A Randomised trial of Healing therapy in a Gastroenterology Outpatient setting

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Final Research Report

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Key Summary

Irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD) are both associated with significant detriment to quality of life and surgical and medical management is established but often fails to fully alleviate symptoms. This study was a collaboration between Freshwinds (charity), University of Birmingham and Heart of England NHS Foundation Trust.

Study Aim: This study aimed to determine benefits of healing therapy (a type of complementary therapy) as an adjunct to conventional management for patients with IBS and IBD.

Methodology: This study incorporated a randomised controlled design which included a total of 200 participants diagnosed with IBS and IBD on adults 18 yrs or over, attending a hospital gastroenterology clinic. Healing therapies was delivered to participants in weekly 30 minute sessions over a 5 week period and were compared against a waiting list control which received only conventional medical treatment. The waiting list controls received therapy after a 12 week period. Outcomes were recorded using validated questionnaires at baseline and again at week 6, 12 and 24 to evaluate disease specific quality of life, symptoms and patient specified primary symptoms. Primary outcomes included; MYMOP, IBS-QOL and IBDQ, whilst secondary symptom measures used to record the severity of the disease were, Birmingham IBS symptom questionnaire, and modified versions of SCCAI and Harvey-Bradshaw index. Qualitative data was also obtained via in depth semi-structured interviews of participants to compliment the quantitative data.

Results: Full results will be reported in the publication of academic papers later this year.

Conclusion: There is an increasing worldwide population trend to seek the use of complementary therapies (CT) particularly for chronic conditions. When faced with this, clinicians who are unfamiliar with CTs usually find difficulty being able to offer advice to patients who may have decided to explore CT. This study will make a considerable contribution to the evidence base on complementary therapies. Based on the results policy makers, clinicians and commissioners will be able to make more informed decisions on the role and use of healing therapy in IBS and IBD as an adjunct to conventional treatment, or as part of a multidisciplinary approach to care.

1. Background

Both irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD) are relatively prevalent conditions which are associated with significant detriment to quality of life. Although these conditions cause similar symptoms they have very different causes. IBD is characterised by grossly abnormal pathophysiology with evidence of inflammation in blood tests, and at endoscopy. Surgical and medical management is established but often fails to fully alleviate symptoms. IBS, in contrast, is a diagnosis made in the absence of such abnormality and is established as a primarily functional disorder with the suggestion that psychological factors impact on symptoms. For many patients with this diagnosis management (i.e. medical management of symptoms with dietary and lifestyle change) remains sub-optimal and the condition is associated with reduced quality of life. Non-denominational, Healing therapy (provided by volunteer members of The Healing Trust www.thehealingtrust.org.uk) has been available at Good Hope hospital for some time and pilot data indicated significant improvement in measures of relaxation, physical discomfort and general well-being post-treatment in patients with both of these conditions. The evidence base for complementary medicine remains weak and no published evidence relating to the value of healing in this patient group could be identified. This identified a need to determine the value of such therapy for patients with IBS and IBD through a formal research trial.

1.1 Irritable Bowel syndrome and Inflammatory Bowel disease

Both irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD) affect young adults, and adversely influence the work and personal lives of sufferers.

IBS is a common functional condition characterised by abdominal pain, bloating and disruption to bowel habit, constipation, diarrhoea and a mixed profile all being recognised symptoms. A UK prevalence of around 10% has been suggested, although not all patients seek medical attention (Hugin & Whorwell, 2003; Wilson et al., 2004). The diagnosis is one of exclusion and is given when symptoms are present in the absence of abnormal pathophysiology. ROME II and III criteria are typically applied in a research context to enable more accurate categorisation of patients with this disorder. IBS results in reduced quality of life, adversely affecting patients' general wellbeing, as well as their social, vocational, and sexual functioning (Hungin et al., 2003; Drossman et al.,1993; O'Keefe et al.,1995). Treatment options are limited for IBS and for a group of patients (typically those seen in secondary care settings) are poorly efficacious. Individuals with IBS are more likely than the general population to be too sick to work, have missed days of work and to have visited their doctor.

