

# A pragmatic, three-arm randomised controlled trial of spiritual healing for asthma in primary care

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## ABSTRACT

### Background

Well-designed trials are required to assess if complementary and alternative medicine (CAM) is effective.

### Aim

This study assessed the effectiveness of spiritual healing for asthma.

### Design of study

Randomised, placebo-controlled trial.

### Setting

Aberdeen, Scotland.

### Method

This was a single-blind, three-armed randomised, controlled trial of spiritual healing for asthma, comparing the effectiveness of five sessions of spiritual healing with placebo (delivered by an actor), and with a control group receiving normal care only. The primary outcome measure was the Juniper Asthma Quality of Life Questionnaire (AQLQ). Secondary outcomes were forced expiratory flow in one second (FEV1), peak expiratory flow (PEF), HADS (Hospital Anxiety Depression Scale), SF-36 and MYMOP (Measure Yourself Medical Outcome Profile). Baseline and follow-up data were collected.

### Results

Eighty-eight adult patients receiving pharmacological treatment for asthma participated. AQLQ scores improved significantly from baseline and the end of treatment in all groups (spiritual healing  $P = 0.008$ ; 'sham' healing  $P = 0.001$  and control  $P = 0.01$ ) but there was no significant difference between groups ( $P = 0.57$ ). These improvements were maintained at follow-up 1 for two of the groups (spiritual healing  $P = 0.016$ ; sham healing  $P = 0.001$  and control  $P = 0.09$ ) but none of the groups showed an improvement at follow-up 2 (spiritual healing  $P = 0.161$ ; sham healing  $P = 0.016$  and control  $P = 0.11$ ). Similar proportions of patients in each group showed a clinically important improvement in AQLQ score. Analysis of AQLQ scores at end of treatment and both follow-up periods indicated no significance between group differences. No consistent changes were seen in secondary outcome measures, possibly due to the small sample size.

### Conclusion

Spiritual healing does not appear to have any specific affect on patient asthma related quality of life.

### Keywords

asthma; complementary medicine; quality of life; randomised controlled trial.

## INTRODUCTION

The costs of poorly controlled asthma are high.<sup>1</sup> Many patients with asthma experience significant morbidity and lifestyle limitation, and tolerate a higher rate of symptoms than would be recommended by guidelines.<sup>1-3</sup> There is increasing interest in factors that may facilitate the management of asthma, reduce the requirement for pharmacotherapy and help patients achieve a higher level of control, thus improving quality of life and activity levels, as well as reducing the emotional burden of disease.<sup>4</sup>

The uptake of complementary, or alternative, medicine by the public is high and increasing,<sup>5</sup> reflecting that patients are progressively expressing their preferences for treatments.<sup>6</sup> Complementary and alternative medicine (CAM) has become increasingly topical in respiratory medicine.<sup>7</sup> However, the British Thoracic Society (BTS)/Scottish Intercollegiate Guidelines Network (SIGN) guidelines<sup>8</sup> state that currently available evidence does not allow any evidence-based recommendations for the use of herbal and traditional Chinese medicine, ionisers, acupuncture, homeopathy or hypnosis for asthma. It is clear that the public, who seem to be turning to alternative

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therapies as a way of exerting their own control over their own disease,<sup>6</sup> are accepting of its benefits in the absence of conclusive evidence. However, only if rigorous, scientific standards are applied to the evaluation of CAM, and conclusive evidence of effectiveness sought, will the medical profession be encouraged to adopt CAM as standard health care.<sup>9</sup> Well-controlled studies with outcome measures other than lung function are required to provide evidence of the effectiveness of CAM.

Spiritual healing is a non-invasive complementary therapy that has been available in the UK since 1977. Spiritual healing has been used in the treatment of restricted neck movement,<sup>10</sup> chronic pain<sup>11</sup> and anxiety.<sup>12</sup> A systematic review of distant healing (prayer, mental healing, therapeutic touch or spiritual healing) found that approximately 57% of the trials reviewed showed a positive treatment effect, concluding that the evidence thus far merits further study.<sup>13</sup> There is some evidence of positive benefits of spiritual healing in quality of life, as well as in physical dimensions.<sup>14,15</sup> However, these studies lack control groups or have other methodological limitations and, thus, their conclusions are limited. Spiritual healing has not been evaluated in reference to its effectiveness in patients with asthma.

The aim of this study was to evaluate the effectiveness of spiritual healing in asthma in a three-arm (control, 'sham' and spiritual healing) pragmatic randomised controlled trial.

