

Title page**Title**

Mindfulness-based cognitive group therapy for women with breast and gynaecologic cancer: **a pilot study to determine** effectiveness and feasibility

Running title

MBCT for breast and gynaecologic cancer

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Abstract

Purpose: Group-based mindfulness training is frequently described in psycho-oncology literature but little is known of the effectiveness of mindfulness-based cognitive therapy (MBCT). We investigated the effectiveness and acceptability of MBCT for women with breast and gynaecologic cancer.

Methods: Fifty women were recruited to participate in 8 weekly 2-hour mindfulness sessions. Outcomes of distress, quality of life (QOL), post-traumatic growth, and mindfulness were assessed pre-intervention, post-intervention and again 3 months later using validated measures. Data were analysed with repeated measures ANOVAs with a Bonferroni correction. Participant satisfaction and evaluation were also assessed.

Results: Forty-two women completed the program and complete data were available for 36 women. Significant improvements with large effect sizes (η^2) were observed for distress ($P < .001$; $\eta^2 = .238$), QOL ($P = .001$; $\eta^2 = .204$), mindfulness ($P < .001$; $\eta^2 = .363$) and post-traumatic growth ($P < .001$; $\eta^2 = .243$). Gains were maintained 3 months post-intervention. Improvements in outcomes did not differ based on diagnostic group, psychological status or physical wellbeing at entry. Change indices further support these findings. Scores on measures of distress, QOL and post-traumatic growth decreased as a function of increased mindfulness at each time-point (all $P < .05$). Participants reported experiencing the program as beneficial, particularly its group-based nature, and provided positive feedback of the therapy as a whole as well as its individual components.

Conclusions: Within the limits of a non-randomized trial, these findings provide preliminary support for the potential psychosocial benefits of MBCT in a heterogeneous group of women with cancer. Future, more comprehensive trials are needed to provide systematic evidence of this therapy in oncology settings.

Key words

Oncology, cancer, mindfulness, distress, quality of life, cognitive therapy

Manuscript

Introduction

It is well established that the diagnosis and treatment of cancer are associated with substantial challenges to quality of life (QOL) and high rates of psychological distress [6, 38]. As survival rates continue to improve and more cancer patients are living longer, identifying effective, cost-efficient psychosocial interventions for individuals with cancer is an important clinical imperative. Group-based meditative practices employing training in mindfulness skills are described with increasing frequency in the psycho-oncology literature and their popularity appears to be growing [28]. Mindfulness has been described as bringing one's attention to experiences in the present moment in an accepting and non-judgemental way [19]. Most empirical data in the oncology setting concern mindfulness-based stress reduction (MBSR), a systematic eight-week mindfulness program shown to improve stress, mood, sleep, and physical wellbeing [8, 9, 15, 26, 28]. Much less is known about the potential benefits to cancer patients of mindfulness-based cognitive therapy (MBCT), a relatively recent refinement of MBSR that specifically targets the cognitive processes associated with relapse to depression [25]. Like MBSR, MBCT is facilitated through eight weekly sessions of two hour duration, emphasizes daily mindfulness meditation as a key component, and routinely offers a full-day session of meditation practice in the later stages of the program [18, 25]. In addition to similar structure, MBCT and MBSR also share an attitudinal framework of kindness, curiosity and willingness to be present. In terms of differences, MBCT is offered to small groups of up to 12 participants and tends to have participants with a presenting issue in common whilst MBSR is routinely offered to much larger, mixed groups. The smaller group allows for more time for each participant and therefore a greater opportunity for tailoring the intervention for individual experiences. In contrast to MBSR, in the middle weeks of the MBCT program, participants are trained in using mindfulness to work with difficulties by suspending the meditation practice, encouraging thought about a current challenge and then resuming the meditation with guidance to work with any reactions. The central difference between MBSR and MBCT is the explicit focus on cognition within the latter: participants are provided with psycho-education on the association between thoughts and mood early in the program and the link between cognition and functioning is emphasized throughout. The role of rumination (i.e., repetitive, passive thinking or brooding about aspects of negative experience without taking action to remedy the situation [23]) is specifically targeted. MBCT also includes instruction in a short meditation practice (the three minute breathing space), options for skilful action (e.g., nourishing activities), and relapse prevention (identifying signs of relapse and action planning) [25]. Essentially, MBCT offers an integration of MBSR and cognitive therapy.