IBD in contrast, has recognised organic pathophysiology. It is characterized by similar symptom presentation as IBS but also typically also presents with blood stained diarrhoea and weight loss. IBD is less prevalent than IBS and affects around 1 in 1000 of the population (Probert et al.1993; Rubin et al., 2009) or around 50,000 individuals (Ehlin et al., 2003). Despite a much wider range of medical and surgical treatment options, many young adults remain symptomatic and experience poor quality of life (Rubin et al., 2009; Feagan et al.2005;Vidal et al.,2008).

1.2 Healing Therapy

The use of complementary therapy in the UK is widespread with estimates of up to 20% using such a therapy in the previous year. Despite this the medical community highlight the dearth of evidence for its adoption into mainstream medicine (Ernst et al., 2008) and evidence currently

available is highlighted as being of poor quality. Despite this obvious difference between public use and medical opinion, medical research councils and charities together with drug companies, the main funders of medical research, are reluctant to support this type of research with <0.01% of total research budget being spent in this area. This public demand combined with lack of evidence often leads to adoption of untested therapies by NHS trusts or significant personal investment of patients trying to seek benefit outside of the NHS.

In the US Healing therapy is also known as 'Therapeutic touch'. Therapeutic touch is based on eastern philosophy and is based on the premise "*that spiritual aspects of oneself (the inner self) inform and guide the physical self, and may direct the conditions of ones life*" (p. 78, Krieger, 2002). The idea of therapeutic touch is to use touch to help influence an individual's vital energy field and in doing so identify problem areas, specifically the therapist is trained to "*pick up pain, fatigue, and other signs of energy imbalance*" (p. 93, Kunz & Krieger, 2004). Therapeutic touch usually takes place in a calm and peaceful area by a trained therapist.

Good Hope hospital has been offering such a therapy option for some time and a recent hospital audit was conducted of 180 patients (including 21 with IBS and IBD) in a gastroenterology clinic. Healing therapy was found to significantly improve symptoms in the three main outcomes of relaxation (z=-9.5, p<0.001), physical discomfort (z=-9.1, p<0.001) and well being (z=-9.4, p<0.001). These results are particularly impressive as each user received just one 20 minute healing session. Participants reported that they would have liked the treatment to be more readily available, e.g., at local GP surgeries and hospital clinics and this is consistent with the increasing use of complementary therapies by individuals throughout the UK. In order to confirm the effectiveness of healing therapy in the NHS, a high quality clinical trial is required.

1.3 Literature Search

To the best of the authors' knowledge, an electronic search of the medical literature revealed no clinical trials of healing therapy (including Reiki and therapeutic touch) in either IBS or IBD. There is evidence of healing therapy being beneficial in other conditions. A review of controlled trials evaluating the effect of therapeutic touch in chronic pain suffers (So et al., 2008) found significant benefits of therapeutic touch in reducing pain. There is also recent evidence of effects in vitro with healing therapy stimulating growth of human osteoblast cells and inducing differentiation and mineralization (Jhaveri et al., 2008). Other studies have not observed benefit in conditions such as diabetic neuropathy (Gillespie et al., 2007) or asthma (Cleland et al., 2006) demonstrating the need to evaluate efficacy in different disease and patient groups before adopting this therapeutic approach.

2. Study Objectives & Research Question

The aim of this study was to determine any benefits of healing therapy as an adjunct to conventional management on the symptoms of individuals with IBS and IBD.
The objectives of the study were:

- To determine the effect of healing therapy as an adjunct to conventional management compared to conventional management alone on physical symptoms of IBS and IBD
- To determine the effect of healing therapy as an adjunct to conventional management compared to conventional management alone on global improvement of patient identified primary symptoms in patients with IBS and IBD
- To determine the effect of healing therapy as an adjunct to conventional management compared to conventional management alone on quality of life scores in patients with IBS and IBD
- To examine the experiences of participants immediately following a course of healing therapy

3. Trial Design

3.1 Design

A mixed methods approach using a pragmatic randomised controlled trial design, where the intervention group receiving healing therapy was compared against a waiting list control group. A waiting list control was used to allow all participants to receive Healing Therapy. This was added to with qualitative interviews of participants at the end of the trial.

