'Cancer Coping Online': A pilot trial of a self-guided CBT internet intervention for cancer-related distress

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Abstract

While internet-based cognitive behaviour therapy (iCBT) programs for mental health conditions has a demonstrated evidence base, the application of iCBT to those experiencing cancer-related distress has not been reported. This study therefore developed and pilot tested a self-guided iCBT program for patients with early stage cancer. Cancer Coping Online is a 6-week intervention which provides information, worksheets, and activities to address commonly experienced physical, emotional, social and communication difficulties. Participants were 12 patients (11 female) recruited over a 3month period from one public hospital. The primary outcome measures were negative affect and posttraumatic stress. The secondary outcome measures were coping styles (helplessness/hopelessness, anxious preoccupation, cognitive avoidance, fatalism and fighting spirit). Changes over time were measured using within group effect sizes (Cohen's d), with reliable change indices (RCIs) used to assess the clinical significance of changes over time. The intervention led to reductions in negative affect (d=0.53), helplessness/hopelessness (d=0.64),preoccupation (d=0.43), and fatalism (d=0.42). These reductions were clinically significant for 33% of the sample for negative affect, and for 25% of the sample for helplessness/hopelessness and anxious preoccupation. These results indicate that an iCBT program for cancer patients can reduce distress, and warrant further investigation through a randomised controlled trial.

Keywords: Cancer; Distress; Online-Intervention; CBT; Self-Help

Introduction

Despite improvements in treatment and survival rates, a cancer diagnosis continues to elicit greater distress than any other medical diagnosis (National Breast Cancer Centre (NBCC) & National Cancer Control Initiative (NCCI), 2003). Research has

consistently found that 30 to 40 per cent of recently diagnosed patients experience clinically significant psychological distress warranting intervention (Carlson et al., 2004; Zabora, Brintzenhofeszoc, Curbow, Hooker, & Piantadosi, 2001), most commonly major depressive or anxiety disorders (NBCC & NCCI, 2003). As a consequence, research over the past two decades has evaluated the efficacy of a range of psychological interventions to alleviate this distress. These interventions, typically implemented in group settings, have included cognitive behaviour therapy (CBT: Beatty & Koczwara, 2010a), supportive expressive therapy (SET: Classen et al., 2008), psycho-education (Zimmermann, Heinrichs, & Baucom, 2007), mindfulness (Foley, Baillie, Huxter, Price, & Sinclair, 2010), and peer-support groups (Helgeson, Cohen, Schulz, & Yasko, 1999). There is clear meta-analytic evidence that while all are efficacious compared to control groups in reducing distress (Osborn, Demoncada, & Feuerstein, 2006; Rehse & Pukrop, 2003), CBT has the largest evidence base (Osborn et al., 2006), particularly when targeted at the time of diagnosis rather than after treatment is completed (Zimmermann et al., 2007).

However, there are two major barriers to attending face-to-face therapy in the Australian setting. First, there are limited psychosocial services available in the public health setting, particularly for those in rural or remote regions (Cancer Council SA & SA Health, 2009). Second, even when psychosocial services are offered, research has demonstrated that less than 25% of Australians attend (Wade, Nehmy, & Koczwara, 2005). As a result, innovative methods of increasing access to supportive care are required (Cancer Council SA & SA Health, 2009).

One method of increasing this access is via selfhelp, or bibliotherapy, where individuals learn well-known therapeutic principles through a printed format. This is a well-established treatment for mental health conditions (Newman, Szkodny, Llera, & Przeworski, 2011). To date, only five selfhelp studies have been reported in cancer populations. Jacobsen et al. (2002) first developed a self-administered CBT-based stress management intervention for heterogeneous cancer populations, which significantly reduced distress for those currently undergoing chemotherapy compared to a no-treatment control. A subsequent study by the same group found that workbook only benefitted those with high baseline distress (Krischer, Xu, Meade, & Jacobsen, 2007). Angel et al. (2003) implemented a self-help SET-based workbook specifically among rural and remote US women with early stage breast cancer. In contrast to Jacobsen and colleagues, this workbook was found to improve PTSD symptoms and coping in women who had completed treatment, but not for those who had recently been diagnosed (Angell et al., 2003). In the Australian setting, our research group recently evaluated two self-help workbooks among 89 women with early stage breast cancer, based on CBT and therapeutic writing principles (Beatty, Koczwara, Rice, & Wade, 2010b; Beatty, Oxland, Koczwara, & Wade, 2010c). Consistent with Jacobsen and colleagues, but in contrast to Angell et al., these studies found that the workbook was not efficacious among those who had completed treatment (Beatty et al., 2010c), but significantly PTSD symptoms, helplessness hopelessness, and cognitive avoidance during the first three months of treatment (Beatty et al., 2010b).

