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**Title:** Evaluating the efficacy of a self-guided web-based CBT intervention for reducing cancer-distress: A randomised controlled trial.

**Running head**: A self-guided web-based intervention for cancer-distress

**Authors:** Lisa Beatty[1,2], Bogda Koczwara[2] & Tracey Wade[1]

[1]School of Psychology, Flinders University, Adelaide, South Australia, AUSTRALIA

[2]Flinders Centre for Innovation in Cancer, Flinders University, Bedford Park, South Australia, AUSTRALIA

**Corresponding Author**: Dr Lisa Beatty, School of Psychology, Flinders University, GPO Box 2100, Adelaide, SA, 5001. Ph: +61 8 8201 2506; Fax: +61 8 8201 3877; Email: lisa.beatty@flinders.edu.au

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## Abstract

**Purpose**: This study evaluated the efficacy of a self-guided web-based cognitive behaviour therapy (CBT) intervention compared to an attention-control in improving cancer-related distress, health-related quality of life (HRQOL), and maladaptive coping, among people recently diagnosed with cancer.

**Methods**: Sixty individuals with cancer diagnosed in the previous 6 months and receiving treatment with curative intent were randomised to receive either the 6-week intervention '*Cancer Coping Online'* (CCO: n=30) or the 6-week web-based attention-control (n=30). Outcome measures, including cancer distress (the Post-Traumatic Stress Scale–Self-Report), general distress (Depression, Anxiety, Stress Scale), quality of life (EORTC QLQ-C30), and coping (mini-MAC) were administered at baseline, immediately post intervention, and at 3-, and 6-months post intervention.

**Results**: Significant main effects for time were found for Cancer-distress, Global QOL, Physical Function, Role Function, Social Function, and Anxious Preoccupation. Post-hoc between-group comparisons showed *CCO* participants had statistically significantly higher Physical Functioning compared to controls at 3-month follow-up ($d$=-.52, $p$=.02). Furthermore, compared to controls, post-hoc comparisons found moderate between-group effect sizes favouring *CCO* post-intervention for Cancer-distress ($d$=.43) and Anxious Preoccupation ($d$=.38); and at 6-month follow-up for Global QOL ($d$=-.43).

**Conclusions**: These results provide preliminary support for the potential efficacy of a self-guided web-based CBT program in improving aspects of HRQOL, cancer-related distress, and anxious preoccupation after cancer diagnosis. This paper provides justification for, and will help inform the development of, subsequent larger multi-site studies.


**Abstract Word count:** 226

**Keywords:** internet, intervention, self-guided, CBT, distress

## Background

Despite the demonstrable evidence base supporting the use of psychosocial treatments for cancer distress [1,2], many barriers to their success in traditional face-to-face settings exist. These range from geographic barriers, particularly for those living in rural or remote areas [3]; to personal and illness-related barriers, including the ongoing stigma associated with seeking mental-health assistance [4,5]; and service-barriers, with the demand exceeding the current level of funding for psycho-oncologists [4,6]. As a result, researchers have started investigating the internet as a treatment-delivery modality for cancer distress [5,4,7], and there is a growing evidence-base for self-guided web-based interventions for physical health complaints [5,7].

Given that 84% of Australians have access to the internet [8], web-based interventions are a logical format for the wide dissemination of evidence-based psychological treatment for cancer patients. However, the evidence base for self-guided web-based psychological therapy specific to cancer distress is only now emerging, with four pilot / preliminary randomised controlled trials (RCT) [9-12], and one case-series study [13] published to date. All studies investigated curatively treated cancer patients or survivors, including early stage breast cancer [9,11], localised prostate cancer [12], and heterogeneous cancer survivors [10,13]. Of the RCTs, two were pilot studies [10,11] that were limited by small sample sizes (31 and 62 participants, respectively) and were therefore underpowered to detect statistically significant effects; however moderator analyses found significant intervention-effects for those with poor perceived baseline health status [11] or high baseline distress [10].

The other two RCTs were large [12,9], and sufficiently powered to find intervention effects. Carpenter et al. [9] found that although the discussion forum component was not well utilised their program improved self-efficacy for coping with breast cancer, regulating negative mood, and reducing cancer-related post-traumatic symptoms [9]. In contrast, Wootten et al. [14] found their program significantly reduced distress among men with prostate cancer who had access to the program combined with an asynchronous discussion forum, when compared to a forum-only condition (a third program-only condition did not significantly differ from the other two conditions).

