Complementary Therapies in Clinical Practice 23 (2016) 1–8

Contents lists available at ScienceDirect

Complementary Therapies in Clinical Practice

journal homepage: www.elsevier.com/locate/ctcp

Use of reflexology in managing secondary lymphoedema for patients affected by treatments for breast cancer: A feasibility study

Judith Whatley [a, *], Rachael Street [a, b], Sally Kay [c], Philip E. Harris [a]

[a] Cardiff Metropolitan University, Cardiff School of Health Sciences, Western Avenue, Cardiff CF5 2YB, United Kingdom
[b] Abertawe Bro Morgannwg University Health Board, Research & Development, Institute of Life Sciences 2, Swansea University, Singleton Park, Swansea SA2 8PP, United Kingdom
[c] Reflexology Lymph Drainage Training and Practitioner, Rogerstone, Newport Gwent NP10 9LG, United Kingdom

ARTICLE INFO

Article history:
Received 2 October 2015
Received in revised form
9 December 2015
Accepted 12 January 2016

Keywords:
Breast cancer
Lymphoedema
Reflexology lymphatic drainage

ABSTRACT

Purpose: The aim of this feasibility study was to examine the use of reflexology lymphatic drainage (RLD) in the treatment of breast-cancer related lymphoedema (BCRL) with a view to further research. Methods: An uncontrolled trial was conducted with 26 women who had developed lymphoedema in one arm following treatment for breast cancer. Changes in upper-limb volumes and in participant concerns and wellbeing were measured. Qualitative data were also collected. Results: A significant reduction in the volume of the affected arm was identified at follow-up compared to baseline. This reduction in volume appeared to be maintained for more than six months. Participant concerns were significantly reduced and their wellbeing significantly increased. No serious adverse effects were reported. Conclusions: RLD may be a useful intervention for BCRL although the results could not be attributed to the reflexology intervention because of research design limitations. The main conclusion was, however, that there was sufficient evidence for further research using a randomized controlled trial.

1. Introduction

Secondary lymphoedema of the upper-limb is a pernicious and often persistent side effect of curative treatment for breast cancer [1–3]. A recent review of incidence estimates [4] concluded that about 1 in 5 women surviving breast cancer will develop arm lymphoedema although estimates vary particularly with the extent of surgical treatment and body mass index [4,5], and also with the measurement of lymphoedema by different methods [6,7]. The incidence of breast-cancer related lymphoedema (BCRL) appears to increase for up to two years after breast cancer diagnosis or surgery [4], and as cancer survival improves the prevalence of BCRL is likely to increase.

BCRL remains a significant quality of life issue [3,8] and its development is associated with diminished strength, fatigue, and pain in the affected arm [2,3,9]; impaired functional ability, loss of self-confidence, and poorer emotional wellbeing [3]. To address these needs it is important that patients with mild symptoms are referred to the appropriate specialist [1], early detection and treatment is likely to lead to more effective management [8,10].

There is no known cure for BCRL and although the optimal treatment protocol remains controversial [8,11], there is broad agreement that the best approach is holistic and multidisciplinary [10]. There is a range of interventions for secondary lymphoedema but this discussion will be restricted to conservative (non-surgical and non-pharmacological) treatments. Firstly, there is moderate evidence of reduction in lymphoedema volume with the use of compression garments and compression bandages [12,13]. However, the evidence base is surprisingly low given that these practises are widespread. Some minor adverse effects have been reported [11], but there appears to be little or no reporting about possible psychological discomforts of compression therapy or adherence to its use.

There is strong evidence that increased exercise is safe [14,15] and can improve physical fitness, functioning and quality of life for those diagnosed with BCRL [13]. One study has indicated that exercise may also reduce arm volume [16], and a review concluded that low physical activity is itself a risk factor for developing arm lymphoedema [4].

Current evidence does not support the use of manual lymphatic drainage (MLD) as a stand-alone intervention for preventing or

* Corresponding author.
E-mail address: jwhatley@cardiffmet.ac.uk (J. Whatley).

http://dx.doi.org/10.1016/j.ctcp.2016.01.002
1744-3881/

treating BCRL [17]. The addition of MLD to compression therapy may help to reduce arm volume [13] and early physiotherapy treatment programmes that include MLD may assist the prevention of secondary lymphoedema [18] but no firm conclusions can be drawn from the available evidence [19].

Finally, two studies examining nutrition and dietary interventions for lymphoedema have been reviewed [13], both demonstrated positive effects on lymphoedema volume reduction. The reviewers concluded that physical activity and healthy eating may help to reduce BCRL and have additional health benefits.

