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Reflexology in the management of low back pain: A pilot randomised controlled trial

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Summary
Objective: The current study was designed as a pilot study for a randomised controlled trial to investigate the effectiveness of reflexology in the management of low back pain (LBP).
Materials and methods: Participants suffering non-specific LBP were recruited and randomised into either a reflexology or a sham group. Patients and outcome assessor were blinded to group allocation. Each patient received either a 40 min reflexology treatment or sham treatment (according to group allocation) once per week for six consecutive weeks. The primary outcome measure was pain (visual analogue scale), secondary outcome measures were the McGill pain questionnaire, Roland–Morris disability questionnaire, and SF-36 health survey. Outcome measures were performed at baseline, week 6, week 12 and week 18.
Results: VAS scores for pain reduced in the treatment group by a median value of 2.5 cm, with minimal change in the sham group (0.2 cm). Secondary outcome measures produced an improvement in both groups (McGill pain questionnaire: 18 points in the reflexology group and 11.5 points in the sham group). Results indicate that reflexology may have a positive effect on LBP.
Conclusion: Reflexology appears to offer promise as a treatment in the management of LBP; however, an adequately powered trial is required before any more definitive pronouncements are possible.

Introduction

Low back pain (LBP) is a major cause of disability, work absenteeism, and medical costs.[1,2] In the United Kingdom (UK) it has been estimated that the annual direct health care cost of LBP is approximately £1.6 billion, making back pain one of the most costly medical conditions in the country.[3]

LBP affects the majority of the population at some point in their lives: life time prevalence is estimated at 60–80%.[4] It has been estimated that 50% of LBP episodes subside within 4 weeks; however 15–20% of sufferers still experience pain after 1 year.[4] Conventional treatments do not appear to be managing the problem effectively,[5] and this has led to other forms of treatment, such as complemen-

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tary and alternative medicine (CAM) to be investigated as a potential adjunct to treatment for LBP.

The popularity of CAM has increased across the Western world,[6] with an estimated one in three adults using CAM at some time in their lives.[7] There are a number of reasons why patients turn to CAM, including dissatisfaction with conventional treatments, reluctance to use invasive techniques, or concerns over the toxicity of drugs.[8–10] Reflexology is an ancient therapy dating back some 5000 years.[11] The UK House of Lords report on CAM (published in November 2000) defined reflexology as: '*a system of massage of the feet based on the idea that there are invisible zones running vertically through the body so that each organ has a corresponding location in the foot. It has also been claimed to stimulate blood supply and relieve tension*'.[6]

The literature available on the treatment of LBP with CAM, and particularly reflexology, is sparse.[12–14]

Previous studies have been completed which compare reflexology treatment to sham treatment for other conditions, with varying results. Williamson et al.[15] found improvements in both reflexology and sham groups in the treatment of menopausal symptoms. Brygge et al.[16] found improvements in quality of life following reflexology in subjects with bronchial asthma. Oleson and Flocco[17] found a significantly greater reduction in premenstrual symptoms following reflexology compared to a sham treatment. However, a study by Tovey[18] investigating irritable bowel syndrome did not show any improvements in either reflexology or placebo groups.

There have been calls from various sources to increase the evidence base for the use of CAM.[9,6,19] The current study was undertaken as a precursor to a randomised controlled trial (RCT) to assess the clinical effectiveness of reflexology in the management of LBP.

Methods

The current study was designed as a pilot for an RCT to investigate the effectiveness of reflexology in the management of LBP. Ethical approval for the study was gained from the Northern Ireland Office for Research Ethics Committee.

Participant selection

Staff employed at the University of Ulster suffering non-specific LBP were recruited via e-mail. Potential participants were first assessed by an experienced physiotherapist. Those diagnosed with non-specific LBP were entered into the trial, providing they met other inclusion criteria: any physiotherapy, medication or other treatment for their LBP had been stabilized for at least 3 months, no involvement in other research projects within the past 3 months, reflexology naïve (with no detailed knowledge of specific reflexology points), not pregnant.

