

BMJ Open Psychoeducational intervention for people at high risk of developing another melanoma: a pilot randomised controlled trial

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ABSTRACT

Introduction Information and psychological needs have been reported as one of the greatest areas of unmet needs for patients with melanoma. To respond to these needs, we developed the *Melanoma Care Intervention*, a developed psychoeducational intervention for people at high risk of developing another melanoma comprising of a newly developed melanoma educational booklet and individually tailored telephone support sessions provided by trained psychologists. The purpose of this study was to investigate the acceptability and feasibility of the *Melanoma Care Intervention*.

Methods Twenty-four adults (14 men, 10 women, mean age: 58 years, SD: 12.2) at high risk of developing a subsequent primary melanoma were recruited and randomly assigned 1:1 to the intervention (a psychoeducational booklet, a Cancer Council booklet on melanoma and up to five telephone-based sessions with a psychologist) or usual care (Cancer Council booklet only). Acceptability, feasibility, fear of cancer recurrence and secondary psychosocial outcomes were assessed at baseline, 1 and 6 months.

Results Satisfaction and perceived benefits were rated highly for all intervention components, particularly the telephone-based psychology sessions (mean satisfaction and benefits: both 9.27 out of 10, SD=2.41). The quality of information and support provided throughout the trial was rated as 'high' by the intervention group, with a mean score of 4.6 out of a possible 5 (SD=0.9) and 4.2 (SD=1.2) for the control group.

Conclusions The intervention was feasible and acceptable for improving psychological adjustment. Timely access to effective, evidence-based, psychological care is a recognised need for people with melanoma. The intervention is designed to directly address this need in a way that is feasible in a clinical setting, acceptable to patients and health professionals.

Trial registration number The trial was registered with the Australian and New Zealand Clinical Trials Registry on 19/03/2013 (Registration Number: ACTRN12613000304730).

BACKGROUND

Early detection and appropriate clinical management of melanoma ensures that most

Strengths and limitations of this study

- The results are generalisable to people who have had early stage melanoma, and further research is needed to know if people with advanced melanoma have a similar response to the intervention.
- Although recommended in the Australian clinical practice guidelines, psychological support (provided by a psychologist) is not currently part of routine care for people diagnosed with melanoma.
- Further research to demonstrate a sustained feasibility when the intervention is delivered by trained nurses or health educators could perhaps facilitate implementation.

people with the disease have a good prognosis, with about 90% of patients still alive 5 years after diagnosis.¹ Despite this good prognosis, melanoma survivors have an ongoing threat of recurrence and are recommended to carry out regular skin self-examinations, have regular clinical skin examinations and undertake behavioural changes to minimise excessive sun exposure,² all of which can add to the psychological burden of melanoma.³ In addition, people with melanoma often experience intense fear that the disease could spread and become untreatable. Studies have reported that 30%–50% of melanoma survivors experience heightened emotional distress² and that many report unmet needs for information and psychological support.^{4–6} Australian clinical practice guidelines for the management of melanoma highly recommended that psychoeducational support be made widely available to people with melanoma.⁷ German guidelines extend this by recommending implementation of regular psycho-oncological screening to identify and offer psychological care to people with melanoma experiencing difficulties adjusting to their disease.⁸ Several psychoeducational

interventions for patients with melanoma have been reported in the literature, with beneficial outcomes.⁹ In a systematic review of 16 interventions, McLoone *et al* concluded that participation in psychological interventions resulted in lower anxiety, health-related distress and melanoma recurrence rates and positive changes in coping with illness.⁹

People at high-risk of a subsequent melanoma are particularly vulnerable to distress. Seventy-five per cent of survivors with high-risk melanoma report persistent fear and uncertainty about the possibility of developing new disease, cancer recurrence or metastases.^{3 10} Despite this, psychological support is not currently offered in Australian high-risk clinics that provide a specialised clinical service for people at very high-risk of primary melanoma¹¹ nor have specific interventions been designed for this high-risk subgroup. To address this gap, our team developed a multifaceted psychological care programme for people at high-risk of developing another primary melanoma (the *Melanoma Care Study*).¹² The intervention comprised up to five individual, telephone-based sessions with a psychologist, combined with an evidence-based psychoeducational booklet designed to respond to the unmet supportive care needs of people who have had melanoma.

