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MINDFULNESS-BASED INTERVENTIONS IN RECURRENT OVARIAN CANCER: A MIXED METHODS FEASIBILITY STUDY

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ABSTRACT

A recurrence of cancer is a traumatic and stressful experience, and a number of approaches have been proposed to manage or treat the associated psychological distress. Meditative techniques such as mindfulness may be able to improve an individual's ability to cope with stressful life events such as cancer diagnosis or treatment. This single arm mixed methods study primarily aimed to determine the feasibility of using a mindfulness-based intervention in managing psychosocial distress in recurrent ovarian cancer. Twenty-eight participants took part in a mindfulness-based programme, involving six group sessions lasting 1.5 hours each delivered at weekly intervals. The study found that the mindfulness-based intervention was acceptable to women with recurrent ovarian cancer and feasible to deliver within a standard cancer care pathway in a UK hospital setting. The results suggested a positive impact on symptoms of depression and anxiety, but further study is needed to explore the effectiveness of the intervention.

INTRODUCTION

Globally, ovarian cancer accounts for approximately 3.5% of all cancer incidence among women[1]. Some of the highest incidence rates are seen in North America, and North and Eastern Europe. For females in the UK, ovarian cancer is the sixth most common form of cancer, with around 7,400 new diagnoses each year[2]. Due to the non-specific symptoms and difficulties in early detection, over 60% of cases of ovarian cancer are diagnosed at an advanced stage[3]), and in most cases the disease has already progressed beyond the pelvis. Five-year survival rates are therefore low, between 30% and 40% in most countries[4]. Despite high initial response rates to treatment, over 70% of patients with ovarian cancer will experience chemoresistance and disease recurrence[5], and ovarian cancer was the cause of over 184,000 deaths worldwide in 2018[1] .

Experiencing a recurrence of any type of cancer is traumatic and stressful, and is associated with a high prevalence of concurrent psychological morbidity[6]. Depression and anxiety are two of the psychological issues most commonly experienced by patients with all cancer types[7]. Psychological distress can impact a number of cancer outcomes, including quality of life, adherence to treatment, health behaviours, and potentially disease progression and survival[8], as well as increase utilisation of healthcare resources[9] . The National Cancer Survivorship Initiative (NCSI), launched in

the UK in 2010[10], set out to understand the needs of those living with cancer. One of this initiative's key goals is to improve the management of psychological conditions associated with cancer diagnosis and treatment.

A number of approaches have been proposed to manage or treat the psychological distress associated with cancer. These have included cancer counselling and education, psychotherapies such as cognitive behavioural therapy, supportive-expressive group therapy and cognitive-existential therapy, and pharmacotherapies such as antidepressant medication[11]. There has also been a growing interest in the therapeutic application of mindfulness-based approaches – including mindfulness based stress reduction (MBSR)[12] and mindfulness based cognitive therapy (MBCT)[13]– across a range of healthcare conditions, including psychological disorders secondary to cancer.

Mindfulness is a meditation practice founded in the traditions of Buddhism. It has been defined as the process of paying attention to the present moment in a non-judgmental manner, and is proposed to foster clear thinking and openheartedness[14]. Mindfulness emphasises the importance of accepting all thoughts and experiences as they are, without trying to alter or change them, and thereby develop a greater sense of well-being. In a clinical context, meditative techniques such as mindfulness may be

able to improve an individual's ability to cope with stressful life events such as cancer diagnosis or treatment. The strongest evidence base is around the use of mindfulness in the treatment of depression and anxiety[15], which has led to national guidelines recommending mindfulness-based cognitive therapy for depression in the UK[16], North America[17,18], and Australia and New Zealand[19]. However, there is also further evidence to suggest that mindfulness-based approaches may additionally be effective in combating the psychological distress associated with cancer[20-23].

A recent meta-analysis by Watts *et al.* found high levels of clinically significant depression and anxiety – 25% and 27% respectively – in patients with ovarian cancer[24]. Despite the high psychosocial morbidity experienced by these women, there is little research on effective interventions. Most mindfulness intervention studies in cancer so far have focused on patients with breast cancer, a condition with a better prognosis than ovarian cancer due to earlier diagnosis. In contrast, the role of mindfulness-based interventions in managing psychosocial distress in recurrent ovarian cancer is so far unknown.

We undertook a single arm mixed methods study to assess the feasibility and acceptability of delivering a mindfulness-based intervention to women with ovarian cancer which had recurred following initial treatment. The intervention was delivered

as a six-week programme of group sessions, and participants were assessed before and after the intervention and at 3 months follow-up, to aid our preliminary understanding of the effects on both psychological and physiological markers. We also conducted focus groups to qualitatively establish participants' experiences and perceptions, and to inform the refinement of the intervention for future study and implementation.

METHODS

Study design

This single arm interventional study was conducted at one site in the UK (Queen Alexandra Hospital in Portsmouth Hospitals NHS Trust), using mixed qualitative and quantitative methods of data collection and analysis. Ethical approval was obtained from the South Central – Berkshire Research Ethics Committee (REC reference 16/SC/0415).

Participants and procedures

Eligible participants included women aged 18 or over with a biopsy-confirmed diagnosis of ovarian cancer who have experienced disease recurrence, at any stage, following initial treatment; were fluent in English; had no concurrent cancer; had no significant mental illness (other than depression and/or anxiety); and were not

receiving other psychological therapy (Figure 1). Eligible patients, irrespective of the time since disease recurrence, were approached about referral to the study by their clinical care teams during outpatient clinics at the single recruitment site. All participants provided written informed consent.