Randomisation

Participants were randomised using a computer-generated random number table to receive either a full reflexology treatment or a sham reflexology treatment. Randomisation was performed by an independent researcher otherwise uninvolved in the trial, and all participants were blinded to their group allocation. Participants were told that they would either receive a reflexology treatment or a foot massage. As participants were reflexology-naive they should not have been aware of which treatment they received. It was not possible to conceal group allocation from the therapist, as this person administered the treatment; however, therapists were instructed not to discuss any aspect of the treatment with the subjects.

Clinical interventions

Participants in the treatment group received precision reflexology involving a sequence of pressure massage which allowed stimulation of the numerous specific reflex points on the feet associated with organs throughout the body. This method was based on that developed by Eunice Ingham[20,21]; and is supported by the International Institute of Reflexology. The reflexology treatment included the key points of the feet that are representative of the vertebrae of the spine and the surrounding musculature; these points are located along in inner edge of the two feet (for specific points see Ref. 22).

Participants in the sham group received a simple foot massage treatment using the same sequence as in the reflexology treatment group. This massage used less pressure (lower level of stimulation to all reflex points) and included the majority of the reflex areas on the feet as indicated above; however the points which are representative of the vertebrae of the spine and surrounding musculature were specifically avoided. According to reflexology theory, this should have had no curative effect on LBP as no stimulation occurred to these specific reflexology points.[18] As benefits of CAM are frequently dismissed as a result of increased contact alone, the main aim of the sham intervention was to control for such contact.[15] Participants in both groups received treatment for 40 min on a weekly basis for six consecutive weeks; based upon results of a survey previously carried out by the authors on 500 reflexologists, indicating that six treatments once a week were sufficient to obtain a reduction in LBP. Both groups received treatment by an experienced reflexologist, using a standardised base oil. Three therapists provided the treatments for the study with a single therapist completing the treatments for an individual participant. All therapists were informed of the details of the reflexology and sham treatments before the study began. Validity of the treatments was tested by one of the authors (CH, an experienced reflexologist) on a regular basis throughout the trial. In order to test the success of blinding, participants were asked at weeks 2 and 12 to indicate to which group they thought they had been assigned.

Outcome measures

Outcome measures were taken at baseline (before the first treatment in week 1), post-treatment (after the last treatment in week 6), week 12 (follow-up), and week 18 (follow-up). The outcome assessor was also blinded to group allocation.

The primary outcome measure used was a visual analogue scale (VAS) for pain. Pain is subjective and its measurement relies on report from the patient.[23] The VAS was a line 10 cm in length anchored with 'no pain' and 'worst ever pain' at either end. The participant placed a mark on the line at a point where they felt represented their perceived average pain in the last week. The distance from the beginning of the line to this point represented their pain score.[24] The VAS has previously been shown to be a reliable and valid method of measuring pain.[25,26]

Secondary outcome measures were the McGill pain questionnaire (PRI: total score 0—77), the Roland—Morris disability questionnaire (total score 0—24), and the SF-36 health survey (total score 0—100).

Data were analysed by Statistical Package for Social Sciences (SPSS) Version 11 (Chicago, IL). Given the relatively small numbers involved, only descriptive statistics were performed, including medians and interquartile values.

Results

A total of 15 participants were enrolled in the trial: seven participants were randomised to the reflexology group, and eight to the sham group. All 15 participants completed the treatments and all outcome measures (see Fig. 1). Six females and one male received reflexology, four females and four males received the sham treatment. The median age of participants in the reflexology group was 42 (Inter-quartile range 24), and in the sham group median age was 45 (Inter-quartile range 20). The levels of low back pain and disability were comparable between groups at the start of the study (Table 1). No other medical conditions were recorded for any participant.

VAS scores are summarised in Table 1. The median scores for the group receiving reflexology improved steadily from baseline to week 18 follow-up, with an overall median decrease of 2.5 cm, which is considered to be greater then the minimal clinically important difference (MCID—greater than 2 cm on the VAS[27]). The largest improvement in pain symptoms was observed between baseline and end of treatment. VAS scores increased slightly (0.5 cm) for the sham group from baseline to the end of treatment period indicating an increase in pain with only minimal improvement (median decrease of 0.2 cm) from baseline to end of follow-up.