In contrast to the above RCTs which contained asynchronous group support as a key feature of their programs, our group tested a purely self-guided web-based intervention (i.e., no forum) for newly diagnosed cancer patients in 2011 [13]. The decision to omit a forum was primarily due to the currently conflicting evidence base for its inclusion in health populations [5]. Our small case-series study of 12 participants found that the intervention reduced distress and maladaptive coping at post-treatment as evidenced by the small-to-moderate effect sizes.

Collectively, these five studies demonstrate the promise of web-based formats for delivering psychosocial programs for cancer; however they all suffer from either being (a) small, underpowered or uncontrolled feasibility studies, and/or (b) not evaluating the longer-term impact of the intervention. Therefore the present study aimed to extend our earlier findings testing the feasibility of the Cancer Coping Online *(CCO)* intervention [13] by conducting an

RCT evaluating the efficacy of *CCO* compared to an attention-control over a 6-month follow-up period.

## Methods

### *Participants*

Participants were cancer patients receiving treatment at a single institution who met the following eligibility criteria: (i) cancer being treated with curative intent; (ii) aged 18+ years; (iii) receiving active treatment or were within 6 months of diagnosis; (iv) spoke sufficient English for informed consent and program use; and (v) had internet access. Participants were recruited between 1st March 2011 and 15th November 2012, with data collection completed 30th June 2013.

### *Procedure*

Procedural elements of this study conformed to the CONSORT statement and checklist [15,16]. Participants were recruited via local media advertisements and referrals from cancer clinicians. Interested patients were contacted by the research team, provided with detailed information about the study, and directed to the website to enrol (comprised of an eligibility screen, information sheet and consent form, and baseline assessment). Informed consent was obtained from all individual participants included in the study. After enrolment, participants were randomised in blocks of 2 to receive either the intervention or the web-based control condition. Randomisation occurred via a computer-generated block random allocation where the sequence was concealed until conditions were assigned. Participants worked through the 6 intervention modules sequentially (new modules were released weekly with an email reminder to use the program). After completing module 6, participants were automatically directed to the post-treatment assessment. Participants who did not immediately complete the post-treatment assessment were sent email reminders 1 and 2 weeks later, with a single telephone reminder used 3 weeks later for non-responders. This same procedure was adopted for the 3-month and 6-month assessments. Figure 1 illustrates the flow of participants through the study. Ethics approval was obtained from the Southern Adelaide Clinical Human Research Ethics Committee, and the study is registered with the Australian New Zealand Clinical Trials Registry (Registration number: ACTRN12613001170718).

### *Intervention Conditions*

*Cancer Coping Online (CCO)* is a 6-module password-protected cognitive behaviour therapy (CBT) program, where each module is comprised of three key elements: (a) psycho-education, (b) CBT-based activities, including worksheets, quizzes, relaxation and meditation exercises, and (c) written survivor testimonials and quotes [13]. Designed for patients currently receiving treatment for curatively-treated cancer, the program was adapted from an evidence-based print-workbook [17]. *CCO* addresses the most commonly reported physical, psychological, and social concerns experienced during treatment, with the 6 modules addressing: (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 audio tracks; (iii) coping with emotional distress – which covers depression, anxiety, anger and stress, and provides cognitive restructuring diaries and mindfulness audio tracks; (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 self-management strategies to facilitate healthy lifestyles. *CCO* also contains an online personal journal / blog, and a resources section with links to reputable cancer-related organisations and other health websites.

*Web-based Control Condition.* An information-only version of *CCO* was developed for this study to provide an appropriate control for demand characteristics and participant expectancies. The control condition contained the same 6 information topics as the intervention but none of the worksheets, activities, relaxation/meditation exercises, or journal. Previous research indicates that an information-only control condition does not significantly reduce distress [17], and having a web-based control is the recommended strategy for testing the efficacy of internet interventions [18].

***Measures***

Participants were emailed links to the online assessments at baseline (pre-treatment), post-treatment (immediately upon completing the program), 3-months post-treatment, and 6-months post-treatment. The battery was comprised of the following measures, which allhave excellent psychometric properties.

*Participant characteristics (baseline only).* Demographic measures included: age, marital status, 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.

