A single-blind trial of reflexology for irritable bowel syndrome

Philip Tovey

SUMMARY

Background: *Irritable bowel syndrome (IBS) is a significant problem for primary care, as treatment options are limited and it can frequently develop into a chronic condition. Complementary and alternative medicine, including reflexology, is being turned to increasingly in an attempt to manage symptoms. There are currently no studies which address the effectiveness of reflexology for IBS. Despite this, it continues to be advocated and used.*

Aim: *To provide the first evidence on the effectiveness of reflexology in the management of the core defining symptoms of IBS.*

Design of study: *A single-blind trial carried out in primary care settings.*

Setting: *Thirty-four participants diagnosed with IBS on the basis of the Rome Criteria.*

Method: *Participants were allocated to receive either a reflexology foot massage or a non-reflexology foot massage control group.*

Results: *On none of the three symptoms monitored — abdominal pain, constipation/diarrhoea, and abdominal distention — was there a statistically or clinically significant difference between reflexology and control groups.*

Conclusion: *On the basis of these results there is nothing to suggest that reflexology produces any specific benefit for patients with IBS. There is currently no evidence to support its use. However, this was one (relatively) small scale study; further research that, for example, assesses the impact of therapist (professional and lay) versus therapy, is still needed.*

Keywords: *irritable bowel syndrome, reflexology; complementary medicine; alternative medicine.*

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Introduction

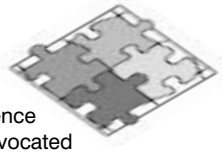
IRRITABLE bowel syndrome (IBS), 'the association of abdominal discomfort with an alteration in bowel habit for which no cause can be found on routine clinical investigation',[1] is a significant and ongoing cause of concern for the providers and users of the primary health care system. There are three principal, interrelated reasons for this. First, IBS constitutes a substantial element of the primary care workload. It is the most common diagnosis made by gastroenterologists.[2] Secondly, IBS remains, despite certain recent apparent advances in knowledge, essentially poorly understood by biomedicine and, as a consequence, is largely unable to be effectively treated by it. Thirdly, against this background, IBS frequently develops into a chronic problem for patients, with more than 50% continuing to report symptoms after five years.[2] Not surprisingly, IBS is a significant drain on health service budgets.

There is both anecdotal and published evidence that complementary and alternative medicine (CAM) is being advocated and used in the treatment of IBS.[3,4] Perhaps not surprisingly in view of the under-researched nature of CAM as a whole,[5] the effectiveness of CAMs on IBS has not been extensively researched. However, there is some evidence indicating the effectiveness of Chinese herbal medicine in some cases,[6] acupuncture,[7,8] and, the most thoroughly researched, hypnotherapy.[9-11]

Reflexology is 'a method of treatment whereby reflex points in the feet are massaged in a particular way to bring about an effect in areas of the body quite distant from the feet'.[12] The basis of the approach is that reflexes on the feet, (and to a lesser extent the hands), correspond to the full range of body parts and organs. While the physiological mechanisms underlying the treatment remain a matter of conjecture, a stimulation of healing induced by an improved blood circulation and a relaxation of tension are consistently stressed.[12,13] While, somewhat contentiously, it has been claimed that some evidence exists to support reflexology,[14] data for or against reflexology remain exceptional.[15] In addition, while the main self-help book for patients states that '[reflexology] has been found to be effective by many who suffer with IBS',[3] there is currently no evidence beyond personal anecdote to support this claim. Two studies in related areas both appear unreliable. In one,[16] it was concluded that reflexology is beneficial for chronic constipation, although no control group was used. In the other,[17] success was claimed with functional constipation, although the impact of reflexology and psychotherapy were not separated.

The aim of this study is to provide the first systematic evidence on the potential for reflexology to improve the symptoms of patients with IBS. The results will aid informed decision making by both patients and professionals, something which is timely both because patients are already paying pri-

HOW THIS FITS IN



What do we know?