There is evidently a need for further effective conservative interventions and for more research into the management of BCRL. Reflexology is a form of complementary healthcare used by patients with cancer [20]. A reflexology treatment typically involves applying pressure to specific areas on the feet using thumb, finger and hand techniques [21]. Although the evidence-base is insufficient [22], a number of studies have indicated that reflexology may benefit the physical and emotional symptoms of patients with cancer [23–26].

An early review of five randomized controlled trials (RCTs) found that no definitive conclusions could be drawn but the available evidence suggested that reflexology may confer symptom relief to people with cancer over those offered by foot massage or no intervention [25]. Since this review, a RCT with 183 women with early breast cancer randomized to three comparison groups concluded that reflexology appeared to have clinically worthwhile effects on their quality of life [24]. This RCT was identified as the only study with a low risk of bias included in a more recent review of the effectiveness of reflexology for the symptomatic treatment of breast cancer, however it was deemed unable to demonstrate the specific effects of reflexology because of the nature of its design [23].

Finally, in a trial of the safety and efficacy of reflexology, 286 women with advanced-stage cancer were randomized to three groups: reflexology, lay foot manipulation (LFM), or conventional care [26]. The findings indicated that both reflexology and LFM were safe even for the most fragile patients with advanced-stage breast cancer. Dyspnoea was identified as the main symptom which was significantly improved by use of reflexology. Both reflexology and LFM improved physical function and symptoms of fatigue compared to controls. Significant effects were not found for nausea, pain, depression, or anxiety.

The current research arose from the clinical experience of a reflexologist working with women with BCRL, where patient reports of benefits led to an exploratory evaluation of six cases in a palliative care setting. Although the results were encouraging it was concluded that more data were needed to justify a controlled trial. The following feasibility study aimed to examine the efficacy of reflexology in thirty patients with breast cancer and secondary lymphoedema.

2. Methods

2.1. Design

Uncontrolled trials are used to establish whether clinical effects warrant further investigation and to provide data on effect sizes [27]. There is little published guidance on sample sizing for pilot or feasibility studies [28] sample sizes varying between 24 and 50 have been recommended [29–31]. This study used a single-subjects experimental design (SSED) [32] and aimed to recruit 30 participants. Data were collected before reflexology intervention began (Phase A1) to give baseline measures for individual participants against which measures taken after intervention (Phase B) and at follow-up (Phase A2) were compared. Efficacious change was measured in terms of limb volume reduction, decreased concerns and increases in wellbeing.

2.2. Participation

A convenience sample of 36 women over the age of 18 years volunteered to participate at three discrete sites in Wales, UK: two cancer-care centres and a University Complementary Healthcare Clinic. Participants were included if they had undergone axillary lymph node dissection and had developed secondary lymphoedema in one arm. Women who had undergone a double mastectomy were excluded. Consequently 28 women were recruited and underwent a consultation with a reflexology practitioner where they were asked about their general health in accord with the professional body code of practice and ethical guidelines. Two participants dropped out for personal reasons (their data were not used), and the remaining 26 participants were distributed across the three sites: Cardiff (n = 15), Bridgend (n = 6), Tredegar (n = 5).

2.3. Treatment protocol

Each of the 26 participants received reflexology lymphatic drainage (RLD) treatments weekly for four consecutive weeks from three reflexology providers trained in the protocol by the study's lead reflexologist. The RLD protocol included 40-min of stimulation to specific zones on both feet. The reflex areas presumed to correspond to the lymphatic and renal systems were worked, firstly on the foot ipsilateral with the unaffected, *normal* arm using a range of finger and thumb techniques. The same sequence was then performed on the other foot corresponding to the lymphoedema, *swollen* arm and, finally, the sequence was repeated on the first foot. All participants continued to receive their usual care from their lymphoedema service providers.

2.4. Data collection

Consent was taken and data gathered by a research associate especially recruited to the study and naïve to the practice of reflexology.

Limb volume data were collected for the swollen arm and the normal arm for each of the 26 participants at 11 data collection points as shown in Table 1: three at baseline; four immediately before treatment (the first of which was also a baseline measure); four immediately after treatment; and one at follow-up a week after the final treatment. All 26 participants were requested to provide a second follow-up and 22 responded. Their response times varied; the mean number of days between the first and second follow-up measures was 195 days (min. 97, max. 277).

The technique of circumference measurement using a tape measure was used to collect volume data for the swollen and normal arms. This is the most commonly used method in the UK [33] and in the current study comprised measuring circumferences starting 2 cm above the wrist joint and then at 4 cm intervals as far as the axilla. These measurements were then used to calculate the volume of the limb as a cylinder based on the formula $v=\pi r^2 h$ simplified to $v = \frac{circumference^2}{\pi}$ (because the circumference of a circle is equal to $2\pi r$, and h equals 4 cm in this instance). In practice, each circumference measurement was squared and the sum of squares divided by Pi to give the limb volume. Water displacement has been regarded as the standard method for accurate measurement of limb volume [34] but it was deemed impractical for the frequent measurements required in the current research. Strong correlations have been reported between circumference measurement and water displacement methods [35], although the methods cannot be used interchangeably for limb volume calculations [36].

