

# A randomised controlled study of reflexology for the management of chronic low back pain

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## Abstract

The use of complementary and alternative medicine (CAM) for the management of chronic low back pain (CLBP) continues to rise. However, questions regarding the efficacy of many CAM therapies for CLBP remain unresolved. The present study investigated the effectiveness of reflexology for CLBP. A pragmatic randomised controlled trial was conducted.  $N = 243$  patients were randomised to one of three groups: reflexology, relaxation, or non-intervention (usual care). All completed a questionnaire booklet before and after the treatment phase, and at six months follow up. This measured their general health status, pain, functioning, coping strategies and mood. After adjusting for pre-treatment scores repeated measures ANCOVA found no significant differences between the groups pre and post treatment on the primary outcome measures of pain and functioning. There was a main effect of pain reduction, irrespective of group. Trends in the data illustrated the pain reduction was greatest in the reflexology group. Thus, the current study does not indicate that adding reflexology to usual GP care for the management of CLBP is any more effective than usual GP care alone.

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## 1. Background

Chronic low back pain (CLBP) is a major health problem in contemporary societies. Estimates imply the cost of direct healthcare for the condition in 1998 was £1632 million (Maniadakis and Gray, 2000). CLBP is notoriously difficult to treat and patients frequently engage in serial consultations with a variety of health professionals in order to gain relief from the condition.

Use of complementary and alternative medicine (CAM) in developed countries has increased (Thomas

et al., 2001; Harris and Rees, 2000; Eisenberg et al., 1998). Evidence suggests patients turn to CAM either because they are dissatisfied with orthodox medicine, or because they believe CAM to be effective for particular conditions (Vincent and Furnham, 1996, 1997). Consulting patterns of CAM users show the majority of visits are for chronic, not life threatening conditions, with musculoskeletal pain being the primary presenting symptom (Thomas et al., 2001, 1991; Paramore, 1997).

Reflexology is a popular non-invasive CAM therapy. It is a specific form of foot massage that involves application of pressure to reflex points, usually on the feet, believed to correspond to other parts of the body. Reflexologists claim such pressure can influence physiological responses in the body which are thought to promote healing and a return to homeostasis. A number of

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theories exist as to how reflexology might work. These include: dispersal of calcium or uric acid crystals, improvement of blood flow, a relaxant effect on the autonomic nervous system, energetic effects (Ernst and Koder, 1997) or psychological mechanisms (Frankel, 1997).

Figures for England suggest that in 1998, an estimated 941,500 people used reflexology, making around 4.33 million visits at a cost of approximately £47million (Thomas et al., 2001). The majority of visits were self funded, but the annual cost of National Health Service (NHS) provision was estimated to be £3.1million. In response to demands for more NHS CAM provision (i.e. CAM free at the point of delivery) are calls for evidence of its effectiveness. The *House of Lords Select Committee report on CAM (2000)* states ‘any therapy that makes specific claims for being able to treat specific conditions should have evidence of being able to do this above and beyond the placebo effect. This is especially true for therapies which aim to be available on the NHS’ [para 4.18].

Despite wide scale practice and claims for efficacy for a variety of conditions, reflexology remains an under researched therapy (Vickers, 1996). CLBP is one of the most common conditions reflexologists treat, however, evidence for its effectiveness in CLBP is primarily anecdotal or derived from case studies (Booth, 1994; Evans, 1990; Tiran, 1996). Overviews of reflexology research highlight the methodological problems and lack of rigour with existing studies, which include: the paucity of randomised controlled trial designs, small sample sizes, absence of control groups, little description of interventions used, lack of recognised outcome measures and rarity of independent outcomes evaluation (Botting, 1997; Ernst and Koder, 1997; Poole, 2002). The present study was designed to address some of these issues. Specifically the aim was to determine the effectiveness of reflexology in the management of CLBP.

## 2. Method

### 2.1. Design

Pragmatic randomised controlled trial. In contrast to explanatory trials, pragmatic trials are designed to assess the *effectiveness* rather than the *efficacy* of interventions (Schwartz and Lellouch, 1967; Roland and Torgerson, 1998). This enables the researcher to determine the benefit treatment produces in routine clinical practice. In the current study, patients were randomised to one of three groups: reflexology, relaxation or non-intervention. Relaxation was incorporated into the design in addition to non-intervention as a comparison group to control for the relaxation response and non-specific effects of the therapeutic encounter in reflexology.

The study received ethical approval from the relevant university and NHS Ethics Committees.

