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A pilot study of the effectiveness of reflexology in treating idiopathic constipation in women

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A B S T R A C T

Objectives: Constipation is a common problem in the UK, affecting up to 20% of the population. Reflexologists claim that reflexology can be beneficial in the treatment of constipation. The aim of this exploratory pilot study was to determine the effectiveness of reflexology in treating idiopathic constipation in women and it is the first study of the effectiveness of reflexology for the treatment of women with idiopathic constipation defined according to Rome II criteria.

Methods: Nineteen female patients referred to a specialist biofeedback service with idiopathic constipation defined by Rome II criteria were recruited. A course of reflexology treatment (weekly for six weeks) was given. Patients' subjective perception of constipation was recorded as well as the Hospital Anxiety and Depression Scale (HAD), the Short form 36 (SF36), whole gut transit and the Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) before and after the intervention.

Results: All participants completed the intervention and none were lost to follow-up. Ninety-four percent of participants identified their constipation to be improved to some extent. Ten participants had improved colonic transit times and two patients had normalised colonic transit. Ten patients (53%, $p = 0.19$) demonstrated an improved anxiety score and 11 participants (58%, $p = 0.14$) demonstrated an improved depression score on the HAD scales. Improvement was seen in general health, mental health and vitality on the SF36 scale, with vitality improving significantly ($p < 0.05$). Sixty-three percent of participants had a more positive attitude ($p = 0.03$) towards CAM and holistic health following treatment.

Conclusions: This study shows that in this sample reflexology has potential benefit for treating idiopathic constipation in women. Further randomised trials are required.

1. Introduction

Idiopathic constipation is a symptom-based disorder defined as "unsatisfactory defecation and is characterized by infrequent stools, difficult stool passage, or both. Difficult stool passage includes straining, a sense of difficulty passing stool, incomplete evacuation, hard/lumpy stools, prolonged time to stool or need for manual manoeuvres to pass stool".[1] It is a common problem in the UK, affecting up to 20% of the population at some point in their lifetime,[2] especially among females. Constipation is a symptom reflecting either slowed colonic transit and/or rectal evacuation difficulties.[3] Symptoms vary widely and in severe cases constipation can adversely affect quality of life. It is also evident that patients with idiopathic constipation may experience symptoms of anxiety and depression.[4]

Increasing dietary fibre is not usually effective in the management of severely constipated patients and may induce symptoms such as abdominal distension and flatulence.[5] In addition, there is no evidence that stool consistency and constipation can be affected by increasing fluid intake or exercise[5] in this diagnostic group. Laxatives are commonly used to treat the problem within a primary care setting, with an estimated £46 million spent each year in England alone on laxatives,[6] but these tend to lose their effect over time.[3] Laxatives are also associated with adverse effects, such as abdominal pain and bloating.[1]

Biofeedback treatment for idiopathic constipation has been shown to be effective[7] and is currently considered the front line medical management for this condition. Biofeedback is a learning strategy based on behaviour modification. It is used to describe any technique which increases the ability of a person to voluntarily control physiological activities by being provided with information about those activities. Gut directed biofeedback retraining has become an established therapy for idiopathic constipation and

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involves patients being taught to defecate effectively using bracing of the abdominal wall muscles and effective use of the pelvic floor muscles.[8] Many studies have reported the effectiveness of biofeedback for constipation since investigators first began to study the therapy in the mid 1980s, with effectiveness ranging between 50 and 90%. The majority of studies have focused on the effectiveness and efficacy of the therapy for patients with constipation due to evacuation disorders. Most authors have reported that biofeedback has no benefit for those with constipation as a result of slow gut transit, with the exception of a few papers published from the St Mark's group[7,8] and more recently from Battaglia and colleagues.[9]

Many of the biofeedback studies are small-scale studies, without long-term follow-up and few are controlled. Investigators have used different outcome criteria, with some focusing on objective physiological measures and others including patient self-report of symptoms for assessment of primary outcomes. Investigators have also used different techniques for providing biofeedback and over different time-scales, with many exclusively providing intra-anal or surface EMG or anorectal manometry biofeedback, while others include patient education as part of a package.[7] Few investigators have considered the possible "human effect" that the interaction with the biofeedback therapist may produce.[10] Biofeedback, however, is not widely available in the UK and many patients are required to travel great distances to reach a centre offering this service. It would therefore be useful to determine the effectiveness of other treatment options for idiopathic constipation that may be more widely accessible.

