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A randomised, controlled trial of the psychological effects of reflexology in early breast cancer ☆

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ABSTRACT

Purpose: To conduct a pragmatic randomised controlled trial (RCT) to evaluate the effects of reflexology on quality of life (QofL) in women with early breast cancer.

Patients and methods: One hundred and eighty-three women were randomised 6 weeks post-breast surgery to self-initiated support (SIS) (comparator intervention), SIS plus reflexology, or SIS plus scalp massage (control for physical and social contact). Reflexology and massage comprised eight sessions at weekly intervals. The primary end-point was 18 weeks post surgery; the primary outcome measure was the Trial Outcome Index (TOI) of the Functional Assessment of Cancer Therapy (FACT-B) – breast cancer version. The secondary end-point was 24 weeks post surgery. Secondary outcome measures were the Hospital Anxiety and Depression Scale (HADS) and the Mood Rating Scale (MRS).

Results: At primary end-point, massage, but not reflexology, was significantly better than SIS on the TOI. Reflexology and massage were both better than SIS for MRS relaxation. Massage was better than reflexology and SIS for MRS easygoingness. At secondary end-point, reflexology, but not massage, was better than SIS on the TOI and MRS relaxation. There were no significant differences between reflexology or massage. There were no significant between group differences in HADS anxiety and depression.

Self-reported use of out of study complementary therapies indicated that this was unlikely to have a significant effect on findings.

Conclusions: When compared to SIS, reflexology and massage have statistically significant, and, for reflexology, clinically worthwhile, effects on QofL following surgery for early breast carcinoma.

☆ The study was registered with the International Standard Randomized Controlled Trial Registry (ISRCTN 87652313) (http://www.controlled-trials.com/).

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1. Introduction

1.1. Exposition

The diagnosis and treatment of breast cancer may cause clinically significant psychological and psychiatric morbidity.[1,2] In an attempt to minimise morbidity and enhance their quality of life (QofL), many women with breast cancer turn to complementary or alternative medicines (CAM)[3] and use of such interventions amongst cancer patients in general is widespread.[4–8]

Reflexology has its origins in Chinese medical thought and practice and consists of identifying and treating energy imbalances in the body through massage of reflexology points or 'terminals' in specific areas of the feet or hands.[9–12] A study in the United Kingdom, found reflexology was the most commonly used CAM (35.2%).[13]

Randomised controlled trials (RCTs) have reported positive effects of reflexology in premenstrual syndrome, Type II diabetes and low back pain.[14–16] A small RCT demonstrated a benefit for chemotherapy-related anxiety.[17] The effects of reflexology more generally on quality of life, mood and coping, in patients with cancer have not previously been evaluated in an adequately powered RCT.

Any beneficial effects of reflexology could be due to the purported effects on energy imbalances in the body or alternatively, they could be because reflexology enhances the relaxation response.[18] A randomised study of 96 women with locally advanced breast cancer demonstrated that relaxation training and guided imagery significantly enhanced mood and other aspects of quality of life during primary chemotherapy.[19] Approximately 50% of patients practised at least daily for 18 weeks and the intervention was of greatest benefit to them. Reflexology might be an alternative intervention for those patients unable to devote the time necessary to derive benefit from relaxation and guided imagery.

Alternatively, any effects of reflexology could be due to the additional social and physical contact the intervention entails.[20] A comparison of reflexology and an intervention which involves the same amount of physical and social contact but does not involve stimulation of reflexology points would clarify this. As reflexologists believe there are no reflexology points on the human scalp, scalp massage would be an appropriate choice of comparator intervention.

1.2. Aims of the study

The aims of the study, therefore, were to evaluate the effects of reflexology in comparison with two comparator interventions (self-initiated support (SIS) in the Oncology Health Centre and scalp massage) on cancer-related quality of life, relaxation, and mood, and adjustment, in women with newly diagnosed early breast cancer.

2. Methods

2.1. Recruitment procedures

Following local ethics approval (reference 01/01/010), patients were recruited at the Princess Royal Hospital, and Castle Hill Hospital, Kingston upon Hull, UK.

2.2. Study eligibility

Eligible patients met the following criteria: female; over 18 years of age; newly diagnosed histologically proven early breast cancer (T1, T2 [<3 cm], N0, N1a, M0); received breast surgery; WHO status 0 or 1; willing to give written, informed consent; and able to complete questionnaires. Exclusion criteria were history of cancer (excluding basal cell carcinoma), participating in another clinical trial and clinically significant cognitive impairment or dementia.