This pilot study had two aims: (1) evaluate the acceptability of, and participant satisfaction with, the *Melanoma Care Study*; (2) determine the feasibility of delivering telephone-based psychology sessions scheduled in relation to dermatological appointments at melanoma high-risk clinics.

METHODS

Study design and participants

A randomised controlled trial design was used to pilot the *Melanoma Care Study*. Participants were recruited from three melanoma high-risk clinics in New South Wales, Australia, two situated in inner-city Sydney and one in a regional coastal city. These high-risk clinics provide a specialised clinical service for people at very high-risk of primary melanoma,¹¹ including people with a previous melanoma and either a strong family history of melanoma, many moles (ie, dysplastic naevus syndrome) or a history of multiple primary melanomas. People aged 18 years or older with a history of stage 0, I or II melanoma were identified from the clinic databases and invited to participate. People were ineligible if they were identified as high-risk but had never had melanoma (eg, people who carry a high penetrance genetic mutation) or had a known history of severe major depression, psychotic illness or other serious psychiatric condition or cognitive deficit or were unable to participate in English. Patients with Active stage III melanoma or metastatic melanoma (stage IV) were excluded as they have different psychosocial needs to patients with stage 0/I/II, where the melanoma has been confined to a primary tumour only.

Ethics approval was obtained from all relevant ethics committees. Informed consent was obtained from all participants prior to study participation.

Intervention arm

The *Melanoma Care Study* had three components: (1) a newly developed psychoeducational booklet in full colour hardcopy, (2) a freely available Cancer Council booklet and (3) up to five telephone-based sessions with a psychologist specifically trained to deliver the intervention according to protocol. The psychoeducational booklet, *Melanoma: Questions and Answers*, was developed by a multidisciplinary team and comprised seven modules and a series of tailored resources: (1) types of melanoma, melanoma diagnosis and treatment; (2) factors that may contribute to melanoma risk; (3) information on skin self-examination, vitamin D and sun protection as well as question prompts for communication with one's health-care team; (4) emotional and social aspects of melanoma; (5) strategies to assist people in coping well with melanoma risk; (6) resources to assist people in keeping track of their melanoma care and (7) sources for further information and support. The booklet content and format was pilot tested and revised on the basis of feedback from 19 people with melanoma and 10 health professionals.

The Cancer Council booklet, *Understanding Melanoma* comprised easy-to-read information about melanoma diagnosis, treatment and emotional and practical issues. The Cancer Council booklet is heavily focused on diagnosis and treatment information while the psychoeducational booklet, *Melanoma Questions and Answers*, provides more in-depth information about emotional and behavioural aspects of coping with melanoma, communicating with one's family and healthcare team and managing one's melanoma care.

Participants in the intervention group were also offered five telephone-based sessions with a psychologist, tailored to the needs of each individual participant and designed to provide *patient-specific* care to address identified difficulties, needs, concerns and goals. The first three sessions were in close connection to their next full dermatological consultation at the melanoma high-risk clinic and the next two sessions were in close connection with their subsequent high-risk clinic appointment approximately 6 months later. Participants who were not able to identify specific difficulties, needs or goals were offered the option of limiting their participation to the first three sessions. The telephone-based sessions were underpinned by the core principles of brief psychodynamically oriented psychotherapy.^{13–15} The goal of the sessions was to provide empathic, active listening at a deep level so as to try to understand participants and their experiences and to assist participants in developing healthy emotional, cognitive and behavioural coping responses.¹⁶ Psychosocial care planning and referrals for further information, support and clinical care were also provided, as appropriate. A manual was developed by a team of psycho-oncologists with extensive experience in the care

of people with melanoma (NAK, SM, PB) to guide the psychologists providing the intervention on a session-by-session basis (see [table 1](#)). The psychologists followed the general principles outlined in the manual, while tailoring the intervention to the specific circumstances, needs, goals and characteristics of individual participants. The psychologists were trained and did also received weekly supervision by one of the senior author (NAK).

