A randomised controlled trial to evaluate the effects of a self-help workbook intervention on distress, coping and quality of life after breast cancer diagnosis

Lisa J Beatty, Bogda Koczwara, Janet Rice and Tracey D Wade

Although breast cancer survival rates are improving,[1] a diagnosis of breast cancer elicits greater distress than other medical diagnoses.[2] Depression, anxiety, and posttraumatic stress occur in up to 66% of women in the first year following diagnosis,[3,4] with quality of life (QOL) being similarly globally adversely affected over this period.[5-7] Maladaptive coping has been shown to predict distress and impaired QOL, and particularly emotional repression, cognitive and behavioural avoidance and helplessness/hopelessness.[8-9] While group interventions are demonstrably effective in improving outcomes,[10] only a fifth of Australian women participate in such interventions.[11] Group programs are generally run during working hours in urban treatment centres, thus rural patients and full-time workers are often unable to attend. Other reasons for non-attendance include: (i) not feeling comfortable in a group setting; (ii) not wanting to hear other women's problems; and (iii) preferring to manage problems alone.[11] In contrast to "information alone" resources, which research shows are insufficient for changing behaviour or attitude,[12] innovative interventions are required that are interactive but can be completed by the individual.

Self-help interventions can provide solutions to attendance barriers, while providing the interactive benefit. A self-help workbook for 100 women either recently diagnosed or recently completing treatment was designed and then evaluated by Ansell and colleagues in a randomised controlled trial.[13] After 3 months, control participants who had completed treatment experienced significantly increased posttraumatic stress symptoms and venting, and decreased fighting spirit compared with workbook participants who reported stable levels. Women closer to diagnosis did not benefit from the workbook, leading the authors to conclude that treatment completion was a more appropriate time to use this resource.[13] This conclusion contrasts with meta-analytic reviews which have found that targeting closer to diagnosis is more effective.[10] Thus, in this study, we examined whether an Australian self-help

ABSTRACT

Objective: To evaluate the efficacy of an interactive self-help workbook in reducing distress, and improving quality of life (QOL) and coping for women recently diagnosed with breast cancer.

Design: Randomised controlled trial comparing the use of the workbook and that of an information booklet.

Participants and setting: 49 women with Stage 0 to II breast cancer diagnosed in the previous month and recruited from 1 February 2007 to 1 February 2008, in two urban Australian public hospitals.

Main outcome measures: The primary outcome measures were depression, anxiety, and posttraumatic stress. Secondary outcomes included QOL, body image, and the coping styles helplessness/hopelessness, cognitive avoidance and anxious preoccupation.

Results: After controlling for baseline levels, interactions at 3-month follow-up showed that participants in the workbook group had significantly lower levels of posttraumatic stress ($F[1,89] = 7.01$; $P = 0.01$), helplessness/hopelessness ($F[1,89] = 4.75$; $P = 0.03$), and cognitive avoidance ($F[1,89] = 4.95$; $P = 0.03$) than those in the control (information booklet) group. However, women in the workbook group had significantly poorer body image than those in the control group ($F[1,89] = 6.43$; $P = 0.01$). At 6 months, only the body image interaction remained significant ($F[1,93] = 7.44$; $P = 0.01$).

Conclusion: These results suggest that a self-help workbook can be an effective, short-term intervention for improving posttraumatic stress, cognitive avoidance, and certain depressive symptoms in women recently diagnosed with breast cancer. However, issues related to body image need to be dealt with differently.

