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**Title:** Moderators of intervention efficacy for *Finding My Way*: A web-based psychosocial intervention for cancer-related distress

**Short Running Title:** Finding My Way RCT moderator analysis

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## Abstract

**Purpose:** The present analysis explores whether demographic, psychosocial, or intervention adherence factors moderated treatment efficacy of Finding My Way (FMW), an efficacious self-directed web-based psychosocial program for newly diagnosed curatively treated cancer patients.

**Methods:** Participants (n=191) completed a 6-module intervention (n=94) or attention-control (n=97) programs. Outcome measures were completed at baseline (T0), post-program (T1), 3-month (T2), and 6-month (T3) follow ups. Age, gender, social support, information processing style (monitoring vs blunting), emotion-regulation difficulties, and intervention adherence were examined as potential moderators.

**Results:** *Age* moderated emotional functioning and general distress at T3 with significant intervention benefits only observed in younger participants; age moderated cognitive functioning at T1, with intervention benefits only found in older participants. *Gender* moderated helplessness/hopelessness, emotional functioning, and cognitive avoidance at T1 with men benefitting more from receiving the intervention vs control. *Monitoring information-processing style* moderated cancer distress and anxious preoccupation at T3: higher monitors benefitted more from receiving the intervention vs control. *Program adherence* moderated global QOL, emotional functioning and social functioning at T2 and T3; cognitive avoidance (T1), anxious preoccupation (T2) and role function (T3), with those who completed more of the program benefitting more if they received the intervention than control. *Emotion dysregulation* and *social support* each moderated role function at T2, with those more dysregulated and less socially supported benefitting more if they received the intervention than control.

**Conclusions:** For select outcomes, FMW is more effective for patients with specific characteristics; these findings can inform future tailoring and targeting of online programs for cancer-distress.

Word count: 250

**Keywords:** cancer; oncology; psycho-oncology; eHealth; self-management; online intervention; moderators

Online psychosocial interventions improve cancer-related distress, coping and quality of life (QOL) and selected late effects, such as fatigue, in survivors with early-stage cancer [1-3]. Three RCTs have evaluated online programs targeting recently diagnosed patients with varying efficacy [4-6]. Our group evaluated our self-directed online CBT-based program, *Finding My Way*, for newly-diagnosed, curatively treated cancer patients [7]. Both the intervention and attention-control (online psychoeducation) programs reduced distress, however the intervention led to greater reductions in health-service utilisation post-intervention, and improved emotional functioning QOL at 3-month follow-up [7].

While promising, psychosocial interventions do not yield universal benefit. Insight into who benefits most can lead to better tailoring of intervention [8]. One meta-analysis of 22 psycho-oncology intervention RCTs indicated that QOL, emotional and social functioning benefits were moderated by age, baseline symptom severity and therapy type [8]; larger effects were found for *younger* patients; patients with *elevated baseline distress*; and those who received *psychotherapy* compared to informational, support-based, and coping skills training programs [8]. Earlier reviews found effects on distress/wellbeing were larger in interventions of longer duration [9]; in patients with higher baseline distress [9] with cancers other than breast cancer [10], and in older, male, and lower income participants [10].

To date, only one study has reported moderators of an *online* psycho-oncology intervention after cancer diagnosis. Willems et al. [11] found that gender, age and receiving chemotherapy moderated specific outcomes at 6-month follow-up: larger effects were found for social functioning in men; for fatigue in participants under 56 years of age; and for depression in those who received chemotherapy. At 12-months, intervention participants with medium levels of education had higher social functioning, whereas those with lower education levels had lower social functioning. One further study has examined moderators of an online skin cancer *prevention* intervention among young adults at risk of, cancer [12]. The study found that intervention effects were larger among those with a family history of skin

cancer; a recent history of indoor tanning; a perception of the intervention as helpful; and higher program engagement/adherence.

Collectively, these studies suggest that selected demographic (age and gender), clinical (cancer type; receiving chemotherapy), psychosocial (baseline distress), and intervention (longer duration, adherence) characteristics all have the potential to moderate outcomes. None of the studies/reviews to date have explored established psychosocial factors known to moderate distress in cancer, such as social support [13,14], a monitoring style of processing health information [15], and being vulnerable to distress via difficulties regulating emotions [16]. The effective use of emotion regulation strategies is theorised as crucial to reducing negative affective states following stressful events in various clinical populations, including cancer [16,17]. Interventions that teach emotion regulation strategies, particularly via online modalities where individuals can self-pace their learning, are likely to benefit those more vulnerable to distress. Likewise, information-processing style impacts outcomes, as those who 'monitor' for information require more detailed content to reduce uncertainty and tolerate distress, compared with low monitors [18]. It thus follows that monitors are likely to benefit more from online CBT-based interventions, like *Finding My Way*, given the accessible and detailed content provided.

