Group interventions to reduce emotional distress and fatigue in breast cancer patients: a 9-month follow-up pragmatic trial

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**Background:** Long-term effects of psychosocial interventions to reduce emotional distress, sleep difficulties, and fatigue of breast cancer patients are rarely examined. We aim to assess the effectiveness of three group interventions, based on cognitive behavioural therapy (CBT), yoga, and self-hypnosis, in comparison to a control group at a 9-month follow-up.

**Methods:** A total of 123 patients chose to participate in one of the interventions. A control group was set up for those who agreed not to participate. Emotional distress, fatigue, and sleep quality were assessed before (T0) and after interventions (T1), and at 3-month (T2) and 9-month follow-ups (T3).

**Results:** Nine months after interventions, there was a decrease of anxiety ($P = 0.000$), depression ($P = 0.000$), and fatigue ($P = 0.002$) in the hypnosis group, and a decrease of anxiety ($P = 0.024$) in the yoga group. There were no significant improvements for all the investigated variables in the CBT and control groups.

**Conclusions:** Our results showed that mind–body interventions seem to be an interesting psychological approach to improve the well-being of breast cancer patients. Further research is needed to improve the understanding of the mechanisms of action of such interventions and their long-term effects on quality of life.

Cancer diagnosis and treatments have significant side effects: pain; physical dysfunction; fatigue; sleep disturbances; and hair loss (Ewertz and Jensen, 2011; Die Trill, 2013; Weis and Horneber, 2015), as they are associated with the concomitant psychological and emotional reactions such as anxiety, depression, and distress (Die Trill, 2013; Tojal and Costa, 2015; Hernández Blázquez and Cruzado, 2016). Given the extent of these negative psychosocial consequences, several group interventions have been evaluated to improve cancer patients’ quality of life (Faller et al, 2013; de Vries and Stiefel, 2014; Mitchell et al, 2014). These programmes, especially those based on cognitive behavioural therapy (CBT), had benefits on both anxiety and depression after the intervention (Osborn et al, 2006; Groarke et al, 2013; Gudenkauf et al, 2015).

Cognitive behavioural therapy is a ‘time-sensitive, structured, present-oriented psychotherapy directed towards solving current problems and teaching clients skills to modify dysfunctional thinking and behaviour’ (Beck Institute for Cognitive Behavior Therapy, 2016). A review showed that CBT interventions were related to short- and long-term effects on quality of life in cancer survivors, with only short-term effects on depression and anxiety.

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Concerning breast cancer patients, Antoni et al (2009) showed that positive effects of CBT intervention for anxiety appeared to hold for the 12-month observation period, whereas Stagl et al (2015) showed that a cognitive behavioural stress management programme had positive effects on depression and quality of life up to 15 years. Finally, in their study, Howell et al (2013) identified several trials that effectively used CBT to increase sleep quality and decrease insomnia in cancer patients.

Mind–body interventions such as yoga and hypnosis have also been studied in oncology settings (Mendoza et al, 2016), mostly in breast cancer patients. Yoga includes various fields such as ethical disciplines, physical postures, and spiritual practices with the aim of unifying mind and body (Smith and Pukall, 2009), whereas hypnosis is defined as ‘a procedure during which a health professional or researcher suggests that a patient or subject experience changes in sensations, perceptions, thoughts, or behaviour’ (The Executive Committee of the American Psychological Association – Division of Psychological Hypnosis, 1994). These mind–body approaches began to show short- and mid-term improvements in breast cancer patient fatigue, sleep, anxiety, and depressive symptoms (Banerjee et al, 2007; Moadel et al, 2007; Farrell-Carnahan et al, 2010; Mustian et al, 2013; Kiecolt-Glaser et al, 2014; Montgomery et al, 2014; Cramer et al, 2015; Lanctôt et al, 2016).