### 2.2. Inclusion/exclusion criteria

Criteria for inclusion in the study were patients aged between 18 and 65 years with benign CLBP. Consistent with other studies, the generally accepted operational definition of CLBP as an unresolved episode of back pain greater than 12 weeks duration was adopted (e.g. Hilde et al., 2002; Furlan et al., 2005; IASP, 1994; Ostelo et al., 2005). Patients were excluded for the following reasons: pregnancy; significant co-existing major medical illness; diagnosis with a significant co-existing psychiatric disorder based on DSM IV criteria and under the care of psychiatric services; in litigation; previous use of reflexology and contraindication to reflexology including: recent surgery and circulatory disorders of the lower limb.

### 2.3. Recruitment and follow-up procedures

Fig. 1 provides an overview of patients’ progress throughout the trial.

Patients were recruited from primary care sources in the North West of England. Initially, general practitioners (GP’s) referred patients who met the inclusion criteria directly to the research team. All eligible patients were contacted by the first author and invited to an initial interview where the details of the study and its implications were explained to them.

Subsequently, in order to expedite recruitment, patients who met the inclusion criteria and were currently engaged in consultation with the GP regarding CLBP were identified by practice staff via their patient database, and sent a letter by their GP inviting them to participate in the study. A total of 650 letters were sent by 12 practices. The number of replies received was 278 (an initial response rate of 42.8%). Of these, 44 indicated they were not interested in the study and a further 20 were excluded after preliminary contact revealed they did not meet the inclusion criteria (14 were aged over 65, 4 were in the process of litigation and 2 had other serious medical conditions). Therefore appointments were made with 214 interested patients. Sixteen patients did not attend the appointment, and of those who did, 7 did not consent. The remaining 191 agreed to participate. In total, 29.4% of those who received letters of invitation were eventually recruited into the study. Those who were contacted but did not reply, or replied indicating they were not interested, did not provide consent. Therefore, no details of their personal characteristics were available to the research team, so it was not possible to determine whether differences existed between this group and those who subsequently participated in the study.