2.3. Enrolment and randomisation procedures

Patients were randomised 6 weeks (plus or minus 1 week) after breast surgery. The first patient was enrolled on 11th June 2002 and the final patient on 15th February 2005.

A permuted blocks randomisation sequence stratified for menopausal status, chemotherapy, and radiotherapy, was obtained online using Graph-Pad (http://graphpad.com): block size was 8 and was concealed. Sequences were stored in sealed, opaque, numbered envelopes. Randomisation was carried out remotely by telephone by the Clinical Trials Section within the Institute of Rehabilitation, Kingston upon Hull, UK. Staff involved in the randomisation procedure were independent of the clinical conduct of the study.

2.4. Setting

The study was carried out in the Oncology Health Centres, Kingston upon Hull. This service, staffed by clinical health psychologists and nurses, provides psychosocial support services for cancer patients and their relatives. Emphasis is placed on the prevention of psychological and psychiatric morbidity, and evidence-based interventions are offered to patients who develop clinically significant problems.[21–24]

2.5. Interventions

Women were randomised to one of three interventions:

- Intervention 1: reflexology plus self-initiated support (SIS) in the Oncology Health Centre.
- Intervention 2: scalp massage plus (SIS) (comparator intervention – identical amount of physical and social contact), or
- Intervention 3: SIS (comparator intervention – treatment as usual).

Patients randomised to reflexology or massage received 8 one-hour sessions at weekly intervals for 8 weeks commencing 7 weeks after surgery. Interventions were designed by our External Consultant, the Secretary of the Scottish Institute of Reflexology. Reflexology was administered by two therapists trained to the standards the Scottish Institute of Reflexology. Patients randomised to massage received gentle scalp massage according to a standardised protocol. Because reflexologists believe that the ears and neck have active reflexology points or 'terminals', care was taken to avoid these areas.

Reflexology and massage were administered according to standardised protocols. Protocols are detailed in Appendix

A. The External Consultant, monitored performance and adherence to the reflexology and massage protocols at regular intervals during the study. All three interventions included self-initiated support in the Oncology Health Centres. Women could access the Oncology Health Centres whenever they wished and received psychological support and treatment as usual in the Centres when they attended.

Each therapist saw a similar number of patients in each of the two physical contact arms of the study. As far as possible each patient had the same therapist throughout. Both treatments were given in the same rooms.

2.6. Conventional treatment

All patients underwent conventional oncological treatment according to current best practice.

2.7. Assessment schedule and outcome measures

Patients were assessed by a clinical and research specialist nurse, who was independent of treatment allocation and delivery, before randomisation (week 6 post surgery), 18 weeks after surgery (primary end-point 1) and 24 weeks after surgery (secondary end-point).

2.8. Baseline psychological assessment

Following recruitment to the study, before randomisation, patients completed the: Functional Assessment of Cancer Therapy (FACT-B). This is a widely used quality of life scale which has been used in previous research by ourselves and others to assess quality of life during both psychosocial and oncological interventions.[25–28] The FACT-B comprises two scales; the FACT-General Scale and the breast cancer concerns subscale.[28]

The Trial Outcome Index (TOI), composed of the sum of scores on the physical, functional and breast cancer concerns subscales, has been used in previous trials,[29] and its use in this investigation permits comparisons with this previous work.

Mood Rating Scale (MRS). This 6-item scale, based on the factor-analytically derived dimensions of the Profile of Mood States has shown acceptable reliability and sensitivity in UK populations.[30–33] The relaxation scale was of particular interest.

Hospital Anxiety and Depression Scale (HADS) used in the detection of clinically significant anxiety and depression.[34–38] Scores on the anxiety and depression scales were classified according to the recommended cut-off scores.[34] Mean scores were used to compare groups (square root transformation for anxiety and log transformation for depression).

Complementary Therapies Questionnaire (CMQ), an ad hoc questionnaire assessed concomitant use of complementary therapies in the three groups during the study.

Structured Clinical Interview for DSM IV^{TR} (SCID).[39] Clinical and research specialist nurses (behavioural oncology) or clinical health psychologists identified clinically significant psychiatric morbidity using the anxiety and mood disorders sections, of the SCID.

2.9. Outcome measures

2.9.1. Primary outcome

The primary outcome measure was the Trial Outcome Index (TOI) from the FACT-B at end-point 1 (week 18 post surgery).