For example, Moadel et al (2007) have shown greater improvements in breast cancer patients at 3 months in the yoga group vs a randomised control group for quality of life (QoL), emotional well-being, and distressed mood. In addition, Lanctôt et al (2016) demonstrated that compared to a waiting list control group, for which depressive symptoms increased during 8 weeks of chemotherapy, no similar increase was found in the yoga group. Kiecolt-Glaser et al (2014) have also shown in a randomised controlled 3-month trial for breast cancer patients that fatigue was reduced and vitality was increased for yoga participants compared to the control group. Groups did not differ on depression at any time. Finally, Mustian et al (2013) showed the efficacy of a yoga-based intervention to improve sleep quality of cancer survivors. However, Chandwani et al (2014) did not find any differences for mental health or sleep quality between yoga, stretching, or waiting control groups.

Concerning hypnosis, the study of Montgomery et al (2014) randomly assigned breast cancer patients to either CBT plus hypnosis (CBTH) or an attention control group. They showed that the CBTH group had significantly lower levels of fatigue at the 6-month follow-up, but there was no measure for distress. A meta-analysis from Cramer et al (2015) also showed that several hypnosis-based interventions positively impacted fatigue and distress. Finally, an online self-hypnosis intervention for cancer survivors showed promising results in improving sleep (Farrell-Carnahan et al, 2010). These initial results are encouraging, but there is still a lack of long-term data about the efficacy of yoga (Smith and Pukall, 2009) and hypnosis (Cramer et al, 2015).

Our article aims to present the results of a non-randomised study assessing the 9-month follow-up effects of three interventions (yoga, self-hypnosis, and CBT) in improving emotional distress, sleep quality, and fatigue in breast cancer patients. These three treatment plans will be compared to a control group, including patients who agreed not to participate in the interventions. For a better understanding of the evolution of the data, we will briefly present the short-term effects of the interventions (Bragard et al, 2017). We would like to test the hypothesis whether these effects persist over time.

MATERIALS AND METHODS

Patients and design. First, 114 patients with non-metastatic breast cancer were recruited up to 18 months after diagnosis (regardless of cancer stage and type of treatment received). They had to choose to participate in a yoga, a self-hypnosis, or a CBT group. We chose this kind of design because patients who receive their preferred treatment might be more motivated and could exhibit greater adherence to the treatment (King et al, 2005; Sedgwick, 2013). Moreover, Mills et al (2015) have already shown that there is not a major difference at baseline between the preference-based groups, as they are comparable even if they were not randomised. Fifteen of them dropped the study after one or two sessions (6 patients in the yoga group (22.2%); 8 patients in the self-hypnosis group (10.5%); and 1 patient in the CBT group (9.1%)), leaving a final sample of 99 patients (N_yoga = 21; N_self-hypnosis = 62; N_CBT = 10). Twenty-four patients were also recruited a second time to form a control group (Figure 1), with the final sample including 123 patients. Inclusion criteria were ≥18 years old and ability to read, write, and speak French. Patients with a diagnosed psychiatric disorder or dementia were excluded. After giving written informed consent, participants completed a baseline assessment, including self-reported measures (T0). Three follow-up assessments were conducted 1 week (T1), 3 months (T2), and 9 months (T3) after the group intervention lasting between 2 and 3 months. For a feasibility issue, the control group completed questionnaires three times only: at T0; T1; and T3. This paper will focus on the data from the last follow-up (T3), but we will briefly present the results from T1 to give more information about the evolution of the data. Table 1 shows the principal demographics and medical data of these patients in each group at baseline.

Interventions. Yoga intervention included six weekly 90 min sessions in groups of 3–8 participants, led by trained teachers and developed in Montreal, QC, Canada (Lanctôt et al, 2010). The Bali Yoga Program-Breast Cancer (based on Hatha yoga) was specifically designed for breast cancer patients. Each participant received a DVD to encourage home practice. More details about the intervention can be found in Bragard et al (2017).