3.2 Intervention

Five weekly sessions of 30 minutes (as suggested by pilot work) of healing therapy (an energy therapy) (Ernst et al., 2008) was delivered by trained therapist at Good Hope hospital in addition to usual clinical management. Therapy was individually focussed (as in usual practice) and normally involved the participant (usually) being in a lying down position. The therapist commenced the treatment by starting from the head by placing their hands at a distance of about 10-12 inches above the body. If necessary they would very gently hold the sides of the head, shoulders, hand or feet (with permission) for short periods of about 2-3 minutes to enhance the healing treatment. Participants were asked to continue with prescribed medication and clinician advice in relation to the management of their condition.

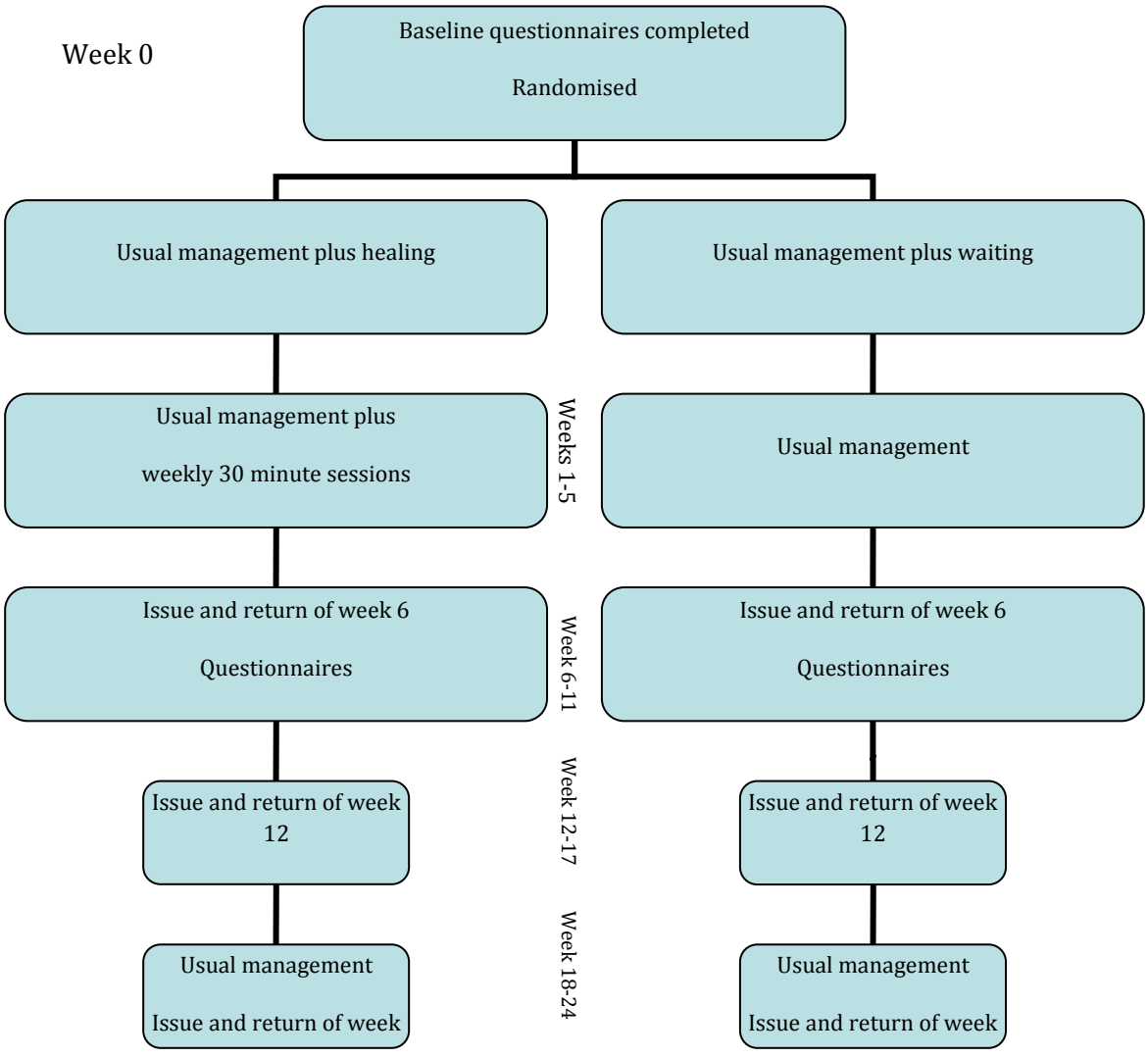
Healing Therapy was delivered by five practicing member of NFSH/The Healing Trust (THT). Although there are a number of energy healing approaches including, Reiki, Healing Touch or Therapeutic Touch, we chose a healer affiliated to THT, which was established in 1954 and is the largest healer membership organisation in the UK with over 4,500 members. The Healing Trust (www.thehealingtrust.org.uk) is a non-denominational charity that promotes safe and effective healing by providing a network of voluntary healing centres throughout the UK and offering a 'find a healer' service for those requiring a local healer. Membership requires satisfactory character references and students are subject to a minimum of 2 years training period, national standards of training by authorised trainers, personal mentoring by an existing member, testimonials and final panel assessment. All members are subject to a professional

