

Treating dyspepsia with acupuncture and homeopathy: reflections on a pilot study by researchers, practitioners and participants

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SUMMARY. Objectives: For people with dyspepsia who are receiving orthodox general practice care, what is the effect on outcome and on NHS costs of adding treatment by a choice of acupuncture or homeopathy? This paper describes and reflects upon a pilot study with user involvement. Design: A randomised pilot study. Patients chose between acupuncture and homeopathy and were then randomised to this preference or to the control group of normal GP care. Setting and participants: Sixty people with dyspepsia (≥ 2 weeks) presenting in one UK general practice were recruited in consultations and by letter to those on repeat prescriptions. There were few exclusion criteria. The homeopath and the acupuncturist treated the patient individually according to their normal practice for up to 6 months. After the trial there was a focus group for participants. Outcome measures: SF-36 health survey, Measure Yourself Medical Outcome Profile (MYMOP), and General Well-being Index (GWBI). Counts of prescriptions, consultations and referrals from practice computer records. Results: No trend or significant difference between the groups for clinical outcome or NHS costs. Major costs for the 6 months, mean (S.D.) cost per patient, were general practitioner consultations £8 (18), prescriptions £64 (73), acupuncture £175 (52), homeopathy £105 (33). Participants gave insights and suggestions which will inform the full trial design. Conclusions: Reflection on the pilot study data and experience by participants, treating practitioners and researchers led to modifications in the design and a sample size calculation. How to demonstrate individual responses to treatment remains a problem. © 2003 Elsevier Science Ltd. All rights reserved.

BACKGROUND

Dyspepsia is a very common illness¹ with high associated prescribing costs. In 1998, the NHS in England and Wales spent £522 million on prescriptions for H2 antagonists, proton pump inhibitors and antacids.² People consult homeopaths and acupuncturists for treatment of their dyspepsia but published research on such treatment is sparse. A literature search found no evidence, other than anecdotal re-

ports, relating to the treatment of dyspepsia with homeopathy. Sodipo studied the effect of 6 weeks of acupuncture in 14 patients with chronic dyspepsia,

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10 of whom had an endoscopically proven peptic ulcer at the start of the study.³ He demonstrated a highly significant reduction in gastric acid secretion and markedly reduced symptoms, and at follow-up 18 months later 7 of the 10 ulcer patients were still pain free. This effect on gastric acid secretion has since been confirmed by others^{4,5} but no further clinical trials have been published.

Our research question was *'For people with dyspepsia who are receiving orthodox general practice care, what is the effect on outcome and on NHS costs of adding treatment by a choice of acupuncture or homeopathy?'* We designed a randomised pilot study with a preference design. We also involved participants in the research process by including a patient generated outcome measure, sending all participants a leaflet detailing the results, and seeking feedback and views on future work in a focus group meeting.

This paper summarises the method and results of this study, describes the participant focus group discussion, and discusses in what ways such a pilot did and did not help our plans to answer the research question.

METHOD

The design was a pragmatic randomised trial incorporating patient preference for treatment with either acupuncture or homeopathy and a control group who receive normal GP care (Fig. 1). Ethical approval was received from the West Somerset Ethics Committee, and all participants gave written informed consent.

Setting and study sample

Sixty patients with dyspepsia presenting in one UK general practice were recruited by general practitioners (GPs) in routine consultations and by letter to those on repeat prescriptions for dyspepsia. A weekly computer search identified patients that may have been eligible and missed, and GPs contacted any such patients by letter. Dyspepsia was defined as 'upper abdominal or retro sternal pain, discomfort, heartburn, nausea, vomiting or other symptom considered to originate from the proximal alimentary tract'⁶ and all patients were included except those with symptoms of less than 2 weeks, those under 16 years, pregnant, or unable to attend the surgery for treatment; those who required specialist referral for investigation or treatment of serious disease; and those who had received complementary therapy for the presenting condition in the last 3 months. Practice guidelines on dyspepsia, gastroscopy and triple therapy were followed for all patients before considering entry into the study. Recruitment took place in 1999 and took 8 months.