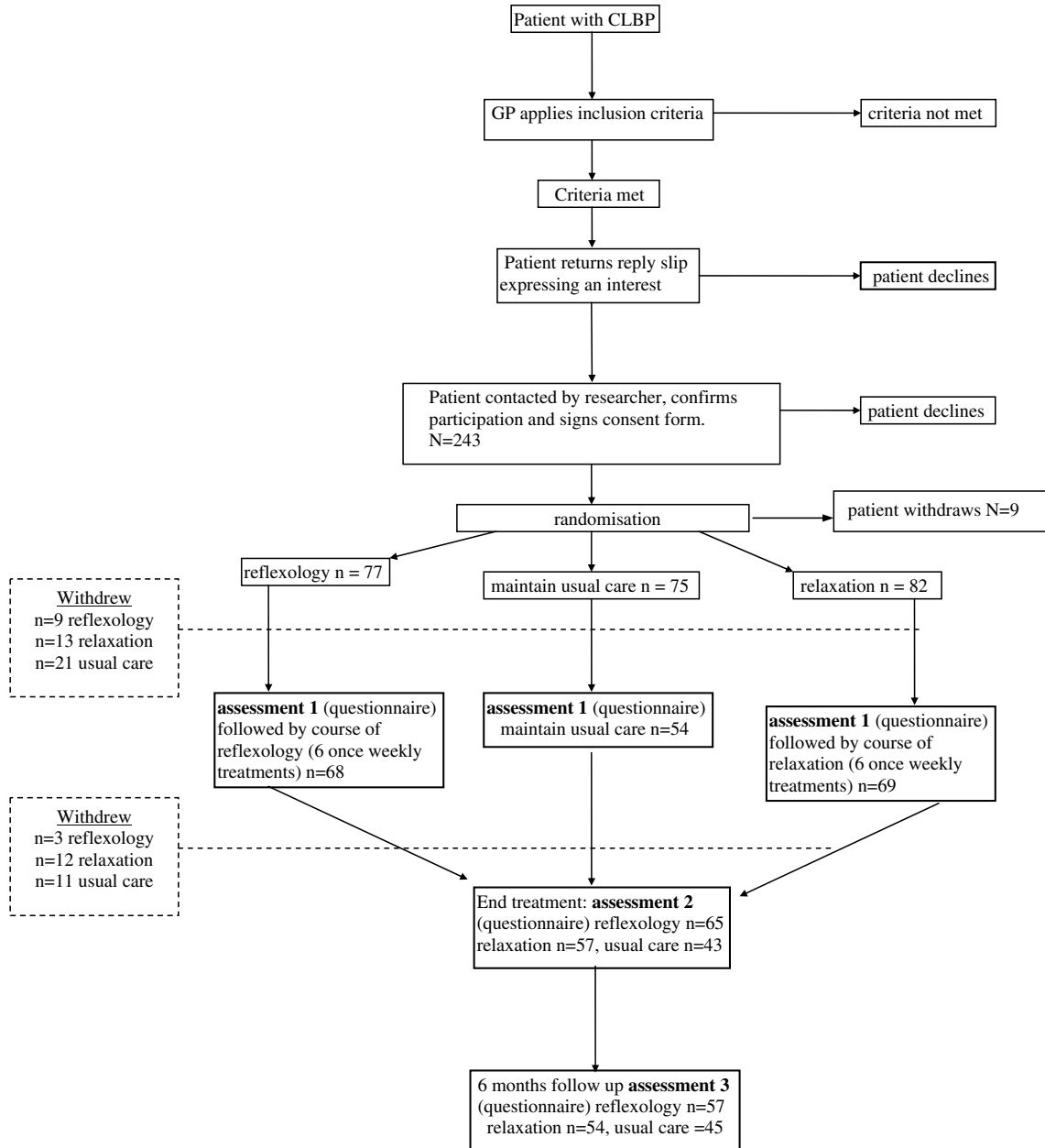


Fig. 1. Patient recruitment and follow up procedures.

A further 29 patients were recruited via the GPs and this resulted in a total of 243 participants who consented and completed the first assessment.

2.3.1. Randomisation

Following informed written consent patients were randomised by the first author, using a minimisation technique, to one of three groups: reflexology, relaxation and non-intervention. Minimisation does not rely solely on chance for group allocation. Rather it is designed to reduce any difference in the distribution of known or suspected determinants of outcome so that any effect can be attributed to the treatment provided (Pocock, 1993). In this study, minimisation was incorporated into

the procedure to ensure that the following factors were equally represented in each group: work status (benefit or non benefit), age and chronicity of pain. Patients were informed of their group allocation by letter.

2.4. Participants

Two hundred and forty-three participants with CLBP were consented and completed assessment 1. Of these, 9 (2 reflexology, 3 relaxation and 4 non-intervention) actively withdrew prior to the treatment phase. Eight withdrew when the results of the randomisation procedure became known. The remaining patient was diagnosed with a serious medical condition unrelated

to their CLBP. Thus descriptive baseline data is provided for the remaining 234 patients. As Table 1 shows, baseline characteristics were similar for the three groups.

### 2.5. Treatment groups

All therapists in the study were trained to at least diploma level, had professional indemnity insurance and had extensive experience working in primary care settings. Throughout the study each was also working within the primary care sector and/or at their own private practice. As this was a pragmatic trial, it was important that the treatment protocol should closely resemble 'usual practice'. Prior to the start of the study therapists were consulted collectively about this. The consensus was that six sessions of foot reflexology would be adequate to determine a positive response to treatment. In addition, therapists contributed to the development of standardised treatment logs, which enabled the research team to monitor the content and outcome of sessions as well as any side effects or adverse events.

Reflexology was provided by five reflexologists, all health professionals experienced in the use of the Morrell technique. This involved the application of firm but gentle compression by the therapist's hands to points of the feet thought to correspond to other parts of the body (Griffiths, 1996). No standardised protocol was provided, reflexologists were instructed to treat the participant's CLBP as per their standard practice. As agreed, reflexology comprised a course of six treatments of approximately 1 hour duration, over a period of 6–8 weeks.

Relaxation was provided by four therapists trained in the use of progressive muscle relaxation (Jacobson, 1977); a technique widely used in the context of chronic pain (Arena and Blanchard, 1996). Progressive muscle relaxation involved the therapist guiding the participant to tense then relax successive groups of muscles, focusing attention on the differential experience of each state. Relaxation treatment also comprised six 1 hour sessions at weekly intervals for six weeks in groups of 1–4.

Reflexology and relaxation treatments were delivered at the patients' GPs surgeries or a local health centre. Throughout the trial all patients continued under the care of their GP. The treatment patients received was monitored and recorded throughout the trial via a self-report form; details for those who completed the study are shown in Table 2.

### 2.6. Assessment and outcomes

Patients were assessed on three occasions: prior to the treatment phase, on completion of the treatment phase and at 6 months follow up via a self report questionnaire which included previously validated measures of health status (details below), as well as a section to record previous and current treatment regimes. Patients completed the questionnaire booklet on their own and returned by post to the first author. Therapists were not involved in collecting questionnaire data.

In common with other therapeutic trials for CLBP, pain and physical functioning were the primary outcomes. As a chronic condition, back pain may impact on many aspects of a patient's life, therefore a general health status measure was added. A measure of depression was also selected as it is one of the most commonly reported co-morbid conditions in patients with CLBP (Fishbain et al., 1997). Furthermore, reflexology is a holistic therapy, practitioners treat the whole person and not simply the primary presenting condition, thus inclusion of the secondary outcome measures was necessary to consider potential secondary effects of the treatment.