Table 1
Treatment and data collection points for 26 participants.

Week	Reflexology treatments	Limb volume measurements	MYCaW questionnaire	Semi-structured interview
1	–	Baseline 1	Baseline	–
2	–	Baseline 2	–	–
3	Treat 1	Pre & Post Treatment	–	–
4	Treat 2	Pre & Post	–	–
5	Treat 3	Pre & Post	–	–
6	Treat 4	Pre & Post	–	–
7	–	Follow-up 1	Follow-up	Post-treatments
–	–	Follow-up 2[a]	–	–

[a] Follow-up 2 measurement times varied by participant as explained in the text.

The Measure Yourself Concerns and Wellbeing (MYCaW) questionnaire was used to collect data about individual concerns and wellbeing at baseline and at follow-up. MYCaW required all 26 participants to identify one or two concerns they would like most help with and to rate these and their general feeling of wellbeing using 7-point scales (0–6); with higher numbers indicating greater concern or poorer wellbeing. The follow-up version included two additional questions 'other things affecting your health' and 'what has been most important to you?' MYCaW was specifically designed to evaluate complementary healthcare use in cancer support services and has been widely used with women with breast cancer [37]. It is quick to administer and acceptable to patients, practitioners and researchers [38]. It is highly responsive to change and captures a wider range of patient-identified concerns compared to similar outcome measures [39], and good inter-rater reliability (kappa .85) has been established for the qualitative analysis [40]. An analysis of work with similar 7-point scales suggests that a change of over .7–1.0 on MYCaW measurements is likely to be clinically significant [41].

Finally, an end of study semi-structured interview was conducted, all participants were asked 'Please tell me about your experiences of arm swelling before you got involved with this study'; 'Can you tell me about your experience of the reflexology treatments you received during the study?'; 'What have you got to say now that the reflexology treatments have finished?'; 'Overall, how helpful do you think the reflexology treatments have been?' (rated on a 7-point scale from 0 *Not helpful at all* to 6 *Extremely helpful*). The participants were also asked if they would recommend reflexology treatments to someone with arm swelling like theirs; and whether they had any suggestions to improve services for people with lymphoedema.

2.5. Data analysis

Quantitative data were analysed using IBM SPSS Version-20. Post-treatment volume differences were calculated by subtracting baseline (the mean of the three baselines) from follow-up measures. The difference between the volumes of the swollen and normal arms was expressed as a percentage of the normal arm (the normal arm acted as a control) at baseline and at follow-up. Inferential analyses tested for differences between the swollen and normal arms over time (mean baseline to follow-up) using a two-way repeated-measures ANOVA. The result of the ANOVA was examined for significant F-ratios indicating main effects for arm type (swollen versus normal) and treatment phase (baseline versus follow-up) as within factors and interaction effects between the two factors. A two-way repeated-measures ANOVA was also performed to test for volume fluctuations in the swollen and normal arms across the three baseline measures. To test whether volume changes were maintained after the treatment phase ended a one-way repeated-measures ANOVA was used to compare the volume data for the swollen arm measured at the second follow-up ($n = 22$) with measures from the first follow-up and mean baseline. For all ANOVAs, Mauchly's test was used when appropriate and adjustments implemented when the assumption of sphericity was violated, post hoc pairwise comparisons were conducted using the Bonferroni correction, and effect sizes (r) were calculated [42]. The Wilcoxon signed rank test was used to compare quantitative data collected at baseline and follow-up using MYCaW, effect sizes (r) were calculated [42], and clinical significance was indicated by mean changes of .7 or greater on the 7-point MYCaW scales [41]. The qualitative data from MYCaW were analysed based on coding categories identified in the MYCaW guidelines [40]. Finally, data transcribed from the semi-structured interviews were thematically analysed using QSR NVivo Version-10.

2.6. Ethical approval

All procedures performed in this study were in accord with the ethical standards of the institutional and national research committees and with the 1964 Helsinki declaration and its later amendments. Permission for the research was granted by the Research Ethics Committee for Wales (ref:13/WA/0225) and written, informed consent was obtained from all participants.

3. Results

3.1. Participants

Twenty-six women were recruited into the study at three sites from January to May 2014, all completed measures at baseline, during intervention, and at follow-up. Between September and November 2014, 22 of the 26 participants completed a second follow-up measure (four participants were unavailable); the interval between the first and second follow-up measures varied from 97 to 277 days (mean interval 195 days).