Randomisation

Participants expressed their preference for homeopathy or acupuncture, and if they had no preference

they were randomised to one. All patients were then randomised to receive their preference or be in the control group receiving normal GP care. Randomisation was in blocks of four, and serially numbered opaque envelopes were used to achieve concealed allocation. Randomisation between receiving the intervention or receiving the control normal GP care was in a 2:1 ratio.

Treatment and outcome measures

All treatment in the trial was free. The homeopath and the acupuncturist treated the patient individually according to the normal custom of that practitioner for up to 6 months. The professional (non-medical) homeopath practised classical homeopathy and the professional (non-medical) acupuncturist used acupuncture within the system of Chinese medicine. Participants completed outcome questionnaires SF-36 health survey,⁷ Measure Yourself Medical Outcome Profile (MYMOP)⁸ and General Well-being Index (GWBI)⁹⁻¹¹ at baseline, 6 weeks, 4 and 6 months. Counts of prescriptions, consultations and referrals on the practice computer records were used to calculate NHS costs for the 6 months of the trial. Twelve months after finishing the trial patients were posted a MYMOP questionnaire and prescription details were collected from the computer. Costs are at 1998/1999 prices¹² with drug costs from the British National Formulary of March 1999. Analysis was on an intention to treat basis.

Patient's 'out of pocket' costs were also collected, but are not reported in this paper.

RESULTS

Figure 1 is a trial profile summarising participant recruitment and flow, numbers and timing of randomisation assignment, and outcome measurements and response rates for each randomised group. The preference design resulted in most people electing to choose a treatment group, only 8 of the 60 having no preference and being randomised. This choice was evenly split between homeopathy and acupuncture.

Participants characteristics

The baseline characteristics of the participants in the three groups are shown in Table 1, and there are no major differences between the groups. There was no difference between the MYMOP score of those recruited by their GP and those recruited from repeat prescriptions (mean score 3.36 and 3.05, respectively). The baseline SF-36 scores of the study sample, compared to those published for a normal population, show worse physical health and pain but little difference in the emotional and mental health dimensions. Computer records showed the diagnostic category of the 60 patients was reflux oesophagitis/acid reflux/hiatus hernia for 32 patients,

