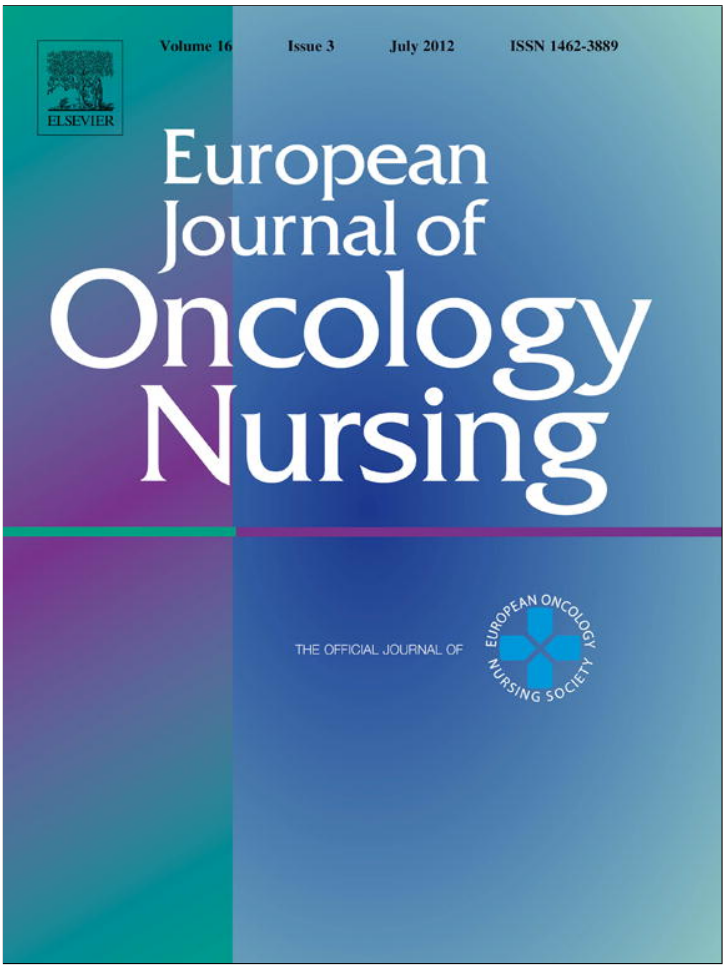

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Assessing the feasibility of using acupuncture and moxibustion to improve quality of life for cancer survivors with upper body lymphoedema

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A B S T R A C T

Purpose: Within a three-step mixed-methods study to investigate using acupuncture and moxibustion (acu/moxa) in the management of cancer treatment-related upper body lymphoedema, Step 2 obtained preliminary data about: 1) whether acu/moxa can improve quality of life, 2) the most troublesome symptoms, and 3) adverse effects.

Methods and sample: An exploratory single-arm observational clinical study included breast (BC) and head and neck cancer (HNC) survivors with mild-to-moderate uncomplicated lymphoedema for ≥3 months, ≥3 months post active-cancer treatment, no active cancer disease, undergoing routine lymphoedema maintenance. Participants received seven individualised treatments (S1), and six optional additional treatments (S2). MYMOP, SF-36 and PANAS were administered at baseline, during each series, and at follow-up 4 and 12 weeks after end-of-treatment. The primary outcome was change in MYMOP scores at the end of each series.

Key results: Of 35 participants recruited, 30 completed S1 and S2, 3 completed S1, 2 were lost to the study. Mean MYMOP profile change scores for BC participants were 1.28 points improvement on a 7-point scale (sd = 0.93, $p < 0.0001$, $n = 25$) for S1; and 1.41 for S2 (sd = 0.94, $p < 0.0001$, $n = 24$). S1 HNC change scores were 2.29 points improvement (sd = 0.62, $p < 0.0001$, $n = 7$); and 0.94 for S2 (sd = 0.95, $p = 0.06$, $n = 6$). Changes in some SF-36 scores for BC participants were significant to 4 weeks after treatment. No serious adverse effects were reported.

Conclusion: This small study suggests acu/moxa is an acceptable adjunct to usual care for cancer survivors with lymphoedema. Further rigorous research is warranted to explore the effectiveness of acu/moxa in reducing the symptom burden.

Introduction

Cancer treatments, specifically surgery and radiotherapy, are the main cause of secondary lymphoedema in the developed world (Lymphoedema Framework, 2006). Chronic swelling affecting the limbs, trunk, head, neck, breast, or genitalia, lymphoedema arises when reduced capacity of the lymphatic transport system causes accumulation of fluid in the tissue spaces (International Society of Lymphology, 2003). Secondary lymphoedema is a common side effect of damage to the lymphatics caused by treatments for many cancers, including breast and head and neck cancers (Keeley, 2000a; Withey et al., 2000). Studies report occurrence ranging from 3% to 89% of breast cancer (BC) patients (Williams et al., 2005), with prevalence of arm oedema calculated to be 29% of BC patients (Moffatt et al., 2003) and incidence generally accepted to be 30% (Hayes et al., 2008). Secondary lymphoedema is reported in 10–40% of head and neck cancer (HNC) patients (Bjordal et al., 2000), and while usually temporary, it may remain longstanding and unresolved (Withey et al., 2000). A generally incurable condition, lymphoedema causes significant physical and psychological morbidity, necessitating life-long care to manage and prevent it progressing (International Society of Lymphology, 2003).

Multi-disciplinary strategies are required to reduce the onset, progression, and complications (Lymphoedema Framework, 2003, 2006). Patients at risk must learn to minimise the possibility of developing lymphoedema, and to identify early signs and symptoms. Once diagnosed, interventions aim to reduce size, physical dysfunction, and complications and include specialised bandaging and massage, wearing of compression garments, and daily adherence

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to self-care programmes (Keeley, 2000b). Occurring up to 20 years or more after surgery (Pain and Purushotham, 2000), lymphoedema can worsen with inadequate care. Cellulitis, an associated infection, may require long-term antibiotic treatment and hospitalisation, lead to recurrent cellulitis, and impact healthcare resources (Al-Niaimi and Cox, 2009; Moffatt et al., 2003).