Control arm

Participants in the control arm received usual care, which consisted of their usual melanoma high-risk clinic appointments and a copy of the Cancer Council booklet. A blank notepad was also included in the study package in order to keep the size of the package consistent with that received by the intervention group.

Procedures

Baseline data were collected using paper-based or web-based questionnaires, as preferred by participants. Randomisation was performed by a statistician at the NHMRC Clinical Trials Centre, The University of Sydney and the statistician was blind to the identity of participants. Once randomisation had occurred, the research coordinator sent study packs to participants and as such was not blinded. The research coordinator analysed the data; however, she was not involved in patient care, intervention delivery or assessment of participant outcomes (which were self-reported). Clinicians at the High Risk Melanoma Clinics were not informed of which patients were participating in the study nor the group to which participants had been randomised; however, it is possible that clinicians became aware because participants were encouraged to take the psychoeducational booklet to their dermatological appointment for discussion and to use the various tools provided within the booklet.

Participants in the intervention arm received the intervention over a 1-month period (if receiving three telephone-based psychology sessions) or a 6-month period (if receiving five sessions). Both the psychoeducational and Cancer Council booklets were sent to participants 2 weeks before their usual 6-monthly high-risk clinic appointment, at which a complete dermatological examination was undertaken. For people who received three sessions, these occurred 1 week before, 1 week after and 3 weeks after this clinic appointment. People who received five sessions participated in two additional sessions; the fourth occurred 1 week before their subsequent high-risk clinic appointment and the fifth occurred the following week. Two psychologists received extensive training in intervention delivery prior to trial commencement.¹² With participants' permission, all sessions were audiotaped and early sessions were reviewed by the clinical psychology supervisor (NAK), who also provided weekly supervision during which sessions were discussed in-depth. Participants randomised to the control arm received the Cancer Council booklet 2 weeks before their 6-monthly high-risk clinic appointment.

Measures

Perceptions of the newly developed intervention and usual care were evaluated using the following purposely designed items:

1. *Intervention acceptability and perceived benefits*: Six months after study enrolment, intervention participants rated their satisfaction with, and perceived benefit of, the psychology sessions, the psychoeducational booklet and the Cancer Council booklet, while control participants rated the Cancer Council booklet only. Participants also indicated any behavioural changes they experienced following their participation in the study (eg, find the emotional support to cope with melanoma, talk more openly with my doctor at the high-risk clinic), using a 5-point scale from 'strongly agree' to 'strongly disagree'. Participants in both arms rated the overall quality of the information and support received, and if they would recommend the intervention to other patients with melanoma. Participants were also provided space to provide qualitative feedback if they wished.
2. *Participants' preferences*: Participants were offered a choice in the number of sessions (between three and five) they would engage in. Data on participants' preferences as well as the duration and timing of sessions were collected to inform the most feasible model on which to design a larger trial.
3. *Adherence to intervention guidelines*: The proportion of participants who attended the telephone-based psychology sessions was recorded as well as the number of sessions attended.
4. *Feasibility issues*: Difficulties, barriers and resources associated with intervention implementation were also systematically recorded by the psychologists and the research team throughout the pilot.
5. *Demographic and medical characteristics*: At baseline, age, gender, education level, marital status and number of children were assessed. Health literacy was also assessed using two validated items.^{17 18} Medical characteristics (eg, number of melanomas, stage of each melanoma at diagnosis, time since first and last melanoma, melanoma treatment) were collected from medical records.

