

# ACUPUNCTURE IN LYMPHOEDEMA MANAGEMENT: A FEASIBILITY STUDY

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## Abstract

**Background:** Acupuncture in lymphoedema management is controversial, with assumptions it will introduce infection or exacerbate swelling. **Aims:** This three-step, patient-centred, mixed-methods study assessed acceptability, impact on quality of life, and adverse events of traditional acupuncture as an adjunct to maintenance care for people with lymphoedema secondary to breast and head and neck cancers. **Methods:** Step 1: focus groups with patients and clinicians assessed acceptability. Step 2: in an observational study, participants chose seven or 13 treatments. Outcome measures included Measure Yourself Medical Outcome Profile (MYMOP) and 36-Item Short Form Health Survey (SF-36). Step 3: focus group participants discussed their perceptions of treatment. **Results:** Step 1: eight focus groups (n=39) found acupuncture acceptable, providing affected areas were not needed. Step 2: 30/35 participants completed 13 treatments. MYMOP change scores were clinically and statistically significant at all measurement points. SF-36 scores remained significant for bodily pain and vitality four weeks after the end of treatment. Step 3: data from six focus groups (n=23) supported quantitative results. **Conclusions:** Acupuncture can be used safely to manage the symptom burden for cancer survivors with upper-body lymphoedema and may improve concordance with long-term management. **Declaration of interest:** None.

## Key words

Acupuncture  
Cancer  
Lymphoedema  
Moxibustion  
Quality of life

Use of acupuncture by people with or at risk of lymphoedema is controversial. They are advised to avoid accidental and non-accidental skin puncture (NASP) in the at risk or affected area to reduce the possibility of introducing infection or exacerbating swelling (Cole, 2006;

Lymphoedema Framework, 2006). Lymphoedema and cancer policy documents do not contraindicate acupuncture, giving guidance consistent

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with that of all NASP interventions, which is to avoid needling the affected area (Filshie, 2001; Tavares, 2003; Lymphoedema Framework, 2006). Nevertheless, popular literature advises people with lymphoedema to avoid acupuncture altogether (UKlymph.com, 2002; O'Connor, 2008).

Acupuncture is a form of traditional East Asian medicine that uses needles inserted superficially under the skin to stimulate sites on the body known as acupuncture points. Traditional practice encompasses moxibustion, the application of heat (usually from the smouldering herb *Artemisia vulgaris* or mugwort) to stimulate the points by warming them (Birch and Felt, 1999). This article refers to these combined processes as 'acu/moxa'. There has been little research into using acupuncture or moxibustion in lymphoedema management. Promising outcomes were reported for acu/moxa as prophylaxis (n=12) and treatment (n=12) for gynaecological cancer treatment-related lymphoedema (Kanakura et al, 2002), and for reduced symptoms and increased range of movement in breast cancer patients (n= 29) treated with acupuncture (Alem and Gurgel, 2008). In the latter study, the affected area was not needed.

In view of the limited published evidence for treating lymphoedema itself, the authors chose to investigate using acu/moxa to promote wellbeing

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and improve quality of life for people with cancer treatment-related upper body lymphoedema. The psychosocial effects of lymphoedema are well-documented internationally for breast cancer patients (Morgan et al, 2005), and to a lesser extent for head and neck cancer patients (Withey et al, 2000; Smith and Lewin, 2010). In taking this approach, the authors were responding to calls in the literature for improved treatments for people with lymphoedema. These should address quality of life, as well as the complex physiological and psychosocial problems (such as pain, restricted movement, psychological distress, poor body image, and poor coping skills) facing patients who have a chronic condition with multiple comorbidities (McWayne and Heiney, 2005; Morgan et al, 2005; Towers, 2008).

Acupuncture is used for symptom improvement and improved physiological and psychosocial coping by people with chronic conditions (Cassidy, 1998; Paterson and Britten, 2003), and there is increasing evidence of its effectiveness in managing chronic pain (Hopton and MacPherson, 2010). The authors' previous research into using acupuncture to manage breast cancer treatment-related vasomotor symptoms demonstrated improvements in emotional and physical wellbeing, as well as reduced symptoms (de Valois et al, 2010). Based on previous experience, the authors wanted to investigate the potential for using acu/moxa in the management of lymphoedema.

### The research

Funding from the National Institute for Health Research (NIHR) Research for Innovation, Speculation and Creativity (RISC) programme facilitated this research. It was carried out from April 2008 through January 2010 at the Lynda Jackson Macmillan Centre, a cancer support and information centre associated with Mount Vernon Cancer Centre, a major cancer treatment centre in the south of England. The Hertfordshire Research Ethics Committee granted ethical approval for this patient-centred mixed-methods exploratory study, which followed Medical Research Council

(MRC) guidelines for researching complex interventions (Craig et al, 2008). The main objectives were to explore key questions about using acu/moxa as an adjunct to usual care for lymphoedema:

- ▶▶ Is this intervention acceptable to people with lymphoedema and their healthcare professionals?
- ▶▶ Can it be used to promote wellbeing and improve quality of life?
- ▶▶ Are there any adverse effects?

The study also sought to identify the symptoms that lymphoedema patients found most troublesome, test recruitment, and assess outcome measures in preparation for a larger study. To answer the questions, the authors used a three-step study design. This paper presents an overview of the three steps of the study; reports of individual steps are published elsewhere (de Valois and Peckham, 2011; de Valois et al, 2011).