*Distress.* Two measures of distress were evaluated: cancer-specific distress and general distress. The 17-item Posttraumatic Stress Scale-Self Report (PSS-SR) [19] was utilised as a measure of cancer-specific distress. This scale measures the severity of each DSM-IV posttraumatic stress disorder symptom criterion. Participants indicate how often they experienced each symptom in the previous week. Total scores range from 0–51, with higher scores indicating higher PTSD symptomatology. In the present study, the PSS-SR had strong internal consistency reliability, $\alpha$=.90. General distress was measured using the total scale score of the Depression Anxiety Stress Scale short form (DASS) [20]. This 21-item scale assesses symptoms of anxiety, depression, and stress over the previous week. Scores range from 0-126, with higher scores indicating higher distress. In the present study, the DASS had strong internal consistency reliability, $\alpha$=.94.

*HRQoL.* Five QoL domains with acceptable internal consistency reliability were assessed using the European Organisation for Research and Treatment of Cancer quality of life core

questionnaire [EORTC QLQ-C30: 21]: Global QoL (α=.86), Physical Functioning (α=.80), Role Functioning (α=.89), Emotional Functioning (α=.87), and Social Functioning (α=.86). Total scores range from 0 to 100, with higher scores indicating better functioning.

*Coping.* Three coping styles with acceptable internal reliability (Helplessness/Hopelessness, α=.81; Anxious Preoccupation, α=.89; and Cognitive Avoidance, α=.75) were assessed using the mini-Mental Adjustment to Cancer Scale (mini-MAC) [22]. Participants indicate on a 4-point scale how much each statement applies to them currently, and scores are calculated by summing items for each respective domain, with higher scores indicating more use of that coping style.

*Adherence*. Multiple measures of adherence were monitored within the website: the number of modules and worksheets completed, the number of visits to the website, and length of time logged in.

***Statistical methods***

*Power calculation.* An a priori sample size calculation was conducted using a program by Hedeker [14]. With 3 follow-up assessment points, 2 groups, power set at 0.80, and statistical significance set at α=.05 (two tailed), and an effect size set at moderate (.50), 55 participants per group were required (total N=110 patients), allowing for 20% attrition over the course of the study in line with previous web-based studies [9,12]. Due to the constraints of completing the trial within the duration of a funded fellowship, a stopping rule was introduced, such that recruitment ceased after a 20 month recruitment window. This resulted in a final sample of 60 participants (30 per condition), with the study therefore being underpowered for moderate or small effect sizes.

*Analytic strategy.* Group differences at baseline were investigated using t tests for continuous variables or $\chi 2$ tests of independence for categorical variables. Intervention effects for each outcome variable were assessed using linear mixed model (LMM) analyses with restricted maximum likelihood (REML). Baseline observations were used as covariates to eliminate the influence of baseline variability, resulting in a 2 (group: intervention; control) X 3 (time: post-program; 3-month follow-up; 6 month follow-up) fixed effects model for each outcome variable, with random effects accounting for individual variation. This approach effectively equalises conditions at baseline and consequently allows for direct comparison between conditions at each follow-up point. In this context, (a) interactions between condition and time, (b) main effects of group and (c) post-hoc pairwise comparisons at each follow-up point are all indicators of intervention-effects. LMM analyses are robust with respect to handling missing data and unbalanced designs in longitudinal research as all participants with at least one observed data point (i.e., one completed follow-up assessment) are included in analyses. As the baseline assessment was operating as a covariate only for analysis of intervention effects, any participants who withdrew prior to the post-intervention assessment - and subsequently only gave baseline data – were not included in the initial LMM (n=5). To correct for this and ensure a true intention-to-treat design was utilised, a separate LMM

including the 5 dropouts was therefore conducted for each outcome variable, by conducting estimation maximisation imputation at post-treatment [23,24].

Because of the limitations that small sample sizes pose to significance testing, between-group effect sizes (Cohen's *d*) were calculated as another indicator of intervention effects. These were calculated from the post-hoc pairwise comparisons, using the difference in means between conditions (control – *CCO*) divided by the pooled standard deviation, with a bias correction applied to account for the small sample size [25]. Cohen's d=0.20 is considered small, 0.50 moderate, and 0.80 large. All analyses were conducted using the statistical software, SPSS for Windows version 19.0 (SPSS Inc, Chicago, IL, USA).

## Results

### Participants

As **Figure 1** demonstrates, 145 patients were approached / screened for eligibility; 21 (14.5%) were unable to be contacted, and 29 (20%) did not meet eligibility criteria. Of the remaining 95 eligible patients, 60 consented to participate (n=30 control; n=30 intervention), resulting in an uptake rate of 63.2%.