Twenty-eight participants were recruited to the study and split into two groups composed of 14 participants each. The programme included six group sessions lasting 1.5 hours each, delivered at weekly intervals. Each group sequentially received an identical intervention, with all sessions facilitated by the same qualified mindfulness teacher and attended by the same specialist cancer nurse. Participants were invited to bring a 'buddy' (family member or friend) to accompany them and provide support, if they wished. The programme trained in both informal and formal practice, including breath awareness, body scan practice, observing thoughts, exploring difficulties and cultivating loving kindness, with specific practices on reducing stress and coping with anxiety incorporated (Supplemental Material). Additional relaxation practices and simple mindful movements were included, as well as short mindfulness tips. Each session included short meditations (between 10 and 25 minutes), which were also available electronically as a CD or via download for home practice. Participants were encouraged to keep a daily journal and practice log. A workbook accompanied each

session, which participants could also use if they were unable to attend a session. All other clinical care continued as normal.

Assessments were conducted prior to starting the intervention, then at baseline (immediately pre-intervention), 6 weeks (immediately post-intervention) and 12 weeks. Sociodemographic data were collected from a brief self-reported questionnaire. Outcome data were collected via postal self-administered written questionnaires, and biomarker analyses of salivary and blood samples were collected during site visits for attendance at the mindfulness sessions.

Three formal focus groups were also conducted with each of the two groups, held six weeks apart (immediately before and after the intervention, and at 6 weeks after the final session). The focus groups lasted approximately one hour and used both topic guides and group discussion. A pre-intervention focus group was used to understand participants' knowledge of mindfulness and their motivations and expectations from the sessions; the Week 6 focus group was intended to explore participants' experiences of the practices, and the final focus group to explore their views and acceptability of the mindfulness intervention in the longer term.

Outcomes

Four different questionnaires were completed at three time points (baseline, 6 weeks and 12 weeks from start of intervention). The questionnaires administered were the Hospital Anxiety and Depression Scale (HADS)[25], the Warwick/Edinburgh Mental Wellbeing Scale (WEMWBS)[26], the Freiburg Mindfulness Inventory (FMI)[27], and the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire OV28 (EORTC-QLQ-OV28)[28]. The HADS is a standard, validated measure of mood disorder, which was used to identify clinically meaningful changes in depression and anxiety. The WEMWBS is a short and reliable measure of mental wellbeing comprised of positively worded items relating to positive mental health. The FMI is a 30-item scale designed to measure the concept of mindfulness, using self-reporting of mindfulness qualities such as awareness of the present moment, non-judgmental accepting attitude, and openness to negative states. The EORTC-QLQ-OV28 is an internationally recognised tool for measuring disease-specific quality of life in patients with ovarian cancer and includes both functional and symptom scales.

Salivary cortisol levels were performed at three time points (baseline, 6 weeks and 12 weeks from start of intervention). Cortisol is a glucocorticoid hormone released in response to stress, and salivary levels of cortisol offer a minimally invasive method of assessing physiological stress responses[29]. Abnormal patterns of secretion have been reported in populations with ovarian cancer, and have been associated with functional

disability, fatigue and depression[30]. Measurements of both the awakening and diurnal responses were taken as indicators of hypothalamo-pituitary-adrenal axis dysfunction, in line with recognised recommendations[31], and participants collected saliva samples on awakening, and at 0.5, 3, 7 and 12 hours after awakening over two consecutive days at each of the three time points. Saliva samples were collected by participants at home using SalivaBio Oral Swabs [Salimetrics LLC., USA], which were then stored temporarily in their domestic refrigerator before returning to the research team at the subsequent mindfulness session. Samples were then processed by centrifugation and stored at -80^{o}C[32] until analysis by enzyme-linked immunoabsorbent assay (ELISA) at a university research laboratory in line with the manufacturer's instructions.

Blood tumour marker levels were also performed as biomarker tests at two time points (baseline and 12 weeks from start of intervention). Elevated serum levels of the mucin-like glycoprotein cancer antigen 125 (CA-125) are an established indicator of response to treatment and progression or recurrence of disease, and measurement of CA-125 is part of the usual care of ovarian cancer patients[33]. Venous blood samples (8mL) were taken prior to routine clinic visits, and then processed by centrifugation and stored at -80^{o}C until analysis. Levels of CA125 were determined by immunoassay at the study site's NHS Pathology Service.

Qualitative information was collected at ~~seven~~ six formal focus groups in total across both cohorts, held at baseline (pre-intervention, n=2), 6 weeks (n=3) and 12 weeks (n=2) from start of intervention. This was sufficient to achieve saturation. The focus groups were digitally recorded and transcribed verbatim. A thematic analysis[34] was conducted to fracture and reorganise the data into codes, and iteratively search for themes from the participants' discussions. Coding was carried out by the first author, a psychologist who had previously conducted research on ovarian cancer, and attended the mindfulness sessions as an observer. Identified themes were discussed with three other authors (GD, who had run the mindfulness sessions; CCY, who had also attended them and RG) and disagreements resolved by discussion.

Statistical analyses

All analyses were carried out using Microsoft Excel. This was a small feasibility study and therefore analyses have remained descriptive, without inferential testing ~~Data from the HADS questionnaires, salivary cortisol levels and CA125 values were analysed using paired sample t-tests comparing differences pre- and post-intervention. Individual missing data points were imputed using the average of the available data.~~

RESULTS

The study was conducted between November 2016 and June 2017. Of the 29 women referred to the intervention, all 29 were eligible for recruitment to the study and all 29 consented to take part (Figure 1). One patient withdrew from the study early in the programme due to non-engagement. The overall programme attendance was 89%, and all participants attended at least three of the six sessions; reasons for non-attendance included holidays, illness and medical treatments. Follow up questionnaires were ~~completed~~ returned (although not always fully completed) by all 28 women who remained in the study.

Sociodemographic and clinical characteristics of participants are reported in Table 1.

CHARACTERISTIC	INTERVENTION GROUP (N=28)
Sociodemographic	
Age, years (mean (SD))	59 (10)
Education (n (%))	
Secondary school	7 (25)
College	10 (36)
Undergraduate	5 (18)
Postgraduate	5 (18)
Not answered	1 (3)
Employment (n (%))	
Retired	9 (32)
Full-time employed	7 (25)

Part-time employed	4 (14)
Housewife	4 (14)
Self-employed	1 (3)
Unemployed	3 (11)
Marital status (n (%))	
Married	21 (75)
Co-habiting	1 (3)
Widowed	3 (11)
Single	3 (11)
Clinical	
Time since initial diagnosis, years (mean (SD))	2.76 (1.94)
CA125 level, units/mL (mean, (SD))	311 (1059)

Table 1 Sociodemographic and clinical characteristics of the study participants

The mean scores and standard deviations for the HADS, WEMWBS, FMI and EORTC QLQ OV28 scales at Weeks 1, 6 and 12 are shown in Table 2.