method of further increasing accessibility of these self-help resources, which is receiving substantial empirical attention, is the internet (Griffiths, Farrer, & Christensen, 2010). Research suggests that cancer consumers prefer multimedia formats to paperback (Bader & Strickman-Stein, 2003), with recent national data indicating that 84% of Australians have access to the internet (Australian Bureau of Statistics, 2006). As health and medical crises being among the most commonly searched terms (ABS, 2006), online interventions for the cancer population are warranted, and overcome many of the attendance barriers relating to access and inequity, particularly for rural/remote areas. They have the advantages of being convenient, cost-effective, anonymous, interactive, and can be easily updated and provide links to other resources (Griffiths et al., 2010). There is a large evidence base supporting internet CBT (iCBT) in reducing distress for various mental health populations (Newman et al., 2011), and evidence has also been gradually building across a range of chronic illness populations, including: chronic pain (Andersson, Lundström, & Ström, 2003; Chiauzzi et al., 2010; Williams et al., 2010); irritable bowel syndrome (Hunt, Moshier, & Milonova, 2009; Ljótsson et al., 2011); diabetes (van Bestelaar, Cuijpers, Pouwer, Riper, & Snoek, 2010); fatigue (Ghahari, Packer, & Passmore, 2009); HIV (Kraaij, van Emmerik, Garnefski, & Schroevers, 2010); insomnia (Strom, Pettersson, & Andersson, 2004), tinnitus (Kaldo et al., 2008), overweight/obesity (Tate, Wing, & Winett, 2001); and epilepsy (Walker et al., 2009). However, a tailored iCBT program for people affected by cancer has not previously been reported.

To date, only two online therapeutic programs for cancer have been examined using randomised controlled trials (Gustafson, Hawkins, Pingree, McTavish, & Arora, 2001; Owen et al., 2005), neither of which utilised CBT. One study found their information and social support program led to improvements in perceived social support, but not distress or quality of life (QOL), when compared to an information-control (Gustafson et al., 2001). The second online coping group program did not yield significant main effects, but did benefit the perceived health status of those with poor perceived health status at baseline (Owen et al., 2005). While these two studies provide evidence of the feasibility of delivering an online intervention for people with cancer, efficacy could arguably be improved through the use of CBT strategies.

To address this gap in the literature, the present pilot study aimed to develop and evaluate the feasibility and efficacy of *Cancer Coping Online*, a self-guided iCBT program for people with cancer being treated with curative intent. In line with Medical Research Council (2000) recommendations, this represents an exploratory trial in order to investigate the usefulness of the approach before a full randomised controlled trial (RCT) is conducted.

Method

Participants

Participants were adult cancer patients currently receiving curative treatment, who spoke English, and were aged 18 years and over. Over the 3 month recruitment period twelve participants consented, who ranged in age from 38 - 62 years (M = 48.33, SD = 9.61), and enrolled in the program on average 8.67 months following diagnosis (SD = 11.49). Two participants had recently completed treatment but specifically requested to participate, while the remaining 10 were currently undergoing treatment. The majority were female (n = 11), 8 of whom had breast cancer; gynaecological (n=2), lymphoma (n=1) and bowel cancers (n=1) were also represented. All participants had received surgery, with 83% also receiving chemotherapy, 50% receiving radiotherapy, and one participant receiving Tamoxifen. The majority were married (75%), had university or graduate certificate-level

education (67%), and 50% were employed at baseline.

Procedure

Participants were recruited into the study via local media advertisements and referrals from cancer clinicians. Participants completed an online registration which included an eligibility screen, information sheet and consent form with an "I agree" button, and baseline assessment. After completing the baseline assessment, participants were emailed their login details and password, and the first module was available for immediate use. Participants worked through the 6 modules sequentially, with a new module released each week along with an email reminder to use the program. The opportunity to provide qualitative and quantitative feedback was provided at the end of each module. At the conclusion of module 6, participants were automatically directed to the post-treatment assessment, and a reminder email was sent one week after the final module had been released for those who had not yet completed the post-treatment assessment. This study was approved by the Cancer Council SA and Flinders University Human Research Ethics Committees.

