Finding My Way: results of a multicentre RCT evaluating a web-based self-guided psychosocial intervention for newly-diagnosed cancer survivors.

Lisa Beatty¹,², Emma Kemp¹,², Joseph R. Coll¹, Jane Turner³, Phyllis Butow⁴, Donna Milne⁵, Patsy Yates⁶, Sylvie Lambert⁷, Addie Wootten⁸, Desmond Yip⁹,¹⁰, and Bogda Koczwara¹,²

Written on behalf of the Finding My Way Authorship Group

¹Flinders University, Adelaide, AUSTRALIA
²Flinders Centre for Innovation in Cancer, Adelaide, AUSTRALIA
³Mental Health Centre, The University of Queensland, Herston, AUSTRALIA
⁴University of Sydney, Sydney, New South Wales, AUSTRALIA
⁵Peter MacCallum Cancer Centre, Parkville, Victoria, AUSTRALIA
⁶Queensland University of Technology, Brisbane, Queensland, AUSTRALIA
⁷McGill University, Ingram School of Nursing, Wilson Hall, 3506 University Street, Montreal, H3A 2A7, Canada
⁸Smiling Mind, Abbotsford, Victoria, AUSTRALIA
⁹The Canberra Hospital, Department of Medical Oncology, Garran, ACT, AUSTRALIA
¹⁰Australian National University, ANU Medical School, Acton, ACT, AUSTRALIA

Corresponding Author: Dr Lisa Beatty, Flinders Centre for Innovation in Cancer, Flinders University, GPO Box 2100, Adelaide, SA, 5001, AUSTRALIA.
T: +61882012506; F: +6182044997; E: lisa.beatty@flinders.edu.au ORCID: 0000-0001-8847-8452

Acknowledgements: This RCT was funded by the National Health & Medical Research Council (Grant No. 1042942). Dr Beatty is supported by a Cancer Council SA Postdoctoral Fellow (Cancer Support). We thank all the men and women who participated in this trial; consumer representative Julie Marker, chair Cancer Voices SA, who reviewed the study protocol and provided input throughout the study; and the research assistants / clinicians / clinical trial / support staff who were critical to the successful recruitment of this study. We also thank Breast Cancer Network Australia and Register4, and their staff, for their assistance in recruitment. We thank our associate investigator and valued colleague, the late Paul Katris, for his important contributions to all aspects of the study design, conduct, and promotion through his extensive network of contacts. The Finding My Way Authorship Group includes Prof Tracey Wade, Dr Sarah McKinnon, Ms Simone Noelker, Dr Louise Gorman, Ms Bernadette Zappa, Ms Judy Allen, Ms Caroline Richards, Mr Michael Fitzgerald, Ms Sally Sara, Ms Lisa Mackenzie, Mr Edward Craft, Ms Kathryn Stafford, Ms Ruby Lipson-Smith, and Ms Rose Kamateros.
Keywords: internet intervention; self-guided; CBT; distress; acute survivorship; RCT

Submitted to: Journal of Supportive Care in Cancer
Abstract

Purpose

This multicentre randomized controlled trial examined the efficacy of *Finding My Way* (FMW), a 6-week/6-module online self-guided psychotherapeutic intervention for newly-diagnosed curatively-treated cancer survivors, in reducing cancer-related distress and improving quality of life compared to an online attention-control.

Methods

Participants were randomised on a 1:1 ratio using a gender-stratified block design to intervention (n=94) or attention-control (n=97), and were blinded to condition. Assessments were completed at baseline (T0), post-intervention (T1), 3-months (T2) and 6-months (T3) post-intervention. Mixed model repeated measures analyses examined differences between groups for cancer-specific distress (primary outcome); general distress, quality of life (QoL), coping, and health service utilisation (secondary outcomes).

Results

While both groups reported reduced cancer-specific and general distress over time, between-group differences were not significant. Intervention participants reported lower total health service utilisation and supportive-care utilisation post-intervention than controls (Total HS use: between-group mean difference = -1.07 (-1.85 to -0.28); supportive-care use: between-group mean difference = -0.64 (-1.21 to -0.06)), and significantly higher emotional functioning at 3-months (between-group mean difference = 7.04 (0.15 to 13.9)). At 6-months, the supportive-care utilisation finding
reversed (between-group mean difference = 0.78-points (0.19 to 1.37). Across remaining QOL and coping outcomes, no significant group differences emerged.

**Conclusions**

While both groups experienced reductions in distress, between-group differences were not significant. This contrasts with the significantly improved emotional functioning observed in FMW participants at 3 months, and the short-term reductions in health service utilisation. Long-term increases in supportive-care service utilisation suggests FMW only met needs while being actively used.

Word Count: 248
Although efficacious, the impact of therapist-delivered psychological interventions for people with cancer is limited by low uptake (between 14 and 41%) [1]. Barriers include geographic, personal or illness-related factors, stigma, and limited or unavailable services [1]. This low uptake has heightened interest in online psychosocial programs [2] which offer potential for increased reach, privacy, convenience, and anonymity [3].

The past five years has seen emerging evidence that online interventions improve early-stage cancer-related distress/anxiety and depression [2]. This evidence has mainly focused on ‘long-term survivors’ – defined as individuals who have completed their anti-cancer treatments [4] – including breast [5-7], prostate [8], testicular [9], and heterogeneous cancer survivors [10,11]. Minimal research has targeted those in “acute survivorship” – i.e. recently diagnosed or currently undergoing treatment [4], despite recognition that psychological programs are needed [1,12], equally [13] or more efficacious [12], and more likely taken up [1,12] early in the survivorship trajectory.

Our group was the first to develop and evaluate an online psychosocial program exclusively targeting this acute survivorship period [14-17]. Phase I and II trials demonstrated feasibility and pilot efficacy of the first iteration of this unguided program, *Cancer Coping Online*, in improving distress, maladaptive coping, and select quality of life domains [14,15]. Two further RCTs have recently been published; a German study comparing the therapist-guided CBT and mindfulness program “STREAM” against a waitlist control in 129 patients [18]; and an Australian study of an unguided web-based CBT program ‘CancerCope’ for 163 patients screened with high distress, compared to a static cancer education website [19]. The STREAM program led to improved quality of life and reduced distress, but no impact
on anxiety or depression [18]. CancerCope did not yield significant group differences for any primary or secondary outcome, however sub-group analyses showed higher program-adherence was associated with reduced psychological and cancer-specific distress, and unmet needs [19]. Collectively these trials demonstrate that targeting the acute-treatment phase is feasible independently or as part of a stepped-care program and has the potential to improve quality of life and reduce distress [20,21]. However, whether this is true without therapist-guidance, or in those not screened for distress, is yet to be established in a large/sufficiently powered RCT. Given increasing emphasis on clinical translation, it is important to trial programs under the same conditions in which they will subsequently be implemented. We therefore designed the second-iteration of our program, Finding My Way ('FMW') [22], to meet these pragmatic aims, and recently summarised uptake and adherence/engagement outcomes [17,16]. This article reports the psychological and health-service outcomes of our multi-site RCT of FMW compared to an online attention-control [22]. We hypothesised that, compared to controls, participants randomised to FMW would demonstrate: a) greater reductions in the primary outcome, cancer-specific distress, from pre- to post-intervention; and b) greater improvements across secondary outcomes: general distress, quality of life (QOL), coping, and reduced health service-utilisation.

