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# Complementary and alternative therapies: do they improve quality of life for women with breast cancer?

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**Background:** The growing incidence of breast cancer in women in the UK has inevitably resulted in the expansion of the roles of health care practitioners in breast cancer care. As women with a diagnosis of this form of cancer are increasingly turning to complementary and alternative medicine (CAM) with a view, amongst others, to improve their quality of life, health care professionals are beginning to question if there is a place for it in their practice.

**Objectives:** The purpose of this study was to review and critically appraise the current research literature to investigate if complementary and alternative therapies improve quality of life in women with breast cancer.

**Major findings:** Following a detailed search of nine electronic databases (AMED, EMBASE, Medline, British Nursing Index, PsychINFO, CINAHL, Cochrane Library, OTDBase and Google Scholar) between the years 2000 and 2010, eight relevant studies were identified. Three of these studies focused on CAM as a whole, three on yoga, one on progressive muscle relaxation training and guided imagery and one on therapeutic massage. Out of the eight studies, six concluded that complementary and alternative therapies improved quality of life in women with breast cancer. The remaining two studies presented somewhat equivocal findings; however, they did identify scope for future research. Despite this, study limitations were identified across the studies and so caution should be exercised when generalizing the results.

**Conclusion:** The combined findings of this literature review indicate that there is great potential for complementary and alternative therapies to be increasingly integrated into clinical practice within breast cancer services. However, prior to this, further high quality research is required, including larger and longer term studies.

**Keywords:** Breast cancer, Quality of life, Complementary and alternative medicine

## Introduction

In the UK, breast cancer is the most common form of cancer in women.<sup>1,2</sup> In 2006 alone, more than 45,000 cases of breast cancer were diagnosed; the majority were women aged 50 years or older who had reached menopause.<sup>3</sup> Despite this, increasing numbers of women are surviving cancer; indeed 8 out of 10 women will now survive the disease beyond five years.<sup>1</sup>

Bearing these statistics in mind, it is evident that the role of health care practitioners in breast cancer care is set to grow exponentially. The NHS Cancer Plan<sup>4</sup> acknowledged this growth, promising greater investment in breast cancer services to improve prospects of survival and quality of life for breast cancer sufferers. The Cancer Reform Strategy<sup>5</sup> built on this, further highlighting the importance of patient choice within the services.

Unruh and Elvin<sup>6</sup> recognized that the impact of breast cancer can have a devastating effect on occupational life. The common physical side effects associated with breast cancer, such as fatigue, lymphoedema, nausea and weakness, undoubtedly reduce overall physical function.<sup>7-9</sup> However, impact on psychosocial factors must also be taken into account when providing care for women with breast cancer, including role function, emotional function and social function.<sup>6,8,10-12</sup>

In recent years, an increasing number of women with a diagnosis of breast cancer have availed themselves of complementary and alternative medicine (CAM).<sup>13-15</sup> Buettner *et al.*<sup>16</sup> reported that approximately 36-83% of women with breast cancer have used CAM, with other studies presenting similar figures.<sup>17,18</sup> The definition of CAM has changed in recent decades and varies considerably throughout literature.<sup>19</sup> For the purpose of this review, the definition given by the National Center for CAM will be utilized: 'A group of diverse medical and health care systems, practices, and

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products that are not normally considered to be conventional medicine'.<sup>20</sup>

A plethora of different forms of CAM are available including relaxation, yoga, mistletoe extracts, acupuncture, massage and high-dose vitamins<sup>16,21</sup> and CAM addresses all aspects of the person: physical, spiritual, affective and environmental components.<sup>20</sup>

Many researchers have investigated why women with breast cancer are motivated to use CAM.<sup>21-24</sup> A recurring finding was the desire to increase quality of life.<sup>13,21,25</sup> Indeed, it is widely accepted that breast cancer and its treatment can exact an enormous toll on quality of life<sup>26</sup> and this outcome has been extensively studied within this population.<sup>25</sup> Therefore, the primary objective of this literature review was to critically appraise recent research studies to explore whether CAM use in women with breast cancer improves their quality of life.