There has been an increase in interest in complementary and alternative medicine (CAM) in recent years with evidence that the use of complementary therapies has grown dramatically in the last 20 years. It is estimated that in the UK around 2 million people use a range of complementary therapies on a regular basis.[11] Over 50% of General Practitioners in the UK are making CAM therapies available to their patients and there is evidence that over 75% of patients would like these therapies to be available through the NHS.[12]

In general there has been significantly less scientific study of most complementary therapies when compared with conventional medicine and therefore the effectiveness of many therapies remains unproven. The need for sound research into the effectiveness and efficacy of complementary therapies is recognised and yet CAM research is often hindered by a lack of funding and research expertise. Efforts to build up an evidence base for CAM with the same rigour required of conventional medicine have been advocated by some,[13] but there has been a long running campaign against the use of CAM within the NHS and CAM research by others. Smallwood[14] also concluded that some CAM therapies appeared effective in managing conditions that were currently poorly addressed by conventional medicine and suggested that the NHS support research into CAM therapies, particularly where there were "effectiveness gaps" in the treatments offered by conventional medicine.

Reflexology is defined as a system of massage and application of pressure to the feet based on the theory that there are invisible zones running vertically through the body, so that each organ has a corresponding location in the foot.[13] The House of Lords Select Committee identified research priorities for CAM, including research into the effectiveness of these therapies and their specific effects and safety.[13]

Although reflexologists often claim, in their promotional literature and reflexology texts, that reflexology can be beneficial in the treatment of constipation, there is a very limited number of studies investigating the effectiveness of reflexology for the treatment of constipation.[15,16] Of these, most are conducted on a small scale and are not controlled studies, but they do seem to suggest that reflexology may be effective for treating this condition. There is a particular lack of randomised controlled trials and case series only provide weak evidence to support the effectiveness of the therapy.

The aim of this pilot study was to investigate the potential for reflexology in treating idiopathic constipation in women. The study sought to determine if there was a significant difference in reported symptoms and global assessment of constipation severity before and after a course of reflexology treatment among women with idiopathic constipation. We also wished to determine whether attitudes towards complementary therapies and holistic health impact on the effectiveness of reflexology and whether attitudes towards complementary medicine and holistic health change following a course of reflexology for treatment of idiopathic constipation. As this was a pilot study the protocol and use of outcome measures were being tested.

2. Methods

This study was a prospective single-group test–retest trial to determine whether reflexology leads to an improvement in severity of constipation symptoms in women with idiopathic constipation. Participants were drawn from the population of female patients referred to the physiology unit of a tertiary referral centre for treatment of chronic idiopathic constipation with biofeedback and behavioural management. Patients were eligible to participate if they were female and aged 18 years or over, had a confirmed diagnosis of idiopathic constipation based on the Rome II criteria,[17] were not receiving treatment from any other complementary therapist or agreed not to alter their current treatment regime in any way for the duration of the trial, did not present with symptoms requiring urgent medical assessment or treatment and were not pregnant.

Patients referred to the biofeedback service and put on the waiting list following Consultant Nurse or Gastroenterologist triage (approximately 4–5 months from referral to initial assessment once placed on the waiting list) were telephoned or were posted details of the study where no telephone number was recorded. A checklist was used to screen for symptoms indicating need for urgent clinical referral. The first 19 consecutive female patients who agreed to participate were recruited.

2.1. Ethics

This pilot study was approved by the Harrow research ethics committee. Written consent to participate in the study was obtained from all participants that included consent to publish anonymised data in scientific journals.

2.2. Whole gut transit study

Patients' ingested gut transit markers prior to the initial reflexology appointment and a single abdominal X-ray on that day (gut transit study) was taken prior to the commencement of the intervention. Three radiologically distinct sets of 20 radio-opaque markers were swallowed on consecutive days and a plain abdominal X-ray was taken approximately 120 h after the ingestion of the first set of markers, following previously published techniques.[18] The number of retained markers for each of the three sets was then compared to a previously validated normal range.[19] Patients were also required to abstain from taking laxatives from the time the first set of markers were ingested until the abdominal X-ray had been taken. Excessive retention of any one of the three sets was regarded as indicative of slow transit.[18]

2.3. Outcome measures

All outcome measures were administered at baseline (before the intervention commenced) and again following the sixth treatment. To determine the impact of reflexology on constipation, patients were assessed before and after the intervention using a standard assessment proforma, currently in use in the NHS nurse-led biofeedback service, through which a standard history was gathered. Patients were required to undergo gut transit studies and were asked to complete a bowel diary for one week.