OUTCOME	WEEK 1	WEEK 6	WEEK 12
HADS			
Anxiety	9.56 (4.93)	8.38 (4.49)	6.94 (4.84)
Depression	5.46 (3.98)	4.38 (3.43)	2.83 (2.17)
WEMWBS			
	47 (10)	52 (14)	54 (7)
FMI			
	32 (10)	38 (7)	40 (7)
EORTC-QLQ-OV28			
Functional			
Body image	53 (31)	69 (29)	59 (28)
Sexuality	80 (21)	75 (40)	72 (33)

Attitude to disease / treatment	40 (30)	51 (29)	54 (32)
Symptom			
Abdominal symptoms	20 (17)	15 (14)	24 (25)
Peripheral neuropathy	30 (29)	26 (30)	27 (28)
Hormonal symptoms	29 (33)	19 (28)	25 (34)
Other chemotherapy side effects	25 (19)	20 (20)	23 (18)
Hair loss	16 (31)	9 (21)	15 (30)

Table 2 Mean scores for the main variables at Weeks 1, 6 and 12. Data presented as mean (standard deviation) unless otherwise stated. Abbreviations: HADS, Hospital Anxiety and Depression Scale; WEMWBS, Warwick/Edinburgh Mental Wellbeing Scale; FMI, Freiburg Mindfulness Inventory; EORTC-QLQ-OV28, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire OV28

Both the HADS Anxiety and HADS Depression scores show ~~significant~~ downward trends between baseline and Week 12 of 2.61 ~~(p-value = 0.08)~~ and 2.63 ~~(p-value < 0.05)~~ points respectively. A HADS score of 8 to 10 is considered to indicate a mild case in both depression and anxiety, and higher scores indicate more severe symptoms[35]. Using these cut-offs, 8% of the study group suffered with depression at baseline, and 60% with anxiety. At 6 weeks, the proportion with depression remained unchanged but the proportion with anxiety had fallen to 42%. By 12 weeks, only one participant had a HADS depression score of 8 or more, and 32% had a HADS anxiety score of 8 or more (see Figure 2). However, the percentage of missing data (defined as the percentage of all participants with no reported HADS score) ranged from 6% at baseline to 33% at Week 12.

The WEMWBS and FMI scales showed an increase in mean scores between baseline and Ww~~w~~eek 12 of 7 and 8 points respectively (Table 2), indicating an improvement in mental wellbeing and mindfulness respectively. The mean EORTC-QLQ-OV28 scores showed an initial trend towards improvement for both the functional and symptom subscales at Week 6, except in the sexuality subscale (Table 2). These improvements are not sustained at Week 12, although all mean EORTC-QLQ-OV28 scores (with the exception of abdominal symptoms) remained below the baseline values.

Cortisol levels are presented in Table 3 and showed no difference in average daily mean values from baseline at either Week 6 ~~(p=0.884)~~ or Week 12 ~~(p=0.115)~~. However, the mean daily values are impacted by high variability over the course of the day, and therefore the mean cortisol levels at each of the five collection time points were also analysed (Table 3). The variation in cortisol levels are shown graphically in Figure 3 and demonstrate 'normal' diurnal variation as classified by Touitou *et al*[36], with a clear rise post-awakening to a peak at 0.5 hours and a gradual continuous decline thereafter during the day (Figure 3). The mean variations in diurnal levels of cortisol again demonstrated no meaningful changes following the mindfulness intervention at any of the collection time points assessed. The dynamic change in cortisol following awakening was analysed by calculating the difference in levels between waking and 30 minutes after waking[37], and also showed ~~no significant~~little

differences in patterns of post-awakening cortisol secretion (Table 3). However, salivary samples were poorly collected and missing data (defined as the percentage of all participants with no reported cortisol level) ranged from 13% of participants at Week 1 to 40% at Week 12.

Cortisol level (µg/ml)	WEEK 1	WEEK 6	WEEK 12
Daily mean cortisol level	0.34 (0.35)	0.33 (0.31)	0.34 (0.33)
Mean cortisol on awakening	0.51 (0.37)	0.46 (0.27)	0.50 (0.35)
Mean cortisol 0.5 hours after waking	0.69 (0.44)	0.68 (0.35)	0.68 (0.37)
Mean cortisol 3 hours after waking	0.26 (0.19)	0.25 (0.18)	0.29 (0.33)
Mean cortisol 7 hours after waking	0.13 (0.08)	0.16 (0.20)	0.32 (0.46)
Mean cortisol 12 hours after waking	0.10 (0.16)	0.09 (0.14)	0.20 (0.29)
Mean cortisol awakening response	0.18 (0.29)	0.23 (0.23)	0.18 (0.28)

Table 3 Mean cortisol levels for all participants as a daily average, at each of the five collection times and as an awakening response, for Weeks 1, 6, and 12 Data presented as mean (standard deviation)

There was no change in CA125 values over the study period. Plasma levels of CA125 varied widely between participants at both Week 1 and Week 12, with calculated medians of 16 units/mL (IQR 53) at baseline and 23 units/mL (IQR 166) after the mindfulness intervention. ~~However, this slight difference in readings was not significant (p=0.98).~~

Qualitative findings relating to the feasibility and acceptability of the mindfulness sessions identified three main themes from the three focus group sessions held:

Experience of Mindfulness Sessions and Practice

Participants liked the group-based format, as they felt supported by a connection with other participants and motivated by the progress they saw in fellow participants. They felt a connection with others in a similar situation, with whom they could talk about both the techniques and their experiences.