### Search Strategy

A comprehensive search of literature was conducted, starting with electronic searches of six databases, namely, AMED, British Nursing Index, EMBASE, Medline, PsycINFO and CINAHL. Additionally, Google Scholar and the Cochrane Centre were extensively searched. Reference lists of published studies were scanned for other relevant studies. If several studies by the same author/s were identified, an author search was subsequently performed. Finally, OTDBase was searched for relevant literature published in occupational therapy specific journals.

Search terms included the following: 'cancer' or 'female' or 'breast' or 'neoplasm' and 'complementary' or 'alternative therap\*' or 'complementary therap\*' or

'complementary and alternative medicine' or 'mind-body therap\*' or 'body therap\*' and 'quality of life'.

In some databases preferred search terms such as 'health and quality of life' were used to ensure relevant articles were captured. It should be noted that women in remission following successful treatment of breast cancer, that is, breast cancer survivors, were excluded in the search criteria as it was considered that women who had an active diagnosis of breast cancer would perceive quality of life differently to those who had recovered from the disease.

The initial database search identified 58 journal articles. This number was reduced to 27 papers following removal of duplicates. On application of the exclusion criteria (Table 1) this was further reduced to six articles. Extensive hand searching identified a further two studies, giving a total of eight research studies that met the inclusion criteria. These studies<sup>27-34</sup> are summarized in Table 2.

### Critical Appraisal

During the selected timeframe, researchers have investigated the effect of a variety of complementary and alternative therapies on quality of life in women with breast cancer, including anthroposophic medicine, yoga, progressive muscle relaxation training and therapeutic massage. These studies will be critically appraised below to assess their methodological quality in relation to study design, sampling (methods, size and recruitment), outcome measures (reliability and validity) and interventions (type and duration) employed. The study findings will be outlined and discussed in relation to the study strengths, limitations and generalizability.

**Table 1** Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Participants	Women aged 18 or over Diagnosis of breast cancer	Women under 18 years of age Women in remission following successful treatment of breast cancer, i.e. breast cancer survivors
Intervention	Complementary and alternative therapies, including: 'body' therapies such as yoga, massage, acupressure and acupuncture 'mind-body' medicines including art therapy, guided imagery, meditation, music therapy, prayer, relaxation therapy and tai chi	Studies that focused solely on biologically based practices, such as melatonin and selenium
Study types	Randomized controlled trials (RCTs) Non-randomized trials Cohort studies Single case designs Before and after designs Case-control designs Cross-sectional designs Case studies	Literature reviews Discussion papers
Outcome measures	Quality of life as main outcome or one of the main outcomes	Quality of life not as main outcome or one of the main outcomes.
Other	English language Published studies from January 2000 to February 2010	Studies published before January 2000 Publications not written in the English language Unpublished studies

**Table 2 Summary of research studies reviewed**

Author and Year	Design and Aim(s) of study	Sample Characteristics	Method and Outcomes	Findings	Strengths and Limitations
Carlsson <i>et al.</i> 2004 <sup>27</sup>	<i>Non-randomized controlled trial</i>  To compare perceived quality of life/life satisfaction in a sample of women with breast cancer who were treated in hospital with alternative/complementary care to a matched sample who received only conventional medicine.	36 matched pairs of Swedish females <75 years with at least 6 months life expectancy	Main outcome: quality of life  EORTC-QLQ30 and LSQ measured on 5 occasions	Women who had anthroposophic care increased their perceived quality of life/life satisfaction, unlike the matched group.	Randomization was not possible therefore the results are not generalizable to women with breast cancer as a whole. The EORTC-QLQ30 is widely used, thus increasing the comparability with similar studies.
Moschen <i>et al.</i> 2001 <sup>28</sup>	<i>Cross-sectional study</i>	n= 117 women with a breast cancer diagnosis of at least 6 months; all aware of diagnosis and able to provide informed consent (n=55 users of alternative therapies, n=62 non-users)	12 month follow-up Main outcomes: quality of life, coping and causal attribution.	CAM users developed a more active style of illness coping. Women using a large number of therapies tended to adopt a more depressive coping style than those using only a small number. No statistically significant differences between users and non-users for quality of life.	This exploratory study identified scope for further research. Some of the alternative therapies used were nutritional, however acupuncture/acupressure and relaxation training were also included therefore the study was not excluded.
Carlsson <i>et al.</i> 2006 <sup>29</sup>	<i>Non-randomized controlled trial follow-up study</i>	n= 13 of the original matched pairs from the authors' study in 2004 took part in this study after 5 years	Freidburg Questionnaire for Coping with Illness, Causal Attribution Questionnaire, EORTC-QLQ30, Profile of Mood States and a self-developed questionnaire on alternative therapies. Outcome measures were completed once. Main outcome: quality of life.	After 5 years there were improvements in overall quality of life compared to admission for the women receiving anthroposophic care. Improvements were between admission and 1 year, but not beyond. Only minor improvements were found in the matching group.	As randomization was not possible, there may have been confounding variables that were uncontrolled by the matching procedure.