To assess the possible psychological impact of the intervention participants were asked to complete the Hospital Anxiety and Depression Scale (HAD)[20] and to assess quality of life, the Short form 36 (SF36).[21] To assess the impact of attitudes on outcome participants were asked to complete the Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ).[22]

Prior to the commencement of the intervention a general health history was taken from the patient, as would be the case in any "normal" reflexology consultation. If any symptoms of concern unrelated to their current bowel problem were identified at this stage, the patient was advised to seek a consultation with their General Practitioner. Patients were also asked to refrain from taking laxatives for the duration of the intervention.

2.4. Reflexology intervention

In this pragmatic trial, contextual factors were optimised to approximate actual practice so that the role expectations play in treatment outcome could be reproduced.[23] The key objective in a pragmatic trial is to evaluate the effectiveness of an intervention as a whole and as it would be practised in a natural clinical setting. This tests all the components of an intervention, including the therapeutic relationship between a patient and the therapist.[24] All participating patients received the intervention. This consisted of a course of six reflexology treatments at weekly intervals, each lasting 35–45 min. This treatment was evaluated under "normal" service conditions, leaving the practitioner free to give individualised patient treatments.[25] The reflexology treatment was given using reflex areas on the patients' bare feet, as defined in a standardised chart produced by the Association of Reflexologists (AoR) and was based on the Ingham method.[26] All treatments were carried out in an NHS hospital out-patient clinic room and to facilitate a relaxing environment a recliner chair and soft background music were used. The treatment commenced with the right foot and was preceded by a few minutes of foot massage. Pressure was then applied in a standardised sequence to all the reflex zones on the right foot, using a "hooking" technique with the thumb and fingers. If any reflex zones were unable to be used on the foot due to a specific foot condition (e.g. athlete's foot, verucca) then the corresponding reflex zone on the hand was used (as would be the case in a routine reflexology consultation). The treatment was then repeated on the left foot.

During the treatment it was normal for the practitioner to converse with the patient, giving a brief overview of the background to reflexology, the potential benefits and evidence base for the therapy and answering any specific questions about the treatment. The patient would normally lead conversation and if a patient simply wanted to relax and close her eyes then the practitioner encouraged this.

Following the treatment the patient was sat up slowly and offered a drink of water. Each patient was advised to drink 1.5–2 l of water within the next 24 h and was warned of possible side-effects such as potential worsening of symptoms or a so-called "healing crisis", that an increase in frequency of bladder emptying, energy levels or conversely relaxation may occur.[27] All patients were advised that if they had any concerns before the next appointment they could contact the researcher. Patients were encouraged not to engage in strenuous activity following the treatment so that the relaxed state could continue.

Patients were also given general health advice relating to their presenting problem, such as ensuring an adequate fibre and fluid intake as part of a healthy balanced diet and that they take adequate exercise. This advice is similar to that given as part of a normal reflexology consultation, but would not include specific advice that would be considered part of a biofeedback treatment plan. It was considered important to offer such advice during this pragmatic trial for the reasons stated above, but was not thought likely to have had any impact on the patients' constipation.[5]

2.5. Data analysis

The quantitative data attained were imported and analysed using SPSS version 12.0.1. Pre- and post-intervention data for the HCAMQ, HAD and SF36 were compared using Wilcoxon signed ranks test; $p < 0.05$ was considered statistically significant.

3. Results

Nineteen women, who met the inclusion criteria, were recruited to the study between March and July 2005. Ages of the participants ranged between 22 and 75 years, with a mean age of 46.2 years (SD $\pm$14.59).

Gut transit studies were carried out for all participants before commencing the intervention. From these, 13 participants (68.4%) were found have an abnormal (slow) colonic transit time and 6 (31.6%) had a normal transit study. The proportion of participants with slow transit (approx. 2/3) and normal transit (approx. 1/3) reflects that seen in routine clinical practice.

All participants completed the course of six reflexology treatments and none was lost to follow up.

3.1. Reflexology outcome measures

Patients were asked to rate their change in symptoms using a 5-point rating scale, selecting one from the following responses: worse, same, improved a little, improved a lot, cured. From the 19 participants three rated their constipation as being the same, eight had improved a little and seven had improved a lot. One participant did not return this outcome instrument and therefore the data are missing from this analysis. In total 15 women (83%) rated their constipation as improved to some extent.