The study focused on upper body lymphoedema, and recruited breast cancer and head and neck cancer survivors under the care of the hospital's lymphoedema service. The authors did not aim to treat the lymphoedema; acu/moxa was an adjunct to usual care and study participants continued their maintenance treatment with the lymphoedema nurse specialist. This encompassed the four components of maintenance therapy, including skin care, external support in the form of compression garments, exercise and movement, and simple lymphatic drainage, along with regular assessment (Lymphoedema Framework, 2006; British Lymphology Society, 2007). Needling was avoided in the affected area, as recommended in the literature (Filshie, 2001; Tavares, 2003), and as discussed below. Changes in volume as an outcome were not focused upon, as obtaining consistent and meaningful measurement is challenging, and many patients prioritise improvements in quality of life over changes in swelling (Ridner, 2005; Piller, 2007). However, volume was monitored to ensure that acu/moxa treatment did not exacerbate swelling.

### Step 1: assessing the acceptability of acu/moxa treatment

#### Step 1: methodology

Step 1 was a consultation process that aimed to:

1. Assess the acceptability of acu/moxa treatment to people with lymphoedema and their healthcare professionals.
2. Identify the most troublesome symptoms.
3. Ascertain the characteristics of an acu/moxa clinic that would be acceptable to research participants.

For this step, we chose qualitative methods to explore the challenges faced by people with lymphoedema, using focus groups to generate interaction among participants and help them explore and clarify their views (Kitzinger, 2006).

In the spring of 2008, breast cancer and head and neck cancer survivors under the care of the hospital's lymphoedema service were invited to participate in focus groups. To ensure that there were participants who had previously experienced acupuncture, breast cancer survivors who had participated in the authors' previous acupuncture research for a different condition, and who also had lymphoedema were invited. Interested parties were sent an information sheet explaining the research, which assured confidentiality and anonymity, and offered to reimburse reasonable travel and hospital parking costs. Participants signed consent forms before the focus groups started.

The authors wrote to local and regional oncologists, nurse specialists, speech and occupational therapists, and GPs, inviting them to participate in separate focus groups. An information sheet was sent to those interested in participating; no incentives were offered.

The research team (BdV and TY) developed a questioning route (Krueger and Casey, 2000) and facilitated and recorded the focus groups. An external agency transcribed the recordings, BdV analysed the transcripts, and TY checked the summaries.

**Table 1**

**Characteristics of step 1 focus groups**

| Participant group                   | Number of focus groups | Participants per group | Total     |
|-------------------------------------|------------------------|------------------------|-----------|
| Breast cancer survivors with:       |                        |                        |           |
| Previous acupuncture experience     | 2                      | 6, 6                   | 12        |
| Little or no acupuncture experience | 2                      | 7, 4                   | 11        |
| Head and neck cancer survivors      | 2                      | 4, 4                   | 8         |
| Healthcare professionals*           | 2                      | 5, 3                   | 8         |
| <b>Total</b>                        | <b>8</b>               |                        | <b>39</b> |

\* Comprising:

- One head and neck and one breast cancer oncology consultant
- One head and neck and one breast cancer nurse specialist
- One lymphoedema nurse specialist
- One speech therapist
- One occupational therapist
- One local GP

**Step 1: results**

During the summer of 2008, eight focus groups were facilitated (n=39), each lasting a maximum of 90 minutes. *Table 1* presents the participant characteristics; *Table 2* shows sociodemographic data for the participants with lymphoedema. Almost half of the lymphoedema participants had previous experience of acupuncture; only one had experienced moxibustion.

The majority of participants expressed enthusiasm for the proposed treatment, although one woman said she would not have acupuncture for fear of worsening the lymphoedema. Breast cancer survivors and clinicians stipulated that needling should be avoided in the associated torso quadrant, as well as the affected arm. In general, clinicians saw a role for acu/moxa in the supportive care of cancer survivors with lymphoedema, and did not anticipate that it would have any effect on the lymphoedema itself.

Participants discussed a range of troublesome symptoms including social embarrassment, pain and discomfort, frustration with restricted mobility and loss of function, and poor body image, as well as the detrimental effects of lymphoedema on social, family, and

**Participants discussed a range of troublesome symptoms including social embarrassment, pain and discomfort, frustration with restricted mobility and loss of function, and poor body image, as well as the detrimental effects of lymphoedema on social, family, and sexual relationships.**

sexual relationships. Anxiety about progression of the condition and concerns about cellulitis were common.

Overall, participants were happy to attend for acu/moxa treatment once-weekly, with appointments lasting up to an hour. However, they wanted to have a choice of days and times for attendance. They were positive about treatment spanning many weeks, provided that there was flexibility to accommodate time out for holidays and other personal activities. Conversely, clinicians were sceptical about long-term attendance, suggesting that participants were likely to attend for a maximum of six sessions.

The overall positive response expressed by these participants provided the green light to progress to step 2, and the data from these focus groups were used to develop the detailed design for the clinical phase of the study.

**Step 2: the clinical phase**

This step comprised a single-arm observational study using before and after measures. An overview is presented below, but for a detailed account of step 2 the reader is referred to de Valois et al, 2011.

**Step 2: methodology**

**Setting and subjects**

The nurse specialist (EM) referred breast and head and neck cancer patients under her care at the hospital's lymphoedema service. Eligibility criteria included a diagnosis of mild to moderate uncomplicated lymphoedema, no active cancer disease, at least three months post-active cancer treatment, and managed by the lymphoedema service for a minimum of two months for head and neck cancer patients, and three months for breast cancer patients. Breast cancer patients who had undergone bilateral surgery were excluded. Restrictions on needling the affected area excluded using acupuncture points on the arm or associated torso quadrant; for bilateral patients this was a severe restriction on usual acupuncture practice, as few points on the upper body would be available for needling. To test whether participants would prefer short- or long-term treatment, two series of acu/moxa treatments were offered. Series 1 (S1) consisted of seven treatments delivered on a weekly basis, and series 2 (S2) comprised an optional additional six treatments. It was the participant's decision whether to continue to S2.