**[Insert Figure 1 about here]**

On average, participants were 52.73 (SD=9.78) years of age (median = 50.50 years; range 30-84), had been diagnosed on average 2.65 months prior to study-enrolment, and the vast majority were females (95%) with breast cancer (82%). As there had been no *a priori* plans to stratify on sex, the three male participants were randomly assigned to the intervention condition. **Table 1** summarises the sample's demographic and medical characteristics, and demonstrates that there were no significant baseline differences between control and intervention participants. Importantly, no significant group differences at baseline were found for any of the psychosocial outcome measures.

**[Insert Table 1 about here]**

### Dropouts

All 5 dropouts were women, with breast cancer, and married. Reasons for drop-out were: n=2 withdrew due to technical difficulties with their computers; n=2 withdrew due to time restraints; n=1 due to the program not being what she was after (support group, in person). No significant differences were found between drop-outs and treatment-completers on baseline demographic, medical characteristics, or outcome variables, with the exception of significantly lower levels of *anxious preoccupation* (Dropouts: M= 12.80, SD=7.46; Completers: M=19.93; SD = 6.36; t(58)=-2.37, $p$=.02); and *helplessness/hopelessness* (Dropouts: M=8.20, SD = 0.45; Completers: M=11.87, SD=4.47; t(58)=2.15, $p$=.001) in drop-outs.

### Program usage

As **Table 1** shows, there were no significant differences between intervention and control participants in terms of number of logins, session length, or average number of modules completed. However, a significant difference emerged in the pattern of how participants used the program: Control participants had a bimodal pattern of usage; either not completing a single module (17%) or completing 5-6 modules (63.3%). In contrast, all intervention participants completed at least one module, with the distribution across modules being even.

**Repeated measures**

**Table 2** displays the estimated marginal means, standard errors, and between-group effect sizes at each assessment time point.

**[Insert Table 2 about here]**

**Distress.** No statistically significant group x time interactions or main effects for group were obtained for either measure. A significant main effect for time was found for Cancer-Distress ($F_{2, 48.35}$=*5.982*, $p$=.005), and post-hoc analysis shows a trend towards significantly lower scores at post-treatment for *CCO* participants ($F_{1, 51.65}$=2.73, $p$=.10). This was supported by the moderate between-group effect size ($d$=.43).

**QOL.** No statistically significant interactions or main effects for group were obtained for either measure. Two trends approaching significance were obtained: (i) an interaction for Global QOL ($F_{2, 48.30}$=2.45, $p$=.097), with covariate-adjusted scores demonstrating that *CCO* lead to greater improvements over time than controls; and (ii) a main effect for group for Physical Function ($F_{1,51.40}$=2.92, $p$=.09), with covariate-adjusted scores indicating that *CCO* participants experienced higher Physical Functioning across all follow-up assessments compared to controls. Significant main effects for time were found for Physical Functioning ($F_{2, 47.86}$=8.48, $p$=.001), Global QOL ($F_{2, 48.30}$=9.46, $p$<.001), Role Function ($F_{2, 48.09}$=8.44, $p$=.001); and Social Function ($F_{2, 45.59}$=17.80, $p$<.001).

As shown in **Figure 2**, post-hoc group comparisons at each follow-up, controlling for baseline levels, found significantly higher Physical Functioning in *CCO* participants at 3-month follow-up ($F_{1, 47.77}$=6.08, $p$=.02), with a moderate between-group effect size ($d$=-.52). This effect was somewhat reduced, but still moderate, at 6-month follow-up (d=-.40). Post-hoc analyses also showed a trend towards a significant group difference in Global QOL at 6-month follow-up ($F_{1, 49.02}$=2.63, $p$=.10), with a moderate between-group effect sizes ($d$=-.43).

**[Insert Figure 2 about here]**

**Coping.** No significant interactions or main effects for group were obtained. A significant main effect for time was found for Anxious Preoccupation ($F_{2, 49.22}$=7.14, $p$=.002). Post-hoc pairwise comparisons showed a trend towards lower Anxious Preoccupation levels in *CCO* participants compared to controls at post-treatment ($F_{1, 51.88}$=3.26, $p$=.08), with a small-to-moderate associated effect size. A non-significant trend towards lower Cognitive Avoidance among *CCO* participants was also found at 3-month follow-up ($F_{1, 48.43}$=3.02, $p$=.09), with a small associated effect size.

**Intention-to-treat.** An intention-to-treat analysis to manage missing data was then applied, using EM maximisation at post-treatment for the 5 participants with missing data, with no significant changes to results obtained.

**Gender.** Given only 3 men participated in the study, and were all randomised to the intervention condition, LMM analyses were re-run excluding them to determine whether they were influential in the results. No changes in results occurred.