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workbook could be efficacious in women recently diagnosed with breast cancer. We hypothesised that workbook participants would show greater reductions than controls in the primary outcome, distress, and greater improvements in the secondary outcomes, QOL and coping.
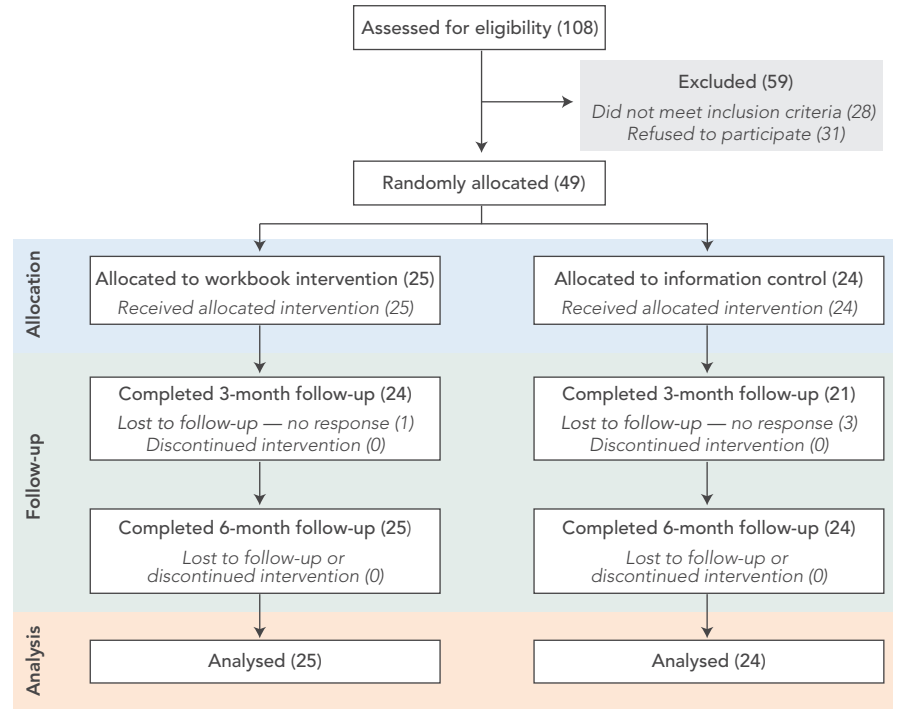
METHODS

Participants were women with Stage 0 to II breast cancer diagnosed in the previous month, who spoke English, were aged 18 years or over, and had no pre-existing neurological conditions. Participants were recruited from 1 February 2007 to 1 February 2008, in two public hospitals located in urban settings and serving a range of socioeconomic groups. While one hospital served a large geographical region, including rural patients, the other served a high proportion

of culturally and linguistically diverse patients. The trial obtained ethics approval from the Flinders Clinical Research Ethics Committee, and is registered with the Australian New Zealand Clinical Trials Registry.

Procedural elements of this study conformed as closely as possible to the 2010 CONSORT (Consolidated Standards of Reporting Trials) statement,[14] and no changes were made to the methods after trial commencement. Block random allocation was used (implemented through the use of numbered containers) and the sequence was concealed until interventions were assigned. Box 1 illustrates the flow of participants through the study. Women were informed of the study by a breast-care nurse, and those interested in participating were contacted by a researcher (L J B).

After completing baseline questionnaires, participants were allocated to the interven-

1 Flow diagram of participant recruitment and involvement in the randomised trial of a workbook intervention for primary breast cancer patients

Primary outcome (distress): Depression and anxiety were measured using the 21-item Depression Anxiety Stress Scales.[15] Total scores on these scales range from 0 to 42, with higher scores indicating higher distress. Traumatic stress was assessed using the total scale score of the 17-item Posttraumatic Stress Diagnostic Scale — Self Report,[16] on which scores range from 0 to 51, with higher scores indicating higher traumatic stress.

Secondary outcomes (quality of life and coping): Two subscales of the European Organisation for Research and Treatment of Cancer quality of life core questionnaire and breast cancer questionnaire module[17] were included: global QOL and body image. On these subscales, total scores range from 0 to 100, with higher scores indicating better functioning. Three coping styles with acceptable internal reliability (helplessness/ hopelessness, anxious preoccupation, and cognitive avoidance) were assessed using the Mini-Mental Adjustment to Cancer scale.[18] Scores on this scale range from 4 to 16 for cognitive avoidance and from 8 to 32 for helplessness/hopelessness and anxious pre-occupation, with higher scores indicating more maladaptive coping.