Table 2 Continued

Author and Year	Design and Aim(s) of study	Sample Characteristics	Method and Outcomes	Findings	Strengths and Limitations
	To examine perceived quality of life/life satisfaction in two samples of women with breast cancer who were treated with either anthroposophic care or conventional medical treatment over a 5 year period.		EORTC-QLQ30 and Life Satisfaction Questionnaire measured on 6 occasions: on admission, after 1, 3 and 6 months, 1 year and 5 years.		The final sample size was small, thus the risk of Type II error was greatly increased.
Danhauer <i>et al.</i> 2009 <sup>30</sup>	<i>Randomized Controlled Trial</i>  To compare self-reported emotional, health-related quality of life, and symptom outcomes between a group of women with breast cancer who received restorative yoga intervention and a control group who received no intervention.	<i>n</i> =44 women who were ≥ 18 years of age, had a diagnosis of breast cancer, were 2-24 months post-primary treatment, physically able to attend yoga classes, able to understand English and free of medical contraindications reported by their physician. Randomisation to intervention or waiting list control group.	Main outcomes: self-reported emotional, health-related quality of life and symptom outcomes.	Health-related quality of life showed a borderline difference between the two groups.	The careful matching procedure and the low dropout rate were study strengths. Sample was not demographically diverse, therefore generalizability is limited.
			Short Form-12, FACT-B, FACT-Fatigue, FACIT-Spirituality, Center for Epidemiologic Studies Depression Scale, Pittsburgh Sleep Quality Index and Positive and Negative Affect Schedule measured at Week 0 and Week 10.		Pilot study therefore strong conclusions were not drawn, however, recommendations for future research were warranted.
Moadel <i>et al.</i> 2007 <sup>31</sup>	<i>Randomized controlled trial</i>  To examine the impact of yoga on quality of life, fatigue, distressed mood, and spiritual well-being among a multiethnic sample of breast cancer patients.	<i>n</i> =128 English/Spanish speaking patients who were 18 years of age or older, and diagnosed with new/recurrent breast cancer within the previous 5 years. Participants were not actively practising yoga and had high performance status. Random assignment to a 12-week yoga intervention or a 12-week waiting list control group (2:1 ratio).	Main outcome: quality of life.  The FACT-General, FACT-Fatigue, FACT-Spiritual and A Distressed Mood Index were administered at baseline, 1, 3 and 6 months.	Although not statistically significant, authors suggested that a yoga intervention was associated with beneficial QoL outcomes among an ethnically diverse, urban population of breast cancer patients.	Random allocation methodology not described.  Due to the heterogeneity in treatment characteristics, results may not be generalizable to other populations.  The findings are limited to the short-term effects of yoga therefore a follow-up study is necessary.