**Methods**

**Setting**

The FMW study protocol has been published elsewhere [22]. We conducted a multicentre randomised controlled parallel-group trial in six hospitals across four
Random Assignment

Randomisation occurred at the patient level, stratified by gender (Figure 1). Patients were randomised 1:1 in blocks of four to receive the intervention or online attention-control. Researchers were blinded to participant allocation.

Participants

Eligible participants were: (a) ‘acute survivors’, defined as diagnosed in the past 6 months with any cancer treated with curative intent; (b) currently receiving anti-cancer treatment; (c) aged 18 years or over; (d) sufficiently proficient in English to provide informed consent and utilise the program; and (e) able to access the internet and had an active email address. Participant characteristics are listed in Table 1.

Ethical approvals were obtained from the Southern Adelaide Clinical (No. 372.10), Royal Brisbane and Women’s (No. HREC/13/QRBW/252) and ACT (No. Eth.2/14/032) Health Human Research Ethics Committees. The trial is registered with the Australian and New Zealand Clinical Trials Registry (registration number ACTRN12613000001796).

Procedure

Recruitment methods included direct approach from clinicians at recruiting sites, posters in clinic waiting areas, advertisements in consumer/advocacy online newsletters, and email invitations distributed via research registries.
Participants were directed to a tutorial on their personalised user-homepage instructing them how to use their respective programs (*FMW* or attention-control). Following completion of the 6-week intervention or control programs, participants received reminders to complete three follow-up assessments immediately post-intervention (T1), 3-months post-intervention (T2), and 6-months post-intervention (T3).

**Intervention**

*Finding My Way* (Figure 2) is a 6-week / 6-module password-protected web-based program comprising: (1) psycho-education, (2) cognitive-behaviour therapy-based strategies (worksheets, quizzes, relaxation/meditation exercises), and (3) survivor testimonials in video and written formats. The 6 modules, released at a rate of one per week, address common psychosocial concerns following diagnosis, including (a) starting treatment and communicating with the treatment team; (b) coping with physical symptoms and side-effects; (c) managing distress; (d) personal challenges (identity, body image/sexuality); (e) social and family concerns; and (f) issues that arise after completing treatment. Participants can self-tailor the order of modules. A booster module, summarising key program strategies, is accessible one month after program completion. Participants had ongoing access to all program materials, including after trial completion.

*Attention Control*: An information-only version of *Finding My Way* was developed for the purpose of the trial, containing the same six topics as the intervention but without the worksheets, activities, relaxation/meditation exercises, or note-taking features. Full details of this control condition have been previously published [22].

**Measures and Outcomes**
Demographic variables assessed were sex, age, area of residence, marital status, employment status, level of educational attainment, annual gross income, and cultural affiliation as per the protocol [22]. Medical data included cancer type, date of diagnosis, treatments received, and family history of cancer.

The primary outcome, *cancer-specific distress*, was measured with the Post-traumatic Stress Scale-self-report [23], with items anchored to cancer diagnosis as the stressor. Participants rate on a 4-point scale (0 = Not at all to 4 = Almost always) the severity of each DSM-IV post-traumatic stress disorder symptom experienced in the previous week. Total scores range from 0 to 51, with a clinical cut-off of 14; higher scores indicate higher cancer-specific distress.

Secondary outcomes were *general-distress* (Depression, Anxiety, Stress Scale) [24]; *global QOL* and *five QOL functioning subscales* – physical, emotional, social, cognitive, and role functioning (EORTC QoL Core Questionnaire) [25]; three *maladaptive coping domains* – helplessness/hopelessness, cognitive avoidance, anxious preoccupation (mini-Mental Adjustment to Cancer scale) [26]; and four *health service utilisation* subscales – total health service use, hospital length of stay, consultant/specialist visits, and number of supportive-care practitioners accessed - including allied health and complementary/alternative medicine (Australian Bureau of Statistics Health Service Utilisation Questionnaire) [27]. A priori potential moderators assessed were social support [28], vulnerability to distress [29], and motivation to seek information [30]. While the moderator analysis is reported separately (manuscript in preparation), these measures were included as potential baseline-covariates for the current analysis.
Metrics of website usage included [16]: (a) number of pages viewed (including repeat views), (b) unique pages viewed (range: 0-119 intervention; 0-72 control), (c) modules accessed (range: 0-6), (d) logins (and duration in minutes), and (e) number of days logged in.

**Statistical Analysis**

A longitudinal sample size calculation for repeated measures was conducted using a program developed by Hedeker [31]. With a conservative small-to-moderate effect size (0.35), anticipated attrition rate of 21% [15], two groups, four assessment points, power set at 0.80, statistical significance set at α = .05 (two tailed), and an expected primary endpoint (cancer-specific distress) standard deviation of 4.0 at each time point [14], 94 participants per group were required. The final sample was 191 (FMW=94, C=97), achieving adequate power from the observed data. The p-values for secondary outcomes were not adjusted for multiple testing.

Data were analysed using SAS version 9.3. Mixed Model Repeated Measures (MMRM) were conducted to examine the intervention effect on change from baseline for each outcome. The baseline observation was entered as a covariate to eliminate influence of baseline variability, resulting in a 2 (Group: intervention, control) x 3 (time category: post-program, 3-month, 6-month) fixed effects model for each outcome variable. A random subject effect was specified in each model to account for the correlation of observations taken on an individual. Contrasts were constructed to test group differences at each post-intervention time within the MMRM. Analyses were tested using a modified intention-to-treat (mITT) analysis of data that included individuals with baseline and at least one post-baseline measurement for each outcome. Two models were run for each outcome; (i) unadjusted - covarying only for
the effects of the baseline measure of each respective outcome, and (ii) fully-
adjusted – controlling for any baseline differences in demographic, clinical, and
psychosocial characteristics between groups, along with a priori specified cancer
variables routinely accounted for – cancer type and time since diagnosis. Sensitivity
analyses was performed by graphically evaluating patterns of missing data against
each outcome and by including the pattern of missing data as a fixed effect in the
unadjusted and fully adjusted models. This verified that the fully-adjusted models
appropriately adjusted the parameter estimates due to missing data, and did not
substantially change any of the results.

Between-group effect sizes (Cohen’s d) were calculated as an indicator of the
strength of intervention effect. These were calculated from the post hoc pairwise
comparisons, using the difference in means between conditions (control – FMW)
divided by the pooled standard deviation. Cohen’s \(d=0.20\) is considered small, \(0.50\)
moderate, and \(0.80\) large.

Clinically significant change was assessed with reliable change indices (RCI),
calculated with the formula: \(SE_{\text{diff}} = SD_1 \sqrt{2 \sqrt{1 - r}}\), where \(SD_1\) is the standard
deviceation at baseline, and \(r\) is the Cronbach’s \(\alpha\) coefficient of the measure. The RCI
equals \(1.96 \times SE_{\text{diff}}\) 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).