> "*I think it's as much meeting other people in the same situation*" [P5, cohort 2, final focus group]

Many felt more relaxed as the programme progressed and appreciated the facilitator.

> "*[She was] very approachable and friendly … You could tell she was passionate about it*" [P1, cohort 2, 6-week focus group]

Mindfulness groups sessions enabled them to develop both a skill and a support network, which they felt would be hard to achieve if the intervention was delivered remotely e.g. online.

Participants were very positive about the experience of practising mindfulness, and several reported that it also helped their partners. They saw practising mindfulness as

an opportunity to take time from their daily routines, to be kind to themselves and prioritise their bodies, and felt it made them take stock and focus on the positives.

> "*I think I'm kinder to myself as a result of it, because I feel as though I'm taking time out for me to replenish*" [P3, cohort 2, final focus group]

However, participants reported that some aspects of the programme took more getting used to. Some found it information-heavy, although the information was considered extremely useful, and felt that it took them about three or four weeks to connect with the mindfulness.

> *"… we had a new thing every week – it would have been nice to have gone back and revisited a couple of techniques*" [P5, cohort 1, final focus group]

The sessions involved a lot of time sitting, and participants would have preferred a short break in the middle, and some standing mindfulness every week.

> "*Being stood up meant … I personally feel like I have a lot more energy this week and we've had a lot more conversation… with movement each week or a chance to have a break – it just sort of helps*." [P1, cohort 2, Week 6 focus group]

Benefits and Difficulties of Mindfulness

Participants saw mindfulness as a tool to help them focus and cope with stress. They felt it changed their way of thinking and reported using it when negative thoughts came into their head, or in specific stressful situations, such as scans, blood tests, and hospital appointments:

"It's given you a tool to use, you know, so you've got it there all the time, which you know that if you don't feel 100%, you can think about that and it helps you calm down." [P4, cohort 1, final focus group]

"*I found it extremely useful, even lying in that CT scanner, because you're lying there, the pictures are being taken and you think … what are they going to find. And then suddenly the exercise came into my mind and I'm lying there and I'm closing my eyes and I'm thinking what I can smell, what I can hear, I can taste and I'm concentrating on my breathing and it just got me through the scan …*" [P2, cohort 1, Week 6 focus group]

Participants noticed a number of mental health benefits, including feeling calmer and more relaxed, being more positive, and feeling less anxious and panicky.

Participants felt that many of the different practices had specific benefits. For example, all participants reported sleeping better, with particular reference to using

the Progressive Neuromuscular Relaxation at night, whereas the Emergency Mind Aid was seen as a tool for stopping events from spiralling out of control.

"I wake up in the middle of the night … I'll sometimes do, you know, still lying in bed, tensing muscles gradually and releasing them, just drift off back to sleep." [P5, cohort 2, final focus group]

Applying mindfulness to everyday activities was felt to increase concentration throughout the day.

Despite an overall positive view of mindfulness, participants experienced some difficulties with specific practices. Many participants reported being unused to sitting still and some found it hard to concentrate. This was expected, as mindfulness practice raises awareness of being unable to concentrate. However, the most significant issue mentioned by almost all participants was the negative emotions that came up during the 'Exploring Difficulties' practice, when they did it in the session, particularly if they were currently feeling positive.

"*If you're in a good place, the last thing you want to do is stop and think of something that's troubling you."* [P4, cohort 2, Week 6 focus group]

However, they were able to understand the rationale behind the 'Exploring Difficulties' practice, which they saw as something to draw on if they were experiencing an all-consuming negative situation.

> "*I can see the positive in learning to do it, but it would take some summoning of courage to perhaps redo it*" [P6, cohort 2, Week 6 focus group]

Barriers and Facilitators to practising Mindfulness

Support from others seemed to be an important factor in enabling practice. Some women found practicing together with partners or friends was helpful. Others saw being committed to a specific goal, or having a schedule, as important for completing home practice.

> "*I made an arrangement with somebody else that I would text them it was done and they would then text – nag me if I hadn't done it*" [P3, second cohort, final focus group]

Physical aids also facilitated practice. Participants found it beneficial to practice with the CD, and many had downloaded the practices to their phones or tablets.

> "*I've got it on my phone so when we go to bed, press it, listen to it and it turns itself off at the end*." [Participant's partner, cohort 2, final focus group]

However, participants who were working full time said they found it hard to make the time to practice, and some reported distractions at home could be problematic.

DISCUSSION

This study has demonstrated the feasibility of delivering a mindfulness-based intervention to women with recurrent ovarian cancer within a standard cancer care pathway in a UK hospital setting. We observed high recruitment and retention rates, and participants told us that they found the programme acceptable. Mindfulness was considered by participants to be a useful tool when managing difficult experiences, and the outcomes suggest a positive impact on depression and anxiety symptoms, mental wellbeing and mindfulness, and health related quality of life. Development of this study ~~in the future~~ may consider introducing screening for clinical levels of anxiety or depression at baseline for entry into future trials, to enable clearer analysis of any improvement following the mindfulness intervention.

These preliminary results did not, however, suggest any effect on the physiological markers studied (salivary cortisol profiles or CA125 biomarker levels). Cortisol levels in particular were challenging to monitor; swabs were not always taken consistently, correctly or sufficiently, and participants found taking samples inconvenient and burdensome. The evidence of mindfulness effects on cortisol levels is mixed[38] and the

insights from this study may be impacted by the relatively 'normal' baseline cortisol profiles of our participant population[36]. Future development of this protocol, therefore, may review the feasibility of some of the outcome measures, and consider alternative means of sample collection or measurement, and/or approaches to simulation of the potential impact of missing data during sample size calculations.

Participants' experiences and perceptions were key to the findings of this study, and their feedback identified important areas for further study. Participants told us that the social support network resulting from the programme was important to them, and many were still in touch with each other after the study had ended. This corresponds with the findings of similar studies[39], and suggests that future work should investigate the impact of this social interaction on the effectiveness of the intervention. More detailed study is also needed into the impact of mindfulness on sleep, as improved sleep duration and patterns were another strong theme from participants' feedback.

