



Aromatherapy Massage for Breast Cancer Patients: A Randomized Controlled Trial

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Abstract

Aim: The aim of this large randomized controlled study was to test the value of Aromatherapy (AM) with breast cancer patients for reducing symptoms, such as pain, anxiety, depression, emotional responses, insomnia, nausea/vomiting and the ability to cope.

Methods: 284 breast cancer patients, were randomized to receive AM provided by a charity-run cancer support centre for an hour a week for six weeks, or to receive care as usual. Both groups completed the European Organization for Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ-C30), EORTC breast (BR23) and the Hospital Anxiety and Depression Scale (HADS) questionnaires before at the first week, and after the third and sixth weeks.

Results: There was no significant difference in pain score between groups ($p=0.409$) or change in pain from baseline. There were however, improvements in the AM group in emotional functioning, fatigue and depression at six weeks ($p<0.05$ and medium effect sizes in all these outcomes). Physical functioning, role functioning, breast symptoms e.g. pain, swelling, sensitivity, together with side effects and future perspectives were not significantly different from the control group ($p>0.05$) after six weeks of treatment. Other symptoms such as pain, insomnia and arm symptoms, were not significantly different.

Conclusion: AM is beneficial for improving emotional functioning and fatigue, as well as reducing symptoms of anxiety and depression among breast cancer patients after six one-hour sessions of weekly treatment.

Keywords: Anxiety; Aromatherapy Massage; Breast Cancer; Depression; Fatigue; Quality of Life.

Introduction

Cancer patients in particular have sought out complementary therapies. Horneber et al. [1] reviewed studies of cancer patients using complementary therapies and concluded that usage had risen from 32% in the 1990's to 49% after 2000. Corner et al. [2] compared massage and aromatherapy treatments with 52 patients receiving eight weekly treatments, those receiving AM had a greater improvement in symptom control.

A number of cancer support centres have incorporated complementary therapies into treatment regimens for cancer patients. At one centre, 58 patients (mainly female) and 40 per cent with a main symptom of anxiety, completed HADS questionnaires following six AM treatments, Kite [3] concluded that AM has a role in reducing psychological distress and improving symptom control in cancer patients. Harrington et al. [4] reported a service evaluation of users at three cancer support centres with breast cancer. Patients received therapies to help relieve cancer treatment side effects and completed the Measure Yourself Concerns and Wellbeing (MYCaW) questionnaire before and after six one-hour complementary therapies. Listing et al. [5] concluded massage

improved mood and reduced physical discomfort and fatigue.

Wilkinson et al. [6] found that AM reduced psychological distress in the short term for cancer patients two weeks after intervention, and Imanishi et al. [7] reported this effect was measurable at four weeks. This finding is supported in reviews from Flemming [8] and Fellowes et al. [9].

Baum et al. [10] published a literature review which concluded that complementary and alternative medicine including AM is effective in decreasing anxiety levels and increasing quality of life. Wilkinson et al. [11] reviewed the evidence of the effectiveness of massage and AM for cancer patients in the reduction of physical and psychological symptoms. They concluded that AM may reduce anxiety in the short term and may improve the symptoms of pain and nausea. Both of these concluded that larger trials and longer follow up periods were required to confirm the efficacy and effectiveness of massage for cancer patients. Dunn et al. [12] showed significant improvements in anxiety and quality of life.

Boehm, Bussing and Osterman [13] published a descriptive systematic review of AM as an adjuvant treatment to cancer care, and found short-term improvements in well-being, anxiety and depression but no long lasting effects.

The 'FORCE' cancer support centre, situated on the site of the Royal Devon and Exeter NHS Foundation Trust hospital, offers a range of complementary therapies to cancer patients and their carers. Since the service started in 1997 it has received very positive anecdotal feedback from patients who expressed improvement in physical and emotional wellbeing, following complementary therapy treatments, particularly the AM. As most previous studies were small and reviews called for larger, well conducted trials, a randomized controlled trial was undertaken, using validated questionnaires, to attempt to measure any benefits of AM treatment.

