

# 16 Psychosocial issues in melanoma

Many people with melanoma and their carers face practical, emotional and psychological demands in addition to the physical effects of the disease and treatment. Challenges in melanoma include the existential fear faced by anyone with a diagnosis of a life-threatening disease,<sup>1</sup> pain and discomfort associated with treatment, and body image changes associated with disfiguring surgery. Patients with deeply indented scars, such as occur with skin grafting following removal of skin, subcutaneous and deep fascia, as well as those whose scars are longer than they anticipated, may be particularly distressed.<sup>2</sup>

While most studies have found that patients adjust well to melanoma in the long term, distress is common. In a prospective survey of 144 patients with stage I melanoma who did not relapse, 21% reported moderate to high levels of distress three months after excision, 26% at seven-month follow-up and 29% at 13-month follow-up.<sup>1</sup> The impact on families of those with melanoma is also considerable, as they share in the fears of relapse, the traumas of treatment and the sadness of late-stage disease.

Patients' psychosocial needs are significant, and frequently go undetected and unmet. Bonevski et al<sup>3</sup> assessed the perceived needs of a sample of patients attending the Newcastle Melanoma Unit. Patients reported the most unmet needs in relation to health information, psychological issues and melanoma-specific issues. The authors recommended that patient needs should be monitored routinely in oncology care so that groups of patients with specific needs could be identified.

## 16.1 Effect of psychosocial interventions in patients with melanoma

There are few studies exploring whether psychosocial interventions reduce psychosocial morbidity and unmet needs in patients with cutaneous melanoma or melanoma in specific sites and none which have explored interventions to reduce morbidity and unmet needs in carers of people with melanoma. Five randomised controlled trials have been conducted evaluating psychological interventions, two of high quality and three of medium quality.

1. Fawzy et al<sup>4-7</sup> conducted the first randomised controlled trial, on which they have reported to date the six-month follow-up for coping/immunological measures and ten-year follow-up for survival.

This was an American study of high quality. Eighty of 92 patients with stage I and II malignant melanoma approached agreed to participate and were randomised to standard care or a six-week structured group intervention incorporating health education, stress management, illness-related problem-solving skills and psychological support. One patient in the intervention group died and another was diagnosed with major depression and excluded, leaving 38. Ten dropped out of the control group and two had incomplete data, leaving 28. The experimental group was significantly older (mean age 46) than the control group (mean age 39). Psychometrically sound measures were used.

Immediately after the intervention (six weeks), intervention patients reported significantly more vigour ( $p=0.03$ , Profile of Mood States – POMS) and active-behavioural coping ( $p=0.0001$ ). At six months intervention patients were significantly less depressed, dejected, fatigued and confused, had more vigour ( $p=0.001$ ) and an overall better mood ( $p=0.006$ ). They continued to display more active-behavioural coping ( $p=0.0001$ ).

2. Fawzy et al<sup>8</sup> in a study of moderate quality randomised 61 consenting patients with stage I or II malignant melanoma to standard care or an intervention comprising an educational manual plus three hours of individual nurse teaching. Consent for randomisation was not sought, rather patients were offered either the control or intervention arm. Three subjects were lost to follow-up, all from the experimental arm. At baseline, intervention subjects had significantly higher Brief Symptom Inventory (BSI) scores and trends to more distress. At three months, total mood disturbance and fatigue were significantly lower in the intervention group ( $p<0.03$  for both), BSI somatisation was lower ( $p=0.05$ ) and intervention subjects were using less passive resignation coping ( $p=0.04$ ). Overall, there were less dramatic effects than observed in the earlier group study which involved more contacts for each patient (six rather than three) and group interaction.
3. Boesen et al<sup>9</sup> in a study of high quality reported a larger replication of the Fawzy et al<sup>4</sup> study with very minor modifications in a Dutch setting. Of 399 patients, 262 (66%) agreed to participate. Dropouts and exclusions resulted in 112 in intervention and 129 in the control group.

At six months there was a larger decrease in total mood disturbance (TMD) in the intervention group ( $p=0.04$ ) largely due to more vigour ( $p=0.003$ ) and less fatigue ( $p=0.04$ ). There was a greater effect on TMD for patients with higher TMD scores at baseline. The intervention group also used more active behavioural and active cognitive coping ( $p=0.0007$  and  $0.0002$ ). However there were no significant differences between the groups at 12 months. Thus this intervention does seem to have a medium-term impact on distress which is dissipated by 12 months.