### Design

This was a randomised, controlled trial of spiritual healing in asthma. The study was pragmatic, single-blind and three-armed, comparing the effectiveness of five sessions of spiritual healing with placebo, or sham treatment. The control group received normal care plus nurse-collected outcome data at the same intervals. Clinical, psychological and quality of life outcomes were compared across groups. Baseline and follow-up data were collected.

Questionnaire data was collected from all participants at week 0 (baseline 1) and week 2 (baseline 2) in order to resolve the issues of spontaneous improvement in health status.<sup>15</sup> Data was then collected in week 4 (first weekly treatment), week 8 (last [fifth] treatment, T5), week 12 (short-term follow-up 1) and week 26 (long-term follow-up 2).

### Recruitment

The study was conducted in Aberdeen, Scotland. Subjects were responders to press advertisements and advertisements in GP surgeries. Eligibility criteria were an age >18 years, a diagnosis of asthma for more than 1 year, receiving pharmacological

## How this fits in

Patients are turning to complementary and alternative medicine (CAM) in the absence of evidence of effectiveness. There are few rigorous studies of CAM for asthma and the BTS/SIGN guidelines currently state that there is insufficient evidence for provision of homeopathy, acupuncture, etc, for asthma. This randomised controlled trial of spiritual healing for asthma did not find any evidence for effectiveness, indicating that this particular CAM should not be currently recommended. However, our results suggest that additional input from a professional interested in the patient's asthma may lead to improvements in patient-reported quality of life. These gains are not maintained once additional contact ends.

treatment for asthma, and patient-reported asthma confirmed by the patient's GP. Participants continued with their individually prescribed treatment as usual with spiritual healing as an additional treatment. Permission for inclusion in the study was sought from the patient's GP.

Participants were randomised into one of the three groups, stratified by sex and age. An independent researcher was given a list of consenting patients and, using computer-generated random numbers in blocks of three, allocated a group to each patient. Participants were blind as to whether or not they were receiving spiritual healing or sham healing. All participants had their FEV1 and PEF measured by an independent nurse, blinded to treatment and control groupings of the participants, at each time point in the study. Questionnaires were completed at these points, and on each visit for treatment and data collection. All three groups provided outcome data at the same intervals.

### Treatment

The treatment offered was 'spiritual healing' defined as:

*'... the use of prayer, healing, meditation and laying on of hands, by the "healer" with the intention of promoting self-healing, a sense of wellbeing, peace and restoration of the balance of body, mind and spirit of the participant' (National Federation of Spiritual Healers, <http://www.nfsh.org.uk/>).*

Treatment and measurement were undertaken at a private CAM suite in central Aberdeen. A single healer with 16 years experience and a diploma in spiritual healing undertook the healing sessions. The healer used the same verbal explanation and guided visualisation for all cases. The procedure in the placebo group was identical other than the intervention (sham healing) was delivered by an actor who had been trained by the healer to duplicate his actions. Sessions lasted for 40 minutes.

**Table 1. Patient demographic and outcome measures at baseline 2: values are mean (SD), *n* (%) or median (IQR).**

| Patient characteristics and outcomes | Control<br>( <i>n</i> = 31) | Spiritual healing<br>( <i>n</i> = 27) | Sham healing<br>( <i>n</i> = 30) |
|--------------------------------------|-----------------------------|---------------------------------------|----------------------------------|
| Age (years)                          |                             |                                       |                                  |
| Mean                                 | 49.0                        | 52.0                                  | 37.78                            |
| SD (range)                           | 12.74 (40–55)               | 14.1 (40–61)                          | 15.3 (51–64)                     |
| Sex                                  |                             |                                       |                                  |
| Male                                 | 8 (25.8)                    | 9 (33.3)                              | 9 (30)                           |
| Female                               | 23 (74.2)                   | 18 (66.7)                             | 21 (70)                          |
| Previous spiritual healing           |                             |                                       |                                  |
| No                                   | 24 (77.4)                   | 20 (74.1)                             | 24 (80)                          |
| Yes                                  | 1 (3.2)                     | 5 (18.5)                              | 4 (13.3)                         |
| Smoker                               | 24 (77.4)                   | 19 (70.4)                             | 25 (83.3)                        |
| Non-smoker                           | 7 (22.6)                    | 8 (29.6)                              | 5 (16.7)                         |
| AQLQ <sup>a</sup>                    | 4.30 (3.46–5.49)            | 5.15 (3.77–5.79)                      | 4.83 (4.13–6.01)                 |
| HAD <sup>b</sup> : Dep               | 4 (12.9)                    | 8 (29.6)                              | 3 (10.0)                         |
| HAD <sup>c</sup> : Anx               | 9 (29.0)                    | 12 (44.4)                             | 11 (36.7)                        |
| MYMOP <sup>d</sup>                   | 4.00 (3.50–5.25)            | 4.50 (3.63–5.00)                      | 3.50 (3.00–4.63)                 |
| SF-36 General Health                 | 16.4 (12–19.4)              | 14.0 (11–19.4)                        | 14.4 (12–18.65)                  |
| FEV1                                 | 1.89 (1.32–2.63)            | 2.1 (1.44–2.87)                       | 2.34 (1.66–3.12)                 |
| PEF                                  | 303 (196–421)               | 321 (204–443)                         | 349 (309–448)                    |

