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ORIGINAL PAPER

# Interim results of a randomised controlled trial of homeopathic treatment for irritable bowel syndrome

Emily J Peckham[1,*], Clare Relton[2], Jackie Raw[3], Clare Walters[3], Kate Thomas[2], Christine Smith[3], Kapil Kapur[3] and Elmuhtady Said[3]

[1]*Department of Health Sciences, University of York, Heslington, York YO10 5DD, UK*
[2]*School of Health and Related Research, University of Sheffield, UK*
[3]*Barnsley Hospital NHS Foundation Trust, UK*

**Irritable bowel syndrome (IBS) is a chronic condition for which there is no consensus on the optimum treatment. Gastroenterology problems are some of the most common conditions treated by homeopaths, yet few trials have explored the effectiveness of individualised homeopathic treatment for IBS. A three-armed trial was conducted which compared: usual care, homeopathic treatment plus usual care and supportive listening plus usual care. The primary outcome was change in irritable bowel symptom severity score between baseline and 26 weeks, calculated using ANCOVA. An interim ANCOVA adjusted for baseline IBS severity, age and employment status found no statistically significant difference between the three arms. However, a post-hoc test comparing homeopathic treatment plus usual care to usual care alone found a statistically significant difference in favour of homeopathic treatment. In addition, 62.5 percent of patients in the homeopathic treatment arm (compared to 25.0 percent of those in the usual care arm), achieved a clinically relevant change in irritable bowel symptom severity score, which indicates a promising effect for homeopathic treatment, though these results should be interpreted with caution due to the low number of participants in the study.** *Homeopathy* (2014) **103**, 172–177.

**Keywords:** Irritable bowel syndrome; Homeopathy; Randomised controlled trial; Attention control

## Background

Irritable bowel syndrome (IBS) is a chronic condition for which, at present, there is no cure.[1] There are an estimated 240,000 primary care consultations per year in the UK of new cases of IBS[2] and the economic costs of IBS in primary care are estimated to be over £200 million.[3] IBS is characterised by recurrent symptoms (i.e., abdominal pain or discomfort, bloating, nausea, vomiting, early satiety, constipation, or diarrhoea) that indicate a dysfunctional gastrointestinal tract despite a lack of organic change or specific diagnosis. There is currently no consensus on optimum treatment, however many sufferers seek complementary and alternative medicine.[4] Homeopathic treatment is one such option, yet there is much debate as to whether or not homeopathic treatment is anything more than a placebo.[5] Gastroenterology problems are the fourth most common referral to NHS homeopathic hospitals[6] and one of the eight most common conditions treated by NHS homeopaths in General Practice.[7] This study therefore aimed to investigate the effectiveness of homeopathic treatment for patients with IBS. The paper presented here reports the interim results of this study.

## Methods/design

The rationale for this study was to test whether or not homeopathic treatment plus usual care was any different from

*Correspondence: Emily J Peckham, Department of Health Sciences, University of York, Heslington, York YO10 5DD, UK.
E-mail: emily.peckham@york.ac.uk
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usual care alone in the treatment of IBS. In addition the study aimed to explore the feasibility of including supportive listening as an attention control arm in a trial of individualised homeopathic treatment. The design was a three armed pragmatic randomised controlled trial which used the novel cohort multiple randomised trial methodology.[8] This involved recruiting patients to an IBS cohort, (Barnsley Irritable Bowel Syndrome Cohort (BIBSC)) from both primary and secondary care. Recruitment was *via* GP databases for primary care and consultants' lists in secondary care. Upon identification potentially eligible participants were mailed a questionnaire to complete and return. Informed consent was sought and given for all participants included in this study.

There were two sets of inclusion criteria for this study: inclusion criteria for the BIBSC and inclusion criteria for the randomised controlled trial (RCT). To meet the inclusion criteria for the RCT participants first had to meet the inclusion criteria for BIBSC. The inclusion criteria for BIBSC were broader due to the potential for BIBSC to be used for future RCTs exploring IBS. The inclusion criteria for both the BIBSC and the RCT are shown in Figure 1.

All patients in the BIBSC who met the inclusion criteria for the RCT were randomly selected to one of the three arms in this trial: usual care alone, the offer of 5 one hour sessions of homeopathic treatment plus usual care or the offer of 5 one hour sessions of supportive listening plus usual care. Full details of the methods and design of this trial are reported elsewhere.[9]

## Interventions

The homeopathic treatment provided was classical/individualised homeopathic treatment delivered by two homeopaths registered with the Society of Homeopaths who had been in practice for at least five years. The homeopaths were able to prescribe any remedy from the homeopathic pharmacopeia in a potency and frequency of their choice.

The supportive listening was delivered by two counsellors registered with the British Association for Counselling & Psychotherapy who had been in practice for at least five years. The purpose of including a supportive listening arm in this trial was to assess the feasibility of including a supportive listening arm as an attention control, and to control for the time and attention given to the patient by the homeopath. All consultations were conducted at Barnsley Hospital NHS Foundation Trust.

This study was pragmatic in design and the nature of the interventions, and the study design, did not allow for the blinding of the therapists or the participants. The analysis was carried out blind to treatment allocation.

## Outcome measures

Patient outcomes were collected at 26 weeks by postal questionnaire. The primary outcome was the difference in the Irritable Bowel Syndrome Symptom Severity Score (IBS-SSS) between baseline and 26 weeks.[10] Secondary outcome measures were the Hospital Anxiety and Depression Scale (HADS),[11] EQ-5D and Consultation and Relational Empathy (CARE)[12] and expectation of benefit. The expectation of benefit is based on a scale designed by Borkovec and Nau[13] and adapted for IBS by Drossman,[14] to assess a treatment's credibility to patients and how likely patients felt that the treatment would help their symptoms. The number of treatment sessions attended by patients in the homeopathic treatment arm and the supportive listening arm were also recorded.

The primary clinical outcome was the difference between IBS-SSS[10] at baseline and 26 weeks analysed using ANCOVA.

## Sample size

It was estimated that to detect a minimal clinical difference of 50 points on the IBS-SSS[10] at 90 percent power and 5 percent significance, a total of 198 people would be

| **Inclusion criteria for BIBSC** | |
|---|---|
| • Age 18 or over<br>• IBS diagnosis using ROME III criteria<br>• Consent to complete and return postal questionnaires | |
| **RCT** | |
| Inclusion criteria | Exclusion criteria |
| • Scored ≤ 100<br>• Fluent in English | • Major gastrointestinal surgery in last 6 months<br>• Pregnant or breast feeding<br>• Current diagnosis of cancer, unstable psychiatric disorder or other serious physical illness |

**Figure 1** Inclusion and exclusion criteria.