The mean age of the 26 women was around 61years and this appears to be similar across the three sites (see Table 2). Twenty-

Table 2
Age and years with lymphoedema

Age in years (as of 01.01.14)	Mean	S.D	Min.	Max.
Total (n = 26)	60.8	11.8	43	86
Cardiff (n = 15)	59.3	9.6	43	73
Tredegar (n = 5)	62.4	11.7	51	75
Bridgend (n = 6)	63.0	17.7	43	86
Years with lymphoedema	**Mean**	**S.D.**	**Min.**	**Max.**
Total (n = 26)	4.7	4.5	.08	17
Cardiff (n = 15)	4.1	3.2	.08	10
Tredegar (n = 5)	9.2	6.1	2	17
Bridgend (n = 6)	2.4	3.8	.25	10

two of the women reported experiencing lymphoedema for more than one-year; the mean was 4.7 years. The data were not tested for difference across sites as the reliability of the statistics is questionable with such small sample sizes.

3.2. Arm volume comparisons

It is evident from Table 3 that all 26 participants had reductions in swelling in the arm affected by lymphoedema; the reduction from mean baseline (mean of three baseline measures) to follow-up ranged from a high of 309.4 ml to a minimum of 19.7 ml with a mean reduction of 133.9 ml (SD 74.8). There was also a reduction in the mean volume for the normal arm although this was smaller (7.6 ml, SD 21.4) and in eight cases the volume had increased. The mean difference between the volumes of the swollen and normal arms at baseline was 348.8 ml (SD 239.7), at follow-up the mean difference was 222.5 ml (SD 190.6); a reduction of 126.3 ml (36.2%).

The means of the three baseline volume measurements for the swollen and normal arms are shown in Fig. 1. The results of the two-way repeated-measures ANOVA showed that the baseline volumes of the swollen arms were significantly higher than those of the normal arms [$F(1,25) = 55.06$, $p < .001$], but neither the swollen nor the normal arms showed significant fluctuations in volume across the three baseline measures [$F(1.13,28.24) = .01$, $p > .05$], and there was no interaction between arm type and baseline measures [$F(2,50) = 1.23$, $p > .05$]. This confirms that the mean volumes of the swollen and normal arms were different from each other and stable at baseline.

Further inspection of Fig. 1 suggests that the mean volume of the swollen arms is consistently larger than the normal arms, both at baseline and follow-up, however the size of this difference appears

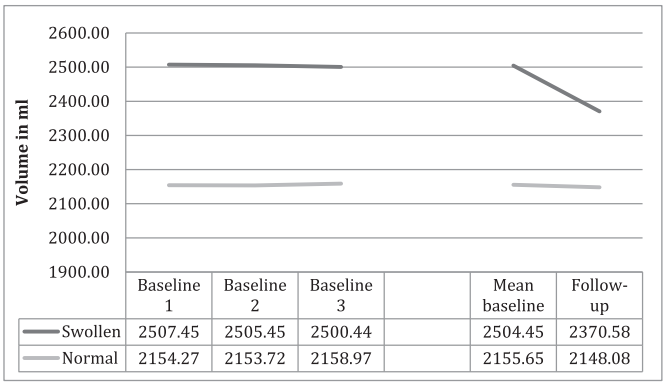

Fig. 1. Arm volumes (ml) at baseline and follow-up1.

to have been markedly reduced in the follow-up measurements. This impression of the arm volume data was assessed by a two-way repeated-measures ANOVA that included arm type (swollen versus normal) and treatment phase (baseline versus follow-up) as within subject factors. The swollen arms did indeed show consistently higher volumes than control arms [$F(1,25) = 46.63$, $p < .001$, $r = .81$]. The impression that the volume of the swollen arm reduced over time whilst normal arms did not was also confirmed by ANOVA with a significant interaction between arm and treatment phase [$F(1,25) = 74.64$, $p < .001$, $r = .87$]. Post hoc pairwise comparisons specifically and separately contrasted swollen and control arms across treatment phases, there was a significant reduction in volume for the swollen arms ($p < .001$) but not for the

Table 3
Arm volume (ml) comparisons from mean baseline to follow-up.