Given the minimal moderator analyses specifically in online interventions, we aimed to address this gap with a moderator analysis of data from our *Finding My Way* study. The present analysis did not evaluate baseline distress; our finding that baseline distress did not moderate outcomes has already been reported [7]. Based on previous studies, our published protocol specified *a priori* moderator hypotheses that (a) those with higher motivation to seek/monitor information, (b) lower social support, and (c) higher vulnerability to distress would benefit more from the intervention [19]. Given the recent online intervention studies outlined above, age, gender, and intervention-adherence were selected to establish whether they likewise moderate outcomes.

## Methods

### Participants

The *Finding My Way* (FMW) RCT [19,7] enrolled 191 cancer patients (41% recruitment rate). Participants were recruited via clinicians and research staff from six participating hospital sites around Australia, two research registries, or self-referral from promotional materials. Participants were eligible if they were: (a) recently diagnosed with a cancer being treated with curative intent; (b) currently receiving anti-cancer treatment (surgery, radiotherapy, chemotherapy) or, for those who received surgery alone, were within 6 months of diagnosis (to ensure relevancy of the intervention's content); (c) aged 18 years or older; (d) with sufficient English to provide informed consent and utilise the program; and (e) able to access the internet and email.

### Procedures:

Ethics 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). Participants completed an online consent and baseline assessment, and were then randomised at the patient level, 1:1 in blocks of four, to receive either the intervention or online attention-control, with randomisation blinded and stratified by gender. Following the 6-week intervention period, participants completed three follow-up assessments: immediately post-intervention (T1), then 3-months (T2) and 6-months (T3) post-intervention.

### Interventions:

***Finding My Way*** (FMW) is a 6-week / 6-module password-protected web-based program comprising: (1) psycho-education including survivor testimonials in video and written formats (72 pages); and (2) cognitive-behaviour therapy-based strategies, including worksheets, quizzes, relaxation and meditation exercises (47 pages). FMW addresses the

most commonly-experienced psychosocial concerns and issues that occur during diagnosis, medical treatment, and treatment-completion. Details of the intervention are published elsewhere [19].

**Attention Control:** An information-only version of FMW contained the same psycho-education provided to intervention participants including video content, but did not contain the worksheets/therapeutic activities.

**Measures:**

The following outcomes were assessed, using established self-report measures with demonstrated psychometric properties among cancer populations. For instrument-specific details see the published protocol [19].

**Participant characteristics:** Self-reported demographic and clinical factors were collected at baseline: gender, age, area of residence, marital status, employment status, level of educational attainment, annual gross income, cultural affiliations, cancer type, date of diagnosis, treatments received, and family history of cancer.

**Primary outcome measure:** *Cancer-specific distress*, was measured with the post-traumatic stress scale self-report [20], with items anchored to cancer diagnosis as the stressor. Participants rate the severity of each DSM-IV post-traumatic stress disorder symptom experienced in the previous week, on a 4-point scale (0=not at all, to 3 = almost always). Total scores range from 0 to 51; higher scores indicate higher cancer-specific distress.

**Secondary outcome measures:** Secondary outcomes were *general distress* (the 21 item Depression Anxiety Stress Scales-21 [21]; *global QOL*, and *five QOL functioning subscales* – physical, emotional, social, cognitive, and role functioning (EORTC QOL Core Questionnaire [22]); three *maladaptive coping domains* – helplessness/hopelessness, cognitive avoidance, anxious preoccupation (mini-Mental adjustment to Cancer scale [23]); 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 [17]).

**Moderators:** Gender, age, social support, information-seeking preferences, vulnerability to distress, and adherence to the program were assessed at baseline. *Social support* was assessed using the total scale score of the 20-item Medical Outcome Study Social Support Survey [24]; *information seeking preferences* was measured by the Miller Behavioral Style Scale [25], which classifies the degree to which people look for and amplify threat-related cues (monitors), versus employ distraction or avoid / minimize such cues (blunters). *Vulnerability to distress* was assessed using the total scale score of the Difficulties in Emotion Regulation Scale [26], a 36-item measure of difficulties in emotion regulation. *Intervention adherence* was tracked on the website itself via the number of pages viewed (of the 72 maximum pages of psychoeducation common to both intervention and control).