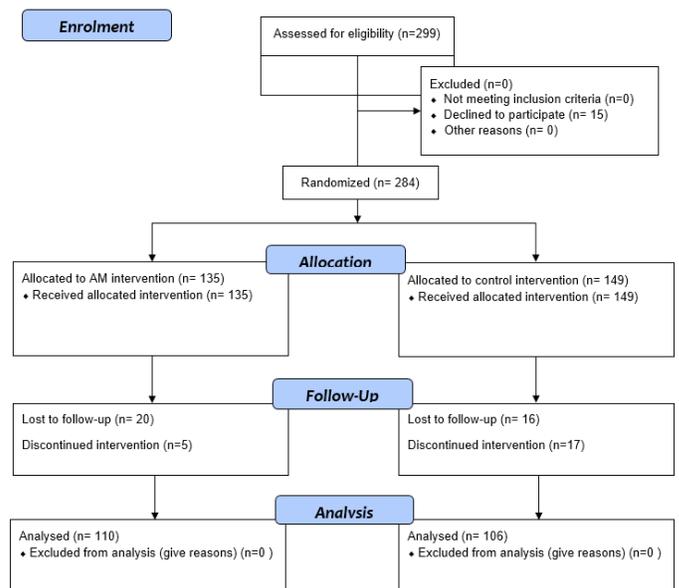
Although complementary therapy was available for all cancer types presenting at the centre, in a scoping exercise of three months' registrations, it was found that 43 percent were breast cancer patients, by far the largest diagnostic group, and Boon et al. [4] reported that uptake of CAM is highest among breast cancer patients - up to 80 per cent. For ease of recruitment, we therefore decided to study breast cancer patients. The aim of this research was to evaluate whether AM is beneficial physically and emotionally for breast cancer patients. The objectives of the study were to conduct a randomized controlled trial of AM versus no additional treatment, recruiting breast cancer patients at various stages of treatment and to use validated outcome measures such as HADS Zigmond & Snaith, [15] and EORTC QLQ-C30 and EORTC QLQ-BR23 (EORTC Charitable Trust) [16] focusing on pain, insomnia, nausea/vomiting, and emotional well-being as well as the ability to cope and feelings of anxiety.

Methods

This was a parallel arm, randomized controlled trial with 1:1 allocation to the two arms. Eligible participants were breast cancer patients undergoing clinical treatment or who had recently completed treatment and were therefore on follow-up appointments. Inclusion criteria were any patient being treated for breast cancer aged 18 or over. Exclusion criteria were psychotic patients and those who did not meet the contraindications of aromatherapy. The setting was the complementary treatment facility of the FORCE Cancer Charity based in Exeter, Devon, UK.

Ethical Approval

Ethical approval was granted by the North and East Devon Local Research Ethics Committee.



Flow Diagram: Consort 2010.

Recruitment, Consent and Randomization

Breast cancer patients (age range 18 to 86 years) were recruited by the researcher from those requesting information about the centre's complementary therapy service, or who were attending the service for additional support. Patients contacting the researcher were given an information sheet and had opportunity to discuss the trial. Those recruited completed a consent form.

A computer-generated randomization list was produced by the statistician and random allocation was completed by the researcher using sequentially numbered, opaque envelopes and allocation was concealed from therapists until interventions were assigned. All patients in both groups were given a code number

for anonymity which reflected the numbered set of questionnaires and a prepaid envelope for returning the completed forms. All questionnaires once returned were kept in a locked filing cabinet in a secure building.

It was not possible to blind patients or therapists but the analyst was blinded to group allocation.

Intervention and Control Groups

The randomized controlled trial offered the treatment group six appointments of AM once a week. A small team of experienced aromatherapists carried out the treatments. Whenever possible each aromatherapist would see the same patient for the duration of their six AM appointments. The AM treatment was individualized: there was a selection of seven essential oils (lavender, lemongrass, neroli, grapefruit, bergamot, frankincense, sandalwood). The aromatherapist made an individualized blend 1% from these oils for each patient, but the most common combination was lavender and bergamot. The oils used and treatment given were recorded on the patient's complementary therapy notes which were kept in a locked filing cabinet. Patients were asked about any known allergy or sensitivity to these oils and adverse reactions to them were noted. Patients in the control group were put on a six week waiting list for AM if they desired it.

Outcome Measures

All participants were asked to complete two questionnaires, the HADS and the EORTC QLQ-C30 with additional BR23 questions specific to breast cancer. The trial group were staged at pre-treatment, after the third and sixth treatments.

The control group completed questionnaires at baseline, three and six week intervals before being offered complementary therapy. The primary outcome was pain as measured by the EORTC questionnaire and the secondary outcomes included anxiety, depression, emotional reactions, fatigue, insomnia, breast and arm symptoms, ability to cope, side effects and future perspectives. These were also measured using the EORTC questionnaires.