Code of Conduct, disciplinary procedures and insurance. THT provides standards that NHS patients would expect of any practitioner offered to them via the Health Service.

3.3 Control

A waiting list control was used. Participants randomised to this arm of the trial were required to continue with prescribed medication and clinician advice in relation to the management of their condition. They were placed on a waiting list for therapy and offered healing sessions once 12 week outcome variables had been recorded.

Fig 1: Trail design



4. Trial Access & Participant Selection

4.1 Recruitment and randomisation

Individuals being treated at Good Hope hospital and Heartlands hospital gastroenterology outpatient department with a diagnosis of either IBS or IBD were eligible for inclusion. A total of 241 patients expressed an interest in taking part in the trial, of who 200 met the eligibility criteria. Participants were selected from all patients attending routine follow-up appointments who had completed initial investigations and had a diagnosis. In the case of individuals with IBS a clinician diagnosis was required. Patients with IBS were required to have both a clinician diagnosis on file and meet the ROME II criteria for IBS.

Gastroenterologists running outpatient clinics were asked to provide eligible patients with written information on the trial and individuals wanting to participate had to return a response slip to the research assistant who then contacted them to arrange a recruitment appointment. Recruitment appointments were held by the research assistant at the hospitals where assessment of eligibility, obtaining of informed consent and completion of baseline outcome measures and off-site randomisation was undertaken. This method ensured the research assistant responsible for recruitment remained blinded to study allocation until the participant is entered to the trial. The randomisation list was according to disease type (IBS or IBD) to ensure equal numbers of each diagnosis was generated.

4.2 Inclusion / Exclusion Criteria

All patients aged 18 and over who attended clinic with a clinician diagnosis of IBS (confirmed by ROME II criteria) or with a clinician diagnosis of ulcerative colitis were included in the trial. Forty one patients were excluded. These included those already receiving healing therapies (or having done so in the previous 6 months), patients unable to give fully informed consent due to learning disability, mental illness or other reason, and those unable to self complete outcome questionnaires. In line with clinical trial guidelines pregnant women were not included and individuals currently engaged in any other clinical trial or having completed such a trial in the previous 8 weeks were also excluded. Healing therapy was offered to all eligible patients ensuring equality of access, and minimising bias.

5. Outcomes

We collected both qualitative and quantitative data to ensure the full range of potential benefits are determined. All outcome measures were validated and suitable for the target population. The following outcomes were recorded at baseline, week 6, week 12 and week 24:

1. Primary Outcome: MYMOP (Measure Yourself Medical Outcomes Profile) (Patterson 1996). This is well validated individualised patient-centred instrument developed by researchers working in the study of alternative and complementary therapies. It enables patients to indicate 2 symptoms which are most significant to them. Patients also indicate an activity of daily living which is prevented or compromised by their health status and are asked to comment on general well-being. These four outcomes are scored on a scale of 0-6 with 0 being 'as good as it could be' and 6 being 'as bad as it could be'. A composite summary score can be calculated. The patient centred nature of this validated outcome measure fits with the proposed study and also allows for the different symptom profiles and experiences patients will have (both due to the range of different conditions which will be included in the study but also due to intra-person variation).

2. Secondary Outcome: Disease specific quality of life questionnaires: Quality of life was measured in both conditions using disease specific quality of life tools. Patients with IBS completed the IBS-QOL (Drossman et al., 2004; Patrick et al., 1998) and individuals with IBD completed the IBDQ (Guyatt et al.,1989, Love et al., 1992) for quantitative assessment.