<sup>a</sup>Asthma Mini Quality of Life Questionnaire. <sup>b</sup>Hospital Anxiety and Depression Scale. (Depression sub-scale). Numbers reaching 'caseness'. <sup>c</sup>Hospital Anxiety and Depression Scale (Anxiety sub-scale). Numbers reaching 'caseness'. <sup>d</sup>Measure Yourself Medical Outcome Profile. FEV1 = Forced expiratory volume in 1 second. PEF = Peak expiratory flow.

### Outcome measures

The primary outcome measure was the Juniper Asthma Quality of Life Questionnaire (AQLQ)<sup>16</sup> where,

based on the results of previous studies examining asthma management, a clinically relevant improvement is an increase of more than or equal to 0.5 in individual AQLQ mean scores. The primary time points for comparison were time of randomisation (baseline 2) and end of treatment (T5). Based on 95% confidence, 90% power and a clinically relevant (within and between group) 0.5 increase on the Juniper AQLQ<sup>16</sup> using a standard deviation of change in overall AQLQ of 0.64 reported by Juniper *et al*, pre-study study power calculation indicated that a sample size of 35 was required per group.

Secondary outcome measures were selected in order to reflect the wider dimensions of the impact of asthma:

- The SF-36 General Health Questionnaire:<sup>17</sup> a well-validated measure of general health used in previous studies of spiritual healing.<sup>10</sup>
- The Hospital Anxiety and Depression Scale (HADS):<sup>18</sup> a well-validated, widely-used measure of mental health status also used in previous studies of spiritual healing.<sup>10</sup>
- The Measure Yourself Medical Outcome Profile (MYMOP):<sup>19</sup> this assesses patients' perceptions of their current health status and medication use. It has been used in studies of complementary medicine in UK primary care.<sup>20</sup>
- Forced expiratory volume in 1 second (FEV1).
- Peak expiratory flow (PEF).

Basic demographic data, information on other treatments and any previous experience of spiritual healing was also collected.

### Analysis

SPSS for Windows was used for data processing and analysis (SPSS for Windows, SPSS Inc., Chicago, IL.). The statistical analysis was performed. During analysis, the study groups were anonymised in order to minimise biased reporting. Groups were examined at baseline 2 for demographic characteristics, clinical status and for scores on the questionnaire measures. Changes from baseline 2 in outcome measures to end of treatment (T5) and both follow-ups, within each of the three groups, were assessed using either McNemar's test or paired *t*-tests where appropriate, depending on whether categorical or continuous. Analysis of covariance was used to examine between group differences in asthma quality of life at follow-up 1 and follow-up 2 after adjustment for baseline 2 differences. An intention to treat analysis was performed throughout. For primary outcomes, a *P*-value of 0.05 was used to denote statistical significance, while a value of 0.01 was used for secondary outcomes.

**Table 2. Patients for whom quality of life had improved, been maintained or deteriorated at the end of treatment (T5), follow-up 1 and follow-up 2.<sup>a</sup>**