**Table 2 Continued**

Author and Year	Design and Aim(s) of study	Sample Characteristics	Method and Outcomes	Findings	Strengths and Limitations
Vadhiraja <i>et al.</i> 2009 <sup>32</sup>	<i>Randomized controlled trial</i>	<i>n</i> =88 women with recently diagnosed operable breast cancer, aged between 30 and 70 years, Zubrod's performance status 0–2, high school education and provision of consent.	Main outcomes: quality of life and positive and negative affect.	Significant improvement in positive affect, and in the QoL measures of emotional function and cognitive function. Decrease in negative affect in the yoga group compared to controls.	Using only patients with high school education could have affected the generalizability of the study findings.
	To compare the effects of an integrated yoga program with brief supportive therapy in breast cancer outpatients undergoing adjuvant radiotherapy at a cancer centre.	Exclusion criteria: presence of any concurrent medical condition that was likely to interfere with the treatment, any major psychiatric, neurological illness or autoimmune disorders or any known metastases. Randomised to receive yoga ( <i>n</i> =44) or supportive therapy ( <i>n</i> =44).	EORTC-QLQ30 and Positive and Negative Affect Schedule administered at baseline and after 6 weeks of radiotherapy treatment.		The homogeneity of the sample was a strength.
Yoo <i>et al.</i> 2005 <sup>53</sup>	<i>Randomized controlled trial</i>	<i>n</i> =60 outpatients with the same type of cancer, who were receiving chemotherapy for the first time.	Main outcome: quality of life.	6 months after chemotherapy the QoL of the intervention group was found to be higher than that of the control group.	Use of well-developed, widely used outcome measures increases comparability with other studies.
	To assess the effectiveness of progressive muscle relaxation training and guided imagery in reducing the chemotherapy side effects in women with breast cancer and to measure their effects on quality of life.	Randomised to intervention group ( <i>n</i> =30) or control group ( <i>n</i> =30).	FACT-B was administered at baseline and after 3 and 6 months. Multiple Affect Adjective Check List was also administered before each of six cycles of chemotherapy.		Small sample size and relatively short-term follow-up were both limitations.
Sturgeon <i>et al.</i> 2009 <sup>54</sup>	<i>Pre/post intervention assessment design</i>	<i>n</i> =51 female patients receiving breast cancer treatment.	Main outcome: quality of life.	Massage therapy performed once a week for 3 consecutive weeks during breast cancer treatment had a positive influence on perceived quality of life concerns on half of the scales measured.	Use of standardized outcome measures and homogeneity of sample were strengths of this study.
	To assess the impact of therapeutic massage on the quality of life of patients undergoing treatment for breast cancer.	Exclusion criteria: contraindications to massage therapy including active skin rash, open cutaneous lesions, venous thrombosis or symptomatic varicosity, untreated anemia or current touch therapy	Main outcome: quality of life.		Main limitations were small sample size, lack of control group and selection bias.
			State Trait Anxiety Inventory, Visual Analogue Scale, Index of Nausea, Vomiting and Retching, Symptoms Distress Scale, Verran and Snyder-Halpern Sleep Scale and FACT scales.		Self-report of symptoms may have presented measurement bias, however, this method is common among exploratory studies.
			Participants completed these onsite prior to the initiation of therapy and one week post massage therapy.		

### Study design

The studies comprised a variety of research designs. Four used randomized controlled trials,<sup>30–33</sup> widely considered as the ‘gold standard’ of research.<sup>35–38</sup> Each of these four studies sought to determine the effectiveness of specific treatments, in keeping with RCT design.<sup>35,39</sup> Despite the apparent rigor of RCTs, there have been recent debates regarding the applicability of this ‘reductionist’ approach in complementary therapy research.<sup>40,41</sup> Indeed, in all four studies, the authors failed to incorporate ‘blinding’, therefore respondent bias and the Rosenthal effect (experimenter expectancy) were not prevented.<sup>42–44</sup> However, it might be argued that this was not appropriate or possible as the therapist was an integral part of the intervention.<sup>40,45</sup> It should be noted that the RCT by Vadiraja *et al.*<sup>32</sup> was the only one of the four that met the two main requirements of randomization as stated by Altman *et al.*<sup>45</sup> in the revised CONSORT statement for reporting RCTs, namely: the generation of an unpredictable allocation sequence and allocation concealment. Thus, the other RCTs<sup>30,31,33</sup> may not have effectively avoided systematic bias.<sup>46–49</sup> This, inevitably, would have affected the overall generalizability of the results.<sup>42</sup>

Conversely, Carlsson *et al.*<sup>27,29</sup> performed a non-randomized controlled trial approach with matched pairs. The researchers individually matched 60 women who had referred themselves to a hospital that used CAM with women from an oncology outpatient department. The second study by this group of authors<sup>29</sup> was a five-year follow up which was the only one of the reviewed studies that provided insight into the long-term effects of CAM on quality of life in women with breast cancer.