2.9.2. Secondary outcomes

The secondary outcome measures (at weeks 18 and 24 post surgery) were the relaxation scale within the MRS, other MRS scales, the physical, functional, emotional, social and additional concerns scales of FACT-B, the HADS, the CMQ and the SCID, and the TOI at end-point 2 (week 24 post surgery).

2.10. Statistical methods

Power calculations were carried out using nQuery.[40] A10% difference in the primary outcome measure (FACT-B total) was considered clinically meaningful. With 60 patients in each group, there would be 95% power to detect a 10% difference in scores (a difference between means of 120 and 132, assuming a common standard deviation of 18).

Data were analysed using SPSS version 14. Alpha was set at 0.05 (two-tailed).

Pre-treatment equivalence of the three groups on clinical, psychological and sociodemographic data was assessed using one-way ANOVA for continuous variables and chi-square (exact test) for categorical variables.

An intention-to-treat analysis was carried out for the continuous outcome variables using univariate analysis of covariance, with age, T stage, and baseline values as covariates.[41] Where data were missing, the mean score for the cohort was imputed as analysis of the reasons for missing data suggested that it was not missing at random. To minimise the risk of a Type I error, paired comparisons were only considered when the three-group comparison was significant at $p < 0.05$ (two-tailed), and Bonferroni corrections used for paired comparisons.

A sensitivity analysis, without imputed data, with the same covariates and using the same analytical strategy was conducted.

For categorical outcomes, the three groups were compared using chi-square (exact test). Paired group comparisons were carried out using the same test. Paired comparisons were only considered appropriate when the three-group comparison achieved the critical p value. Where data were being compared at all three time points simultaneously, a Bonferroni correction was applied which adjusted the critical p value to $p < 0.015$. All data were included in the analyses of categorical variables, and missing data were not imputed as cohort averages would not have been appropriate.

3. Results

3.1. Recruitment

A consecutive series of 243 women were assessed for eligibility (Fig. 1). Of the 234 who were eligible, 183 (78.2%) agreed to be randomised. Four (1.7%) eligible patients refused randomisation because they did not wish reflexology.