Both anecdotal and published evidence suggest that reflexology is being advocated for, and used in, the treatment of irritable bowel syndrome (IBS). Little or no research existed previously in this area.

What does this paper add?

Following this study, there is still no evidence that reflexology provides any specific benefit for people with IBS. However, this was one small-scale study with a particular group of patients. More and varied research is still needed.

vately for reflexology, and because there is increasing pressure for the integration of it into mainstream practice.[18]

Method

The research was conducted in a single geographical area of a city in the north of England during 1999. After full consideration of methodological debates surrounding CAM research,[5] it was designed as a single-blind trial. Four general practices were used; all served predominantly white patients.

Tight inclusion criteria were employed. These were: patients currently under the care of a primary care physician following referral to a gastroenterologist; diagnosis of IBS in line with the Rome Criteria;[21] and, therefore, the exclusion of other causes of symptoms. One exclusion criterion — previous use of reflexology — was used. The purpose of this approach was threefold. First, to ensure that the IBS classification was as standard as possible from patient to patient and that symptoms were not caused by other conditions. Secondly, to ensure that participants were chronic sufferers, thereby minimising the potential for spontaneous symptom remission or for symptom reduction owing to increased attention alone. Thirdly, the exclusion criterion was employed to ensure that patients would be unable to distinguish between treatment and control groups. Written consent from participants, and ethical approval from a Local Ethics Committee, were sought and received.

Participants, identified via a notes search, were initially contacted by their GP, and then by the researcher. Ninety per cent of those sent full details agreed to participate. All were currently under the care of their GP following secondary care referral.

Patients were randomised to one of two groups (Figure 1):

- *Reflexology group*. Treatment consisted of six (four weekly and two fortnightly) 30-minute sessions conducted as close as possible to 'normal' practice.
- *Indistinguishable control group*. As benefits of CAM are frequently dismissed as the result of increased contact alone, the main aim was to control for that contact. This group were exposed to exactly the same number of contact sessions as the experimental group. Sessions were carried out in exactly the same way, following the same procedures, with the single exception of a non-reflexology foot massage was given (a massage that did not include the application of pressure on key points of the feet that is characteristic of reflexology). According to reflexology theory this should have no curative effect as no stimulation of healing has occurred.

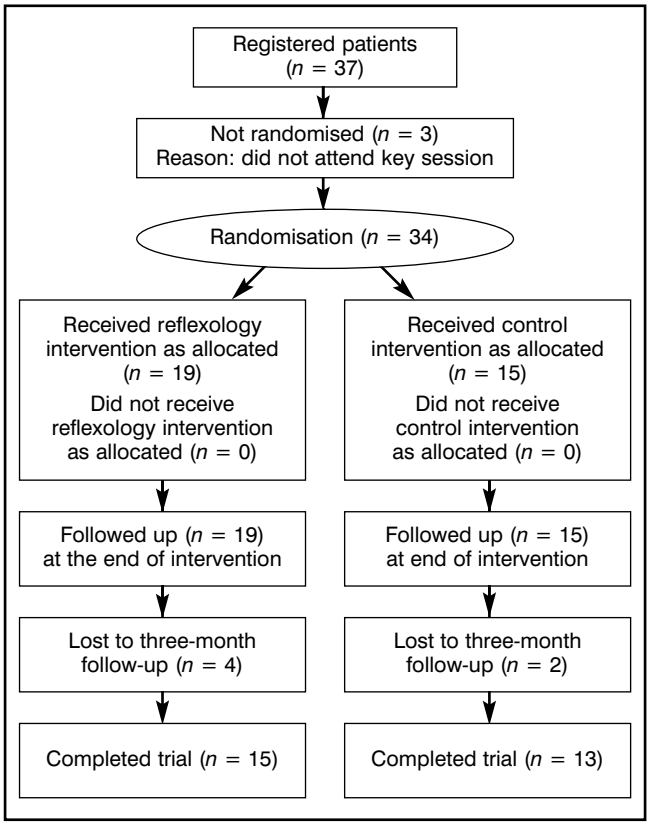


Figure 1. Trial profile.

