Insights from our study suggests that a 6-week study period may not provide enough time to cultivate the skills necessary to achieve lasting benefits, as these skills are typically developed through daily practice with longer meditation sessions [32].

At baseline, nearly three quarters in both study arms scored over the clinical cutoff of ≥ 13 on the FCRI severity subscale [33]. Those in the intervention arm reported significantly reduced FCRI score on completion of the study, but few achieved scores below the clinical cutoff. Participants in our study were undergoing regular medical follow-up. The need to return to hospital and undergo repeat tests may have contributed to their ongoing fear of recurrence [24]. Another explanation could be that the clinical cutoff of ≥ 13 may have inadequate specificity in this population group. A higher cutoff of ≥ 22 has been reported to be more suitable for identifying clinically significant levels of FCR among breast, colorectal and melanoma cancer survivors [34]. The incongruence between these two clinical cutoff scores highlights an area for further research.

In this study, nearly 60% of the 120 eligible people were males, reflective of melanoma statistics in Australia [35]. Despite this, only one third of eligible males enrolled in the study. This is consistent with results from a systematic review exploring participant representation by sex in MBIs, which found that overall, only 29% of study populations were males [36]. This differential by sex is reflected in mental health service use [37], consultation with primary care providers [38], and utilisation of preventive care [39] where men tend to engage less than women. In order to avoid this disparity among study participants, our randomisation process was stratified by sex to ensure males and females were equally represented in both groups. A greater understanding of the barriers preventing males from participating in MBIs is required.

Table 5 Outcome comparison between control and intervention groups ($N = 69$)

	Control ($n = 23$) Mean (SD)	Intervention ($n = 46$)* Mean (SD)	Between group difference Mean difference (95% CI)	P value
FCRI severity (0–36)				
Baseline	15.96 (1.60)	17.15 (1.03)	− 2.55 (− 4.43, − 0.67)	0.008
Follow-up	16.26 (1.57)	14.90 (1.03)		
FCRI trigger (0–32)#				
Baseline	15.30 (1.27)	16.26 (0.84)	− 0.94 (− 2.71, 0.82)	0.295
Follow-up	15.00 (1.38)	16.01 (1.01)		
FCRI distress (0–16)#				
Baseline	4.91 (0.78)	4.52 (0.53)	− 0.09 (− 1.43, 1.24)	0.889
Follow-up	4.69 (0.91)	4.21 (0.52)		
FCRI coping strategies (0–36)#				
Baseline	14.57 (1.67)	17.37 (0.92)	1.26 (− 1.53, 4.05)	0.375
Follow-up	12.97 (1.84)	17.02 (1.12)		
FCRI functioning (0–24) #				
Baseline	2.74 (0.82)	3.72 (0.63)	− 1.35 (− 3.27, 0.57)	0.168
Follow-up	3.52 (1.09)	3.15 (0.72)		
FCRI insight (0–12)#				
Baseline	0.83 (0.20)	1.04 (0.23)	− 0.52 (− 1.38, 0.34)	0.238
Follow-up	1.09 (0.37)	0.79 (0.26)		
FCRI reassurance (0–12)#				
Baseline	2.57 (0.31)	3.27 (0.42)	− 0.54 (− 1.44, 0.36)	0.236
Follow-up	2.39 (0.38)	2.54 (0.39)		
FCRI total (0–168) #				
Baseline	56.87 (5.14)	63.33 (3.47)	− 6.22 (− 13.12, 0.68)	0.077
Follow-up	56.99 (5.65)	57.23 (3.79)		
Rumination (12–60)#				
Baseline	34.48 (2.01)	35.80 (1.55)	− 2.76 (− 6.67, 1.17)	0.169
Follow-up	35.09 (2.23)	33.66 (1.67)		
Mindfulness (10–40)#				
Baseline	29.22 (1.48)	28.17 (0.81)	− 0.51 (− 2.19, 1.17)	0.552
Follow-up	29.91 (1.49)	28.36 (0.78)		
Worry (8–40)#				
Baseline	17.00 (1.35)	17.78 (1.33)	− 0.40 (− 3.76, 2.95)	0.814
Follow-up	14.57 (1.12)	14.94 (1.33)		
Perceived Stress (0–40)#				
Baseline	15.30 (1.66)	14.28 (1.01)	− 0.95 (− 6.13, 4.23)	0.719
Follow-up	15.43 (1.58)	13.46 (1.06)		

*$n = 46$ at baseline, $n = 32$ at follow-up

Range of possible scores

Limitations

This intervention was a web-based intervention, which required internet data usage for participants. This was an issue during recruitment, and for some participants in the intervention group due to limited access to the internet. In order to explore the full potential of online MBI delivery and to accommodate individual digital and technological capacity, future studies should assess the intervention through more digitally versatile delivery modes (i.e. application-based, or emails).

Additionally, monitoring of meditation practice was based on self-report, and the tracking of website usage did not occur due to technical issues. Tracking participants' online behaviour and meditation times will provide valuable information on the impact of and preferences for the various aspects for the MBI (i.e. educational components, formal and informal practice).

It is possible that only participants interested in meditation have responded to the weekly questionnaires. Non-respondents and low adherence to mediation may indicate a lack of relevance of the program for these groups.

Conclusion

This study provides preliminary evidence that a self-guided online MBI may be helpful in reducing levels of FCR among people with high risk of melanoma recurrence. The positive feedback on the program indicates that patients valued accessing the program at their own pace and convenience. The outcomes of this study will inform a larger randomised controlled trial to test these findings. Studies to assess potential benefit among other cancer survivors are also warranted.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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