This work sought to test the study protocol and operational feasibility and acceptability of this intervention, to help design further confirmatory studies; accordingly, it includes an appropriately small sample size without a control group. The findings therefore require cautious interpretation given the size, design and duration of the study. There is a risk of bias and imprecision due to missing data,

particularly at Week 12, and development of the protocol should address challenges in data collection at this time point. We additionally note other factors which may have influenced the success of this work. The gender and age of the study population may have meant that they had more time to participant in mindfulness activities and were more receptive to this type of intervention, and there is a risk of influence by the "popularity effect" of a growing acceptance of mindfulness techniques[40]. The mindfulness intervention delivered during the study differed from standard MBSR programmes, being a reduced programme, with fewer, shorter sessions and practices. The programme also stated explicitly the possible benefits of practice and offered tools which participants could use in certain situations; this differs from the transitional programmes of self-discovery offered by conventional mindfulness. Future studies should investigate whether mindfulness in general, or specific interventional approaches, are most effective for a given illness.

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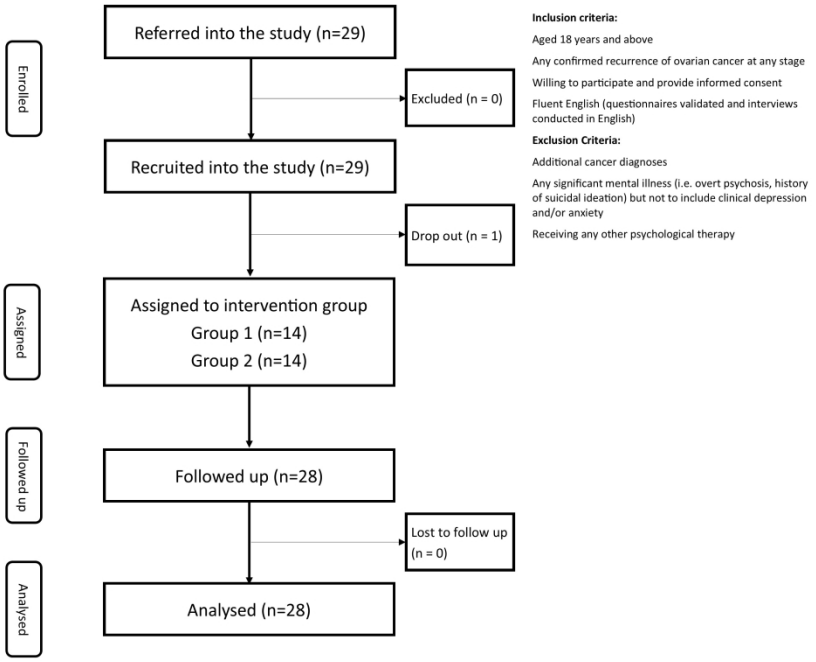

Figure 1 Patient flow diagram

297x209mm (300 x 300 DPI)

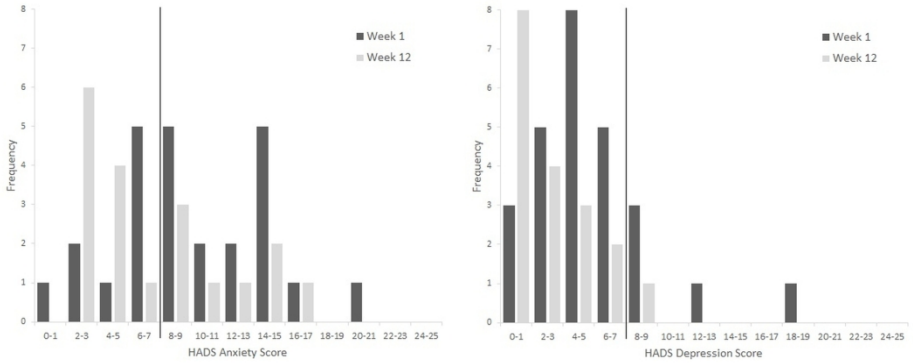

Figure 2 Changes in number of patients with Hospital Anxiety and Depression Scale anxiety and depression scores at Week 1 (black) and 12 (grey). Threshold of a score of 8 (black line)

108x40mm (600 x 600 DPI)