Existing publications of MBCT in oncology settings are **more limited** (n=5) but reported findings are encouraging [4, 11, 12, 27, 35]. In 2010, the first randomized controlled trial (RCT) of MBCT in individuals with cancer reported significant improvements in distress, depression, and anxiety with gains maintained three months post-intervention in this group of mixed diagnosis patients [12]. Subsequently, two other RCTs have been published, one showing improvement in chronic fatigue and wellbeing in a mixed diagnosis sample [35] and the other, a brief mindfulness-based cognitive behavioural intervention, reporting improved sexual response in women with gynaecologic cancer [5]. Finally, two small pilot studies, one of 12 men with prostate cancer [11] and the other of 16 patients with mixed diagnoses [27] showed significant improvements in anxiety [11, 27], mindfulness [11, 27], avoidance [11] and depression [27], with gains maintained three months after the completion of treatment.

The current setting, a tertiary women's hospital in metropolitan Australia, provides services to women with breast and gynaecologic cancer. Together, breast and gynaecologic cancers account for the majority of cancer diagnoses in Australian women [3]. Evidence shows that the experience of these conditions and the treatment may cause significant negative changes in bodily functional ability and QOL [24]. For many women, psychological distress can persist over time [2, 16, 22]. A group program like MBCT that aims to develop independent coping skills may be an effective and cost efficient intervention for this population. Mindfulness training, with its focus on being present and kind awareness, may be an antidote to worrying about the future and striving that are commonly experienced by women with breast and gynaecologic cancers. The development of equanimity through mindfulness practice may directly target the reactive process that can cause and worsen psychological distress [33].

We sought to investigate the effectiveness and acceptability of MBCT in this patient population with a view to providing pilot data for a future RCT and also possible inclusion of the program in routine care. Given that MBCT was designed to target unhelpful relationships to thoughts (such as rumination), and the development and maintenance of psychological distress can be attributed to ruminative processes [33], it was hypothesized that the MBCT intervention would be associated with improvements in distress and QOL. As secondary

outcomes, we hypothesized that MBCT would also be associated with positive changes in posttraumatic growth and mindfulness.

Methods

Sample

Women with a diagnosis (new or recurrent) of breast or gynaecological cancer for which treatment or active follow-up was currently being received were recruited. Other inclusion criteria were age 18 years or older; ability to provide informed consent; absence of cognitive impairment or mental illness that would impair ability to provide consent or participate in the program; physical ability to attend and participate in the program; and ability to read, write, speak and understand English.

Procedure

Recruitment

The study received institutional ethical approval prior to commencement of recruitment. Recruitment took place in two phases. In the first phase, researchers met with medical, surgical, nursing and supportive care clinicians from three major metropolitan tertiary facilities that offer oncology services to women with breast or gynaecologic cancer. Clinicians were asked to bring the project to the attention of patients thought to be suitable or ask their permission to be contacted by the study research assistant (RA). Flyers were distributed in treatment and waiting rooms at these sites and clinicians were given flyers to distribute to patients. Interested patients were encouraged to contact the RA for further discussion. **To increase participation, a second phase of recruitment was instituted.** Promotional flyers were mailed to subscribers of a state-wide education and support group for women with breast and gynaecologic cancer. Invitations to participate were also mailed to patients who had been diagnosed with breast or gynaecologic cancer in the preceding six months at two of the afore-mentioned tertiary hospitals. Finally, flyers were posted at an off-site radiotherapy centre affiliated with one of these hospitals.

Once in contact with potential participants, the RA assessed eligibility, explained the nature of the program including the time commitment required, the emphasis on home practice, and that the group would be composed of women with varying stages of disease. Eligible women who expressed further interest were then mailed a study information package and consent documents. Upon receipt of written informed consent, participants were mailed the pre-MBCT study questionnaire and were assigned to a group.

Intervention

The MBCT program was delivered in two rounds of three groups, with each group comprising 8 to 10 women. The first round took place from October to December 2010 and the second from February to March 2011. The intervention involved intensive training in mindfulness meditation, provision of theoretical material and group discussion. Treatment was based on the original MBCT manual that was modified for use in oncology settings by the second author. These modifications included the replacement of depression-specific parts of the manual (in sessions 2, 4 and 6) with those relevant for cancer, by including instructions for working with treatment-related discomfort during meditation and allowing discussion of current existential issues raised by the participants (e.g., loss, identity, suffering and death issues). The program was delivered across eight weeks in two-hour sessions. Sessions were delivered by two facilitators with experience in oncology, personal, long-term meditation practice and professional training in MBCT. Facilitators were provided with weekly clinical supervision.

Participants were provided with a workbook summarizing each weekly session, a copy of Jon Kabat-Zinn's book, *Full Catastrophe Living* [18], which discusses the main themes of the MBSR/MBCT program and two meditation CDs with 40 minute recordings of classic mindfulness meditations (i.e., the body scan, a moving meditation and a mixed mindfulness practice). These were recorded by the second author. Daily homework of up to one hour of mindfulness meditation was recommended. Home practice also included optional reading and periodic cognitive and behavioural exercises. An optional (health permitting) extended mindfulness practice session of six hours of meditation was offered between weeks 6 and 7 of the program. An outline of the main themes of each session, including the home practice component, is shown in Table 1.