| AQLQ mean score                       | Group             |              |           |
|---------------------------------------|-------------------|--------------|-----------|
|                                       | Spiritual healing | Sham healing | Control   |
| Improvement change $\geq 0.5$         |                   |              |           |
| End of treatment                      | 42.0 (10)         | 43.0 (12)    | 28.6 (8)  |
| Follow up 1                           | 41.0 (9)          | 61.0 (14)    | 40.9 (9)  |
| Follow up 2                           | 38.0 (8)          | 32.0 (9)     | 34.6 (9)  |
| Maintenance change $> -0.5$ to $<0.5$ |                   |              |           |
| End of treatment                      | 50.0 (12)         | 50.0 (14)    | 60.7 (17) |
| Follow up 1                           | 50.0 (11)         | 26.0 (6)     | 40.9 (9)  |
| Follow up 2                           | 38 (8)            | 54.0 (15)    | 46.2 (12) |
| Deterioration change $\geq -0.5$      |                   |              |           |
| End of treatment                      | 8.0 (2)           | 7.0 (2)      | 10.7 (3)  |
| Follow up 1                           | 9.0 (2)           | 13.0 (3)     | 18.2 (4)  |
| Follow up 2                           | 24.0 (5)          | 14.0 (4)     | 19.2 (5)  |
| Missing data                          |                   |              |           |
| End of treatment                      | 11.0 (3)          | 6.0 (2)      | 9.7 (3)   |
| Follow-up 1                           | 19 (5)            | 23 (7)       | 29.0 (9)  |
| Follow-up 2                           | 22 (6)            | 7.0 (2)      | 16.1 (5)  |
| Net improvers <sup>b</sup>            |                   |              |           |
| End of treatment                      | 34.0              | 36.0         | 17.9      |
| Follow-up 1                           | 32.0              | 48.0         | 22.7      |
| Follow-up 2                           | 14.0              | 18.0         | 15.4      |

<sup>a</sup>Data are presented as %. Analysis used the mean changes from baseline two. <sup>b</sup>% showing improvement minus % showing deterioration. AQLQ = Asthma Quality of Life Questionnaire.

## RESULTS

Recruitment took place between October 2001 and October 2003. Three hundred and nine patients responded to the study advertisements of whom 286 were eligible. Eleven were ruled out as possible participants by their GP. 101 patients attended baseline 1: and 93 attended baseline 2. Ninety-two patients were randomised. Four dropped out after T1 and thus were not included in the current analysis.

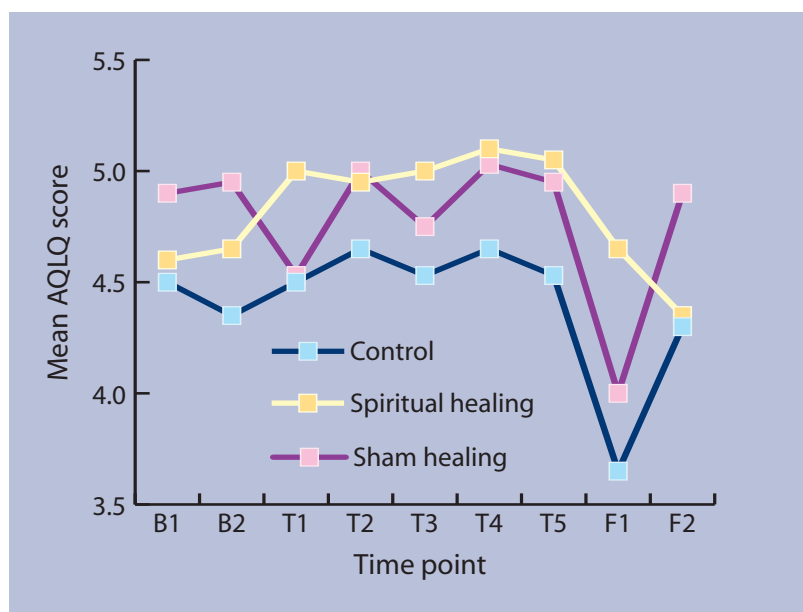
Groups appeared well matched in terms of age, sex, whether or not they had previous experience of spiritual healing, smoking status, or clinical and health outcome measures at baseline (Table 1).

### Mean change in AQLQ scores from baseline

Examination of the distribution of individual AQLQ scores at baseline 2, end of treatment and both follow-ups indicated that the untransformed data was more normally distributed than that resulting from log or square root transformations and, hence, the untransformed data was utilised. Each group reported a significant improvement in mean (95% CI) asthma quality of life scores between baseline 2 and end of treatment (spiritual healing = 0.64 [0.18 to 1.09],  $P = 0.008$ ; sham healing = 0.38 [0.17 to 0.60],  $P = 0.010$  and control = 0.50 [0.13 to 0.87],  $P = 0.001$ ). These improvements were maintained at follow-up 1 in two of the groups (spiritual healing = 0.67 [0.14 to 1.20],  $P = 0.016$ ) and sham healing = 0.62 [0.30 to 0.94],  $P = 0.001$ ), but dropped to non-significance at follow-up 2 in all groups (spiritual healing  $P = 0.161$ ; sham healing  $P = 0.061$  and control  $P = 0.115$ ).