**Results**

A total of 191 (41%) eligible, contactable patients consented to participate and were
randomised (Fig 1). Participants who completed at least one follow-up assessment
were included in the mITT analysis (n=164).
There were no differences at baseline between drop-outs (n=27) and the mITT sample (n=164) on any outcome measure, with two exceptions: drop-outs were younger (Drop-outs M=49.1 yrs ± 11.7 vs mITT. M=54.8 yrs ± 10.4) with lower social functioning (mITT M=48.1 ± 32.5; vs Drop-outs M=61.6 ± 30.4).

Baseline characteristics

Table 1 depicts baseline characteristics of the 164 participants. Consistent with CONSORT guidelines, statistical testing of differences in baseline characteristics was not conducted; however descriptively it was noted that intervention participants had higher salaries than controls, and higher rates of undergraduate degrees, but lower rates of postgraduate degrees. These baseline differences were thus entered as covariates. Participants were on average 135 (Intervention) / 143 days (Control) post-diagnosis and were either mid-chemotherapy or mid-radiotherapy.

Intervention Delivery

Uptake and adherence to the program have been reported [16]. Overall adherence was acceptable, with 60% of participants completing 4 or more modules. Control participants accessed, on average, one module more than intervention participants (Int. M=3.7 ± 2.2 vs Cont. M=4.8 ± 1.9), and had higher rates of full program completion (53% vs 29%). However, intervention participants accessed significantly more pages (M=184.4±114.8) than control participants (M=149.6±71.7). This was explored as a potential moderator of outcomes, however the pattern of findings did not differ, and are thus not reported. Of the total 72 common information pages that could be viewed within the programs, control participants accessed significantly more pages (m=45.1±21.2) than intervention participants (m=28.8±21.4). No
differences between groups occurred for number of logins, days logged in, or login duration.

**Primary Outcome: Cancer-specific distress**

Thirty percent of the sample scored over the clinical cut-off for cancer-specific distress at baseline. Table 2 lists the results of the MMRM analysis for cancer-specific distress. Across all follow-ups, there were no significant differences between intervention and control groups; both groups reported only minor reductions from baseline.

**Secondary Outcomes: General distress, QOL, Coping, Health Service Utilisation**

Table 2 lists the results of the MMRM analysis for all secondary outcomes.

**General Distress:** Both groups reported decreased mean scores across follow-up, however there were no significant differences between groups, in either unadjusted or fully-adjusted models.

**QOL:** Intervention participants had significantly higher emotional functioning at T2, with a 9.47-point increase in EORTC scores compared to a 2.58-point increase in control participants; the baseline-adjusted mean difference between groups was 6.89 points (95%CI: 0.59 to 13.19, P=0.032). After adjusting for covariates in the full model, the difference remained statistically significant (P=0.045; Table 2), with a small-to-moderate effect size (d=0.34).

No significant differences between groups were observed for Global QOL, Physical Function, Role Function, Social Function, or Cognitive Function.
Coping: No significant baseline-adjusted group differences were observed for any coping domain.

Health Service Utilisation: Both groups had increased total health service utilisation from T0 to T1 (while receiving anti-cancer treatment). Intervention group participants accessed significantly fewer health services compared to control participants (baseline-adjusted mean group-difference = -1.07 (95%CI: -1.85 to -0.28, P=0.01). This remained significant in the fully-adjusted model (P=.02), with a small-to-moderate effect size (d=-0.38), but was not sustained at T2 or T3.

This pattern was replicated in the number of supportive-care practitioners accessed; participants in the intervention group had significantly fewer baseline-adjusted number of practitioners accessed at T1 compared to controls (between-group difference = -0.64 (95%CI: -1.21 to -0.06, P=0.03)). This remained significant in the fully-adjusted model (P=0.04, Table 2) with a small-to-moderate effect size (d=-0.32). These between-group differences were no longer significant at T2, and reversed in direction at T3 when intervention participants had significantly higher baseline-adjusted supportive-care practitioner use (between-group difference = 0.78 (95% CI: 0.19 to 1.37, P=0.01)), and remained significant in the fully adjusted model, with a small-to-moderate effect size (d=0.34, P=0.03, Table 2).

There were no baseline-adjusted differences at any time-point between groups for hospital length of stay, or consultant/specialist visits.

To assess whether outcomes differed depending on baseline levels of cancer-specific distress, a moderator analysis was conducted using a fully adjusted ANCOVA model at each time point. The models included the baseline covariate, group, moderator (baseline cancer-specific distress) and group*moderator
interaction as fixed effects; and adjusted for monitoring, education, income, age, gender, marital status, cancer type and days since diagnosis as covariates. Cancer-specific distress did not significantly moderate outcomes at any time point.

**Clinically Significant Change**

Table 3 summarises the percentage of participants who experienced clinically significant levels of change over time. At T1, more intervention participants than control participants reported clinically significant improvements in general distress (25.0% v 17.8%), global QOL (21.7% v 12.3%), role functioning (25.4% v 13.7%), and social functioning (18.3% v 13.7%). Fewer intervention participants experienced clinically significant deteriorations across most measures, except emotional functioning (5% v 2.7%) and cognitive avoidance (11.7% v 4.1%). This pattern was evident at T2 and T3 with sizeable differences between groups in the number of participants reporting clinically significant improvements. The exception was cognitive avoidance, where consistently more intervention participants deteriorated at each time point. Across other measures most participants did not achieve reliable change.

**Discussion**

This multi-site clinical trial of a self-guided online CBT-based psychosocial intervention, *Finding My Way*, failed to find significant group differences in the primary outcome, cancer-specific distress, compared to an online educational attention-control. For secondary outcomes, *FMW* demonstrated mid- to long-term improvements in the QoL domain emotional functioning, and short-term efficacy in reducing health service utilisation.
These outcomes add to the findings from three recent RCTs of online programs for recently diagnosed acute cancer survivors [19,15,18]. In contrast with the CancerCope trial for newly diagnosed distressed-patients [19], where no QOL impact was found, our study found FMW significantly improved emotional functioning. This QOL benefit differs somewhat from our pilot RCT where physical, rather than emotional, functioning was improved [15], and the STREAM program for newly-diagnosed patients [18], where all QOL domains except emotional functioning improved. Collectively, this evidence suggests that online programs can improve QOL during, as well as following, cancer treatment [5,10,9,8]. Our findings further indicate that while the intervention did not impact subjective experience of distress, it did impact participants’ ability to live with and manage that distress. This improved emotional functioning was sustained at 6-months, only reduced to trending-significance due to late (and lesser) improvements observed in controls.

The short-term reductions observed in both total health service utilisation and supportive-care utilisation have not been previously reported, as no previous online intervention has assessed health service impact. While the current study cannot yield a cost savings estimate (as the scale did not document how many visits per practitioner, but rather total number of practitioners), it provides justification for future health economic research. Untreated distress has been demonstrated to lead to an 18-19% increase in emergency presentations and hospital admissions [32], thus self-guided programs like FMW that can improve emotional functioning, or reduce distress, have the capacity to reduce demands on health systems.

