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# **A Controlled Trial of Cognitive Behavioural Group Therapy for Irish Breast Cancer Patients.**

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# **A Controlled Trial of Cognitive Behavioural Group Therapy for Irish Breast Cancer**

## **Patients**

### **ABSTRACT**

**Objective:** The aim was to evaluate the effectiveness of a manualised six week cognitive behavioural programme for early-stage breast cancer patients.

**Method:** 69 women diagnosed with early-stage breast cancer were recruited not later than one year post completion of radiotherapy at an Irish national specialist oncology hospital and assigned to a six week cognitive behaviour group therapy programme or an educational control group. Patients were assessed before and after treatment, and at six months follow-up.

**Results:** Groups X Time (2 X 3) analyses of variance showed that the Time to Adjust Programme did not lead to significantly greater improvement on standardised measures of coping, quality of life or mood compared with the educational control group. Regression analyses showed that maladaptive coping and psychological distress at baseline were predictive of psychological adjustment at six months follow-up, accounting for between 28-38% of the variance. Psychological distress at baseline was also predictive of quality of life at six months follow-up, accounting for about 12% of the variance. Repeated measures analyses of variance of data from cases in the intervention group across test occasions showed that patients who completed the Time to Adjust Programme showed significant improvement in problem severity, impact of problems, coping ability and goal attainment from pre-treatment to post-treatment, and these gains were maintained at follow-up for problem severity and impact of problems, but not for coping ability or goal attainment. Participation in the Time to Adjust

Programme did not lead to significantly less health service usage during the period from baseline to six months follow-up, compared with the educational control group

**Conclusion.** A controlled evaluation of the Time to Adjust Programme provided no evidence for the effectiveness of brief cognitive behaviour intervention in enhancing psychological adjustment of early-stage breast cancer patients with normal levels of psychological distress. Future research should evaluate the effectiveness of the programme for patients with clinically significant levels of psychological distress and limited coping resources.

## INTRODUCTION

In common with other cancer patients, breast cancer patients are vulnerable to psychological distress at the diagnostic and treatment phase; post-treatment, when treatment has ended and the support received within the clinical setting has been removed; and fear of recurrence and the prospect of a secondary diagnosis and additional treatments represent additional sources of distress. Zabora and colleagues reported clinically significant psychological distress in 32.8% of breast cancer patients (Zabora et al., 2001). Breast cancer patients report concerns relating to overall health, cancer recurrence or metastases, body image, sexual concerns, and psychosocial concerns related to worry about children and burdening the family (Ashing-Giwa et al, 2004).

In a meta-analysis of 45 randomised controlled trials (14 in breast cancer) of psychological treatments for cancer patients, Meyers and Mark (1995) found an effect size of .24 and concluded that psychological intervention can moderate patients' functional and emotional adjustment to their disease and its treatment. Sheard & Maguire (1999) conducted two separate meta-analyses of trials with anxiety or depression as the main outcome variables. For anxiety, their meta-analysis of 19 trials of varying methodological quality yielded an effect size of 0.42. The authors reported a more robust effect size of 0.36, based on a subset of trials that were randomized, scored well on a rating of study quality, had a sample size > 40 and in which trials with very large effects were omitted. Their meta-analysis of 20 trials in which depression was the main outcome variable, yielded an effect size of 0.36. The authors calculated a more robust but clinically weak effect size of 0.19, after controlling for study quality and the very large effects of three trials, factors which may have inflated their initial estimate. When the authors considered the four studies that had recruited patients on

the basis of their experiencing or being at risk of psychological distress, the effect sizes were more powerful compared with preventative trials. The effect sizes for anxiety and depression were 0.94 and 0.85 respectively. The analyses also revealed that group therapy, particularly psychoeducational intervention, is at least as effective as individual treatment, and that short, intensive courses by highly trained therapists were more effective than protracted interventions conducted by staff with less psychological training (Sheard & Maguire, 1999).

Newell et al. (2002) conducted a systematic review of 627 papers reporting on 329 interventions. Of these, 129 studies pertained to psychosocial intervention targeting distress. Using the Cochrane Collaboration guidelines the trials were assessed for study quality (Murrow & Oxman, 1998). All but 34 trials were subsequently excluded from the analysis. Multiple tests were conducted across outcomes for these trials. Statistically significant outcomes were observed in 45/175 (26%) for anxiety, 26/120 (22%) for depression, 43/154 (28%) for general affect, and 19/74 (26%) for global distress. Studies of group interventions evidenced significant effects in 1/4 (25%) for anxiety, 2/6 (33%) for depression, 1/4 (25%) for global stress/distress, and 3/6 (50%) for general affect..