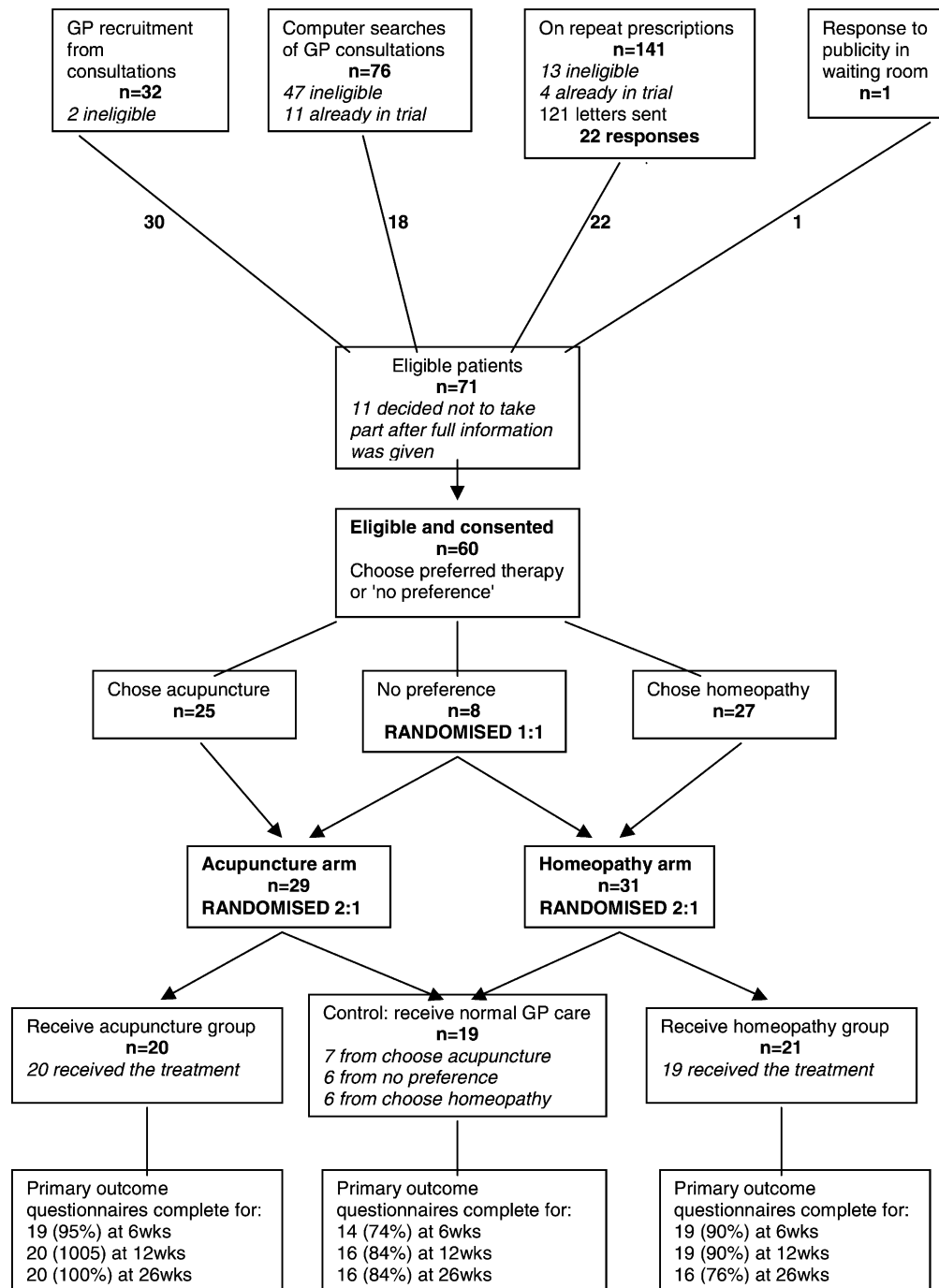


Fig. 1 Trial flow diagram.

peptic ulcer for 4, and dyspepsia (presumed functional) for 24 patients. Endoscopy or barium meals had been performed at some time on 33 patients. During the 6 months before recruitment, 31 of the patients had received two or more prescriptions for acid reducing drugs (excluding antacids).

Clinical outcome

The primary outcomes were specified as the changes in MYMOP and GWBI score at 6 weeks (Table 2). These change scores are characterised by small mean changes and wide confidence intervals, and an unpaired *t*-test of the mean change in the acupuncture

group versus control, and the homeopathy group versus control showed no significant difference between groups, a result confirmed by an analysis of co-variance. Mean MYMOP change scores at 12 weeks, 6 and 18 months showed all three groups improving up to 6 months and then reaching a plateau and no significant difference or major trend between the groups. The SF-36 and GWBI scores showed little change over time.

Dyspepsia related NHS costs

The major dyspepsia related NHS primary care costs are those of general practitioner consultations and

	All patients (n = 60)	Acupuncture group (n = 20)	Homeopathy group (n = 21)	Control group (n = 19)
Age, mean (range)	58 (29–84)	63 (33–84)	56 (29–79)	54 (30–78)
Sex (M:F)	22:38	7:13	6:15	9:10
Numbers with symptoms for ^a				
>1 year	51	19	18	14
12–51 weeks	8	1	2	5
2–12 weeks	1	1	0	0
Reduction/avoidance of medication ^a				
Not important	7	2	3	2
A bit important	15	7	5	3
Very important	38	11	13	14
Initial MYMOP score, mean (S.D.)	3.25 (1.16)	2.85 (1.07)	3.57 (1.22)	3.31 (1.11)
Initial GWBI score, mean (S.D.)	52 (13.3)	50.5 (11.9)	54.3 (15.0)	50.3 (13.3)
Initial SF-36 score	Mean (S.D.)	Mean	Mean	Mean
Physical functioning	68.75 (25.72)	62.75	71.90	71.57
Role, physical	56.25 (37.57)	50	50	69.73
Bodily pain	49.70 (23.83)	47	51.04	51.05
General health	62.15 (21.64)	63.8	60	62.68
Vitality	53.7 (20.59)	49.85	55.23	56.05
Social functioning	74.1 (28.53)	80.75	67.52	74.36
Role, emotional	75.32 (33.97)	83.40	70	72.27
Mental health	72.66 (16.73)	72.60	69.71	76