Case	Site[a]	Swollen	Swollen	Swollen	Normal	Normal	Normal	Swollen -normal	Swollen -normal	Swollen -normal	Swollen -normal	% Difference follow-up *minus* baseline
		Baseline	Follow-up	Difference	Baseline	Follow-up	Difference	Difference at bbaseline[b]	Difference at follow-up[b]	% Difference at baseline[c]	% Difference at follow-up[c]	
1	B	2043.66	2004.27	**−39.39**	1873.70	1875.49	**1.79**	169.96	128.78	9.07	6.87	**−2.20**
2	B	2550.34	2320.33	**−230.01**	2430.12	2428.90	**−1.22**	120.22	−108.57	4.95	−4.47	**−9.42**
3	B	3335.29	3138.75	**−196.54**	2674.94	2670.99	**−3.95**	660.35	467.76	24.69	17.51	**−7.17**
4	B	1777.41	1686.94	**−90.47**	1579.07	1577.38	**−1.69**	198.34	109.56	12.56	6.95	**−5.61**
5	B	1653.99	1577.86	**−76.13**	1479.57	1478.28	**−1.29**	174.42	99.58	11.79	6.74	**−5.05**
6	B	1997.75	1893.71	**−104.04**	1587.03	1589.48	**2.45**	410.72	304.23	25.88	19.14	**−6.74**
7	T	1862.01	1726.64	**−135.37**	1625.72	1620.39	**−5.33**	236.29	106.25	14.53	6.56	**−7.98**
8	T	2143.08	2056.29	**−86.79**	1911.90	1912.34	**.44**	231.18	143.95	12.09	7.53	**−4.56**
9	T	1957.61	1891.46	**−66.15**	1759.36	1733.13	**−26.23**	198.25	158.33	11.27	9.14	**−2.13**
10	T	2600.10	2475.37	**−124.73**	2268.40	2250.31	**−18.09**	331.70	225.06	14.62	10.00	**−4.62**
11	T	3120.09	2979.30	**−140.79**	2767.79	2749.08	**−18.71**	352.29	230.22	12.73	8.37	**−4.35**
12	C	3185.71	3071.91	**−113.80**	2904.06	2895.84	**−8.22**	281.65	176.07	9.70	6.08	**−3.62**
13	C	2287.00	2180.86	**−106.14**	2083.98	2080.81	**−3.17**	203.02	100.05	9.74	4.81	**−4.93**
14	C	2881.27	2705.68	**−175.59**	2457.10	2466.71	**9.61**	424.17	238.97	17.26	9.69	**−7.58**
15	C	2710.90	2591.54	**−119.36**	2354.03	2342.55	**−11.48**	356.87	248.99	15.16	10.63	**−4.53**
16	C	3923.82	3614.42	**−309.40**	2881.63	2897.30	**15.67**	1042.19	717.12	36.17	24.75	**−11.42**
17	C	3316.51	3061.77	**−254.74**	2475.96	2446.91	**−29.05**	840.55	614.86	33.95	25.13	**−8.82**
18	C	2419.02	2383.87	**−35.15**	2304.17	2324.03	**19.86**	114.86	59.84	4.98	2.57	**−2.41**
19	C	2859.41	2761.81	**−97.60**	2383.19	2389.06	**5.87**	476.22	372.75	19.98	15.60	**−4.38**
20	C	2392.31	2293.95	**−98.36**	2204.16	2202.31	**−1.85**	188.15	91.64	8.54	4.16	**−4.38**
21	C	2157.66	1971.41	**−186.25**	2015.77	1919.48	**−96.29**	141.90	51.93	7.04	2.71	**−4.33**
22	C	1708.82	1689.16	**−19.66**	1625.64	1626.02	**.38**	83.19	63.14	5.12	3.88	**−1.23**
23	C	2674.40	2393.86	**−280.54**	2163.66	2162.95	**-.71**	510.74	230.91	23.61	10.68	**−12.93**
24	C	2358.41	2287.85	**−70.56**	1920.74	1920.37	**-.37**	437.68	367.48	22.79	19.14	**−3.65**
25	C	1891.24	1753.50	**−137.74**	1707.10	1687.29	**−19.81**	184.14	66.21	10.79	3.92	**−6.86**
26	C	3307.76	3122.52	**−185.24**	2608.24	2602.59	**−5.65**	699.52	519.93	26.82	19.98	**−6.84**
Mean		**2504.45**	**2370.58**	**−133.87**	**2155.66**	**2148.08**	**−7.58**	**348.79**	**222.50**	**15.61**	**9.93**	**−5.68**
SD		**599.49**	**552.26**	**74.82**	**428.26**	**430.45**	**21.40**	**239.68**	**190.61**	**8.65**	**7.27**	**2.82**

[a] B = Bridgend, C = Cardiff, T = Tredegar; ƒ Follow-Up minus Mean Baseline.
[b] Swollen minus Normal.
[c] Difference expressed as a percentage of the normal arm.

normal arms ($p > .05$). A less interesting observation was that arm volumes generally reduced between baseline and post-treatment measurements with a main effect of treatment phase [$F(1,25) = 79.33$, $p < .001$, $r = .87$], however, the above interaction indicates that this within subjects effect is mostly driven by the reduction in volume for the swollen arms and not the normal arms.