More recently increasingly conservative conclusions have been drawn about the effectiveness of psychological intervention for people with cancer (Lepore & Coyne, 2006; Coyne, Lepore & Palmer, 2006; Coyne & Lepore, 2006). Lepore & Coyne (2006) offer an explanation for discrepancies in findings across successive reviews. Specifically, the authors refer to a preponderance of narrative reviews over systematic reviews. Narrative reviews are subject to systematic, random, and inferential error. In contrast, a reduction in bias is achieved by conducting systematic reviews. In such reviews criterion-based inclusion criteria provide for assessment and controlling of study quality. The authors add that the quality and comprehensiveness of the search further affects the extent to which findings may be biased.

Of note, the only review to merit a high quality rating according to Lepore and Coyne was that conducted by Newell et al. (2002), described above.

Results of systematic reviews and meta analyses show that educational interventions were most effective at improving medical knowledge and compliance, specific symptoms were best managed by cognitive and behavioural approaches, and supportive counselling was found to be most effective in assisting emotional adjustment (Lepore & Coyne, 2006).

A common process in group-based psychological interventions is decreasing patients' feelings of alienation through interacting with others in similar circumstances. In addition to a normalising effect psycho-educational and cognitive behavioural group-based programmes may reduce anxiety and depression, correct misperceptions and misinformation, lessen feelings of isolation, helplessness and the impression that the patient is being neglected. Addressing feelings of helplessness and hopelessness may encourage patients to take more a more active role in their biomedical treatment process.

From this review it is clear that a range of psychological interventions can reduce distress and improve the functioning for a proportion of oncology patients, including patients with early stage breast cancer. Brief, group-based, psycho-educational cognitive –behavioural programmes show particular promise. Previous trials of such interventions have had methodological shortcomings. These include use of heterogeneous samples, lack of randomisation, poorly defined intervention programmes, treatments that have not been specifically tailored to the unique needs of specific oncology patients, small sample sizes and inadequate follow-up periods. The aim of the present study was to evaluate the impact of a group-based psychoeducational cognitive behavioural programme for breast cancer patients within an Irish context in a methodologically rigorous way. The study focused specifically on early-stage breast cancer patients. The programme, which is described below, was called the



Time to Adjust Programme. The study was the first of its kind to be carried out with people experiencing cancer in Ireland and was designed to overcome some of the methodological shortcomings that have characterised past research in the area

In evaluating the Time to Adjust Programme it was hypothesised that the treatment group would show greater improvement than controls on standardised measures of coping, quality of life and mood, and that improvements would be maintained at six months follow-up. Additionally, we hypothesised that participants who used more adaptive and fewer maladaptive coping strategies and those with lower levels of psychological distress at baseline would show greater improvements on standardised measures of mood and quality of life at six months follow-up. It was also hypothesised that participants would show a significant reduction in problem severity and impact, an increase in coping ability and goal attainment from pre-treatment, through post-treatment to follow-up. Finally, we conjectured that programme participants would make less use of other health services during the follow-up period than those in the control group.

## **METHOD**

### **Setting and Procedure**

Patients were recruited from Saint Luke's Hospital, Dublin, Ireland which is a national specialist oncology centre. This 179 bed hospital provides a full range of specialist oncology assessment and treatment services, as well a psycho-oncology service with two staff.

Potential participants were initially notified of the study by post. This was followed by a telephone-screening interview for interested patients in order to confirm eligibility. Written informed consent was received from all participants and the study protocol was reviewed and approved by the hospital's ethical review board. Patient recruitment was conducted during the

period beginning March 2005 and ending September 2007. Data were first collected from a series of 36 patients recruited and assigned to the treatment group over an 18-month period. An additional 33 patients were recruited in the subsequent 12-month period and assigned to the control group. The numbers of patients that entered the study, refused entry, and dropped out are given in Figure 1. The overall acceptance rate was 48%, and the overall dropout rate at six months follow-up was 61%. Participants were assessed before and after treatment and at 6 months follow-up. Details of the sample, and the assessment and treatment protocols are given below.

## **Sample**

To determine an appropriate sample size, a power analysis was conducted. It was concluded that in order for statistical tests with  $p$  values of .05 and power values of .80 to detect moderate differences ( $d = .75$ ) between two groups, a sample size of 60 (30 cases per cell) was required for this study (Hinkle, Wiersma, & Jurs, 2003).