Statistical analysis

A total sample size of 24 participants was deemed sufficient for refining the study protocol and assessing feasibility of the psychoeducational intervention to inform the larger randomised controlled trial. Guidelines¹⁹ suggest that small sample sizes may be appropriate for demonstrating the ability to execute a specific research protocol or for testing acceptability and engagement with a new intervention, and these were the objectives of the present pilot study. Descriptive statistics were used to summarise sample characteristics and feasibility outcomes. Being a pilot study, the small sample precluded use of inferential statistics; thus, mean scores and SDs (including the standardised mean difference at each time point as a measure

Table 1 Description of the five telephone-based sessions with a psychologist

Telephone session	Session goals	Schedule	Duration
Booking session	<ol style="list-style-type: none"> 1. Psychologist introduction 2. Check that both booklets have been received 3. Check the person's understanding of the intervention and what is involved to ensure informed consent 4. Answer any questions the participant may have about the intervention and what can be offered 5. Discuss confidentiality and 'psychologists' duty of care 6. Discuss the audiotaping of sessions and request the person's permission 7. Schedule and assist the person in preparing for Session 1 	<p>One week before the first session</p> <p>One week before patients' 6-monthly dermatological appointment at the high-risk clinic</p>	<p>Up to 10min</p> <p>Up to 90min</p>
Session 1	<ol style="list-style-type: none"> 1. Allow the participant an opportunity to begin the session 2. Begin to establish a therapeutic relationship 3. Carry out a psychological assessment, including an assessment of the person's supportive care needs in relation to melanoma 4. Assist the participant in setting goals for their involvement in the programme 5. Assist the participant in using the booklets and tools provided 6. Explore the participant's thoughts and feelings about their upcoming high-risk clinic appointment and assess and discuss any concerns regarding appointment 7. Check to see how the participant experienced the session and if any modifications need to be thought about together 	<p>One week after patients' 6-monthly dermatological appointment at the high-risk clinic</p>	<p>Up to 50min</p>
Session 2	<ol style="list-style-type: none"> 1. Allow the participant an opportunity to begin the session 2. Explore the participant's experience of their dermatological appointment and whether they used the booklets in the consultation with their doctor 3. Continue to explore participant's goals, difficulties or concerns 4. Respond to any new difficulties or concerns 5. Check to see how the participant is experiencing the sessions and if any modifications need to be thought about together 	<p>Three weeks after patients' 6-monthly dermatological appointment at the high-risk clinic</p>	<p>Up to 50min</p>
Session 3	<ol style="list-style-type: none"> 1. Allow the participant an opportunity to begin the session 2. Continue to build on the relationship with the participant 3. Continue exploring the participant's identified goals, difficulties or concerns 4. Respond to any new difficulties or concerns 	<p>One week before patient's subsequent 6-monthly dermatological appointment at the high-risk clinic</p>	<p>Up to 50min</p>
Session 4*	<ol style="list-style-type: none"> 1. Allow the participant an opportunity to begin the session 2. Continue to build on the relationship with the participant 3. Summarise what has been explored during the three previous sessions 4. Explore the participant's thoughts and feelings about their upcoming high-risk clinic appointment and, if appropriate, how they could use their booklets in the consultation 5. Continue exploring the participant's identified goals, difficulties or Respond to any new difficulties or concerns. Explore the participant's feelings about coming to the end of the programme and prepare for the final session 	<p>One week after patient's subsequent 6-monthly dermatological appointment at the high-risk clinic</p>	<p>Up to 50min</p>
Session 5*	<ol style="list-style-type: none"> 1. Allow the participant an opportunity to begin the session 2. Summarise what has been explored during the four previous sessions 3. Explore the participant's experience of their high-risk clinic appointment 4. Respond to any new difficulties or concerns 5. Explore the participant's feelings about coming to the end of the programme and prepare for the final session 6. Provide referral pathways for psychological treatment or psychosocial support, as needed 	<p>One week after patient's subsequent 6-monthly dermatological appointment at the high-risk clinic</p>	<p>Up to 50min</p>