Self-hypnosis/self-care intervention included 6 sessions of 120 min every 2 weeks in groups of 3–8 participants. This was developed and led by one of the authors (MEF), an anesthesiologist with experience in oncology who was also trained in hypnosis (Faymonville et al, 2010). It is a negotiating approach that fosters shared decision-making through tasks on general well-being rather than the health problem itself. At the end of the session, a 15 min hypnosis exercise was conducted. They received CDs with the hypnosis exercises and homework assignments between sessions (Vanhaudenhuyse et al, 2015). More details are given in Bragard et al (2017).

Cognitive behavioural therapy intervention included 6 weekly 90 min sessions in groups of 3–8 participants led by CBT-trained psychologists with experience in psycho-oncology. This programme was developed by team leaders (AME, IB, and MD) and modelled on the work of Andersen et al (2009) and Savard (2010). Relaxation training took place at the end of each session and participants performed tasks between sessions. More details about the intervention are given in Bragard et al (2017).

The control group included patients who agreed not to attend any of the groups. They continued to benefit from their usual care throughout the duration of the study.

Measures. The following measures were contained in the assessment battery.

Demographics and medical history. A questionnaire looking at age, marital status, education, and cancer-related variables (e.g., treatment types) was completed.

The Hospital Anxiety Depression Scale. The Hospital Anxiety Depression Scale (HADS) is a reliable and validated 14-item measure assessing anxiety and depression in physically ill subjects.
Seven items for anxiety and 7 for depression are rated on a 4-point Likert scale (0 = symptoms not present to 3 = symptoms considerable). Each subscale was scored from 0 to 21 (0–7: ‘normal range;’ 8–10: ‘borderline;’ or 11–21: ‘probable presence of anxiety or depressive disorder’) (Zigmond and Snaith, 1983).

European Organization for Research and Treatment of Cancer-QoL Core Questionnaire-30. The core questionnaire (30 items) to assess the QoL of cancer patients incorporates five functional scales, three symptom scales, a global health status/QoL scale, and several single items for additional symptoms and the perceived financial impact of the disease. The responses indicate the extent to which the patient experienced symptoms or problems. Each item is scored on a 4-point Likert scale (‘not at all’ to ‘very much’), excepted for the global health status/QoL that is a 7-point scale (‘very bad’ to ‘excellent’) (Aaronson et al., 1993). In this paper, we only discuss the fatigue-related items of this questionnaire (3 items).

Insomnia Severity Index. (Savard et al., 2005) This is a 7-item measure of subjective sleep complaints and associated distress. Items are scored on a 5-point Likert scale, ranging from 0 to 4 with higher total scores representing more severe insomnia symptoms. The cutoff scores are 0–7 (no clinically significant sleep difficulties), 7–14 (sleep difficulties warranting further investigation), and 15 + (presence of clinically significant insomnia).

The data collected from these questionnaires are displayed in Table 2.

Outcomes. The outcome measures assessed the 9-month follow-up effects of three interventions for breast cancer patients’ emotional distress (anxiety and depression), fatigue, and sleep difficulties, to then compare the three intervention groups with the control group.

Data analysis. Baseline (T0) demographic, medical, and psychological data were compared between groups to test for initial group equivalency with ANOVA and χ2-tests. To be considered for data analysis, patients attended at least three sessions and completed the first (T0) and last assessments (T3).

Group-by-time changes in emotional distress, fatigue, and sleep difficulties were processed using multivariate analysis of variance with repeated measures, followed by post hoc comparisons (Tukey’s HSD test). All tests were two-tailed and the alpha was set at 0.05.