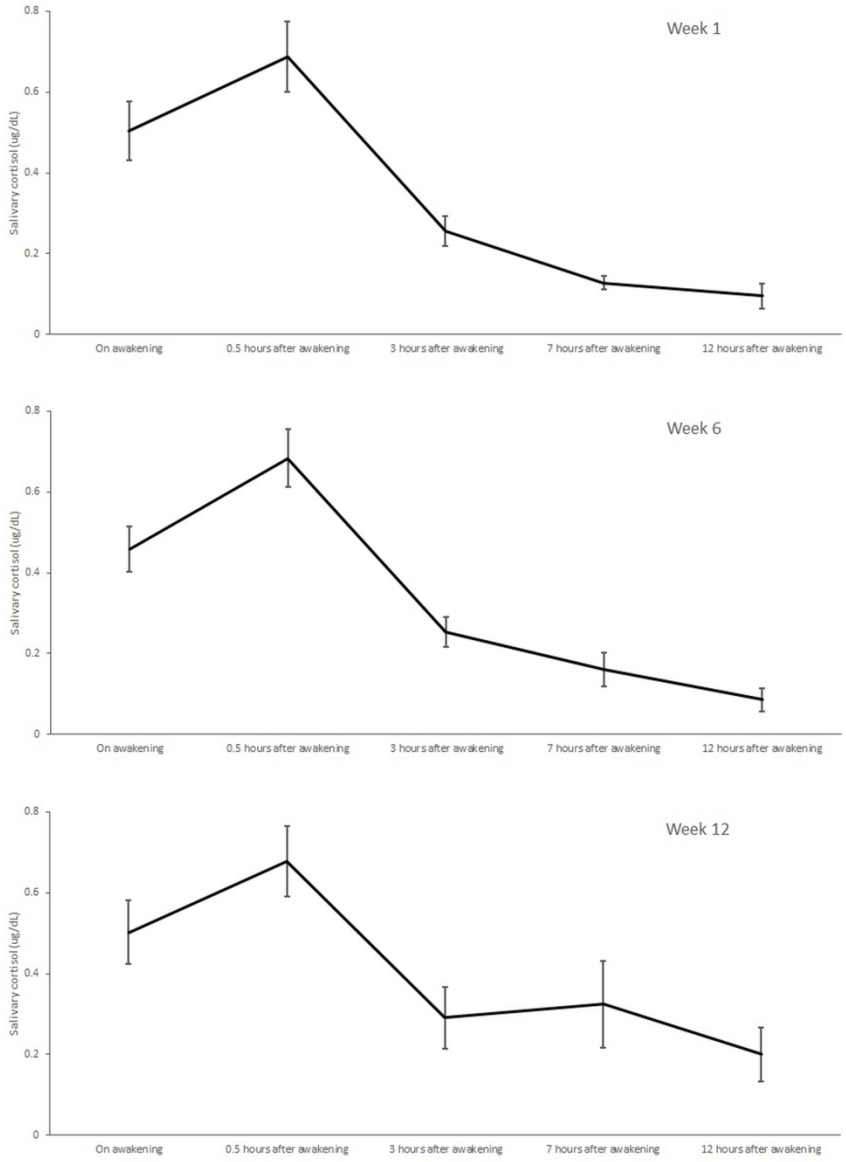

Figure 3 Changes in diurnal cortisol levels between Week 1, 6 and 12 including standard error about the mean (vertical bars)

76x105mm (600 x 600 DPI)

Supplementary Information 1
Detailed Overview of the Mindfulness-Based Intervention in Recurrent Ovarian Cancer

This programme was delivered as six sessions, developed and delivered by an experienced and qualified instructor complying with UK good practice guidelines

Session 1	**Checking in and releasing tension** Commonly, when we are anxious or stressed, we hold tension in the body. Learning to "check in" and "release tension" is a useful way to reduce stress levels. We will use this simple informal practice to consciously switch on the parasympathetic nervous system. Over time, it is possible to identify what experiences or thoughts cause us to tense and hold our breath, and to deliberately let them go.
Theme & content	**Getting started on a personal mindfulness journey** *Mindfulness is about starting from where you are. It is experiential and this journey will start with these women sharing their own stories so far, their hopes and fears about the future.* Introductions • Personal stories & what they hope to gain from this course • Commitment to practice Ground rules of the group & safety measures/support Looking after yourself during the course. Introduction to mindfulness • What it is? • Relevance to participants • Short video of how others have used mindfulness to deal with cancer & survivorship How mindfulness works • Intention (Set this in Journal as a motivation to practice) • Attention & Approach • Discuss the importance of approach – non-judging, kindness, curiosity etc… Stress • Modern living & extra burden of cancer • Biochemical impact • Fine tuning the autonomic system • How to switch on the relaxation response Befriending the breath • Power of the breath • Practical issues around breathing properly • Using the breath to relax or invigorate
Practices	Informal mindfulness practice – "checking in and releasing tension"
Teaching points	Learning to release and let go of tension Relaxation is the natural state
Homework	Daily practice of "checking in and releasing tension" Practice log & journal (observations – thoughts, feelings, body sensations, comments) Choose specific approach/ attitude each day and explore that as you go about activities

Session 2	**Training attention using a Breath Awareness Practice** Learning to pay attention, noticing when the mind has wandered and simply bringing it back is central to mindfulness (Gunaratana, 2002). Mind-wandering is prevalent, is associated with being unhappy and is exacerbated by stress (Killingsworth & Gilbert, 2010). It is known to correlate with neural activity in a network of brain areas that support self-referential processing, known as the default-mode network (Brewer *et al.* 2011; Farb *et al.* 2007). Consequently, we can easily lose conscious control; amplify emotions and fall into habitual patterns of thoughts and behaviours, so exacerbating our stresses, anxieties and sadness (Williams & Penman 2011). Furthermore, it is thought that concentration-based mindfulness meditation helps "de-automise" mental processes that cloud perception of stimuli in the present moment (Lutz *et al.* 2008) and that this is central to the benefits of practising mindfulness, coming off automatic pilot and seeing things clearly as they are. Typically, the breath - sensations of breathing - is used to train attention (Grossman, 2010; Gunaratana, 2002). This provides an anchor to the present moment and facilitates disengaging with other mind activities such as rumination (Williams *et al.* 2007). As the mind becomes focused it has a calming effect, reducing stress and anxiety.
Theme & content	**"Gathering a scattered mind"** *We know that nearly 50% of the time our mind is not where we intended it to be and when we are stressed, anxious or have low mood this increases. Furthermore, a wandering mind is not a happy mind; it has a negative bias, and can take us to dark places, caught up in rumination and proliferation. In this session we will use mindfulness to gather and focus a wandering mind; bring it back to a neutral place grounded in the present moment.* "Checking in" • Practice • Discussion of how the week has been - was it possible to practice? • Experiences of mindfulness able to share • Barriers and obstacles to practice Living on autopilot & the dangers of a wandering mind • Background of mind wandering and where it can take us • Common having survived cancer that there are anxieties, worries and how mindfulness can be used to gather the mind when it is all over the place and bring it back to focus on something neutral such as the breath • Taking control of a wandering mind • Video showing impact of mindfulness on the brain Training attention • Breath awareness • Breath used as focus of attention – it is in the present moment and considered a neutral focus • Reminder that this is not just a concentration exercise as the attitude we bring is important e.g. kindness and curiosity • If problems with the breath provoking anxiety, can use external object such as sound • Experience of the practice discussed in pairs and then open to the group Revisit Breath and breathing from first session • Power of the breath – indicator of how we are