Lymphoedema is disabling, disfiguring and distressing. Swelling causes discomfort, with associated restriction of movement and function. Disfigurement and the wearing of specialist bandaging may cause social embarrassment, body image problems, and low self-esteem. "One of the most troublesome and feared consequences of breast-cancer surgery"(Ganz, 1999), the psychosocial effects for women are well documented internationally (Ahmed et al., 2008; Chachaj et al., 2010; Dawes et al., 2008; Johansson et al., 2003; Morgan et al., 2005; Towers et al., 2008; Tsuchiya et al., 2008). For HNC patients, disfigurement is obvious, and together with functional impairment can cause complex psychosocial problems (Smith and Lewin, 2010; Withey et al., 2000). A "forgotten complication" of cancer treatment (Farncombe et al., 1994), there is a need for improved treatment for people with lymphoedema. This should address quality of life, as well as the complex physiological and psychosocial problems associated with a chronic condition in patients with multiple comorbidities (McWayne and Heiney, 2005; Moffatt, 2008; Towers, 2008). Multidisciplinary approaches are required to address this range of needs.

Complementary and alternative medicine (CAM) is a popular choice of people with cancer, with recent European studies reporting usage by 35.9% of cancer patients (Molassiotis et al., 2005a), 44.7% of BC patients (Molassiotis et al., 2006) and 22.7% of HNC patients (Molassiotis et al., 2005b). Acupuncture is a form of traditional Chinese medicine chosen by many people with chronic disease who value it for symptom improvement and improved physiological and psychosocial coping (Cassidy, 1998; Gould and Macpherson, 2001; Paterson and Britten, 2003). Based on our previous research, which demonstrated measurable improvements in wellbeing, improved quality of life, and symptom relief for BC patients experiencing side effects of adjuvant hormonal treatment (de Valois 2006 PhD thesis, de Valois et al., 2010), we wanted to investigate whether acupuncture could be used in the management of lymphoedema. In this study we have used acupuncture and moxibustion, two modalities of traditional acupuncture practice (de Valois, 2007). Acupuncture needling is the superficial insertion of fine, solid, stainless steel needles under the skin to stimulate sites on the body known as acupuncture points. Moxibustion uses the application of heat (usually from the smouldering herb *Artemesia vulgaris* or mugwort) to stimulate the points by warming them. In this article, we refer to these processes as "acu/moxa".

Acupuncture in relation to lymphoedema is controversial. People with or at risk of lymphoedema are advised to reduce the possibility of introducing infection and exacerbating swelling by avoiding accidental and non-accidental skin puncture (NASP) in the affected area (Cole, 2006; Lymphoedema Framework, 2006). In lymphoedema and cancer policy documents, acupuncture is not contraindicated and the guidance is the same as for all NASP interventions, in that needling the affected area should be avoided (Filshie, 2001; Tavares, 2003). However, much popular literature advises lymphoedema patients to avoid acupuncture altogether (Hansard, 2010; O'Connor, 2008; UKlymph.com, 2002).

Furthermore, there is scant evidence for using acupuncture or moxibustion in lymphoedema management. A small Japanese study reported successful outcomes in using acu/moxa both as treatment ($n = 12$) and prophylaxis ($n = 12$) for lower limb lymphoedema associated with treatment for gynaecologic cancers (Kanakura et al., 2002). Brazilian researchers reported significant improvements in range of movement, degree of lymphoedema, and discomfort in 29 BC patients treated with acupuncture (Alem and Gurgel, 2008). Results from these uncontrolled exploratory studies suggest the interventions were safe and warrant further research.

Acupuncture is a safe procedure when carried out by trained professionals (MacPherson et al., 2001; White et al., 2001). Adverse effects are usually minor, transient and may include mild pain, bruising or bleeding at the needling site; tiredness after treatment; and, rarely, nausea or feeling faint. Similarly, moxa treatment is safe when carried out by a trained professional, and there is little discussion in the literature about safety issues.

Objectives

Following Medical Research Council (MRC) guidelines for researching complex interventions (Craig et al., 2008a, b), this three-step patient-centred exploratory study used mixed-methods to investigate the feasibility of using acu/moxa to promote wellbeing and improve quality of life for BC and HNC survivors with secondary lymphoedema. In Step 1, focus groups with patients and clinicians explored the acceptability of acu/moxa. Step 2 comprised a single-arm observational clinical study using before-and-after measurements. In Step 3, participants of Step 2 took part in focus groups to discuss their experiences of acu/moxa treatment. The qualitative data collected in Steps 1 and 3 are reported elsewhere (Verhoef and Boon, 2010). In this paper, we report the quantitative results of Step 2, the clinical treatment phase, which sought answers to three key questions:

1. Can acu/moxa improve wellbeing in cancer survivors with lymphoedema?
2. What symptoms are most troublesome for these individuals?
3. Is acupuncture a safe intervention for people with lymphoedema?

As an early stage exploratory study, we also wanted to evaluate the acceptability of acu/moxa to people with lymphoedema, test recruitment, and assess outcome measures in preparation for a larger study (Craig et al., 2008b).

It was not an aim to treat the lymphoedema. Acu/moxa was an adjunct to usual care, and participants continued the maintenance programme prescribed by the nurse specialist. Needling was avoided in the affected area, as recommended in the literature (Filshie, 2001; Tavares, 2003). For BC participants, this restriction included the torso quadrant on the affected side, as per findings from our focus groups with lymphoedema patients and their medical healthcare professionals in Step 1 of the overall study (reported elsewhere).

We also chose not to focus on changes in swelling as an outcome. The challenges of obtaining meaningful and consistent measurement are well documented, and many patients prioritise reducing the symptom burden, increasing function, and improving quality of life over changes in swelling (Pillar, 2007; Ridner, 2005; Sitzia et al., 1997). We monitored changes in volume as a safety measure, to ensure that acu/moxa treatment did not exacerbate swelling.