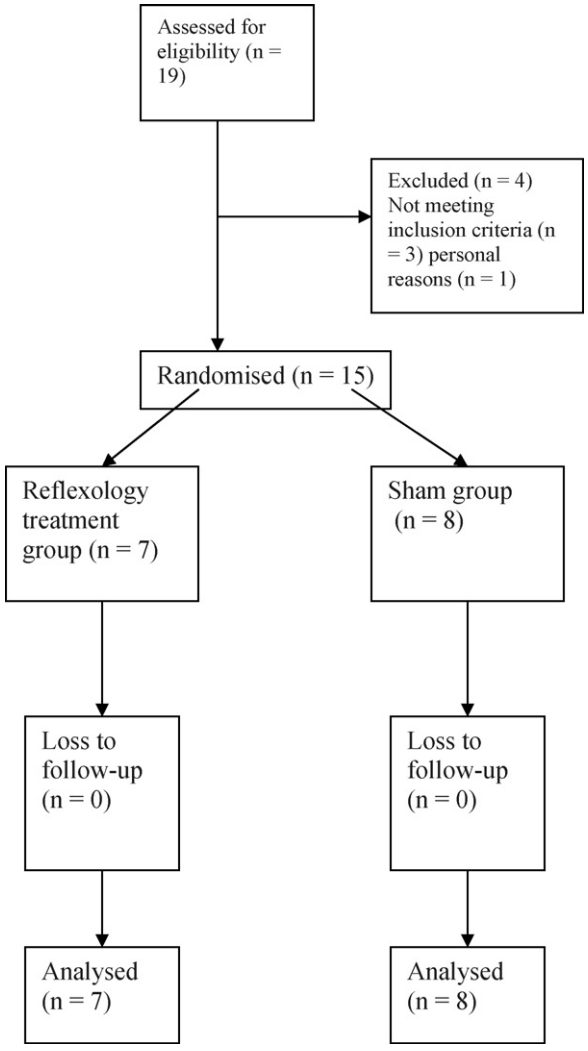

Figure 1 Summary: participants' progress throughout RCT.

Table 1 Results: summary of VAS, Roland—Morris disability questionnaire and McGill pain questionnaire Scores median and interquartile values

	Reflexology group	Sham group
VAS		
Baseline	4.7 (3.5—6.6)	3.4 (3.0—4.2)
Week 6	3.1 (3.1—3.6)	3.9 (3.2—5.3)
Week 12	2.1 (1.5—4.9)	4.1 (2.7—5.1)
Week 18	2.2 (1.6—3.2)	3.2 (2.6—4.6)
Roland—Morris		
Baseline	5 (4—8.6)	7.5 (3—9.3)
Week 6	6 (4—6.5)	5 (1.8—5.3)
Week 12	4 (3—4.5)	4.5 (1—7)
Week 18	4 (2—5)	3.5 (1.8—4.8)
McGill pain		
Baseline score	24 (22.5—28)	19 (12.8—21.8)
Week 6	12 (10—6)	11.5 (8.5—6.3)
Week 12	11 (6—17)	6.5 (5—13)
Week 18	6 (4—13)	7.5 (3.8—9.8)

Values are median (1st and 3rd interquartiles).

Fig. 2 shows changes in VAS scores from baseline to the end of treatment at week 6 for each individual participant. Three of the participants in the reflexology group showed a decrease in pain that achieved clinical relevance, three others showed a small improvement and only one participant felt that their pain was worse at the end of treatment. One individual in the reflexology group received only four of the six treatments; however, VAS for this individual indicated a clinically important reduction in paint from week 1 to 6. In the sham group four of the participants had increased VAS scores at the end of treatment indicating that their pain had worsened. The other four participants felt a reduction in pain; however, none of these improved scores were clinically important. Two participants received physiotherapy during the follow-up period; both of these participants received the

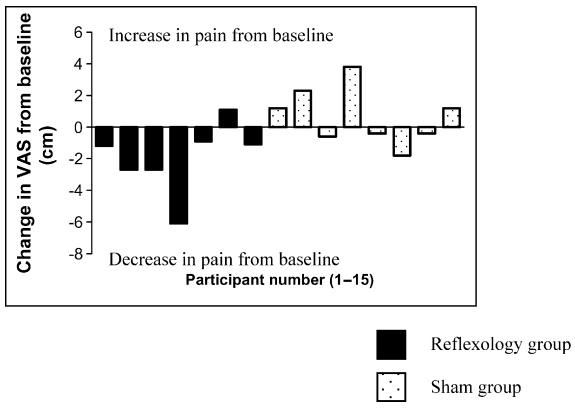

Figure 2 Results: VAS difference scores for all participants (differences between baseline and end of treatment).

sham treatment: one showed no change in VAS during this follow-up period, however the other showed a reduction in VAS score from week 6 to 18 of 1.8 cm.