The IBS-QOL is a widely used, and validated questionnaire to measure quality of life in IBS, which we have previous experience of using. It comprises 34 questions covering the following 8 domains : Dysphoria, Interference with Activity, Body Image, Health Worry, Food Avoidance, Social Reaction, Sexual, and Relationships.

The IBDQ is also widely used in clinical research and a UK version has been developed and validated (Cheung et al., 2000). It considers 30 questions and evaluates 5 subscales (Bowel symptoms (general), Bowel symptoms (bowel movement and use of facilities), Systemic symptoms, Emotional function, and Social function). The instrument produces separate dimension scores and a global IBDQ score with higher scores indicating a better quality of life.

3. Secondary Outcome Symptoms: Symptom measures help to measure the severity of the disease. Individuals with IBS were required to complete the Birmingham IBS symptom questionnaire a validated, reliable and reproducible measure of symptoms in IBS suitable for clinical trial use (Roalfe et al, 2008). Results produced dimension scores for pain, diarrhoea and constipation.

Patients with ulcerative colitis completed a modified version of the Simple Clinical Colitis Activity Index (SCCAI) (Walmsley et al, 1998). For patients with crohn's disease the fully validated modified version of Harvey-Bradshaw index (Harvey & Bradshaw, 1980) was used.

4. Qualitative data: The use of qualitative data was selected to have a primarily validating role for the quantitative methods (Pope and Mays, 2006). The purpose of the qualitative data was to interpret and explore changes occurring in individuals with IBS and IBD following treatment. 22 interviews were completed using a semi structured format which allowed the interviewer and interviewee to pursue ideas or responses in more detail (Britten, 2006). The pilot work identified several areas of perceived benefit by the participant and the research was able to give

more in-depth understanding of changes that patients experienced which are not normally measured by quantitative outcomes. The interview guide was based on the piloted research and previous related research and from group expertise. The interview guide was devised by an expert in qualitative research methods, consultant in complementary/integrated medicine, a consultant in gastroenterology, specialist in healing and an integrated medicine practitioner.

The sampling strategy was purposeful or judgement (Marshall, 1996) sample, that was based on accessing individuals presenting with the full range of scores from the IBS and IBD related scales. The total number of individuals selected was determined by data saturation (Pope et al., 2000) rather than a pre-identified number. Individual interviews took place within the hospital in a private area or room following the therapy session. Where required the interviews were arranged at a location more convenient for the individual participant. Two qualitative interviews were conducted, one following completion of the 5 healing treatments (post treatment) and then follow up interview at a 3 months post therapy. All interviews were conducted by an experienced qualitative interviewer. The interview data underwent preliminary analysis at around the 10th month of the study and continued up to the point that the research team collectively agreed that theoretical saturation had been achieved and no new information was being gathered. The research data collected included in-depth information on; perceived needs of individuals, the experience of therapy, perceived effects of intervention, exploration of individuals' perspectives of their experiences, understandings of their illness, and how these related to therapy.

6. Sample Size

The study was powered on the primary, all group outcome (MYMOP) although consideration of numbers of participants with IBS and IBD has also contributed to final sample size estimates. We calculated that ninety one individuals in each arm would enable identification of a 0.6 unit difference in MYMOP score change at the 5% significance level with 90% power (assuming a mean change of 1.14 units and SD of 1.38 (Abbot, 2001). Assuming a 10% loss to follow up a total of 100 participants in each arm were recruited.

7. Trial Schedule

The trial had originally been developed to be undertaken over a period of 24 months, plus 2 months at the start to finalise trial design protocol and obtain ethical approvals. However due to difficulties in participant recruitment the trial period was extended by an additional 7 months. This delay was essential to the success of the research outcomes and has allowed the study to be fully completed.

8. Data Analysis

8.1 Quantitative Data Analysis

Primary analyses were undertaken on 6 and 12 week data. All analyses were undertaken on an intention to treat basis. Needs and symptoms defined by patients in the MYMOP was presented using descriptive statistics. Irrespective of diagnosis a comparison was made between the Healing group verses Waiting list group. For all individuals change from baseline to week 6 and 12 was calculated and groups compared using parametric or non-parametric statistics as appropriate after testing for normality of data. Separate analyses were repeated on individuals with IBS and IBD to see if there was greater benefit accrued by one sub-group or other.