RESULTS

Of the 123 women in the intervention or control groups, 1 patient died in the hypnosis group. Thus, in that group, there were data at T0 and T3 for 67 patients; in the yoga group, there were data at T0 and T3 for 21 patients; in the CBT group, there were data at T0 and T3 for 10 patients; and in the control group, there were data at T0 and T3 for 24 patients (Figure 1). The four groups did not differ at baseline on demographics, medical history, psychological variables (anxiety, depression, fatigue, and sleep quality), or number of sessions (for each group). The average attendance rate was 5.8 sessions for yoga, 5.4 for self-hypnosis, and 5.7 for CBT.
Impact of interventions on emotional distress, fatigue, and sleep quality at T1 and T3. To present the evolution of the data between T0 and T1, we conducted a multivariate analysis of the psychological variables with repeated measures on time of evaluation. No significant effect by group and no significant group-by-time interaction effect were revealed, but a significant effect of time of the evaluation appeared ($F(4) = 4.59; P = 0.002; \eta^2_p = 0.14$). Post hoc comparisons revealed a decrease of anxiety ($P = 0.000$), depression ($P = 0.004$), and fatigue ($P = 0.045$) in the hypnosis group, and a decrease of anxiety ($P = 0.010$) in the yoga group.

Another multivariate analysis of the psychological variables with repeated measures on time of evaluation (between T0 and T3) indicated no significant effect by group, except for a significant
After the intervention for anxiety, depression, and fatigue. In the psychological characteristics were homogenous in the four groups compared to self-hypnosis. Patients’ demographic, medical, and objective outcomes of three interventions (yoga, self-hypnosis, and CBT) in improving emotional distress and fatigue. The two mind–body interventions led to better outcomes than the control and yoga group. Anxiety also decreased at the 9-month follow-up. Given the lack of long-term results regarding the efficacy of mind–body interventions in oncology settings, it is difficult to contrast our results with existing ones. However, we see that they contrast with those of Chandwani et al. (2014), who found no effect of yoga after 6 months on breast cancer patients’ emotional or mental health, but positive effects of yoga on fatigue at a 6-month follow-up, as did several other authors at a 3-month follow-up (Bower et al., 2011, 2012; Derry et al., 2007; Kiecolt-Glaser et al., 2014). Our results are congruent with those of Banerjee et al. (2007) who found a positive impact of yoga on anxiety in breast cancer patients undergoing radiotherapy. Concerning hypnosis, our results contrast with those of Jensen et al. (2012) who found no effect of an hypnosis-based intervention on anxiety at a 6-month follow-up, but are congruent with the study of Montgomery et al. (2014), where CBTH created lower levels of fatigue at a 6-month follow-up. Despite the fact that we did not investigate the effects of our intervention later than at 9-month follow-up, our study seems to give a first argument in favour of a long-term effect of alternative psychotherapeutic approaches, especially hypnosis, as part of self-care intervention for emotional distress and fatigue in breast cancer patients. We found no improvement in the CBT group after 9 months. These results contrast with the review of Osborn et al. (2006), showing that CBT interventions were related to short-term effects on depression and anxiety in cancer survivors, but they are congruent with those of Groarke et al. (2013) and Boesen et al. (2011), who did not find long-term effect on distress in their studies. Considering our results, we concluded that the two mind–body interventions led to better outcomes than the control and CBT did, especially self-hypnosis in terms of improvement of emotional distress and fatigue. The two mind–body interventions were also the only ones to lead to positive results immediately after