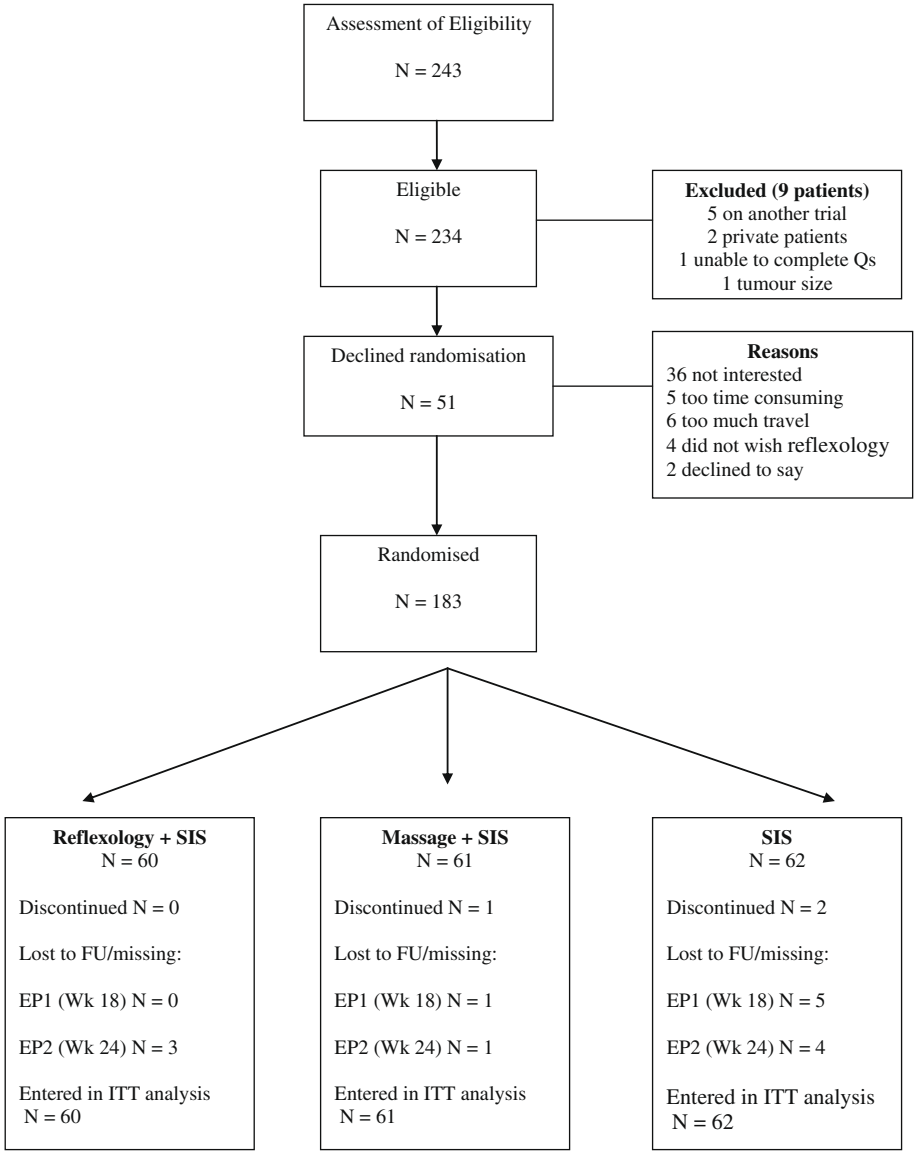

Fig. 1 – CONSORT flowchart of patient recruitment.

3.2. *Subjects*

Sixty patients were randomised to reflexology, 61 to massage, and 62 to self-initiated support.

The characteristics of the women by randomisation are shown in Table 1. The three groups did not differ significantly for any of the demographic, clinical or outcome variables.

3.3. *Missing data*

Complete data for all outcome measures were available for all 183 patients at baseline. At end-point 1, complete data were available for 177 patients. At end-point 2, complete data were available for 175 patients.

Complete data for all three time points were available for 57 (95%) patients randomised to reflexology, 60 (98%) randomised to massage and 56 (90%) randomised to SIS.

3.4. *Compliance with reflexology and massage*

Seventy-five percent of women received all eight sessions of reflexology and 75.4% received all eight sessions of massage. The mean number of sessions of reflexology was 7.65 (SD = 0.73, range 4–8)) and the mean number of massage sessions was 7.52 (SD = 1.06, range 2–8).

3.5. *Quality of life and mood*

3.5.1. *Primary end-point (week 18) (Table 2)*

At the primary end-point, TOI scores for the three groups differed significantly: massage patients had significantly higher scores on the TOI (indicating a better quality of life) than those receiving SIS. The differences between reflexology and SIS, and massage and reflexology, were not statistically significant.

Table 1 – Characteristics of patients.

	Total (N = 183)	Reflexology (N = 60)	Massage (N = 61)	SIS (N = 62)	p Value
Mean age (years)	58.78	59.37	57.70	59.36	.61
SD	10.31	10.47	10.12	10.23	
Age range	32–81	32–81	36–76	36–77	
Ethnicity					
Caucasian	183	60	61	62	1.00
Other	0	0	0	0	
ER status					
Positive	164	53	56	55	.78
Negative	18	6	5	7	
Unknown	1	1	0	0	
PR status					
Positive	150	47	52	51	.65
Negative	30	11	8	11	
Unknown	3	2	1	0	
T stage					
DCIS	3	2	0	1	.42
T1	124	40	43	41	
T2	52	15	18	19	
T3	4	3	0	1	
Breast surgery					
Wide local excision	144	47	46	51	.87
Quadrantectomy	1	1	0	0	
Mastectomy	26	8	11	7	
Mast + reconstruction	12	4	4	4	
Radiotherapy					
Yes	149	52	50	47	.31
No	34	8	11	15	
Chemotherapy					
Yes	30	10	11	9	.88
No	153	50	50	53	
Baseline TOI					
Mean	69.19	68.70	68.75	70.00	.80
SD	12.10	12.39	13.82	9.95	
Baseline HADS					
Depression					
<8	167 (91.3%)	54 (90.0%)	55 (90.2%)	58 (93.5%)	.84
8–10	9 (4.9%)	3 (5.0%)	3 (4.9%)	3 (4.8%)	
>11	7 (3.8%)	3 (5.0%)	3 (4.9%)	1 (1.6%)	
Anxiety					
<8	112 (61.2%)	37 (61.7%)	37 (60.7%)	38 (61.3%)	.63
8–10	45 (24.6%)	12 (20.0%)	15 (24.6%)	18 (29.0%)	
>11	26 (14.2%)	11 (18.3%)	9 (14.8%)	6 (9.7%)	
Baseline SCID					
Positive	19 (10.4%)	7 (11.7%)	7 (11.5%)	5 (8.1%)	.79
Negative	164 (89.6%)	53 (88.3%)	54 (88.5%)	57 (91.9%)	

The three groups did not differ on any of the five FACT scales, or FACT total score.