Symptom and quality of life data was similarly compared between groups but comparisons within disease groups was compared in the two (intervention and waiting list) IBS patient groups. Similar comparison was also carried out for the two IBD groups.

Per protocol analyses was undertaken where appropriate to allow exploration of benefit in individuals who are fully compliant with the therapy as defined in the protocol.

8.2 Qualitative Data Analysis

The use of semi structured interviews allowed us focus to the specific topic chosen and some flexibility for the participants to decide what is discussed. All interviews were digitally tape-recorded and the data was transcribed verbatim. The transcribed data was subjected to what Lieblich, Tuval-Mashiach and Zilber (1998) term a 'categorical-content analysis' to identify themes in the data. This type of analysis has been successful in previous research and is good at answering the salient issues of a particular group of respondents (Green & Thorogood, 2009). At certain points of this process the generated themes and categories were presented to relevant members of the steering group who acted in the role of a "critical friend" (Melia, 2000; Norris, 1997) and provide a theoretical sounding board to encourage reflection upon, and exploration of alternative explanations and interpretations as they emerged in relation to the data.

9. Consent & Confidentiality

To ensure appropriate consent processes the research assistant was trained up in consent procedures and GCP (Good clinical practice guidelines). Fully informed consent was obtained from all participants prior to randomisation. Exclusion criteria ensured individuals unable to comprehend information or lacking capacity to make an informed decision were not included. The role of the research assistant in negotiating consent removed any element of coercion which could have applied if carried out by the treating clinician. Participants were made aware that any decision they make would not affect their usual clinical care. They were also given sufficient time to discuss participation with friends and family prior to arranging a randomisation appointment and were made aware of their right to withdraw at any point without giving reason or impact on medical care. For every participant the gastroenterologist responsible was informed to ensure medical records are complete and patients are not recruited to further trials whilst this one is ongoing. Participants were informed that a record of their participation would be made on file.

All research data was maintained on a secure system in a password protected database and used only for study administration e.g. sending of study questionnaires. All hardcopy documentation and signed consent forms were housed in locked filing cabinets and were treated with the same level of protection as patient records. All data has been securely archived for 3 years post-publication for full audit purposes.

10. Dissemination & Academic Publications

To inform the participants of the trial outcomes a dissemination event was organised on the 21st January 2013 where a summaries of research outcomes were presented to immediate stakeholders. This was also used as an opportunity to thank participants for agreeing to take part in the trial.

At the time of writing this report a total of two main publications have been identified. One being a quantitative while the other is a qualitative paper. Both of these papers are presently being written up by the research team and we anticipate they will be submitted later this year (2013) to appropriate peer reviewed journals. Further an unexpected outcome is an additional paper comparing quality of life between IBS and IBD groups has also been prepared and submitted for publication. With each of these publications BIG Lottery will be acknowledged as the funding body. Once the papers are published a press release will be organised to endure wider dissemination of the research outcomes. Details of the final publications will be forwarded to BIG. Where appropriate, presentations will also be made at relevant conferences and meetings.

11. Conclusion

There is an increasing worldwide population trend to seek the use of complementary therapies (CT) particularly for chronic conditions. Most medical doctors are not knowledgeable of complementary therapies. When faced with a patient who is requesting for information on the use of CT for their condition most doctor's do not feel confident to offer such advice. With any research the aim is to contribute to the evidence base and make a difference to policy and practice. Due to the holistic person centred nature of CAM it has traditionally faced difficulties in developing relevant trial methodology and design to ensure that all of the relevant parameters are evaluated whilst also ensuring that the results stand up to rigor. This trial took into consideration these concerns and we believe will deliver results that are a comprehensive measure of the relevant outcomes and will add to the existing literature on CAM, healing therapy and the management of IBS and IBD.

Overall the project has achieved its aim to undertake a research trial to evaluate the effects of healing therapy in patients with IBS and IBD. Through the life of the trial there has been considerable interest from the media and other in the results, which has influenced the importance of having a successful completion and subsequent dissemination of research outcomes.

12. References

Abbot, N.C., Harkness, E. F., Stevinson, C., Marshall, F. P., Conn, D. A., & Ernst, E. (2001) Spiritual healing as a therapy for chronic pain: a randomised controlled trial. *Pain, 91*:78-89

Britten, N. (2006). Qualitative interviews. In Pope, C., & Mays, N. (Eds). *Qualitative research in health care (3rd ed)*. BMJ Books, Blackwell publishing.