Sixty nine adult females who met the following inclusion criteria participated in the study: (1) diagnosis of primary breast cancer, stages I through IIIA; (2) completed radiotherapy no more than 12 months prior to recruitment; (3) no detectable disease present; and (4) geographically available to participate. Exclusion criteria included: (1) evidence of metastases beyond adjacent lymph nodes; (2) recurrence of cancer prior to group assignment; (3) presence of any other major medical problems likely to limit life expectancy to less than 10 years; (4) a history of major psychiatric illness for which the patient was hospitalised or medicated, with the exception of anxiety or depression treated for a period of less than one year; and (5) substance abuse (i.e. substance abuse or dependence followed by abstinence for less than two years). Demographic characteristics of treatment and control groups are

given in Table 1. The groups did not differ significantly on age, marital status, socio-economic status or number of children.

## **Treatment Protocol**

**Time to Adjust Programme.** Patients assigned to the treatment group participated in the Time to Adjust Programme (McKiernan, 2005) which is a group-based manualised cognitive behavioural treatment. For this programme, groups comprising between four and seven women attended six consecutive weekly sessions of 90 minutes in duration. The programme was described in therapist and participant versions of a treatment manual. Both versions of the manual covered the same material, but the therapist version included directions for facilitating the programme. The programme followed a structured closed group approach, and incorporated stress management and coping skills training. The aim of the programme was to help participants to take a more active role in their recovery, to reduce tension and facilitate adjustment. Facilitators and group members discussed strategies for coping with cancer; considered the interrelationships between feelings, thoughts and behaviours associated with the experience of cancer; and practiced relaxation exercises. The programme also covered the nature of effective communication, the impact of negative automatic thinking, the role of assumptions and core beliefs in informing perception of cancer, approaches to problem solving, and patients' values and goals for the future.

**Group therapists and programme integrity.** Four of the five groups were led by a Clinical Psychologist. The remaining group was facilitated by a Counselling Psychologist. Both psychologists had specialist skills and experience on psycho-oncology. All groups were co-

facilitated by the Principal Investigator (AMK), a PhD student. Programme integrity was maintained through adherence to the programme manual.

**Educational programme.** Educational materials were offered to participants in both control and treatment groups and comprised pamphlets and booklets published by the Irish Cancer Society. The materials covered such topics as the emotional effects of cancer, hormonal treatment, and communicating with someone who has cancer.

### **Assessment protocol**

Before and after the six week treatment programme and at six months follow-up patients in treatment and control groups completed the following primary outcome measures all of which have been shown to have adequate psychometric properties: the brief COPE scale (Carver, 1997), the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30 version 3.0 (QLQ; Aaronson, et al., 1993) and the Profile of Mood States – Brief Form (POMS; McNair, Lorr & Droppleman, 1992). Before treatment all participants also completed the Brief Symptom Inventory (BSI ; Derogatis, 2001) which served as a baseline measure of psychological distress. Brief descriptions of these standardized instruments are given below. Patients the treatment group completed the Participants Problem and Goals Questionnaire (PPGQ) and a Services Use Questionnaire (SUQ). On the PPGQ participants rated problem severity, problem impact, coping ability and goal attainment on visual analogue scales. On the SUQ participants indicated the number of visits they had made to their GP, whether they had used other services and whether they had attended all follow-up oncology appointment.

The BSI (Derogatis, 2001) is an 18-item instrument which yields a total score and scores on depression, anxiety, and somatisation subscales. Five-point response formats are used for all items. Norms are available for adult community and oncology populations. The scales and subscales all have acceptable levels of reliability ( $\alpha >.7$ ). The BSI has good validity and correlates highly ( $r >.9$ ) with the longer 90 item Symptom Checklist 90 parent instrument from which it is derived.

The brief COPE (Carver, 1997) is a 28 item coping inventory which yields factor scores for adaptive and maladaptive Coping (Meyer, 2001). Examples of adaptive strategies include active coping, use of emotional support, use of instrumental support, positive reframing, planning, humour, acceptance and religion. Denial, substance use, and self-blame are examples of maladaptive strategies. Four point response formats are used for all items, ranging from 1 = not at all, to 4 = a lot. The brief COPE, like the longer parent inventory from which it is derived, has been used in studies of breast cancer patients. Meyer (2001) reported internal consistency coefficients of .81 and .57 for Adaptive Coping and Maladaptive Coping respectively.

The QLQ (Aaronson et al., 1993) is a 30-item measure used to assess health-related quality of life which yields a total quality of life score and scores on five sub scales (physical, emotional, role, cognitive and social functioning). It has been validated and cross-culturally tested in cancer patients.

