

Acupuncture for Depression: First Steps Toward a Clinical Evaluation

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ABSTRACT

Aim of study: To explore issues that need to be addressed in the design of a clinical trial of acupuncture for people with depression.

Methods: In this study we conducted a focus group with 6 volunteer participants with experiences of depression, and a prospective case series of 10 patients who received acupuncture treatment for their depression. In the case series study, 10 patients were referred by their general practitioner, and received up to 10 individualized acupuncture treatments from one of two acupuncturists. Acupuncturists recorded traditional acupuncture diagnoses and details of the treatment provided. Measures of depression (Beck Depression Inventory and the Hospital Anxiety and Depression Scale) and health status (SF-36) were taken at baseline and 10 weeks later. Changes in mean before and after scores were analyzed using the Wilcoxon signed ranks test. Adverse events were also monitored.

Results: The focus group and the case series both identified considerable heterogeneity among people with depression. In the case series, only 6 patients both received treatment and completed 10-week questionnaires; however, significant improvements between before and after were found in their levels of depression ($p < 0.05$). Many factors, as well as the acupuncture, may have contributed to these improvements. No serious adverse events occurred. In the context of designing a clinical trial of acupuncture for depression, a series of methodological challenges is explored.

Conclusion: This study highlighted the complexities of evaluating acupuncture for patients with depression. Successfully addressing the identified methodological challenges in the design of a trial will increase its relevance and impact.

INTRODUCTION

Depression is the second most common cause of disability in the world (Murray and Lopez, 1996) and in the United Kingdom it is the third most common reason for consulting in primary care (Singleton et al., 2001). While there are extensive reports of successful acupuncture treatments of emotional and mental conditions in the classical texts, the evidence-based medical literature on the subject in the West is extremely limited. The few randomized, con-

trolled trials to date, however, do lend some support to the evidence from the classics that acupuncture has potential in the treatment of depression (Acupuncture Resources Research Centre, 2001; Ernst, 2001). We also know from clinical experience that patients in the West are interested in acupuncture treatment for depression (MacPherson and Kaptchuk, 1997), whether as an adjunct or as an alternative to conventional medication.

The evidence base for pharmaceutical treatments for depression is not as strong as might be expected. Researchers

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have found a large placebo effect with drugs used for depression. The additional benefit from selective serotonin reuptake inhibitors (such as Prozac) may only account for around 25% of the overall benefit (the true drug effect), with 25% due to the natural course of the disease and 50% due to the placebo effect (Kirsch, 2003).

For acupuncture, a generic problem has been that research under experimental conditions has not always been easily generalized to the real world, while clinical research of routine practice has often lacked scientific rigor. These factors have contributed to the evidence base remaining weak, in contrast to acupuncture's steady rise in popularity with patients. For credibility among policy makers, practitioners, and the public, our goal for acupuncture research is that it satisfies three important criteria: that it is scientifically rigorous, that it is respectful of the integrity of acupuncture as a system of medicine, and that it takes into account what patients experience and may value about acupuncture (Fitter and Thomas, 1997; Thomas and Fitter, 1997).

It is in this context that we set out to explore issues that need to be addressed in order to evaluate acupuncture's potential as a treatment for patients with depression. We see this study as part of a modeling phase, similar to Phase 1 of the framework proposed by the Medical Research Council for the clinical evaluation of complex interventions (Medical Research Council, 2000). In this paper we summarize this exploratory investigation, as well as provide an outline of how we propose to take the research forward.

The aims of this study were to learn from patients about their experiences of depression and its treatment, both conventional and alternative; explore process and outcome for patients who receive a short course of traditional acupuncture; and identify the methodological challenges that need to be addressed in designing a rigorous clinical evaluation of acupuncture for depression.

MATERIALS AND METHODS

Focus group

To learn from patients about their depression and experiences of treatment, we approached a local mental health group, York & District Mind, and with them formed a focus group which met once for 2 hours. Participants in the group were 2 researchers (HM and LT) and a stratified sample (Kuzel, 1992) of 6 volunteers, identified through York and District Mind, who had experienced depression and were either staff ($n = 2$), participants ($n = 2$), or users of mental health services ($n = 2$). We used a topic guide with 3 topics to provide structure for the meeting. The topics were: personal experiences of depression, experiences of both conventional and alternative treatment for depression, and feedback on our research plans. The staff at York &

District Mind were concerned that using a tape-recorder might inhibit individual contributions so, as an alternative, extensive notes were taken (by LT) during the meeting. These were transcribed immediately afterward and later analyzed manually (by HM) using thematic content analysis (Ritchie and Lewis, 2003). An analytic framework was provided by the a priori themes given in the topic guide. Emergent themes were identified through repeated scrutiny of the transcript.