Scores for the Roland–Morris disability questionnaire decreased in both groups (see Table 1). A reduction of three points in the Roland–Morris disability questionnaire indicates a MCID. By week 18 the treatment group's score decreased by one point, while the sham group decreased by four points, indicating a clinically important improvement in disability in the sham group.

McGill pain questionnaire scores also indicated a reduction in participants' LBP in both groups (see Table 1). The reflexology group had an overall decrease of 18 points, with the greatest improvement between baseline and end of treatment, while the sham group's score overall decreased by 11.5 points. Al-Smadi[28] has proposed a three-point difference in the McGill pain questionnaire's pain rating index (PRI) as representing a MCID, which was achieved by both groups in the current studies.

Table 2 shows the norm-based scores of each of the sub-scales of the SF-36 health survey. An improvement was observed in both the treatment and sham groups for some of the SF-36 sub-scales, particularly *vitality*, *social functioning*, *role-emotional*, *and mental health*. Improvements were also noted in the reflexology group (but not in the sham group) for *role physical* and *bodily pain scores*. Therefore there was an improvement in both groups for the mental summary scale but only in the reflexology group for the physical summary scale.

The success of participant blinding to group allocation was recorded during the trial. 53.3% ($n = 8/15$) of participants wrongly guessed their group allocation 46.7%; ($n = 7/15$) participants correctly guessing. Based upon these results, participant blinding was considered as mostly successful.

No adverse effects of reflexology or sham reflexology were reported throughout the treatment period.

Discussion

The current study aimed to assess the feasibility of an RCT to assess the effectiveness of reflexology in the treatment of patients suffering LBP. To date, this is the first controlled study to investigate the effectiveness of reflexology in the

Table 2 Results: norm based SF-36 health survey scores (median and interquartile values)

	Baseline		Week 6		Week 12		Week 18	
	Reflexology group	Sham group	Reflexology group	Sham group	Reflexology group	Sham group	Reflexology group	Sham group
Physical functioning	48.6 (46–50)	43.4 (39–51)	48.6 (47–50)	43.4 (40–50)	50.7 (44–51)	45.5 (44–50)	48.6 (48–51)	44.4 (44–48)
Role physical	42.2 (33–48)	48.3 (41–49)	49.5 (48–52)	49.5 (41–54)	49.5 (43–53)	44.6 (39–51)	49.5 (48–51)	49.5 (41–52)
Bodily pain	41.4 (33–46)	45.6 (42–46)	46.1 (41–48)	41.8 (37–50)	51.1 (46–53)	43.7 (40–51)	51.1 (44–53)	46.1 (46–47)
General health	48.2 (46–52)	39.8 (36–48)	52.9 (49–54)	42.2 (40–51)	48.2 (46–52)	47.0 (38–53)	51.5 (48–50)	44.6 (37–51)
Vitality	45.8 (38–47)	39.6 (36–50)	52.1 (50–55)	48.0 (43–53)	52.1 (44–53)	44.3 (40–50)	52.1 (46–52)	49.0 (44–55)
Social functioning	35.0 (27–51)	45.9 (32–56)	45.9 (38–57)	37.8 (30–57)	45.9 (43–51)	54.1 (43–57)	51.4 (43–57)	48.7 (43–57)
Role emotional	40.3 (33–42)	48.1 (39–56)	48.1 (36–52)	48.1 (30–56)	48.1 (36–54)	55.8 (42–56)	48.1 (44–53)	55.9 (53–56)
Mental health	44.4 (36–48)	44.4 (41–50)	47.2 (43–56)	47.2 (42–53)	52.8 (39–53)	48.6 (44–51)	50.0 (47–53)	50.0 (44–54)
Physical summary	44.1 (39–48)	41.5 (38–45)	47.3 (47–48)	41.1 (39–47)	47.1 (45–49)	40.3 (38–48)	47.6 (45–48)	41.1 (40–45)
Mental summary	38.1 (29–44)	43.1 (35–52)	45.8 (37–55)	44.3 (33–54)	47.8 (36–51)	51.5 (41–53)	48.1 (42–52)	51.9 (46–56)