Follow-up: Treatment fidelity for both groups was assessed at 3-month and 6-month follow-up using a self-help compliance measure.[19] Three items assessed (i) how much of the workbook or information booklet they had read, (ii) the average amount of time spent per week using the workbook or information booklet, and, for workbook participants, (iii) how many suggestions and exercises were completed. Scores were dichotomised into high versus low levels for analyses. Workbook participants completed a short structured telephone interview 1 and 2 months after receiving the workbook, to provide evaluative feedback on how helpful the workbook components were.

tion or control group and informed of their treatment status on receiving the workbook (treatment intervention) or an information booklet (control condition). Follow-up questionnaires were completed 3 and 6 months later. Non-respondents numbered four at 3 months follow-up and zero at 6 months follow-up.

Interventions

Treatment participants received a self-help workbook entitled "Finding your way: a workbook to help you cope with your breast cancer diagnosis and treatment". Informational content was derived in consultation with consumers, cancer volunteers, and health professionals during a series of focus groups.[5] Each chapter contained educational information on common medical and psychosocial issues; suggestions and worksheets to address the issues; and survivors' quotes. Chapters dealt with: (i) relaxation and meditation, which included six progressive muscle relaxation and four mindful meditation tracks on compact disc; (ii) coping with side effects, including worksheets on insomnia management, and activity pacing for fatigue and pain; (iii) emotional adjustment, including cognitive restructuring for self-blame, stress management activities, goal setting, identifying values, and

future-oriented therapeutic writing; (iv) body image and identity, including mirror-desensitisation and exposure, developing positive body statements, body-oriented therapeutic writing, and values-based writing exercises; (v) social support, including a support network quiz, assertive communication training, and needs-clarification exercises; and (vi) survivorship, including cognitive restructuring for fear of recurrence, goal setting, and benefit-finding worksheets. The introduction recommended gradually reading chapters over a 3-month period to reduce participant burden, and to select sections of higher relevance rather than reading sequentially.

Control participants received a booklet that contained identical information to that in the workbook, but were provided with no suggestions, worksheets or compact disc with relaxation and meditation tracks.

Measures

All assessments were self-administered via a battery of questionnaires which sought the information described below.

Demographic characteristics: Age, marital status, education, employment, family history of breast cancer, stage of disease, surgery, chemotherapy, radiation, and hormonal therapy.

Statistical analysis

A priori sample size calculations were conducted, using a repeated measures Cohen's f^2 power analysis. A moderate effect size coefficient of 0.15 was selected, alpha set at 0.05 and desired power set at 0.80, resulting in a required sample of 65 participants (33 per condition). Due to the constraints of completing the trial within a PhD candidature, recruitment ceased after 12 months, resulting in a final sample of 49 women. The study was therefore underpowered to detect

2 Baseline demographic and illness variables for women in the intervention (workbook) and control groups

Variable	Intervention group (n = 25)	Control group (n = 24)	t or χ^2 value	P
Mean age (SD)	56.0 (12.9)	54.5 (12.7)	t(49), −0.40	0.69
Married/partnered	13	19	χ^2(1,49), 2.88	0.09
Employed	10	11	χ^2(1,49), 0.02	0.90
Education			χ^2(2,48), 4.06	0.13
Primary	8	2		
Secondary	4	4		
Tertiary	13	17		
English speaking	23	22	χ^2(1,49), 0.01	>0.99
Family history	7	13	χ^2(1,49), 2.47	0.12
Stage			χ^2(2,48), 1.83	0.4
0	2	2		
I	4	8		
II	18	14		
Mastectomy type			χ^2(2,48), 0.96	0.62
Partial	13	13		
Total	11	10		
Bilateral	1	0		
Oestrogen-receptor positive	14	18	χ^2(2,47), 4.05	0.13
Node positive	8	11	χ^2(2,48), 3.40	0.18
Chemotherapy	16	15	χ^2(1,49), 0.01	>0.99
Radiotherapy	16	17	χ^2(1,49), 0.04	0.84
Hormonal treatment	13	15	χ^2(1,47), 0.23	0.64

moderate effect sizes; however, it was sufficiently powered to detect large effect sizes (f^2, 0.35).