Measures

Participants completed self-report assessments at three times over the course of the study: prior to the start of the MBCT program (T1), immediately after completion of the program (T2) and then three months subsequently (T3).

Primary outcomes

Distress was measured with the Depression, Anxiety, Stress Scale short form (DASS-21) [14] which measures features of depression, physical arousal, agitation and psychological tension. Higher scores on this 21-item instrument indicate greater symptom severity with a 6.2-point decrease considered a clinically meaningful change [17]. Internal consistency and concurrent validity of the DASS-21 have been confirmed [1, 14].

Quality of life was measured with the Functional Assessment of Cancer Therapy-General (FACT-G) [10], a 28-item self-report measure of QOL for cancer patients. The FACT-G score is a composite of subscales relating to physical, social, emotional and functional well-being. Higher scores indicate better wellbeing and a 5.4-point change is considered clinically significant [10]. Reliability and validity of the FACT-G have been well documented [10].

Secondary outcomes

Mindfulness was measured with the short form of the Freiburg Mindfulness Inventory (FMI) [37], a 14-item instrument which includes items relating to attentive awareness of the present moment, disidentification, diminished emotional reactivity, insightful understanding of the personal experience, and an accepting attitude. Higher scores denote higher levels of mindfulness. The FMI has been found to have acceptable psychometric properties [37].

Posttraumatic growth was measured with the Post-Traumatic Growth Inventory (PTGI) [32], a 21-item scale which measures positive changes and benefit finding following traumatic events (i.e., cancer). Items relate to appreciation of life, personal strength, relating to others, new possibilities, and spiritual change. Scores range from 0 to 105 with higher scores indicating better outcome. The PTGI has established psychometric properties [32].

Program evaluation

Self-report measures at T2 included questions about the relative acceptability and benefit of specific components of the program and the program overall. At T3, participants were asked about the extent to which mindfulness practice had been maintained and to comment on factors that influence the frequency of mindfulness practice. Women were also asked to comment on the experience of participating in a group with women of varying degrees of illness.

Analyses

Data were analysed using repeated measures analysis of variance (ANOVA). Pairwise comparisons with Bonferroni adjustment were used to examine differences between each time point. Given that we purposively recruited women from two diagnostic groups and were inclusive with regard to physical and psychological status at study entry, we investigated variations in outcome of these variables. To examine variations in outcomes based on cancer diagnosis and psychological status, tumour stream (breast vs gynaecologic) and receipt of current formal mental health treatment (receiving treatment vs not) were used as a between-subjects factors. To determine the effect of physical health on outcomes, a median split of the Physical Wellbeing subscale of the FACT-G at T1 was performed and entered as a between subjects factor. This analysis was not performed for the repeated measures ANOVA of QOL as measured by the FACT-G total score because this total score is an aggregate score of, *inter alia*, the Physical Wellbeing Score. Cross-sectional associations between mindfulness and other outcomes were analysed with simple bivariate correlations. Data were analysed using SPSS version 20.0.

Results

Recruitment outcomes and study participation

Recruitment outcomes and study participation are depicted in Figure 1. A total of 105 women were telephonically assessed for participation in the project. From clinician referral (n=47), 25 women consented, 21 declined and one woman was ineligible. From responses to flyers (n=23), 18 women consented, two declined and three were ineligible. There were 27 responses to an unknown quantity of flyers sent to the support group members of whom five women consented, 19 were ineligible and three declined. Of the 137 letters of invitation sent, there were eight responses (6%); three women declined and five consented. A total of 23 women were ineligible, all of whom did not meet the criterion of currently receiving active treatment or follow-up. Among the 29 women who declined participation, reasons given were not interested (n=10), child care commitments (n=2), working commitments (n=3), not convenient (n=8), no transport (n=4), and medical treatment commitments (n=2). Three women consented to participate but did not and eight women attended the program only briefly. **Among these eight women, five women attended two sessions and three women attended one session only. Two of these women were too ill to continue with the program.** Consequently, 42 women completed the MBCT program.