MRS scores at the primary end-point showed, massage and reflexology patients were significantly more relaxed than those randomised to SIS, and total MRS scores for reflexology and massage patients were significantly higher than SIS patients. At this end-point, massage patients were significantly more easy going than either reflexology or SIS patients.

Scores on HADS anxiety and depression did not differ significantly between the three groups. Also the proportion of patients obtaining one or more DSM IV diagnoses did not differ significantly.

3.5.2. *Secondary end-point (week 24) (Table 3)*

Reflexology patients scored significantly higher than those receiving SIS on the TOI. The differences between massage and SIS, and reflexology and massage, were not statistically significant.

The three groups differed on FACT functional wellbeing (one of three scales contributing to the TOI) and FACT total

Table 2 – Adjusted means (95% confidence intervals), overall comparisons and paired comparisons for the TOI, FACT scales, Mood Rating Scale (MRS) and HADS anxiety and depression, at end-point 1 (18 weeks) (statistically significant *p* values in bold.)

	A Reflexology + SIS N = 60	B Massage + SIS N = 63	C SIS N = 61	A versus B versus C *F* test *p* Value	A versus B *F* test *p* Value	A versus C *F* test *p* Value	B versus C *F* test *P* Value
TOI	72.25 (70.06–74.43)	73.06 (70.89–75.23)	69.05 (66.90–71.21)	**.02**	1.00	.13	.03
MRS – relaxation	100.94 (91.36–110.53)	100.23 (90.77–109.69)	74.02 (64.58–83.45)	**<.0005**	1.00	**<.0005**	**<.0005**
MRS – happiness	112.83 (105.51–120.14)	109.25 (101.97–116.53)	103.17 (95.98–110.36)	.17	1.00	.19	.73
MRS – energy	72.28 (61.89–82.67)	78.84 (68.52–89.17)	61.21 (50.96–71.47)	.06	1.00	.41	.06
MRS – clear headedness	114.64 (106.51–122.77)	117.02 (108.96–125.08)	108.97 (100.96–116.97)	.36	1.00	.98	.49
MRS – easy goingness	98.70 (90.12–107.27)	113.98 (105.49–122.46)	89.18 (80.73 to 97.63)	**<.0005**	**.04**	.37	**<.0005**
MRS – confidence	111.64 (105.06–118.22)	113.03 (106.49–119.56)	103.07 (96.6–109.54)	0.07	1.00	.21	.10
MRS – total	614.98 (581.90–648.05)	633.36 (600.61–666.11)	534.78 (502.20–567.36)	**<.0005**	1.00	**.003**	**<.0005**
FACT-B – physical wellbeing	23.30 (22.50–24,11)	24.24 (23.44–25.04)	22.90 (22.10–23.69)	.06	.32	1.00	.06
FACT-B – social/Family wellbeing	22.35 (21.42–23.28)	23.00 (22.08–23.93)	22.04 (21.13–22.95)	.34	1.00	1.00	.44
FACT-B – emotional wellbeing	20.36 (19.62–21.10)	20.36 (19.63–21.10)	19.97 (19.24–20.70)	.69	1.00	1.00	1.00
FACT-B – functional wellbeing	22.54 (21.60–23.5)	21.95 (21.02–22.9)	21.04 (20.11–21.97)	.08	1.00	.08	.52
FACT-B – additional concerns	26.34 (25.19–27.48)	26.85 (25.72–27.99)	25.20 (24.08–26.33)	.12	1.00	.49	.13
FACT-B – total Score	115.34 (112.29–118.32)	116.01 (113.02–119.90)	111.13 (108.16–114.09)	**.05**	1.00	.16	.07
HADS – anxiety (square root)	2.24 (2.11–2.38)	2.22 (2.09–2.35)	2.39 (2.25–2.52)	.17	1.00	.40	.25
HADS – depression (log_{10})	0.45 (0.39–0.51)	0.45 (0.40–0.51)	0.49 (0.43–0.54)	.67	1.00	1.00	1.00
HADS – total	**7.12 (6.11–8.11)**	**7.28 (6.28–8.28)**	**8.05 (7.01–9.09)**	.40	1.00	.60	.88

Table 3 – Adjusted means (95% confidence intervals), overall comparisons and paired comparisons for the TOI, FACT scales, Mood Rating Scale (MRS) and HADS anxiety and depression, at end-point 2 (24 weeks) (statistically significant *p* values in bold).