Methods

Study design, setting and subjects

The design of this single-arm observational study with before-and-after measurements was informed by findings from focus groups with patients and healthcare professionals, who stated their preferences for treatment in Step 1 of the overall study. To test

whether participants would prefer short or long-term treatment, we offered two series of acu/moxa appointments: Series 1 (S1), comprising treatment once weekly for seven treatments, followed by six optional additional treatments, called Series 2 (S2). It was the participant's choice whether to continue to S2.

Breast cancer and HNC patients meeting the following criteria were eligible: male or female patients with mild to moderate uncomplicated lymphoedema, age 18 or over, under the care of the lymphoedema service for at least two (HNC) or three (BC) months, no active cancer disease, at least three months post active cancer treatment (surgery, radiotherapy, chemotherapy, intravenous treatment), able to understand and communicate in English, able to travel to the centre once weekly for at least seven treatments, and having no acupuncture treatment within the previous six months. Concurrent adjuvant hormonal treatment and concurrent anti-depressant medication were acceptable. Patients with advanced cancer disease and bilateral BC patients were excluded.

The lymphoedema nurse specialist (EM) referred interested patients attending for routine maintenance treatment to the research acupuncturist (BdV), who supplied them with an information sheet and arranged an intake interview. At this interview, the acupuncturist discussed the study, demonstrated acupuncture and moxibustion, and answered any questions before obtaining written consent, after which the seven appointments for S1 were agreed. The Hertfordshire Regional Ethics Committee approved the study. It was carried out from September 2008 through December 2009 in a cancer drop-in and information centre associated with a major cancer treatment centre in South East England, in collaboration with the hospital's lymphoedema service.

Outcome measures

We selected three validated questionnaires as outcome measures. The primary outcome was change in scores on the Measure Yourself Medical Outcome Profile (MYMOP). MYMOP is widely used for evaluating interventions based on holistic and participative principles, and allows patients to specify and measure outcomes that are important to them (Paterson, 1996, 2004; Paterson and Britten, 2000). We chose MYMOP as an appropriate measure to collect data on the most troublesome symptoms and facilitate measurement of changes in wellbeing (our key questions 1 and 2).

The respondent, with structured guidance, specifies one or two symptoms for which they are seeking treatment, as well as one activity of daily living that is affected by the symptom(s). S/he scores these on a seven-point scale (6 is "as bad as it could be; 0 is "as good as it could be"), according to the severity over the past week, along with their feeling of wellbeing. On the MYMOP follow-up questionnaires, the respondent scores the original concerns. A "profile score" is derived from the mean of all the individual scored items.

The Medical Outcomes Study Short Form (SF-36) is a generic 36-item functional status questionnaire that assesses eight domains of physical and psychological health. Responses are calculated on a scale from 0 (worst possible health state) to 100 (best possible health state). The SF-36 is self-administered, can be completed in ten minutes, is widely used in studies of oncology and complementary medicine, and is the National Cancer Survivorship Initiative's (NCSI) standard measure for outcomes relevant to cancer survivorship (Department of Health et al., 2010). We chose the SF-36 to measure improvements in wellbeing (question 1), and to allow the possibility of comparison with other studies.

The Positive and Negative Affect Schedule (PANAS) is a 20-item validated measure used to assess mood states (Watson et al., 1988). Respondents score ten adjectives each for positive affect (PA) and negative affect (NA) on a 5-point scale from "very slightly or not at all" to "extremely" according to their state over the previous week. Both subscales range from 10 (low) to 50 (high). High positive affect scores reflect states of high energy, full concentration, and pleasurable engagement; high negative affect scores indicate more distress (Voogt et al., 2005). An initial study suggested that PANAS might provide a basis for measuring positivity in complementary medicine studies (Hyland et al., 2008) and we chose it to assess its potential contribution to the evidence base in this area.

Data collection

Participants completed baseline measures for the SF-36 and PANAS before meeting the acupuncturist at their first treatment. They completed the MYMOP with the acupuncturist, after the clinical history and before treatment. Follow-up questionnaires (MYMOP Follow-up, SF-36 and PANAS) were administered prior to the seventh treatment of S1. Participants continuing to S2 completed a new MYMOP at their eighth appointment, with follow-up questionnaires administered prior to the 13th treatment. Follow-up SF-36 and PANAS questionnaires were sent by post for completion four and twelve weeks after the last treatment.

Data analysis

Data were analysed across all participants and by diagnosis using SPSS version 19. Frequency counts were calculated for sociodemographic and clinical variables. Paired *t* tests were used for comparing MYMOP, SF-36 and PANAS data across all measurement points. In this paper, we present these data by cancer diagnosis.

We calculated MYMOP changes by taking the score collected prior to the first treatment of each series and subtracting the scores collected prior to the last treatment of each series, so that a positive change denotes improvement. We calculated SF-36 changes by subtracting the baseline score for each domain (defined as the score collected prior to the first treatment of S1) from the scores collected at each subsequent measurement point, so that a positive change denotes improvement. PANAS outcomes were also calculated in this way, and improvement is denoted by increased PA and decreased NA scores.

Acupuncture protocol

As participants of the Step 1 focus groups described a range of symptoms, we chose to use a flexible approach rather than impose a restricted acupuncture protocol. The aim was to emulate usual clinical practice, in which treatments tailored to the presenting signs, symptoms and priorities evolve as the individual progresses through a course of treatment. This "real-world" acupuncture has a high external validity (MacPherson et al., 2008) and accords with recommendations for best practice for managing lymphoedema, in which treatment and plans of care are individualised to meet the patient's specific needs (Lymphoedema Framework, 2006).