Sample characteristics

Among the 42 women who completed the intervention, 30 (71%) had a diagnosis of breast cancer and 12 (29%) had gynaecologic cancer (n=1 cervical, n=6 ovarian, n=1 vaginal, n=3 endometrial). Ten women (24%) had recurrent cancer. Median and mean (SD) time since cancer diagnosis were 33.1 weeks and 48.2 (47.0) weeks, respectively with a range from 5.9 to 236.0 weeks. At the time of commencing the program, 11 (26%) women were undergoing chemotherapy, 9 (21%) were having radiotherapy, 12 (29%) were having endocrine treatment, and 9 (21%) were receiving targeted therapy. Mean (SD) age of participants was 50.15 (10.0) years with a range from 31 to 66 years. A total of 38 (90%) women lived in the metropolitan area, 24 (57%) were employed in some capacity, 26 (62%) were married or cohabiting, 25 (60%) **had educational qualifications beyond secondary schooling**, 9 (21%) lived alone, 26 (57%) reported a past history of anxiety or depression and 23 (55%) were receiving treatment for anxiety or depression at the time of commencing the intervention. Of the 42 women who completed the program, complete data were available for 36 (n=1 deceased, n=5 did not return all questionnaires).

Primary outcomes

As shown in Table 2, there were significant improvements in distress over time as measured by the DASS-21. Pairwise comparisons showed significant differences between T1 and T2 (P=.007) scores as well as T1 and T3 scores (P=.001). QOL scores on the FACT-G also significantly improved over time with pairwise comparisons showing improvements between T1 and T3 (P=.003) and T2 and T3 (P=.038).

Secondary outcomes

There were significant changes in mindfulness and posttraumatic growth over time (Table 2). Pairwise comparison showed that mindfulness scores on the FMI improved significantly from T1 to T2 (P<.001) and also from T1 to T3 (P<.001). Scores on the PTGI improved significantly from T1 to T2 (P<.001).

There were no significant interactions between time and diagnostic group or current receipt of mental health treatment in analyses for QOL, distress, post-traumatic growth and mindfulness. There was also no interaction effect between low versus high T1 physical wellbeing at baseline and improvement over time for all outcomes other than QOL.

As shown in Table 3, there were significant correlations between mindfulness and levels of posttraumatic growth, distress and QOL at each respective time point indicating that increased levels of mindfulness were associated with decreased levels of distress and higher levels of posttraumatic growth and QOL.

Acceptability and benefit of the intervention

Table 4 shows participants' perceptions of the helpfulness of different components of the program. As depicted in this table, most women (93%) found the overall program to be *quite a bit helpful* or *very helpful* and all individual components of the program were similarly endorsed by the majority of women. Participants particularly enjoyed doing the program as a group, meditating and listening to others talk about their experiences but more than half of the participants also liked the emphasis on home-based practice and the experiences that arose as a result of mindfulness practice. All women (100%) said that they would recommend the program to other individuals with cancer and also to other women with breast or gynaecologic cancer.

In answer to the open-ended question of how participants experienced participation in a program with women of varying degrees of wellness, most (n=32) responses were positive without qualification. For instance:

"It was rewarding in a way...made me appreciate my own situation and also be aware of what others are going through and appreciate the positive support of others."

"Comfortable...I felt useful to those at the beginning of their journey and I could lean on those who were further down the track."

"This was the most interesting part. I found there were others more fortunate and less fortunate than myself and that was the greatest discovery as self-reflection was imminent. There were lots of tears of joy and sadness."

"A really good levelling in respect to my own journey...seeing others accepting and living life as they can was very helpful for me."

Two women noted that it was “*challenging*” or “*confronting*” at first but both felt this became less of an issue as the group progressed. Two women took a pragmatic view, stating that this is “*part of life*”, “*a realistic part of any group*” and “*a reflection of how we live in the world.*”

Maintenance and frequency of meditative practice

Prior to the intervention, 9 (21%) women reported having some form of meditative practice. At T2, 15 (36%) women reported their likelihood of maintaining a mindfulness practice as *quite likely* and 27 (46%) said it was *very likely*. At T3, three women (8%) reported daily maintenance of meditative practice, 14 (39%) meditated every few days, 10 (28%) meditated once a week, 7 (19%) meditated once a month, 2 (6%) reported that they never meditated. The most commonly reported reason for not meditating was lack of time (n=15). Other reasons were lack of discipline (n=4), only feeling the need to meditate when extremely stressed or worried (n=4), and difficult personal circumstances such as pain, fatigue, and illness (n=6).

Discussion

These findings provide preliminary support for the use of MBCT as an effective and acceptable psychosocial intervention for women with breast and gynaecologic cancer. As hypothesized, the MBCT intervention was associated with significant improvements with large effect sizes in distress, QOL, mindfulness and post-traumatic growth, and these gains were maintained three months after completion of the program. Simultaneously, participants reported finding the program beneficial and provided positive feedback of the therapy as a whole as well as its individual components. The acceptability of the program to participants was further demonstrated by the low attrition rate. This is the first study to investigate changes in post-traumatic growth associated with MBCT but together, these findings are consistent with the limited existing data of the psychosocial benefits of MBCT in oncology settings [11, 12, 27, 35] as well as the many reports of MBSR among cancer patients [28].