Moschen *et al.*<sup>28</sup> used a cross-sectional design, a design often employed to measure time-related phenomena, or in other terms, a snapshot of one period of time.<sup>50,51</sup> This design was appropriate for their study aim which was to determine the prevalence of complementary therapy use in women with breast cancer.<sup>52</sup> Sturgeon *et al.*<sup>34</sup> utilized a pre/post intervention assessment design, a suitable exploratory design as minimal previous research had been published in their area of interest. Nonetheless, these two studies cannot firmly differentiate between cause and effect,<sup>47,53</sup> therefore their findings should be regarded merely as preliminary research.

### Sampling

The sample, method of sampling and number in each group varied across studies. Four of the studies<sup>27,29,32,33</sup> used power calculations, indicating the implementation of a very thorough approach. By determining how large a sample they needed to detect a true difference between the groups,<sup>46,54</sup> the authors enhance the reader’s confidence. In spite of this, all four studies failed to attain

their estimated required sample size, thus increasing the risk of a Type II error.<sup>46,51</sup>

Moschen *et al.*<sup>28</sup> recruited one of the largest samples. Nevertheless, participants were recruited from out-patient clinics only, therefore selection bias was introduced and strong intervention effects would have been inhibited.<sup>55–57</sup> However, when viewed from a different perspective, the study was only intended to be a preliminary investigation therefore it could be claimed that this convenience sampling method was adequate in this instance.<sup>58</sup>

All four of the RCTs also used convenience sampling from local cancer centres, thereby limiting the ecological validity of the results.<sup>59,60</sup> However, Danhauer *et al.*<sup>30</sup> recruited volunteers in addition to this, thus expanding the study population and ultimately increasing the generalizability of the results.<sup>61</sup> Selection bias was decreased in the study by Moadel *et al.*,<sup>31</sup> in which random assignment of participants was stratified by treatment status, resulting in a 2:1 ratio, thereby increasing representativeness.<sup>62,63</sup>

The study by Sturgeon *et al.*<sup>34</sup> was the only one of the eight that did not recruit a control/comparison group due to a lack of funding. In addition to this, the sample was very small ( $n=51$ ) and the inclusion criteria were not clearly defined. Hence, selection bias was a major weakness of this study.<sup>64</sup>

The two studies by Carlsson *et al.*<sup>27,29</sup> used convenience sampling with matching procedures. Commendably, the authors acknowledged that randomization would have been preferable but was not possible. The matching criteria were based on four principles; however, baseline quality of life was not included in these, therefore the matched pairs were still not entirely equivalent.<sup>16,46,65,66</sup> Both studies suffered from attrition bias,<sup>52</sup> particularly the five-year follow-up study.<sup>29</sup> Despite this, the latter study<sup>29</sup> is important in that it was the only one that provided insight into the longer term effects of complementary therapy on quality of life.

The inclusion and exclusion criteria were generally similar across the eight studies reviewed although some were more constraining than others. Only one of the studies<sup>33</sup> reported that the groups were well matched for demographic variables such as age, educational level and marital status. These confounding variables could provide an alternative explanation for the effect on quality of life in women with breast cancer, thus the internal validity of the studies could be queried.<sup>60,67,68</sup> Another possible limitation of all the studies was the Hawthorne effect, whereby subjects may have responded differently because of their awareness of being observed.<sup>42,52,54</sup>

### Outcome measures

Quality of life is an important outcome for patients with breast cancer.<sup>69,70</sup> Montazeri<sup>69</sup> found that the

European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30)<sup>71</sup> and the Functional Assessment Chronic Illness Therapy-Breast (FACIT-B)<sup>72</sup> were the most common and well-developed instruments that measured quality of life in breast cancer patients. Correspondingly, all eight studies utilized either one of these instruments.

Out of the four studies that used the EORTC QLQ-C30, three reported on its validity and reliability<sup>27,29,32</sup> although only one of these supported this with psychometric data.<sup>32</sup> Despite this, evidence stipulates that the EORTC QLQ-C30 shows a high degree of validity and reliability.<sup>73–75</sup> Furthermore, as it is widely used, the reader's ability to draw comparisons across studies is enhanced.<sup>58</sup> Likewise, numerous studies also acknowledge the well-developed psychometric properties of the FACIT-B and other FACIT/FACT scales.<sup>72,76,77</sup> All four studies that used the FACIT/FACT scales reiterated this, with Danhauer *et al.*,<sup>30</sup> Yoo *et al.*,<sup>33</sup> and Sturgeon *et al.*<sup>34</sup> providing co-efficients to enhance the reader's confidence in their use. It is notable that both scales take a holistic approach to quality of life, measuring outcome areas such as physical, emotional, role and social functioning.