**Outcome measures**

Three validated outcome measures were chosen for this step. The primary outcome was the change in mean scores at the end of each series on the Measure Yourself Medical Outcome Profile (MYMOP). MYMOP, a questionnaire widely used for evaluating interventions based on holistic and participative principles, enables

**Table 2**  
**Sociodemographic data for all three steps**

|   | Step 1<br>n=31, n (%) | Step 2<br>n=35, n (%) | Step 3<br>n=23, n (%) |
|---|-----------------------|-----------------------|-----------------------|
| <b>Age</b>  |                       |                       |                       |
| Mean (SD)   | 65.6 (9.2)            | 57.5 (9.3)            | 59.9 (8.6)            |
| Minimum–maximum   | 38–78                 | 40–83                 | 43–83                 |
| <b>Gender</b>   |                       |                       |                       |
| Female  | 24 (77.4)             | 30 (85.7)             | 20 (87.0)             |
| Male  | 7 (22.6)              | 5 (14.3)              | 3 (13.0)              |
| <b>Marital status</b>                                   |                       |                       |                       |
| Single  | 5 (16.1)              | 3 (8.6)               | 2 (8.8)               |
| Married (first marriage)                                | 15 (48.4)             | 21 (60.0)             | 12 (52.2)             |
| Remarried   | 4 (12.9)              | 2 (5.7)               | 2 (8.7)               |
| Living with partner                                     | 1 (3.2)               | 2 (5.7)               | 1 (4.3)               |
| Divorced/separated                                      | 4 (12.9)              | 5 (14.3)              | 4 (17.4)              |
| Widowed   | 2 (6.5)               | 2 (5.7)               | 2 (8.7)               |
| <b>Educational qualifications</b>                       |                       |                       |                       |
| Less than compulsory school education                   | 5 (16.1)              | 4 (11.4)              | 2 (8.7)               |
| Compulsory school education                             | 11 (35.5)             | 10 (28.6)             | 6 (26.1)              |
| Post compulsory school education below university level | 6 (19.4)              | 9 (25.7)              | 8 (34.8)              |
| University level  | 5 (16.1)              | 10 (28.6)             | 5 (21.7)              |
| Postgraduate level                                      | 4 (12.9)              | 2 (5.7)               | 2 (8.7)               |
| <b>Current employment status</b>                        |                       |                       |                       |
| Retired   | 20 (64.5)             | 15 (42.9)             | 11 (47.8)             |
| Not working at present                                  | 4 (12.9)              | 5 (14.3)              | 3 (13.0)              |
| Working part-time                                       | 3 (9.7)               | 8 (22.9)              | 5 (21.7)              |
| Working full-time                                       | 4 (12.9)              | 7 (20.0)              | 4 (17.4)              |
| <b>Country of birth</b>                                 |                       |                       |                       |
| United Kingdom  | 25 (80.6)             | 28 (80.0)             | 19 (82.6)             |
| Other   | 6 (19.4)              | 7 (20.0)              | 4 (17.4)              |
| <b>Ethnic background</b>                                |                       |                       |                       |
| White British or Irish                                  | 26 (84.0)             | 29 (82.8)             | 20 (87.0)             |
| Asian   | 2 (6.4)               | 4 (11.4)              | 3 (13.0)              |
| Other   | 2 (6.4)               | 1 (2.9)               | 0                     |
| Missing data  | 1 (3.2)               | 1 (2.9)               | 0                     |
| <b>Previous acupuncture experience</b>                  |                       |                       |                       |
| Yes   | 15 (48.4)             | 10 (28.6)             | 5 (21.7)              |
| No  | 16 (51.6)             | 25 (71.4)             | 18 (78.3)             |

respondents to specify and measure the treatment outcomes that are important

to them (Paterson, 1996). In addition, the Medical Outcomes Study 36-Item

Short Form Health Survey (SF-36) was used. This is a widely used functional status questionnaire that assesses eight domains of physical and psychological health (Ware, no date). The SF-36 and the Positive and Negative Affect Scale (PANAS), a measure used to assess mood states (Watson et al, 1988), were administered at baseline, the end of each series, and at four and 12 weeks after the end of treatment. Participants also completed semi-structured questionnaires at end of treatment and at the two follow-up points.

**Assessment of swelling**

Reducing volume was not an aim of this study. However, the nurse specialist measured breast cancer participants with arm oedema to ensure that acu/moxa treatment was not exacerbating swelling. Excess limb volumes were calculated from circumferential measurements taken at 4cm intervals, starting from 2cm above the ulnar styloid (Lymphoedema Framework, 2006) using a LymCalc® (Colibri Systems Software, Wrexham) pre-programmed calculator. To minimise possible variations due to differences in technique, the same nurse specialist (EM) took all measurements. She measured each patient when she referred them to the study (baseline), and again after the last treatment of each series of acupuncture treatments.

Breast cancer participants were likely to have long-standing lymphoedema, and it was unlikely that their preoperative arm measures were recorded in the hospital notes. Therefore, the nurse specialist indicated that an increase in the % excess volume of >5% was outside the normal range of change that could be expected for stable patients on maintenance treatment. When monitoring participants, she also used visual and physical assessment, and took into account clinical history and concordance with their self-management programme.

**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 to compare MYMOP, SF-36 and PANAS data across all measurement points. This paper presents sociodemographic, MYMOP and SF-36 data for all participants; for data by cancer diagnosis and for a detailed discussion of the outcome measures used (including PANAS), please refer to de Valois et al, 2011.