In busy clinical environments, coordinating psychosocial interventions stratified by tumour stream, disease severity and distress levels is unwieldy and inefficient. We set out to recruit women from two diagnostic groups and were purposively inclusive with regard to physical and psychological status at study entry. Qualitative analyses reveal that patients had little difficulty participating in groups with those at a different stage of disease or recovery. This is important for clinical practice. Furthermore, our analyses show that improvements in QOL, distress, mindfulness and post-traumatic growth did not differ based on cancer diagnostic group or whether women were receiving other, concurrent psychological treatment. Similarly, physical well-being at baseline did not interact with improvement over time for all outcomes other than QOL as measured by the FACT-G (for which the equivalent analysis was not performed because of use of the Physical Wellbeing subscale of the FACT-G as the between-subjects factor). Selection of a suitable variable to reflect physical health status is complex. Although data about time since cancer diagnosis, stage of cancer at diagnosis and receipt of chemotherapy, radiation or endocrine therapy at study entry were available, none of these variables accurately reflect level of physical disability. The Physical Wellbeing subscale of the FACT-G, however, is highly relevant and includes items relating to energy, nausea, pain, side effects of treatment, feeling ill, being able to meet family needs, and having to spend time in bed. Consequently, further study is needed to determine the impact of inclusion of patients with different levels of illness on QOL outcomes over time.

The benefits of MBSR in cancer populations are well established. For instance, Hoffman et al’s [13] recently published MBSR trial showed significant improvements in mood and QOL in breast cancer patients. The data from the current study add to the evidence that MBCT is also well-suited to oncology patients. Some of the features of MBCT that are suitable for cancer patients include the small number of participants **per group, offering containment** of the high level of suffering in this population. The **generous** inquiry time for each participant in MBCT may be particularly important given that cancer patients often report not having other places in which to express their experience so honestly. The common presenting issue (cancer) allows specific formulations of how mindfulness might be useful. The specific focus on rumination and the importance of one’s relationship to common thinking themes addresses the high level of distress experienced by this population and may function to prevent ongoing distress. The inclusion of a short meditation is particularly beneficial as it makes the training ‘portable’. Finally, the inclusion of relapse prevention strategies tends to have an existential value for this population, who can be re-evaluating their identity.

Posttraumatic growth, as conceptualized in this paper, refers to discovering or actively searching for benefits of the cancer experience and the positive life changes that follow [13]. Literature on such ‘benefit finding’ has proliferated in the past decade and shows that individuals, including cancer patients, often emerge from highly adverse events with enhanced interpersonal relationships, changed philosophy of life and a new sense of self [30, 32]. Benefit-finding among cancer patients has been associated with a “better

appreciation for life” [13] and appreciation of “smaller things in life” [34]. Possibly, the findings of improved posttraumatic growth observed in this study may be explained by the systematic training in moment-by-moment awareness and MBCT’s focus on viewing thoughts and feelings as mental events. Such a ‘decentred’ relationship enables a perception of mental events as aspects of experience moving through awareness, rather than necessarily representing reality in any given moment. This heightened openness to possibilities may account for better post-intervention posttraumatic growth levels. This observation is consistent with qualitative data from MBSR participants [21] showing that mindfulness practice supports personal growth and transformation. There is, however, much work to be done in this area. Sumalla and colleagues [31] have commented on the difficulties of clearly defining the processes associated with this subjective feeling of growth following cancer recovery, raising doubts about the real or illusory nature of the phenomenon and its adaptive value.

As discussed elsewhere [28, 29], the exact component(s) of the group intervention associated with the observed improvements is unclear. MBCT comprises components of mindfulness, cognitive therapy and supportive peer interaction, any of which, alone or in combination, may be integral to the success of the intervention. Certainly the perceived benefit of peer support, group membership and the opportunity to share experiences was demonstrated in this study: 92% (n=36) of participants expressed extreme (*liked this aspect a lot*) preference for doing the MBCT program as a group rather than individually. This finding is consistent with other reports [11] and warrants some unravelling. Further study incorporating a randomized design with one of more of these alternate conditions as comparison is required to clarify the essential or active ingredient of a successful group psychosocial program. Investigation of the delivery of these programs could potentially incorporate mindfulness practice in forms that are simpler, more flexible and briefer than the current MBCT program, thereby presenting a less daunting commitment to potential participants. For instance, Brotto et al [5] reported on a three-session mindfulness-based cognitive behavioural intervention improved sexual functioning in women with gynaecologic cancer. Brevity would also likely suit patients who are very unwell or palliative and would have important cost implications. The cost considerations inherent in MBCT are not insubstantial. These include the best practice requirements that MBCT facilitators have ongoing personal mindfulness practice, receive supervision from a mindfulness teacher, and attend annual mindfulness retreats [18, 25]. **Indeed, the major financial cost of this pilot study was the fees associated with hiring suitably qualified mindfulness facilitators and paying for their clinical supervision. We contracted to external individuals (non-employees) for this purpose, which dramatically inflated the cost. If offered as part of routine care in the future, both facilitation and supervision would need to be conducted by a member of staff as part of their role. Furthermore, in practice, MBCT groups are better facilitated when there are two MBCT therapists per group, which adds to expense. Other cost issues include a group coordinator who, like the RA in the present study, organizes venues, follows up on patients who do not attend, and arranges for completion of questionnaires. This job requires a considerable time commitment but is important to the smooth running of the program.** Thus, the actual cost effectiveness of MBCT group programs requires closer examination.