Cheung, W-Y., Garratt, A. M., Russell, I. T., & Willaims, J. G. (2000). IBDQ- A British version of the inflammatory bowel disease questionnaire: development and validation. *Journal of Clinical Epidemiology, 53*: 297-306.

Cleland, J. A., , Price, D. B., Lee, A. J. Amanda J Lee, Gerard, S., & Sharma, A. (2006). A pragmatic, three-arm randomised controlled trial of spiritual healing for asthma in primary care. *British Journal of General Practice, 56*: 444-49.

Drossman, D. A., Li, Z., Andruzzi, E., Temple, R. D., Talley, N. J., Thompson, W. G., Whitehead, W. E, Janssens, J., Funch-Jensen, P., & Corazziari, E, et al. (1993). U.S. householder survey of functional gastrointestinal disorders. Prevalence, sociodemography, and health impact. *Digestive Diseases and Science, 38*:1569-80.

Drossman, D. A., Patrick, D. L., Whitehead, W. E., Toner, B. B., Diamant, N. E., Hu, Y., Jia, H., Bandiwala, S. I. (2004). Further validation of the IBS-QoL; a disease specific quality of life questionnaire. *The American Journal of Gastroenterology, 95*: 999-1007.

Ehlin, A. G., Montgomery, S. M., Ekbom, A., Pounder, R. E., & Wakefield, A. J. (2003). Prevalence of gastrointestinal diseases in two British national birth cohorts. *Gut, 52*:1117-21.

Ernst, E., Pittler, M.H., Wider, B., Boddy, K. (2008). *Oxford Handbook of Complementary Medicine*. Oxford University press, 2-3.

Feagan, B. G., Bala, M., Songkai, Y., Olson, A., Hanauer, S. (2005). Unemployment and disability in patients with moderately to severely active Crohn's disease. *Journal of Clinical Gastroenterology, 39*: 390-95.

Gillespie, E. A., Gillespie, B. W., & Stevens, M. J. (2007). Painful diabetic neuropathy: impact of an alternative approach. *Diabetes Care, 30*: 999-1001.

Green, J., & Thorogood, N. (2009). *Qualitative methods for health research (2nd Ed)*. Sage, London.

Guyatt, G., Mitchell, A., Irvine, E. J., Singer, J., Williams, N., Goodacre, R., & Tompkins, C. (1989). A new measure of health status for clinical trials in Inflammatory Bowel Disease. *Gastroenterology, 96*:804-810

Harvey, R. F., & Bradshaw, J. M. (1980). A simple index of crohn's-disease activity. *The Lancet, 315*: 514.

Hugin, A. P. S., Whorewell, P. J., Tack, J., Mearins, F. (2003). The prevalence, patterns and impact of irritable bowel syndrome: a international survey of 40000 subjects. *Ailment Pharmacological Therapy, 17*: 643-650.

Hungin, A. P., Whorwell, P. J., Tack, J., & Mearin, F. (2003). The prevalence, patterns and impact of irritable bowel syndrome: an international survey of 40,000 subjects. *Alimentment & Pharmacolocal Therapy, 17*: 643-50.

Izadi, H (2009). Perceived facilitators to physical activity in individuals with progressive neurological conditions; a focus group and questionnaire study. *The International Journal of Therapy and Research*. *January* Edition.

Jhaveri, A., Jhaveri, A., Walsh, S. J., Wang, Y., McCarthy, M., & Gronowicz, G. (2008). Therapeutic touch affects DNA synthesis and mineralization of human osteoblasts in culture. *Journal of Orthopedic Research*. 26: 1541-46.

Krieger, D. (2002) *Therapeutic touch*. Lantern books, New York, USA.

Kunz, D., Krieger, D. (2004). *The spiritual dimension of therapeutic touch*. Bear and Company: Vermont, USA.

Lieblich, A., Tuval-Mashlach, R., & Zilber, T (1998). *Narrative research*. London: Sage

Love, J. R., Jan, I . E., & Fredorak, R. N. (1992). Quality of life in inflammatory Bowel Disease. *Journal of Clinical Gastroenterology, 14*: 15-19

Marshall, M. N. (1996). Sampling for qualitative research. *Family Practice, 13*:522-525

Medical Resarch Council (2000). *A framework for the development and evaluation of RCTs for complex interventions to improve health*. London, MRC.