*The fourth and fifth sessions were omitted for participants who chose three sessions.

of effect size) were used to compare groups. A priori feasibility objectives were based on our previous experience: >30% consent, <15% lost to follow-up per group, 80% engagement rate (ie, participation in all scheduled telephone sessions). Acceptability objectives were: average satisfaction scores $\geq 7/10$, <15% negative qualitative responses within the questionnaire. All analyses were performed using SAS V.9.3 (SAS Institute, Cary, North Carolina, USA).

RESULTS

Sample characteristics

Twelve participants were randomly assigned to the treatment arm and 12 to the control (table 2). One intervention participant withdrew from the study after one psychology session, as he felt the intervention would not benefit him. The intervention group comprised eight men and four women, with a mean age of 57 years (SD=14), and a median melanoma Breslow thickness of 0.78 mm (range 0.3–2.95 mm). The control group comprised six men and six women, with a mean age of 61 years (SD=14), and a median Breslow thickness of 1.3 mm (range 0.3–3.5 mm). For both groups, superficial spreading melanoma was the most common histopathological subtype.

Acceptability

Four out of 11 participants in the intervention group reported reading the psychoeducational booklet, *Melanoma: Questions and Answers*, from ‘cover to cover’, 1/11 ‘quite thoroughly’, 4/11 ‘only for parts they found relevant’ and 1/11 ‘briefly’. The Cancer Council booklet was read from ‘cover to cover’ by 3/11 intervention participants versus 2/12 control participants; ‘quite thoroughly’ (2/11 vs 4/12); ‘only for parts they found relevant’ (4/11 vs 3/12) and ‘briefly’ (2/11 vs 3/12). Ratings for different components of the intervention are shown in table 3.

Satisfaction

Intervention participants rated the intervention highly in terms of perceived satisfaction and benefits, particularly the psychology sessions (perceived satisfaction and benefits both mean=9.3 out of a possible 10, SD=2.4) and the psychoeducational booklet (both mean=8.8, SD=1.0). Intervention participants rated the difficulty of reading both booklets as not at all difficult (mean=1.7, SD=3.2 for both). The control arm rated the Cancer Council booklet for perceived satisfaction (mean=7.2, SD=2.1), perceived benefit (mean=6.7, SD=2.2) and perceived difficulty (mean=2.0, SD=2.7). Most intervention participants (7/11) provided qualitative feedback on the benefits they experienced through taking part in the intervention. These included: having an opportunity to share one’s fears and discuss issues in depth, feeling understood by the psychologist, having positive experiences acknowledged, and improved communication with their doctor.

Table 2 Demographic and clinical characteristics of the sample

Characteristics	Intervention (n=12)	Control (n=12)
	n (%) or Mean (SD)	
Gender		
Male	8 (67%)	6 (50%)
Female	4 (33%)	6 (50%)
Age at baseline		
Mean, SD	56.7 (14.0)	61.0 (10.5)
Area		
Metropolitan	7 (58%)	7 (58%)
Regional	4 (33%)	5 (42%)
Rural	1 (8%)	0 (0%)
Country of birth		
Australia	11 (92%)	11 (92%)
Other	1 (8%)	1 (8%)
Marital status		
Married	11 (92%)	8 (72.7%)
Other	1 (8%)	3 (27.3%)
Children		
Yes	11 (92%)	8 (67%)
No	1 (8%)	4 (33%)
Highest level of education		
No tertiary education	9 (75%)	8 (67%)
University	3 (25%)	3 (25%)
Other	0	1 (8%)
Number of previous melanomas		
	3.3 (2.9)	2.3 (1.9)
Most recent melanoma subtype		
Superficial spreading melanoma	9 (75%)	4 (40%)
In situ	2 (17%)	2 (20%)
Nodular	0	2 (20%)
Melanoma not classified	1 (8%)	2 (20%)
Breslow thickness (mm)		
	0.78 (0.3 to 2.9)	1.3 (0.3 to 3.5)

Table 4 summarises all themes and provides sample quotes from participants.