Difficulties encountered in recruiting participants are a lesson for future studies. Letters of invitation to patients diagnosed in the preceding six months were ineffective in generating interest, yielding a low 6% response rate. In future, if such invitations were to be sent, they would be followed up with a telephone call from the RA. Promotional flyers sent out via the community support group generated much interest but nearly all of those interested were not eligible for the study. Only half (25/47=53%) of women referred by a clinician consented to participate. Obtaining consent from those who responded based on seeing the study flyer in a treatment setting was most successful (18/23 = 78%). Regular visits and phonecalls from recruitment staff to the recruitment sites would be implemented to recruit in future studies. It is also of interest that only 10% (10/105) of those assessed were simply not interested, and that most that declined did so for practical reasons such as transport problems or commitments to treatment, child care, or work. In all, the challenges of recruiting patients to this pilot study demonstrate the complexity that is likely involved in attempts to recruit patients to RCTs with strict and inflexible protocols.

Future research might also include closer scrutiny of the role of adherence to home-practice of meditation. In our study, participants did not record their home-practice and so it is not possible to investigate a dose-response relationship. The necessity for daily home practice of meditation is an important feature of MBCT but its association with positive outcomes is a complex issue [7, 26, 29, 36].

We recognize the limitations of this work lending caution to the interpretation of the results. Some of the limitations are inherent in a pilot/feasibility study but we note that these include a small sample size (though substantially larger than other pilot studies of its type (e.g., [11, 27]) with attendant lack of

power. Information regarding reasons for women not being interested in the study was not recorded. It is recognized that sample was highly self-selected and that it is likely that very motivated individuals, who were willing and open to learning new skills, attended the program. Clinical and demographic data of non-participants were not collected so the representativeness of the sample is not known. Some 60% of this sample had high levels of education, a finding that is consistent with recent reviews of mindfulness-based interventions in cancer care [20, 28]. Furthermore, in the absence of a randomized design, it is not possible to conclude that the improvements are attributable solely to the MBCT program. Nonetheless, the systematic variation in mindfulness scores alongside changes in levels of QOL, distress and posttraumatic growth does suggest that mindfulness practice is associated with better psychosocial outcomes.

In conclusion, these preliminary findings add to the limited existing data on MBCT in oncology settings and show the potential benefits of this intervention in a heterogeneous group of women with cancer. Future, more comprehensive RCTs are needed to provide systematic evidence of this therapy for improvements in psychosocial outcomes in oncology settings.

Acknowledgements

This study was supported by a generous financial contribution from the Collier Charitable Trust. The Centre for Women's Mental Health is supported by the Pratt Foundation.

Conflict of interest

The authors do not have a financial relationship with the Pratt Foundation or Collier Charitable Trust. The authors have full control of all primary data and agree to allow the journal to review these data if requested.

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Figure 1
Recruitment and study participation flow diagram