Finally, arm volume data were collected for 22 participants at a second follow-up. The mean volume (ml) for the swollen arms at baseline was 2478.02, and 2344.59 and 2346.78 respectively at the first and second follow-ups. Both follow-up measures appear to differ from baseline but not from each other. The result of the one-way repeated-measures ANOVA indicated a significant difference across the three measures for the swollen arms [$F(1.34, 28.13) = 43.50$, $p < .001$]. Pairwise comparison showed that the baseline and first-follow-up measures differed significantly ($p < .001$, $r = .86$), as did baseline and second-follow-up measures ($p < .001$, $r = .81$). There was no significant difference between volume measures taken at first and second follow-up ($p > .05$). This finding from 22 participants supports the conclusion that the reduction in volume of the swollen arms was maintained for the duration between the two follow-up measures (a mean of 195 days).

3.3. Concerns and wellbeing comparisons

The MYCaW scores for the 26 participants at baseline and first-follow-up are shown in Fig. 2 (higher scores denote greater levels of concern, and poorer wellbeing). A downward trend is evident in the participants' scores for primary and secondary concerns and in wellbeing.

These trends were confirmed by the results of the Wilcoxon's signed rank tests comparing baseline and follow-up scores. The level of the primary concerns as rated by participants was significantly lower at follow-up (Mdn = 1.5) compared to baseline (Mdn = 4.0), $T = 2$, $p < .001$, $r = -.56$, as was the level of the secondary concerns (follow-up Mdn = 2.0 to baseline Mdn = 5.0), $T = 2$, $p < .001$, $r = -.57$. Wellbeing increased significantly from baseline (Mdn = 2.0) to follow-up (Mdn = 1.0), although the effect size was smaller $T = 8$, $p < .01$, $r = -.4$. Furthermore, clinical significance was suggested by mean changes of .7 or greater [41]: mean change Concern 1 = 2.5; Concern 2 = 2.4; and Wellbeing = .7.

3.4. Qualitative data

Unsurprisingly, the MYCaW qualitative data identified wanting help with the swollen arm as the most common concern; this was identified by 24 participants. One of the two remaining participants reported arm-ache as their primary concern and the other having to wear a compression garment. From the follow-up MYCaW data, the three most important improvements identified were reduced arm swelling (n = 16), increased relaxation (n = 10), and less pain (n = 4).

Four main themes emerged from the semi-structured interviews conducted after the course of reflexology treatments was completed. The themes and their indicative content are shown in Box 1 and illustrated by quotations from one or more of the participants. It seems that participants reported both physical and psychological improvements related to their lymphoedema including reduced swelling, decreased pain, less stress, improved wellbeing, better body image, increased confidence and improved mobility.

Although the safety of RLD was beyond the remit of this study, all 26 participants had opportunity during the interview to identify any discomforts associated with the treatments; no serious incidents or adverse reactions were reported. Brief accounts of feelings of discomfort were given by 10 participants: four reported feeling cold during the treatment e.g. 'I went freezing cold, I was shivering'; one participant reported pain radiating from the elbow to the top of the shoulder; discomfort due to temporary breast engorgement was indicated by another participant; another mentioned a crushing feeling 'like somebody was sitting on my arm'; one participant said they felt a pressure 'like a pressure on my chest'; another felt very weak after the treatment; and a slight feeling of dizziness was related by another participant. There was no evidence that any of these discomforts worsened and all of them appeared to be transient.

4. Discussion

The findings from this case series of 26 women with breast cancer-related lymphoedema in one arm showed that the volume of the swollen arm was significantly reduced following four reflexology treatments and the effect size was large. The reduction in volume was maintained, on average, for over six months. The concerns identified by the 26 participants were also significantly reduced from baseline to follow-up, and their perceived wellbeing increased, effect sizes were medium to large and there was some indication that the changes were clinically significant.

The qualitative data analysis provided some insight into the nature and impact of these changes for the participants' quality of life. Perceived physical and psychological benefits included reduced swelling, pain, and stress; improved self-confidence; more positive body image; and increased mobility. These findings are in accord with those from a previous study [24] which concluded that reflexology was associated with improvements to quality of life for women with early breast cancer. Although data on the safety of reflexology was not directly sought in the current study, the participants reported a number of discomforts all of which appeared to be minor and transient.

The research design did not permit inferences about cause and effect as the influence of potential confounding variables was not controlled for. The main aim of this uncontrolled trial was, however, to identify whether there was justification for further research to rigorously test the efficacy of reflexology lymphatic drainage (RLD). We conclude that the data from the study is sufficient to warrant a randomized controlled trial (RCT), and the effect sizes identified can be used to calculate the required sample sizes.