Table 2  
Usual care used throughout the trial, reported at the end of the trial

| Treatment                   | Reflexology<br><i>n</i> = 65 | Relaxation<br><i>n</i> = 57 | Non-intervention<br><i>n</i> = 43 |
|-----------------------------|------------------------------|-----------------------------|-----------------------------------|
|                             | <i>n</i>                     | <i>n</i>                    | <i>N</i>                          |
| None                        | 31                           | 21                          | 13                                |
| Prescribed medication       | 28                           | 30                          | 24                                |
| Over the counter medication | 12                           | 9                           | 8                                 |
| Osteopathy                  | 1                            | 1                           | –                                 |
| Acupuncture                 | –                            | 2                           | 2                                 |
| Physiotherapy               | –                            | 1                           | 5                                 |
| Aromatherapy massage        | –                            | 1                           | 2                                 |
| TENS                        | –                            | 2                           | 1                                 |
| Sports therapy massage      | –                            | 1                           | –                                 |
| Chiropractic                | –                            | 1                           | –                                 |
| Reiki                       | –                            | 1                           | –                                 |
| Herbal remedies             | –                            | –                           | 3                                 |
| Pain Management Programme   | –                            | –                           | 1                                 |

Table 1  
Baseline demographic characteristics

| Variable                                  | Reflexology ( <i>N</i> = 77) | Relaxation ( <i>N</i> = 82) | Non-intervention ( <i>N</i> = 75) |
|---|------------------------------|-----------------------------|-----------------------------------|
| Age (mean/SD) years                       | 47.2 (10.5)                  | 45.6 (12.0)                 | 47.45 (10.2)                      |
| Duration of pain (mean/SD) months         | 120.6 (114.5)                | 128.4 (104.5)               | 114.7 (106.7)                     |
| Female/male ( <i>N</i> )                  | 48/29                        | 53/29                       | 38/37                             |
| Used/not used CAM previously ( <i>N</i> ) | 34/43                        | 45/37                       | 40/35                             |

The questionnaire booklet included the following previously validated measures of health status:

#### 2.6.1. The SF-36 (Ware and Sherbourne, 1992)

A generic self report measure designed to provide an assessment of individuals health related quality of life. It comprises 36 items which measure eight dimensions: physical functioning; social functioning; role limitations due to physical problems; role limitations due to emotional problems; mental health; energy and vitality; pain and general perception of health. An additional item questions changes in health over the previous 12 months. Responses to items are coded, summed and transformed into a scale from 0 to 100 for each dimension, where 0 is the worst possible health status and 100 is equivalent to best possible health status. The SF36 demonstrates good face validity and reliability with Cronbach's alphas ranging from 0.73 (social functioning) to 0.96 (physical role limitations) (Jenkinson et al., 1999).

#### 2.6.2. The Oswestry low back pain disability questionnaire (ODQ) (Fairbank et al., 1980)

A self report measure originally developed to assess levels of functioning in low back pain sufferers undergoing rehabilitation, it has been widely used in research and to monitor treatment success and demonstrates good validity and reliability (e.g. Wind et al., 2005). The ODQ comprises 10 questions designed to assess limitations on the following activities of daily living: lifting, personal care, walking, social life, standing, sitting, sex life, sleeping and travelling. In addition pain intensity is also measured. Each statement is scored on a scale of 0 (no disability) to 5 (greatest disability), with the total score expressed as a percentage. Higher percentages indicate higher impairment, and thus reduced functioning.

#### 2.6.3. Beck depression inventory II (BDI-II) (Beck et al., 1997)

Comprising 21 items, a self report measure designed to measure the presence and severity of depressive symptoms during the past 2 weeks. Items are scored on a 4 point scale ranging from 0 to 3, with higher scores indicating the presence of more depressive symptoms. The BDI-II has good validity and reliability (Beck et al., 1997; Viljoen et al., 2003) and high internal consistency (Cronbach's alpha .92) has been demonstrated in patients with chronic pain (Poole et al., 2006).

#### 2.6.4. Pain visual analogue scale (Wallerstein, 1984)

Used to assess current pain intensity via a scale ranging from 0 to 100 mm, representing 'no pain' and 'worst possible pain' respectively.