	A Reflexology + SIS N = 60	B Massage + SIS N = 63	C SIS N = 61	A versus B versus C *F* test *p* Value	A versus B *F* test *p* Value	A versus C *F* test *p* Value	B versus C *F* test *p* Value
TOI	74.82 (72.13–77.55)	72.39 (69.70–75.08)	69.42 (66.75–72.09)	**.02**	.62	**.02**	.37
MRS – relaxation	107.30 (97.91–116.69)	102.91 (93.65–112.18)	89.07 (79.82–98.32)	**.02**	1.00	**.02**	.12
MRS – happiness	110.34 (102.40–118.28)	103.98 (96.08–111.87)	103.08 (95.28–110.88)	.38	.79	.59	1.00
MRS – energy	68.62 (58.91–78.32)	76.92 (67.27–86.56)	61.45 (51.87–71.03)	.08	.69	.90	.07
MRS – clear headedness	115.62 (107.62–123.63)	118.53 (110.59–126.47)	113.91 (106.03–121.79)	.71	1.00	1.00	1.00
MRS – easy goingness	108.75 (99.26–118.25)	104.31 (94.92–113.71)	96.67 (87.31–106.02)	.20	1.00	.22	.77
MRS – confidence	114.32 (106.35–122.30)	105.14 (97.22–113.07)	104.42 (96.58–112.27)	.15	.32	.24	1.00
MRS – total	628.23 (589.91–666.55)	612.41 (574.47–650.36)	564.82 (527.07–602.56)	.06	1.00	.07	.24
FACT-B – physical wellbeing	24.57 (23.58–25.54)	23.82 (22.85–24.79)	23.10 (22.15–24.06)	.11	.85	.11	.90
FACT-B – social/family wellbeing	22.71 (21.76–23.67)	22.69 (21.74–23.64)	22.57 (21.64–23.51)	.98	1.00	1.00	1.00
FACT-B – emotional wellbeing	20.75 (19.98–21.52)	20.17 (19.40–20.93)	19.64 (18.88–20.40)	.13	.89	.13	.98
FACT-B – functional wellbeing	23.17 (22.01–24.33)	21.98 (20.83–21.13)	21.04 (19.90–22.17)	**.04**	.45	**.03**	.75
FACT-B – additional concerns	27.02 (25.88–28.16)	26.59 (25.46–27.72)	25.36 (24.24–26.48)	.11	1.00	.12	.38
FACT-B – total score	118.60 (114.93–112.26)	114.89 (111.26–118.52)	111.70 (108.10–115.30)	**.03**	.47	**.03**	.66
HADS – anxiety (square root)	2.14 (1.98–2.30)	2.2 (2.05–2.36)	2.36 (2.20–2.52)	.14	1.00	.17	.50
HADS – depression ($\log_{10}$)	0.39 (0.33–0.46)	0.44 (0.37–0.51)	0.50 (0.43–0.56)	.10	1.00	.09	.67
HADS – total	**6.38 (5.07–7.70)**	**7.46 (6.19–8.74)**	**8.25 (6.95–9.55)**	.14	.74	.14	1.00

Table 4 – Categorical outcomes for morbidity at the primary and secondary End-points.

		Total	A	B	C	*p* Value (A versus B versus C)
			Reflexology	Massage	Self-initiated support	
Primary end-point						
HADS Anxiety	<8	140 (79.5%)	48 (80.0%)	49 (81.7%)	43 (76.8%)	.70
	8–10	23 (13.1%)	6 (10.0%)	7 (11.7%)	10 (17.9%)	
	>11	13 (7.3%)	6 (10.0%)	4 (6.7%)	3 (5.4%)	
HADS depression	<8	165 (93.8%)	55 (91.7%)	55 (91.7%)	55 (98.2%)	.35
	8–10	10 (5.7%)	5 (8.3%)	4 (6.7%)	1 (1.8%)	
	>11	1 (0.6%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	
SCID positive		9 (5.1%)	6 (10.2%)	3 (5.0%)	0 (0.0%)	.04[a]
SCID negative		166 (94.9%)	53 (89.8%)	57 (95.0%	56 100.0%)	
Secondary end-point						
HADS anxiety	<8	142 (81.1%)	47 (82.5%)	47 (78.3%)	48 (82.8%)	.94
	8–10	16 (9.1%)	5 (8.8%)	7 (11.7%)	4 (6.9%)	
	>11	17 (9.7%)	5 (8.8%)	6 (10.0%)	6 10.3%)	
HADS depression	<8	160 (91.4%)	52 (91.2%)	54 (90.0%)	54 (93.1%)	.81
	8–10	13 (17.4%)	5 (8.8%)	5 (8.3%)	3 (5.2%)	
	>11	2 (1.1%)	0 (0.0%)	1 (1.7%)	1 (1.7%)	
SCID positive		12 (6.9%)	6 (10.5%)	5 (8.3%)	1 (1.7%)	.17
SCID negative		163 (93.1%)	51 (89.5%)	55 (91.7%)	57 (98.3%)	