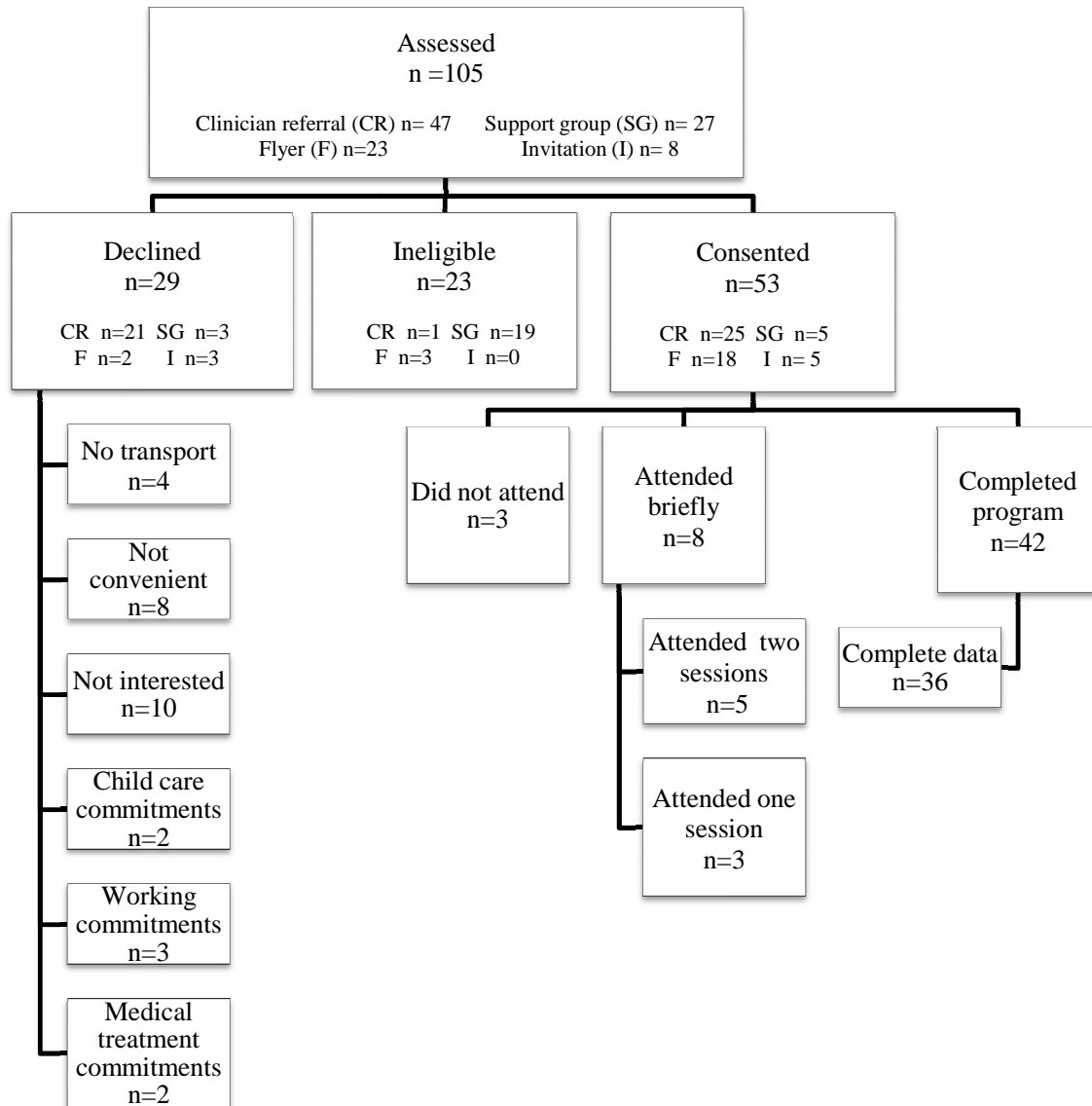


Table 1
Overview of MBCT for individuals with cancer

Session number	Session theme	Content overview	Meditation component	Recommended home practice component
1	Stepping out of automatic pilot	Rationale for course Defining mindfulness and 'automatic pilot' Introducing the body as a focus	Eating meditation Breath and body scan	Mindfulness of everyday activities Formal practice (body scan)
2	Dealing with barriers	Identifying common barriers Thoughts and feelings exercise	Body scan Mindfulness of breath	Mindfulness of everyday activities Mindfulness of breath Formal practice (body scan) Pleasant Events Calendar
3	Attending to the present	Identifying the "doing" mode and the "being" mode	Mindfulness of seeing, hearing and breath Mindful stretching and walking	Formal practice (alternate body scan and moving meditation) Mindfulness of breath Unpleasant Events Calendar
4	Taking a wider perspective	Aversion and attachment Focus on reactions to distress including reactions to cancer experience	Mindfulness of seeing, hearing, breath and body, sounds and thoughts Three minute breathing space	Formal practice (alternate mixed meditation and moving meditation) Three minute breathing space Notice automatic reactions to stress
5	Allowing/letting be	Group discussion about allowing/letting be 'Introducing a difficulty' and noticing physical and psychological reactions	Mindfulness of seeing, hearing, breath and body, sounds and thoughts with difficulty introduced Three minute breathing space with coping instruction	Formal practice (mixed meditation) Three minute breathing space
6	Thoughts are not facts	Group discussion including identifying common thinking themes Breathing space as the first step towards a wider view	Mindfulness of seeing, hearing, breath and body, sounds and thoughts with difficulty introduced Three minute breathing space	Formal practice (mixed meditation) Three minute breathing space Cultivate awareness of thinking themes
7	Taking care of myself	Exploring link between activity and mood Integrating mindfulness into daily schedule Recognizing signs of personal distress and how to respond Breathing space as the first step towards mindful decisions	Mindfulness of seeing, hearing, breath and body Three minute breathing space	Relapse prevention exercises – increasing mindfulness in daily schedule and responding to stress Formal practice (participant choice) Three minute breathing space
8	Acknowledging efforts and planning for future struggles	Review of program Plans for future practice and strategies for maintaining momentum Personal reflections	Body scan Closing meditation	