Treatment frequency was once weekly for seven sessions (S1), and participants could choose a further six sessions (S2), for a possible total of 13 treatments. Appointments were 50 min, except the first, which lasted up to two hours to accommodate completion of questionnaires and case history taking. Flexibility in attending for treatment allowed maximum completion times of nine weeks for S1 and eight weeks for S2, with a gap of up to four weeks between the two series.

Two licensed acupuncturists (LicAc), members of the British Acupuncture Council (MBAcC), administered the treatments. Employed by the NHS Trust, the principal investigator is a research acupuncturist, the other acupuncturist is employed on an ad hoc sessional basis for research projects; neither are registered with the

Health Professions Council. They avoided needling the affected area, including the associated torso quadrant for BC participants. Needling on the midline was permitted.

Moxibustion was used as appropriate to the individual's presenting symptoms and priorities. Hertfordshire REC approved the use of moxibustion, as did the hospital's Health and Safety and Fire officers. The fire officer changed the smoke detector to a heat detector in the treatment room. Other interventions included lifestyle advice, offered as appropriate to the individual's needs and capacity for taking advice, and included advice for healthy dietary habits, rest, exercise, and maintaining a sensible weight. The acupuncturists encouraged participants to adhere to the self-care programmes prescribed by the nurse specialist for the on-going management of their lymphoedema.

Monitoring adverse effects

Our main concern was to monitor whether acu/moxa treatment exacerbated lymphoedema or caused cellulitis. To this end, the nurse specialist monitored all participants for exacerbation of swelling. She measured arm volume in BC participants at baseline, and after the 7th and 13th acupuncture treatments, and visually assessed HNC participants at their regular appointments at the lymphoedema clinic. The acupuncturists recorded any other adverse effects of acupuncture and moxibustion in the participant's notes.

Results

Recruitment

We recruited 35 participants between October 2008 and May 2009, comprising 27 BC and eight HNC participants. Thirty participants (24 BC, 6 HNC) completed both Series (13 treatments); three (2 BC, 1 HNC) completed S1 only (7 treatments). One BC participant, an elderly carer, withdrew from the study as she found participation stressful in addition to her caring duties. One HNC participant withdrew because of cancer recurrence, and another moved away after commencing S2. In total, 420 treatments were administered, with a mean of 12 per participant.

Sociodemographic and clinical characteristics

The majority of the 35 participants were female, reflecting the large proportion of BC survivors in the study, and the mean age was 57.5 (sd = 9.3). Characteristics by diagnosis are presented in Table 1 and overall, participants were partnered, well-educated, UK born, and of White British or Irish ethnicity. Seventy-one percent ($n = 25$) had not previously used acupuncture.

Clinical data, presented in Table 2, show the wide variation in times since lymphoedema onset and diagnosis after cancer treatment. With a mean duration of lymphoedema of just over four years, onset for BC participants could be immediately or as long as 12 years after cancer treatment. HNC participants also showed a wide variation, with average duration of lymphoedema at just over two years, ranging from six months to 11 years. Onset was much earlier, with diagnoses ranging from immediately to 2 years after cancer treatment. Participants joined the acupuncture study an average of 6.8 (BC) and 3.7 (HNC) years after surgical treatment for cancer.

Table 3 shows the MYMOP scores by diagnosis at the beginning and end of each Series, and the changes in scores for each Series. SF-36 and PANAS scores, shown in Table 4, include data for each series, and for 4- and 12-week follow-up points.

Table 1
Sociodemographic characteristics at baseline.

	All participants $n = 35$ n (%)	BC $n = 27$ n (%)	HNC $n = 8$ n (%)
Age			
Mean [SD]	57.5 [9.3]	56.7 [8.4]	59.9 [12.2]
Min – Max	40–83	40–73	41–83
Gender			
Female	30 (85.7)	27 (100.0)	3 (37.5)
Male	5 (14.3)	0	5 (62.5)
Marital status			
Single	3 (8.6)	2 (7.4)	1 (12.5)
Married/partnered	25 (71.4)	20 (74.1)	5 (62.5)
Separated/divorced	5 (14.3)	3 (11.1)	2 (25.0)
Widowed	2 (5.7)	2 (7.4)	0
Educational qualifications			
< Compulsory school education	4 (11.4)	2 (7.4)	2 (25.0)
Compulsory school education	10 (28.6)	8 (29.6)	2 (25.0)
Post compulsory school education below university level	9 (25.7)	8 (29.6)	1 (12.5)
University level	10 (28.6)	7 (25.9)	3 (37.5)
Postgraduate level	2 (5.7)	2 (7.4)	0
Current employment status			
Retired	15 (42.9)	10 (37.0)	5 (62.5)
Not working at present	5 (14.3)	3 (11.1)	2 (25.0)
Working part time	8 (22.9)	8 (29.6)	0
Working full time	7 (20.0)	6 (22.2)	1 (12.5)
Country of birth			
United Kingdom	28 (80.0)	22 (81.5)	6 (75.0)
Other	7 (20.0)	5 (18.5)	2 (25.0)
Ethnic background			
Black-Caribbean	1 (2.9)	1 (3.7)	0
Asian	5 (14.3)	4 (14.8)	1 (12.5)
White British or Irish	29 (82.8)	22 (81.5)	7 (87.5)
Previous acupuncture experience?			
Yes	10 (28.6)	8 (29.6)	2 (25.0)
No	25 (71.4)	19 (70.4)	6 (75.0)

Analysis of troublesome symptoms

To gain insight into what participants found most troublesome, we analysed the symptoms on the MYMOPs. Participants specified 129 symptoms on 35 MYMOPs completed for S1 and 31 for S2. We categorised these using the International Classification for Primary Care (ICPC) as a guideline (WONCA International Committee, 1998) and, as shown in Fig. 1, these differ according to cancer diagnosis. Although it was emphasised that treating lymphoedema was not an aim of the study, BC participants mainly specified lymphoedema-related symptoms, which they described as pain, nagging ache, dull pain, discomfort, aching, heaviness, sensations of a "bag" or "sausage" under the arm, inability to wear clothes. HNC

Table 2
Clinical data at baseline by diagnosis.