All sessions were conducted in the participants' surgery. 'Holistic' features of a standard consultation, such as lifestyle advice, were excluded from the procedure. This was because it can be argued that the fundamental validity of reflexology rests on the extent to which its specific form of foot massage produces an impact — a discernible change unrelated either to the process of consulting or to behavioural change. The study's lead reflexologist was consulted throughout to minimise grounds for the *post hoc* rejection of findings by advocates of reflexology on the basis of the inappropriateness or artificiality of project design. A written code of conduct, refined during pilot work with two people from outside of the trial, was followed to maximise procedural rigour.

Randomisation by alternation was used. Participants were recruited practice by practice since, given the small numbers involved in each practice, full randomisation in these small blocks would have been impractical.

A Health Assessment Sheet, similar to those used successfully in other IBS trials,[11] was used to provide a quick and easy means for participants to record symptom intensity. The defining symptoms of IBS — abdominal pain and constipation/diarrhoea, plus bloatedness/abdominal distention, were assessed daily on a five-point (0 to 4) scale. The forms were completed by all participants for two weeks before the first session (details of sessions below), throughout the interven-

tion, for two weeks after, and again for two weeks at follow-up three months after the final session. Results are based on a comparison of symptoms at baseline: end of Week 2 (prior to the first session), and outcome: Week 10 (after the last session). Follow-up data were based on a comparison of symptom intensity at baseline with symptom intensity three months after the end of the intervention. There was an 80% power (aiming at 18 patients per arm), with 5% significance to detect a difference of 50% of controls and 90% of the experimental group achieving health improvement on the principal outcome measure (abdominal pain). As no published evidence existed in the area, the figures resulted from an assessment of the kind of difference that would be regarded as clinically significant (and from clinical experience might be anticipated), i.e., the kind of difference that might underpin integration into mainstream practice. Data were analysed using a Mann–Whitney U test.

Results

Thirty-four patients (28 female, six male, mean age = 48, age range = 19 to 72) — a number larger than in much of the related work on IBS[19] and CAM[14,20] — completed the study. Symptom duration ranged from 18 months to 15 years. Baseline depression was negligible (mean = 3.6, Hospital Anxiety and Depression Scale [HAD]), baseline anxiety was higher (mean = 9.6 HAD, ([7 to 10 indicates mild anxiety, 11 to 14 indicates moderate anxiety]). The intervention was completed by 19 participants in the reflexology group (15 at the three-month follow-up) and 15 in the control group (13 at the three-month follow-up).

There were no significant differences in baseline characteristics between the two groups (abdominal pain: reflexology — median = 1.4, interquartile range (IQR) = 0.6 to 2.1, control — median = 0.7, IQR = 0.5 to 1.3; constipation/diarrhoea: reflexology — median = 1.9, IQR = 1.2 to 2.1, control — median =1.2, IQR = 0.3 to 1.7; bloatedness: reflexology — median = 2.5, IQR = 1.3 to 3.1, control — median = 2.0, IQR = 1.0 to 2.2).

Fifteen participants were approached at varying stages of the trial and asked if they could confidently identify which group they belonged to. None expressed a 'confident' assessment although two offered a 'guess' and both of these guesses were correct. A reasonable degree of confidence that the blind nature of the trial was maintained can therefore be expressed.

Abdominal pain

Abdominal pain is the principal outcome measure and one of the key defining symptoms of IBS laid out in the Rome Criteria.[21] These data show no significant difference between the impact of reflexology and control on this symptom (control — median = -0.40, IQR = -0.90 to 0.00, *n* = 15; reflexology — median = -0.10, IQR = -0.80 to 0.10, *n* = 19; U = 114.0, *P* = 0.32; Figure 2). No change in outcome was recorded at the three-month follow-up (control — median = -0.25, reflexology — median = 0.00)

Constipation/diarrhoea

This is the second variable drawn from the Rome Criteria for IBS. Again, there is no evidence of any difference between the groups (Figure 3), and on this measure very little impact was recorded at all (control — median = -0.30, IQR = -0.80 to 0.20, *n* = 15; reflexology — median = 0.05, IQR = -0.53 to 0.43, *n* = 18; U = 115.0, *P* = 0.47). This was confirmed at follow-up (control — median = 0.00; reflexology — median = 0.10).