## Conclusions

Overall, while results were promising they must be interpreted with caution, given the lack of power to detect statistically significant interactions. Several notable findings emerged. First, extending the findings of our feasibility study [13], statistically significant main effects for time were obtained in six of the ten outcomes evaluated, with post-hoc pairwise comparisons and/or between-group effect sizes demonstrating that *CCO* was driving the changes observed for four of these six outcomes. That is: there was (i) statistically significantly higher levels of Physical Functioning at 3-month follow-up, with a moderate between group effect size (d=.52); (ii) a trend towards a significant group x time interaction for Global QOL; and immediate post-treatment reductions in (iii) Cancer-Distress and (iv) Anxious Preoccupation compared to controls, as evidenced by the small-to-moderate between-group effect sizes.

Second, while not statistically significant, group differences with small-to-moderate effect sizes favouring *CCO* were obtained at 3- and 6-month follow-ups for General Distress and Emotional Function, and at 3-months for Cognitive Avoidance. However, this pattern of findings must be balanced against the three outcomes where no group differences at any follow-up emerged: Role Function, Social Function, and Helplessness/hopelessness. This lack of group differences over time for Helplessness/hopelessness contrasts with both our prior feasibility study [13] and our RCT evaluation of the original print-workbook that *CCO* was adapted from [17]. These results clearly need to be substantiated with statistically significant results in a larger-scale adequately powered RCT.

Of interest, there were differing patterns of program usage between groups: 17% of control-participants were non-users (i.e., did not access a single module), while all intervention-participants accessed at least one module. This difference is noteworthy given that attempts were made to reduce allocation-bias: the conditions were described as two different versions of the same program that were being compared to establish which one is more helpful. Neither condition was posited as being superior, and the terms ‘control’ and ‘intervention’ were deliberately not used. Whether this non-usage therefore related to treatment allocation, individual/personal factors, or to chance cannot be determined. Conversely, nearly two-thirds of control participants were high-users (i.e., they completed 5-6 out of the 6 available modules), while the number of modules completed was evenly distributed for *CCO* participants. It is interesting that fewer *CCO* participants were categorised as high-users compared to web-based controls; whether this indicates that participants found the intervention condition less engaging, or too demanding to complete warrants further investigation. This finding is not novel: other non-cancer online interventions have found

control-group membership to be associated with higher adherence [26-28], however non-usage or treatment-attrition evaluations for cancer interventions are only now emerging [29]. Our adherence results compare favourably to a recent usage-analysis of a web-based breast cancer-survivor intervention RCT [29] which classified 9 of their 70 intervention participants (13%) as non-users, 43% as low-users, and 44% as high-users. It was beyond the scope of the current paper to conduct in-depth analyses of *within*-program usage, such as whether specific modules were qualitatively less-well received than others, or whether the various program ingredients (such as specific CBT worksheets) were well-utilised or could be omitted in future iterations. Qualitatively, previous research suggests that adherence is reduced when participants have negative experiences with specific program components [30], therefore these analyses are planned for future dissemination and publication. Further sub-analysis of variables that quantitatively predict program adherence is also warranted which will further inform this research area.

The current study should be interpreted in the context of the following limitations: First, the small sample size and resulting lack of power limited our ability to obtain statistically significant intervention effects. This resulted from a slower than anticipated recruitment rate at the study site, rather than from a low uptake rate. Second, our sample reported overall low baseline levels of distress, therefore floor effects were operating, reducing our likelihood of detecting intervention effects. While other studies have implemented distress cut-offs as an eligibility criteria, we elected not to do this in order to increase the potential recruitment pool. A third limitation related to the over-representation of breast cancer in our sample, therefore reducing the generalizability of these results to other curatively-treated cancer patients. Whether the fact that this intervention was standardised (that is, it was not tailored to specific cancer types) was a factor in the reduced uptake of non-breast cancer patients warrants consideration. Interventions tailored to cancer types are likely to be more desirable, and qualitative research suggests that more personalised interventions may also yield higher levels of adherence [26,30,31]. This, however, must be balanced against the cost-effectiveness of developing a single intervention that can have a broader reach (across cancer types). Fourth, given the pilot nature of this RCT, we did not stratify gender at randomisation, and all three male participants were allocated to the intervention condition. Therefore this study cannot comment on the benefits of online self-help for men. The fact that only seven men were approached for the study indicates a potential screening bias among recruiters. This gender imbalance is consistent with the online-intervention research literature [32]. Finally, whether users received other formal psychological services during the study was not monitored and therefore could not be controlled for in the analyses.