Time in Months	Mean (SD)	Min–Max
Duration of lymphoedema		
BC	50.0 (30.1)	3–108
HNC	35.1 (43.5)	6–132
Months from end of active cancer treatment to lymphoedema diagnosis		
BC	27.7 (43.0)	0–144
HNC	4.3 (8.7)	0–24
Time from surgery to start of acupuncture treatment		
BC	82.2 (60.1)	14–278
HNC	44.9 (42.1)	6–131

BC $n = 27$ HNC $n = 8$

Table 3
MYMOP outcomes by diagnosis.

	Series 1 (Treatments 1 to 7)				Series 2 (Treatments 8 to 13)			
	Before treatment 1	Before treatment 7	Change in score treatment 1– treatment 7		Before treatment 8	Before treatment 13	Change in score treatment 8– treatment 13	
	Mean (SD)	Mean (SD)	Mean (SD)	p	Mean (SD)	Mean (SD)	Mean (SD)	p
BC	$n = 27$		$n = 25$		$n = 24$		$n = 24$	
Symptom 1	3.74 (1.02)	2.64 (1.50)	*1.12 (1.54)*	**0.001**	3.75 (1.26)	2.08 (1.35)	*1.67 (1.61)*	**0.000**
Symptom 2	3.96 (1.02)	2.08 (1.08)	*1.88 (1.30)*	**0.000**	2.81 (1.03)	1.76 (1.14)	*1.05 (1.20)*	**0.001**
Activity	4.07 (1.07)	2.60 (1.58)	*1.48 (1.74)*	**0.000**	3.62 (1.02)	1.62 (0.97)	*2.05 (1.23)*	**0.000**
Wellbeing	2.78 (1.40)	2.00 (1.25)	*0.63 (1.17)*	**0.016**	2.58 (1.38)	1.67 (1.31)	*0.92 (1.44)*	**0.005**
MYMOP Profile	3.64 (0.87)	2.34 (0.99)	*1.28 (0.93)*	**0.000**	3.18 (0.78)	1.77 (0.92)	*1.41 (0.94)*	**0.000**
HNC	$n = 8$		$n = 7$		$n = 6$		$n = 6$	
Symptom 1	4.50 (1.07)	1.71 (1.25)	*3.00 (1.00)*	**0.000**	3.14 (1.46)	1.67 (1.03)	*1.33 (1.03)*	**0.025**
Symptom 2	4.25 (1.39)	2.14 (1.07)	*2.29 (1.38)*	**0.005**	3.29 (1.50)	1.83 (1.17)	*1.33 (1.03)*	**0.025**
Activity	5.00 (0.82)	2.83 (2.50)	*2.33 (1.37)*	**0.009**	4.40 (1.34)	3.17 (1.47)	*1.00 (2.34)*	0.37
Wellbeing	2.62 (2.20)	1.29 (0.95)	*1.57 (1.81)*	0.062	1.71 (1.11)	1.67 (1.37)	0.17 (0.75)	0.61
MYMOP Profile	4.00 (1.28)	1.89 (1.13)	*2.29 (0.62)*	**0.000**	3.02 (1.12)	2.08 (1.03)	*0.94 (0.95)*	0.06

MYMOP scored 0–6 with lower scores indicating better health.
p = significance on a 2 tailed paired *t* test.
Bolding indicates statistical significance ($p < 0.05$).
Italics indicate clinical significance (change ≥0.5).

participants cited musculo-skeletal problems, including those affecting the jaw, neck, shoulder, back, knee, legs and feet. Many of these lower-body complaints were associated with removal of tissue for facial reconstruction. Both groups specified a range of psychological symptoms, which included anxiety, stress, feeling depressed, sleep disturbance, insomnia, and bereavement issues. For BC participants, overweight, oedema (as opposed to lymphoedema), and respiratory conditions were relatively frequent

Table 4
SF-36 and PANAS outcomes by diagnosis.