### 2.7. Statistical analysis

Sample size calculations were carried out to determine the number of patients needed to detect a clinically significant change in the two primary outcome measures using previously published studies for the SF36 (Fitter and MacPherson, 1995) and the ODQ (Fisher and Johnston, 1997). At the 5% level of significance in order to have 80% chance of detecting a mean difference from baseline between groups at follow up of 12 points on the ODQ, 41 patients were needed in each group. To detect a mean score change of 10 points on the SF36 Pain dimension, 59 were required. Potential dropout was anticipated to be in the region of 25%, so the numbers required in each group were increased to 80. Thus a total of approximately 240 patients with CLBP who met the inclusion/exclusion criteria were required to ensure the power of the study. Analysis was based on intention to treat. Repeated measures analysis of covariance (using scores before treatment as the covariate) was used to estimate the effects of treatment on the primary outcome measures.

One way analysis of variance was used to look at baseline differences between those patients who completed the study with those who did not. Differences in categorical variables were assessed by the chi-square test. For these analyses, Bonferroni adjustment (.002) was implemented to adjust for the number of tests conducted.

Post hoc, an analysis of covariance was conducted to examine for individual therapist effects.

## 3. Results

Fig. 1 provides an overview of the progress of participants throughout the trial.

Half the sample (50.9%) had previously used some form of CAM, with many participants listing more than one type of therapy. CAM treatments used included: aromatherapy massage, acupuncture, chiropractic, homeopathy, hypnotherapy, herbalism, faith healer, Bowen technique, Alexander technique, Reiki, and osteopathy.

Table 3 presents the mean scores for all measures at pre-treatment, post-treatment and at six months follow-up.

#### 3.1. Primary outcome variables: SF36 Pain and ODQ

After adjusting for pre-treatment scores, repeated measures ANCOVA revealed no significant differences in either pain ( $F_{2,138} = 0.382$ ,  $P > 0.05$ ) or functioning ( $F_{2,136} = 0.018$ ,  $P > 0.5$ ) between the three groups. However, there was a significant effect of pain reduction

Table 3  
Group mean scores (SD) for each variable pre-treatment, post-treatment and at 6 months follow up and *F* values for main and interaction effects

| Scale                             | Pre-treatment |      |            |      |                  |      | Post-treatment |      |            |      |                  |      | Follow-up   |      |            |      |                  |      | <i>F</i> main <sup>a</sup><br><i>F</i> interaction <sup>b</sup> |
|-----------------------------------|---------------|------|------------|------|------------------|------|----------------|------|------------|------|------------------|------|-------------|------|------------|------|------------------|------|---|
|                                   | Reflexology   |      | Relaxation |      | Non intervention |      | Reflexology    |      | Relaxation |      | Non intervention |      | Reflexology |      | Relaxation |      | Non intervention |      |   |
|                                   | M             | SD   | M          | SD   | M                | SD   | M              | SD   | M          | SD   | M                | SD   | M           | SD   | M          | SD   | M                | SD   |   |
| <i>SF 36</i>                      |               |      |            |      |                  |      |                |      |            |      |                  |      |             |      |            |      |                  |      |   |
| Physical functioning              | 49.6          | 29.6 | 56.7       | 29.1 | 45.4             | 27.7 | 53.9           | 27.8 | 57.1       | 30.2 | 45.2             | 28.9 | 57.1        | 30.2 | 57.3       | 31.8 | 52.2             | 29.5 | .15<br>2.00   |
| Social functioning                | 58.4          | 30.5 | 61.9       | 30.4 | 58.2             | 29.7 | 65.3           | 29.6 | 69.4       | 28.1 | 59.2             | 29.5 | 68.1        | 31.8 | 66.7       | 31.6 | 61.5             | 30.8 | 2.16<br>.94   |
| Role limitations (physical)       | 36.4          | 44.0 | 36.1       | 42.1 | 29.1             | 39.8 | 45.0           | 42.6 | 42.3       | 43.8 | 23.2             | 37.2 | 48.2        | 46.4 | 53.2       | 45.1 | 37.8             | 42.5 | 3.54<br>.90   |
| Role limitations (emotional)      | 61.9          | 44.0 | 58.0       | 46.2 | 58.1             | 46.0 | 59.4           | 46.2 | 66.1       | 43.7 | 54.0             | 43.6 | 55.0        | 46.5 | 63.0       | 43.8 | 62.0             | 44.0 | .37<br>2.19   |
| Pain                              | 38.4          | 22.9 | 43.8       | 23.3 | 37.5             | 20.3 | 50.0           | 25.7 | 47.2       | 26.3 | 41.8             | 25.6 | 50.7        | 27.1 | 48.8       | 25.9 | 44.4             | 28.5 | 8.18 <sup>*</sup><br>1.15                                       |
| Mental health                     | 59.7          | 21.7 | 61.3       | 21.6 | 60.2             | 18.4 | 66.6           | 20.6 | 65.8       | 18.0 | 63.6             | 20.5 | 66.1        | 22.3 | 64.4       | 20.7 | 67.7             | 18.5 | 7.13 <sup>**</sup><br>1.94                                      |
| Energy/vitality                   | 42.0          | 21.4 | 41.1       | 22.3 | 39.7             | 23.2 | 47.7           | 20.  | 48.0       | 22.4 | 39.2             | 21.7 | 48.2        | 23.2 | 44.8       | 21.3 | 43.3             | 21.8 | .07<br>2.54   |
| General health perception         | 54.3          | 22.6 | 52.1       | 24.7 | 55.0             | 23.1 | 54.4           | 23.3 | 55.5       | 24.0 | 48.6             | 23.6 | 57.6        | 24.7 | 52.4       | 22.8 | 55.0             | 24.1 | 1.65<br>4.86  |
| Oswestry disability questionnaire | 33.0          | 8.2  | 33.2       | 19.8 | 36.6             | 17.7 | 29.8           | 19.6 | 33.4       | 22.3 | 36.7             | 19.9 | 29.0        | 20.2 | 31.3       | 21.1 | 32.9             | 17.6 | .02<br>1.22   |
| Beck depression inventory         | 12.9          | 8.8  | 13.5       | 11.5 | 14.4             | 9.8  | 11.0           | 10.2 | 12.9       | 11.7 | 14.4             | 10.5 | 11.6        | 10.9 | 12.6       | 10.9 | 12.8             | 9.2  | .58<br>1.53   |
| Pain VAS                          | 44.5          | 24.8 | 40.7       | 28.6 | 40.6             | 26.7 | 35.0           | 25.9 | 37.9       | 27.0 | 48.9             | 29.3 | 39.8        | 29.2 | 41.3       | 28.5 | 42.7             | 28.4 | 1.08<br>2.23  |