Ratings of the psychoeducational booklet, *Melanoma: Questions and Answers*

All participants in the intervention group found the information in the psychoeducational booklet on different types of melanoma, risk of developing melanoma (presented as pictographs), skin self-examination and sun protection ‘quite’ or ‘very helpful’. Nine of the 11 participants found the information on genetics and

Table 3 Acceptability ratings for different components of the *Melanoma Care Study*

	Response options	Intervention (n=11) Mean (SD)	Control (n=12) Mean (SD)
Satisfaction with:			
Booklet, <i>Melanoma: Questions and Answers</i>	From 0 'Not at all satisfied'	8.8 (1.0)	
Booklet, <i>Understanding Melanoma</i>	to 10 'Extremely satisfied'	9.0 (1.1)	7.2 (2.1)*
Telephone-based psychology sessions		9.3 (2.4)	
Overall programme		8.7 (2.2)	
Benefit of:			
Booklet, <i>Melanoma: Questions and Answers</i>	From 0 'Not at all beneficial'	8.9 (1.2)	
Booklet, <i>Understanding Melanoma</i>	to 10 'Extremely beneficial'	8.8 (1.2)	6.7 (2.2)*
Telephone-based psychology sessions		9.3 (2.4)	
Overall programme		8.6 (2.1)	
Difficulty of:			
Booklet, <i>Melanoma: Questions and Answers</i>	From 0 'Not at all difficult'	1.7 (3.2)	
Booklet, <i>Understanding Melanoma</i>	to 10 'Extremely difficult'	1.7 (3.2)	2.0 (2.7)*
Telephone-based psychology sessions		1.1 (2.4)	
Overall programme		1.1 (2.1)	
Quality of:			
Information	From 1 'Poor' to 5 'Excellent'	4.6 (0.9)	4.17 (1.2)
Support		4.7 (0.9)	3.83 (1.4)
Recommend to other patients with melanoma			
Yes		10 (91%)	9 (75%)
No		0	0
Unsure		1 (9%)	3 (25%)

*For the control group, these questions only applied to the Cancer Council booklet.

family history, vitamin D, how melanoma can affect the way people feel, coping strategies and living with the fear that melanoma may come back 'quite' or 'very helpful'.

Participants also rated the tools provided in the booklet highly. The tool on how to perform a skin self-examination was perceived as most helpful (9/11), followed by the tool about the UV index (8/11). The least helpful tool was the SunSmart telephone application designed to provide sun protection and exposure information across Australia (3/11). The majority of participants (9/11) agreed or strongly agreed that participation in the study had helped them to learn more about the recommended frequency of skin examinations and how to find the information to assist in coping with melanoma. Most participants (8/11) reported that participation in the intervention helped them talk more openly with their doctor at their high-risk clinic appointment.

Ratings of the Cancer Council booklet, understanding melanoma

The Cancer Council booklet was perceived as a good source of medical information and reassurance that supplemented information from their doctors (table 3). One participant in the intervention group (woman, MS353) stated that she 'had read the [Cancer Council] book

before.' Nine participants in the control group commented on the benefits they gained from reading the booklet.

Difficulties

When asked about difficulties or challenges associated with the intervention, four intervention participants identified difficulties discussing their concerns with a psychologist; one participant (man, MS282) reported 'I've usually tried to avoid thinking about melanoma rather than being prepared to discuss the subject so initially at least, the study was a little uncomfortable.' Another participant (woman, MS155) found 'the telephone session a little intense. Found the questions that were asked/discussed during the session raised issues/concerns that I had not really thought of before the session.' In the control group, one participant (man, MS223) described the information provided in the Cancer Council booklet as 'confronting'.