### **Statistical Analyses**

The SAS statistics program was used for all analyses. Two ANCOVA models were run at each time point for each outcome: (i) unadjusted – which included the baseline covariate of each respective outcome, group, moderator, and group\*moderator interaction as fixed effects; and (ii) fully adjusted ANCOVA models which additionally included the following baseline covariates to control for any baseline differences in demographic, clinical and psychosocial characteristics between groups, to replicate the covariates entered the main FMW outcome efficacy analysis [7]: age, gender, marital status, income, education, monitoring, cancer type, days since diagnosis, and the baseline measure of the outcome. Sensitivity analyses verified that the fully adjusted models did not change results. Statistically significant results were defined as  $p < 0.05$ , with a two-tailed significance level.

## Results

### Participant characteristics:

Figure 1 shows the flow of participants through the trial. A total of 191 eligible, contactable patients consented to participate and were randomised. Compared to decliners, trial-participants were younger, more likely to be female, and have breast cancer [27]. Participants who completed at least one follow-up assessment were included in the modified intention-to-treat moderator analysis (n=166). As shown in table 1, intervention participants were an average age of 55.4 years (SD=11.1) and controls, 54.3 years (SD = 9.9). The majority were women (n=138; 83%), had breast cancer (104; 63%), were partnered (n=128; 77%), and tertiary educated (n= 118; 71%).

### Moderation analyses:

Significant results are summarised in Table 2; for full results refer to online supplementary files A (tables) and B (plots).

*Demographic characteristics:* Age moderated general distress (interaction estimate = -0.593,  $p=0.03$ ) and emotional functioning (interaction estimate = 0.89,  $p=0.01$ ) at 6-month follow-up (T3), with younger participants showing more improvement if they received the intervention versus control, compared to older participants. Age also moderated cognitive functioning at post-intervention (T1) (interaction estimate = -0.72,  $p=0.05$ ); however *older* participants had higher cognitive functioning than control participants if they received the intervention, whereas younger intervention participants had lower cognitive functioning than controls at this timepoint.

*Gender* moderated a number of post-intervention (T1) outcomes – emotional functioning (interaction estimate = 23.33,  $p=0.02$ ), helplessness/hopelessness (interaction estimate=-3.75,  $p=0.04$ ), and cognitive avoidance (interaction estimate=-2.91,  $p=0.04$ ). Male

participants had higher emotional functioning, lower helplessness/hopelessness and lower cognitive avoidance if they received the intervention rather than control; no differences between female intervention and control participants were found, with the exception that female intervention participants had higher cognitive avoidance than control.

*Social Support:* Social support moderated role functioning at 3-month follow-up (T2) (interaction estimate = 0.65,  $p=0.04$ ), such that those with *lower* social support benefitted more from receiving the intervention than the control. No other outcome was moderated by social support.

*Vulnerability to Distress (difficulties regulating emotions):* Difficulties regulating emotions moderated Role Functioning at 3-month follow-up (T2) (interaction estimate = -0.44,  $p =0.04$ ), with those who had *more* difficulties with regulating their emotions benefitting more from receiving *FMW* than the control condition, than those lower in emotion dysregulation. It did not moderate treatment efficacy for other outcomes.

*Information Processing Style:* Having a *monitoring* information processing style moderated two outcomes at 6-month follow-up (T3): cancer-related distress (interaction estimate 1.38,  $p =0.05$ ), and anxious preoccupation (interaction estimate = 1.14,  $p = 0.02$ ). Higher monitors had lower distress if they received the intervention compared to control; while lower monitors had lower distress if they received the control compared to the intervention. For anxious preoccupation, higher monitors benefitted more from receiving the intervention vs control, whereas there were no differences in levels of anxious preoccupation between intervention and control groups for low monitors. Having a *blunting* information processing style did not moderate any outcome.

*Intervention adherence:* The number of pages accessed by participants moderated several outcomes across the follow-up period. At post-intervention (T1), adherence moderated cognitive avoidance (interaction estimate=-0.05,  $p=0,04$ ): as adherence increased (i.e., more pages were completed) cognitive avoidance increased for participants

allocated to the intervention vs control condition. Adherence moderated multiple QOL outcomes, including Global QOL, emotional functioning and social functioning. Adherence moderated global QOL at 3-month (T2) (interaction estimate = -0.50,  $p=0.01$ ) and 6-month (T3) follow-up (interaction estimate=-0.45,  $p=0.01$ ): higher adherence was associated with higher global QOL among intervention participants compared to control; whereas lower adherence was associated with higher global QOL among control compared to intervention participants. At 6-month follow-up (T3), adherence also moderated emotional functioning (estimate=-0.39,  $p=0.02$ ), with intervention participants having higher emotional functioning than control participants as they accessed more pages. For social functioning (estimate=-0.47,  $p=0.04$ ) at 6-month follow-up, intervention participants had higher social functioning than controls as they completed more pages, while control participants had higher levels than intervention participants when adherence levels were low.