4. Bares et al<sup>10</sup> conducted a small RCT of medium quality of cognitive-behavioural therapy for patients with heterogeneous melanomas who were reporting clinically significant levels of distress. The primary goal of the study was to conduct a cost-effectiveness analysis of the intervention above standard care, and the description of the methods was more detailed for that aspect than for the randomisation. Only 38 patients participated in the study, which was nonetheless able to report a significant reduction of distress at three months post intervention for the CBT group ( $p=0.005$ ). CBT was marginally more expensive (49c per minute) than the cost to nursing staff of dealing with distress-driven phone calls during standard care (41c per minute). However, the cost/benefit ratio (total costs/change in distress) was significantly lower for CBT. The cost to change distress in standard care was  $> \$402$  for a one-point change in standard care, versus \$7.66 for CBT. Including reimbursement for service in the analysis, CBT would generate \$1.16 per minute while standard care would cost the hospital \$0.40. Thus CBT is cost-effective.

5. Trask et al<sup>11</sup> conducted a small RCT of CBT of moderate quality using the same methods as Bares et al.<sup>10</sup> The sample size was somewhat higher (n=48) and it is not clear whether the Bares sample was a sub-sample of this one, or a separate sample. In this study, however, there was no group effect for distress at two-month or six-month follow-up by intent to treat analysis, although a group effect for distress was detected at two months and a trend at six months when analysed by treatment received. In the ITT analysis at two months, State Anxiety was lower (p=0.02) and aspects of QOL higher (e.g. p=0.008 for general health) in the intervention group; at six months, anxiety was lower on the BSI (p=0.02) and general health higher (p=0.05). Thus even in this small sample, some important psychological outcomes were effected.

One non-randomised controlled study was reported by Rudy et al<sup>12</sup> of a peer telephone intervention for stage III and IV melanoma patients undergoing immunotherapy. The intervention was assessed after two phone calls had been made by volunteers. Questions were primarily qualitative, although intervention subjects (n=29) did report significantly more providers of social support (p<0.05) than control subjects (n=27). Intervention subjects and peer providers reported that the intervention was effective.

One qualitative study has been reported<sup>13</sup> in which 26 patients with metastatic melanoma who were participating in an RCT of individual CBT versus relaxation training were interviewed about the benefits of therapy by a researcher blinded to allocation. Patients reported similar benefits regardless of allocation, which pertained to receiving patient-centred care from someone outside their family who they trusted and to whom they could speak openly. Thus non-specific therapist factors appeared to be more important than the actual therapy delivered.

Two psychiatric case reports<sup>14,15</sup> reported the benefits of: (a) supportive-expressive therapy and a focus on anxiety reducing techniques and (b) imagery in assisting patients with a poor prognosis.

In summary, all five RCTs produced evidence that psychological interventions can improve psychosocial outcomes for melanoma patients, including reducing general mood disturbance, distress and anxiety. The two studies of high quality reported large effects. Two of the studies of moderate quality reported small effects but their sample sizes were small, and one reported large effects despite a small sample size. Three of the studies targeting coping reported an increase in active coping or a reduction in passive coping in the intervention group. Qualitative studies supported a clinical benefit.

### 16.1.1 Educational interventions

Two non-randomised controlled studies evaluated educational interventions.

One study by Orringer et al<sup>16</sup> evaluated an educational intervention in a *non-randomised controlled trial* in which patients were allocated sequentially to receive or not to receive an educational video on melanoma before their first clinic visit. Patients in the intervention group were instructed to complete colour-coded questionnaires measuring knowledge, anxiety and distress immediately before and after viewing the video at home, while control patients completed the baseline measure at home and the follow-up measure after their

initial clinic visit. Knowledge improvement was significantly greater in the video group (who had unlimited time and were in their own space) but reduction in anxiety and distress was significantly higher in the control group, who had seen a doctor. It is hard to draw conclusions from this study given the methodological limitations.