A strength of this study was the methodology utilised: it was the first to evaluate an internet intervention for cancer using a web-based control rather than a waitlist-control [9,11] or second active-treatment group / no control group [10,13]. This is an important distinction as using a web-based control provides a more stringent test of the intervention compared to waitlist-control conditions [7], and one would expect to obtain smaller effect sizes when using an active-control condition [18]. While this is a methodological strength in study design, it may have limited our ability to detect significant effects, as the web-based control

may have performed better than predicted. The fact that *CCO* obtained promising trends compared with our web-based control, with moderate between-group effect sizes for four outcomes is therefore indicative of its potential, and provides justification for a larger RCT to be conducted.

In conclusion, while limited by its small sample size, this study adds to the emerging web-based cancer-distress intervention literature [13,9-11], and suggests that *CCO* holds promise for improving distress, coping, and aspects of health-related quality of life in cancer patients. It will be important for all future studies to conduct usage- as well as efficacy-analyses to continue to more appropriately tailor interventions to the users they are designed for; and to incorporate longer-term follow-up assessments in order to evaluate whether intervention effects are sustained.

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**Ethical approval**

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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**Table 1.** Sample characteristics and *CCO* site-usage.

| | **Intervention (n=30)** | **Control (n=30)** | ***p**** |
|---|---|---|---|
| *Demographic characteristics* | | | |
| Age (yrs) | 51.57 (10.10) | 53.90 (9.48) | .36 |
| Female % | 27 (90%) | 30 (100%) | .24 |
| Married % | 25 (86.2%) | 20 (66.7%) | .13 |
| Tertiary educ % | 17 (56.7%) | 19 (63.3%) | .79 |
| Employed % | 20 (66.7%) | 18 (60%) | .65 |
| *Medical characteristics* | | | |
| Time since diagnosis (mths) | 3.00 (2.41) | 2.30 (1.78) | .21 |
| Family history Ca % | 24 (80%) | 20 (69%) | .25 |
| Cancer Type (%) | | | .55 |
| Breast | 23 (76.7%) | 26 (86.7%) | |
| Bowel | 4 (13.3%) | 1 (3.3%) | |
| Lymphoma | 1 (3.3%) | 0 | |
| Ovarian | 1 (3.3%) | 1 (3.3%) | |
| Uterine | 1 (3.3%) | 1 (3.3%) | |
| Thyroid | 0 | 1 (3.3%) | |
| Treatments received | | | |
| Surgery % | 27 (90%) | 26 (89.7%) | 1.00 |
| Chemo % | 25 (86.2%) | 22 (78.6%) | .50 |
| Radio % | 15 (51.7%) | 16 (61.5%) | .59 |
| Other (e.g., hormonal)** | 4 (13.8%) | 10 (35.7%) | .06 |
| *CCO Site Usage Indicators* | | | |
| Logins | 6.97 (3.96) | 9.23 (8.74) | .20 |
| Session length (mins) | 13.60 (7.26) | 10.88 (7.24) | .16 |
| Modules completed | 3.50 (1.89) | 4.07 (2.29) | .30 |
| % participants who completed: | | | .01 |
| 0 modules | 0 | 5 (16.7%) | |
| 1-2 modules | 10 (33.3%) | 2 (6.7%) | |
| 3-4 modules | 10 (33.3%) | 4 (13.3%) | |
| 5-6 modules | 10 (33.4%) | 19 (63.3%) | |

*Notes.* Sample characteristics and site usage are presented as means (SD) or number (%). **p* value reflects the significance of t tests for continuous variables or $\chi 2$ tests of independence for categorical variables.**Other treatments reported included: tamoxifen / femara /hormone therapy (n=6); Herceptin (n=3); additional surgery (n=2); brachytherapy (n=1); iodine therapy (n=1); complementary therapy (n=1).