Case series

To explore process and outcome for patients with depression treated with acupuncture, we set up a case series in the form of an uncontrolled observational study. We recruited 10 patients with depression, all referred by a general practitioner (DG) to one of the study researchers (LT) who met with them individually, obtained informed consent, and collected baseline measures. Patients received up to 10 acupuncture treatments, while remaining in the care of their general practitioner (GP). Practitioners undertook a traditional acupuncture diagnosis and monitored all treatment that was provided on an individualized basis, with each practitioner treating as they normally would. Adverse events were monitored. The study had local National Health Services (NHS) research ethics committee approval.

Patient eligibility. Our initial intention was to recruit only patients who had a diagnosis of mild to moderate depression based on criteria for major depression in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (American Psychiatric Association, 1994), and assessed as suitable for management in primary care by their GP. However, the criteria relating to the severity of the depression were not applied, and patients with severe depression were also recruited. Patients were excluded if they were simply adjusting to a recent difficult situation, such as a recent bereavement; if they had an acute psychotic or bipolar disorder, for example with hallucinations or manic episodes; if there was harmful use of alcohol or drugs; or if the cause was iatrogenic, as some prescribed medications may cause depressive symptoms. Other exclusions were: elderly depressed patients in care homes; patients with pending litigation; and patients with bleeding disorders (e.g., hemophilia).

Treatment process. All 10 patients were referred for treatment to 1 of 2 professional acupuncturists (one of them HM) based at private acupuncture clinics in York. The acupuncturists were members of the British Acupuncture Council, the professional association that requires a 3-year full time training or equivalent, and both had over 10 years experience. Patients were offered up to 10 treatments free of charge. They were treated once or twice a week, as considered appropriate by the practitioner. The treatment was in-

dividualized at each visit, based on the principles of Traditional Chinese Medicine (TCM). The precise number of treatments received was determined by clinical need, as judged by the acupuncturist, in dialogue with the patient. This pragmatic approach, allowing practitioners to treat how they normally would, was modeled on a trial we conducted into acupuncture for back pain (Thomas et al., 1999). Patients could discontinue at any time, and without having to give a reason. Patients continued to have access to normal GP management. Practitioners completed booklets describing treatments and adverse events.

Outcome measures. Two validated psychological outcomes measures were used to monitor changes over time: the Beck Depression Inventory (BDI) with a range of 0 to 63 (the higher, the more severe) (Beck et al., 1961); and the Hospital Anxiety and Depression Scale (HADS), which has an anxiety and a depression component with a range of 0 to 21 (the higher, the more severe) (Zigmond and Snaith, 1983). In addition, the Short-Form 36-item health status questionnaire (SF-36) was administered (Brazier et al., 1992). Baseline measures were completed prior to acupuncture treatment in the presence of the researcher, and a follow-up questionnaire was mailed out at the end of a 10-week period (which approximated the end of treatment). At the end of the questionnaire, patients were also asked for any comments. To reduce loss to follow-up, nonresponders were sent a reminder after 2 weeks. Comparisons between before and after mean scores were made using the paired Wilcoxon signed ranks test.

RESULTS

Focus group

In the focus group, the three most common themes that emerged within the first topic regarding people's experiences of depression were: the distress of depression itself; the isolation that can accompany it; and the challenge of coping, or not coping, with it. For the first of these themes, words used to describe depression included:

- emptiness,
- hollowness,
- disconnectedness,
- darkness,
- frightening,

In addition, some patients experienced "a very dark place," a "scary feeling," "everything is so large and intimidating," or a "shroud of darkness." These descriptions capture a sense of how painful and difficult it is to be depressed. For the isolation theme, descriptions included: "It feels like being in Alice in Wonderland"; being "at the bottom of a well";

"I just don't know how I got out of feeling like that"; "I didn't like to ask for any help"; and "you are disconnected from everything." For the challenge of coping theme, people talked about wanting to commit suicide, dependency on medication, abusing alcohol and drugs, and self-harming behavior. As one person reported, "You have to keep whatever is inside you alive and safe from self-harm."