Quality of information and support provided throughout the trial

The mean score for the quality of information as rated by the intervention group was 4.6 out of a possible 5 (SD=0.9) and 4.2 (SD=1.2) for the control group. The mean score for the support given was 4.7 (SD=0.9) by the intervention arm and 4.2 (SD=1.4) by the controls. Ten out of 11 participants in the intervention group reported that they

Table 4 Summary of participants' views on the perceived benefits of the Melanoma Care Study

Major themes	Participant's ID*	Participant quotations
An opportunity to share one's fears and feel understood	WP1	<i>Cancer can be lonely and frightening and this allowed me to express all of those fears before and after appointments and about the impact on my life. This had never happened before. Other patients may not have anyone to talk to either. This was the best opportunity and I was in a dark place – you feel so much more alive.</i>
	MP1	<i>I feel sharing private fears helped me deal with these issues.</i>
	WP2	<i>It helps to talk to someone who understands when you get your first melanoma.</i>
An opportunity to explore one's experiences in depth	WP3	<i>Engaging in a conversation with the psychologist made me realise that I still needed to address particular issues which I thought I had dealt with but obviously had not.</i>
	MP1	<i>I felt that the sessions with my psychologist were the first real extended discussions I've had in relation to my melanoma risk in over 20 years of melanoma care. I was very satisfied at the end of the sessions because I felt I'd been able to share a burden and get some sensible advice.</i>
Positive experiences	MP2	<i>Education gives understanding and comfort.</i>
	WP1	<i>I feel happier for having someone to talk to about it. My psychologist made me think about taking control of my life and I feel I have been given the skills to understand and manage my fear and to feel worthwhile.</i>
	MP3	<i>Reinforced my confidence</i>
	MP4	<i>The psychologist assisted greatly with dealing with emotional feelings.</i>
Improved doctor-patient communication	MP1	<i>I was given suggested strategies for dealing with negative thoughts about my melanoma risk. I was encouraged to discuss longstanding and new concerns with the high-risk clinic doctor. I felt that the psychologist was genuinely interested in helping me address concerns.</i>
Good source of medical information	WP4	<i>Understand what happens after diagnosis, what to expect and support options available.</i>
	WP5	<i>A clearer understanding of the different stages of melanoma.</i>
Supplement information from the doctors	WP4	<i>I would recommend the booklet because it answers a lot of questions that you would sometimes forget to ask medical staff and you can also refer to it at any time to clarify any areas of confusion.</i>
	MP6	<i>If various things are not explained by your GP, the booklet fills that void.</i>
Reassurance	WP6	<i>Statistics on recurrence that helped me feel calmer.</i>
Requests for continued psychological support	MP5	<i>I wish the support was ongoing and not just a study and I hope that the study will result in this service eventually being a part of patients' treatment.</i>
Challenge for future support	MP1	<i>Provide an annual 'catch-up' counselling call.</i>
	WP1	<i>The study and help came at the right time and the challenge for me will be to seek the help I may need in the future</i>
	WP3	<i>I suggest at the beginning of the sessions that patients might find they'd like help and support beyond the study and help them to find a suitable psychologist... I'm not sure how to find someone who might be better for cancer patients.</i>
	WP1	<i>Feeling withdrawn and empty for a few weeks after the counselling stopped for a few months. Knowing it's only a study, even though I've been strongly encouraged to seek support after the study.</i>

*WP, female participant; MP, male participant.

would recommend the programme to other patients with melanoma and 9 out of 12 participants in the control group would recommend the Cancer Council booklet.