**Acupuncture protocol**

Participants in step 1 focus groups described a range of symptoms. Thus, the authors chose not to impose a restricted acu/moxa protocol. Treatments were individualised according to the needs of the participant, changed as they progressed through treatment, and acute conditions (such as colds or back problems) were treated as they presented (see de Valois and Peckham, 2011 for detailed case histories illustrating this approach). As agreed in the step 1 focus groups, needling was avoided in the affected area, including the torso quadrant on the affected side of breast cancer participants. However, needling points on the midline of the torso and along the spine was permitted. Acu/moxa was supplemented with guidance for healthy living, which could include advice for healthy dietary habits, rest, exercise, or other advice as appropriate for the individual participant. There were no restrictions on developing the therapeutic relationship between the participants and their acupuncturist. Two experienced members of the British Acupuncture Council administered the acu/moxa treatments. They reinforced the messages for self-management as prescribed by the nurse specialist.

**Step 2: results**

**Recruitment**

Between October 2008 and May 2009, 35 participants were recruited, of whom 27 were breast cancer and eight were head and neck cancer survivors. Thirty participants (86%) chose to complete both series of treatment, three (8%) completed only series 1, and two (6%) were lost to the study. Figure 1 shows the rationale for non-completion and withdrawal. A mean of 12 treatments

per participant were administered, for a total of 420 treatments.

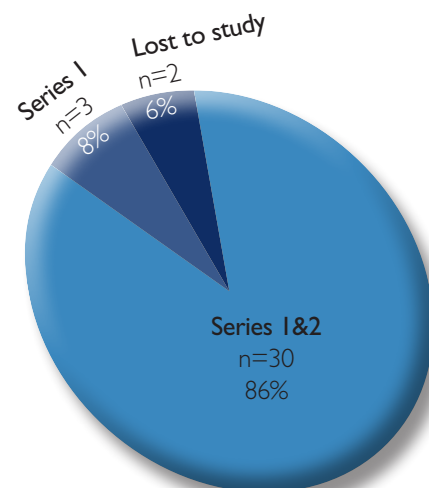
**Sociodemographic and clinical data**

The majority of participants were female, reflecting the high proportion of breast cancer survivors recruited (see step 2 in Table 2). Overall, participants were partnered, well-educated, born in the UK, of White British or Irish ethnicity, and only one-quarter had previous experience of acupuncture.

Clinical data (Table 3) indicate that breast cancer participants had been diagnosed with lymphoedema an average of over four years before joining the study. There was a wide variation in time since diagnosis, ranging from three months to nine years. Head and neck cancer participants had been diagnosed with lymphoedema an average of three years before joining the study. They showed a similar variation in time from diagnosis, ranging from six months to 11 years.

**MYMOP and SF-36 data**

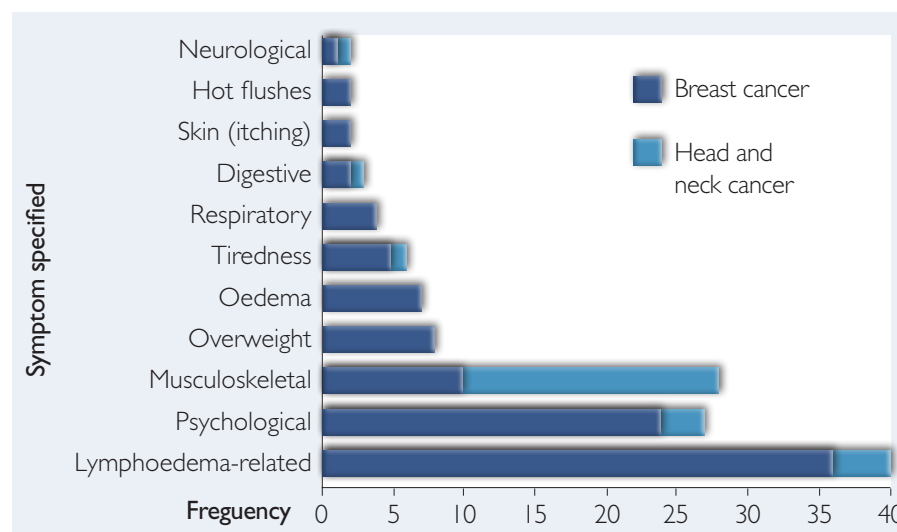
Changes in mean MYMOP scores for all participants at the end of each series compared to the first treatment of each series were statistically significant (Table 4). A change of more than 0.5 to 1.0 point on a seven-point scale is clinically significant and noticeable to the patient (Paterson, 2010). The changes in scores for each MYMOP item are all clinically significant for both series.



- 35 participants recruited
- 30 completed series 1 and 2
- Three completed series 1 only: one relocated; one found travelling onerous; one found treatment not beneficial
- Two lost to study: one cancer recurrence; one carer who found attendance too difficult

**Figure 1. Recruitment, compliance, and losses for step 2.**

Analysis of the symptoms that participants specified on the MYMOP questionnaires showed that breast cancer participants focused on lymphoedema-related symptoms (Figure 2), including heaviness, aching, pain, discomfort, and swelling. They also indicated a range of psychological conditions, including stress, anxiety,



**Figure 2. Analysis of symptoms specified on MYMOP questionnaires.**



**Table 3**  
**Clinical data for step 2 participants at baseline by diagnosis**

| Time in years   | Mean (SD) | Minimum–maximum |
|---|-----------|-----------------|
| <b>Duration of lymphoedema</b>  |           |                 |
| Breast cancer   | 4.2 (2.5) | 0.25–9.0        |
| Head and neck cancer  | 2.9 (3.6) | 0.5–11.0        |
| <b>Years from end of active cancer treatment to lymphoedema diagnosis</b> |           |                 |
| Breast cancer   | 2.3 (3.6) | 0–12.0          |
| Head and neck cancer  | 0.4 (0.7) | 0–2.0           |
| <b>Time from surgery to start of acupuncture treatment</b>                |           |                 |
| Breast cancer   | 6.9 (5.0) | 1.2–23.2        |
| Head and neck cancer  | 3.7 (3.5) | 0.5–10.9        |

Breast cancer, n=27; head and neck cancer, n=8

depressed mood, sleep problems and bereavement issues. Head and neck cancer participants specified mainly musculoskeletal symptoms, including pain and restricted movement. For a discussion of these symptoms, please refer to de Valois et al, 2011.