The brief POMS (McNair, Lorr & Droppleman, 1992) is a 30-item scale that yields a total mood disturbance score and scores for the following six dimensions: tension-anxiety, depression-dejection, anger-hostility, vigour-activity, fatigue-inertia, and confusion-bewilderment. Five point response formats are used for all item from 0 = not at all to 4 = extremely. The six scales have acceptable internal consistency reliability ( $\alpha >.8$ ). The scale

has good factorial and criterion validity and correlates highly ( $r > .9$ ) with the 65-item POMS longer version of the scale from which it is derived.

## RESULTS

### Comparison of treatment and control group

Before comparing change in treatment and control groups from pre-treatment, through post-treatment to follow-up, preliminary analyses were conducted to determine if there were significant differences between trial completers and dropouts on demographic variables (age, SES, marital status, number of children) and clinical variables (COPE adaptive and maladaptive scales, and total scores on the QLQ, POMS and TSI). Trial completers and dropouts did not differ significantly on any variable except the COPE maladaptive scale. The mean for trial completers ( $M = 20.08$ ,  $SD = 5.33$ ) was greater than that of dropouts  $M = 17.30$ ,  $SD = 5.70$ ;  $F = 4.65$ ,  $df = 1, 53$ ,  $p < 0.05$ ). Given that completers and dropouts were similar on four demographic variables and four out of five clinical variables, we concluded that trial completers were representative of cases who entered the trial.

To test the first hypothesis that participants in the Time to Adjust programme would show greater improvement than controls in coping, quality of life and mood, a series of 2 X 3, Groups X Time, mixed-model ANOVAs were conducted on primary outcome measures (COPE, QLQ and POMS). To reduce the risk of Type 1 error, the analysis strategy was to first conduct ANOVAs on instrument total or summary scores, and if these yielded significant Groups X Time interactions, then to proceed to further analyses of subscale scores.

Means, standard deviations and results of 2 x 3, Groups x Time ANOVAs for summary scores from the B-COPE, QLQ-C30 and POMS-B are given in Table 2. From the table it may be seen that no significant Groups x Time effects occurred. Thus the results of this main analysis did not support the hypothesis that the treatment group would show significantly greater improvements in summary indices of coping, quality of life and mood compared with the control group from pre- through post-treatment to follow-up.

From Table 2 it may be seen that there were significant Groups effects for the COPE adaptive coping scale and the POMS. In both instances, treatment group means at the start of the trial were significantly higher than those of the control group. In view of this, a series of ANCOVAs were conducted in which pre-treatment scores on dependent variables were used as covariates. These ANCOVAs yielded similar results to the ANOVAs presented in Table 2. Thus, pre-treatment differences on dependent variables did not account for the similarity in outcomes for the treatment and control groups. The results of this ancillary analysis did not support the main hypothesis.

### **Factors predictive of outcome**

Regression analyses (preceded by correlational analyses) with pre-treatment age, BSI and COPE variables as predictors and POMS total mood disturbance and QLQ total quality of life at six months follow-up as the dependent variables were conducted to test the second hypothesis that less distressed patients with more adaptive and fewer maladaptive coping strategies would show greater improvement.

For trial completers, Pearson correlations were computed between pre-treatment COPE adaptive and maladaptive coping scales, the pretreatment BSI total, the follow-up POMS total and the follow-up QLQ total. There were significant correlations between the

COPE maladaptive coping scale ( $r = .55, p < .01$ ) and the BSI total ( $r = .63, p < .01$ ) before treatment on the one hand, and the POMS total mood disturbance at six months follow-up on the other. Linear regression analyses showed that the pre-treatment COPE maladaptive coping scale accounted for 28.2% of the variance in POMS total mood disturbance at six months follow-up (Adjusted  $R^2 = 0.28$ ;  $F = 14.35, df = 1,34; p < .05$ ). Pre-treatment BSI total scores accounted for 38.2% of the variance in POMS total mood disturbance at six months follow-up (Adjusted  $R^2 = 0.38$ ;  $F = 25.08, df = 1,39; p < .05$ ).

There was a significant correlation between pre-treatment BSI total scores and QLQ total quality of life at six months follow-up ( $r = .36, p < .01$ ). A linear regression analysis showed that pre-treatment BSI total scores accounted for 11.5% of the variance in QLQ total quality of life at six months follow-up (Adjusted  $R^2 = 0.12$ ;  $F = 6.31, df = 1,41; p < .05$ ). The second hypothesis was partially supported.