<sup>a</sup> Degrees of freedom for main effects between 1, 132 1, 138.

<sup>b</sup> Degrees of freedom for interaction effects from 2, 132 and 2, 138.

\* *P* < 0.0005.

\*\* *P* < 0.001.

over time for all groups ( $F_{1,138} = 8.18, <0.0005$ ) and this was greatest in the reflexology group. See Figs. 2 and 3.

3.2. Secondary outcomes

Mean scores (SD) for all variables are reported in Table 3. Repeated measures ANCOVA revealed a main effect for the SF36 mental health dimension ( $F_{(1,132)} = 7.13, P < 0.002$ ) and an absence of any significant differ-

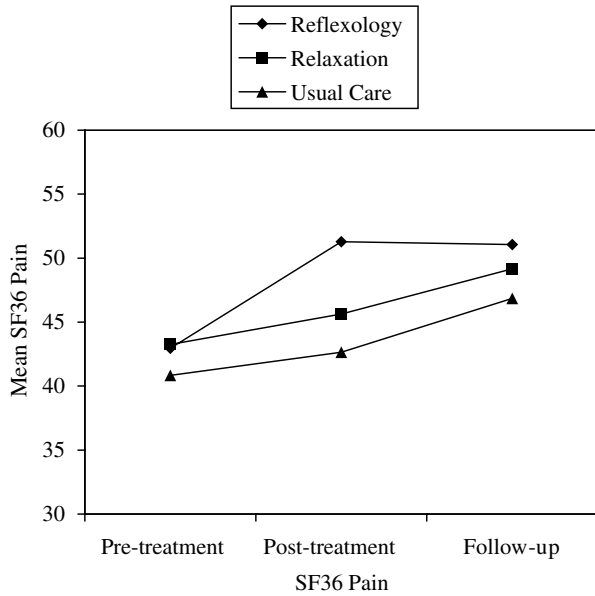


Fig. 2. Mean SF36 Pain pre, post treatment and at 6 months follow up.

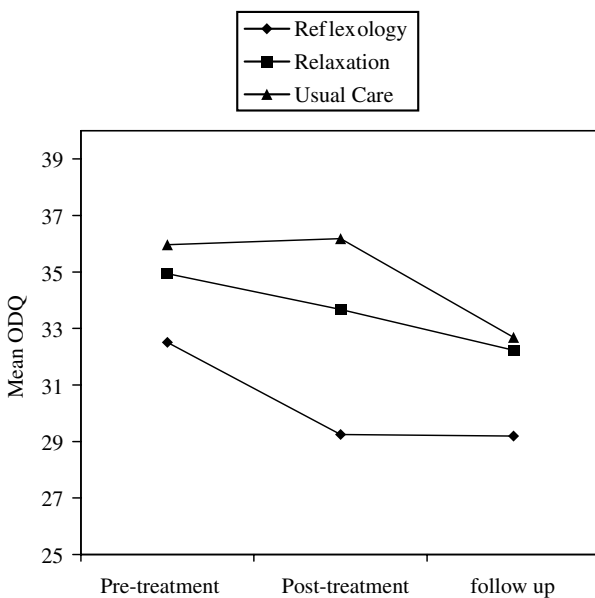


Fig. 3. Mean ODQ scores pre, post treatment and at 6 months follow up.