The second topic related to people's experiences of both conventional and alternative treatments for their depression. Regarding experiences of conventional medical treatment, there were individual reports that "it doesn't feel like medication does any good," and that it was "not helpful." Two people reported that they had been pressured into taking conventional medication, and concerns were also raised about dependency. However other patients made comments such as "Prozac was brilliant," "antidepressants did help," "they made me stop seeing bizarre off-the-wall things," and "they enabled me to survive." Regarding experiences of non-pharmacologic interventions, there were positive reports on psychotherapy ("I am much kinder to myself"); crisis counseling ("fantastic"); homeopathy ("helped me come off the medication"); a neutral report of acupuncture ("I don't know if it helped"); and a negative report on group psychotherapy ("made me more ill").

The third topic explored in the focus group was the design of the proposed case series study. Participants expressed concern that some people do not even consult their GP, so could not be part of the study. Concerns were also raised about the definition of depression, and who should be targeted in a research study. The idea of having a cut-off point so that only people with mild to moderate depression were to be included was discussed. It was argued that people with severe depression who had exhausted all other treatment options might also be interested, as well as not wanting to be discriminated against by being excluded. Practical feedback on approaches to recruitment of patients to the case series was also offered.

Case series

The patients. Ten (10) patients were referred by one York-based GP over a period of 4 months in 2002. The initial plan was to refer patients at the time of their initial consultation. Because of time constraints within the 10-minute appointment, it proved difficult to discuss referral into the study at the time of most consultations. To facilitate recruitment, the GP also searched his database, and either wrote to or telephoned individuals who he felt might benefit from the offer of acupuncture. Key features of the 10 patients are presented in Table 1. Six (6) were female and 4 male, mean age 50.5 years (range, 30–77 years). All patients identified themselves as white or British. Eight (8) patients were on pharmaceutical medication for depression; half the patients were receiving, or about to receive, additional nonpharma-

TABLE 1. BASELINE DETAILS OF PATIENTS RECRUITED TO THE ACUPUNCTURE FOR DEPRESSION STUDY

<i>Patient</i>	<i>Sex (age)</i>	<i>Duration of current episode</i>	<i>Past history of depression</i>	<i>Employment status</i>	<i>Currently taking medication</i>	<i>Other concurrent treatment</i>	<i>Other health problems and symptoms</i>	<i>BDI score</i>
1	F (30)	2 months	Numerous occasions	Unemployed	No	None	Migraines, fluctuating energy, some disturbed nights, heavy periods	16
2	F (45)	3 weeks	Numerous episodes since aged 13	Full-time education	Yes	Community psychiatric nurse, psychotherapy	Heavy periods	27
3	F (63)	4 months	Once, post-natal 39 years ago	Retired	Yes	None	Irritable bowel syndrome, slight deafness and tinnitus, heartburn, low energy	14
4	F (68)	ongoing	Continuous	Retired	No	Community psychiatric nurse, cognitive behavioral therapy	Bad hip, poor sleep, constipation, allergy to certain food, headaches, thyroid deficiency	28
5	M (43)	3 months	Numerous episodes since teens	Full-time work	Yes	Waiting to hear from psychiatrist	Low energy, poor sleep, easily stressed, tense shoulders, poor concentration, hot flushes	26
6	M (33)	5 months	2 or 3 times in last 10 years	Full-time work	Yes	Waiting to see a psychologist	Agoraphobia, anxiety, panic attacks, diarrhea, low energy, not sleeping well	28
7	F (52)	5 months	Numerous episodes since 20s	Keeping house	Yes	None	Multiple sclerosis, tense neck and shoulders, headaches, stress affects stomach, hot flushes	44
8	F (77)	6 weeks	Once previously	Retired	Yes	None	Feelings of panic, palpitations, low back pain, night sweats, always tired, diverticulitis, insomnia	6
9	M (37)	6 months	None	Full-time work	Yes	None	"Stomach problems"	33
10	M (57)	9 years	7 to 8 episodes	Unemployed	Yes	Community psychiatric nurse, therapy group	Irrational fears, physical shaking, burning sensation, tiredness, diabetes	25

colological treatments, such as talking therapies. All patients had other health problems or symptoms. Half the patients did not know whether or not acupuncture would help their depression, while half thought that it would.