In the process of conducting this study, other limitations were identified which need to be considered when designing a RCT. First, the participant's overall body weight was not monitored during the current study, however arm volume is likely to fluctuate with changes in body mass index (BMI), and there is evidence that a raised BMI is associated with poorer outcomes for people with lymphoedema [2]. Second, data concerning the use of compression garments was not collected although there is moderate evidence of their effectiveness [12,13] and a number of participants reported usage. We recommend that measurement of BMI and monitoring of compression garment use is included in the data collection process of a RCT.

Some methodological factors emerged which also require consideration in the design of a RCT. Limb volume is a key measure in evaluating treatments for lymphoedema, a recent review [34] examined the merit of four objective methods: water displacement has been the standard method but has logistical difficulties and is generally impractical for research purposes; circumference measurement is commonly used but is sensitive to tester error; opto-electrical devices to minimize volume measurement error, now regarded by many as the gold standard, have the disadvantage of being expensive, non-portable, and are unavailable in many clinics; bioelectrical spectroscopy devices are portable, reliable and

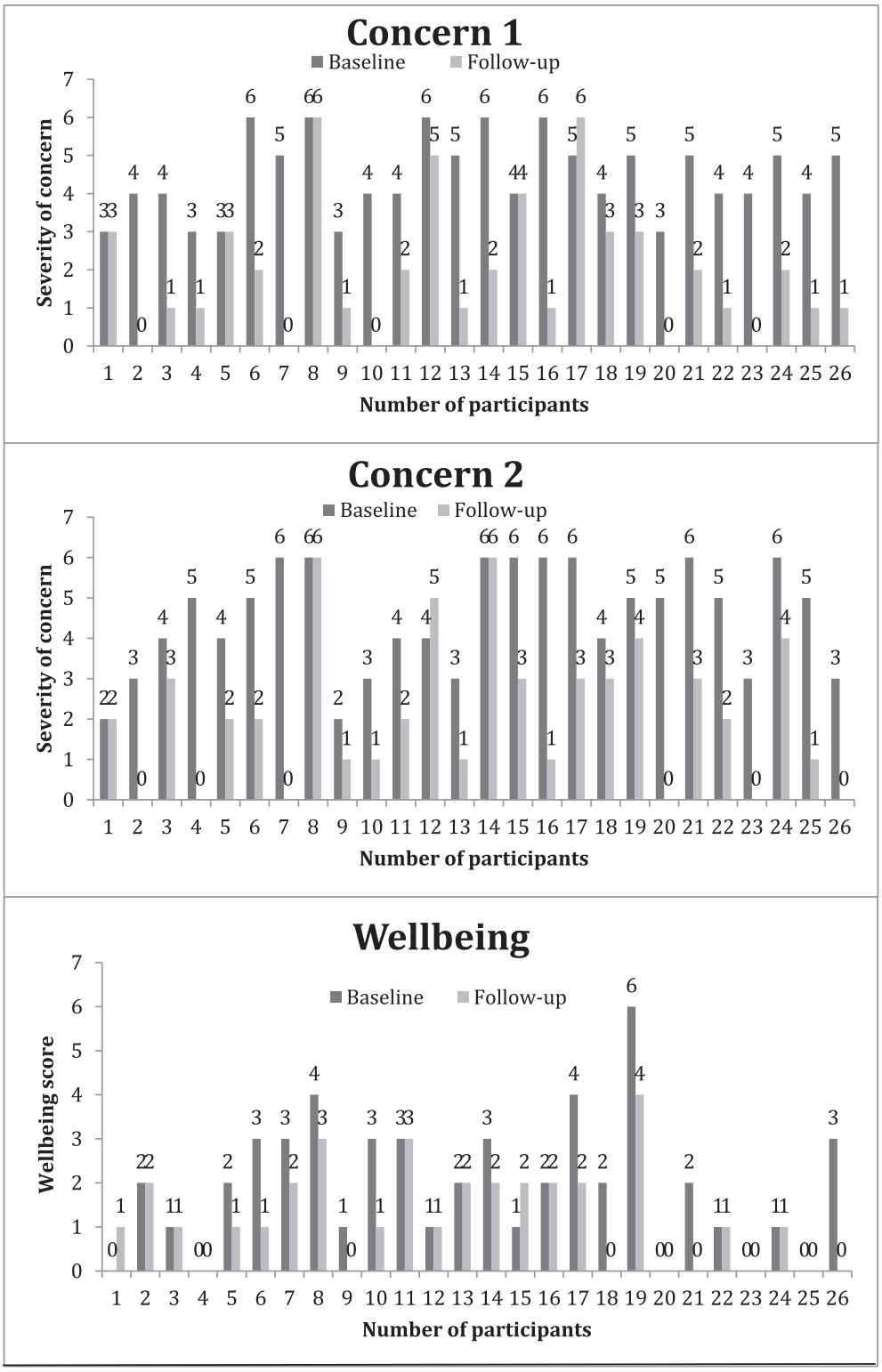

Fig. 2. MYCaW concerns and wellbeing baseline to follow-up.

valid and have the additional advantage of being able to detect changes specifically related to extracellular fluid [34].