Changes in SF-36 scores (Table 5) for all participants at each measurement point from baseline were significant for the domains of bodily pain (BP) and vitality (VT) up to and including four weeks after the end of treatment. The Physical Component Score (PCS) was significantly different at the end of series 1, and at four and 12-week follow-ups.

**Changes in percentage of excess volume and cellulitis**

Of the 27 breast cancer participants recruited, two had midline lymphoedema. One other participant, with arm oedema, withdrew from the study after three treatments. Measurements for the remaining 24 participants with arm oedema show that two participants had overall increases of >5% excess volume (Table 6). Based on her long-term clinical knowledge of these individuals, the nurse specialist identified them as having a history of non-adherence to self-care, and did not associate these increases with acupuncture treatment.

Two breast cancer participants

reported cellulitis: one during series 1, the other three weeks after the end of completing series 2. The nurse specialist confirmed that these were unrelated to acupuncture treatment; one was due to a paper cut, the other was related to trauma that resulted when the participant accidentally hit her arm.

**Other adverse effects**

Minor adverse effects of acupuncture treatment included infrequent incidents of bruising or bleeding at the needle site, pain on needling, and tiredness after treatment. One participant reported feeling light-headed after treatment in the early stages of series 1, while another experienced headaches after treatment. These adverse effects are typical of those recorded in several large safety studies of acupuncture (MacPherson et al, 2001; Witt et al, 2009). The majority of participants tolerated moxibustion, and many reported that they found it pleasant and relaxing. One neck cancer participant, however, was concerned that moxa might irritate his stoma, and the acupuncturist refrained from using it in his treatment.

**Step 3: methodology**

Focus groups with the participants of step 2 were conducted to gather data on their perceptions and experiences of having acu/moxa treatment. Participants

were sent an information sheet describing the focus groups, in which confidentiality and anonymity were assured. Reasonable travel and parking costs were reimbursed, no other incentives were offered. Participants signed a consent form before the focus groups started.

An external independent qualitative researcher worked with the research team to develop a questioning route. She facilitated and recorded the focus groups, transcribed the tapes and analysed them thematically (Braun and Clarke, 2006) using NVivo 2.0 software.

**Step 3: results**

Of the 32 invitees, six head and neck cancer and 17 breast cancer survivors (total n=23) participated in six focus groups during the summer of 2009. Sociodemographic data are presented in Table 2.

Focus group participants discussed a range of physical and emotional benefits. These included reduced pain, improved sleep, increased energy levels, reduced stress levels, and reduced medication. Although it was not the study's aim to treat the lymphoedema itself, many participants reported changes in associated sensations such as pain, discomfort and perceived reduction in swelling, as well as increased mobility. The qualitative data gathered in these focus groups support the quantitative data collected in step 2. These data accord with the MYMOP symptoms specified by participants (Figure 2) and corroborate the SF-36 scores. Participants reported variation in the duration of beneficial effects, which could be short-term or long-lasting.

Several participants reported increased motivation to manage their long-term health issues, such as taking initiatives to lose excess weight or improving concordance with self-care. One breast cancer participant reported an especially significant change in attitude to her health care, when she had an episode of cellulitis:

*Normally I 'put off' going to the doctor until things are really bad. This time*

Table 4

## MYMOP outcomes for all participants

|               | Series 1 (treatments 1 to 7) |                    |                                |              | Series 2 (treatments 8 to 13) |                     |                                 |              |
|---------------|------------------------------|--------------------|--------------------------------|--------------|-------------------------------|---------------------|---------------------------------|--------------|
|               | Before treatment 1           | Before treatment 7 | Change in score, treatment 1–7 |              | Before treatment 8            | Before treatment 13 | Change in score, treatment 8–13 |              |
|               | Mean (SD)                    | Mean (SD)          | Mean (SD)                      | p            | Mean (SD)                     | Mean (SD)           | Mean (SD)                       | p            |
|               | n=35                         |                    | n=32                           |              | n=30                          |                     | n=30                            |              |
| Symptom 1     | 3.91 (1.07)                  | 2.44 (1.48)        | 1.53 (1.63)                    | <b>0.001</b> | 3.61 (1.31)                   | 2.00 (1.29)         | 1.60 (1.50)                     | <b>0.001</b> |
| Symptom 2     | 4.03 (1.10)                  | 2.09 (1.06)        | 1.97 (1.31)                    | <b>0.001</b> | 2.93 (1.15)                   | 1.78 (1.12)         | 1.11 (1.16)                     | <b>0.001</b> |
| Activity      | 4.26 (1.08)                  | 2.65 (1.58)        | 1.65 (1.68)                    | <b>0.001</b> | 3.77 (1.11)                   | 1.96 (1.26)         | 1.84 (1.49)                     | <b>0.001</b> |
| Wellbeing     | 2.74 (1.60)                  | 1.84 (1.21)        | 0.84 (1.37)                    | <b>0.002</b> | 2.39 (1.36)                   | 1.67 (1.30)         | 0.77 (1.36)                     | <b>0.004</b> |
| MYMOP profile | 3.72 (0.97)                  | 2.24 (1.02)        | 1.51 (0.96)                    | <b>0.001</b> | 3.15 (0.85)                   | 1.84 (0.93)         | 1.32 (0.94)                     | <b>0.001</b> |