Group differences at baseline were investigated using t tests for continuous variables or χ^2 tests of independence for categorical variables. Differences between groups from baseline to 3 and 6 months were assessed separately using linear mixed model analyses.[20] The model includes participants with missing data by calculating a regression line for each individual while controlling for independent variables (fixed main effects). This approach allows for direct comparisons between the groups at the 3-month follow-up and at the 6-month follow-up, by making the groups identical at baseline. The fixed main effects were treatment condition (workbook, control), time (3-month, 6-month), with the baseline measure entered as a covariate. Within-group effect sizes were calculated, obtaining Cohen's d where 0.20 is considered small, 0.50 moderate, and 0.80 large. Reliable change indices (RCIs) were calculated as an indicator of clinical significance,[21] 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).

Post-hoc models were then run to determine whether baseline distress moderated significant outcomes. Baseline distress was dichotomised using median splits as high or low for each measure. Qualitative feedback data was analysed thematically.

RESULTS

Of the 80 women who met inclusion criteria, 49 (61%) consented to participate (25 in the intervention group, 24 in the control group). The overall mean age was 55.2 years (SD, 12.7; range, 32–86). There were no differences between groups at baseline (Box 2). The median amount of information read by women in the workbook group was 100%, compared with 75% for those in the control group. Women in both groups used their intervention for up to 15 minutes each week. Participants in the workbook group completed a median of 25% of worksheets.

Baseline to 3 months

Primary outcome (distress): One significant interaction was obtained (Box 3). Women experienced a significantly greater decrease in posttraumatic stress if they received the workbook compared with the information booklet ($F[1,89] = 7.01$; $P = 0.01$), with effect sizes of $d = -0.59$ and $d = -0.16$, respectively.

Secondary outcomes (quality of life and coping): Three significant interactions were obtained. First, participants in the workbook group experienced significant deteriorations in body image ($F[1,89] = 6.43$; $P = 0.01$), with a moderate effect size of $d = -0.54$, while participants in the control group experienced stable levels of this variable ($d = 0.13$). Second, participants in the workbook group experienced significantly reduced helplessness/hopelessness ($F[1,89] = 4.75$; $P = 0.03$), with a small effect size of $d = -0.24$, while those in the control group reported significant increases, with an effect size of $d = 0.32$. Third, participants in the workbook group experienced significantly reduced cognitive avoidance ($F[1,89] = 4.95$; $P = 0.03$), with an effect size of $d = -0.39$, while those in the control group experienced a small increase in cognitive avoidance, with an effect size of $d = 0.07$.

Baseline to 6 months

Primary outcome (distress): No significant interactions were found (Box 3).

Secondary outcomes (quality of life and coping): Participants in the workbook group continued to report reduced body image ($F[1,93] = 7.44$; $P = 0.01$), with an effect size of $d = -0.41$, compared with control participants with $d = 0.17$.

Post-hoc analysis

At 3 months, significant three-way interactions (between group, time and baseline distress) were found for posttraumatic stress disorder ($F[4,83] = 7.76$; $P < 0.01$), cognitive avoidance ($F[4,65] = 3.96$; $P < 0.01$), and body image ($F[4,58] = 3.95$; $P < 0.01$). Across all three outcomes, the workbook provided superior benefit for women with high distress at baseline compared with those with low distress and those in the control group. At 6 months, the three-way interactions obtained for posttraumatic stress disorder ($F[4,87] = 3.05$; $P = 0.02$)

3 Means and SEs for all outcome measures at baseline for all participants, and at 3-month and 6-month follow-ups, by intervention (workbook) and control groups