Participants' preferences for three or five telephone-based sessions with a psychologist

Of the 11 participants who completed the intervention, six preferred to receive three psychology sessions and five preferred five sessions. Mean perceived satisfaction and benefits were very high irrespective of session number; for participants who received three sessions, mean satisfaction was 10/10 (SD=0) and mean perceived benefits was 9.4/10 (SD=0.6) and for participants who received five sessions, mean satisfaction was 8.7 (SD=3.3) and mean perceived benefits was 8.7 (SD=3.3). On average, participants engaged in 3 hours of telephone-based psychological support (mean=3.0, SD=1.4), with a mean session duration of 50 min (range: 9–95 min).

Cooperation with and retention in the intervention

All but one intervention participant completed the intervention, and 96% (23/24) of all study participants completed 1-month and 6-month questionnaires. Of the five participants who received all five telephone-based psychology sessions, four had sessions timed around their high-risk clinic appointments as per protocol, and one participant missed her subsequent high-risk clinic appointment but still took part in her last psychology session. For the six participants who received three psychology sessions, five received them as planned and one participant had this final last session delayed by a week.

DISCUSSION

This pilot randomised controlled trial examined the acceptability and feasibility of a psychoeducational intervention for people at high-risk of developing another primary melanoma. Participants in the intervention group reported very high levels of satisfaction with the intervention, perceived the intervention as highly beneficial and did not associate it with many difficulties. Patients with melanoma in this study highly valued the access to individual psychological support, particularly in terms of having a health professional with whom to explore their fears and concerns. This finding is consistent with the results from a recent qualitative study with patients with melanoma that found the most expressed needs were to be given time to ask questions and to express melanoma-related concerns and fears.²⁰

Satisfaction with the newly developed psychoeducational booklet, *Melanoma: Questions and Answers*, was also very high. Participants described receiving information about diagnosis, staging and prognosis as highly valuable and as providing a sense of comfort and confidence. Another Australian study that analysed 29 in-depth interviews with patients undergoing long-term follow-up after surgical treatment of stage I/II melanoma found that patients highly valued the opportunity to learn about their ongoing

prognosis and the changing risk of recurrence over time.²¹ Other patient-reported benefits of our intervention were positive experiences (such as a sense of comfort, confidence and feeling 'worthwhile') and improved doctor–patient communication. Nevertheless, participants expressed the need for ongoing support and were also aware of the future challenges in accessing support when the study was completed. As to be expected, a small proportion of participants did experience difficulties related to opening up and discussing personal issues with a psychologist. The timing of the intervention in relation to high-risk clinic appointments was found to be feasible, and there was very high study retention (96%).

The exclusive recruitment of people who have had early stage melanoma to this study limits generalisability to people with early-stage-disease and further research is needed to know if people with advanced melanoma have a similar response to the intervention. Nevertheless, pilot studies are not designed to evaluate the efficacy of an intervention; the primary purpose of a pilot is to optimise intervention delivery and to identify the barriers and facilitators to intervention implementation.²² The highly positive feedback from participants and the direction of outcomes support wider testing of the intervention.

Based on our experience with this pilot study, minor modifications were made to the protocol for the larger trial. First, we considered it to be more practical and feasible to limit the number of psychology sessions to three. This decision was made to best meet participants' needs as well as ensure the trial was feasible in terms of study management, budget and timelines. Participants in our study who received three sessions still gave high ratings, and evidence from other studies has showed that brief interventions can be beneficial for cancer patients.^{23 24}

CONCLUSION

This pilot study suggests that tailored psychoeducation and psychological support for people at high risk of developing another melanoma provided both before and after dermatological appointments by a highly trained and well supported psychology team was perceived by participants as needed and highly beneficial.

The implementation of a telephone-based psychoeducational programme scheduled around high-risk clinic appointments was highly feasible and acceptable to patients. These findings inform the possible implementation of this model of psychological support in clinical care of patients with melanoma. We are currently carrying out a larger randomised controlled trial to evaluate the efficacy and cost-effectiveness of this intervention, comprising the full colour psychoeducational booklet and three telephone-based sessions with a psychologist compared with usual care.¹² These findings will further inform the implementation of this model of psychological support in clinical care of patients with melanoma.

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