### **Changes in problem severity, coping and goal attainment in the Time to Adjust group**

Repeated measures ANOVAs were conducted on PPGQ treatment group data to test the third hypothesis that participants in the Time to Adjust Programme would show a significant reduction in problem severity and impact, and an increase in coping ability and goal attainment from pre-treatment, through post-treatment, to follow-up. Means and standard deviations for the treatment group on each subscale of the PPGQ are given in Table 3. Patients showed significant improvement in problem severity, impact of problems, coping ability and goal attainment from pre-treatment to post-treatment. These gains were maintained at follow-up for problem severity and impact of problems, but not for coping ability or goal attainment. The third hypothesis was partially supported.



## **Service use**

T-tests and chi-square tests were conducted on SUQ data for treatment and control groups to test the fourth hypothesis that Time to Adjust programme participants would make less use of other health services during the follow-up period than those in the control group. Treatment and control groups reported similar number of visits to their GPs (Treatment group mean = 1.57, SD = 2.14; Control group mean = 2.14, SD = 1.80,  $t = 0.85$ ;  $df = 33$ ;  $p > .05$ ). Similar numbers of participants availed of other services during the 6 month follow up period (Treatment group = 7.10%, Control group = 19.0%,  $\chi^2 = 5.43$ ;  $df = 2$ ;  $p > .05$ ). Similar numbers of participants reported attending all specialist oncology appointments during the 6 month follow up period (Treatment group = 78.6%, Control group = 100%,  $\chi^2 = 4.92$ ;  $df = 2$ ;  $p > .05$ ). The fourth hypothesis was not supported.

## **DISCUSSION**

The first hypothesis that the treatment group would show greater improvement than the control group on standardised measures of coping, quality of life and mood, and that improvements would be maintained at six months follow-up was not supported. The second hypothesis that participants who used more adaptive and fewer maladaptive coping strategies and those with lower levels of psychological distress at baseline would show greater improvements on standardised measures of mood and quality of life at six months follow-up was supported. The hypothesis that participants would show a significant reduction in problem severity and impact, and an increase in coping ability and goal attainment from pre-treatment, through post-treatment, to follow-up was partially supported. Improvements in all four areas occurred over the course of treatment but those in coping ability and goal attainment were not sustained at follow-up. The final hypothesis that Time to Adjust programme

participants would make less use of other health services during the follow-up period than those in the control group was not supported.

### **Limitations and strengths**

Our intention was to conduct a study which overcame methodological shortcomings that have characterised much past research in the area such as use of heterogeneous samples, lack of randomisation, the use of poorly defined intervention programmes, the use of treatments that have not been specifically tailored to the unique needs of specific oncology patients, small sample sizes and inadequate follow-up periods. We achieved this aim with two exceptions. First, practical constraints made random assignment of cases to groups non-viable, and this is the principal limitation of the study. Consecutive cases were allocated by block assignment first to the treatment group, and then to the control group. However, it is noteworthy that groups were matched for demographic variables and for psychological distress as assessed by the BSI. Second, there was considerable attrition, with only 20/36 treatment cases and 22/33 control cases completing the trial, which limited the statistical power of the trial.

The study had a number of strengths. We recruited a homogeneous group of patients. The programme we evaluated incorporated cognitive behavioural interventions that had been shown in previous studies to be particularly effective, and it was tailored to the unique needs of breast cancer patients. The programme was manualized and programme integrity was maintained over the course of the study through adherence to the treatment manual. Therapy groups were led by qualified psychologists with specialist psycho-oncology skills, and co-facilitated by the programme evaluator who ensured that session agendas adhered to the treatment manual thus minimising the potential for a therapist effect. The control group received 'treatment as usual' which involved the receipt of educational materials, and these were also made available to the treatment group. Cases were assessed with a

psychometrically robust assessment protocol before and after treatment and at six months follow-up. Attrition analysis showed that trial completers were representative of cases who entered the trial so there was a minimal risk of attritional bias.

### **Consistency with results of previous studies**

Results of the primary analysis of standardised outcomes of coping, psychological adjustment and quality of life were inconsistent with findings from several evaluation studies (e.g. Simpson et al., 2001; Edelman and Kidman, 1999; Fukui et al., 2000). The failure to detect statistically significant treatment effects was, however, in keeping with findings from a series of recent reviews (Lepore & Coyne, 2006; Coyne, Lepore & Palmer, 2006; Coyne & Lepore, 2006). In contrast to the contentions of oft-cited meta-analyses (e.g. Sheard and Maguire, 1999; Meyer and Mark, 1995), recent reviews have argued that close examination of the empirical evidence suggests that the 'average' cancer patient does not stand to benefit significantly from psychological intervention and that most patients adjust well, irrespective of intervention.