| Table 2. Mean baseline and follow-up scores in different outcomes by group |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
|                             | T0 Mean (s.d.) | T1 Mean (s.d.) | Evolution T0–T1 |
|                             | P              | P              | T3 Mean (s.d.) |
|                             | P              | T0–T3 Evolution |
|                             | P              | P              | P              |
| **Self-hypnosis (N = 68)**  | 8.68 (4.12)    | 6.70 (3.58)    | 0.000          |
| HADS Anxiety                | 5.06 (3.17)    | 3.84 (3.01)    | 0.004          |
| Depression                  | 2.59 (0.78)    | 2.34 (0.65)    | 0.045          |
| EORTC QLQ C30               | 12.65 (6.49)   | 10.60 (6.15)   | 0.052          |
| Fatigue                     | 2.36 (0.74)    | 2.18 (0.67)    | 0.064          |
| ISI                         | 6.67 (4.12)    | 6.67 (2.48)    | 0.002          |
| **Yoga (N = 21)**           | 9.76 (4.62)    | 7.05 (3.35)    | 0.010          |
| HADS Anxiety                | 5.06 (3.74)    | 3.90 (3.03)    | 0.026          |
| Depression                  | 2.44 (0.74)    | 2.38 (0.90)    | 0.099          |
| EORTC QLQ C30               | 12.76 (6.91)   | 11.05 (6.26)   | 0.868          |
| Fatigue                     | 2.07 (0.49)    | 2.07 (0.52)    | 0.442          |
| ISI                         | 6.67 (4.12)    | 6.67 (2.48)    | 0.002          |
| **CBT (N = 10)**            | 8.60 (3.78)    | 6.70 (4.24)    | 0.654          |
| HADS Anxiety                | 5.70 (3.89)    | 5.00 (3.59)    | 0.989          |
| Depression                  | 2.20 (0.65)    | 2.07 (0.49)    | 0.999          |
| EORTC QLQ C30               | 12.30 (5.74)   | 11.50 (5.44)   | 0.999          |
| Fatigue                     | 2.18 (0.67)    | 2.18 (0.67)    | 0.089          |
| ISI                         | 8.45 (5.15)    | 8.45 (5.15)    | 0.089          |
| **Control (N = 24)**        | 7.17 (2.96)    | 7.58 (3.40)    | 0.999          |
| HADS Anxiety                | 4.13 (3.72)    | 4.04 (3.00)    | 1.00           |
| Depression                  | 2.56 (0.92)    | 2.36 (0.74)    | 0.844          |
| EORTC QLQ C30               | 10.54 (6.73)   | 12.00 (5.54)   | 0.916          |
| Fatigue                     | 10.96 (5.82)   | 10.96 (5.82)   | 0.999          |
| ISI                         | 11.70 (6.07)   | 11.70 (6.07)   | 0.999          |

Abbreviations: CBT = cognitive behavioural therapy; EORTC QLQ C30 = European Organization for Research and Treatment of Cancer-Quality of Life Core Questionnaire-30; HADS = Hospital Anxiety Depression Scale; ISI = Insomnia Severity Index. Bold values highlight significant effects. Effect of time of the evaluation (\(\alpha = 0.795; F(4) = 7.23; P = 0.000; \eta^2_p = 0.21\)), and a significant group-by-time interaction effect (\(\alpha = 0.830; F(12) = 1.80; P = 0.047; \eta^2_p = 0.07\)). Post hoc comparisons revealed a decrease of anxiety (\(P = 0.000\)); depression (\(P = 0.000\)), and fatigue (\(P = 0.002\)) in the hypnosis group, as well as a decrease of anxiety (\(P = 0.024\)) in the yoga group. There were no significant improvements for all the investigated variables in the CBT and control groups.

The graphic evolution of the results over time in each group is displayed in Figure 2. We can see that in each experimental group, different variables improved over time, as their means decreased, even though some effects are not significant.

**DISCUSSION**

This non-randomised study assessed the 9-month follow-up effects of three interventions (yoga, self-hypnosis, and CBT) in improving emotional distress, fatigue, and sleep quality in breast cancer patients. In all, 99 breast cancer patients participated in the interventions: 68 in the hypnosis group (1 patient died); 21 in the yoga group; and 10 in the CBT group, while 24 participated as a control group. The number of participants in the hypnosis group has been recently discussed (Bragard et al., 2017) and could be explained in terms of the notoriety of the trainer, and the greater availability of yoga or individual psychological counselling outside the hospital compared to self-hypnosis. Patients’ demographic, medical, and psychological characteristics were homogenous in the four groups at baseline.

