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Research paper

A pragmatic randomised controlled trial of healing therapy in a gastroenterology outpatient setting

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ABSTRACT

Introduction: To determine the benefits of healing therapy (spiritual healing) as an adjunct to conventional management in irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD).
Methods: 200 outpatients with IBS or IBD were randomised to either conventional treatment (control) or conventional plus five sessions of healing therapy (intervention). After 12 weeks controls also had healing therapy. Outcomes used were, the Measure Yourself Medical Outcomes Profile (MYMOP). IBS-QOL, IBDQ, and symptom measures.
Results: There was a significant improvement in the MYMOP score at week 6 ($p < 0.001$) which was maintained to week 12 ($p < 0.001$) and 24 ($p < 0.001$). Improvements in MYMOP were significantly greater in the intervention group at both 6 ($p < 0.001$) and 12 weeks ($p < 0.001$) with effect sizes of 0.7 (95% CI: 0.4–1.1) and 0.8 (95% CI: 0.4–1.2). Condition-specific data for IBS showed that most QoL dimensions had a significant minimum 10-point score improvement at 6 and 12 weeks. The overall score improvement was 12.9 units at week 6 ($p < 0.001$), 12.4 units at week 12 ($p < 0.001$) and 13.8 units at week 24 ($p < 0.001$). In IBD there was also similar score improvement, but only up to week 12 were there associations of improved social and bowel functions ($p < 0.001$, respectively). Between group differences were identified for QoL scores in IBS at both week 6 ($p < 0.001$) and 12 ($p < 0.001$) but only for week 12 ($p < 0.001$) in the IBD group.
Conclusions: The addition of healing therapy to conventional treatment was associated with improvement in symptoms and QoL in IBS, and to a lesser extent in IBD.

1. Introduction

Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD) are both gastrointestinal disorders of unknown aetiology that significantly reduce quality of life (QoL), impacting on several aspects of personal, physical, psychological, mobility, social and employment status (IBS [1–5]) (IBD [6–8]) with high demands on healthcare resources [9,10]. IBS is considered a functional disorder with symptoms of abdominal pain or discomfort with alternating diarrhoea and constipation or a predominance of either one. It has a community prevalence of 10.5–11.5% [1,5], accounting for 30% of "gut problems" presented in primary care [11]. IBD includes ulcerative colitis (UC) and Crohn's disease (CD) with a UK prevalence rate of 0.25–0.3% for UC and 0.15–0.375% for CD [12,13]. Both are associated with abdominal pain and diarrhoea marked by episodes of flare-up and periods of remission resulting in long term morbidity. Furthermore, in UC there is diffuse mucosal inflammation of the colon along with bloody diarrhoea while CD is characterised by weight loss and patchy inflammation of the intestinal mucosa [14]. There is no

Abbreviations: IBS, irritable bowel syndrome; IBD, inflammatory bowel disease.
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universally effective treatment for IBS [15] or IBD [14,16,17] and it varies between pharmacological drugs, dietary advice and lifestyle changes, but also surgical treatment in around half of CD patients. Complementary and Alternative Medicine (CAM) is a holistic person-centred approach to patient care prevalent in the general population [18–20]. It covers a wide range of therapies e.g. acupuncture, massage and herbal medicine, and is accessed by around 10% of the UK adult population [21] typically to supplement conventional care [22]. Amongst patients with gastrointestinal complaints it is estimated that 50% commonly use CAM [23,24]. Around 90% of CAM provision in the UK is purchased privately, the estimated value of which was £1.6 billion in 2000 [18]; which excludes NHS and charity-funded CAM usage [25]. Smallwood's report into the cost effectiveness of CAM within the NHS concluded that CAM should be targeted at the effectiveness gaps of conventional health care [25].

Healing therapy forms part of the energy therapy sub-group of CAM. Energy therapies are based upon the putative concept that humans are permeated by subtle energy fields; imbalances in an individual's energy field may occur which can be detrimental for health [26]. Some methods of healing have a long history in their country of origin, eg spiritual healing in the UK and reiki in Japan. Others have been developed relatively recently, eg Therapeutic Touch in the USA. Therapeutic touch is described as "The conscious use of the hands to direct or modulate, for therapeutic purposes, selected nonphysical human energies that activate the physical body" [27]. Because of preliminary experience spiritual healing was the form of healing therapy evaluated in this study. Spiritual healing is described as the channelling of energy through the healer to the patient. In this form of healing therapy, the therapist need not know of the patient's symptoms as there is no conscious direction of therapy. The aim of the therapy is to facilitate self-healing within the patient.