The treatment process. Of the 10 patients who were referred for acupuncture, patients 2 and 9 withdrew from the study prior to their first consultation: patient 2 wrote at 10 weeks that her “mood dipped so dramatically” that she had “taken two near fatal overdoses and have been in intensive care following each of them.” We do not know why patient 9 withdrew. The remaining 8 were diagnosed with between 2 and 4 syndromes, based on the principles of TCM (Table 2). Most common syndromes were Liver Qi Stagnation and Spleen Qi (or *Yang*) Deficiency, which in 2 cases was associated with damp. Prescriptions of acupuncture points were chosen based on the diagnosis and the patient’s presenting symptoms, with each patient’s treatment being individualized at each visit. Patients were needled with 25–40 mm long needles, 0.25–0.30 mm in diameter, with the exception of patient 3, who had acupressure as an alternative because of her worries about needles. Additional modalities provided by acupuncturists for 3 patients included acupressure, massage, flower remedies, and relaxation exercises.

Self-help advice and techniques were also provided by acupuncturists for 2 patients.

Outcomes. Of the 8 patients who attended their acupuncturist for at least 1 session, only 6 completed 10-week follow-up questionnaires. At baseline, 1 patient had minimal depression (BDI < 10), for 2 it was mild to moderate (BDI, 10 to 18), for 5 it was moderate to severe (BDI, 19 to 29), and for 2 it was severe (BDI, 30 to 63). The patient with minimal depression at the outset (patient 8) improved her scores slightly over the 10 weeks. The 2 patients with mild to moderate depression at the outset (patients 1 and 3) experienced a major improvement in symptoms, with a reduction of over 80% in their BDI scores. The remaining 3 patients (patients 4, 7, and 10) experienced more marginal improvements. The changes to the BDI scores were reflected in equivalent changes in the HADS and SF-36 scores

The combined scores for these 6 patients are presented in Table 3. The mean BDI score dropped from 22.2 (moderate to severe depression) to 16.0 (mild to moderate), and the HADS scores for both anxiety and depression showed similar improvements (lower scores). The differences between before and after scores for BDI and HADS were statistically significant ($p < 0.05$). Changes in the SF-36 scores showed

TABLE 2. DETAILS OF TRADITIONAL ACUPUNCTURE DIAGNOSIS AND TREATMENT

Patient	Traditional acupuncture diagnosis	Number of treatments	Typical acupuncture prescription	Acupressure and massage	Other modalities	Self-help advice and techniques
1	Kidney-Spleen <i>Yang</i> Deficiency, Liver <i>Qi</i> Stagnation	9	SP-6, ST-36, KID-3	Massage	Flower remedies	
2	—	0	—	—	—	—
3	Kidney Deficiency, Liver and Lung <i>Qi</i> Stagnation	10	—	Acupressure: P-6, KID-3, KID-7, SP-4, SP-6, HE-3, DU-20	Relaxation exercises, Flower remedies	Making choices, affirmations, visualization
4	Heart Blood Deficiency, Spleen <i>Qi</i> Deficiency, Liver <i>Qi</i> Stagnation	10	SP-6, ST-36	—	—	Advice about sleep and rest
5	Heart-Liver-Kidney <i>Yin</i> Deficiency, Spleen <i>Qi</i> Deficiency and Damp, Liver <i>Qi</i> Stagnation	4	LIV-3, SP-6, LI-4, GB-21, DU-20	—	—	—
6	Spleen <i>Qi</i> Deficiency and Damp	1	SP-9, LIV-3, ST-36, LI-4, DU-20	—	—	—
7	Heart Blood Deficiency, Spleen <i>Qi</i> Deficiency, Liver <i>Qi</i> Stagnation	6	SP-4, ST-36, LIV-3, REN-12, DU-20	—	—	—
8	Kidney-Heart <i>Yin</i> Deficiency, Liver <i>Qi</i> Stagnation, Kidney <i>Yang</i> Deficiency	7	LU-7, KID-6, LIV-3, LI-4, ST-36	—	—	—
9	—	0	—	—	—	—
10	<i>Chong-Ren</i> Disharmony, Heart Blood Deficiency, Spleen <i>Qi</i> Deficiency, Liver <i>Qi</i> Stagnation	10	SP-4, ST-36, REN-12, LIV-3, P-6	Acupressure: P6	—	—

TABLE 3. MEAN SCORES ON BECK DEPRESSION INVENTORY (BDI), HOSPITAL ANXIETY & DEPRESSION SCALE (HADS), AND SHORT FORM-36 (SF-36) OUTCOME MEASURES BEFORE TREATMENT AND 10 WEEKS LATER ($n = 6$)