These positive findings must be balanced against the finding that FMW intervention participants subsequently increased their supportive-care service utilisation at 6-month follow-up, consistent with an RCT of women with metastatic breast cancer,
who increased their supportive-care use after completing a low-intensity therapeutic writing intervention [33]. It fits with the ‘treatment-readiness gateway’ argument [34], that low-intensity online interventions increase readiness to subsequently access more intensive psychological support, as part of a stepped-care paradigm [35]. This result may also be reflective of participants’ increased consciousness of their personal and psychological health needs, and facilitate early and appropriate beneficial access to supportive care. Regardless, this suggests a need for longer-term maintenance strategies, such as reminder emails or text messages, to continue to engage *FMW* users.

In contrast to RCTs in recently-diagnosed acute cancer survivors [15,19,18], including our pilot RCT [15], which found evidence of reduced distress, our study did not find any statistically significant differences between groups over time for either cancer-specific or general distress. While it may simply be that *FMW* does not ameliorate distress, two factors should be noted. First, our sample reported overall low baseline levels of distress, reducing our likelihood of detecting intervention effects. While some studies have implemented distress cut-offs as an eligibility criterion [19], or have stratified by distress [18], we elected not to do this, to more closely replicate the likely conditions of use in the ‘real world’ setting it has subsequently been implemented in. While limiting inclusion to distressed samples remains a topic of controversy, on a pragmatic level, in clinical practice both non-distressed and distressed patients facing oncology treatments will often seek information/resources.

Second, both the *FMW* and control groups reduced in distress, at a time when peaks in distress for control participants are typically observed [15]. *FMW* utilised a tailored attention-control - our control participants had access to 60% of *identical* content to
intervention participants, including the survivor/HCP videos; thus our ‘control’ was actually a low-dose intervention (active-comparator), rather than the attention-control it was intended to be. This is supported by qualitative analysis of adherence to Finding My Way [17], in which control participants indicated the survivor videos and the normalisation of symptoms were particularly helpful. Having an ‘active’ control/comparator reduces power to detect differences between groups [36], as differences will be smaller. It is unclear if the reductions that occurred in this active ‘control’ condition related to the program, or represented natural recovery.

Importantly, in our previous RCT of the first iteration of the program, Cancer Coping Online [15], the control condition did not contain any video content, and control participants reported increases in both cancer-specific and general distress in post-intervention and 3-month follow-up assessments, before decreasing at 6-months [15]. This directly contrasts with the current trial’s findings, and suggests reductions observed in both Finding My Way conditions are likely attributable to the resources received, rather than purely from natural recovery.

This study had three notable limitations. First, one item of the health use survey was missing at the final follow-up (number of times a family physician was seen); we thus excluded this item from analyses and focused on specialist visits. Sensitivity analyses indicated the same pattern of findings emerged when retaining this item for the first two data waves, compared to when the item was dropped, thus this omission was unlikely to impact our results. Second, participants’ demographic profile was limited, comprising predominantly white, younger, educated, women with breast cancer. Of note, this profile is reflective of general (non-cancer) internet users [37]. Furthermore, users who match this profile still form a large percentage of patients. Third, we did not measure, nor control for, duration of adjuvant treatments received.
Given the heterogeneous population, this may have influenced results, however our sensitivity analyses of all other medical characteristics collected showed these factors did not differ between groups, nor impact on outcomes when controlled for.

Overall this study adds to the evidence base for web-based interventions in the acute cancer survivorship setting where the online delivery modality is a useful early-step within a broader stepped-care model for those experiencing psychosocial concerns [38]. The demonstrated short-term impact of FMW on health service utilisation, along with the reversal noted at 6-month follow-up, warrants further investigation/replication in future studies, which could be further strengthened via the collection of objective, as well as subjective, health service use data.

Conclusion

To our knowledge, this is the first multi-centre RCT of an unguided online psychosocial intervention for newly diagnosed acute cancer survivors showing sustained improvements in emotional functioning, and short-term reductions, but long-term increases, in health service usage. While there were no significant group differences in the primary outcome, distress, both groups experienced reductions at a time when escalations in distress are typically documented [15]. Future research investigating implementation of FMW, and similar programs, within the community is warranted.

Conflict of Interest

The authors have no conflicts of interest. The authors have full control of all primary data and agree to allow the journal to review our data if requested.
References

1. Brebach R, Sharpe L, Costa DS, Rhodes P, Butow P (2016) Psychological intervention targeting distress for cancer patients: a meta-analytic study investigating uptake and adherence. Psychooncology 25 (8):882-890. doi:10.1002/pon.4099

2. Bouma G (2015) Internet-based support programs to alleviate psychosocial and physical symptoms in cancer patients: a literature analysis. Crit Rev Oncol Hematol 95. doi:10.1016/j.critrevonc.2015.01.011

3. Andrews G (2010) Computer therapy for the anxiety and depressive disorders is effective, acceptable and practical health care: a meta-analysis. PLoS ONE 5. doi:10.1371/journal.pone.0013196

4. Surbone A, Tralongo P (2016) Categorization of Cancer Survivors: Why We Need It. Journal of Clinical Oncology 34 (28):3372-3374. doi:10.1200/jco.2016.68.3870

5. Carpenter KM, Stoner SA, Schmitz K, McGregor BA, Doorenbos AZ (2012) An online stress management workbook for breast cancer. Journal of Behavioral Medicine 37 (3):458-468. doi:10.1007/s10865-012-9481-6

6. Owen JE, Klapow JC, Roth DL, Shuster Jr JL, Bellis J, Meredith R, Tucker DC (2005) Randomized pilot of a self-guided internet coping group for women with early-stage breast cancer. Annals of Behavioral Medicine 30 (1):54-64

7. van den Berg SW, Gielissen MFM, Custers JAE, van der Graaf WTA, Ottevanger PB, Prins JB (2015) BREATH: Web-Based Self-Management for Psychological Adjustment After Primary Breast Cancer-Results of a Multicenter Randomized Controlled Trial. Journal Of Clinical Oncology 33 (25):2763-2771

8. Wootten AC, Abbott J-AM, Meyer D, Chisholm K, Austin DW, Klein B, McCabe M, Murphy DG, Costello AJ (2015) Preliminary Results of a Randomised Controlled
Trial of an Online Psychological Intervention to Reduce Distress in Men Treated for Localised Prostate Cancer. European Urology 68 (3):471-479.
doi: http://dx.doi.org/10.1016/j.eururo.2014.10.024

9. Heiniger L, Smith AB, Olver I, Grimison P, Klein B, Wootten A, Abbott JAM, Price MA, McJannett M, Tran B, Stockler MR, Gurney H, Butow PN (2017) e-TC: Development and pilot testing of a web-based intervention to reduce anxiety and depression in survivors of testicular cancer. European Journal of Cancer Care 26 (6). doi: 10.1111/ecc.12698

10. Duffecy J, Sanford S, Wagner L, Begale M, Nawacki E, Mohr DC (2013) Project onward: an innovative e-health intervention for cancer survivors. Psycho Oncology 22:947-951