Intervention

Cancer Coping Online (CCO) is a 6-module password-protected treatment program, adapted from a previous print self-help workbook for women with breast cancer (Beatty et al., 2010b). Developed in consultation with consumers (Beatty, Oxland, Koczwara & Wade, 2008), the content was extensively revised to ensure its relevance to heterogeneous cancer populations; workbook chapters were reorganised, sections warranting deletion were identified, particularly the body image worksheets previously found to be unhelpful (Beatty et al., 2010b). Opportunities to improve content were identified, via: (a) increasing the number of CBT-based worksheets per module, (b) adding immediate-feedback quizzes, and (c) incorporating new sections on psychosexual issues and decision making. The resulting 6 weekly modules address: (i) starting treatment - working with your medical team, covering assertive communication and decision making, (ii) coping with physical symptoms and side effects - including fatigue, pain, insomnia, and provides activity pacing worksheets, and relaxation audiotracks; (iii) coping with emotional distress which covers depression, anxiety, anger and stress, and provides cognitive restructuring diaries, and mindfulness audiotracks; (iv) body image, identity and sexuality - with psychosexual worksheets, and therapeutic writing activities; (v) your family and friends comprising further assertive communication and needs assessment worksheets; and (vi) completing treatment, which includes selfmanagement strategies to facilitate healthy lifestyles. Each module provides psycho-education, cognitive-behavioural worksheets / strategies, and survivor stories and quotes. *CCO* also contains a personal blog for online-journal writing, and a resources section.

Measures

Online self-report assessments comprising the following measures were administered at baseline (pre-treatment), and at 7-weeks (post-treatment).

Participant characteristics. Demographic measures included: marital status. age, occupational status, annual gross income, level of educational attainment, area of residence (rural, urban, state), and contact details. Medical treatment measures included cancer type, date of diagnosis, treatment received (surgery, chemotherapy, radiotherapy, hormonal therapy, other), any other chronic health conditions.

Primary outcome: distress. Two measures of distress were evaluated: negative affect and traumatic stress. The total scale score for the short form of the Depression Anxiety Stress Scale (DASS: Lovibond & Lovibond, 1995), was utilised as the measure of negative affect. This 21-item self-report scale assesses levels of anxiety, depression and stress over the previous week where responses are indicated on a four-point scale ranging from (0) Did not apply to me at all to (3) Applied to me very much, or most of the time. The DASS has demonstrated good psychometric properties among both community (Crawford & Henry, 2003), and cancer populations (α =.88; Beatty et al., 2010b).

The 17-item The Posttraumatic Stress Scale-Self Report (Foa, Riggs, Dancu, & Rothbaum, 1993), was utilised to further analyse distress. This scale measures the severity of each DSM-IV post-traumatic stress disorder symptom criterion. Participants indicate, on a 4-point scale (0 = Not at all or only one time to 3 = 5 or more times per week / almost always), how often they experienced each symptom in the previous week. Among PTSD populations, the PSS-SR demonstrated acceptable psychometric properties (Foa et al.), with the internal reliability of the PSS-SR among cancer populations also acceptable in our previous workbook study, α =.93 (Beatty et al., 2010b).

Secondary outcome: coping. Coping was evaluated with the mini-Mental Adjustment to Cancer Scale (mini-MAC: Watson et al., 1994), which contains 29 items and yields 5 factors: Fighting Spirit, Helplessness/Hopelessness, Anxious Preoccupation, Fatalism, and Cognitive Avoidance. Participants indicate on a 4-point scale how much each statement applied to them

currently, and scores are calculated by summing items for each respective domain. The mini-MAC has acceptable psychometric properties (Watson et al.).

Compliance. Compliance was measured via the following website use indicators: the number of visits to the website, length of time logged in, and the number of modules and worksheets completed.

Participant feedback. Levels of satisfaction with the website were assessed as a measure of whether this intervention improved psychosocial support for patients. In addition, qualitative feedback was gathered within the website and at follow-up assessments.