**Table 2**. Mixed model estimated marginal means for all outcome measures, by group (2) and time (3).

| | | Post-program | | | 3 month follow-up | | | 6 month follow-up | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Measures** | **Baseline covariate value** | **CCO** | **Control** | | **CCO** | **Control** | | **CCO** | **Control** | |
| | | **Mean (SE)** | **Mean (SE)** | ***d*** | **Mean (SE)** | **Mean (SE)** | ***d*** | **Mean (SE)** | **Mean (SE)** | ***d*** |
| *Distress* | | | | | | | | | | |
| Cancer Distress[a] | 12.40 | 10.08 (1.26) | 13.04 (1.26) | .43 | 11.54 (1.32) | 12.60 (1.31) | .15 | 9.29 (1.11) | 9.93 (1.08) | .11 |
| General Distress | 26.05 | 26.27 (4.43) | 28.96 (4.43) | .11 | 24.46 (4.31) | 27.46 (4.33) | .12 | 19.48 (3.43) | 24.68 (3.42) | .28 |
| *QOL* | | | | | | | | | | |
| Global[a,b] | 55.78 | 56.22 (3.88) | 59.37 (3.92) | .15 | 68.50 (3.64) | 62.85 (3.64) | -.28 | 74.04 (3.78) | 65.27 (3.81) | -.43[+] |
| Physical Function[a,c] | 78.53 | 78.11 (3.66) | 79.16 (3.63) | .05 | 85.63 (3.50) | 75.66 (3.47) | -.52[*] | 90.41 (3.39) | 83.67 (3.36) | -.40 |
| Role Function[a] | 59.89 | 60.56 (9.49) | 63.83 (9.46) | .06 | 79.61 (8.34) | 73.45 (8.33) | -.14 | 81.61 (8.09) | 81.25 (8.04) | -.01 |
| Emotional Function | 67.00 | 69.03 (4.81) | 69.16 (4.79) | .01 | 72.59 (4.87) | 67.43 (4.89) | -.20 | 76.54 (4.22) | 71.38 (4.21) | -.23 |
| Social Function[a] | 60.20 | 57.26 (5.49) | 66.56 (5.41) | .31 | 77.87 (4.62) | 75.08 (4.61) | -.11 | 87.98 (4.26) | 83.84 (4.75) | -.16 |
| *Coping* | | | | | | | | | | |
| Helplessness/hopelessness | 11.95 | 10.93 (0.92) | 12.22 (0.92) | .26 | 11.59 (0.86) | 11.36 (0.87) | -.05 | 10.71 (0.61) | 11.02 (0.61) | .09 |
| Anxious Preoccupation[a] | 20.03 | 17.49 (1.10) | 19.74 (1.10) | .38[+] | 17.70 (1.16) | 18.36 (1.17) | .10 | 15.53 (1.04) | 17.21 (1.03) | .30 |
| Cognitive Avoidance | 9.15 | 8.52 (1.09) | 9.01 (1.09) | .08 | 8.56 (1.12) | 9.97 (1.12) | .23[+] | 8.66 (1.17) | 9.28 (1.17) | .09 |

Notes.

d=Cohen's *d* (with Hedge's bias correction) between-group effect size. Calculated as Control-*CCO*/pooled SD for all outcomes; therefore positive values favour *CCO* for Distress and Coping Outcomes, and negative values favour *CCO* for QOL outcomes.

[a]p<.01 (significant main effect for time);

[b]p<.10 (trend towards significant interaction).

[c]p<.10 (trend towards main effect for group).

*p<.05, significant pairwise comparisons between groups within a follow-up assessment.

[+]p<.10, trend towards significant pairwise comparisons between groups within a follow-up assessment.

