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ORIGINAL ARTICLE

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

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Abstract

Purpose This multicentre randomised 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) and 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 suggest *FMW* only met needs while being actively used.

Trial registration ACTRN12613000001796; http://www.ANZCTR.org.au/ACTRN12613000001796.aspx

Keywords Internet intervention · Self-guided · CBT · Distress · Acute survivorship · RCT

Written on behalf of the *Finding My Way* Authorship Group

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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 5 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 [16, 17]. This article reports the psychological and health service outcomes of our multisite 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 states/territories in Australia, with the trial promoted nationally through advocacy groups' research databases. Participation in the study occurred entirely online via www.findingmyway.org.au.

Random assignment

Randomisation occurred at the patient level, stratified by gender (Fig. 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

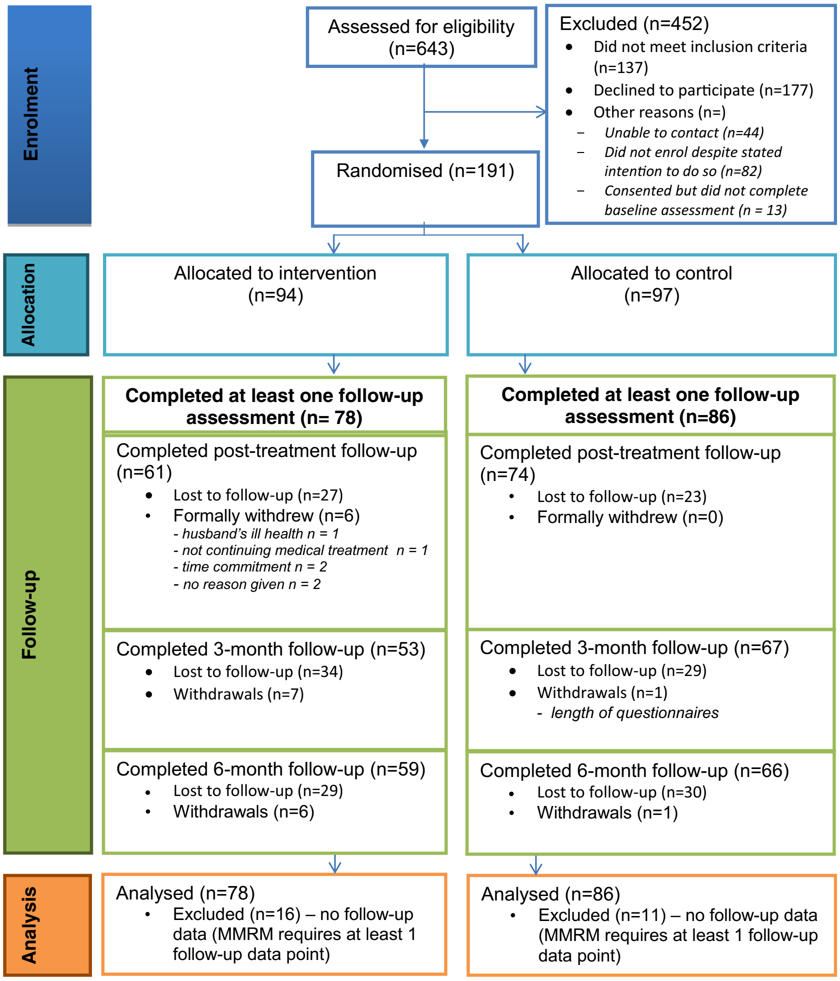

Fig. 1 CONSORT flow diagram

received reminders to complete three follow-up assessments immediately post-intervention (T1), 3-month post-intervention (T2), and 6-month post-intervention (T3).

Intervention

Finding My Way (Fig. 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 1 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.

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			0.358
Stages 0–2	39 (45.3%)	30 (38.5%)	
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
Total difficulty regulating emotions	82.9 (24.1)	83.2 (21.5)	0.925
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

*Other cancer types included; throat, oesophageal, GIST, stomach, rectal, cervical, appendix, parotid, adrenal, multiple myeloma, acute myeloid leukaemia