11. Willems RA, Bolman CA, Mesters I, Kanera IM, Beaulen AA, Lechner L (2017) Short-term effectiveness of a web-based tailored intervention for cancer survivors on quality of life, anxiety, depression, and fatigue: randomized controlled trial. Psychooncology 26 (2):222-230. doi:10.1002/pon.4113

12. Zimmermann T, Heinrichs N, Baucom DH (2007) "Does One Size Fit All?“ Moderators in psychosocial interventions for breast cancer patients: A meta-analysis. Annals of Behavioral Medicine 34:225-239

13. Kalter J, Verdonck-de Leeuw IM, Sweegers MG, Aaronson NK, Jacobsen PB, Newton RU, Courneya KS, Aitken JF, Armes J, Arving C, Boersma LJ, Braamse AMJ, Brandberg Y, Chambers SK, Dekker J, Ell K, Ferguson RJ, Gielissen MFM, Glimelius B, Goedendorp MM, Graves KD, Heiney SP, Horne R, Hunter MS, Johansson B, Kimman ML, Knoop H, Meneses K, Northouse LL, Oldenburg HS, Prins JB, Savard J, Beurden M, Berg SW, Brug J, Buffart LM (2018) Effects and moderators of psychosocial interventions on quality of life, and emotional and
social function in patients with cancer: An individual patient data meta-analysis of 22 RCTs. Psycho-Oncology 27 (4):1150-1161. doi:10.1002/pon.4648

14. Beatty L, Koczwara B, Wade T (2011) ‘Cancer Coping Online’: A pilot trial of a self-guided CBT internet intervention for cancer-related distress. Electronic Journal of Applied Psychology 7 (2):17-25

15. Beatty L, Koczwara B, Wade T (2016) Evaluating the efficacy of a self-guided Web-based CBT intervention for reducing cancer-distress: a randomised controlled trial. Support Care Cancer 24 (3):1043-1051. doi:10.1007/s00520-015-2867-6

16. Beatty L, Kemp E, Binnion C, Turner J, Milne D, Butow P, Lambert S, Yates P, Yip D, Koczwara B (2017) Uptake and adherence to an online intervention for cancer-related distress: older age is not a barrier to adherence but may be a barrier to uptake. Supportive Care in Cancer 25:1905–1914. doi:10.1007/s00520-017-3591-1

17. Beatty L, Binnion C, Kemp E, Koczwara B (2017) A qualitative exploration of barriers and facilitators to adherence to an online self-help intervention for cancer-related distress. Supportive Care in Cancer 25 (8):2539-2548. doi:10.1007/s00520-017-3663-2

18. Urech C, Grossert A, Alder J, Scherer S, Handschin B, Kasenda B, Borislavova B, Degen S, Erb J, Faessler A (2018) Web-Based Stress Management for Newly Diagnosed Patients With Cancer (STREAM): A Randomized, Wait-List Controlled Intervention Study. Journal of Clinical Oncology 36 (8):780-788. doi:10.1200/JCO.2017.74.8491

19. Chambers SK, Ritterband LM, Thorndike F, Nielsen L, Aitken JF, Clutton S, Scuffham PA, Youl P, Morris B, Baade PD (2018) Web-Delivered Cognitive
Behavioral Therapy for Distressed Cancer Patients: Randomized Controlled Trial. Journal of medical Internet research 20 (1):e42. doi:10.2196/jmir.8850

20. Jansen F, Krebber AMH, Coupé VMH, Cuijpers P, Bree Rd, Becker-Commissaris A, Smit EF, Straten Av, Eeckhout GM, Beekman ATF, Leemans CR, Leeuw IMV-d (2017) Cost-Utility of Stepped Care Targeting Psychological Distress in Patients With Head and Neck or Lung Cancer. Journal of Clinical Oncology 35 (3):314-324. doi:10.1200/jco.2016.68.8739

21. Krebber AM, Jansen F, Witte BI, Cuijpers P, de Bree R, Becker-Commissaris A, Smit EF, van Straten A, Eeckhout AM, Beekman AT, Leemans CR, Verdonck-de Leeuw IM (2016) Stepped care targeting psychological distress in head and neck cancer and lung cancer patients: a randomized, controlled trial. Ann Oncol 27 (9):1754-1760. doi:10.1093/annonc/mdw230

22. Beatty L, Kemp E, Wade T, Koczwara B (2015) Finding My Way: protocol of a randomised controlled trial evaluating an internet self-help program for cancer-related distress. BMC cancer 15 (1):328. doi:10.1186/s12885-015-1322-x

23. Foa EB, Riggs DS, Dancu CV, Rothbaum BO (1993) Reliability and validity of a brief instrument for assessing posttraumatic stress disorder. Journal of Traumatic Stress 6:459-473

24. Lovibond SH, Lovibond PH (1995) Manual for the Depression Anxiety Stress Scales (DASS). University of New South Wales, Sydney

25. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, Filiberti A, Flechtner H, Fleishman SB, Haes JCJMld, Kaasa S, Klee M, Osoba D, Razavi D, Rofe PB, Schraub S, Sneeuw K, Sullivan M, Takeda F (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. doi:10.1093/jnci/85.5.365

26. Watson M, Law M, dos Santos M, Greer S, Baruch J, Bliss J (1994) The Mini-MAC: Further development of the Mental Adjustment to Cancer scale. Journal of Psychosocial Oncology 12 (3):33-46

27. Australian Bureau of Statistics (1991) 1989-1990 National health survey users' guide. ABS. Cat No. 4363.0., Canberra

28. Sherbourne CD, Stewart AL (1991) The MOS social support survey. Social Science & Medicine 32 (6):705-714

29. Gratz KL, Roemer L (2004) Multidimensional Assessment of Emotion Regulation and Dysregulation: Development, Factor Structure, and Initial Validation of the Difficulties in Emotion Regulation Scale. Journal of Psychopathology and Behavioral Assessment 26 (1):41-54. doi:10.1023/b:Joba.0000007455.08539.94

30. Miller SM (1987) Monitoring and blunting: Validation of a questionnaire to assess styles of information seeking under threat. Journal of Personality and Social Psychology 52:345-353

31. Hedeker D, Gibbons RD, Waternaux C (1999) Sample size estimation for longitudinal studies with attrition:comparing time related contrasts between two groups. Journal of Educational and Behavioral Statistics 24:70-93

32. Zebrack B, Kayser K, Bybee D, Padgett L, Sundstrom L, Jobin C, Oktay J (2017) A Practice-Based Evaluation of Distress Screening Protocol Adherence and Medical Service Utilization. Journal of the National Comprehensive Cancer Network 15 (7):903-912. doi:10.6004/jnccn.2017.0120

33. Mosher CE, DuHamel KN, Lam J, Dickler M, Li Y, Massie MJ, Norton L (2012) Randomised trial of expressive writing for distressed metastatic breast cancer
34. Andersson G, Titov N (2014) Advantages and limitations of Internet-based interventions for common mental disorders. World Psychiatry 13 (1):4-11. doi:10.1002/wps.20083

35. Butow P, Price MA, Shaw JM, Turner J, Clayton JM, Grimison P, Rankin N, Kirsten L (2015) Clinical pathway for the screening, assessment and management of anxiety and depression in adult cancer patients: Australian guidelines. Psychooncology 24 (9):987-1001. doi:10.1002/pon.3920

36. Danaher B, Seeley J (2009) Methodological Issues in Research on Web-Based Behavioral Interventions. Annals of Behavioral Medicine 38 (1):28-39. doi:10.1007/s12160-009-9129-0

37. Australian Bureau of Statistics (2016) 8146.0 - Household Use of Information Technology, Australia, 2014-15. Australian Bureau of Statistics, Canberra

38. Shaw JM, Price MA, Clayton JM, Grimison P, Shaw T, Rankin N, Butow PN (2016) Developing a clinical pathway for the identification and management of anxiety and depression in adult cancer patients: an online Delphi consensus process. Supportive Care in Cancer 24 (1):33-41. doi:10.1007/s00520-015-2742-5
Figure 1. CONSORT flow diagram.