In another study by Brandberg et al<sup>17</sup> stage I melanoma patients were offered an educational intervention. Interested patients were randomised to receiving the intervention before or after their post-surgical clinic visit. Patients not interested in education acted as controls. The allocation process was inconsistent, with some controls ending up in the post-visit education session, and some randomised to the pre-visit session ending up in the post-visit session. Analysis was not by intention to treat. Knowledge was higher in those who received the education session both at the pre-surgical clinic visit and six months later ( $p < 0.01$ ). Psychological variables were not affected by pre-visit versus post-visit receipt of education and a comparison with the control group was not provided. Thus few conclusions can be drawn from this study about the impact of the educational intervention on psychosocial outcomes.

### 16.1.2 Studies in cancers other than melanoma

The NICE guidelines (2006) recently reviewed evidence for the efficacy of psychosocial interventions in all cancer patients. Three systematic reviews or meta-analyses of good quality, four systematic reviews or meta-analyses of poor quality, four RCTs of poor quality and one observational study of fair quality were identified.

The majority of studies reported benefits, with few inconclusive studies. Benefits included both affective and physical improvements, improved coping and better understanding. The systematic review by Bottomley<sup>18</sup> suggested that structured interventions may offer more benefit than those of a purely supportive nature.

The most recent high-quality systematic review on this topic by Newell et al<sup>19</sup> reviewed 329 intervention trials, most of which were deemed of poor quality. The authors concluded: 'There is tentative evidence for a beneficial psychosocial effect arising from group therapy, education, counselling and cognitive behavioural therapy, all of which are believed to operate in the medium to long term.'

The Scottish Intercollegiate Guidelines Network (2003) concluded from the evidence that 'Health service patient support groups should be structured; facilitated by trained professionals and incorporate health education. Information on all patient support groups should be made easily available to patients'.

The UK guidelines (2002) do not review evidence of outcomes following psychosocial intervention, but recommend that patients with IIB or more advanced melanoma should be managed in a Cancer Centre by a multidisciplinary team which includes a counsellor, while all patients with metastatic melanoma should have access to a palliative care team offering psychosocial support.

The National Comprehensive Cancer Network (NCCN) guidelines do not review the evidence for psychosocial support but do recommend a structured follow-up program in part to provide ongoing psychosocial support (MS-8).

Evidence summary	Level	Reference
Overall, the evidence supports the provision of psychosocial interventions such as cognitive behavioural group therapy and psycho-education, as well as support groups, to assist patients with melanoma in optimally adjusting to and coping with their illness	I, II	8–12

Recommendation	Grade
1. Structured psychosocial interventions, such as cognitive behavioural group therapy and psycho-education, as well as support groups, be made available to all patients with melanoma to improve their quality of life	<b>B</b>

## 16.2 Communication strategies to reduce psychosocial morbidity and unmet needs in patients with melanoma

Two RCTs evaluated formal structured interventions by nurses<sup>8,17</sup> which reported small benefits in terms of increased knowledge,<sup>17</sup> less passive coping and reduced anxiety.<sup>8</sup> These studies provide some support for the role of members of the multidisciplinary team in delivering formal interventions.

One prospective cohort study<sup>20</sup> followed 133 patients with primary melanoma. Patients were interviewed about their experiences at diagnosis 3.8 months post diagnosis and psychological adjustment was measured at four and thirteen months. Large effect sizes were found for communication variables and patient satisfaction, anxiety and depression. In particular, getting full and clear information, having life expectancy discussed and receiving emotional support from their doctor influenced patients' psychosocial outcomes.

Three cross-sectional studies eliciting patient preferences<sup>21–23</sup> reinforced these messages, with patients expressing strong preferences for particular communication practices. Receiving the news face-to-face, not having another health professional present, and receiving assistance and support from the doctor were strongly endorsed. Butow et al (1996) reported a relationship between satisfaction with communication (particularly emotional support) recalled four years later and psychological adjustment reported three months after diagnosis.

In summary, there is preliminary support from one prospective study with very large effects sizes that communication from the multidisciplinary team has a significant impact on patient outcomes. Notably, prospective studies are the most feasible design for this research question, since randomising health professionals to provide different sorts of information to patients in different sorts of ways will rarely be acceptable, ethical or feasible. Patients have strong preferences for receiving full and clear information and emotional support from their doctor at the time of diagnosis.