[†] 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

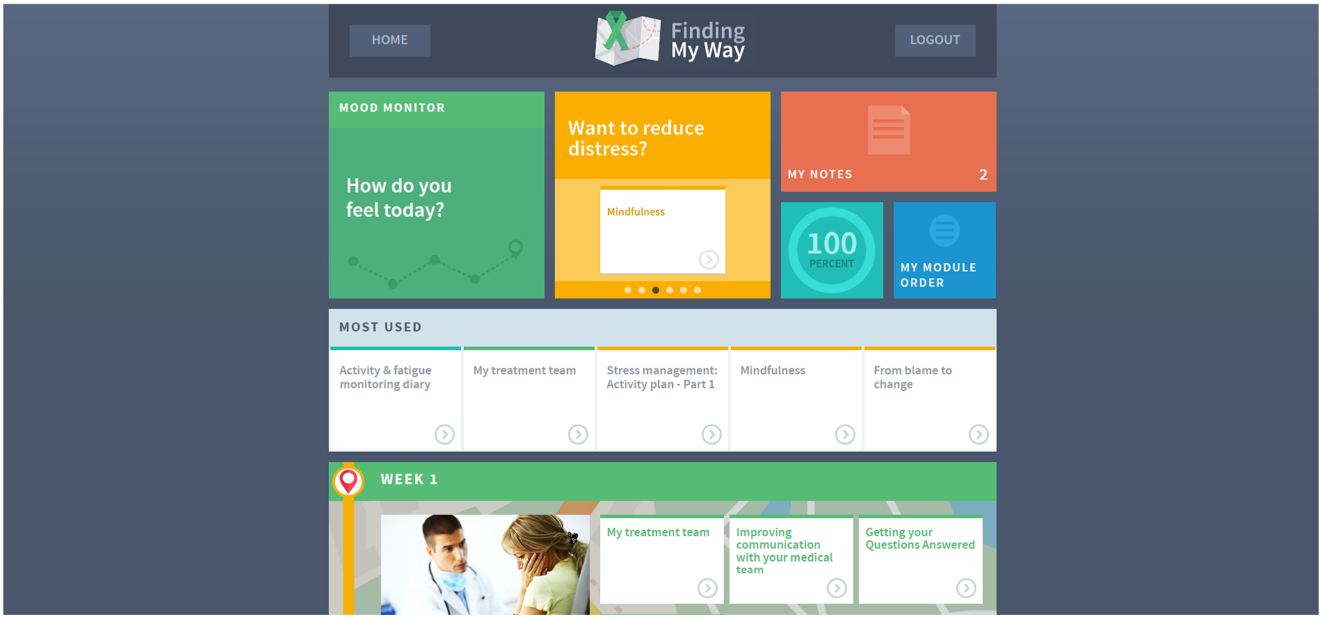

Fig. 2 Screenshot of *Finding My Way* website user homepage

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 $\alpha = .05$ (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) × 3 (time category: post-program, 3 months, 6 months) 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 $SE_{diff} = SD_1\sqrt{2}\sqrt{(1-r)}$, where SD_1 is the standard deviation at baseline and r is the Cronbach's α coefficient of the measure. The RCI equals $1.96 \times SE_{diff}$ and thus represents a cut-off; if a participant's change in scores over two assessments exceeds the RCI value, this is considered to indicate reliable change with 95% confidence (thus above chance).

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 dropouts ($n = 27$) and the mITT sample ($n = 164$) on any outcome measure, with two exceptions: dropouts were younger (*dropouts* M = 49.1 years ± 11.7 vs *mITT.* M = 54.8 years ± 10.4) with lower social functioning (*dropouts* M= 48.1 ± 32.5; vs *mITT* 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 patterns 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 ($P = 0.02$), with a small-to-moderate effect size ($d = -0.38$), but was not sustained at T2 or T3.