Data analysis

Given the small sample size, inferential statistics were not performed. Changes over time for distress and coping measures were primarily assessed by within-group effect sizes (Cohen's d). This calculation determines whether the intervention led to any improvements over time for the group as a whole using the formula: $d = M_{Tl} - M_{T2} / SD_{pooled}$. M_{TI} refers to the raw mean score at baseline, M_{T2} refers to the raw mean score at post or follow-up, and SD_{pooled} refers to the average standard deviation for the sample. A positive effect size therefore indicates that the score has decreased over time, while a negative effect size indicates that scores have increased over time. Effect sizes of 0.2 are considered to be small, 0.5 moderate, and 0.8 large (Matthey, 1998). Individual change scores were then examined to determine the number of individuals who improved, deteriorated or did not change over time. The clinical significance of these change scores was then evaluated using reliable change indices (Jacobsen & Truax, 1991), using the formula: $SE_{diff} = SD_1\sqrt{2}\sqrt{(1-r)}$, where SD_1 is the standard deviation at baseline and r is the Cronbach's α coefficient of the measure. The RCI equals $1.96 \times SE_{diff}$, and thus represents a cut-off; if a participant's change in scores over two assessments exceeds the RCI value, this is considered to indicate reliable change with 95% confidence (thus above chance). Qualitative feedback was analysed thematically.

Results

Feasibility

The recruitment rate averaged at one participant enrolment per week. The technical performance of *CCO* was faultless. *CCO* was delivered using an established Learning Management System, Moodle 2.0, which offered a reliable platform for the program. Neither the program itself, nor the host web-server (Flinders University), had connection issues.

Treatment Efficacy

All 12 participants provided post-treatment assessment data. The means, standard deviations and effect sizes for each dependent variable at both assessment phases are shown in Table 1. The clinical significance of these changes over time are presented in Table 2.

Table 1
Means, Standard Deviations and Effect Sizes on
Treatment Outcome Measures from Pre- to Posttreatment

Variable	Pre-	Post-	Effect
	treatment	treatment	size
D' /	M (SD)	M (SD)	(d)
Distress		• • • •	
Negative affect	36.33	26.00	0.53
	(25.27)	(13.99)	
Traumatic	17.08	14.25	0.27
Stress	(11.87)	(9.17)	
Coping			
Helpless /	14.33	11.42	0.64
Hopeless	(5.60)	(3.50)	
Anxious	22.67	20.08	0.43
preoccupation	(5.28)	(6.775)	0.15
Cognitive	9.17 (3.07)	8.33	0.26
avoidance	7.17 (3.07)	(3.42)	0.20
Fatalism	13.92	12.92	0.42
	(1.98)	(2.75)	-
Fighting spirit	12.00	11.58	0.14
2 · -8 · P	(2.49)	(3.34)	

Note. d = 0.2 small effect size; d = 0.5 medium effect size; d = 0.8 large effect size.

Primary outcome (distress). Negative affect: Table 1 demonstrates that CCO resulted in overall reductions in negative affect from pre to post treatment for the group as a whole, with a moderate associated effect size (d=0.53). Examining individual change scores, 10 participants reported decreases in negative affect over time, with 4 participants (33%) achieving clinically significant improvements as demonstrated by change above the RCI (Table 2). Two participants reported small increases in negative affect, however these deteriorations did not reach clinically significant levels.

PTSD symptoms: Only small overall mean reductions were observed for the group, with a small associated effect size (d=0.27). Individually, reductions in scores over time were reported by 8 participants, with two of these participants achieving clinically significant improvement (Table

2). Increased PTSD symptoms occurred for 2 participants, with one of these participants

experiencing clinically significant levels of deterioration. This participant was provided with

Table 2

Number (and %) of Participants who Experienced a Clinically Significant Level of Change from Baseline to Post-Treatment, Based on Reliable Change Indices

	RCI value	Improvement	Deterioration
Distress			
Negative affect	± 14.35	4 (33%)	0
Traumatic Stress	± 8.58	2 (16.7%)	1 (8.3%)
Coping			
Helpless / Hopeless	±5.51	3 (25.0%)	0
Anxious preoccupation	±5.72	3 (25.0%)	1 (8.3%)
Cognitive avoidance	± 4.00	1 (8.3%)	1 (8.3%)
Fatalism	± 4.56	0	0
Fighting spirit	± 6.12	0	0

Note: For a person to significantly improve or deteriorate on each measure, the change in his or her score over time must be greater than the reliable change index value listed for each follow-up period.

referral information for telephone counselling services.