**Figure 1. CONSORT flow diagram.**

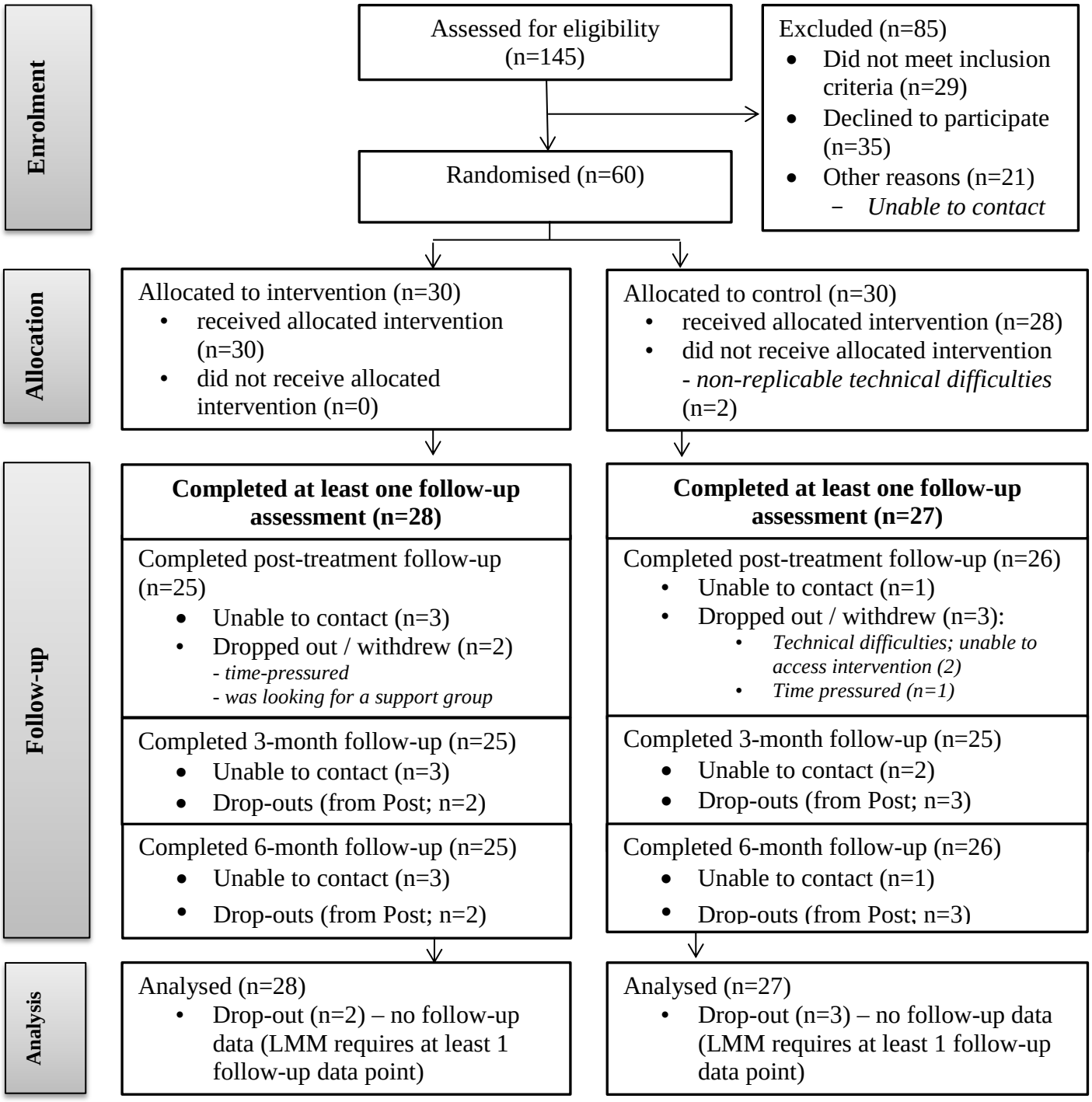
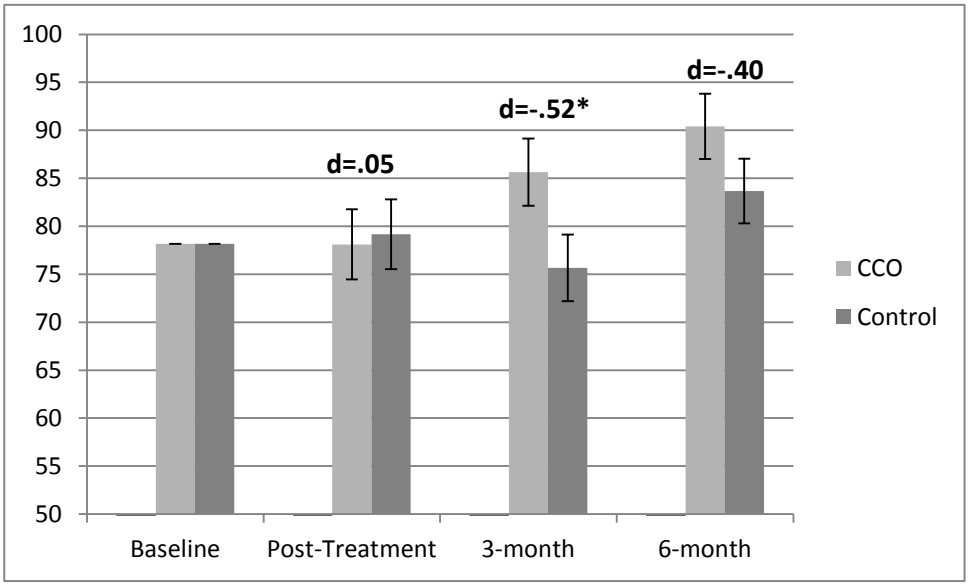


**Figure 2.**

Physical function scores by group (2), time (4), and between group effect-sizes at follow-up.




*Notes.* **p*=.02, Bonferroni-adjusted pairwise group-comparison at 3-month follow-up.