[a] When a Bonferroni correction for multiple comparisons is applied, $p < 0.015$ to achieve statistical significance.

score. In both cases, reflexology patients scored significantly higher than SIS. The differences between massage and SIS, and reflexology and massage, were not statistically significant.

The only significant difference for the MRS Scales was for relaxation: reflexology patients were significantly more relaxed than SIS patients.

Scores on HADS anxiety and depression did not differ significantly between the three groups. Also the proportion of patients obtaining one or more DSM IV diagnoses did not differ significantly (Table 4).

3.6. *Complementary medicine use*

None of the paired comparisons achieved statistical significance at baseline or either end-point.

3.7. *Sensitivity analysis*

A sensitivity analyses, using all available data, and without imputing missing data, was carried out for the TOI, FACT scales and MRS scales. All of the significant differences remained, and no new significant results emerged.

4. Discussion

This is the largest randomised controlled trial of reflexology reported in the cancer literature to date. The use of conventional outcome measures enables the magnitude of the effects obtained to be compared with those of other interventions (e.g. ATAC).[29] The study was carried out in a carefully defined population, namely women with early breast cancer who had received breast surgery six weeks prior to recruitment.

A consecutive series of 243 women were assessed for eligibility. Of the 234 who were eligible, 183 (78.2%) agreed to be randomised, this demonstrating a high level of acceptability in this population.

Compliance with reflexology and massage was very high and did not differ significantly between the groups.

Previously, we had shown using relaxation and guided imagery that the 48% of women with locally advanced breast cancer undergoing neoadjuvant chemotherapy who practised relaxation and guided imagery showed benefit. It appears that reflexology and massage are acceptable alternatives to such relaxation and guided imagery interventions.

The primary outcome measure was the Trial Outcome Index of FACT-B. At the primary end-point, massage, but not reflexology, was significantly better than self-initiated support. In a recent study in breast cancer conducted after the inception of the current trial Eton and colleagues[42] used a combination of distribution and anchor based approaches to the determination of minimally important differences (MID) in the TOI and concluded that the MID for FACT-B TOI is between 5 and 6 points. The adjusted mean difference between massage and self-initiated support was 4.01 points, which falls short of their suggested MID. At the secondary end-point, however, reflexology, but not massage, was significantly better than self-initiated support and the adjusted mean difference (5.4) does meet the MID criteria suggested by Eton and colleagues.[42] Week 18 was chosen as the primary end-point, because this was 4 weeks after the end of the final session of reflexology or massage. This suggests that the effects of reflexology may take longer to show on those quality of life variables assessed by the TOI.

The TOI appears an appropriate choice of outcome in that it proved more sensitive to intervention effects at the primary end-point than any of the five FACT-B subscales or indeed

FACT-B total scores. The three groups did differ on FACT-B total at the 0.05 level (with Bonferroni correction), but none of the paired comparisons was significant. At the secondary end-point, consistent with the TOI findings, FACT-B total scores also favoured reflexology over self-initiated support, as did scores on the functional wellbeing scale.

On MRS relaxation scale scores at the primary end-point, massage and reflexology patients were significantly more relaxed than those randomised to SIS. At the secondary end-point, however, only reflexology showed a statistically significant benefit over self-initiated support. These data suggest that the effect of reflexology and massage on TOI scores may be mediated by relaxation.

The only statistically significant difference to emerge between reflexology and massage was at the primary end-point when patients randomised to massage were more easy going than those receiving reflexology. These data are consistent with the TOI findings in that they also suggest that the beneficial effects of reflexology may have a slower onset than those of massage.

The three groups did not differ at any time point on the proportion of patients scoring in the normal, borderline, or clinically significant ranges of HADS anxiety or depression, or the proportion obtaining a positive DSM IV SCID diagnosis, or on transformed mean scores for HADS anxiety and depression.