All eight studies employed at least one other measurement instrument in addition to the two discussed above. Several of these were standardized, for example, the Positive and Negative Affect Schedule (PANAS),<sup>78</sup> while others were developed by the authors and reliability and validity data were not provided. The studies by Moschen *et al.*,<sup>28</sup> Danhauer *et al.*,<sup>30</sup> and Sturgeon *et al.*<sup>34</sup> used five, seven and six outcome measures, respectively, which could have had a detrimental effect, especially when the small sample is taken into account.<sup>59,79</sup>

The frequency of measurement differed among the studies. The participants in the study by Moschen *et al.*<sup>28</sup> only completed their questionnaires once. However, this was deemed adequate considering that the authors had adopted a cross-sectional approach. The three studies that investigated the short-term effects of specific intervention programs, namely yoga and therapeutic massage,<sup>30,32,34</sup> carried out assessments at baseline and post treatment. The short time frames of these three studies may not have been sufficient for a noticeable effect on quality of life in the women with breast cancer,<sup>46,79,80</sup> therefore follow-up studies would be strongly advised. The other four studies<sup>27,29,31,33</sup> conducted additional assessments besides the standard pre and post measurements, further enhancing the quality of measurement.

### Intervention

The types and duration of intervention varied across the eight studies. Three of the studies investigated the

effects of CAM as a whole on quality of life in women with breast cancer.<sup>27–29</sup> Interventions in these studies ranged from relaxation and therapeutic massage to mistletoe and megavitamins. Because of the number of methods listed, these three studies lacked detail on the specific content and intensity of the interventions, therefore reducing their replicability and comparability.<sup>81</sup>

By contrast, the three studies that investigated the effects of yoga on quality of life<sup>30–32</sup> gave comprehensive descriptions of the intervention. Two of these studies<sup>31,32</sup> provided participants with audio-tapes with the instruction to self-practice at home. This, however, would have run the risk of compliance bias as differences in subject adherence to their 'home-work' may have affected the study outcomes.<sup>82</sup>

Yoo *et al.*<sup>33</sup> administered progressive muscle relaxation training and guided imagery as their interventions, while Sturgeon *et al.*<sup>34</sup> performed massage therapy on their participants. Unlike the three yoga studies,<sup>30–32</sup> Yoo *et al.*<sup>33</sup> and Sturgeon *et al.*<sup>34</sup> did not establish how well qualified or experienced the therapists were, signalling potential intervention bias.<sup>79,82</sup>

It should be noted that most of the women in the studies were in receipt of adjuvant conventional cancer treatment, mainly chemotherapy and radiotherapy. Therefore, it is likely that co-intervention occurred, which could have had either a positive or negative influence on the findings.<sup>79</sup>

### Results

The results yielded by the eight studies were quite wide-ranging. Carlsson *et al.*<sup>27</sup> reported significant improvements following CAM in the intervention group on two of the functional scales of the EORTC QLQ-C30, one of these being global quality of life ( $P=0.002$ ). In the five-year follow-up study<sup>29</sup> there were significant improvements in four of the functional scales, again including global quality of life ( $P<0.001$ ). These strict levels of significance increase the reader's confidence in the results reported.<sup>81</sup> An interesting finding in the follow up study by Carlsson *et al.*<sup>29</sup> was that the improvements in the anthroposophic group took place between admission and one year, but not beyond. No significant changes were reported in the corresponding control group.

No statistically significant differences were reported by Moschen *et al.*,<sup>28</sup> who explored CAM as a whole, or by Moadel *et al.*<sup>31</sup> who investigated the effects of yoga on quality of life. Despite this, Moadel *et al.*<sup>31</sup> still concluded that yoga intervention benefits quality of life outcomes. This assertion should be treated with caution as it was not supported by statistical evidence. Conversely, Danhauer *et al.*<sup>30</sup> reported a borderline difference between their yoga and control groups.