Table 2
Results of repeated measures ANOVAs showing means, F, and effect sizes for primary and secondary outcome variables

Outcome variable	T1 Pre-MBCT^e M (SD)	T2 Post-MBCT M (SD)	T3 3 Months Post-MBCT M (SD)	F	P	Effect size (partial eta squared)
DASS-21 ^a	38.22 (19.47)	28.33 (17.96)	24.22 (22.60)	10.95	<.001	.238
FACT-G ^b	65.81 (17.15)	70.30 (16.32)	74.80 (17.46)	9.0	.001	.204
FMI ^c	40.0 (7.33)	46.76 (6.39)	46.15 (7.03)	18.23	<.001	.363
PTGI ^d	53.50 (22.31)	68.22 (16.16)	62.08 (22.75)	11.24	<.001	.243

^a Depression Anxiety Stress Scale short form

^b Functional Assessment of Cancer Therapy-General

^c Freiburg Mindfulness Inventory

^d Post-Traumatic Growth Inventory

^e Mindfulness-based cognitive therapy

Table 3
FMI scores correlated with DASS-21, PTGI and FACT-G scores

		DASS-21 ^c scores		FACT-G ^d scores		PTGI ^e scores	
		r	P	r	P	r	P
	Pre-MBCT^b	-.388	.013	.363	.021	.331	.037
FMI^a scores	Post-MBCT^b	-.415	.008	.375	.017	.525	<.001
	3 months post-MBCT^b	-.665	<.001	.630	<.001	.474	.004

^a Freiburg Mindfulness Inventory

^b Mindfulness-based cognitive therapy

^c Depression Anxiety Stress Scale short form

^d Functional Assessment of Cancer Therapy-General

^e Post-Traumatic Growth Inventory

Table 4
Participants' views of the program

	n (%)				
	<i>Not at all helpful</i>	<i>A little bit helpful</i>	<i>Somewhat helpful</i>	<i>Quite a bit helpful</i>	<i>Very helpful</i>
Getting to know other women with breast or gynaecologic cancer	1 (3)	5 (15)	5 (13)	9 (23)	18 (46)
Becoming more aware of my body, thoughts and feelings	-	-	3 (8)	9 (23)	27 (69)
Knowing that I am not alone in my experiences	-	1 (3)	4 (10)	10 (26)	24 (62)
Learning how to live more in the present moment	-	1 (3)	4 (10)	10 (26)	24 (62)
Learning how to meditate	-	1 (3)	3 (8)	13 (33)	22 (56)
Finding ways to cope with difficult thoughts, feelings or bodily sensations	-	2 (5)	3 (8)	10 (26)	24 (62)
Overall, how helpful did you find it to attend the therapy?	-	-	3 (6)	12 (30)	25 (63)
	<i>I disliked this aspect a lot</i>	<i>I disliked this aspect a little bit</i>	<i>I neither liked nor disliked this aspect</i>	<i>I liked this aspect a little</i>	<i>I liked this aspect a lot</i>
Listening to other people talk about their experiences	-	1 (3)	1 (3)	9 (23)	28 (72)
Doing the course as part of a group (rather than one-to-one)	-	-	1 (3)	2 (5)	36 (92)
Meditating	-	-	-	7 (17)	32 (82)
Emphasis on home-based practice	-	-	4 (10)	12 (31)	23 (59)
Experiences that arose as a result of practising mindfulness	-	1 (3)	2 (5)	10 (26)	26 (67)
Time commitment required	-	4 (10)	9 (23)	11 (28)	15 (39)



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Title:

Mindfulness-based cognitive group therapy for women with breast and gynecologic cancer: a pilot study to determine effectiveness and feasibility

Date:

2013-11-01

Citation:

Stafford, L., Foley, E., Judd, F., Gibson, P., Kiropoulos, L. & Couper, J. (2013). Mindfulness-based cognitive group therapy for women with breast and gynecologic cancer: a pilot study to determine effectiveness and feasibility. SUPPORTIVE CARE IN CANCER, 21 (11), pp.3009-3019. <https://doi.org/10.1007/s00520-013-1880-x>.

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