	• Practices to invigorate or relax • Now introduced as an anchor to gather and calm a scattered mind. What causes you to hold your breath? • Notice when this happens, release and let go
Practices	Informal mindfulness practice – "checking in and releasing tension" Formal attention training using Breath Awareness
Teaching points	Learning to pay attention, beginning to gain more control over a wandering mind by focusing it on a neutral object such as the breath (or sound). As we focus the mind, it calms the mind. The Breath awareness practice is used to skilfully attend to mind-wandering, starting to allow things to be as they are. Learning how the breath can be a "vehicle" for directing awareness. This is used in all other practices (Killingsworth & Gilbert, 2010)
Homework	Daily Formal practice of attention training using Breath Awareness Informal mindfulness practice – "checking in and releasing tension" Practice log & journal (observations – thoughts, feelings, body sensations, comments) Choose specific approach/attitude each day and explore that as you go about activities

Session 3	**Session 3: Reconnecting mind and body using the Body Scan Practice** Practices, such as the body scan, use body sensations as the focus of attention (Dreeben *et al.* 2013). Tuning into body sensations cultivates an awareness of the body-mind system. Formal practice has a significant effect on the insula (Hölzel *et al.* 2008; Lazar *et al.* 2005), which is implicated in interoceptive perception (Craig, 2003). This improvement in interoceptive perception, provides valuable information about the general state of our bodies, our stress levels, our moods and our behavioural urges (Fletcher *et al.* 2010). Effectively, through practice we are training to use the body as a barometer (Williams & Penman, 2011). Over time, we are able to identify personal signatures of emotions such as stress and anxiety and we can use these physiological signals from the body as an early warning system to offset emotional hijacks (Williams & Penman, 2011). The body scan is used to train familiarity of body sensations as they arise, learning to approach and explore them, effectively reducing avoidance of contacting them. This is an important therapeutic process, which is useful in conditions such as panic disorder, some form of posttraumatic stress disorder and pain (Fletcher *et al.* 2010).
Theme & content	**"Reconnecting mind & body"** *Emotions are useful physiological signals unfortunately we often don't "read" them correctly and amplify them to the extent that they are overwhelming. We are subject to "emotional hijack" and they seem to be more in control of us rather than the other way around.* *Using mindfulness we can increase awareness of body sensations and begin to use the body as a barometer, an early warning system for emotions arising and gain more emotional control.* "Checking in" • Practice • Discussion of how the week has been - was it possible to practice? • Experiences of mindfulness able to share • Barriers and obstacles to practice Emotions

	• What are they, why are they useful? • Interconnectedness – body – mind loop • Body as amplifier or early warning detection system • Examples of embodied cognition Physiological signatures in the body • Exercise – bringing fear or happiness to mind, what does it feel like in the body? • Video – Bodily maps of emotion Practice Body Scan • Training attention broad and narrow using sensations in the body • Increasing awareness of bodily sensations • Appreciating the difference between thinking about sensations and experiencing them • Body is a different way of processing emotions (later session) • If brings up difficulties (may be hard to "befriend" the body) then returning to the breath as an anchor. • Experience of the practice discussed in pairs and then open to the group Emotional regulation • Emotions detected as physiological signals are quick and tangible • Emotions drive behaviour and colour experience • Refractory period • How mindfulness by increasing self-awareness can help • Simple Tool when caught up in emotion e.g. RAIN
Practices	Informal mindfulness practice – "checking in and releasing tension" Body Scan
Teaching points	Reconnecting mind and body. Increasing body awareness. Identifying own physiological signatures of emotions arising and learning to interrupt them over time. "Body–mind loop"- bringing awareness to body can interrupt this and can be a different way of processing emotions Using the body as a valuable source of information – bodily maps of emotions (Nummenmaa et al. 2013) Recognising signals from your body, a personal "barometer" signalling inclement emotions, such as unhappiness, anxiety and stress before they arise (Williams and Penman, 2011)
Homework	Daily Formal practice of Body scan Informal mindfulness practice – "checking in and releasing tension" Practice log & journal (observations – thoughts, feelings, body sensations, comments) Herbert Benson stress trigger form

Session 4	**Session 4: Increasing cognitive awareness using a practice of Breath Body Sounds and Thoughts** A formal meditation practice will be used to guide through observing sensations of breathing, bodily sensations, sounds and thoughts as they come and go without getting caught up in them. In addition, to this practice we will use psycho-education exercises reinforcing that thoughts are just thoughts and not facts (Segal *et al*. 2013). Opening up to observe thoughts provides an opportunity to better understand how our mind works and how it affects us (Grossman, 2010).

Theme & content	**"Mind games"** *Mindfulness can be used to increase cognitive awareness, to look at what goes on in our heads, the familiar stories and patterns of thoughts. Aware that thoughts are just thoughts and are not facts.* *Appreciating that it is not our experience per se that causes emotions to arise and illicit certain behaviours but rather our interpretation of experience. Using mindfulness to strip away the layers and see things clearly for what they are not what we think they are.* "Checking in" • Practice • Discussion of how the week has been - was it possible to practice? • Experiences of mindfulness able to share • Barriers and obstacles to practice • What is working and not working Exercise – thoughts are not facts • Using simple scenario see where our mind takes us Mind games • Common mental habits • How many do you do? Exercise – Interpretation • Using scenario looking at thoughts & feelings • Aware that we all interpret same thing differently and this impacts on how we feel and what action we want to take Practice – Breath Body Sounds & thoughts • Realising that everything comes and goes • Thoughts come and go • Learning to observe them • Coming back to the breath if caught up or too difficult • Gaining insight into what goes on in our heads • Experience of the practice discussed in pairs and then open to the group Practical ways of dealing with thoughts • Observing rather than pushing away or trying to stop them • Appreciate thoughts are just thoughts not facts – perhaps reappraise Tools for getting out of our heads • Anchor to the breath • Senses – Overthinking mode of mind vs experiential mind • Looking after yourself during the course. Breathing Space • Giving some distance - reappraise Stress • Modern living & extra burden of cancer • Biochemical impact • Fine tuning the autonomic system • How to switch on the relaxation response Befriending the breath