	Mean score \pm SD before treatment ($n = 6$)	Mean score \pm SD 10 weeks later ($n = 6$)	Difference between before and after	P-value
BDI ^a	22.2 \pm 13.3	16.0 \pm 15.9	6.2	0.03
HADS ^b				
Anxiety	15.3 \pm 4.6	12.0 \pm 5.9	3.3	0.03
Depression	11.7 \pm 7.3	8.0 \pm 6.4	3.7	0.04
SF-36 ^c				
Physical functioning	53.3 \pm 35.2	60.8 \pm 29.6	7.5	0.10
Social functioning	50.0 \pm 18.3	66.7 \pm 34.4	16.7	0.11
Role physical	20.8 \pm 40.1	62.5 \pm 49.4	41.7	0.10
Role emotional	5.6 \pm 13.6	44.4 \pm 45.5	38.8	0.07
Mental health	48.0 \pm 21.5	50.0 \pm 29.5	2.0	0.21
Energy/vitality	33.0 \pm 18.2	35.8 \pm 23.7	2.8	0.50
Pain index	48.1 \pm 23.0	63.0 \pm 26.0	14.9	0.13
General health	45.2 \pm 15.3	57.7 \pm 18.4	12.5	0.12

^aBeck's Depression Inventory scores range from 0 to 63: the lower the score, the less depressed.

^bHospital Anxiety and Depression Scale scores range from 0 to 21: the lower the score, the less anxious or depressed.

^cShort Form 36 has 8 subscales, with scores ranging from 100 to 0: the higher the score, the better the health status.

a trend towards improvement (higher scores), but not statistically significant.

A range of mood-related improvements were also reported by patients to practitioners. These included feeling less fearful, less tearful, more happy, and more motivated; other treatment benefits were reported, such as sleep improvement, migraines stopping, no more panic attacks, and no more night sweats. In the 10-week questionnaire, patients made more general statements about the value of the acupuncture, including writing that "I have learnt a great deal about depression and how to combat the same," and finding the treatment "really worthwhile." All 6 reported that they would use acupuncture (or acupressure) again.

In terms of adverse reactions associated with acupuncture, 2 patients reported moderate or severe temporary worsening of symptoms, 1 reported moderate tiredness and drowsiness following acupuncture; and 3 patients reported feeling moderately relaxed or energized after treatment. Two patients (patients 2 and 7) each took 2 overdoses during the 10-week monitoring period: the former did not receive acupuncture, as her first overdose occurred before she could attend her first appointment; for the latter patient, who had the most severe depression at the outset, the overdoses occurred after her third acupuncture session, though she did subsequently return for further acupuncture treatment.

From this case series, we explicitly do not draw conclusions about acupuncture's effectiveness. While BDI and HADS scores did show statistically significant improvements over time, we cannot know whether these changes can be ascribed to the treatment the patients received from their acupuncturists. This is because there was no control group to assess the contribution to the improvement that might have come from some combination of other factors,

including regression to the mean, benefit from medication and other therapies, nonspecific and context effects associated with acupuncture, and the natural changes to depression that might be expected over time. The mean improvement in the BDI scores of only 6 points is modest when compared to changes found in studies of other therapeutic interventions for patients with depression in primary care (Chilvers et al., 2001; Ward et al., 2000).

DISCUSSION

In this exploratory study we have used a focus group and a small case series to investigate the issues that relate to a rigorous clinical evaluation of acupuncture for depression. The focus group helped us orient ourselves to the views of potential acupuncture users of the nature of depression and some of the difficulties associated with its proposed evaluation. The case series was a useful method of identifying some of the design issues that we will need to address. Within the context of our overall goal of developing meaningful clinical evidence, we have identified 5 methodological challenges.

The patients: Should we target a specific group?

Despite the small scale of both the focus group and the case series, we observed considerable diversity among people who are depressed, and how they experience it. Patients in the case series also varied considerably in age, employment status, comorbidity, whether on medication or not, the utilization of nondrug treatment modalities, traditional acupuncture diagnoses, and the severity of depression. In

Major Depression Coding

Major depression can be coded according to severity, psychotic features, and somatic (melancholic) features.

The severity of depression can be classified as mild, moderate, or severe.