Measure	Baseline* All	3-month follow-up				6-month follow-up			
		Intervention group (n = 25)	d	Control group (n = 24)	d	Intervention group (n = 25)	d	Control group (n = 24)	d
Distress									
Depression	6.49	7.76 (0.83)	0.15	7.03 (0.89)	0.03	8.08 (1.08)	0.20	6.41 (1.11)	−0.06
Anxiety	5.62	7.48 (0.76)	0.19	7.21 (0.81)	0.17	7.97 (0.83)	0.33	7.03 (0.85)	0.18
Posttraumatic stress	10.76	5.43 (0.91)	−0.59	9.46 (0.98)	−0.16[†‡]	6.78 (1.07)	−0.47	8.98 (1.10)	−0.13[‡]
Quality of life									
Global	66.13	66.56 (2.42)	0.10	67.75 (2.58)	0.18	69.02 (2.71)	0.18	72.21 (2.77)	0.37[‡]
Body image	75.27	59.98 (3.07)	−0.54	77.32 (3.28)	0.13[†‡§]	62.87 (3.33)	−0.41	79.65 (3.40)	0.17[†§]
Coping									
Anxious preoccupation	18.44	15.77 (0.65)	−0.44	17.58 (0.70)	−0.18[‡]	16.28 (0.65)	−0.40	16.01 (0.64)	−0.34[‡]
Helplessness/hopelessness	10.70	10.07 (0.50)	−0.24	12.00 (0.54)	0.32[†§]	10.26 (0.45)	−0.15	10.44 (0.46)	−0.09
Cognitive avoidance	9.54	8.38 (0.37)	−0.39	10.04 (0.40)	0.07[†§]	9.79 (0.43)	0.05	10.17 (0.44)	0.17

d = within-group effect size, where the negative and positive values represent the direction of change (a negative value indicates a decreased score from baseline, and a positive value indicates an increased score from baseline); 0.2 = weak effect, 0.5 = moderate effect, and 0.8 = strong effect. * Calculated by the repeated measures linear mixed model analyses (collapsed across intervention groups), and has no standard error. † Significant interaction. ‡ Significant fixed effect for time. § Significant fixed effect for group (all $P < 0.05$). ◆

and body image ($F[4,54] = 2.83$; $P = 0.03$) remained significant. Body image scores were lowest at 3 and 6 months among women in the workbook group who were not distressed at baseline.

Clinical significance

At 3 months, more women in the workbook group experienced clinically significant reductions in posttraumatic stress (7/24 v 2/21), and body image (8/24 v 1/21) compared with those in the control group (Box 4). This pattern continued at 6 months. Across other measures, most participants did not achieve reliable change, and the differences between the numbers of women in the workbook and control groups who experienced improvements or deterioration were too small to draw conclusions.

Workbook engagement

The amount of information read decreased significantly over time ($t[23] = 2.07$; $P = 0.05$). Two engagement variables significantly predicted anxiety at 3 months: (i) those who spent more time using the workbook had significantly lower anxiety than those who spent less time using it ($F[1,42] = 4.39$; $P = 0.04$); however (ii) those who read more of the workbook had higher anxiety than those who read less of the workbook ($F[1,42] = 4.61$; $P = 0.04$).

Qualitatively, three themes arose. First, women stated that the workbook had broad utility, being (i) comprehensive, (ii) reassuring, and (iii) highly relevant. Second, they stated that the workbook had a preparatory function (eg, "it prepares me for what may happen and takes some of the fear away"). Third, the workbook provided a sense of, and strategies to enhance, social support.

DISCUSSION

Current findings indicate that a self-help workbook can be an effective resource for women recently diagnosed with breast cancer, and particularly for those with higher baseline distress, but that modifications need to be made to the body image module. At 3 months, participants in the workbook group had greater reductions in posttraumatic stress, cognitive avoidance, and helplessness/hopelessness compared with those in the control group. While no longer significant at 6 months, the benefits obtained by workbook participants in posttraumatic stress and helplessness/hopelessness were maintained, and the loss of significance was the result of control group participants making later improvements. Workbook group participants returned to baseline levels of cognitive avoidance at 6 months, but did not experience the deterioration reported by control group participants. Thus, it is clear that the workbook was effective in the short term while women actively used it, helping them to decrease distress more quickly. Further support was

obtained from the finding that those with high baseline distress received superior benefit from the workbook compared with those with low distress, consistent with previous group intervention research.[10,22] These favourable results must be balanced against the significantly greater reductions in body image experienced by participants in the workbook group compared with those in the control group at both follow-ups, and the lack of impact that the workbook had on anxiety and depression. The most substantial clinically significant change supported the beneficial impact of the workbook on symptoms of posttraumatic stress and the detrimental impact on body image.