**Studies outside of melanoma** have provided evidence for an impact of multidisciplinary team communication on patient outcomes. *The Psychosocial Clinical Practice Guidelines for the Psychosocial Care of Adults with Cancer*<sup>24</sup> quote a number of studies supporting the impact of empathy and clear information on patient recall, and psychological adjustment in the short and long term. A small number of large randomised controlled trials have shown that communication skills training can improve the communication skills of health professionals.<sup>25,26</sup>

Evidence summary	Level	Reference
There is a small body of evidence that the way the treatment team communicates with patients in providing information, empathy and support can influence patient satisfaction and adjustment in the long term	II, III-2	8, 17, 20–23
Communication skills training for all members of the treatment team is warranted	II, III-2	8, 17, 20–23

### Recommendation

	Grade
2. Communication skills training be provided to health professionals treating people with melanoma to assist them in effectively providing information, patient-centred care, shared decision-making where desired, empathy and support	C

## 16.3 Influence of patients' psychosocial characteristics on prognosis

Nine prospective cohort studies have explored the impact of psychosocial characteristics on outcome in melanoma. (One was a randomised controlled trial of a psychiatric intervention in which an analysis that controlled for group allocation explored the impact of baseline characteristics on outcome.<sup>6</sup>) Studies varied in the length of follow-up, the psychosocial variables measured and the potential confounders controlled for in the analyses. Only one explored outcomes in patients with metastatic melanoma.

**In early stage melanoma, three studies reported a null effect.** In the largest study with the longest follow-up (to 11 years), Bergenmar et al<sup>27</sup> followed 437 patients with localised cutaneous melanoma who had completed measures of anxiety and depression at their first follow-up after surgery. There was no relationship between baseline anxiety and depression and time to recurrence, although as mood can fluctuate, this is perhaps not surprising. Canada<sup>28</sup> followed 60 patients with stage I melanoma for ten years, and found no relationship between stable personality traits (extroversion, neuroticism, psychoticism) and time to recurrence. Finally, Gibertini et al<sup>29</sup> followed 75 patients for a brief period (unspecified in the paper) in which six of the cohort relapsed, and unsurprisingly observed no significant relationships between psychosocial variables and time to recurrence in univariate analysis.

**Three studies reported a weak effect.** Cassileth et al<sup>30</sup> followed 61 patients with cutaneous malignant melanoma (> 0.76mm thick) among a larger cohort of heterogeneous cancers for eight years. Patients had completed a number of psychosocial measures at baseline, including helplessness/hopelessness and effort needed to adjust to diagnosis. Some weak associations between psychosocial factors and time to recurrence were found in the melanoma group but they were inconsistent, depending on cut-off scores and sub-groups compared. The authors concluded that the data did not support a role for psychosocial factors.

Brandberg et al<sup>1</sup> followed 64 patients with stage I melanomas > 0.8mm. In contrast to the findings of Bergenmar<sup>27</sup> at two-year follow-up, baseline anxiety was significantly higher in those that recurred ( $p=0.05$ ) but there was no difference in the proportion scoring as a case on anxiety or depression at baseline. Perhaps the shorter follow-up time in this study meant that baseline measures of mood more accurately represented patients' prevailing psychological state before recurrence.

Fawzy et al<sup>6</sup> explored psychosocial predictors of time to recurrence in 68 patients with stage I or II malignant melanoma who had participated in a randomised controlled trial of a psychiatric intervention. Controlling for group allocation, and disease and demographic prognostic variables, at six-year follow-up higher baseline rates of total mood distress on POMS and higher baseline coping (active-behavioural) were associated with lower recurrence and death rates, and increase in active-behavioural coping over the study period was related to better survival ( $p=0.03$ ), with a trend apparent for recurrence ( $p=0.06$ ). Fawzy et al posited that the more distressed patients and those who tended to cope by taking active steps to solve problems, may have been more motivated to prevent recurrence by staying out of the sun and protecting their skin.

