

## ***Acupuncture for Irritable Bowel Syndrome: practical experiences of collaborative research within the NHS***

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### ***Background to the study (Dr Alastair Forbes)***

The impetus for this study came from Dr Alastair Forbes who was interested in investigating the effectiveness of acupuncture for irritable bowel syndrome. IBS is one of the most common gastrointestinal complaints seen by gastroenterologists, and although not considered serious in the sense of leading to death or a need for mutilating surgery, it is certainly a cause of misery for many thousands of patients.

Conventional medical therapy for IBS at present consists of dietary changes such as exclusion diets/ additional fibre, antispasmodics, sedatives, antidepressants, new 5HT drugs as well as hypnotherapy and psychotherapy – to varying degrees of effect. Acupuncture has been shown to be effective for IBS in a small scale, uncontrolled study by Mayberry & Chan (1997) though there are little other biomedical data. Sceptics make much of the potent placebo effect of acupuncture and therefore any uncontrolled trial of acupuncture for IBS is always open to criticism that placebo effects are in operation. In addition, previous acupuncture studies (including that by Mayberry & Chan) have often come under criticism by acupuncturists for not individualising therapy and relying on standardised treatment only.

The study design used in this trial therefore represents a compromise between the need for individualised therapy and thus meaningful acupuncture, and the need from the biomedical establishment for defined ‘fixed’ regimes for comparison in scientific method.

### ***The trial design***

The study design uses a novel approach to get round the problem of blinding the practitioner to the treatment – seen as necessary to avoid treatment bias. Two acupuncturists are needed for each patient. The first acupuncturist is the ‘diagnosing acupuncturist’, whom the patient sees for the initial consultation and prior to each of ten weekly treatments, as per any normal treatment program, and for a follow-up feedback session. This first acupuncturist devises the treatment plan and points to be used, then the second acupuncturist carries out the treatment – either according to instructions, or using sham points, depending on which type of treatment the patient has been randomised to. The first ‘diagnosing’ practitioner also sees the patient briefly at the end of each session to take pulses. Sham acupuncture points are chosen from three different areas on the body, and these are varied, to some degree each week, as they might in genuine treatment. This variation extends to ‘needle technique’ and length of time needles are left in place. No deqi needling sensation is sought or obtained on sham points.

12 visits are scheduled: an initial consultation, followed by 10 weekly treatments, and a follow up feedback session. Patient monitoring is in the form of standard questionnaires and also verbal feedback, assessment of pulses and tongue. Patients know that they have a 50% chance of receiving sham acupuncture, and also that, if this turns out to have been the case that, at the end of their 12 week participation in the study, they will be offered a course of genuine acupuncture. Patients continue with any conventional treatment they may be receiving whilst on the study.

### ***Duration and setting***

The study is being carried out at St Mark’s Hospital, a specialist gastroenterology hospital at Northwick Park. Recruitment of patients is from the outpatient clinics at the hospital. The study started in January 1999 – originally envisaged to last approximately one year, though has taken quite a bit longer so far. Originally we aimed to treat 50 patients in total to achieve significant results, though this was increased to 60 to replace patients who did not complete the study or who had to be excluded for other reasons. The study will probably be finished by the end of this year.

### *Practical experiences from the acupuncturists*

We decided to go ahead as we felt that the compromise was acceptable and the opportunity simply too good to miss, both in terms of being able to participate in research and having the scope to offer acupuncture to patients beyond the usual confines of our private practice. We have summarised the main 'pros' and 'cons' of our experiences of being involved in this study:

#### *Pros*

- We are given free rein to **individualise acupuncture treatment** as normal.
- Dietary and lifestyle advice is given to all patients for whom it seems appropriate, regardless of the type of treatment they receive on the study.
- Our diagnosis is based on our training in both **TCM and Five Element** theory
- We offer a **realistic number of treatments** to each patient (10 weekly treatments) plus a full initial consultation. Treatment sessions last one hour.
- Opportunity to **work as a team**, sharing the same patients – as compared to the isolation of private practice
- Many patients expressed a lot of **appreciation** for being offered acupuncture treatment in a hospital setting, including many who were subsequently found to be receiving sham acupuncture. Many found the weekly opportunity to talk about distressing symptoms beneficial.

#### *Cons*

- The benefit of **ongoing pulse feedback**, during the course of a treatment, is absent, as the treating practitioner is not allowed to ad lib. The treatment strategy and all points are prescribed at the beginning of each treatment.
- **Weekly treatment planning**: Not knowing, as diagnosing practitioner, whether your patient is actually receiving the treatment you are prescribing for them each week, is very challenging, especially if a patient is coming back week after week without improving.
- In our role as treating practitioners, we have felt troubled at times when we have had to knowingly withhold effective treatment from certain patients, who have been in considerable pain or distress, because they happen to have been randomised to **sham acupuncture**.
- We have not been able to use **moxa** due to smoke regulations and the blinded nature of the study. Our treatment of Yang Xu patients and /or patients with chronic diarrhoea has been significantly compromised, as a result
- Patients continue with any **conventional medication** they are taking while on the study, without the introduction of new drug regimes. Nevertheless, there have been several instances where patients' regimes of medication have been altered. GPs have appeared to lack an understanding of energetic medicine and, consequently, have not realised that medication intended to deal with an apparently unrelated condition is likely to impact greatly on syndromes we are treating and the progress of their treatment.

#### *Other practical considerations*

- It is worth making the point that coming into an NHS hospital environment as acupuncturists, and hence outside the orthodox medical establishment, has not been easy. At times we have found that we lack the status and authority to have our practical needs met.

#### *Comment*

This study design is a compromise and, as such, is certainly not ideal. Criticism may be levelled at it on ethical and logistical bases. However, we feel that there is still merit in conducting this type of research because of the weight it will carry among the medical establishment - should genuine acupuncture be shown in the study to be more effective than placebo – and the potential implications this could have for the use of acupuncture in the future.