Melia, K. (2000). Conducting an interview. *Nurse Researcher, 7*: 75-89.

Norris, N. (1997). Error, Bias and Validity in Qualitative Research. *Educational Action Research, 5*:172-176.

O'Keefe, E. A., Talley, N. J., Zinsmeister, A. R., & Jacobsen, S. J. (1995). Bowel disorders impair functional status and quality of life in the elderly: a population-based study. *Journals of Gerontology Series A: Biological Sciences and Medical Sciences. 50*: M184-M189.

Pallis, A.G., Vlachonikolis, I. G., & Mouzas, I. A. (2002). Assessing health-related quality of life in patients with inflammatory bowel disease in Crete, Greece. *BMC Gastroenterology*, *2*:1

Paterson C. (1996). Measuring outcomes in primary care: a patient generated measure, MYMOP, compared with the SF-36 health survey. *British Medical Journal, 312*: 1016 – 1020

Patrick, D. L., Drossman, D. A., Frederick, I. O., Dicesare, J., Puder, K. L. (1998). Quality of life in persons with irritable bowel syndrome. Development and validation of a new measure. *Digestive Diseases and Sciences, 43*: 400-411.

Patterson, C. (1996). Measuring outcomes in primary care: a patient generated measure, MYMOP, compared with the SF-36 health survey. *British Medical Journal, 312*: 1016-1020

Pope, C., Mays, N. (2006). *Qualitative research in health care*. BMJ books, Blackwell Publishing, London.

Pope, C., Ziebland, S., & Mays, N. (2000). Qualitative research in health care analysing qualitative data. *British Medical Journal, 320*: 114-116.

Probert, C. S., Jayanthi, V., Hughes, A. O., Thompson, J. R., Wicks, A. C., & Mayberry, J. F. (1993). Prevalence and family risk of ulcerative colitis and Crohn's disease: an epidemiological study among Europeans and south Asians in Leicestershire. *Gut, 34*: 1547-51.

Riessman C. (2008). *Narrative methods for the human sciences*. London: Sage

Roalfe, A. K. (2008). Evaluation of the Birmingham IBS symptom questionnaire. *BMC Gastroneterology, 8*:30

Roberts L, Wilson S, Singh S, Roalfe A, & Greenfield S. (2006). Gut-directed hypnotherapy for irritable bowel syndrome: piloting a primary care-based randomised controlled trial. *British Journal of General Practice, 56*:115-121.

Rubin, D. T., Siegel, C. A., Kane, S. V., Binion, D. G., Panaccione, R., Dubinsky, M. C., Loftus, E. V., & Hopper, J. (2009). Impact of ulcerative colitis from patients' and physicians' perspectives: Results from the UC: NORMAL survey. *Inflammatory Bowel Disease, 15*: 581-88.

Rubin, G. P., Hungin, A. P. S., Kelly, P. J., & Ling, J. (2000). Inflammatory bowel disease: epidemiology and management in an English general practice population. *Alimentary Pharmacology & Therapeutics. 14*: 1553-59.

Seo, M., Okada, M., Yao, T., Okabe, N., Maeda, K., & Oh, K. (1995). Evaluation of disease activity in patients with moderately active ulcerative colitis: comparisons between a new activity index and Truelove and Witts classification (comments). American Journal of Gastroenterology, 90:1759–1763.

So, P. S., Y. Jiang, & Y. Qin. (2008). Touch therapies for pain relief in adults. *Cochrane Database for Systematic Reviews, 4*: CD006535.

Vidal, A., Gómez-Gil, E., Sans, M., Portella, M. J., Salamero, M., Piqué, & J. M., Panés, J. (2008). Health-related quality of life in inflammatory bowel disease patients: the role of psychopathology and personality. *Inflammatory Bowel Disease, 14*: 977-83.

Walmsley RS, Ayres RCS, Pounder RE, & Allan RN. A Simple Clinical Colitis Activity Index (1998). *Gut, 43:29-32*

Wilson, S., Roberts, L., Roalfe, A., & Bridge, P. (2004). Prevalence of irritable bowel syndrome: a community survey. *British Journal of General Practice, 54*: 495-502.