However, even though a definitive conclusion was not reached, this study helps direct future research. The remaining three studies<sup>32–34</sup> which investigated the effects of yoga, relaxation and guided imagery, and therapeutic massage, respectively, all asserted that their interventions improved quality of life in women with breast cancer, and provided supporting statistical evidence.

## Discussion

The purpose of this critical appraisal was to ascertain if complementary and alternative therapies improve quality of life in women with breast cancer.

Out of the eight studies reviewed, six concluded that CAM improved quality of life in women with breast cancer.<sup>27,29,31–34</sup> The other two studies reported no major differences between users and non-users of CAM regarding quality of life<sup>28</sup> and a borderline difference in health related quality of life between the intervention and control groups (in favour of the intervention group),<sup>30</sup> respectively.

Prior to drawing overall conclusions, however, certain limitations should be taken into account. As addressed earlier, the ideal study design for complementary therapy research is somewhat debatable. As none of the four RCTs were able to incorporate blinding procedures, knowledge of group assignment, both on the parts of the investigators and the participants, could have influenced responses to treatment. This concern has been addressed by Richardson,<sup>40</sup> who queried whether alternative methodologies such as single case designs would be more effective for investigating this type of treatment. Her conclusion was that RCTs should still be conducted as far as possible, albeit with a highly rigorous randomization process.

Bearing in mind this recognition of the importance of randomization, it is notable that the results of the two non-randomized controlled trials by Carlsson *et al.*<sup>27,29</sup> may have been invalidated by baseline differences between the intervention and control groups. Another limitation that should be highlighted is that several of the studies were not demographically diverse,<sup>27–29,34</sup> therefore their generalizability was limited. Furthermore, all studies had small samples, thus the risk of Type II error was largely increased.

Despite this, the studies share certain strengths. Specifically, the use of well-developed measurement instruments enhanced the reliability and comparability of the studies. Furthermore, the exploratory studies by Moschen *et al.*<sup>28</sup> and Sturgeon *et al.*<sup>34</sup> identified clear scope for future research.

Although six out of the eight studies found that quality of life in women with breast cancer was enhanced, it is not possible to draw firm conclusions due to the disparate nature of the CAM methods

reviewed. One assertion that can be made, however, is that complementary therapies are not detrimental to the quality of life of women with breast cancer.

It is also noteworthy that the six studies that concluded that CAM improves quality of life in women with breast cancer<sup>27,29,31–34</sup> are supported by other authors. Kolden *et al.*<sup>26</sup> emphasized that complementary therapies can play a significant quality of life-enhancing role in cancer care. In addition, Tacon and McComb<sup>83</sup> are currently completing a pilot study in which the two complementary therapies of mindfulness and exercise are being considered in relation to quality of life in women with breast cancer. Within their protocol these authors affirmed their belief that mind-body medicine should play an integral role in evidence-based, cost-effective, quality health care.

## Recommendations

A definitive finding that emerged from the studies was the need for more rigorous and larger scale research on individual complementary and alternative therapies and their impact on quality of life in the specified study population. Moreover, as the study by Carlsson *et al.*<sup>29</sup> was the only one to examine the long-term effects on quality of life, there is a need for future studies to follow suit in this respect. Indeed, it is paramount to establish this before these interventions can confidently be implemented into clinical practice. Franck *et al.*<sup>84</sup> have argued that complementary and alternative therapies deserve a full evaluation from the National Institute of Clinical Excellence (NICE), particularly when their usage is continuously on the increase.

## Conclusion

Overall, results suggest that there is considerable potential for complementary and alternative therapies to be used for women with breast cancer, with the aim of improving quality of life. However, despite providing important insight, the methodological flaws of the studies reviewed, the general dearth of research in this area and the limited number of studies investigating the effectiveness of individual CAMs limits the generalizability of the findings. Further high quality research is needed to strengthen the evidence base for these therapies, including larger studies with longer-term follow-up periods.

## Disclosure statement

This article is based on a non-funded final year dissertation that was submitted by Katherine Bleakley in April 2010 as part of her BSc (Hons) Occupational Therapy degree at the University of Ulster.

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