Secondary outcome (coping). Table 1 shows that CCO lead to mean reductions over time in three maladaptive coping styles, with moderate associated effect sizes: Helplessness / Hopelessness (d=0.64); Anxious Preoccupation (d=0.43); and Fatalism (d = 0.41). For helplessness / hopelessness and anxious preoccupation, 7 and 8 participants respectively reported reductions in scores over time, with these reductions reaching clinically significant levels for 3 participants (25%). Two participants reported increased anxious preoccupation and helplessness/hopelessness from pre- to post-treatment, however only one participant achieving clinically significant deteriorations in anxious preoccupation (see Table 2), and was provided with referral information. For while 9 individuals fatalism, reported improvements and 2 reported deteriorations over time, these changes did not reach clinical significance according to the RCI.

Treatment compliance

The level of engagement with the program was high. Ten of the 12 participants logged in weekly for an average of 30 minutes, and completed the program. Two participants completed less than two modules, due to treatment side effects (n=1), and lack of time and interest (n=1).

Qualitative Feedback

Qualitative responses given in the end-of-module surveys and at post-treatment assessments were grouped according to the following themes: program usage (technical aspects), program content, and overall satisfaction.

Program usage. All participants stated that the website was easy to navigate and use. Two participants reported that the time commitments required to complete a specific module within a week was high; this was not an issue for the remaining 10 participants. Participant feedback regarding the technical aspects of the program included:

The website was easy to navigate, and was user-friendly.

The program provided numerous navigation options, which was helpful, and the content layout was well done.

Program satisfaction. Feedback about the module content overall was very positive. Eleven participants (91.7%) reported finding the program quite or very helpful, and stated that *CCO* was a valuable resource to be used over time, e.g.,

The program provided a wealth of information and useful strategies.

I keep looking back at it even now [that I've completed it] as other parts have now become relevant'.

It gives me a chance to think about the situation in a way that I would not have if the information was not available. Thanks!

One participant reported disliking the program, stating that she did not enjoy spending her spare time on the computer, and noted that the program would have been more beneficial during chemotherapy, as she did not enter the study until completion of chemotherapy and commencement of radiotherapy.

I would like this program to be available as soon as diagnosed.

The worksheets and activities were rated as quite / very helpful by 8 participants, and somewhat helpful by 1 participant. The remaining three participants reported not utilising the worksheets, with one participant stating worksheets were 'not for her', and one participant stating that 'they were still valuable to read through'. In terms of relaxation and meditation activities, one participant stated they chose not to use relaxation for cancer, as they did not believe it would help with physical side effects; while 8 participants stated that the relaxation and meditation audio-tracks were particularly beneficial, e.g.,: Setting aside time to go through a very specific relaxation process [helped me] as I hold a lot of tension in my body.

The majority of participants did not recommend content changes; suggestions that were made related to incorporating their own personal cancer experiences into the content. The modal distress rating after completing modules was 'none', two participants reported being 'a little' distressed after completing one module, however these modules differed per participant.

Discussion

This pilot study aimed to demonstrate the feasibility and acceptability of utilising the internet to deliver a CBT-based self-help program for cancer, and to provide preliminary evidence regarding its efficacy. Current findings indicate that Cancer Coping Online can be an effective distressmanagement resource for individuals with early stage cancer, as evidenced by the substantial reductions negative affect in and helplessness/hopelessness, their moderate associated effect sizes and the percentage of individuals achieving clinically significant improvements from pre to post-treatment. In addition, Cancer Coping Online led to reductions in anxious preoccupation and fatalism, with smallto-moderate effect sizes, but the intervention was not efficacious in improving traumatic stress, cognitive avoidance or fighting spirit.

These findings are of interest as they provide support for, but also contrast with, our previous workbook study results (Beatty et al., 2010b; Beatty et al., 2010c). First, with respect to the primary outcome, distress, the current reductions in negative affect obtained indicated that the online format yielded a superior performance over three previous print workbook studies, where no reduction in negative affect/distress was obtained (Angell, et al., 2003; Beatty et al., 2010b; Krischer, et al., 2007). Indeed in our prior study, minor (nonsignificant) increases in depression and anxiety were observed (Beatty et al., 2010b). However, the improvement in distress found in the present study, and associated moderate effect size, is consistent

with an earlier print self-help heterogeneous cancer patients undergoing chemotherapy (Jacobsen, et al., 2002), and other more recent online studies among both mental (Newman, et al., 2011), and physical health populations (e.g., Chiauzzi, et al., 2010; Hunt, et al., 2009; Ljótsson, et al., 2011; van Bestelaar, et al., 2010; Williams, et al., 2010). In contrast to the findings of Angell et al. (Angell, et al., 2003), and to our previous print workbook study where moderate effect sizes were found (Author, 2010b), CCO was not demonstrably efficacious in reducing our second measure of distress, traumatic stress. The present study only obtained a small reduction in total scores, and only two individuals obtained clinically significant improvements. improvements would have occurred at 3 month follow-up, when both previous studies obtained significant reductions, was beyond the scope of the present study.