Scale	Series 1 (Treatments 1 to 7)				Series 2 (Treatments 8 to 13)			4 Week Follow-up			12 Week Follow-up		
	Before Tx 1 Baseline	Before tx 7	Δ Tx 7 − Baseline		Before tx 13	Δ Tx 13 − Baseline		Follow-up 4	Δ Follow-up 4 − Baseline		Follow-up 12	Δ Follow-up 12 − Baseline	
	Mean (SD)	Mean (SD)	Mean (SD)	p	Mean (SD)	Mean (SD)	p	Mean (SD)	Mean (SD)	p	Mean (SD)	Mean (SD)	p
SF-36 BC Participants													
	$n = 27$	$n = 26$			$n = 24$			$n = 26$			$n = 25$		
PF	68.7 (21.9)	71.4 (20.7)	2.6 (9.6)	0.2	72.3 (16.9)	2.8 (16.2)	0.4	73.0 (18.5)	3.9 (9.8)	0.06	74.5 (20.7)	5.6 (11.4)	**.02**
RP	73.3 (24.2)	82.1 (20.4)	8.8 (23.2)	0.06	76.0 (21.6)	3.9 (28.7)	0.5	79.3 (18.2)	6.8 (26.1)	0.2	75.3 (26.0)	1.8 (30.3)	0.8
BP	64.7 (21.0)	72.0 (22.3)	7.3 (17.3)	**.04**	73.9 (22.7)	10.6 (16.6)	**.005**	74.8 (21.8)	10.2 (15.7)	**.003**	70.5 (23.1)	6.1 (20.8)	0.2
GH	64.5 (20.4)	66.0 (20.5)	1.5 (10.6)	0.5	69.6 (18.1)	6.0 (17.5)	0.1	69.8 (16.9)	5.3 (18.1)	0.2	70.7 (17.8)	4.6 (17.1)	0.2
VT	51.4 (21.2)	61.5 (23.4)	10.0 (16.4)	**.005**	60.2 (20.3)	10.9 (24.7)	**.041**	63.0 (17.0)	11.5 (25.1)	**.027**	54.5 (26.2)	2.5 (24.1)	0.6
SF	83.2 (22.4)	88.0 (25.6)	4.8 (14.2)	0.1	84.4 (22.5)	2.1 (22.9)	0.7	83.7 (23.1)	0.5 (25.9)	0.9	78.0 (29.2)	−4.5 (33.6)	0.5
RE	80.8 (25.4)	84.6 (26.1)	3.9 (23.1)	0.4	84.7 (25.3)	5.6 (24.2)	0.3	86.5 (21.0)	5.8 (27.2)	0.3	81.0 (27.8)	0.3 (33.6)	1.0
MH	73.3 (15.7)	75.0 (19.6)	1.7 (15.3)	0.6	76.9 (19.0)	4.4 (16.2)	0.2	73.7 (20.3)	0.4 (19.9)	0.9	70.4 (25.2)	−3.0 (25.4)	0.6
SF-36 HNC Participants													
	$n = 8$	$n = 7$			$n = 6$			$n = 6$			$n = 6$		
PF	60.7 (29.6)	66.0 (36.5)	5.2 (25.8)	0.6	62.7 (32.0)	8.7 (23.2)	0.5	65.5 (35.0)	3.8 (26.3)	0.7	62.6 (38.5)	0.9 (28.4)	0.9
RP	57.1 (35.3)	60.7 (25.7)	3.6 (18.7)	0.6	53.1 (31.6)	−5.2 (19.1)	0.5	55.2 (31.0)	−3.1 (13.6)	0.6	47.9 (37.2)	−10.4 (10.2)	**.054**
BP	53.3 (23.4)	65.3 (18.5)	12.0 (14.1)	0.07	68.0 (13.7)	9.5 (20.8)	0.3	57.7 (22.2)	−0.8 (18.3)	0.9	53.0 (24.4)	−5.5 (24.1)	0.6
GH	51.6 (28.3)	52.3 (27.8)	0.7 (3.2)	0.6	49.2 (22.2)	2.4 (13.9)	0.7	52.3 (30.8)	−2.8 (6.3)	0.3	51.0 (27.5)	−4.2 (8.8)	0.3
VT	50.0 (31.9)	53.6 (24.7)	3.6 (18.7)	0.6	55.2 (32.0)	4.2 (16.6)	0.6	43.8 (39.0)	−3.8 (7.1)	0.3	47.9 (38.9)	−3.1 (8.6)	0.4
SF	69.6 (33.0)	80.4 (14.2)	10.7 (37.1)	0.5	60.4 (33.9)	−8.3 (23.3)	0.4	68.8 (28.2)	0.0 (17.7)	1.0	64.6 (25.5)	−4.2 (28.1)	0.7
RE	75.0 (23.6)	71.4 (17.9)	−3.6 (24.0)	0.7	72.2 (24.5)	−1.4 (29.5)	0.9	66.7 (22.4)	−7.0 (19.3)	0.4	51.4 (34.7)	−22.2 (25.1)	0.8
MH	67.9 (20.2)	74.3 (10.6)	6.4 (14.9)	0.3	65.8 (19.6)	−3.3 (18.1)	0.7	62.0 (18.2)	−5.0 (9.4)	0.3	59.2 (16.6)	−10.0 (17.6)	0.2
PANAS BC Participants													
	$n = 27$	$n = 26$	$n = 26$		$n = 24$	$n = 24$		$n = 26$	$n = 26$		$n = 25$	$n = 25$	
PA	29.7 (9.3)	30.8 (9.4)	1.4 (8.9)	0.42	32.9 (9.1)	3.5 (10.4)	0.12	32.5 (9.0)	3.1 (11.3)	0.17	31.4 (11.1)	1.9 (11.5)	0.41
NA	17.2 (6.7)	16.1 (9.4)	−0.8 (5.1)	0.42	16.1 (6.5)	−1.2 (5.1)	0.28	16.3 (7.1)	−0.5 (5.9)	0.65	16.0 (8.8)	−0.8 (9.5)	0.65
PANAS HNC Participants													
	$n = 8$	$n = 7$	$n = 7$		$n = 6$	$n = 6$		$n = 6$	$n = 6$		$n = 6$	$n = 6$	
PA	35.5 (8.1)	36.2 (8.4)	0.8 (5.6)	0.71	37.2 (9.8)	2.6 (3.4)	0.12	37.0 (8.2)	2.4 (3.8)	0.19	32.0 (5.6)	−2.6 (7.9)	0.45
NA	16.5 (4.1)	14.3 (2.7)	−2.2 (3.5)	0.15	18.5 (5.2)	1.7 (7.2)	0.58	17.8 (5.1)	1.1 (5.7)	0.67	15.7 (4.8)	−1.1 (5.6)	0.67

SF-36: PF = Physical Functioning; RP = Role limitation due to Physical problem; BP = Bodily Pain; GH = General Health; VT = Vitality; SF = Social Functioning; RE = Role limitation due to Emotional problem; MH = Mental Health.
SF-36: Domains scored 0 to 100. Higher scores indicate better quality of life.
PANAS: PA = Positive Affect; NA = Negative Affect.
PANAS: Schedules scored 10–50. Higher PA scores indicate higher energy, concentration, enthusiasm. Higher NA scores indicate more distress.
For all measures: p = significance on a 2 tailed paired *t* test. Bolding indicates statistical significance ($p < 0.05$).