Sample Size

The sample size calculation was based on evaluation data that had been collected from 133 patients with a variety of cancer diagnoses, before treatment and after six weeks of complementary therapy treatment. 58 per cent of patients were experiencing pain before treatment which had reduced to 42 per cent at six weeks. Based on these results, to be 80 per cent certain of detecting a change in pain score of 16 percentage points at the five per cent significance level, 153 patients per group would be needed (306 in

total). In the eventual trial, 135 treatments and 149 controls (284 in total) were recruited and these were all breast cancer patients.

Statistical Analysis

Split-Plot Analysis of Variance was used as the study design, which included a combination of between subjects and within-subjects comparisons. Two arms of the trial were being compared (Between Subjects) and also the three time points (Within Subjects). Raw data were transferred from the EORTC and HADS questionnaires into Excel spreadsheets manually. These were checked for errors and missing data from unanswered questions were highlighted. Where possible, missing data were replaced by imputed values according to the guidelines supplied by EORTC. Domain scores, which are scaled from 0 to 100, were calculated and transferred into new spreadsheets for analysis. Data analysis was completed using SPSS Inc. Release 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc. The analyst was blind to treatment allocation. Scores were tested for normality using Shapiro-Wilk tests and inspection of plots and histograms. The trial data were analyzed using SPANOVA, which also requires independence of data, homogeneity of variances, sphericity (equal variances of repeated measurements: Mauchly's test) and homogeneity of inter-correlations (equal variance-covariance matrices across between-subject's effects: Box's M test). If sphericity was violated, adjusted results (e.g., Greenhouse-Geisser) were interpreted. Results were expressed as mean domain scores with 95% confidence intervals for precision.

All tests were conducted at the five per cent significance level. Baseline EORTC scores were compared with those from a normal population (EORTC 2002). Cohen's d effect sizes, categorized as small (0.2), medium (0.5) or large (0.8), were calculated for each outcome measure and EORTC domain Cohen [17]. No radiotherapy or chemotherapy sub-group analyses were attempted as there was insufficient power and a risk of Type II errors.

Results

The mean age of patients in the intervention group was 55.4 years (sd 10.89, range 34 to 86 years) and in the control group 55.62 years (sd 10.12, range 25 to 80 years). The proportions having chemotherapy were: intervention 58 (42 per cent) and control 72 (48 per cent). Those having radiotherapy were intervention 37 (27 per cent) and control 36 (24 per cent). Among the baseline EORTC scores, only the emotional functioning score was similar to that provided by EORTC (2002). The trial population scored higher on physical functioning, fatigue and insomnia and lower on role functioning and pain (see Table 1).

Domain	EORTC mean	Trial Baseline mean	95% confidence interval
Emotional functioning	67.3	68.6	(64 to 73.1)
Physical functioning	73.6	80.4	(77.2 to 83.6)
Role functioning	76.6	68.7	(63.0 to 74.1)
Fatigue	31.4	41	(36.3 to 45.8)
Pain	29.1	20.4	(16.0 to 24.8)
Insomnia	31.1	39.7	(33.3 to 46.2)

Table 1: A comparison of EORTC population domain scores and baseline scores measured in this trial.

EORCT Pain Scores

There was no significant difference in pain scores overall ($p=0.409$) and no significant change in pain score in the AM group from baseline: 19.56 (95per cent CI 15.61 to 24.01); six weeks: 17.4 (95percent CI 13.08 to 21.72). Neither the breast or arm symptoms were significantly different in main effects throughout the six-week trial period ($p=0.179$ and $p=0.483$ respectively) (Table 2).