The posttraumatic stress and coping benefits obtained in our study generally support previous research,[17] but two important differences emerged. First, in the previous study, the workbook was not effective in women who had recently been diagnosed, while the present study obtained significant interactions for this population. Second, Angell and colleagues found their workbook prevented the increase in posttraumatic stress symptoms which occurred in control participants,[13] while the workbook in our study actually reduced symptoms.

Our finding of impaired body image in participants in the workbook group was surprising and contrary to our hypothesis. One potential explanation relates to the mirror desensitisation worksheets in the

4 Number of participants who experienced a clinically significant level of change from baseline to the 3-month and 6-month follow-ups based on reliable change indices, for intervention (workbook) and control groups

Outcome	Reliable change index*		3 months				6 months			
			Improvement		Deterioration		Improvement		Deterioration	
	3 months	6 months	Intervention group (n = 24)	Control group (n = 21)	Intervention group (n = 24)	Control group (n = 21)	Intervention group (n = 25)	Control group (n = 24)	Intervention group (n = 25)	Control group (n = 24)
Distress										
Depression	7.77	7.13	1	2	4	2	3	3	4	2
Anxiety	9.72	8.06	1	0	4	1	0	2	4	2
Posttraumatic stress	8.11	7.60	7	2	0	0	7	3	2	1
Quality of life										
Global	16.91	29.30	1	1	3	1	5	3	1	0
Body image	17.59	25.95	1	2	8	1	1	3	6	2
Coping										
Anxious preoccupation	5.17	5.15	4	3	0	1	5	4	2	1
Helplessness/ hopelessness	7.17	5.88	3	1	1	2	3	2	1	0
Cognitive avoidance	5.15	5.47	1	1	1	0	0	1	2	0

* 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. ◆

workbook, which asked women to develop an exposure hierarchy to different body parts and then systematically view these body parts using a mirror until the anxiety response resolved. One recent review of treatments for body image disturbance reported mixed evidence for the utitlity of mirror desensitisation.[23] Numerous sessions are required for benefits to be obtained, and might result in deteriorations in mood and self-esteem in the short term.[23] Thus, these worksheets may have sensitised women to an issue they had been previously unaware of, during a potentially vulnerable time (during chemotherapy). Given that sub-analyses demonstrated that women in the workbook group who were not distressed about body image at baseline experienced deteriorations, self-help may not be an appropriate method for addressing body image. Clearly, information can be provided (as both groups received this), but women who wish to address body image should be referred to alternative resources.

This study had three methodological strengths. First, it adhered rigorously to the 2010 CONSORT statement for the reporting of randomised trials.[14] Second, it included a 6-month follow-up assessment,

to further delineate the impact of the workbook. If only 3-month data had been gathered, the workbook would have appeared more efficacious than it really was. Third, the control group was exposed to information alone, rather than receiving no intervention. Given the evidence that suggests that receiving information alone is not enough to effect change,[12] providing information to the control group is considered a better test of the strength of the intervention condition than just treatment as usual. However, one limitation of our study — small sample size — means that our results must be interpreted cautiously and that further studies are required before firm conclusions can be drawn.

Future research might valuably compare the self-help workbook with existing group interventions to compare benefits and cost-effectiveness. Alternative methods for delivering self-help also warrant exploration, in particular, via the internet, as this has demonstrated efficacy in other populations and further increases accessibility.[24] Overall, our study provided preliminary support that a self-help workbook can beneficially impact on post-traumatic stress, cognitive avoidance and

helplessness/hopelessness in women currently undergoing treatment for breast cancer.

COMPETING INTERESTS

None identified.

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