Results from the examination of the the mediatory role of coping in psychological adjustment were consistent with findings from international studies in which coping as been shown to predict psychological adjustment (e.g. Hack & Degner, 2004; Schnoll et al., 1998).

Our finding that that the use of GP or other support services was unaffected by participation psychological treatment is inconsistent with the results of Simpson et al. (2001) who found that the provision of psychological intervention is associated with health care cost savings.

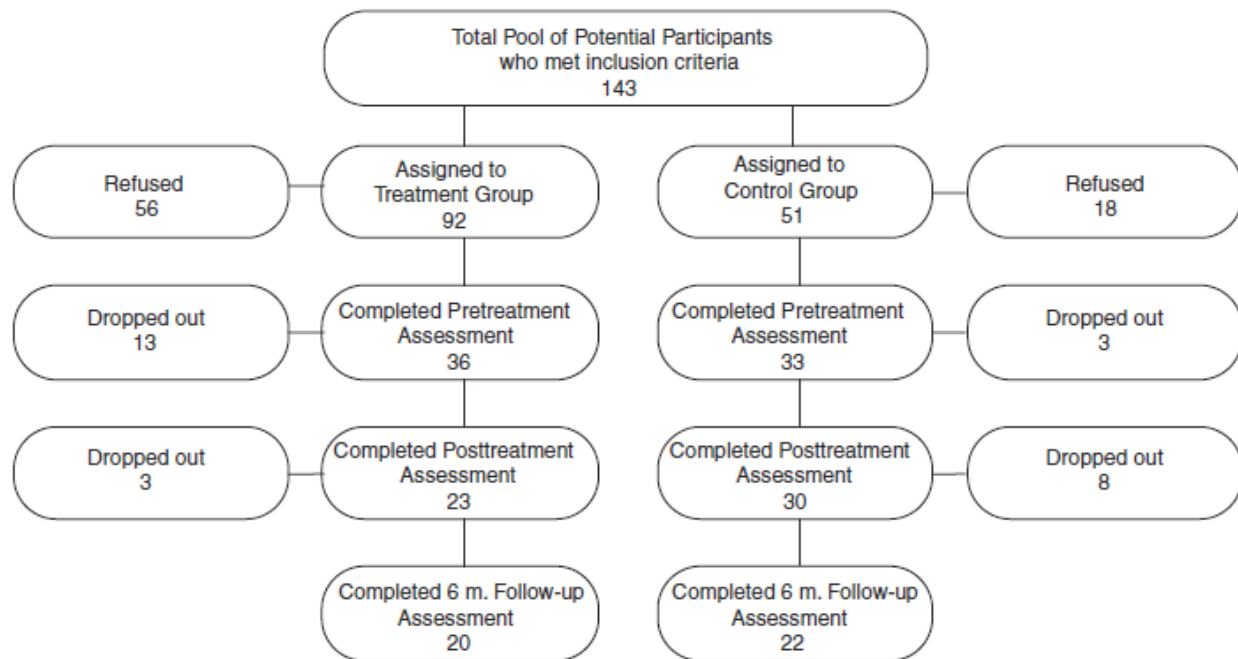
## Implications

The current study provided no evidence to justify referring all early-stage breast cancer patients to the Time to Adjust Programme, because the outcome was not better than routine care. However, it may be that for a subgroup of patients with limited coping resources and high levels of psychological distress, referral is appropriate. This hypothesis deserves evaluation in further research. The study requires replication with larger samples across multiple sites, but with patients who show considerable deficits in coping resources and significant levels of sustained psychological distress. Precedence should be given to randomised controlled designs. In light of evidence indicating that the support of partners in committed relationships has a significant impact on patients' psychological adjustment to cancer (e.g. Halford, Scott, & Smythe, 2002), it would be useful to evaluate an adapted version of the Time to Adjust Programme for patients and their partners in an Irish context.