### Clinical important differences in AQLQ scores

Numbers of patients in each group for whom AQLQ scores were available at end of treatment, short-term follow up and long-term follow up are indicated in Table 2. A similar proportion of patients



in the spiritual healing and sham healing groups showed deterioration, no change or improved overall mean AQLQ scores at the end of treatment (Figure 1 and Table 2).

At follow-up 2, a higher proportion of patients in the sham healing group reported improved quality of life, compared to the spiritual healing or control

**Figure 1. Group mean AQLQ scores across time points.**

**Table 3. Asthma quality of life scores at end of treatment (T5), follow-up 1 and follow-up 2 by group — data are adjusted for AQLQ score at baseline.**

|                       | Spiritual healing      | Sham healing           | Control                | P-value (between groups) |
|-----------------------|------------------------|------------------------|------------------------|--------------------------|
| End of treatment (T5) | 5.39<br>(5.05 to 5.72) | 5.18<br>(4.87 to 5.49) | 5.17<br>(4.86 to 5.48) | 0.570                    |
| Follow-up 1           | 4.67<br>(3.74 to 5.61) | 3.74<br>(2.86 to 4.61) | 4.00<br>(3.10 to 4.89) | 0.333                    |
| Follow-up 2           | 4.30<br>(3.53 to 5.07) | 4.42<br>(3.70 to 5.15) | 4.77<br>(4.04 to 5.50) | 0.659                    |

Values are adjusted mean (95% confidence interval).

**Table 4. Group median (interquartile range) scores on SF36 general health sum of scores.<sup>a</sup>**

| SF36 general health sum of scores | Control (n = 31)    | P-values (compared to B2) | Spiritual healing (n = 27) | P-values (compared to B2) | Sham healing (n = 30) | P-values (compared to B2) |
|-----------------------------------|---------------------|---------------------------|----------------------------|---------------------------|-----------------------|---------------------------|
| Baseline 2                        | 0.0<br>(0.0–10.0)   | –                         | 0.0<br>(0.0–0.0)           | –                         | 0.0<br>(0.0–12.25)    | –                         |
| End Treatment                     | 16.4<br>(10.0–18.4) | <0.001                    | 14.4<br>(9.0–21.4)         | 0.02                      | 15.4<br>(13.0–18.4)   | <0.001                    |
| Follow-up 1                       | 10<br>(0.0–18.4)    | 0.10                      | 14.4<br>(11.0–20.4)        | <0.001                    | 14.7<br>(8.55–18.4)   | <0.001                    |
| Follow-up 2                       | 15.0<br>(10.0–18.4) | <0.001                    | 15.4<br>(7.0–21.4)         | <0.001                    | 16.4<br>(11.75–19.4)  | <0.001                    |

<sup>a</sup>P-values refer to differences within groups across time points compared to baseline 2 using the Wilcoxon signed-rank test.

groups although this difference was not statistically significant ( $P = 0.28$ ). The proportion of patients reporting improved AQLQ scores at follow-up 2 was similar in all three groups ( $P = 0.62$ ). Sham healing exhibited the greatest number of net improver scores (per cent showing improvement minus those showing deterioration in AQLQ scores) although, as stated, there were no statistically significant differences between groups at the end of treatment, or at either follow-up.

Table 3 shows the results of the between groups analyses of AQLQ scores at end of treatment and follow-up visits following adjustment for baseline 2 values. Although all groups showed an improvement in scores, there was no significant difference between groups at any of the three time points (all  $P > 0.05$ ).

#### **Other differences between groups at end of treatment and follow-up**

The change in median PEF scores from baseline 2 to end of treatment did not differ significantly by group ( $P = 0.32$ ). Each group reported improved scores on the SF36 General Health sum of scores between baseline 2 and each of end of treatment, follow-up 1 and 2. However, it should be noted that there was wide variation in SF36 scores within all three groups at each time point.