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 point)

*I had the confidence to request an urgent appointment and get prompt treatment. I feel this is due to the acupuncture/moxibustion treatment I received.*

The majority of participants were enthusiastic about their experiences of acu/moxa. Most said they would like to continue having acu/moxa, although the cost of private treatment was cited as a barrier. A detailed report of this step is in preparation for publication; however, the following quotation from a breast cancer participant succinctly summarises the experiences of many of the participants:

*I think we were always made aware from the very beginning, that it wasn't going to cure lymphoedema... And I think we've had such incredible results from it for other things, that it almost overshadowed what was happening with the lymphoedema... It wasn't such a dominating factor in your life.*

### Discussion

The aim of this study was to explore the feasibility of using acupuncture in the management of lymphoedema. This is a controversial concept, due to perceptions about the potential risk

### A particularly interesting finding of this study was that many participants were motivated to improve their self-care by taking action to lose weight or improve adherence to their lymphoedema maintenance programmes.

factors of acupuncture introducing infection or increased swelling. This study followed MRC guidelines for researching complex interventions before designing a randomised controlled trial (Craig et al, 2008). It allowed the authors to:

- ▶▶ Examine the acceptability of using acu/moxa in lymphoedema management
- ▶▶ Assess its potential for improving wellbeing in cancer survivors with upper body lymphoedema
- ▶▶ Monitor adverse effects.

It also allowed the authors to test recruitment, assess outcome measures, and increase their understanding of the physical and emotional symptoms experienced by people with lymphoedema. In this three-step design, people with lymphoedema were

consulted at each stage of the study to ensure that the research reflected their needs.

### Acceptability

Data from the step 1 focus groups indicated that acu/moxa was acceptable to cancer survivors with lymphoedema and to their healthcare professionals. However, breast cancer patients and their clinicians stipulated that acupuncturists should not needle in the arm or the torso quadrant on the affected side. The high level of retention to the clinical phase of the study, with 86% of the participants opting to continue with and complete series 2 of the treatments, also indicates that they found acu/moxa acceptable. This was confirmed in the step 3 focus groups, where participants discussed their satisfaction with this form of treatment, with many reporting that they would like to continue treatment if it were available in the National Health Service.

### Wellbeing

Improvements in wellbeing were apparent in the changes in MYMOP scores, which were both statistically and clinically significant. Analysis of the symptoms showed that for breast cancer participants, improvements related to reducing lymphoedema-

Table 5

SF-36 outcomes for all participants

| Scale | Series 1 (treatments 1 to 7) |             |                 |             | Series 2 (treatments 8 to 13) |                  |             | 4-week follow-up |                        |             | 12-week follow-up |                         |             |
|-------|------------------------------|-------------|-----------------|-------------|-------------------------------|------------------|-------------|------------------|------------------------|-------------|-------------------|-------------------------|-------------|
|       | Before tx 1<br>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           |
|       | n=35                         | n=33        |                 |             | n=30                          |                  |             | n=32             |                        |             | n=32              |                         |             |
| PF    | 67.0 (23.4)                  | 70.2 (24.3) | 3.2 (14.1)      | 0.2         | 70.6 (19.8)                   | 3.8 (17.2)       | 0.2         | 71.5 (22.1)      | 3.9 (13.8)             | 0.1         | 72.2 (24.8)       | 4.7 (15.6)              | 0.1         |
| RP    | 69.9 (27.1)                  | 77.6 (23.0) | 7.7 (22.1)      | <b>0.05</b> | 71.5 (25.1)                   | 2.1 (27.0)       | 0.7         | 74.6 (22.8)      | 4.8 (24.4)             | 0.3         | 70.0 (29.9)       | -0.61 (27.8)            | 0.9         |
| BP    | 62.2 (21.6)                  | 70.6 (21.5) | 8.3 (16.6)      | <b>0.01</b> | 72.7 (21.2)                   | 10.4 (17.1)      | <b>0.01</b> | 71.6 (22.6)      | 8.1 (16.5)             | <b>0.01</b> | 67.1 (24.0)       | 3.9 (21.6)              | 0.3         |
| GH    | 61.8 (22.4)                  | 63.1 (22.5) | 1.4 (9.5)       | 0.4         | 66.1 (20.1)                   | 5.3 (16.8)       | 0.1         | 66.5 (20.8)      | 3.7 (16.8)             | 0.2         | 66.7 (21.1)       | 2.9 (16.0)              | 0.3         |
| VT    | 51.1 (23.3)                  | 59.8 (23.5) | 8.7 (16.8)      | <b>0.01</b> | 59.2 (22.5)                   | 9.6 (23.3)       | <b>0.03</b> | 59.9 (22.3)      | 9.1 (23.8)             | <b>0.04</b> | 53.2 (28.4)       | 1.4 (21.9)              | 0.7         |
| SF    | 80.3 (25.0)                  | 86.4 (23.7) | 6.1 (20.5)      | 0.1         | 79.6(26.4)                    | 0.0 (23.0)       | 1.0         | 80.9 (24.4)      | 0.4 (24.3)             | 0.9         | 75.4 (28.6)       | -4.4 (32.2)             | 0.5         |
| RE    | 79.6 (24.8)                  | 81.8 (25.0) | 2.3 (23.1)      | 0.6         | 82.2 (25.2)                   | 4.2 (24.9)       | 0.4         | 82.8 (22.3)      | 3.4 (26.1)             | 0.5         | 75.3 (31.0)       | -4.0 (33.0)             | 0.5         |
| MH    | 72.1 (16.6)                  | 74.9 (17.9) | 2.7 (15.1)      | 0.3         | 74.7 (19.3)                   | 2.8 (16.5)       | 0.4         | 71.8 (20.2)      | 0.5 (18.6)             | 0.9         | 68.2 (24.0)       | -4.4 (24.0)             | 0.3         |
| PCS   | 44.0 (9.2)                   | 46.5 (8.7)  | 2.5 (6.2)       | <b>0.03</b> | 46.3 (8.4)                    | 2.4 (7.4)        | 0.1         | 47.4 (9.2)       | 3.1 (5.4)              | <b>0.01</b> | 47.0 (9.5)        | 2.5 (5.7)               | <b>0.02</b> |
| MCS   | 48.9 (10.7)                  | 50.8 (11.2) | 1.9 (10.5)      | 0.3         | 49.6 (12.4)                   | 1.9 (11.8)       | 0.4         | 49.1 (12.3)      | 0.5 (13.3)             | 0.9         | 45.6 (16.2)       | -3.2 (16.5)             | 0.3         |