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)					
T1:Change at post	72	− 0.8 (6.6)	58	− 0.8 (6.4)	0.35 (− 1.73 to 2.44)	0.74	0.32 (− 1.99 to 2.63)	0.79	0.04
T2:Change at 3 months	67	− 1.8 (6.7)	50	− 1.7 (6.5)	0.10 (− 2.06 to 2.26)	0.93	0.06 (− 2.31 to 2.44)	0.96	0.01
T3:Change at 6 months	66	− 2.2 (6.2)	58	− 1.9 (6.9)	0.08 (− 2.03 to 2.19)	0.94	− 0.00 (− 2.33 to 2.32)	0.99	− 0.00
General distress									
T0:Baseline	86	25.5 (19.1)	78	26.5 (21.7)					
T1:Change at post	73	− 0.9 (17.7)	60	− 3.6 (16.0)	− 1.43 (− 6.40 to 3.54)	0.57	− 1.90 (− 7.41 to 3.61)	0.50	− 0.11
T2:Change at 3 months	67	− 4.2 (17.7)	51	− 8.5 (15.2)	− 4.14 (− 9.35 to 1.07)	0.12	− 4.47 (− 10.2 to 1.26)	0.13	− 0.24
T3:Change at 6 months	66	− 5.4 (16.9)	59	− 9.2 (15.6)	− 2.96 (− 8.03 to 2.11)	0.25	− 3.48 (− 9.07 to 2.10)	0.22	− 0.19
Global QoL									
T0:Baseline	86	56.9 (21.7)	78	55.6 (23.5)					
T1:Change at post	73	− 1.9 (24.1)	60	6.4 (23.1)	6.11 (− 0.42 to 12.6)	*0.07*	3.32 (− 3.71 to 10.3)	0.35	0.15
T2:Change at 3 months	67	4.6 (23.6)	52	10.6 (21.9)	4.90 (− 1.93 to 11.7)	0.16	1.64 (− 5.68 to 8.95)	0.66	0.07
T3:Change at 6 months	66	9.0 (22.6)	59	9.9 (24.0)	1.15 (− 5.52 to 7.82)	0.73	− 1.77 (− 8.90 to 5.36)	0.62	− 0.08
Emotional function									
T0:Baseline	86	69.5 (21.5)	78	67.6 (22.3)					
T1:Change at post	73	0.8 (20.1)	60	3.7 (20.7)	1.70 (− 4.33 to 7.74)	0.58	1.67 (− 4.98 to 8.32)	0.62	0.08
T2:Change at 3 months	67	3.7 (20.2)	52	10.6 (18.4)	6.89 (0.59 to 13.2)	*0.03*	7.04 (0.15 to 13.9)	*0.045*	0.32
T3:Change at 6 months	66	4.3 (21.0)	59	8.5 (18.5)	5.58 (− 0.57 to 11.7)	0.08	5.45 (− 1.29 to 12.2)	0.11	0.25
Physical function									
T0:Baseline	86	80.8 (19.8)	77	80.4 (20.6)					
T1:Change at post	73	− 4.2 (16.6)	59	− 3.8 (21.2)	0.03 (− 5.25 to 5.31)	0.99	− 2.74 (− 8.49 to 3.01)	0.35	− 0.15
T2:Change at 3 months	67	1.5 (20.4)	51	3.3 (18.8)	1.46 (− 4.11 to 7.03)	0.61	− 1.07 (− 7.10 to 4.96)	0.73	− 0.05
T3:Change at 6 months	66	3.0 (18.6)	58	6.3 (19.2)	1.63 (− 3.79 to 7.05)	0.55	− 1.12 (− 6.98 to 4.75)	0.71	− 0.06
Role function									
T0:Baseline	86	65.5 (29.1)	77	62.1 (33.0)					
T1:Change at post	73	− 3.4 (30.2)	59	6.2 (30.3)	6.90 (− 1.65 to 15.4)	0.11	4.91 (− 4.32 to 14.1)	0.30	0.16
T2:Change at 3 months	67	11.4 (33.6)	51	21.2 (29.1)	6.77 (− 2.27 to 15.8)	0.14	5.48 (− 4.23 to 15.2)	0.27	0.17
T3:Change at 6 months	66	16.4 (31.4)	58	23.3 (38.0)	2.48 (− 6.30 to 11.3)	0.58	0.79 (− 8.64 to 10.2)	0.87	0.03
Social function									
T0:Baseline	86	63.8 (29.2)	78	59.2 (31.6)					
T1:Change at post	73	− 0.5 (26.9)	60	4.4 (24.9)	− 0.03 (− 7.97 to 7.91)	0.99	− 2.11 (− 10.8 to 6.60)	0.63	− 0.07
T2:Change at 3 months	67	9.7 (30.9)	52	16.3 (26.5)	2.43 (− 5.91 to 10.8)	0.57	0.64 (− 8.45 to 9.73)	0.89	0.02
T3:Change at 6 months	66	15.4 (31.5)	59	18.6 (32.2)	− 0.77 (− 8.91 to 7.36)	0.85	− 1.88 (− 10.8 to 6.99)	0.68	− 0.07
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)	3.72 (− 3.09 to 10.5)	0.28	2.64 (− 4.81 to 10.1)	0.49	0.11
T2:Change at 3 months	67	5.0 (21.5)	52	7.1 (21.2)	− 0.77 (− 7.89 to 6.36)	0.83	− 1.75 (− 9.50 to 5.99)	0.66	− 0.07
T3:Change at 6 months	66	7.8 (23.1)	59	4.8 (25.3)	− 4.10 (− 11.1 to 2.85)	0.25	− 5.54 (− 13.1 to 2.02)	0.15	− 0.23
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)	− 0.23 (− 1.58 to 1.13)	0.74	− 0.38 (− 1.86 to 1.10)	0.61	− 0.08
T2:Change at 3 months	67	− 1.9 (4.3)	51	− 1.8 (4.4)	0.02 (− 1.40 to 1.43)	0.98	− 0.14 (− 1.67 to 1.40)	0.86	− 0.03
T3:Change at 6 months	66	− 1.9 (4.9)	59	− 2.3 (4.5)	− 0.68 (− 2.06 to 0.71)	0.34	− 0.71 (− 2.21 to 0.79)	0.35	− 0.15

Table 2 (continued)