## Discussion

This study adds to the published literature, in both cancer and non-cancer populations, by being the first to explore whether psychosocial factors, beyond baseline distress, moderate online intervention outcomes. The main finding from this study was that *no* demographic, psychosocial, or adherence factor consistently moderated an outcome across *all* follow-up time points. Thus, more work needs to be done to understand why different factors moderate different outcomes over time. However, for select outcomes and time points, *FMW* was relatively more efficacious than attention-control for younger participants, with the exception of cognitive function where older participants benefitted more; in men; among those with monitoring information-processing style; and for those who had higher program-adherence. In addition, social support and difficulties regulating emotion were found to moderate role functioning, with those more vulnerable (i.e., less social support, and more emotionally dysregulated) benefitting more from the intervention.

Our finding that the intervention had a greater effect for men than women in improving emotional function, lower helplessness/hopelessness coping style, and less

cognitive avoidance, is consistent with meta-analytic findings of therapist-delivered psycho-oncology interventions [10], and has similarities to the findings obtained by Willems et al. [11], who found that at 6-month follow-up, their Cancer Aftercare Guide led to larger effects for social functioning for men. In our study there were no differences between female intervention and control participants on these measures post-intervention, except for having higher cognitive avoidance if they received the intervention. This gender effect directly contrasts with the bias often reported with uptake – where far more women than men are screened for, and take up, psychosocial interventions [10] – a finding also observed in our RCT [27]. Indeed, it is well established that there are gender differences in the prevalence of help seeking for, and diagnosis of emotional difficulties and coping, with women more likely to recognise and seek support for distress symptoms [19]. Yet once enrolled, men derive more benefit on selected short-term outcomes. Heron-Speirs et al. [10] provided a comprehensive evaluation of possible explanatory mechanisms for this gender effect, including that due to men delaying seeking help, they often have more elevated baseline distress with a resulting larger scope for improvements; thus, these programs fill a particular need for men given the limited availability of (or willingness to seek) other supports and resources. Whether a three-way interaction (gender x baseline distress x intervention group) exists could usefully be explored in future studies.

Our findings regarding age as a moderator add to Willems et al. [11] online intervention study, who found a larger effect for fatigue in younger patients; younger participants in our study benefitted more from receiving the FMW intervention than controls for two outcomes: general distress and emotional functioning. This supports the broader evidence-base for age moderating outcomes irrespective of delivery modality, and gives weight for the notion of tailoring interventions to this group, given recent meta-analytic findings also demonstrate younger patients had higher QOL following receipt of therapist-administered psycho-oncology interventions [8]. Given the literature demonstrating that younger cancer patients are more likely to have elevated distress [28], it is logical that they

would have more scope to benefit from a program aimed at ameliorating distress and improving emotional functioning.

A unique finding of the present study was that the reverse pattern occurred for cognitive functioning, where older participants benefitted more. The exact mechanism for FMW improving cognitive function in older patients is less clear but it may be that consenting to a program which required weekly attention and concentration improved functioning simply through participation [29]. Evidence suggests that (a) sustained attention interventions, and (b) physical activity are two key non-pharmacological interventions for cognitive functioning. In addition, many of the skills taught and encouraged in the program – behavioural activation, activity pacing, and mindfulness may also have indirectly led to improved cognitive functioning outcomes via the stress-reduction pathways in the brain[29].

Our findings that high monitors tended to have lower distress and less anxious preoccupation at 6-month follow-up if they received the intervention than control, and that low monitors benefitted from receiving less information (i.e., the control version), was consistent with our predictions, and is the first study to demonstrate this in an online intervention. Prior research demonstrates that high monitors tend to focus on threat, generally know more about their illness, and acquire more detailed information compared to low monitors; thus seeking this information tends to help reduce uncertainty[18]. High monitors tend to experience more negative affective outcomes when left untreated[15], such as more anxiety during periods of uncertainty than low monitors [18]. Reviews have suggested that psychoeducational interventions will improve outcomes when the level and type of information provided is consistent with the monitoring style [15]; the present findings thus provide evidence that online interventions should be tailored to monitoring style. Future iterations of our program can be refined to tailor content based on this finding with built in functionality that users can ‘reduce’ or ‘expand’ content to regulate the amount of information they can view.