Measures	Aromatherapy (n = 110)			Control: Usual care (n=106)			Comparisons over 6 weeks			
	Initial	3 weeks	6 weeks	Initial	3 weeks	6 weeks	Within subjects F with 1, 210 df	P value	Between subjects F with 1, 210 df	P value (effect size)
HADs anxiety	7.15 (6.35, 7.94)	6.14 (5.36, 6.91)	5.20 (4.41, 5.99)	7.20 (6.39, 8.01)	7.08 (6.29, 7.87)	7.07 (6.27, 7.87)	2.381	0.124	3.183	0.076 (0.44)
HADs depression	3.93 (3.33, 4.53)	3.80 (3.17, 4.40)	3.50 (2.9, 4.1)	4.63 (4.02, 5.24)	5.00 (4.38, 5.62)	5.14 (4.53, 5.75)	2.03	0.156	9.338	0.003 (0.50)
EORTC physical functioning	80.43 (77.29, 83.57)	81.90 (78.64, 85.16)	82.10 (79.00, 85.20)	80.41 (77.2, 83.63)	78.57 (75.24, 81.91)	79.34 (76.20, 82.54)	2.05	0.154	0.951	0.330 (0.18)
EORTC Role functioning	68.23 (62.77, 73.68)	71.12 (65.54, 76.70)	74.55 (69.09, 80.02)	68.56 (62.98, 74.14)	64.72 (59.01, 70.43)	68.72 (62.90, 74.10)	1.286	0.258	1.46	0.228 (0.21)
EORTC fatigue	38.73 (34.13, 43.34)	35.54 (30.98, 40.10)	32.6 (28.16, 37.03)	41.03 (36.31, 45.75)	41.06 (36.39, 45.73)	40.68 (36.13, 45.22)	0.598	0.44	3.681	0.056 (0.34)
EORTC emotional functioning	68.58 (64.04, 73.11)	75.27 (71.00, 79.54)	79.57 (75.71, 83.43)	68.58 (63.93, 73.23)	69.50 (65.12, 73.87)	69.23 (65.27, 73.19)	1.1	0.295	4.073	0.045 (0.51)
EORTC insomnia	40.43 (34.18, 46.68)	34.99 (29.24, 40.74)	32.47 (26.84, 38.11)	39.74 (33.31, 46.17)	36.44 (30.52, 42.35)	40.07 (34.28, 45.87)	0.784	0.377	0.563	0.454 (0.26)

EORTC pain	19.86 (15.61, 24.01)	17.77 (13.45, 22.09)	17.4 (13.08, 21.72)	20.41 (16.03, 24.81)	19.99 (15.52, 24.45)	21.21 (16.75, 25.68)	1.238	0.267	0.684	0.409 (0.18)
BR-23 future perspectives	46.20 (39.99, 52.41)	57.13 (51.04, 63.21)	56.75 (51.38, 62.12)	45.55 (39.34, 51.76)	50.14 (44.05, 56.22)	51.83 (46.46, 57.20)	0.46	0.632	1.297	0.256 (0.18)
BR-23 systemic side effects	20.57 (16.66, 24.49)	19.09 (15.89, 22.30)	16.70 (13.27, 20.14)	24.19 (20.19, 28.18)	20.40 (17.13, 23.66)	20.63 (17.13, 24.13)	0.117	0.733	1.82	0.179 (0.23)
BR-23 breast symptoms	20.57 (16.66, 24.49)	19.09 (15.89, 22.30)	16.70 (13.27, 20.14)	24.19 (20.19, 28.18)	20.40 (17.13, 23.66)	20.63 (17.13, 24.13)	0.117	0.733	1.82	0.179 (0.23)
BR-23 arm symptoms	17.69 (13.863, 21.52)	15.47 (12.18, 18.77)	15.79 (12.39, 19.20)	19.07 (15.11, 23.03)	17.89 (14.48, 21.30)	16.77 (13.25, 20.29)	0.116	0.734	0.493	0.483 (0.07)

Table 2: Individual outcome measures in intention to treat analysis of all randomised patients.

HADS Anxiety and Depression Scores (0 to 21)

Mean HADS Anxiety scores were similar at baseline (AM group 7.15; control: 7.2) but improved in the AM group to 5.2 (95 per cent CI: 4.41 to 5.99) at six weeks while remaining relatively unchanged in the control group 7.07 (95 per cent CI: 6.27 to 7.87). This gave a significant time by group interaction ($p < 0.001$) but no overall difference between subjects ($p = 0.076$). The cutoff for HADS anxiety and depression caseness is 8/21 Bjelland et al. [18]. There were 45 (42 per cent) anxiety cases in the aromatherapy group at baseline and 43 (41 per cent) in the control group. This reduced to 29 (26 per cent) after 6 weeks' treatment but increased in the control group to 46 (44 per cent).