MYCaW was a useful tool in the current study for identifying and evaluating personalised participant outcomes. The measure has a broad coverage of patient identified-concerns, it is quick, acceptable, reliable, and gives some indication of clinically meaningful change [39–41]. However MYCaW is not in itself suitable as a quality of life measure [39], for this a condition-specific assessment tool is needed. The lymphoedema quality of life scale (LYMQOL) was developed by healthcare professionals in consultation with service users; separate tools were developed for arm and leg lymphoedema. There is evidence to support the reliability and

Box 1
Themes, concepts, indicative content and illustrative quotations

Theme	Indicative content	Participant comments
Perceived physical impact (pre-treatment)	Swelling causing pain and discomfort Heaviness and tightness restricting use of arm and interfering with daily activities and sleep	" ..some days it was very painful- the swelling, and also I found that I couldn't form a fist with my hands, there was so much. Also things began to get tight, like my watches and things like that." "It was a real nightmare, it was really painful, it was like a blood pressure cuff permanently on my arm, so I had that permanent throbbing." "Very tight, even though I still continue to do exercises I was given when I was in the hospital um, but most days to reach my arm up to get something I used to have pain and it used to pull. So you would only use the arm really if you really had to use it." "It was very heavy, the swelling was making my arm ache, it was just an overall big ache, it was uncomfortable when I was sleeping"
Perceived psychological impact (pre-treatment)	Swelling as a reminder of what they had been through Distorted body image	"..it's a constant reminder of the fact you've had surgery for breast cancer, you know. Like walking around with a big badge." "I was really quite embarrassed about it actually, I know it's stupid, but it really was to the extent that I almost felt deformed because my arm was that bad." ".. most of my clothes were out of bounds because my arm was too swollen I couldn't get it in and it's made a huge difference."
Perceived physical changes (post-treatment)	Reduced swelling and changes to physical appearance Reduced pain and improved mobility Increased activity	*"The swelling has gone down immensely and my husband even commented on it. I think because I have got it every day I don't notice it as much but I look at myself in the mirror now and I can see there's an actual shape to my arm whereas before it went straight down. So yeah, it's good."* *"So it has made a big difference, no pain is the main thing, it's fantastic being without that pain."* *"Yeah it was quite uncomfortable, it was pulling quite a lot but I find now since I've had the therapies I can move my arm a lot better."* *"I enjoy gardening and I did a little bit last week which I haven't done for a long time, so that was good, I enjoyed doing that, the fact that I'd achieved something. I was always afraid to do it before."*
Perceived psychological changes (post-treatment)	Improvement in self-confidence and more positive body image Able to wear clothes that were previously too tight Stress relief and improved wellbeing	*"Well the swelling is considerably less on my arm and I am far less conscious of it, in fact I went out last night and didn't wear my sleeve and didn't really think about it and that's probably the first time I have done that, because I think I've always been very conscious of it"* *"I can fit into blouses that I couldn't fit into before because the swelling isn't so bad. And my jackets, leather jackets, you know, sometimes you feel a little bit restricted around the arm, they now fit comfortably."* *"with reflexology people look at you and think 'Oh it's only a foot rub' but it's not when somebody knows what they are doing and it can be.. it relieves stress, you feel when you've had a treatment 'Oh my God I feel so much better', so on all levels it's good but this is particularly good."*

validity of LYMQOL as a clinical assessment tool and as an outcome measure [43]. We recommend that a condition-specific quality of life measure is used as an adjunct to MYCaW to strengthen the qualitative assessment in a RCT.

5. Conclusions

In conclusion, there is a need for more, effective conservative treatments of BCRL. The evidence from this uncontrolled trial suggests that RLD may be efficacious in reducing the volume of lymphoedema in the arm and in reducing patient-identified concerns. We recommend further research using a RCT with validated objective measurement of upper limb volume and valid subjective measures of patient concerns, wellbeing and quality of life.

Conflict of interest

Author C provides training for practitioners in the RLD technique of reflexology.

Acknowledgements

Our thanks to the 26 participants and 3 reflexologists for their time and commitment; to Dr Lalage Sanders for her advice; Dr Andy Watt for his statistical support and help with the manuscript; to the Tenovus Research Advisory Group for their commitment and support, and to Tenovus Cancer Care for funding the project (TIG20012-10) and for advice and support.

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