^a Duration of symptoms and medication views are part of the MYMOP questionnaire.

prescriptions, which amount to a mean (S.D.) cost per patient for the 6 months of the trial of £8 (18) and £64 (73), respectively (Table 3). There was wide individual variation and no statistical difference between the groups. Mean drug costs per patient for the whole 18 months after recruitment were similar in the three groups but suggested there may be a temporary increase in costs in the treatment groups for the 6 months immediately after the end of the trial treatment period. Referrals to hospital for dyspepsia in the trial 6 months were rare. Two individuals had been seen and costing the endoscopy at £305,¹³ and the outpatient visits at £60¹² the total secondary care costs for the whole sample over 6 months were £850.

Cost of acupuncture and homeopathy treatment

All 20 patients randomised to acupuncture started treatment and they had a mean of 11 treatments each (range 4–18). The patients randomised to homeopa-

thy had a mean of 4 treatments (range 0–8), two dropped out before seeing the homeopath. Complementary practitioner costs are taken as their normal private fees charged elsewhere in the vicinity which would therefore include an allowance for rent, reception, insurance, etc. and are £30 an hour. Homeopathic prescriptions averaged three per patient with a mean cost of £17.78 per patient. Total mean (S.D.) cost of acupuncture per patient was £175 (52) and total mean cost of homeopathy per patient was £105 (33).

REFLECTIONS OF PARTICIPANTS, PRACTITIONERS AND RESEARCHERS

Feedback from participants

The 60 participants were sent a leaflet summarising the study results and an invitation to attend an evening meeting at the surgery to hear more and

	Mean (S.D.) change in scores at 6 weeks	Mean difference (95% confidence intervals) between control group and treatment group
Changes in scores at 6 weeks of MYMOP (a seven point scale, a positive change is improvement)		
Control group, n = 15	0.53 (1.76)	
Acupuncture group, n = 19	0.28 (1.34)	−0.24 (−1.33, 0.83)
Homeopathy group, n = 19	0.44 (1.41)	−0.09 (−1.19, 1.01)
Changes in scores at 6 weeks of GWBI (scale from 22 to 110, positive change being improvement)		
Control group, n = 14	2.14 (14.33)	
Acupuncture group, n = 19	0.05 (7.78)	−2.09 (−10.0, 5.82)
Homeopathy group, n = 19	−1.63 (9.22)	−3.77 (−12.13, 4.58)

Table 3 Dyspepsia related, primary care NHS costs for 6 months after randomisation

	Mean	S.D.
Number of GP consultations per patient		
Acupuncture group	0.8	1.75
Homeopathy group	0.09	0.31
Control group	0.53	1.07
Costs of GP consultations per patient in £ ^a		
Acupuncture group	13.6	29.5
Homeopathy group	1.62	5.11
Control group	8.95	18.25
Number of prescriptions per patient		
Acupuncture group	2.85	2.21
Homeopathy group	2.52	3.04
Control group	3.16	2.99
Costs of prescribed drugs per patient in £ ^b		
Puncture group	70	68.66
Homeopathy group	57.64	74.18
Control group	63.98	79.15
Total NHS primary care costs per patient in £ ^c		
Acupuncture group	85	81.69
Homeopathy group	59.26	74.83
Control group	73.39	84.39

Complete data for each group: acupuncture group = 20, homeopathy group = 21, control group = 19.

^a Costed at £17 per consultation, telephone consultations included.

^b Costed at March 1999 BNF prices.