	• Power of the breath • Practical issues around breathing properly • Using the breath to relax or invigorate
Practices	Informal mindfulness practice – "checking in and releasing tension" Formal practice – Breath Body Sounds and Thoughts Informal Breathing Space
Teaching points	The key learning here is "de-centring" seeing thoughts and feelings simply as thoughts and feelings, as an observer rather than defining ourselves by them. It enables us to step back and effectively be able to relate to them rather than from them, caught up in them. We are starting to cultivate a spaciousness of mind, a wider perspective and so reducing the power of thoughts, able to see "thoughts as thoughts" and not facts. This enables us to see things more clearly as they really are and make better choices. Comparisons are seen between thoughts and sounds; they come and go and they are not "us". Over time we begin to recognise unhelpful thought patterns and learn to read and acknowledge them. They could simply signify a "weather pattern" and serve as a warning.
Homework	Daily Formal practice of Breath, Body, Sounds and Thoughts Informal mindfulness practice – "checking in and releasing tension" Informal practice –Breathing Space

Session 5	**Session 5: Practices looking at Facing difficulties & cultivating Loving Kindness** Formal mindfulness meditation practices to explicitly explore dealing with difficulties or pain, both physical and emotional, will be explored (Segal *et al.* 2013). Instead of getting caught up in the psychological and emotional struggle with pain and difficulties, individuals are encouraged to live alongside them, employing a more acceptance-based approach (Cusens *et al.* 2010). Acceptance and self-awareness are generally proposed as the mediating factors to explain how mindfulness affects pain (Baer, 2003; Shapiro *et al.* 2006). Harsh self-criticism is key to a wide range of mental health problems, especially depression. Through mindfulness practice kindness and friendliness can be developed, which is more supportive of healthy emotional processing and wellbeing. Kindness is transformative: this change in attitude enhances openness, creativity and happiness, while acting as an antidote to fear and guilt and reducing stress and anxiety (Williams and Penman, 2011). It helps to switch off the "aversion" pathways in the mind, which lead to exhaustion and chronic discontent and rather switching on the "approach" pathways. A formal Loving Kindness practice will be used to cultivate kindness.
Theme & content	**"Facing difficulties"** *Dissatisfaction and "suffering" come from wanting things to be different. When we brace against things, push things away, we expend effort and add layers to our suffering.* *Mindfulness offers a different approach, a "softening" and turning towards. This acceptance and letting be allows us to deal with difficulties. Through mindfulness we can put processes into place to manage difficulties adaptively.* *Cultivating kindness and compassion is central to transformation in mindfulness.* "Checking in" • Practice • Discussion of how the week has been - was it possible to practice?

	• Experiences of mindfulness able to share • Barriers and obstacles to practice • What is working and not working? • Have there been any shifts? Facing difficulties – pain physical and emotional • Usual strategies • Using mindfulness – turning towards, acceptance, letting be, curiosity • Reminder of the practice "checking in and releasing tension" Practice – Exploring difficulties • Breath, Body, opening up to intense sensations • Exploring, softening • Bringing difficulty to mind, body sensations, processing emotions in the body • Experience of the practice discussed in pairs and then open to the group Loving kindness – Self compassion • Cultivating kindness and equanimity towards self • Short practice of Loving kindness • Short Self compassion practice as a tool
Practices	Formal practice – Exploring difficulties Formal practice – Loving kindness Informal mindfulness practice – "checking in and releasing tension"
Teaching point	During the exploring difficulties practice we learn to "drop into" physical sensations in the body when there are strong negative thoughts and emotions around. Turning to these physical sensations helps stop mental proliferation and anchors awareness in the flux of present moment experience. We notice the natural variation, changes in intensity, and it provides one way of "riding the waves" of powerful internal experiences. In doing so, we are able to let go of fuelling them by trying to suppress or change things.
Homework	Daily Formal practice of Exploring difficulties or Loving Kindness Informal mindfulness practice – "checking in and releasing tension" Informal practice –Breathing Space

Session 6	**Session 6: Formal sitting practice of "choiceless" awareness** As the course progresses and with practice, it becomes possible to move participants to meditate on whatever arises (Lutz *et al.* 2008). Over time, with continued mindfulness practice, participants will become more self-aware, which leads to better self-regulation of cognitions, emotions and behaviours (Gross, 1998).
Theme & content	**"Closing and going forward"** *What are my insights from this journey so far and where do I want to go? How do I continue my mindfulness journey in a way that serves me?* "Checking in" • Practice

	• Discussion of how the week has been - was it possible to practice? • Experiences of mindfulness able to share • Barriers and obstacles to practice • What is working and not working? • Have there been any shifts? Recap of the practices & learning so far • Overview of course • Discuss in pairs what you take away • Open to group Formal Practice of Open monitoring or "choiceless" awareness • Awareness of whatever arises • Sitting meditation • Experience of the practice discussed in pairs and then open to the group Cultivating mindfulness in everyday life • Practice of mindful walking or movement • Suggestions of integrating mindfulness Looking after yourself • Nourishing and depleting exercise • Exhaustion funnel • Pacing • Breathing Space with an action step • Gratitude practice Going forward • Open discussion Closing practice
Practices	Formal practice of "choiceless" awareness Informal mindfulness practice – "checking in and releasing tension" Mindful movement
Teaching points	This practice of "choiceless" awareness focuses on the full range of experience and for many is considered as the formal sitting meditation of mindfulness. It cultivates acceptance of what is by simply allowing whatever arises to be our experience in this moment. Equally accepting pleasant, unpleasant and neutral. Developing a spacious quality of mind, aware of all experiences as they arise and pass away in consciousness. Recognising recurring patterns of the mind. Seeing more deeply into the nature of human experience and life. The experience of "choiceless" awareness practice parallels daily life. As we learn to notice and be with the flux in formal practice, we can bring greater awareness to flux in our daily experience.
Homework	Ongoing practice formal and informal, whatever works for you

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