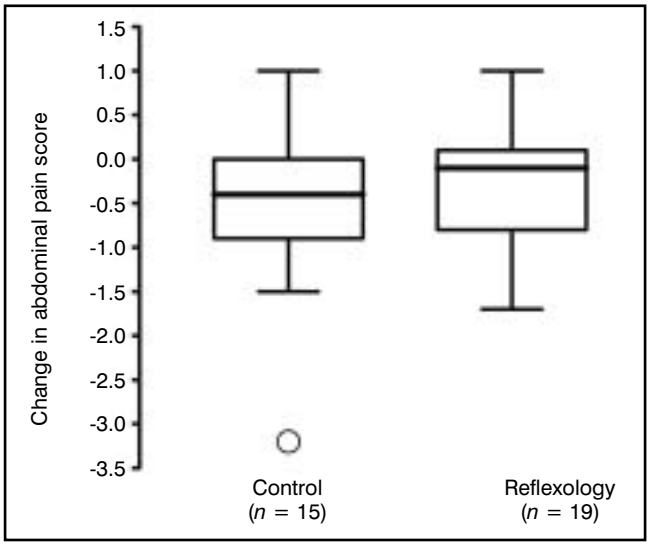


Figure 2. Change in abdominal pain score at end of intervention. Key: ☐ IQR; —median; ⊢⊣ all data excluding outliers; ○outliers (> 1.5 x IQR from the edge of the box).

Bloatedness

The pattern established with the first two symptoms is repeated with bloatedness (Figure 4) (control — median = -0.40, IQR = -1.05 to -0.15, *n* = 13; reflexology — median = -0.10, IQR = -0.60 to 0.20, *n* = 17; U = 77.5, *P* = 0.17. Again, these results were confirmed at follow-up (control — median = -0.42; reflexology — median = -0.10).

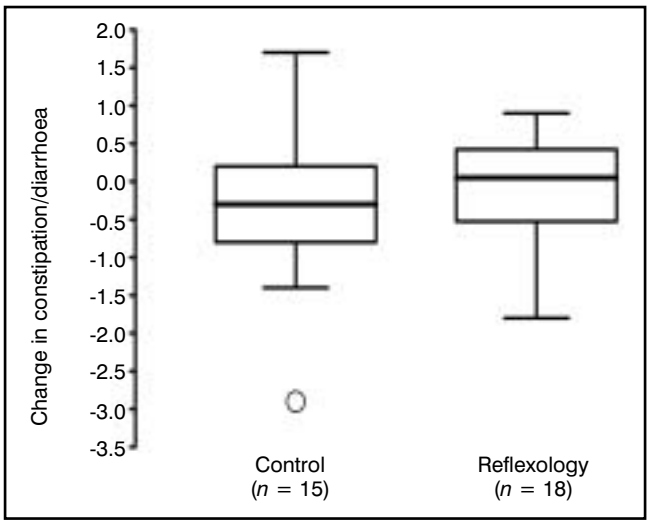


Figure 3. Change in constipation/diarrhoea at end of intervention. Key: ☐ IQR; —median; ⊢⊣ all data excluding outliers; ○outliers (> 1.5 x IQR from the edge of the box).