At follow-up 1 (week 12), the control group reported more severe symptoms and symptom impact on the MYMOP than did the sham healing and spiritual healing groups ( $P = 0.02$ ). The earlier 'end of treatment' (week 8) median score showed a similar trend ( $P = 0.05$ ). This difference was not maintained at follow-up 2, week 26 ( $P = 0.44$ ). The spiritual healing group reported fewer numbers of participants reaching 'caseness' on anxiety on follow-up 1 ( $P = 0.03$ ) but this change was not seen at the end of treatment ( $P = 1.0$ ) or follow-up 2 ( $P = 0.06$ ). The sham healing group had significantly poorer results on FEV1 at follow-up 1 compared to baseline ( $P = 0.01$ ), but this change was not seen at the end of treatment ( $P = 0.58$ ), nor maintained at follow-up 2 ( $P = 0.27$ ). The sham healing group also had significantly poorer results on PEF at follow-up 1 compared to baseline ( $P = 0.01$ ), but this change was not seen at the end of treatment ( $P = 0.72$ ), nor maintained at follow-up 2 ( $P = 0.72$ ).

## **DISCUSSION**

### **Summary of main findings**

This study found no evidence for statistically significant or clinically valuable impacts from spiritual healing for asthma. When compared to sham healing and the control group, spiritual healing had no better impact on clinical outcome

data, quality of life scores, and self-reported mental and general health status in patients with asthma. The main finding of interest of this study was that all three groups showed significant improvements in AQLQ and SF36 scores at the end of the main trial. The small sample size of the study limits conclusions but we suggest that the data seems to demonstrate a 'Hawthorne effect'<sup>21</sup> where ongoing, regular (additional to normal) contact with healthcare professionals/researchers who are interested in the patient and their asthma, is associated with an improvement in patient health and quality of life ratings. Thus, it may be that it is not who provides the complementary input, or what the nature of that input is, that matters. Rather the additional input itself, in this case due to clinical trial participation, may affect patient outcomes in a beneficial manner. Alternatively, it may be that those volunteering to take part in the study could have been at a low point in terms of individual asthma related quality of life and some improvement from the point of recruitment may have been expected without intervention.

### **Strengths and limitations of the study**

This was a pragmatic, single-blind randomised controlled trial of an area of treatment (CAM) often criticised for poorly designed and methodologically unsound studies. In addition, this is the first reported pragmatic randomised controlled trial of spiritual healing for chronic disease management that includes an appropriate placebo group (sham healing). As recommended by the British Thoracic Society, we adopted outcome measures other than lung function. A possible limitation of this study was the use of one spiritual healer. While this could be argued to allow for consistency in terms of delivery of spiritual healing, a more robust design would have been to use a number of healers in order to control for the effect of an individual, rather than the effect of a technique. Another limitation was the small sample size. This may reflect that spiritual healing appeals to fewer patients than some other CAM therapies which are more organised and regulated, and have a research base as well as being available in parts of the NHS (acupuncture, chiropractice, herbal medicine, homeopathy, and osteopathy). In addition, patients were recruited from only one area of Scotland; this may have limited recruitment and generalisability.

### **Comparison with existing literature**

This is the first reported evaluation of spiritual healing for asthma in a primary care setting and this is one of the few studies of CAM using robust, controlled and randomised methodology. Our results are similar to those of previously published well-designed studies



of other CAM therapies for asthma in that we have found no evidence for the use of a specific form of CAM, spiritual healing. CAM studies reporting patient improvements have been criticised for poor methodological quality: our finding that all three groups demonstrated similar improvements supports the need for robust, randomised trials of CAM treatments for asthma, so the effects of trial participation can be separated from those of the treatment under scrutiny.

### Implications for clinical practice and future research

The majority of alternative medicine users appear to be turning to complementary medicine so largely because they find these healthcare alternatives to be more congruent with their own values, beliefs, and philosophical orientations toward health and life.<sup>13,22</sup> Our results indicate that it may not be the complementary therapy per se that is the key to patient preferences for CAM. Rather the effect seems non-specific: the patient-centred and holistic consultation, diagnosis and treatment inherent in CAM may be the basis for patients turning to such treatments.

Bearing in mind that this is a small study with low numbers, our results do not provide support for the NHS provision of spiritual healing for asthma. However, future qualitative research exploring patient views of CAM consultations, and comparing these with traditional medicine consultations, may identify the key differences which are of importance to patients.

### Supplementary information

Supplementary information accompanies this paper at <http://www.rcgp.org.uk/Default.aspx?page=2482>

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### Ethics committee

Grampian Research Ethics Committee (01/0158 18 July 2001)

### Conflicts of interest

Arun Sharma is a member of the National Federation of Spiritual Healers. Stan Gerard is a practising spiritual healer. David Price and Jennifer Cleland have received educational and research grants from a number of pharmaceutical companies in the field of asthma

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