**Finally, two studies reported larger effect sizes.** In a large and well-conducted study, Brown et al<sup>31</sup> followed 426 patients with locoregional melanomas > 0.7mm for six years who were assessed for a range of psychological variables at diagnosis. In an analysis that controlled for all other prognostic demographic and disease variables, patients who at baseline used less avoidance ( $p=0.03$ ) and were more concerned about their disease ( $p=0.008$ ) had a greater time to recurrence, and there was a trend for patients who perceived the aim of treatment as cure ( $p=0.06$ ) to have longer time until recurrence. As in Fawzy et al (1993) these psychosocial variables might be related to active behaviours aimed at prevention, although this was not measured.

In one of the older studies, Rogentine et al<sup>32</sup> followed 64 patients for just one year, and found that patients who reported more difficulty in adjusting at baseline had a shorter time to recurrence ( $p<0.001$ ).

One study explored psychosocial predictors of time to death in late-stage melanoma. Butow et al<sup>33</sup> followed 125 patients with metastatic melanoma for six years. Controlling for other prognostic factors, patients who perceived the aim of treatment to be cure ( $p<0.001$ ), minimised their illness ( $p<0.05$ ), were more angry ( $p<0.05$ ), were married ( $p<0.01$ ), and who reported better QOL ( $p<0.05$ ) survived longer. Patients who believed treatment would lead to cure survived about twice as long (10.6 months) as those who did not (5.6 months).

### 16.3.1 Conclusions

As in all cohort studies, it is hard to interpret positive results as it is always possible that at baseline, patients were influenced by illness characteristics that were prognostic but not recorded in the traditional prognostic measures. The studies measured a wide range of psychosocial variables. Those which were found to be associated with outcome tended to reflect active coping styles or general distress. These may have promoted active lifestyle efforts to promote good health and avoid risk factors for melanoma, suggesting that increasing awareness of threat and mobilising active coping can assist survival.

The single study in metastatic melanoma reported large effect sizes and is intriguing. This study requires replication, perhaps with stronger measures.

Further research is required to establish if there is a link between psychosocial factors and outcome in melanoma.

Evidence summary	Level	Reference
There is inconclusive evidence that psychosocial factors influence outcome in melanoma	III-2	1, 6, 27–33

Recommendation	Grade
3. If the matter is raised, patients be advised that there is no known (or proven) link between psychosocial factors and survival outcome	<b>C</b>

## 16.4 Influence of psychosocial interventions on prognosis

Only one study has explored the impact of a psychosocial intervention on prognosis in melanoma.<sup>4,5</sup> All patients were analysed by intent to treat. Stage II patients were excluded, leaving 68 to analyse.

Immediately after the intervention there was a significant increase in one of the large granular lymphocyte sub-populations, CD8. There were no other significant changes.

At six months, the intervention group had an increased number of natural killer cells and an increased cytotoxicity, decrease in a major T-cell subpopulation-CD4 helper/inducer cells, and some increases in the percentage of larger granular lymphocytes. This was correlated with change in depression and anxiety.

At the six-year follow-up, 10/34 in the control group had died and three had local recurrences. In the intervention group 3/34 had died and four had recurrences.<sup>6</sup> Participation in the intervention lowered the risk of recurrence by more than 2.5, and decreased the risk of death sevenfold.

At ten-year follow-up, Fawzy et al reported that 11/34 control subjects had had recurrences and died and 3/34 had had recurrences and were still alive. In the intervention group, 9/34 had recurrences and died and two had recurrences and were still alive.<sup>7</sup> Univariate survival analysis showed non-significant differences between groups for recurrence

and survival. A multivariate cox regression analysis revealed a significant effect for the intervention on survival ( $p=0.05$ ) but not for recurrence. By ten years, participation in the intervention did not lower the risk of recurrence but decreased the risk of death threefold.

### Results in cancers other than melanoma

Few well-conducted RCTs have explored the impact of psychosocial interventions on cancer prognosis. Overall, the results have been equivocal. A recent systematic review concluded that there was insufficient evidence for a relationship between psychosocial interventions and survival of cancer, given methodological flaws and contradictory findings.<sup>34</sup>

Further research is required to establish the impact of psychosocial intervention on prognosis in patients with melanoma.

Evidence summary	Level	Reference
There is insufficient evidence that psychosocial intervention can impact on prognosis in patients with melanoma	II	4–7

Recommendation	Grade
4. Patients be advised that individual or group psychosocial intervention may not improve their overall survival	C

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