Two new findings from our study were that stronger intervention effects on role functioning at 3-month follow-up were found among those with *lower* social support and *higher* emotional dysregulation respectively. These results extend recent findings that emotion dysregulation correlates with distress and is a useful screen for referral to intervention[16], and the demonstrated role of social support in buffering distress [14], by collectively suggesting that those who are more vulnerable may benefit more from an online psychosocial program for cancer.

Finally, our finding that multiple intervention effects were moderated by higher program engagement/adherence was consistent with the recent study of an online skin cancer prevention [12], and with previous meta-analyses of moderators of psycho-oncology interventions [9]. While the global, emotional and social quality of life findings were in the direction anticipated – with higher QOL among participants who completed more of the program – the finding that higher cognitive avoidance was also found in intervention participants with higher program adherence was unexpected and counterintuitive. One could speculate this is related to our finding of reduced anxious preoccupation among high monitors; that these coping styles fall on a spectrum, thus reducing one and increasing the other actually achieves a middle-ground state of acceptance. Conversely, it is possible that the content was perceived as overwhelming, leading to disengagement post-intervention, thus driving up avoidance scores. However, given the absence of similar increases across other distress outcomes, this seems less likely. Researchers should consider how programs are designed and whether we are inadvertently exposing some end-users to information-overload. Future studies should consider utilising an iterative co-design framework, which would reduce these issues [30,31].

A number of limitations should be noted. Bonferroni adjustments were not made, given the exploratory nature of the study; caution is therefore warranted when interpreting findings given the large number of analyses conducted. Second, selective drop-out might have influenced the results, given the modestly higher dropout rates observed in the

intervention group. Third, adherence for this analysis was only measured in terms of number of psychoeducational pages viewed; whether adherence to the CBT worksheets may have impacted outcomes was not assessable in the present study. In addition, as previously reported, while the study was open to all early stage cancer patients, women, typically with breast cancer, were overrepresented in our sample. While this impacts generalisability of our findings, the profile of our participants reflects the cancer population more broadly, with women with breast cancer representing a large percentage of patients annually diagnosed.

### **Clinical implications**

While further research is required to elucidate robust moderators of outcomes over time, and the reasons why certain moderators are more impactful, our findings hint at who may stand to derive the most benefit from online intervention— younger, men, those with higher tendencies to monitor for information, and those with low social support and higher emotion dysregulation. This information can be used to assist clinicians to tailor screening of individuals with these characteristics to refer to FMW and to inform the personalisation of digital interventions. Just as personalised medicine [32], digital psychosocial interventions could be personalised to target those who may benefit the most [33]. Finally, the finding that program adherence moderated a number of outcomes highlights the importance of strategies to promote program adherence more broadly.

### **Conclusion**

The results of the current study provide new insights into who benefits most from an online psychosocial program for cancer. FMW was more effective than attention-control for younger participants (except cognitive function where the reverse was true), in men, among those with monitoring information-processing style, and for those who complete more of the program. For role functioning, stronger intervention effects were also found for those with lower social support and higher emotional dysregulation. While replication in larger studies



powered specifically for moderator analyses is required, these exploratory findings can be used to inform future tailoring and targeting of online programs for cancer-distress.

## **Declarations**

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**Conflicts of Interest:** The authors have no conflicts of interest to declare.

**Ethics approval:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by 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.

**Consent to participate/publish:** Informed consent was obtained from all individual participants included in the study.

**Availability of data and material:** De-identified data and material are available upon request.

**Code availability:** not applicable.

**Authors contributions:** All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Lisa Beatty and Emma Kemp (with statistical consultation from Joseph Coll). The first draft of the manuscript was written by Lisa Beatty and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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**Conflict of interest statement:** None declared.