Values are median (1st and 3rd interquartiles).

treatment of LBP under controlled conditions (i.e. compared to a sham reflexology treatment).

Participants for this study were recruited from staff of the University of Ulster including academic, clerical and cleaning staff, and represented all levels of educational backgrounds, and included both manual and professional workers and are therefore reflective of the general population.

The reduction in VAS scores in the treatment group compared to the sham group in the current RCT appears to support reflexology theories: i.e. that reflexology is a precision treatment, where specific reflexes in the foot correspond to specific areas of the body.[29] Although the sample size was too small to allow statistical significance to be calculated, the results show a clinically important reduction in average pain assessed by VAS in the reflexology group compared to no reduction in the sham group. Three of the participants within the reflexology group showed a clinically important reduction in pain by the end of treatment and a further participant achieved this reduction by week 18; one of these participants had received only four of the reflexology treatments. In contrast none of the participants within the sham group achieved a clinically important reduction in pain at any time during the study. The overall trend within the reflexology group was that decreases in VAS scores continued until week 18, indicating that the effects of reflexology appeared to extend beyond the treatment period. VAS scores in the sham group had slightly *increased* by the end of treatment period (by 0.5 cm), followed by a slight decrease (0.2 cm) by week 18. These changes are minimal, not clinically relevant, and could be due to natural fluctuation in results over time and therefore no real trends were observed in the sham group. In addition, one of the participants within the sham group had received physiotherapy treatment during this follow up period and showed a reduction of 1.8 cm in VAS score. Had this participant not received this additional physiotherapy treatment this slight median decrease of 0.2 cm at week 18 in the sham group may not have been observed.

McGill pain questionnaire scores decreased in both groups. This questionnaire assesses multiple dimensions of pain, rather than just pain intensity. Reflexology has been shown to improve factors other than pain, and which may influence scores on the McGill questionnaire, such as relaxation,[29] sleep quality,[30] and anxiety.[31] As the sham group received a gentle foot massage which followed the sequence of a standard reflexology treatment with the omission of points relating to the spine, it is possible that the other benefits associated with reflexology may have contributed to these improvements; however as this is a small study it is not possible to draw any definite conclusions. Such improvements in other symptoms may also explain why no difference was observed between the groups in the Roland—Morris disability questionnaire, or in the mental summary scales of the SF-36. Again, these psychological and emotional symptoms have been shown in previous studies to be improved by reflexology in subjects with cancer,[31] asthma,[16] PMS[17] and undergoing menopause.[15] Therefore, changes observed in the current study may be unrelated to any changes in subjects' LBP. However, it is important to note that only the scores from the reflexology group improved for the physical summary scale within the SF-36. This did not improve for the sham group, supporting the results from the VAS that reflexology may be of more benefit than a sham treatment in the reduction of pain in a specific area of the body.

Although the sample size of this pilot study was too small to determine if results were statistically significant or not, the results can be used for power analysis for a larger trial. Based upon a power of 90%, a significance level of 95% and a desired change in the VAS of 2 cm, and using the standard deviation of the differences between pre and post treatment VAS for all participants, a larger trial would require 37 participants per group (given a 20% attrition rate) to show significant differences between groups.

Conclusion

The results of the current pilot study are encouraging. The median VAS scores of participants who received treatment omitting the spinal area points displayed minimal change in pain associated with their low back. In contrast, those participants who received a full reflexology treatment including the spinal points showed a clinically important reduction in pain. These results suggest that reflexology may be of benefit in the treatment of LBP, and may also have some wider benefits in terms of quality of life. A suitably powered RCT would be required to draw any definitive conclusions.

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