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 problems; MH = mental health; MCS = mental composite score; PCS = physical composite score  
 Domains scored 0 to 100. Higher scores indicate better quality of life  
 p = significance on a 2-tailed paired t-test. Bolding indicates statistical significance (p<0.05)

related symptoms, such as heaviness and discomfort of the arm, as well as a range of psychological problems, namely anxiety, stress, insomnia, and emotional issues such as bereavement. Head and neck cancer participants showed improvements in musculoskeletal conditions, including pain.

SF-36 results corroborate the MYMOP results in terms of improvement in physical health, but do not reflect the reported benefits in emotional wellbeing. Participants discussed these benefits in the step 3 focus groups, citing reduced stress, improved confidence, more positive outlook, and a sense of increased control of their lives. A particularly interesting finding of this study was that

many participants were motivated to improve their self-care by taking action to lose weight or improve adherence to their lymphoedema maintenance programmes. The authors aim to explore this aspect in future research.

**Adverse events**

Monitoring adverse events was an essential feature of this study. Major studies into the safety of acupuncture show that there are few serious adverse events (MacPherson et al, 2001; Witt et al, 2009). The minor adverse events observed in this study are similar to those reported in these large studies, comprising mild and transient occurrences of pain, bleeding or bruising, light-headedness, and headaches.

Risk of introducing infection is a major concern about using acupuncture in the management of lymphoedema. In this study, there were two reports of cellulitis, both of which were unrelated to acu/moxa treatment. It is interesting to note that treatment may even have facilitated earlier medical intervention for one woman. She reported that she was more proactive in seeking immediate treatment for cellulitis, a behavioural change that she attributed to acu/moxa treatment, as evidenced by her quotation on pp 26–27.

While it was not an aim of this study to reduce volume, the nurse specialist measured changes in % excess volume for breast cancer participants with arm oedema to identify whether



Table 6

## Changes in % excess volume for breast cancer participants with arm oedema

| Participant no | % excess volume at baseline | % excess volume at end of S1 | % excess volume at end of S2 | Δ % excess volume at end of S1 | Δ % excess volume at S2 from S1 | Δ % excess volume at S2 from baseline |
|----------------|-----------------------------|------------------------------|------------------------------|--------------------------------|---------------------------------|---------------------------------------|
| 1*             | 27.9                        | 27.5                         | n/a                          | -0.4                           | n/a                             | n/a                                   |
| 2*             | 27                          | 32.3                         | n/a                          | 5.3                            | n/a                             | n/a                                   |
| 3              | 27                          | 25.2                         | 16.1                         | -1.8                           | -9.1                            | -10.9                                 |
| 4              | 20.1                        | 12.3                         | 10.9                         | -7.8                           | -1.4                            | -9.2                                  |
| 5              | 22.3                        | 20.6                         | 15.7                         | -1.7                           | -4.9                            | -6.6                                  |
| 6              | 10.7                        | 7.4                          | 4.8                          | -3.3                           | -2.6                            | -5.9                                  |
| 7              | 8.2                         | 4                            | 2.5                          | -4.2                           | -1.5                            | -5.7                                  |
| 8              | 34                          | 35.2                         | 29.9                         | 1.2                            | -5.3                            | -4.1                                  |
| 9              | 7.4                         | 0.8                          | 3.4                          | -6.6                           | 2.6                             | -4                                    |
| 10             | 16.2                        | 7.9                          | 13.7                         | -8.3                           | 5.8                             | -2.5                                  |
| 11             | 25                          | 23                           | 23                           | -2                             | 0                               | -2                                    |
| 12             | 10.6                        | 11.1                         | 8.9                          | 0.5                            | -2.2                            | -1.7                                  |
| 13             | 1.9                         | 3.9                          | 0.2                          | 2                              | -3.7                            | -1.7                                  |
| 14             | 12.7                        | 8.1                          | 11.4                         | -4.6                           | 3.3                             | -1.3                                  |
| 15             | 7.3                         | 8                            | 7.4                          | 0.7                            | -0.6                            | 0.1                                   |
| 16             | 14.6                        | 13.5                         | 14.7                         | -1.1                           | 1.2                             | 0.1                                   |
| 17             | 0.5                         | 1.5                          | 2.4                          | 1                              | 0.9                             | 1.9                                   |
| 18             | 23                          | 28                           | 25                           | 5                              | -3                              | 2                                     |
| 19             | 19                          | 22                           | 21.9                         | 3                              | 0.1                             | 2.9                                   |
| 20             | 4.2                         | 4.5                          | 7.2                          | 0.3                            | 2.7                             | 3                                     |
| 21             | 22.7                        | 23.5                         | 26.2                         | 0.8                            | 2.7                             | 3.5                                   |
| 22             | 10.8                        | 12.3                         | 15.8                         | 1.5                            | 3.5                             | 5                                     |
| 23             | 27                          | 25.1                         | 33                           | -1.9                           | 7.9                             | 6                                     |
| 24             | 23.7                        | 26.7                         | 33.4                         | 3                              | 6.7                             | 9.7                                   |