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*	
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)	− 0.17 (− 1.23 to 0.90)	0.76	0.02 (− 1.15 to 1.19)	0.98	0.00
T2:Change at 3 months	67	0.2 (3.6)	51	− 0.3 (3.6)	− 0.40 (− 1.52 to 0.71)	0.47	− 0.17 (− 1.39 to 1.04)	0.78	− 0.04
T3:Change at 6 months	66	− 0.5 (4.2)	59	− 0.4 (3.2)	− 0.12 (− 1.21 to 0.96)	0.82	0.15 (− 1.04 to 1.33)	0.81	0.04
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)	0.84 (− 0.10 to 1.79)	*0.08*	0.84 (− 0.16 to 1.83)	0.10	0.26
T2:Change at 3 months	67	− 0.3 (3.2)	51	0.6 (3.1)	0.65 (− 0.35 to 1.64)	0.20	0.66 (− 0.39 to 1.70)	0.22	0.19
T3:Change at 6 months	66	− 0.3 (3.3)	59	0.6 (2.9)	0.64 (− 0.32 to 1.61)	0.19	0.58 (− 0.43 to 1.59)	0.26	0.18
Total health service use									
T0:Baseline	86	1.3 (0.5)	78	1.3 (0.5)					
T1:Change at post	73	5.0 (3.5)	61	3.8 (2.7)	− 1.07(− 1.85 to − 0.28)	*0.01*	− 1.04(− 1.89 to − 0.19)	*0.02*	− 0.38
T2:Change at 3 months	67	2.1 (1.9)	53	2.0 (1.9)	0.03 (− 0.80 to 0.86)	0.94	− 0.04 (− 0.92 to 0.85)	0.93	− 0.01
T3:Change at 6 months	66	2.0 (1.8)	59	2.5 (2.0)	0.70 (− 0.11 to 1.51)	0.09	0.63 (− 0.24 to1.49)	0.15	0.22
Hospital length of stay									
T0:Baseline	86	1.1 (1.3)	78	1.4 (2.1)					
T1:Change at post	74	0.6 (4.5)	60	0.2 (5.7)	− 0.10 (− 0.56 to 0.36)	0.67	0.09 (− 0.39 to 0.57)	0.72	− 0.05
T2:Change at 3 months	67	0.9 (6.8)	53	0.5 (5.1)	0.02 (− 0.47 to 0.50)	0.95	0.20 (− 0.31 to 0.70)	0.45	− 0.09
T3:Change at 6 months	65	0.4 (5.1)	59	− 0.6 (3.0)	0.06 (− 0.41 to 0.54)	0.79	0.17 (− 0.32 to 0.67)	0.49	− 0.13
No. of specialists/consultants accessed									
T0:Baseline	86	1.0 (0.5)	78	0.8 (0.6)					
T1:Change at post	73	2.6 (2.8)	61	2.7 (3.0)	0.05 (− 0.73 to 0.83)	0.91	0.09 (0.94to − 0.77)	0.84	0.03
T2:Change at 3 months	67	1.2 (1.9)	53	1.4 (2.0)	0.25 (− 0.57 to 1.07)	0.56	0.35 (− 0.54 to 1.24)	0.45	0.12
T3:Change at 6 months	66	1.7 (2.2)	59	1.4 (1.5)	− 0.27 (− 1.07 to 0.54)	0.51	− 0.12 (− 0.99 to 0.75)	0.79	− 0.04
No. of supportive care practitioners accessed									
T0:Baseline	86	0.8 (0.5)	78	0.7 (0.5)					
T1:Change at post	73	2.5 (2.5)	61	1.7 (2.1)	− 0.64(− 1.21 to − 0.06)	*0.03*	− 0.64(− 1.27 to − 0.02)	*0.04*	− 0.32
T2:Change at 3 months	67	1.1 (1.5)	53	1.1 (1.2)	0.14 (− 0.46 to 0.74)	0.64	0.11 (− 0.54 to 0.75)	0.75	0.05
T3:Change at 6 months	66	0.9 (1.4)	59	1.5 (1.5)	0.78 (0.19 to 1.37)	*0.01*	0.71 (0.07 to 1.34)	*0.03*	0.34

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% vs 17.8%), global QoL (21.7% vs 12.3%), role functioning (25.4% vs 13.7%), and social functioning (18.3% vs 13.7%). Fewer intervention participants experienced clinically significant deteriorations across most measures, except emotional functioning (5% vs 2.7%) and cognitive avoidance (11.7% vs 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 multisite 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 [15, 18, 19]. In contrast with the CancerCope trial for newly diagnosed distressed patients [19], where no QoL impact was found, our study found FMW significantly improved

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%

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 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, 8–10]. 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, 18, 19], 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 multicentre RCT of an unguided online psychosocial intervention for *newly diagnosed* acute cancer survivors to show 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.

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Compliance with ethical standards

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.

Conflict of interest The authors declare that they have no conflict of interest.

Disclaimer The authors have full control of all primary data and agree to allow the journal to review our data if requested.

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