Mean HADS depression scores were not significantly different at baseline: AM 3.93 (95 per cent CI 3.33 to 4.53); control: 4.63, (95 per cent CI: 4.02 to 5.24) but while control group depression scores continued to worsen over six weeks, those in the AM group improved (see Figure 1), giving AM 3.5 (95 per cent CI 2.9 to 4.1); control: 5.14 (95 per cent CI: 4.53 to 5.75) at that time and significant between subject's effects ($p = 0.003$). There were 15 (13 per cent) depression cases in the aromatherapy group at baseline and 23 (21 per cent) in the control group. This reduced to 12 (10.9 per cent) after treatment but increased in the control group to 30, (28 per cent).

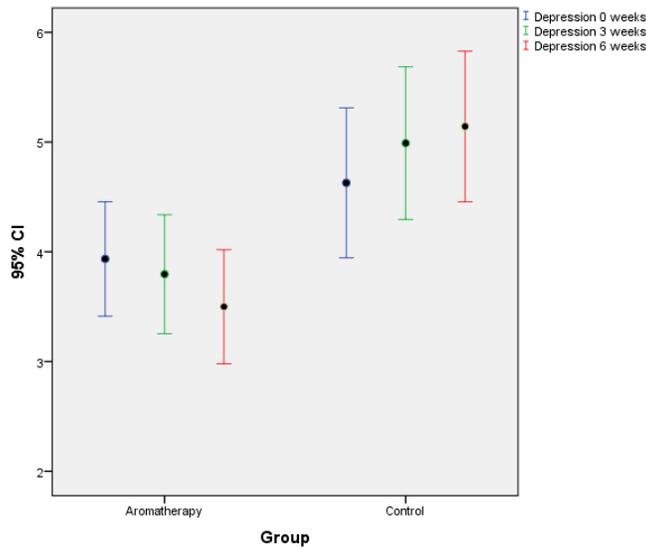


Figure 1: Effect of AM versus control for HADS depression score over a 6 week period. Mean scores (+/- 95% CI).

EORTC Emotional Functioning Scale (0 To 100)

Emotional functional scales of EORTC-30 were the same at baseline but while control scores remained relatively unchanged over six weeks, mean AM scores improved from 68.58 to 79.57 (see Figure 2). The difference between the two groups overall was significant ($p=0.045$): AM 79.57 (95 per cent CI 75.71 to 83.43); control group 69.23, (95 per cent CI 65.27 to 73.19). Neither physical nor role functioning were significantly different in main effects overall ($p=0.330$ and $p=0.228$ respectively). EORTC symptom scores (0 to 100).

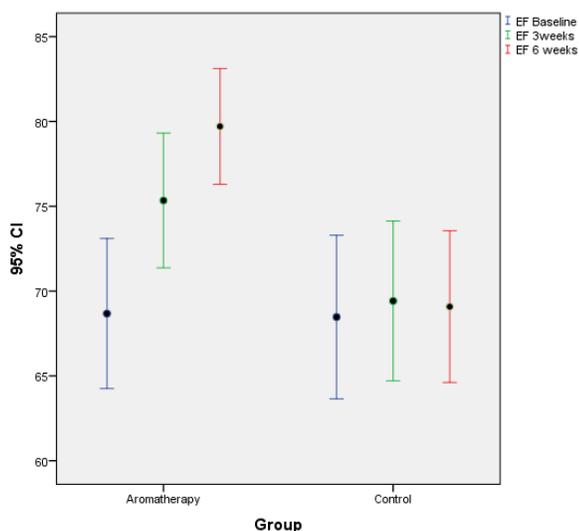


Figure 2: Effect of AM versus control on EORTC emotional functioning score over a 6-week period. Mean scores (+/- 95% CI).

Mean EORTC symptom scores of fatigue improved from 38.73 to 32.6 in six weeks in the AM group but remained relatively unchanged in the control group (41.03 at baseline and 40.68 at six weeks). However, this difference at six weeks did not reach significance ($p=0.056$): AM score 32.6, (95 per cent CI 28.16 to 37.03); control group 40.68, (95 per cent CI 36.13 to 45.22).

While EORTC insomnia scores improved steadily in the AM group, they also began to drop in the control group but rose again at six weeks. This resulted in no overall significant difference between the groups ($p=0.454$): AM insomnia score at six weeks 32.47, (95per cent CI 26.84 to 38.11); control group score 40.07, (95per cent CI 34.28 to 45.87).

EORTC Side Effects and Future Perspectives Scores

There were no significant differences in side effects or the patient's future perspectives over the six-week trial period ($p=0.179$ and $p=0.256$ respectively). No serious adverse events occurred during the trial and no adverse reactions to the aromatherapy massage were recorded.