In the self-hypnosis group, there were improvements 9 months after the intervention for anxiety, depression, and fatigue. In the yoga group, anxiety also decreased at the 9-month follow-up. Given the lack of long-term results regarding the efficacy of mind–body interventions in oncology settings, it is difficult to contrast our results with existing ones. However, we see that they contrast with those of Chandwani et al. (2014), who found no effect of yoga after 6 months on breast cancer patients’ emotional or mental health, but positive effects of yoga on fatigue at a 6-month follow-up, as did several other authors at a 3-month follow-up (Bower et al., 2011, 2012; Derry et al., 2014; Kiecolt-Glaser et al., 2014). Our results are congruent with those of Banerjee et al. (2007) who found a positive impact of yoga on anxiety in breast cancer patients undergoing radiotherapy. Concerning hypnosis, our results contrast with those of Jensen et al. (2012) who found no effect of an hypnosis-based intervention on anxiety at a 6-month follow-up, but are congruent with the study of Montgomery et al. (2014), where CBTH created lower levels of fatigue at a 6-month follow-up. Despite the fact that we did not investigate the effects of our intervention later than at 9-month follow-up, our study seems to give a first argument in favour of a long-term effect of alternative psychotherapeutic approaches, especially hypnosis, as part of self-care intervention for emotional distress and fatigue in breast cancer patients.

We found no improvement in the CBT group after 9 months. These results contrast with the review of Osborn et al. (2006), showing that CBT interventions were related to short-term effects on depression and anxiety in cancer survivors, but they are congruent with those of Groarke et al. (2013) and Boesen et al. (2011), who did not find long-term effect on distress in their studies. Considering our results, we concluded that the two mind–body interventions led to better outcomes than the control and CBT did, especially self-hypnosis in terms of improvement of emotional distress and fatigue. The two mind–body interventions were also the only ones to lead to positive results immediately after.
expressive suppression (Dick et al, 2017). Yoga is known to reduce mind and body seem to constantly communicate in a bidirectional branch, to reduce the physiological response to stress. Indeed, the autonomic nervous system by activating its parasympathetic role (Carlson and Bultz, 2008). Carlson et al (2014) showed in a randomised-controlled trial, which is the most scientifically rigorous trial design for assessing the efficacy of an intervention (Pocock, 1983; Millat et al, 2005), and by collecting data during longer periods of time. Larger sample sizes would also help measure more significant effects. Future research might include all types of cancer, not only breast cancer, and some objective measures of emotion regulation and sleep quality such as cardiac frequency, activity, or sleep pattern monitoring. At a clinical level, the group. More specifically, 1 week after the intervention, emotional distress and fatigue improved in the hypnosis group, whereas anxiety improved in the yoga group. These results suggest that self-hypnosis is a powerful tool to improve well-being quickly. To explain these differences between the interventions, we can focus on the mechanisms of change of these different techniques. On one hand, mind–body techniques in general focus on balancing the autonomic nervous system by activating its parasympathetic role (Carlson and Bultz, 2008). Carlson et al (2014) showed in a randomised-controlled trial, which is the most scientifically rigorous trial design for assessing the efficacy of an intervention (Pocock, 1983; Millat et al, 2005), and by collecting data during longer periods of time. Larger sample sizes would also help measure more significant effects. Future research might include all types of cancer, not only breast cancer, and some objective measures of emotion regulation and sleep quality such as cardiac frequency, activity, or sleep pattern monitoring. At a clinical level,
Hypnosis, yoga and CBT for breast cancer patients

IB and CG participated in the conception and design of the study, in the acquisition and interpretation of data, and in drafting the manuscript. A-ME, M-EF, PC, GD, DL, and GJ participated in the conception and design of the study, in the interpretation of data, and in revising the manuscript critically for important intellectual content. All authors read and approved the final manuscript, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

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In conclusion, this study showed the benefits of self-hypnosis in improving anxiety, depression, and fatigue of breast cancer patients immediately after the intervention and until the 9-month follow-up. Yoga also seems to be useful in decreasing anxiety quickly after the intervention, with this effect lasting at least 9 months. Larger samples would be necessary to determine differences between the three types of interventions.

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