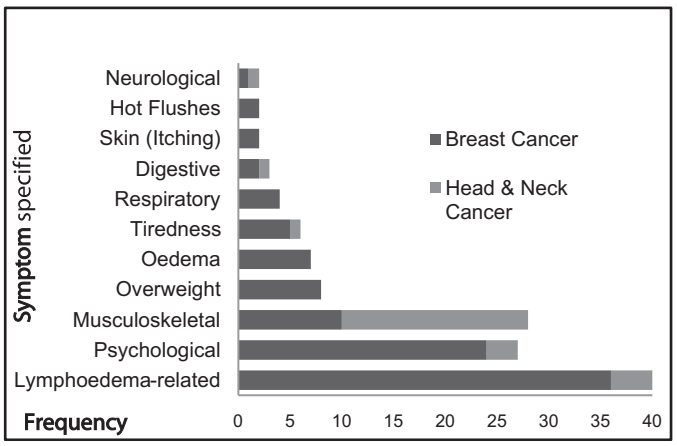

Fig. 1. Analysis of MYMOP symptoms (categorised by ICPC).

concerns, with hot flushes and medication-related itching being isolated symptoms. A few participants from both diagnoses prioritised tiredness, digestive, and neurological symptoms.

Adverse effects

The nurse specialist reported that there were no changes in volume outside the usual range for each BC participant, and there were no exacerbations of swelling in HNC participants. Two incidents of cellulitis were reported during the study; the nurse specialist confirmed that these were unrelated to acu/moxa treatment.

Acupuncture and moxibustion were well tolerated, with no serious adverse effects reported or observed. Minor adverse effects of acupuncture included bruising and/or bleeding at the needle site, tiredness after treatment, and pain on needling. One BC participant reported feeling lightheaded after treatment in the early stages of S1; another reported headaches. One HNC participant, who had a laryngectomy, felt that even smokeless moxa could potentially irritate the lining of the stoma and valve, and the acupuncturist avoided using it.

Discussion

In a health condition for which the use of acupuncture is controversial, and given the limited evidence for treating lymphoedema itself, we chose to explore the use of acu/moxa as an adjunct to usual care for improving quality of life. We focussed on upper body lymphoedema, as lower-body lymphoedema has more practical difficulties resulting from restricted mobility, which may lead to more complex comorbidities (such as increased tendencies to overweight and associated depression). Thus, this study aimed to obtain preliminary measures of 1) whether acu/moxa could improve wellbeing, 2) the most troublesome symptoms and 3) adverse effects. It also explored the feasibility of recruiting people with lymphoedema to an acupuncture study, and tested the treatment approach and outcome measures for use in subsequent research.

Changes in MYMOP scores, the primary outcome, were statistically significant at all measurement points, except for changes in HNC Wellbeing scores for both series, and HNC Activity and MYMOP Profile scores for S2. The small number of HNC participants, and the limitations of short-term measurement (discussed below), may be contributors to the non-significance of these items. As Table 5 shows, the results compare favourably with other studies using MYMOP to measure outcomes of acupuncture treatment for patients with long-term conditions (Paterson, 2010) and those attending a general practice clinic (Hull et al., 2006). Work with seven-point scales suggests that clinically important changes are represented by mean changes over 0.5 (small), over 1.0 (moderate) and over 1.5 (large) (Guyatt et al., 1998; Paterson, 2010). In this study, change scores were moderate or large, except for Wellbeing which were mostly small (apart from HNC scores which varied widely). These small changes in Wellbeing scores correspond with other studies using MYMOP and may be the result of wider issues, such as social and economic factors, on overall wellbeing.

Our analysis of the MYMOP symptoms provides rich data about the symptoms people with lymphoedema find most troublesome. Assessed in conjunction with the MYMOP scores, we conclude that acu/moxa may have a potential role in reducing the symptom burden in cancer survivors with lymphoedema, and for BC participants especially, treatment alleviated many lymphoedema-related symptoms.

Of the eight SF-36 domains, only Bodily Pain and Vitality showed significant improvements, and these lasted up to and including the four-week follow-up for BC participants. HNC scores show no significant results. While it has been suggested that the SF-36 is not responsive to small treatment effects (Paterson, 1996), its widespread use and global assessment for health status makes it useful to compare study populations.

PANAS positive affect scores improved to 4-week follow-up for both diagnoses. BC participants showed slight decreases in negative affect, while changes for HNC were variable. However, none of the changes was significant. PANAS appears to have been the most challenging of the questionnaires for participants to complete. This was demonstrated by the relatively high proportion of missing data (12.2% of positive affect and 6.1% of negative affect items were

Table 5
Comparison of MYMOP outcomes in three acupuncture studies.

MYMOP Item	de Valois et al.				Paterson et al. (Paterson, 2010)		Hull et al. (Hull et al., 2006)	
	Change in score for Series 1 All participants		Change in score for Series 2 All participants		Change in score between baseline & 7th treatment		Change score (pre/post)	
	Mean (SD)	CS	Mean (SD)	CS	$n = 114$	CS	Mean (SD)	CS
	$n = 32$		$n = 30$				$n = 67$ to 73	
Symptom 1	1.53 (1.63)	**L**	1.6 (1.5)	**L**	1.01 (1.67)	**M**	1.7 (1.8)	**L**
Symptom 2	1.97 (1.31)	**L**	1.11 (1.16)	**M**	1.11 (1.74)	**M**	1.2 (1.5)	**M**
Activity	1.65 (1.68)	**L**	1.84(1.49)	**L**	1.05 (1.67)	**M**	1.1 (2.1)	**M**
Wellbeing	0.84 (1.37)	**S**	0.77 (1.36)	**S**	0.58 (1.81)	**S**	0.7 (1.6)	**S**
MYMOP Profile	1.51 (0.96)	**L**	1.32 (0.94)	**M**	0.97 (1.22)	**S**	1.2 (1.3)	**M**

MYMOP scored 0–6 with lower scores indicating better health.
Clinical significance (CS) indicated by the following codes: **S** = small (>0.5), **M** = moderate (>1.0) and **L** = large (>1.5).

missing), as well as the questions participants asked about completing it. Participants also expressed dislike of this questionnaire in written feedback and in the Step 3 focus groups (reported elsewhere). For these reasons, we question its value and will not use it in our future studies.