Table 4

Mean pre and post treatment SF36 pain scores for patients treated by each therapist

| Therapist | Mean (SD) SF36 pain pre-treatment | Mean (SD) SF36 pain post-treatment |
|-----------|-----------------------------------|------------------------------------|
| 1         | 34.95 (22.69)                     | 46.81 (26.71)                      |
| 2         | 44.93 (27.72)                     | 40.52 (29.11)                      |
| 3         | 56.57 (22.72)                     | 60.49 (22.94)                      |
| 4         | 51.58 (23.26)                     | 58.02 (19.07)                      |
| 5         | 43.16 (22.29)                     | 44.44 (24.46)                      |

ences between groups on all remaining SF36 dimensions.

As with all longitudinal studies, attrition occurred in the present study. Analysis of the baseline data revealed that those who completed the study were more likely to be older than those who did not ( $48.64 \pm 10.31$  years and  $41.94 \pm 11.01$  years, respectively). Furthermore patients who had used CAM previously were more likely to comply with completion. Analyses of individual groups showed that this effect was confined to patients in the relaxation group ( $X^2 = 12.83, df1, P = 0.001$ ). There were no significant differences in other baseline measures between those who completed the study and those who did not.

Therapist effects: given the lack of significant differences between treatments, the possibility that some therapists may have been more effective was explored. Mean pre and post treatment scores for each therapists group of patients are presented in Table 4. After controlling for pre-treatment level of pain, analysis of covariance, with therapist effects treated as a fixed factor, showed no significant differences between therapists ( $F_{4,309} = 1.086, P = 0.367$ ).

4. Discussion

There were no significant differences between groups on the primary outcome variables of pain and functioning over the period of the trial. Thus the current study does not indicate that adding reflexology to usual GP care for the management of CLBP is any more effective than usual GP care alone. Following the treatment phase there was a trend towards greater pain reduction in the reflexology group, but this was not significantly different to the changes experienced in the other two groups, nor was it indicative of clinically significant change on the SF36 pain dimension (Lansky et al., 1992; Ruta et al., 1994; Ware and Sherbourne, 1992; MacPherson et al., 1999).

These findings highlight a strength of the pragmatic trial and provide a partial explanation for the previous anecdotal and case study evidence which suggests reflexology is beneficial in reducing pain and anxiety (e.g. Stevenson et al., 2000). Taken in isolation, data from the

reflexology group indicates a reduction in pain over time that patients could have attributed to the treatment. The use of comparative groups demonstrated that this reduction also occurred in the absence of reflexology in patients from the same population. Thus it is unlikely that reflexology alone was responsible for the change.

Failure to detect a difference between treatment groups leads to a number of possible conclusions. First that there were no differences between groups and therefore all treatments were equally effective or indeed equally ineffective, in which case the natural history of the condition could account for the difference. This is in accordance with the definition of CLBP proposed by Croft et al. (1998) wherein it is viewed as a chronic condition interspersed with periods of relative freedom from pain. Further explanations include the possibility that the chosen outcome measures may not have been sensitive enough to detect the subtle changes that occur in response to CAM treatments such as reflexology. Alternatively, the greater number of additional treatments reported by patients in the relaxation and non-intervention group during the study may have influenced the lack of significant differences between treatments. That patients in the reflexology group sought fewer additional treatments could support the view that this was because reflexology made them feel better, however this is speculative. Lastly, there may have been insufficient power to detect a difference that actually existed. In this regard, other factors may be implicated, e.g. attrition.

Attrition, or loss to follow up is common in longitudinal studies and RCTs generally (Prescott et al., 1999). In the current study, the overall dropout rate was 34% and the prospective design which required patients to complete a number of assessments may have partially accounted for this. Difference in dropouts between groups varied from 26% (reflexology), 34% (relaxation) to as high as 40% in the non-intervention group. Patients in the reflexology group were more likely to comply, and interestingly attrition was less in relaxation than non-intervention suggesting that the provision of additional treatment was responsible for this. Richmond and Carmody (1999) suggest that dropout may be more of a problem when treatment is provided at no cost to the patient, as in the present study. This has important implications for the provision of CAM within the NHS.