^c Includes nurse consultations, total of four in whole sample, costed at £8.80.

give us their feedback. Eight people, three men and five women, attended the meeting and a further three people gave written feedback in letters. An experienced social science researcher and facilitator led the group, and topics discussed included the recruitment process, information received, randomisation, outcome measures, the organisation of treatment, and ideas for how future trials could be improved. The treatment effects experienced by the individuals who attended the group were not systematically discussed or analysed, although they were talked about in relation to the above topics. Two GPs, the research administrator, the research assistant, and the acupuncturist attended as observers and to answer questions. Participants joined in the discussion with interest and the small numbers and expert facilitation allowed everyone to speak freely. The meeting lasted about 2 hours and was audio-taped. None of the people attending the meeting were from the control group of the trial and subsequently the facilitator carried out individual interviews with two of this group. Notes made at the time of the meeting, and from the taped meeting and interviews, were summarised by one researcher, and subsequently discussed by the research team members who had attended the meeting. The main points to emerge from the meeting, interviews and letters were:

- Participants were very pleased that 'their' practice was taking part in research, and saw it as a sign of good quality care. They were grateful for a chance to take part in the research and were motivated by altruistic as well as personal reasons.
- Participants were pleased to be involved in the meeting but had not appreciated how valuable their own views were to us nor that most of the meeting would be spent eliciting them. They suggested the letter of invitation could have stressed this more.
- Most, but not all, of the participants had some interest in complementary medicine before the trial and this prior knowledge made their choice of therapy an easy one.
- There were no criticisms of the recruitment, consent and initial data collection aspects of the trial, but several people wanted more information about the likely effects of the first treatment, especially exacerbation of symptoms. There were problems reported with the organisation of the homeopathy arm of the trial and it was suggested that we should more closely monitor the treatment aspects of future trials.
- Participants were concerned that data collection was not detailed enough and not carried on for long enough. For example, as some of them had episodic symptoms they would have liked to complete diary cards every week. However, they agreed that they may represent the keenest of participants. There was a useful discussion about length of treatment and follow-up in relation to resources available and a year or 18 months of treatment was regarded as the minimum for a fair assessment of its value.
- Most people were keen to reduce their prescribed medication and anticipated that this would indeed happen if the complementary treatment relieved symptoms.

- A few people had gained benefit from going on diets of various kinds, and would have liked dietary advice to be included in the package of care. Provision of standard dietary advice for all participants in a future trial may be beneficial.
- The two control group members who were interviewed at home had experienced very mild symptoms throughout the study but had been happy to take part for altruistic reasons.

Reflections of practitioners

Discussion with the two treating practitioners elicited the following problems:

- Some patients had very minimal symptoms to start with, making improvement difficult, and for some patients dyspepsia was not the main problem because of other more serious and symptomatic health and life problems.
- These patients having free treatment were more likely to request continuation of treatment than their normal private clientele even when effects were small.
- Most people had a long history of dyspepsia and might require occasional maintenance treatment, in the same way as they might require long-term drug treatment.

Reflections of researchers: what did we learn, what improvements in design can we make, and what problems remain?

Recruitment

The intensive recruitment strategy was very successful in reaching target numbers, and in recruiting a sample that was representative of all patients presenting with dyspepsia in primary care. The weekly computer search for missed opportunities not only increased numbers, but it instilled into GPs that there was really 'no escape' from the task! A single letter to 141 patients on repeat prescriptions generated 22 eligible patients with the same baseline MYMOP scores as those recruited from attenders, which confirms Johannessen's findings that patients taking H2 antagonists and proton pump inhibitors remained symptomatic,¹⁴ and validates using both methods of recruitment in a further trial. This high recruitment rate, the fact that only two patients did not begin their therapy, and the feedback from participants suggests that the choice of the two complementary therapies was popular amongst patients.

Measuring treatment effects

The study highlighted the difficulty in striking a balance between choosing a sample which is representative of primary care and therefore provides results which can be transferred back to that setting, and choosing a sample which maximises the expected treatment effect so that it can be experi-

mentally demonstrated. We recognised two factors which increased the 'background noise' and thereby make the measurement of the 'signal' of any treatment effects difficult. Firstly the heterogeneity of the study sample, and secondly the low intensity and high variability of symptoms.