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## Tables

**Table 1. Baseline participant demographic and clinical characteristics (n=166)**

|                                     | <b>Control<br/>(n=86)</b> | <b>FMW<br/>(n=78)</b> | <b><i>p</i></b> |
|-------------------------------------|---------------------------|-----------------------|-----------------|
| Mean age at baseline (SD), years    | 54.3 (9.9)                | 55.4 (11.1)           | 0.522           |
| Female sex                          | 73 (84.9%)                | 65 (83.3%)            | 0.786           |
| 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 |                           |                       | <b>0.007</b>    |
| 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%)            | <b>0.036</b>    |
| 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           |

**Table 1 continued.**

|                                      | Control<br>(n=86) | FMW<br>(n=78) | <i>p</i>     |
|--------------------------------------|-------------------|---------------|--------------|
| 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 <sup>†</sup>                 | 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        |
| <b><i>A Priori Moderators</i></b>    |                   |               |              |
| 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)     | <b>0.029</b> |
| Blunting                             | 2.2 (1.2)         | 2.4 (1.1)     | 0.264        |

Notes: \*other cancer type included:

<sup>†</sup>Unclear stage = could not be determined based on information provided by participant;

<sup>††</sup>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. Moderator analyses (ANCOVA) – Summary of significant group x moderator interactions

| <b>Outcome</b>            | <b>Time<sup>1</sup></b> | <b>Group estimate</b> | <b>Group <i>p</i></b> | <b>Moderator estimate</b> | <b>Moderator <i>p</i></b> | <b>Interaction estimate</b> | <b>Interaction <i>p</i></b> |
|---------------------------|-------------------------|-----------------------|-----------------------|---------------------------|---------------------------|-----------------------------|-----------------------------|
| Cancer Distress           |                         |                       |                       |                           |                           |                             |                             |
| Monitoring                | 3                       | -6.10                 | 0.05                  | -0.56                     | 0.29                      | 1.38                        | 0.05                        |
| General Distress          |                         |                       |                       |                           |                           |                             |                             |
| Age                       | 3                       | 34.06                 | 0.03                  | 0.22                      | 0.21                      | -0.59                       | 0.03                        |
| Global QOL                |                         |                       |                       |                           |                           |                             |                             |
| Adherence                 | 2                       | 18.48                 | 0.03                  | 0.14                      | 0.30                      | -0.50                       | 0.01                        |
| Adherence                 | 3                       | 20.11                 | 0.01                  | 0.24                      | 0.07                      | -0.45                       | 0.01                        |
| Emotional Function        |                         |                       |                       |                           |                           |                             |                             |
| Gender                    | 1                       | -23.9                 | 0.02                  | -15.16                    | 0.07                      | 23.33                       | 0.02                        |
| Age                       | 3                       | -51.14                | 0.01                  | -0.22                     | 0.30                      | 0.89                        | 0.01                        |
| Adherence                 | 3                       | 14.19                 | 0.05                  | 0.10                      | 0.40                      | -0.39                       | 0.02                        |
| Social Function           |                         |                       |                       |                           |                           |                             |                             |
| Adherence                 | 3                       | 22.57                 | 0.03                  | 0.38                      | 0.03                      | -0.47                       | 0.04                        |
| Cognitive Function        |                         |                       |                       |                           |                           |                             |                             |
| Age                       | 1                       | 35.27                 | 0.09                  | 0.28                      | 0.27                      | -0.72                       | 0.05                        |
| Role Function             |                         |                       |                       |                           |                           |                             |                             |
| Social Support            | 2                       | -59.89                | 0.02                  | -0.08                     | 0.77                      | 0.65                        | 0.04                        |
| Emotion dysregulation     | 2                       | 29.80                 | 0.11                  | 0.08                      | 0.67                      | -0.44                       | 0.04                        |
| Helplessness/Hopelessness |                         |                       |                       |                           |                           |                             |                             |
| Gender                    | 1                       | 4.40                  | 0.01                  | 0.69                      | 0.66                      | -3.75                       | 0.04                        |
| Cognitive Avoidance       |                         |                       |                       |                           |                           |                             |                             |
| Gender                    | 1                       | 1.93                  | 0.14                  | 3.89                      | 0.01                      | -2.91                       | 0.04                        |
| Adherence                 | 1                       | 1.39                  | 0.19                  | 0.02                      | 0.32                      | -0.05                       | 0.04                        |
| Anxious Preoccupation     |                         |                       |                       |                           |                           |                             |                             |
| Monitoring                | 3                       | -4.00                 | 0.06                  | -0.64                     | 0.08                      | 1.14                        | 0.02                        |

*Notes: <sup>1</sup>Time (1, 2, 3) refers to follow-up periods 1 (post-intervention), 2 (3-month follow-up), and 3 (6-month follow-up).*

## Figure legends

Figure 1. CONSORT flow diagram.

Figure 1. CONSORT flow diagram.