The point prevalence of clinically significant psychiatric morbidity as assessed by the SCID and the proportion of patients scoring in the clinically significant range for anxiety and depression on the HADS did not differ significantly across the three arms of the trial at any time point. These rates were also very low in comparison with other studies of psychiatric morbidity in women with early breast cancer in the United Kingdom.[1,2] The low rates reported at recruitment and throughout the present study are consistent with our previous work on the benefits of fully integrated psychosocial support services.[19–24] Whatever the explanation, the low distress level in the main comparator intervention (self-initiated support) ensured a stringent test of the effectiveness of reflexology and scalp massage. Reported use of reflexology and massage out with the study protocol was very uncommon and unlikely to have materially affected the size of the between group differences in outcomes. Similarly, use of all other complementary therapies studied was similar across the three groups.

Scalp massage was chosen to control for the effects of extra physical and social contact, both of which could enhance relaxation and act as a buffer against stress and massage did enhance relaxation. Massage is often combined with aromatherapy, and beneficial effects of aromatherapy massage have been reported.[43–45] Further research to evaluate the relative contributions of the extra physical contact and the extra social contact would be of considerable interest.

The present study demonstrates that it is feasible to evaluate CAM using randomised controlled trial methodology employing conventional, well-validated outcome measures research funders should be encouraged, to support definitive trials of other complementary therapies using conventional, well-validated outcome measures in other cancer populations.

5. Conclusions

The findings reported here suggest that when compared to SIS, reflexology and massage have statistically significant, and, for reflexology, clinically worthwhile, effects on quality of life following surgery for women with early breast cancer accessing a UK NHS support centre.

Reflexology can therefore be considered an evidence-based complementary interventions for improving the quality of life of women with early breast cancer. Given that no statistically significant differences in efficacy were found between reflexology and the control intervention scalp massage, this latter intervention may also repay further investigation.

The present study further demonstrates that it is feasible to evaluate CAM using randomised controlled trial methodology employing conventional, well-validated outcome measures.

Conflict of Interest Statement

None declared.

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Appendix A. Protocol for each reflexology session

A.1. *Preliminary techniques*

1. Cleanse both feet before treatment.
2. Massage both feet using warm up techniques with lotion.

A.2. *Treatment for right foot, work each area three times*

1. Hold Solar Plexus, breathing.
2. Work Diaphragm, area.
3. Work Lung and shoulder areas.
4. Work Eye, Eustachian Tube and Ear areas.
5. Work Parathyroids, Thyroid and Thyroid helpers areas.
6. Work Great Toe, Nail, Face, Head, Brain and Sinus areas.

6a. Work remaining Toes, Nail, Face, Head, Brain and Sinus areas.

7. Work Upper Lymphatic and Breast/Chest areas.
8. Work Arm, Knee and Hip areas.
9. Work Inguinal Lymphatic/Groin areas.
10. Work Stomach, Pancreas, Liver and Gall Bladder areas.
11. Work Adrenal, Kidney, Ureter and Bladder areas.
12. Work Spinal areas up and down foot [Coccyx, Sacral, Lumbar, Thoracic and Cervical].
13. Work Sacro-iliac, Ovary, Fallopian Tube and Uterus areas.
14. Work Sciatic area.
15. Work Small Intestines, Ileo-caecal valve, Ascending and Transverse colon areas.
16. Work Pituitary area
17. Warm down with massage techniques

A.3. *Treatment for left foot*

Repeat as for Right Foot with the following exceptions:

3 Work Lung, Heart and Shoulder areas.

10 Work Stomach, Pancreas and Spleen areas.

15 Work Small Intestines, Transverse Colon, Descending Colon, Sigmoid Colon and Rectum areas.

Appendix B. Protocol for each scalp massage session

B.1. *Preliminary techniques*

1. Patient seated, therapist behind, place hands slightly on top of head.
2. Support head and ask patient to breathe deeply 3 times.
3. Rock head gently to ease tension.
4. Breathe deeply three more times, rock head again.

B.2. *Scalp massage*

Confined to hairline, each move 3 times.

1. Circles around occiput, fingers, thumbs.
2. Friction around occiput.
3. Deep circles over scalp.
4. Windscreen wipers, fingers, heel of hands.
5. Sweep through hair.
6. Scalp movement, hands, fingers.
7. Deep circles and tension release upward movement.
8. Sweep through hair.
9. Finger tapping, hacking, ruffling, plucking.
10. Hair pulls.
11. Racking.
12. Hold head.
13. Hairline circles, full head circles.
14. Tension release upward movement.
15. Smooth hair, fingers gently through.
16. Repeat whole procedure again.
17. Hold head and breathe deeply three times.

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