Participants were also asked to rate their symptom change on an 11-point numerical rating scale, which ranged from -5 to $+5$. This scale has been used extensively in clinical practice to assess outcome from biofeedback for both faecal incontinence and constipation.[28] One participant rated change as zero. The remaining 17 (94%) for whom data are available recorded a positive score ranging from $+1$ to $+5$ (median $+2.5$). These results are represented in Table 1. In total 17 women (94%) rated their constipation as improved using the numerical rating scale.

3.2. Transit study

Ten out of the 19 participants had improved colonic transit times following the intervention (53%). Of those who had a slow transit prior to the intervention ($n = 13$), ten (77%) had improved transit times (fewer markers retained) and of these two (15%) normalized their colonic transit.

Table 1
Numerical rating scale results.

Rating	No. of responses
Negative scores	0
0	1
+1	5
+2	3
+3	6
+4	1
+5	2

3.3. HCAMQ scores

The HCAMQ is an 11 item self-complete questionnaire that measures attitudes to complementary and alternative medicine and holistic health beliefs.[22] It calculates two separate sub-scores, one for attitude towards holistic health and one for attitude towards complementary and alternative medicine, as well as a total score out of 66. The lower the HCAMQ score, the more positive the participant's attitude towards holistic health and complementary and alternative medicine (CAM). Of the 19 participants nine (47%) demonstrated a more positive attitude towards holistic health (mean holistic health scores before treatment 9.4; mean holistic health scores after treatment 9.2), 14 (74%) demonstrated a more positive attitude towards CAM (mean CAM scores before treatment 19; mean CAM scores after treatment 17.4). Twelve patients (63%) had a lower overall score following the intervention, demonstrating a statistically significantly more positive attitude ($p = 0.03$) towards CAM.

3.4. HAD scores

Cut off points for the HAD scale were as follows: 7 or less for non-cases, 8–10 for mild or possible cases and 11 or more for definite cases.[20] Before the intervention commenced, there were eight definite cases, five mild cases and six non-cases of anxiety as scored using the HAD scale. There were also five definite cases, two mild cases and 12 non-cases of depression identified by the HAD scale. Following the intervention there were four definite cases, five mild cases and 10 non-cases of anxiety as scored using the HAD scale. There were also two definite cases, three mild cases and 14 non-cases of depression identified using the HAD scale. In total 10 patients (53%, $p = 0.19$) demonstrated an improved anxiety score and 11 participants (58%, $p = 0.14$) demonstrated an improved depression score.

3.5. SF36 scores

Mean, standard deviation and change following the intervention of corrected SF36 scores before and after reflexology are presented in Table 2, identifying numbers of participants for whom scores improved. A score of 100 is the best possible score, decreasing scores indicate worsening health status and increasing scores indicate improving health status for all categories except health transition, for which a score of 60 represents an unchanging health status.

Greatest numbers of patients reporting improvement were seen in general health, followed by mental health categories of the SF36 scale, but the only subscale to reach statistically significant improvement was vitality. Bodily pain and physical functioning tended towards a statistically significant improvement.

Table 2
Mean and standard deviation of SF36 scores pre- and post-reflexology.

	Pre-reflexology	Post-reflexology	Improved *n* (%, *p* value)
	Mean (SD)	Mean (SD)	
Physical functioning	75.83 (28.9)	80.78 (24.5)	9 (47%, $p < 0.08$)
Role physical	55.56 (45.0)	69.44 (34.9)	6 (31%, $p < 0.19$)
Bodily pain	50.21 (21.2)	63.84 (29.5)	8 (42%, $p < 0.07$)
General health	54.42 (28.6)	61.74 (25.4)	14 (74%, $p < 0.13$)
Vitality	35.26 (27.7)	49.21 (30.6)	9 (47%, $p < 0.05$)*
Social functioning	66.26 (33.3)	77.53 (28.8)	7 (37%, $p < 0.21$)
Role-emotion	64.84 (45.1)	78.29 (33.3)	6 (31%, $p < 0.33$)
Mental health	59.58 (22.1)	65.68 (24.2)	10 (53%, $p < 0.19$)
Health transition	58.89 (8.3)	54.74 (11.2)	2 (10%, $p < 0.21$)

*Statistically significant $p < 0.05$.