The heterogeneous study population, maximised by the intensive recruitment strategy, few exclusion criteria and the provision of choice between acupuncture and homeopathy, included a wide variety of patients, many of whom had many other diseases being treated by a variety of medications. The problem with this was, as expected, the wide range of change scores and confidence intervals. A full scale trial may need to exclude people who are taking more than three or four other regular drugs. The low intensity and high variability of symptoms was also demonstrated in Johannessen's descriptive study of patients waiting for endoscopy.¹⁴ The outcome measures used were completed to a high standard by participants and high response rates were obtained. MYMOP was the most responsive and the SF-36 was useful in providing a health status profile of the study sample. Neither the SF-36 nor the GWBI detected the improvement in all groups shown by the MYMOP scores. The only validated condition specific measure for dyspepsia would not be suitable for the patients in this study as it is developed for those with peptic ulcers.¹⁵ Participants favoured recording their symptoms in a diary format, which would overcome the high variability of symptoms, if high response rates could be maintained. The low intensity of symptoms could be overcome by recording symptoms for a baseline period and setting an eligibility level.

A sample size calculation made on MYMOP scores suggests that a full scale trial would require 60 in each group. (The calculation specified a difference of 1 in mean MYMOP scores, and assumed a S.D. of 1.5 as suggested by Table 2, 80% power and 0.05 significance level, and resulted in $n = 37$ per group. Thus a sample size of 60 per group allows for people dropping out of the 12-month follow-up.)

Length of treatment, follow-up and relation to costs

The MYMOP results plotted over time, and the feedback from participants, suggests that any treatment effect will be slow and prolonged. Both the treatment period and the follow-up should therefore be longer, and a year may be the most practical choice. The follow-up period is also extremely relevant to costs. This pilot confirmed that prescription and consultation numbers and costs can be collected from the practice computer, and provides good data on the extent, and the variability, of these, as well as the cost of the complementary therapies. Some monitoring of the process and outcome of the complementary treatment during this period will be required with a degree of rationing of treatment sessions to maximise

efficiency. In order to make any meaningful conclusion about the relationship of short-term costs of extra treatment to long-term costs of a chronic illness, especially repeat prescribing costs, an extended follow-up of prescribing costs may be necessary. Differences in secondary care costs, which in the pilot were rare but large, would need a larger sample size to evaluate.

Unanswered questions: how to demonstrate individual response to treatment

The orthodox and complementary practitioners involved in the clinical care of the study patients were struck by the dramatic improvement in a few individuals who had a long history of dyspepsia, apparently in response to acupuncture or homeopathy treatment. The wide distribution of the MYMOP change scores at 6 weeks (ranging from +3 to -2 on a seven point scale) and 26 weeks (range +4 to -3) confirm this very individual change in symptoms in all three groups. The traditional presentation of results as means does not demonstrate this individual response, nor does it help to answer such vital questions as 'how can we predict who will benefit from what intervention?' and 'do some people respond to drugs, some to acupuncture and some to homeopathy?' In a full trial, qualitative methods could be used to understand something of people's experiences of their illness and its treatment and how this relates to the quantitative results. The use of a cross-over design and *n*-of-1 trials are other designs to consider, but are problematic in therapies such as acupuncture and homeopathy where long lasting treatment effects are anticipated by practitioners. Whilst we are aware of the wider debate about how to relate the results of randomised trials to individual patients, our involvement in this pilot study has brought the problem sharply into focus.

CONCLUSIONS

This pilot study provides high quality data on preferences, number and costs of treatments, outcome scores and NHS costs. As would be expected from such a small study, it does not show a significant difference between the groups for clinical outcome or NHS costs, nor does it show any trends. Major costs for the 6 months, as mean (S.D.) cost per patient, were general practitioner consultations, £8 (18), prescriptions £64 (73), acupuncture £175 (52) and homeopathy £105 (33). Eighteen months after being offered normal GP care, with or without the addition of acupuncture or homeopathy, this group of 60 patients had a mean MYMOP score of over

2 (on a scale of 0-6) and have mean drug costs of £65 (78) for the last 6-month period. Systematic reflection on the method and results of the study by participants, practitioners and researchers resulted in some important modifications to the planned design for a full-scale study.

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