**Enrollment**
- Assessed for eligibility (n=643)
- Excluded (n=452)
  - Did not meet inclusion criteria (n=137)
  - Declined to participate (n=177)
  - Other reasons (n=)
    - Unable to contact (n=44)
    - Did not enrol despite stated intention to do so (n=82)
    - Consented but did not complete baseline assessment (n=13)
  - Assessed for eligibility (n=643)
- Randomised (n=191)
- Excluded (n=16)
  - No follow-up data (MMRM requires at least 1 follow-up data point)

**Allocation**
- Allocated to intervention (n=94)
- Allocated to control (n=97)

**Follow-up**
- Completed at least one follow-up assessment (n=78)
  - Completed post-treatment follow-up (n=61)
    - Lost to follow-up (n=27)
    - Formally withdrew (n=6)
      - Husband’s ill health (n=1)
      - Not continuing medical treatment (n=1)
      - Time commitment (n=2)
      - No reason given (n=2)
  - Completed 3-month follow-up (n=53)
    - Lost to follow-up (n=34)
    - Withdrawals (n=7)
  - Completed 6-month follow-up (n=59)
    - Lost to follow-up (n=29)
    - Withdrawals (n=6)
- Completed at least one follow-up assessment (n=86)
  - Completed post-treatment follow-up (n=74)
    - Lost to follow-up (n=23)
    - Formally withdrew (n=0)
  - Completed 3-month follow-up (n=67)
    - Lost to follow-up (n=29)
    - Withdrawals (n=1)
      - Length of questionnaires
  - Completed 6-month follow-up (n=66)
    - Lost to follow-up (n=30)
    - Withdrawals (n=1)

**Analysis**
- Analysed (n=78)
  - Excluded (n=16) – no follow-up data (MMRM requires at least 1 follow-up data point)
- Analysed (n=86)
  - Excluded (n=11) – no follow-up data (MMRM requires at least 1 follow-up data point)
Table 1. Baseline participant demographic and clinical characteristics (n=166)

|                          | Control (n=86)       | FMW (n=78)        | p     |
|--------------------------|----------------------|-------------------|-------|
| Female sex               | 73 (84.9%)           | 65 (83.3%)        | 0.786 |
| Mean age at baseline (SD), years | 54.3 (9.9)          | 55.4 (11.1)       | 0.522 |
| Marital Status           |                      |                   | 0.146 |
| Partnered                | 63 (73.3%)           | 65 (83.3%)        |       |
| Divorced/Widowed         | 11 (12.8%)           | 9 (11.5%)         |       |
| Single                   | 12 (14.0%)           | 4 (5.1%)          |       |
| Area of residence: Rural/regional | 28 (32.6%)       | 22 (28.2%)        | 0.545 |
| English first language   | 83 (96.5%)           | 75 (96.2%)        | >0.999|
| Highest educational level completed |                   |                   | 0.007 |
| Primary school           | 11 (12.8%)           | 5 (6.4%)          |       |
| Secondary school         | 12 (14.0%)           | 18 (23.1%)        |       |
| Vocational / certificate | 32 (37.2%)           | 21 (26.9%)        |       |
| University Undergraduate | 8 (9.3%)             | 21 (26.9%)        |       |
| University Postgraduate  | 23 (26.7%)           | 13 (16.7%)        |       |
| Employed                 | 31 (36.0%)           | 33 (42.3%)        | 0.412 |
| Annual Income >$35,000   | 47 (54.7%)           | 55 (70.5%)        | 0.036 |
| Australian Ethnicity/Cultural Group | 77 (89.5%)       | 74 (94.9%)        | 0.791 |
| Cancer type              |                      |                   | 0.217 |
| Breast                   | 52 (60.5%)           | 52 (66.7%)        |       |
| Melanoma                 | 8 (9.3%)             | 7 (9.0%)          |       |
| Bowel                    | 4 (4.7%)             | 8 (10.3%)         |       |
| Lymphoma                 | 5 (5.8%)             | 1 (1.3%)          |       |
| Ovarian                  | 3 (3.5%)             | 1 (1.3%)          |       |
| Prostate                 | 0 (0.0%)             | 2 (2.6%)          |       |
| Lung                     | 2 (2.3%)             | 0 (0.0%)          |       |
| Other*                   | 12 (14.0%)           | 7 (9.0%)          |       |
| Days since diagnosis     | 144.7 (102.7)        | 135.3 (91.9)      | 0.540 |
| Cancer Stage                        | Control (n=86) | FMW (n=78) | p   |
|-----------------------------------|----------------|------------|-----|
| Stages 0-2                        | 39 (45.3%)     | 30 (38.5%) | 0.358 |
| Stage 3-4 (locally advanced)      | 19 (22.1%)     | 26 (33.3%) |     |
| Unclear†                          | 16 (18.6%)     | 15 (19.2%) |     |
| Unknown                           | 12 (14.0%)     | 7 (9.0%)   |     |

| Adjuvant Treatments               |                |            |     |
|-----------------------------------|----------------|------------|-----|
| Surgery                           | 73 (84.9%)     | 70 (89.7%) | 0.352 |
| Chemotherapy                      | 69 (80.2%)     | 59 (75.6%) | 0.478 |
| Radiotherapy                      | 51 (59.3%)     | 43 (55.1%) | 0.589 |
| Other adjuvant treatment**        | 39 (45.3%)     | 26 (33.3%) | 0.116 |

| Family History of Cancer          | 67 (77.9%)     | 59 (75.6%) | 0.731 |

| A Priori Moderators               |                |            |     |
|-----------------------------------|----------------|------------|-----|
| Total Social Support              | 80.3 (15.5)    | 79.7 (15.3) | 0.796 |

| Information-Seeking Style         |                |            |     |
|-----------------------------------|----------------|------------|-----|
| Monitoring                        | 4.1 (1.8)      | 3.5 (1.7)  | 0.029 |
| Blunting                          | 2.2 (1.2)      | 2.4 (1.1)  | 0.264 |

Notes: *other cancer type included:†Unclear stage = could not be determined based on information provided by participant; ††Unknown stage = Participant did not know their cancer stage.