## REFERENCES

- Aaronson, N. K., Ahmedzai, S., Bergman, B., Bullinger, M., Cull, A., Duez, N. J., et al. (1993). The European Organization for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. *Journal of the National Cancer Institute*, *85*(5), 365–376.
- Ashing-Giwa, K. T., Padilla, G., Tejero, J., Kramer, J., Wright, K., Coscarelli, A., et al. (2004). Understanding the breast cancer experience of women: A qualitative study of African American, Asian American, Latina and Caucasian cancer survivors. *Psycho-Oncology*, *13*(6), 408–428.
- Carver, C. S. (1997). You want to measure coping but your protocol's too long: Consider the Brief COPE. *International Journal of Behavioral Medicine*, *4*, 92–100.
- Coyne, J. C., & Lepore, S. J. (2006). Rebuttal: The black swan fallacy in evaluating psychological interventions for distress in cancer patients. *Annals of Behavioral Medicine*, *32*(2), 115–118.
- Coyne, J. C., Lepore, S. J., & Palmer, S. C. (2006). Efficacy of psychosocial interventions in cancer care: The evidence is weaker than it first looks. *Annals of Behavioral Medicine*, *32*, 104–110.
- Derogatis, L. R. (2001). *Brief Symptom Inventory 18 (BSI-18) manual*. Minnetonka, MN: NCS Assessments.

- Edelman, S., Lemon, J., Bell, D. R., & Kidman, A. D. (1999). A group cognitive behavior therapy program with metastatic breast cancer patients. *Psycho-Oncology*, *8*, 295–305.
- Fukui, S., Kugaya, A., Okamura, H., Kamiya, M., Koike, M., Nakanishi, T., et al. (2000). A psychosocial group intervention for Japanese women with primary breast carcinoma. *Cancer*, *89*, 1026–1036.
- Hack, T. F., & Degner, L. F. (2004). Coping responses following breast cancer diagnosis predict psychological adjustment three years later. *Psycho-Oncology*, *13*, 235–247.
- Hinkle, D., Wiersma, W., & Jurs, S. (2003). *Applied statistics for the behavioral sciences* (5th ed.). Boston: Houghton Mifflin.
- Lepore, S. J., & Coyne, J. C. (2006). Psychological interventions for distress in cancer patients: A review of reviews. *Annals of Behavioral Medicine*, *32*(2), 85–92.
- McKiernan, A., Steggles, S., & Carr, A. (2005). *Time to Adjust Programme: Treatment manual* (Unpublished manuscript). University College Dublin, Dublin, Ireland.
- McNair, D. M., Lorr, M., & Droppleman, L. F. (1992). *Edits manual for the Profile of Mood States*. San Diego, CA: Educational and Industrial Testing Service.
- Meyer, B. (2001). Coping with severe mental illness: Relations of the Brief COPE with symptoms, functioning, and well-being. *Journal of Psychological and Behavioral Assessment*, *23*(4), 265–277.
- Meyer, M., & Mark, M. (1995). Effects of psychosocial interventions with adult cancer patients: A meta-analysis of randomized experiments. *Health Psychology*, *14*(2), 102–108.
- Murlow, C. D., & Oxman, A. D. (Eds.). (1998). *Cochrane collaboration handbook* (Cochrane Review on CD-ROM). Oxford, UK: Cochrane Library.
- Newell, S. A., Sanson-Fisher, R. W., & Savolainen, N. J. (2002). Systematic review of psychological therapies for cancer patients: Overview and recommendations for future research. *Journal of the National Cancer Institute*, *94*, 558–584.
- Schnoll, R. A., Harlow, L. L., Stolbach, L. L., & Brandt, U. (1998). A structural model of the relationships among stage of disease, age, coping, and psychological adjustment in women with breast cancer. *Psycho-Oncology*, *7*, 69–77.
- Sheard, T., & Maguire, P. (1999). The effect of psychological interventions on anxiety and depression in cancer patients: the results of two meta-analyses. *British Journal of Cancer*, *80*(11), 1770–1780.
- Simpson, J. S., Carlson, L. E., & Trew, M. E. (2001). Effect of group therapy for breast cancer on healthcare utilization. *Cancer Practice*, *9*(1), 19–26.
- Zabora, J., BrintzenhofeSzoc, K., Jacobsen, P., Curbow, B., Piantodosi, S., Hooker, C., et al. (2001). A new psychosocial screening instrument for use with cancer patients. *Psychosomatics*, *42*, 241–246.



**FIGURE 1** Numbers of patients assigned to treatment and control groups, refusers and dropouts.

Session 1: Coping	Identifying strategies for coping with the experience of cancer.
Session 2: Relaxation	Introduction to the cognitive behavioral theory model: practicing relaxation and activity scheduling.
Session 3: Communication	Understanding the value of effective communication with health care professionals, friends and family.
Session 4: Thought monitoring	Recognizing cognitive distortions and monitoring negative automatic thoughts.
Session 5: Assumptions & beliefs	Examining the influence of assumptions and core beliefs in adjusting to the cancer experience.
Session 6: Problem solving & goal setting	A systematic approach to problem solving: defining values and goals.