Discussion

When this research was planned, much of the data available from other studies had been collected from palliative care patients. This trial included patients who were undergoing clinical treatment, or who had recently completed treatment and were therefore on follow-up appointments. Molinaro et al. [19] stated the scarcity of articles when researching.

Many of the previously published studies on the outcomes of AM and massage treatment of cancer patients have been criticized for their limited sample size and lack of randomization of controls. Ernst [20] and Boehm et al. [3] carried out literature reviews and highlighted such limitations, concluding that this subject warranted further investigation in order to provide more conclusive data. The current study addresses these two issues by using a large number of participants in a randomized controlled trial.

Jane et al. [21] in reviewing the literature showed that massage had positive effects on pain, anxiety and depression. They identified that future studies would benefit from an extended number of massages and larger sample sizes.

The patients in the study were all women with breast cancer. Most of the improvements in the AM group relative to the control group were in anxiety, depression, fatigue and emotional functioning. Medium effect sizes were observed for HADS anxiety (0.44), HADS depression (0.5), EORTC emotional functioning (0.51) and EORTC fatigue (0.34). Whilst insomnia, physical and role functioning, breast symptoms, side effects and future perspectives were not significantly different from the control group and had small effect sizes (around 0.2). Other symptoms such as

pain and arm symptoms, were not significantly different.

A weakness of the study was that some data were not returned or not completed on some of the questionnaires. Also, many of the patients were still receiving chemotherapy/radiotherapy and therefore some did not feel well enough to attend sessions and some lived a considerable distance from the centre. 58 (20 per cent) participants dropped out by the end of six weeks mostly in the control group (42, 28 %). The sample size was based upon data from a group of patients who were not all breast cancer patients but had other cancers. It is possible that pain was more of an issue for this group, so that the study was powered on a variable (Pain) that was not the most relevant for breast cancer patients. Blocking would have helped to keep numbers in both arms of the study even at all times. With questionnaires there is always the possibility for response bias to occur but this is less likely with the validated, self-completed EORTC cancer questionnaires used in this study. Although there is an effect on emotional status, anxiety and depression in this study, it is difficult to say what was responsible for this effect: the essential oils, the AM, or having time to relax in a quiet environment with the undivided attention of an aromatherapist. Any one of these in isolation or in combination may be responsible.

Strengths of the study are that this was a large trial with adequate participant numbers recruited into each of the two arms, in agreement with the sample size calculation. Six treatments were received. The researcher recruited all patients to this trial with concealment of random allocation from the aromatherapists, thus minimizing any selection bias. The same aromatherapist treated the patient throughout their treatments whenever possible which provided consistency in the application of the essential oils. As the EORTC questionnaire does not fully cover all aspects of psychological symptoms, a second validated questionnaire, HADS was also used.

Cawley [22] reviewing the evidence for the benefits of massage in general, demonstrated it to be effective for a range of conditions. Fourteen research studies were found, dating from 1982 to 1996. The aims were focusing on improvements in relaxation, coping with symptoms/symptom distress, mood, pain, anxiety states, depression, stress, psychological wellbeing and quality of life. Only eight studies had a statistical analysis and all reported significant improvements in outcomes. Six of the studies involved cancer patients and all but one study was statistically analyzed and they reported significant improvements in outcome such as anxiety, symptom distress, heart rate, pain (Males) and quality of life. Three of the 14 studies reviewed included AM. Cooke and Ernst [23] published a systematic review of evidence for the effectiveness of AM. Of the 12 trials identified, the six trials of AM massage were concentrated upon; the remaining six studies were unique comparisons of different AM interventions. These studies suggested that AM massage had a mild, transient anxiolytic effect.

However, they argued that the effects of AM were probably not strong enough for it to be considered for the treatment of anxiety. The hypothesis that it is effective for any other indication was not supported by the findings of rigorous clinical trials.

Conclusion

We conclude that the provision of AM is a useful adjunct to conventional treatment for patients with breast cancer. There were improvements in emotional functioning and a reduction in anxiety and depression which were sustained for at least ten weeks from the commencement of the weekly one-hour therapy sessions provided over a six-week period.

The implications of the results reported here for clinical practice are for AM to be offered alongside orthodox treatments and as a part of integrated supportive cancer care. Further research would benefit from expanding this to selecting patients from other cancer groups and the involvement of male patients. AM could be provided on the wards with the expectation of improving patients' symptoms, emotional states and well-being.

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