** Other adjuvant treatments included: hormone therapy; additional surgery; scans/tests; other drug treatments/clinical trials; and dressings.
Table 2. Effect of Treatment by Intention-to-treat Analysis on Primary and Secondary Outcomes at Post-Intervention, 3-month, and 6-month Follow-up (n=166)

| Outcome               | Control | FMW | Unadjusted Between-Group Difference | Adjusted Between-group Difference | Cohen d Effect Size |
|-----------------------|---------|-----|------------------------------------|----------------------------------|-------------------|
|                       | No.     | Mean (SD) | No.     | Mean (SD) | LS-Mean Difference (95% CI) | P | LS-Mean Difference (95% CI) | P |                      |
| Cancer Distress       |         |           |         |           |                           |   |                           |   |                      |
| T0:Baseline           | 86      | 11.6 (8.4)| 76      | 11.8 (9.5)|                          | .74 | 0.32 (-1.99 to 2.63) | .79 | 0.04                 |
| T1:Change at Post     | 72      | -0.8 (6.6)| 58      | -0.8 (6.4)| 0.35 (-1.73 to 2.44)      | .74 | 0.32 (-1.99 to 2.63) | .79 | 0.04                 |
| T2:Change at 3 months | 67      | -1.8 (6.7)| 50      | -1.7 (6.5)| 0.10 (-2.06 to 2.26)      | .93 | 0.06 (-2.31 to 2.44) | .96 | 0.01                 |
| T3:Change at 6 months | 66      | -2.2 (6.2)| 58      | -1.9 (6.9)| 0.08 (-2.03 to 2.19)      | .94 | -0.00 (-2.33 to 2.32) | .99 | -0.00                |
| General Distress      |         |           |         |           |                           |   |                           |   |                      |
| T0:Baseline           | 86      | 25.5 (19.1)| 78      | 26.5 (21.7)|                        | .57 | -1.90 (-7.41 to 3.61) | .50 | -0.11                |
| T1:Change at Post     | 73      | -0.9 (17.7)| 60      | -3.6 (16.0)| -1.43 (-6.40 to 3.54)    | .57 | -1.90 (-7.41 to 3.61) | .50 | -0.11                |
| T2:Change at 3 months | 67      | -4.2 (17.7)| 51      | -8.5 (15.2)| -4.14 (-9.35 to 1.07)    | .12 | -4.47 (-10.2 to 1.26) | .13 | -0.24                |
| T3:Change at 6 months | 66      | -5.4 (16.9)| 59      | -9.2 (15.6)| -2.96 (-8.03 to 2.11)    | .25 | -3.48 (-9.07 to 2.10) | .22 | -0.19                |
| Global QOL            |         |           |         |           |                           |   |                           |   |                      |
| T0:Baseline           | 86      | 56.9 (21.7)| 78      | 55.6 (23.5)|                        | .07 | 3.32 (-3.71 to 10.3)  | .35 | 0.15                 |
| T1:Change at Post     | 73      | -1.9 (24.1)| 60      | 6.4 (23.1)| 6.11 (-0.42 to 12.6)     | .07 | 3.32 (-3.71 to 10.3)  | .35 | 0.15                 |
| T2:Change at 3 months | 67      | 4.6 (23.6)| 52      | 10.6 (21.9)| 4.90 (-1.93 to 11.7)     | .16 | 1.64 (-5.68 to 8.95)  | .66 | 0.07                 |
| T3:Change at 6 months | 66      | 9.0 (22.6)| 59      | 9.9 (24.0)| 1.15 (-5.52 to 7.82)     | .73 | -1.77 (-8.90 to 5.36) | .62 | -0.08                |
| Emotional Function    |         |           |         |           |                           |   |                           |   |                      |
| T0:Baseline           |         |           |         |           |                           |   |                           |   |                      |
|                         | T1: Change at Post | T2: Change at 3 months | T3: Change at 6 months |
|-------------------------|--------------------|------------------------|------------------------|
| Physical Function       |                    |                        |                        |
| T0: Baseline            | 86                 | 69.5 (21.5)            | 78                     |
|                         | 67                 | 67.6 (22.3)            |
| T1: Change at Post      | 73                 | 0.8 (20.1)             | 60                     |
|                         | 67                 | 3.7 (20.7)             | 3.7 (20.4)             |
| T2: Change at 3 months  | 67                 | 10.6 (18.4)            | 6.89 (0.59 to 13.2)    |
|                         | 66                 | 8.5 (18.5)             | 5.58 (-0.57 to 11.7)   |
| T3: Change at 6 months  | 66                 | 4.3 (21.0)             | 78.0 (19.8)            |
|                         | 66                 | 65.5 (29.1)            | 62.1 (33.0)            |
|                         | 63.8 (29.2)        | 32.5 (24.9)            | 16.3 (26.5)            |
|                         | 59                 | 9.7 (30.9)             | 15.4 (31.5)            |
| Role Function           | 86                 | 65.5 (29.1)            | 62.1 (33.0)            |
| T0: Baseline            | 86                 | 60.8 (19.8)            | 77                     |
|                         | 66                 | 60.4 (20.6)            |
| T1: Change at Post      | 73                 | -4.2 (16.6)            | 59                     |
|                         | 67                 | 1.5 (20.4)             | 51                     |
| T2: Change at 3 months  | 67                 | 3.3 (18.8)             | 6.2 (30.3)             |
|                         | 66                 | 6.3 (19.2)             | 2.27 (15.8)            |
| T3: Change at 6 months  | 66                 | 3.0 (18.6)             | 21.2 (29.1)            |
|                         | 66                 | 6.3 (19.2)             | 23.3 (38.0)            |
| Social Function         | 86                 | 63.8 (29.2)            | 78                     |
| T0: Baseline            | 86                 | 59.2 (31.6)            |
| T1: Change at Post      | 73                 | -0.5 (26.9)            | 60                     |
|                         | 67                 | 4.4 (24.9)             | 4.4 (24.9)             |
| T2: Change at 3 months  | 67                 | 16.3 (26.5)            | 2.43 (-5.91 to 10.8)   |
|                         | 66                 | 18.6 (32.2)            | -0.77 (-8.91 to 7.36)  |
| T3: Change at 6 months  | 66                 | 15.4 (31.5)            | 18.6 (32.2)            |