3.6. Bowel diaries

Participants were asked to complete a daily log of bowel movements, symptoms and laxative use for one week prior to and for one week following the reflexology intervention. While all participants completed this bowel diary before the intervention commenced, five were not completed after the intervention, most commonly because they forgot to fill it in and return the document. It was found that symptoms reported in these diaries were consistent with findings from the patient assessments conducted by the researcher at commencement and completion of the study. It has previously been reported that there is high correlation between self-reported symptoms at interview and symptoms recorded in the form of diary observations.[32]

3.7. Laxative use

Prior to the commencement of the intervention, 15 out of the 19 participants were taking regular laxatives. At the end of the study 12 (80%) of these patients had ceased using laxatives and two had greatly reduced their laxative consumption. Of these, one patient had been taking daily doses of senna and had reduced to one dose approximately every three weeks and the other had reduced laxative consumption from twice weekly doses of Picolax® to a once weekly dose of senna. Data for one participant were missing.

4. Discussion

This pilot study indicates that reflexology has the potential to compare well with the gold standard treatment for idiopathic constipation, i.e. biofeedback, which is reported to improve approximately 70% of patients.[29–31] Ninety-four percent of patients reported improvement in their constipation to at least some extent following reflexology on the primary outcome measure of an 11-point numerical scale. Symptom improvement related not only to bowel frequency, but also to other symptoms such as bloating that patients often regard as more troublesome.

Over a quarter of bowel diaries were not completed following the intervention. As there is evidence that there is high correlation between self-reported symptoms at interview and symptoms recorded in the form of diary observations,[32] analysis of laxative use has therefore been conducted from the interview data where the diary record was missing. Reduction in laxative use following reflexology compares favourably with reduction following biofeedback in previous studies.[7]

It was noted that severity of symptoms varied widely between individuals. For some participants bloating was identified by the patient as their most troublesome symptom, while for others it may have been uncontrollable passage of flatus, reduced frequency of bowel movements or straining. Further studies should therefore

consider the individual nature of these symptoms and the use of patient-generated outcome measures, which allow patients to identify their most bothersome symptoms.

Anecdotally some of the participants also volunteered that they felt much better and perceived an improved sense of well-being. Many of the participants reported feeling as though they had more energy and were sleeping better. Results from the SF36 demonstrated that some aspects of health related quality of life were improved, most notably vitality. It is unclear, however, whether this was related to improvement in bowel symptoms or to a more general non-specific effect of reflexology on feelings of energy and well-being. Many participants in this study were shown to have psychological symptoms in addition to their constipation and there was a trend towards improvement in both anxiety and depression subscales of the HAD scale, although this did not reach statistical significance.

It is also evident that participants' attitudes towards holistic health and complementary therapies were significantly more positive following the reflexology intervention. This was not correlated with a positive outcome for improvement in constipation symptoms. Participants may therefore have derived some benefit from the therapeutic relationship and contact with the reflexologist. It is not possible to exclude these human factors as a mechanism for improvement in physical symptoms, as has previously been described for biofeedback[10] and further research is indicated.

5. Limitations and further research

There are a number of limitations to this study. Convenience sampling was utilised, which may have introduced an element of self-selection bias. It is likely that women with a particular interest in CAM were those who volunteered to participate and those who were averse to such interventions did not reply to the letters of invitation. The sample for this study may therefore not be representative of the total population in this regard, but it was not possible to investigate these differences. Representativeness of a wider population of women with idiopathic constipation is also called into question as the sample was drawn from patients referred to a tertiary referral centre and may therefore be those with more severe or bothersome symptoms than those patients treated for the symptoms within primary or secondary care.

The reflexology intervention was delivered in such a way as to optimise contextual factors and to approximate actual practice, including the use of soft background music. It is possible that this in itself had a therapeutic effect; it has been previously shown that listening to music in a relaxed state can lead to alterations in psychological and physiological parameters.[33,34]

The protocol and outcome measures used within this pilot study are suitable in the main for use within a larger randomised trial of the intervention. As bowel diaries were not completed by all participants and the data can be collected equally well through other methods, such as interviews, bowel diaries are not recommended for use in further studies. In addition it became apparent that the most bothersome constipation-related symptoms differed from one patient to the next. For this reason a patient-generated outcome measure, such as MYMOP[35] that allows patients to identify the most bothersome symptom for them, may prove useful in further studies. MYMOP also facilitates collection of data on perceived well-being, which was often commented on by participants, and has been used previously in trials of CAM therapies and compares favourably to valid and reliable generic quality of life measures such as SF36.

In conclusion this study has shown the potential benefit for treating idiopathic constipation with reflexology, a therapy that is much more widely available than biofeedback. This pilot study helps to inform and develop research work and such exploratory, feasibility studies are a necessary preliminary step, but further randomised controlled trials are required to determine whether reflexology is as effective for improving constipation symptoms and quality of life as biofeedback, and the long-term effects of this treatment.

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