This study is the first, to our knowledge, that investigates acu/moxa as an adjunct to usual care in lymphoedema management. It is unique in its patient-centred approach, allowing participants to specify the symptoms that concern them most. Furthermore, the acupuncturists had the freedom to direct treatment towards those symptoms, meeting the participants' needs as they would in their usual clinical practice.

This study, although small, indicates that acupuncture may be a safe intervention for people with lymphoedema, especially if needling is avoided in the affected area. This is important, as acupuncture is widely used by people with cancer, particularly BC patients (Carmady and Smith, 2011). A major concern is that acupuncture, as a non-accidental skin puncture, will exacerbate lymphoedema or cause cellulitis (Cole, 2006), and people with lymphoedema are often advised to avoid this treatment (Hansard, 2010). We adopted a cautious approach and avoided needling the affected area, including the associated torso quadrant in BC participants, but needled on the midline. The nurse specialist confirmed there were no cases of exacerbated swelling, and that the two reported incidents of cellulitis were unrelated to acu/moxa treatment. The British Acupuncture Council, the association for professional acupuncturists in the UK, has recorded four reports of cellulitis (out of an estimated 10 million treatments administered by its members) over the past five years, none of which were related to people with cancer and/or lymphoedema (U. Wirth 2011, personal communication, 21 January).

No other serious adverse effects were reported, and the minor adverse effects reported by participants conform to those recorded in major safety studies, with minor bleeding or bruising at the needling site being the most common event, and tiredness, headache, or dizziness being less common (MacPherson et al., 2004, 2001; White et al., 2001; Witt et al., 2009). We were also able to test using moxibustion in an NHS setting. While many participants actively enjoyed the aroma and warmth of moxa treatment, the smell was not universally appreciated, and several members of staff had difficulty adjusting to it. We considered installing an extraction fan, and may do so for further studies.

We have also demonstrated that it is possible to recruit people with lymphoedema to an acupuncture study. Participants overcame concerns about safety and their reluctance to experience further needle-based interventions following cancer treatment (reasons cited by some patients who declined to participate). HNC experts had advised us that recruitment in this patient group would be difficult, and we were disappointed in the small numbers referred to the study. This was due to a lower than usual number of HNC patients referred to the lymphoedema service during the study, as well as a number of potential participants who were too weakened by cancer treatment to participate. However, the majority of those recruited complied with attendance and questionnaire completion. The small number of HNC participants provides sparse data from which to draw meaningful conclusions; however, our findings suggest that chronic musculo-skeletal pain and anxiety are issues for these patients and further research into using acupuncture to alleviate these symptoms may be warranted. Overall, acu/moxa appeared to be acceptable to the participants, as evidenced by their decisions to complete the optional second series of treatment.

In testing the outcome measures, we found MYMOP easy to administer and analyse, although we recommend thorough training of the acupuncturists who administer it. We observed that some participants were unaccustomed to setting their own healthcare priorities. Some others appeared to specify symptoms that they felt were "acceptable", until a relationship of trust developed with their acupuncturist, at which point they revealed more troublesome symptoms (such as feelings of depression). These were not registered on the MYMOPs, and thus some of the more complex emotional symptoms are not reflected in the formal monitoring in this study. Although the SF-36 is a useful questionnaire for comparison across patient groups, we found it had some limitations for lymphoedema patients, who are advised to avoid certain physical activities (lifting and carrying) and for the elderly, whose physical activities are restricted by their age. For future studies, we will seek to include a validated lymphoedema-specific quality of life measure, such as the Lymphoedema Quality of Life (LYMQOL) (Keeley, 2008).

Our design of administering questionnaires before the final treatment in each series was effective for ensuring completion. Return of postal questionnaires required considerable administrative follow-up, with many participants citing their dislike of questionnaires as reasons for late or non-return. A further limitation of the outcome tools relates to their measurement period. MYMOP measures items as experienced in the previous week, and for consistency, we chose to use the SF-36 acute (1-week) rather than the standard (4-week) recall version. A consequence of this short-term measurement was the negative impact on scores by unusual events affecting several participants in the week before final measurements (such as the Norovirus, burglary, and bereavement). This particularly affected MYMOP Wellbeing and Profile scores, as well as SF-36 responses.

Limitations of this study include the uncontrolled study design, its location in a single setting, the small number of HNC participants, and the fact that the research acupuncturist was also the principal investigator. These may bias the results and limit generalisability. However, NIHR RISC funding facilitated speculative research into an innovative treatment for a neglected patient group. The study accorded with MRC guidelines for conducting research prior to designing a randomised controlled trial; as such, it allowed us to explore the feasibility and begin to assess the effectiveness of carrying out research in this controversial and unexplored area.

Conclusion

These promising initial results suggest further research is warranted. Our next planned steps are to conduct a randomised controlled trial focussing on breast cancer related lymphoedema. We are also designing an exploratory study to investigate the feasibility of using acu/moxa to improve quality of life for people with lower limb lymphoedema.

Whilst making no claims about acupuncture's ability to treat lymphoedema, this study opens the door to reassuring people with lymphoedema that they can safely use acupuncture to address a range of physical and emotional conditions, and alleviate their symptom burden. Thus, it increases their options in managing their healthcare. For the acupuncture community, it provides evidence that treatment can be effective, even if large areas of the body are inaccessible for needling. This study also demonstrates that acupuncturists and lymphoedema specialists can work together to bring about improved healthcare for cancer survivors with upper body lymphoedema.

Cancer incidence continues to increase, and with early diagnosis and improved treatments, greater numbers of people are living with the long-term challenges associated with survival. It is estimated that up to 500000 people in the UK are currently experiencing adverse impacts on their quality of life due to the consequences of cancer and its treatments (Department of Health

et al., 2010). While it is hoped that improved treatment interventions (such as sentinel node biopsy) may reduce the incidence (Hack et al., 2010), it is essential to find multi-disciplinary approaches to support existing patients with lymphoedema, as well as those who develop it in the future.

Conflict of interest

None declared.

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