Inclusion criteria in this study were broad, i.e. back pain of greater than three months duration which may have resulted in a widely heterogeneous sample. A symptom based diagnosis was adopted due to the difficulties inherent in classifying sub groups of CLBP in any meaningful way, e.g. by aetiology (Croft et al., 1998). It is possible that particular types of patients may have responded more favourably than another type, e.g. those whose pain was of less than 12 months duration.

Importantly, over 50% of the current sample described themselves as employed. This could be interpreted as an indication that they were managing their pain effectively and coping in contrast to other research populations from secondary care sources. Nevertheless, baseline data for the study sample appeared to be broadly analogous to that of other CLBP populations (e.g. Turner et al., 2000; Pflugsten et al., 1997; van Tulder et al., 1997; Hartigan et al., 2000; Von Korff et al., 1998).

An advantage of the pragmatic design is that it can enhance clinical relevance and ecological validity of the study. In this instance it also provided a solution to the problem of therapists' unwillingness to provide sham treatment and ethical problems associated with this (Fitter and Thomas, 1997). In this study, treatment was not standardised, but rather therapists were instructed to treat patient's back pain. Thus therapists remained autonomous and treatment was not simply reduced to a mechanistic procedure, but individualised as it would be in practice. Previous studies of reflexology have been criticised for their use of a single therapist (e.g. Eichelberger, 1993; Petersen et al., 1992). Vickers (1996) argued that failure to demonstrate an effect may be due to the ineffectiveness of the therapist not the therapy. We considered that the use of more than one therapist would substantially reduce this potential problem. The post hoc analyses on the practice of individual therapists supports this, but it is acknowledged that the sample size may not have been large enough for these analyses to detect differences. It must be accepted therefore, that whilst unlikely, it is possible that all the therapists in the study could have been ineffective.

This is one of the first large randomised trials of reflexology for CLBP. In contrast, there have been a number of studies of relaxation for chronic pain. A narrative review by Carroll and Seers (1998) found conflicting evidence for the effectiveness of relaxation in chronic pain. A total of nine RCTs were reviewed, of these 3 reported a positive result for relaxation, 2 found better results in the control group compared to the relaxation group and the remaining 4 did not find any significant differences between treatments. One reason for the lack of difference between reflexology and relaxation may be that the relaxation response is promoted by reflexology. Previous studies have shown that reflexology promotes a profound relaxation response in some patients (Oleson and Flocco, 1993). Relaxation response is integral to many CAM therapies and said to stimulate the release of endorphins causing analgesic effect. Both reflexology and relaxation were associated with slight improvements in pain and functioning but it is impossible to determine whether these are due to the non-specific effects of treatment such as attention and expectation, or can parsimoniously be attributed to the natural history of the condition, or regression to the mean.

Participants in this study had a maximum of six reflexology treatments. This could be viewed as a limitation. It may be that given additional treatment pain and functioning scores would have improved. However, whilst designing the study extensive consultation with therapists and consideration of the limited literature suggested that six treatments over a period of two months would be a fair trial. Additionally if treatments were to be provided in primary care, such limitations would apply.

The appropriateness of a RCT design to the evaluation of CAM has been the subject of much debate in the past decade (e.g. Vickers et al., 1997; Liverani et al., 2000; Nahin and Straus, 2001; Verhoef et al., 2002). Individual practitioners may argue that idiosyncratic responses to interventions are more relevant than group means from which individuals differ in often subtle ways. It is argued that such designs are necessary in order to provide some indication of the utility of CAM for the treatment of major health issues, such as CLBP. As a condition for which few conventional treatments convincingly demonstrate effectiveness, it is perhaps one that is more likely to lead sufferers to seek their own alternatives. Individuals undertake such treatments usually in the hope or expectation of some improvement in their condition. It is only via evidence from RCTs that we can hope to provide some assurance that their efforts are not in vain.

It is possible that those who self fund their use of reflexology have more invested in the therapy than the patients in this study and thus may be more likely to express a positive outcome. The majority of visits to reflexologists are self funded (Thomas et al., 2001). However, some NHS provision is available in the UK. Whilst this is not exclusively directed at pain management, such provision does raise important questions for the equitable delivery of health care as well as the notion of evidence based practice.

## 5. Conclusions

Results of the present study did not demonstrate that adding reflexology to usual GP care was any better than usual GP care alone. However, there was a slight trend towards a more favourable outcome for patients who received reflexology, which suggests that reflexology may be beneficial for some patients and prompts the need for further research. Nevertheless on the basis of current evidence, the use of reflexology as a treatment for the management of CLBP cannot be recommended, nor can its widespread use or funding within the NHS be sanctioned. There is however a caveat: given the favourable trends in pain reduction patients in the reflexology group experienced, it is suggested that individuals who express an interest in reflexology should not be discouraged from trying what appears to be a safe therapy.

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