|                         |                     |                        |
|                         | .58                 | 1.67 (-4.98 to 8.32)   |
|                         | .03                 | 7.04 (0.15 to 13.9)    |
|                         | .08                 | 5.45 (-1.29 to 12.2)   |
|                         | .58                 | 3.7 (20.7)             |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 6.89 (0.59 to 13.2) | 1.46 (-4.11 to 7.03)   |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                         | .99                 | -2.74 (-8.49 to 3.01)  |
|                         | 1.46 (-4.11 to 7.03)| .61                     |
|                         | 1.63 (-3.79 to 7.05)| .55                     |
|                          | T0: Baseline | T1: Change at Post | T2: Change at 3 months | T3: Change at 6 months |
|--------------------------|--------------|--------------------|------------------------|------------------------|
| **Cognitive Function**   |              |                    |                        |                        |
| T0: Baseline             | 86           | 68.0 (25.3)        | 78                     | 65.8 (28.4)            |
| T1: Change at Post       | 73           | -3.9 (22.0)        | 60                     | 2.2 (20.5)             |
| T2: Change at 3 months   | 67           | 5.0 (21.5)         | 52                     | 7.1 (21.2)             |
| T3: Change at 6 months   | 66           | 7.8 (23.1)         | 59                     | 4.8 (25.3)             |
|                          |              |                    |                        |                        |
| **Anxious Preoccupation**|              |                    |                        |                        |
| T0: Baseline             | 86           | 18.3 (6.2)         | 78                     | 18.1 (6.3)             |
| T1: Change at Post       | 73           | -1.1 (4.4)         | 60                     | -1.4 (4.1)             |
| T2: Change at 3 months   | 67           | -1.9 (4.3)         | 51                     | -1.8 (4.4)             |
| T3: Change at 6 months   | 66           | -1.9 (4.9)         | 59                     | -2.3 (4.5)             |
|                          |              |                    |                        |                        |
| **Helpless/Hopelessness**|              |                    |                        |                        |
| T0: Baseline             | 86           | 11.3 (3.8)         | 78                     | 11.6 (4.2)             |
| T1: Change at Post       | 73           | 0.0 (3.8)          | 60                     | -0.4 (3.1)             |
| T2: Change at 3 months   | 67           | 0.2 (3.6)          | 51                     | -0.3 (3.6)             |
| T3: Change at 6 months   | 66           | -0.5 (4.2)         | 59                     | -0.4 (3.2)             |
|                          |              |                    |                        |                        |
| **Cognitive Avoidance**  |              |                    |                        |                        |
| T0: Baseline             | 86           | 9.0 (3.2)          | 78                     | 8.4 (3.0)              |
| T1: Change at Post       | 73           | -0.4 (2.6)         | 60                     | 0.6 (2.9)              |
| T2: Change at 3 months   | 67           | -0.3 (3.2)         | 51                     | 0.6 (3.1)              |
| T3: Change at 6 months   | 66           | -0.3 (3.3)         | 59                     | 0.6 (2.9)              |
| Total Health Service Use                        | T0:Baseline | T1:Change at Post | T2:Change at 3 months | T3:Change at 6 months |
|-----------------------------------------------|-------------|-------------------|-----------------------|----------------------|
|                                               | 86          | 5.0 (3.5)         | 2.1 (1.9)             | 2.0 (1.8)            |
|                                               | 73          | 3.8 (2.7)         | 2.0 (1.9)             | 2.5 (2.0)            |
|                                               | 67          | 67                | 67                    | 67                   |
|                                               | 66          | 1.3 (0.5)         | 1.3 (0.5)             | 1.3 (0.5)            |
|                                               |             | -1.07 (-1.85 to -0.28) | 0.03 (-0.80 to 0.86)  | 0.70 (-0.11 to 1.51) |
|                                               |             | 0.86              | 0.86                  | 0.86                 |
|                                               |             | -0.04 (-0.92 to 0.85) | 0.04 (-1.00 to 1.00)  | 0.04                 |
|                                               |             | -0.01             | -0.01                 | -0.01               |
| Hospital length of stay                      |             |                   |                       |                      |
|                                               |             | 1.1 (1.3)         | 0.6 (4.5)             | 0.4 (5.1)            |
|                                               |             | 1.4 (2.1)         | 0.2 (5.7)             | -0.6 (3.0)           |
|                                               |             |                   |                       |                      |
| No. Specialists/Consultants                  |             | 1.0 (0.5)         | 2.6 (2.8)             | 0.4 (5.1)            |
| Accessed                                     |             | 1.3 (0.5)         | 2.7 (3.0)             | -0.6 (3.0)           |
|                                               |             |                   |                       |                      |
| No. Supportive-Care Practitioners Accessed   |             | 0.8 (0.6)         | 1.7 (2.2)             | 1.4 (1.5)            |
|                                               |             |                   |                       |                      |
|                                               |             | 0.7 (0.5)         | 0.9 (2.5)             | 0.9 (1.4)            |
|                                               |             |                   |                       |                      |
Table 3. Percentage of intervention (n=78) or control (n=86) participants who experienced clinically significant improvements or deteriorations, based on reliable change indices, at each follow-up assessment.

| Outcome                  | Post | 3 months | 6 months |
|--------------------------|------|----------|----------|
|                          | Improved | Deteriorated | Improved | Deteriorated | Improved | Deteriorated |
|                          | FMW | C | FMW | C | FMW | C | FMW | C | FMW | C | FMW | C |
| Cancer distress          | 12.1%  | 9.7% | 8.6%  | 9.7% | 16.0%  | 13.4% | 6.0%  | 7.5% | 15.5%  | 18.2% | 6.9%  | 9.1% |
| General distress         | 25.0%  | 17.8% | 10%  | 13.7% | 31.4%  | 16.4% | 5.9%  | 7.5% | 27.1%  | 19.7% | 5.1%  | 10.6% |
| Global QOL               | 21.7%  | 12.3% | 8.3%  | 16.4% | 25.0%  | 16.4% | 3.8%  | 10.4% | 30.5%  | 25.8% | 8.5%  | 6.1% |
| Emotional Fn             | 6.7%  | 8.2% | 5.0%  | 2.7% | 11.5%  | 9% | 3.8%  | 4.5% | 16.9%  | 10.6% | 0%  | 4.5% |
| Physical Fn              | 6.8%  | 2.7% | 11.9% | 15.1% | 15.7%  | 9% | 5.9%  | 7.5% | 17.2%  | 12.1% | 3.4%  | 3% |
| Role Fn                  | 25.4%  | 13.7% | 11.9% | 16.4% | 41.2%  | 34.3% | 3.9%  | 13.4% | 46.6%  | 37.9% | 6.9%  | 7.6% |
| Social Fn                | 18.3%  | 13.7% | 10.0% | 12.3% | 36.5%  | 23.9% | 5.8%  | 10.4% | 40.7%  | 33.3% | 6.8%  | 6.1% |
| Cognitive Fn             | 1.7%  | 0% | 5%  | 6.8% | 5.8%  | 3% | 1.9%  | 1.5% | 5.1%  | 4.5% | 1.7%  | 3% |
| Help/hopeless            | 6.7%  | 9.6% | 3.3%  | 8.2% | 5.9%  | 6% | 7.8%  | 7.5% | 5.1%  | 9.1% | 3.4%  | 7.6% |
| Anxious Preocc           | 11.7%  | 12.3% | 3.3%  | 5.5% | 23.5%  | 16.4% | 5.9%  | 3.0% | 22.0%  | 16.7% | 3.4%  | 6.1% |
| Cog Avoidance           | 0%  | 5.5% | 11.7% | 4.1% | 2%  | 11.9% | 13.7% | 3.0% | 0%  | 10.6% | 6.8% | 9.1% |

*Notes.* 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. RCIs could not be calculated for Health Service Utilisation measures.
Figure 2.
Screen shot of Finding My Way website user homepage