In terms of secondary outcomes, results from the present pilot study are consistent with the possibility of yielding treatment effects, and therefore provide support for both our previous workbook studies (Beatty et al., 2010b; Beatty et al., 2010c), and that of Angell et al. (2003) in addressing maladaptive coping. In particular, the present study replicates and extends our previous workbook findings that self-help resources can lead to reductions in helplessness/hopelessness (Beatty et al., 2010b), as a stronger effect size was obtained. The present study's findings for anxious preoccupation also replicate our previous study (Beatty et al., 2010b), with a similar effect size and percentage of people reporting clinically significant improvements being obtained. While the present study did not replicate our previous finding that the intervention was efficacious for cognitive avoidance, it should be noted that this previous workbook prevented the increases in avoidance that were observed in controls, rather than reducing avoidance (Beatty et al., 2010b). Given the nonrandomised nature of the present pilot study, it cannot be determined whether the intervention would have yielded a similar effect if a control group had been utilised.

Qualitative feedback suggested high levels of satisfaction with both the program content and the program's online-format. The level of engagement reported was higher compared to our previous workbook studies (Beatty et al., 2010b; Beatty et al., 2010c), with a higher time usage per week, more worksheets and activities completed, and low attrition, indicating that providing this resource online can improve compliance. Technically, the website performance was sound, with no occasions occurring where participants could not log on recorded, and participants found the website easy to use. However, these benefits must be balanced against the fact that this resource will not be as

universally available as a print-resource, as not all patients have access to the internet. It is also noteworthy that the two participants who did not complete all six modules had lower levels of education than treatment completers. Whether this same pattern occurs in a larger sample warrants future attention. The present study did not collect data on non-participants, thus it is unknown what percentage of patients would not be able to make use of this resource. These data are important to collect in the future, in order to gain a balanced understanding of the feasibility and reach of online interventions.

While the current study obtained promising results and extended those of our previous studies. three important differences in the design of the current study should be noted: first, while CCO is based on our previous workbook (Beatty et al., 2010b), it was heavily revised prior to being implemented online, thus the present study was testing a new intervention in addition to a new treatment modality, and an identical pattern of results should not be anticipated. Second, the data collection timeframe differed between the two studies, that is, while the present study utilised a pre-post design, our previous print workbook did not collect post-treatment data and instead collected 3- and 6 month follow-up. Thus the two studies are not comparing results at the same time point. Given that previous pure self-help CBT studies have shown that further improvements can be observed between post-treatment and follow-up (Pleva, 2007), there is potential for the gains observed in the present study to be enhanced at follow-up. Third, and most important, this was a nonrandomised pilot study with a very small sample; caution is therefore warranted in interpreting the results. The present findings require replication in a randomised controlled trial in order to confirm the benefits that CCO appears to deliver. This is currently underway, where two versions of CCO are being compared - an information-control version with the fully-interactive version reported

To summarise, the current study results appear to suggest that treatment effects are possible following the implementation of an online self-help intervention. This, combined with our previous print-workbook data (Beatty et al., 2010b; Beatty et al., 2010c), indicates that self-help resources may be of therapeutic benefit in the oncology setting. Consistent with other recent studies for physical health populations, the online delivery format clearly holds promise in ameliorating cancer-related distress and maladaptive coping.

Acknowledgements

With thanks to the Flinders Medical Centre Cancer Care Coordinator, Ms Caroline Richards for your assistance with recruitment, and to the Cancer Council South Australia for supporting and advertising this study, particularly Dr Vikki Knott, Professor Carlene Wilson, and Ms Christine Hygonnet. This study was funded by a pilot study grant from the South Australian Department of Health. Dr Lisa Beatty's postdoctoral research fellowship has been co-funded by the South Australian Department of Health, the Cancer Council South Australia, and Flinders University. Finally, thanks to those who participated in this pilot study, and for the helpful feedback, we hope you found the program beneficial.

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Research Profile

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