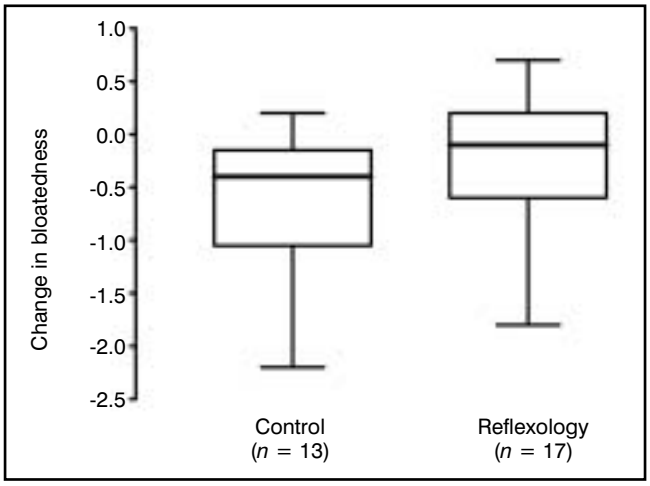


Figure 4. Change in bloatedness at end of intervention. Key: ▭ IQR; —median; ⊢⊣ all data excluding outliers; ○outliers (> 1.5 x IQR from the edge of the box).

Discussion

The aim of this research was to provide the first systematically conducted study of reflexology and symptom management in patients with IBS. While due caution should be exercised in generalising from a single (relatively small) study, the nature of the data is such that clear conclusions can be drawn.

On the basis of this study, there is no evidence that reflexology provides any specific benefit for patients with IBS. On none of the three symptoms was there anything approaching a positive difference in support of reflexology. According to reflexology theory, there should have been a clear benefit for the reflexology group; however, this was not the case. This is an important finding given the existing evidence vacuum, the context of patients paying privately for reflexology, and the apparent preparedness of practices and primary care groups to consider referral or practice-based utilisation of CAMs[21]. There is nothing in these initial data to support the purchase of reflexology by individuals or the allocation of health service resources to it by professionals.

However, it is important to recognise that these results are from one ethnically homogeneous study with a quite specific group of patients. More research is needed, not only to test these initial findings but also to extend the range of participants to, for instance, those newly diagnosed with IBS. Indeed, it might well be argued that the group of participants included in this study were a 'hard to treat' group, as they were all chronic sufferers who had all been through both primary and secondary orthodox care systems without alleviation of symptoms. This is certainly a fair point: reflexology is only failing to produce results with those for whom orthodox approaches have provided little benefit. While the tight inclusion criteria served to establish a clear identity for the sample, a more pragmatic GP-defined, or even patient-defined, population may have provided greater potential for success. However, the crucial point is that reflexology is being advocated and sold on the basis that it can make a difference to those unable to be helped by orthodox medicine — it may be a stiff test but it is one demanded by the claims of the therapists. And it is important to reiterate that it was a test designed in consultation with reflexology practitioners.

The study might also have produced a different outcome had a different type of control group involving no physical contact been used. While this would have permitted comparison of standard care with intervention, it was considered crucial to control for the impact of enhanced physical contact (of whatever sort) to be able to identify what the specific benefits of reflexology might be. Clearly, extending the nature of groups is an option for future work. Also, it might be argued that the study was underpowered. Certainly, a larger trial could be established in which less demanding assumptions about the level of differences necessary to establish clinical significance are made. This would have been more of a concern if any indication of an effect, however weak, had been found.

I want to conclude with a note of caution. Although the results of this study are quite clear, they should not be used to dismiss reflexology as a treatment option across the board, nor indeed to argue against the effectiveness of CAM as a whole. The simple fact is that we know very little about the effectiveness of very many treatment options in relation to very many conditions. Reflexology in particular remains not just under-researched but almost unresearched[15] — something that is quite startling given the extent of its use. For instance, we need to examine the varying impact of individual practitioners and indeed the extent to which the legitimacy held by orthodox practitioners, for instance general practitioners and/or nurses, might impinge on the effectiveness of reflexology. And even with IBS, as noted above, varying the definition and selection of patients may yet yield different outcomes. There is clearly a need for substantially more research, using a range of controlled and naturalistic approaches, before definitive conclusions can be reached.

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