**FIGURE 2** Breakdown of session agendas of the Time to Adjust Programme.

**TABLE 1** Demographic Characteristics

Variable	Variable	Treatment Group ( <i>n</i> = 36)	Control Group ( <i>n</i> = 33)	Total ( <i>N</i> = 69)
Age (in years)	<i>M</i>	52.50	48.79	50.72
	<i>SD</i>	11.39	12.4	11.94
	Range	37–73	29–73	29–73
Relationship status	Single:	7 (19.4%)	3 (9.1%)	10 (14.5%)
	Married:	23 (63.9%)	23 (69.7%)	46 (66.7%)
	Other:	5 (13.9%)	(21.2%)	12 (17.4%)
	Unknown:	1 (2.8%)	—	1 (1.4%)
Socioeconomic status	Higher professional	6 (16.7%)	6 (18.2%)	12 (17.4%)
	Lower professional	12 (33.3%)	5 (15.2%)	17 (24.6%)
	Other nonmanual	1 (2.8%)	1 (3.0%)	2 (2.9%)
	Skilled manual	3 (8.3%)	7 (21.2%)	10 (14.5%)
	Semiskilled manual	1 (2.8%)	2 (6.1%)	3 (4.3%)
	Unskilled manual	—	3 (9.1%)	3 (4.3%)
	Unknown	13 (36.1%)	9 (27.3%)	13 (18.8%)
Number of children	<i>M</i>	2.27	2.47	2.37
	<i>SD</i>	1.60	2.05	1.83
	Range	0–7	0–9	0–9



**TABLE 2** Means of Treatment and Control Groups Before and After Treatment and at Six Months Follow-Up, and Results of  $2 \times 3$ , Groups  $\times$  Time ANOVAs for Measures of Coping, Quality of Life, and Mood

	Treatment Group		Control Group			ANOVA <i>F</i> values				
		T1 <i>N</i> = 36	T2 <i>N</i> = 23	T3 <i>N</i> = 20	T1 <i>N</i> = 33	T2 <i>N</i> = 30	T3 <i>N</i> = 22	Group	Time	Group $\times$ Time
Adaptive Coping— COPE	<i>M</i>	41.81	44.00	38.31	38.00	37.83	34.00	2.79	6.14*	0.38
	<i>SD</i>	7.36	7.23	10.98	8.96	11.10	10.75			
Maladaptive Coping— COPE	<i>M</i>	22.22	20.61	20.50	17.78	17.55	15.55	7.83*	3.33*	0.82
	<i>SD</i>	5.65	5.17	6.95	4.15	5.19	3.11			
Quality of Life— QLQ	<i>M</i>	5.20	5.60	5.30	5.55	5.55	5.55	0.66	0.56	0.26
	<i>SD</i>	1.10	0.76	0.86	1.06	1.02	1.48			
Total Mood Disturbance— POMS	<i>M</i>	35.39	27.67	26.33	16.68	19.06	14.16	5.17*	2.56	2.00
	<i>SD</i>	21.02	16.48	23.15	19.71	19.06	18.65			

Note: T1 = pretreatment; T2 = posttreatment, 6 weeks after T1; T3 = 6-month follow-up .

COPE = Brief COPE inventory; QLQ = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire—Core 30 version 3.0; POMS = Short form of the Profile of Mood States.

\* $p < .05$ .

**TABLE 3** Treatment Group Mean PPGQ Scores for Problem Severity, Problem Impact, Coping Ability and Goal Attainment at Pretreatment, Posttreatment and Follow-Up

Scale	Pretreatment	Posttreatment	6 months follow-up	ANOVA F
Problem Severity				
<i>M</i>	6.57	4.38	3.96	8.50*
<i>SD</i>	1.82	2.10	1.78	
Impact of Problems				
<i>M</i>	5.00	3.19	2.63	14.41*
<i>SD</i>	2.47	1.63	1.64	
Coping ability				
<i>M</i>	5.56	7.69	6.31	9.48*
<i>SD</i>	2.16	1.62	2.65	
Goal Attainment				
<i>M</i>	4.41	7.76	6.74	21.94*
<i>SD</i>	2.01	1.69	2.05	

Note:  $N = 16$ . PPGQ = Participants Problem and Goals Questionnaire.

\* $p < .05$ .