\* Participants completed series I only

acu/moxa exacerbated swelling. The data in Table 6 are taken from the measurements recorded by the nurse specialist in the patient notes. They are presented in an abbreviated format for the sake of simplicity, showing only the final % excess volume as calculated from combined distal and proximal measurements comparing the affected arm to the non-affected arm. In the study, two participants registered changes in % excess volume of >5%. The nurse specialist, drawing on her clinical experience with these patients,

confirmed that these increases were related to their chronic non-adherence to self care, and were unlikely to be associated with acu/moxa treatment.

Overall, the changes in % excess volume suggest that acu/moxa treatment is unlikely to exacerbate swelling. This might be expected, in view of the authors' conservative approach to needling, which avoided the arm and the associated torso quadrant. Participants in step I focus groups stipulated this condition. This approach

accords with widespread guidelines for avoiding skin puncture to minimise risk of adverse events in people with or at risk of lymphoedema. The risks of causing adverse effects through needling the affected or at risk area are unknown. While some researchers are studying the safety aspects of needling into the affected area (Matecki et al, 2010; Cassileth et al, 2011), the wide margins of safety observed in this study ensure that potential risk to people with lymphoedema is minimised. This reassures healthcare professionals and

patients that acupuncturists can work within the boundaries of concern for patient safety. It also avoids potential confusion that could result from giving people with lymphoedema mixed messages about avoiding skin puncture in the affected or at risk area.

Although % excess volume reduced for many participants during the trial, these reductions cannot be attributed to acu/moxa treatment. Such changes may be part of the normal course of the condition, or due to changes in season, level of activity, improved concordance with maintenance therapy, or reductions in stress levels of the participant. The data in *Table 6* show how volumes can fluctuate over time. To gather meaningful data on acupuncture's potential role in reducing volume, measurement would need to be long-term and sensitive to the complex factors (such as changes in activity and stress levels, and concordance to maintenance therapy) that may influence fluctuations in lymphoedema swelling. Preoperative measures would also be beneficial, but this criterion could exclude patients with long-standing lymphoedema (like many in this study), where such measurements are not available.

#### Other findings

Essential to this study was the strong working relationship between the nurse specialist and the acupuncturists. This facilitated the introduction of acu/moxa treatment as part of the multi-disciplinary approach to treatment of lymphoedema, and it contributed to improved overall patient care. The acupuncturists were able to reinforce the messages about adherence to self-care, and acu/moxa treatment appeared to increase motivation to improve self-care in people with lymphoedema. Furthermore, the nurse specialist's expertise was essential for monitoring and interpreting changes in lymphoedema.

This study also has important findings for the acupuncture community. It demonstrates that acupuncture has the potential to be effective even when large areas of the body are not accessible for needling.

#### Strengths and limitations of this study

To the authors' knowledge, this is the first study to explore using acu/moxa as an adjunct to usual care in lymphoedema management. Its patient-centred approach helped to ensure that the design met the needs of people with lymphoedema, and allowed study participants to stipulate the problems that were of most concern to them. In the cautious approach to needling, it adhered to the guidelines for best practice for minimising risk of infection or exacerbated swelling from skin puncture. Changes in % excess volume were measured systematically and assessed by a lymphoedema nurse specialist on an ongoing basis throughout the study.

Limitations of this study include the uncontrolled study design in a single setting, the small number of participants (especially of head and neck cancer survivors), and the fact that the research acupuncturist was also the principal investigator. While these factors may potentially bias the results and limit generalisability, this was an exploratory study. Funding from the NIHR RISC programme facilitated this early stage research into an innovative treatment approach that aimed to improve care for a neglected patient group. It allowed the authors to explore the feasibility and to assess the potential for carrying out further research in this controversial and unexplored area.

#### Conclusion

This feasibility study has provided a platform from which to conduct further research in this area. A randomised controlled trial focusing on breast cancer-related lymphoedema is planned by the authors, who are also designing an exploratory study to investigate the feasibility of using acupuncture to improve wellbeing in people with lower limb lymphoedema, including cancer and non-cancer related lymphoedema.

This study makes no claims about the potential of acupuncture to treat lymphoedema itself, nor to assess the safety of acupuncture skin puncture

#### Key points

- » Cancer survivors with upper body lymphoedema and their healthcare professionals found traditional acupuncture was acceptable as adjunctive treatment, provided that the affected area was not needed.
- » Participants reported a range of physical and emotional benefits, including improvements in lymphoedema and non-lymphoedema related symptoms.
- » No serious adverse events were reported. There were no incidents of cellulitis or exacerbated swelling related to acupuncture treatment.

in the affected or at risk area. The authors worked within the parameters of best practice for the management of lymphoedema, in maintaining skin integrity by avoiding skin puncture in an affected area. Thus, this research opens the door to reassuring people with lymphoedema that they can safely use acupuncture to address a range of physical and emotional conditions. This increases the options for managing their symptom burden.

For acupuncturists, this study provides evidence that acupuncture can be effective, even when large areas of the body are inaccessible to needling. This study also demonstrates that acupuncture can be part of the multi-disciplinary approach to addressing the needs of people with multiple comorbidities, with acupuncturists working as part of the team alongside lymphoedema specialists to improve the wellbeing of people with lymphoedema. JL

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