To the best of the authors' knowledge, and an electronic search of medical literature, there have been no previous clinical trials of healing therapy in either IBS or IBD. There is evidence of healing therapy stimulating growth of human osteoblastic cells and inducing differentiation and mineralization [28]; and being beneficial in pain relief [29], osteoarthritis of the knee [30], burn patients [31], and fibromyalgia [32]. Other studies on diabetic neuropathy [33] and asthma [34] did not show any benefit, and a Cochrane review on wound healing [35] was inconclusive. These variable results suggest the need to evaluate its efficacy in different patient groups before adopting it as a therapeutic intervention. This study aimed to determine the benefits of healing therapy as an adjunct to conventional management of individuals with IBS and IBD.

2. Methods

2.1. Trial design

This study was a randomised controlled trial of healing therapy for people with a clinical diagnosis of IBS or IBD. It was pragmatic using a two-armed design, comparing the effectiveness of five sessions of healing therapy as an adjunct to conventional treatment against a waiting list control receiving conventional treatment only. One change regarding the inclusion of CD patients was made after the original protocol (http://www.isrctn.com/ISRCTN13039379) was submitted. The allocation ratio was 1:1 (waiting-list: intervention); the computer generated blocked randomisation list (block size = 6) was stratified by disease type (IBS and IBD) to ensure equal allocation to each arm. Allocation was concealed and randomisation was carried out remotely via telephone between the hospital based research assistant and the list controller (co-investigator) once eligibility had been confirmed and consent achieved. Randomisation took place after informed consent was achieved and baseline questionnaires had been completed in the presence of the participant who was then informed immediately of the outcome. Due to the nature of the intervention no blinding was possible. At the end of 12 weeks the waiting list control group also received treatment. This allowed all participants to receive the intervention. This trial was approved by The Black Country Research Ethics Committee, West Midlands, UK (identifier 10/H1202/36), and informed written consent was obtained by all participants. Formal between-group comparisons are those undertaken at week 6 and 12, although we report data from week 24 both to enable the longer-term impact of the intervention to be assessed in the intervention group and impact between week 12 and 24 in the waiting list control group.

The trial was conducted at two Birmingham (UK) study sites located within the Heart of England NHS Foundation Trust. Participants were recruited from gastroenterology outpatient's clinics either through routine appointments or by postal invitation following retrieval from the patient database. Initially, eligibility criteria were an age 18 years and over, having attended clinic in the previous 12 months with a clinical diagnosis of IBS (confirmed by ROME II criteria) or with a clinician diagnosis of Ulcerative Colitis. In month 8 due to low recruitment rates this was extended to include individuals with a clinician diagnosis of Crohn's Disease to supplement the IBD group. Exclusion criteria included: having received healing therapy in the last 6 months; being unable to provide fully informed consent; being unable to self complete outcome questionnaires; those engaged in or having completed another clinical trial in the previous 8 weeks; and pregnant women.

2.2. The intervention

The intervention consisted of 5 weekly sessions of 30 min of healing therapy delivered by therapists in addition to usual clinical management. Participants who failed to attend an appointment were offered a replacement session. For uniformity of method, healing therapy was delivered by healers trained in spiritual healing by, and members of The Healing Trust [36] in a private consultation room within the hospital. The Healing Trust was established in 1954. Members undergo a minimum of 2 years of nationally standardised training and mentoring by a qualified member, testimonials and final panel assessment. Participants received healing therapy fully clothed on a clinic couch or seated in a chair with back support, depending on comfort and/or disability. Therapy was not standardised but was administered as per training, each session beginning by the healer lightly placing their hands on the patient's shoulders. Thereafter the healer's hands are maintained a short distance (10–12 in.) from the participant's body gradually working towards the feet and placing the hands there. With verbal consent, some healers worked with light touch on the shoulders, feet, arms and legs for short periods of time. Depending on the therapist, music may have been played to promote a relaxed atmosphere during the session.

2.3. Data collection

A selection of validated self-report outcome measures were used, with outcomes recorded at week 0 (baseline), 6, 12, and 24. Qualitative data were also collected to ensure the full range of potential experiences were determinable, published in a separate paper [37]. The primary outcome measure, the Measure Yourself Medical Outcome Profile (MYMOP) [38], is a validated patient-centred problem-specific instrument specifically developed for use in the study of complementary and alternative medicine. This individualised measure has demonstrated greater responsiveness