In *mild depression*, the individual has some symptoms of depression, and extra effort is required to do the things that need to be done. Mild depression is usually associated with only minor impairment in occupational or social functioning.

Moderate depression involves occupational or social impairment which is midway between the impairment associated with mild and severe depression. The individual has many symptoms of depression that often keep him or her from doing things that need to be done.

Severe depression involves marked impairment in these areas and may include psychotic symptoms. The individual has nearly all the symptoms of depression and the depression almost always keeps the individual from doing his or her regular day-to-day activities.

Somatic features are nearly always present.

primary care in the UK, it is likely that this patient variability is the norm. Given the different clinical presentations and diagnoses, it seems plausible that “depression” is experienced as more than one distinct condition.

This leads to a major question: to what extent should a specific patient group be targeted for a clinical trial? The case for doing this is that if one can identify the patients who respond best, then a trial that targets these patients will be more likely to show an effect if there is one. Potential patient groupings include those who do not want medication, or choose not to consult, or discontinue medication because of side effects, or want acupuncture as an adjunct, or seek support to withdraw from drugs.

While there is stronger evidence in the literature on acupuncture successfully treating mild to moderate depression (Allen et al., 1998), supported anecdotally by the 2 patients with this level of severity at baseline in the case series we report here, we are unsure whether it makes sense to exclude patients with severe depression in a clinical trial. As the focus group data suggest, there may well be patients with severe depression who will benefit from acupuncture,

and to exclude them on the basis of no hard evidence would be seen as unfair by users of mental health services. A key issue here is that even if we wanted to preselect, we would not know which patients to target. It should be noted that targeting a specific group of patients might limit the generalizability of the results.

To take this forward, we are currently conducting face-to-face semistructured interviews with GPs, acupuncturists, and patients in order to provide qualitative data (Murphy and Dingwall, 2001) to better inform us as to whether there should be a specific group of patients targeted, and if so, who.

Recruitment and referral

From the case series, we know that there may be difficulties in establishing satisfactory referral routes from primary care. One such difficulty is the time taken by a GP to explain the options to patients, given the additional discussion required for the patient to consider participating in a trial, at a time when the patient may well be in a state of distress. We also know that there is a danger of suicide, and

Major Depression Symptoms

For a diagnosis of major depression (DSM-IV), 5 or more of the following symptoms should have been present for at least 2 weeks. Either item 1 or 2 must always be present.

1. Low or sad mood (especially if worse in the morning)
2. Loss of interest or pleasure in usual activities (anhedonia)
3. Fatigue or loss of energy
4. Appetite disturbance or weight change
5. Sleep disturbance (especially early morning waking)
6. Difficulties in concentrating
7. Feelings of guilt or self blame
8. Feelings of worthlessness or loss of self confidence
9. Suicidal ideas or thoughts
10. Objective evidence of agitation or retardation

GPs may well want to err on the side of caution, given their responsibility towards their patients. We also know that there is some skepticism among GPs about acupuncture and its potential for helping people with depression. However, to evaluate acupuncture as an option for people with depression in primary care, GPs need to want to be involved and be willing to refer.

These factors together raise the question of whether recruitment at the time of consultation is the best method, or whether retrospective recruitment using GP records would be preferable (McCarney et al., 2002). This question relates to the previous issue of whether to target specific patients for a trial. The more narrow the inclusion criteria, the longer it will take to recruit at the time of consultation.

We have also, subsequent to the case series, considered how to tackle the underlying skepticism that may reduce GPs willingness to be involved in referring patients into a trial. One potential solution would be a survey of GPs to establish data leading to a quantitative measure of the influence of trial design (e.g. sample size, comparison group, outcome measures, effect size) on referral decisions (Spiegelthaler et al., 2001). These findings would help in optimizing the design of a clinical trial and help predict the likely effect of such trials after their results were known.

The therapeutic relationship

From both practitioners in the case series, and from prior research (Gould and MacPherson, 2001), we know that considerable value is placed by patients on the therapeutic relationship. Some aspects of the relationship are unique to acupuncture, for example, the use by practitioners of specific explanations and metaphors to help their patients understand their condition, and the encouragement of specific lifestyle changes so that patients can learn to keep themselves by reducing the impact of their patterns of disharmony. We could usefully identify the components of the therapeutic relationship that might enhance the overall effect of acupuncture. Qualitative research using in-depth interviews would likely be the most appropriate method of exploring what patients value about the therapeutic relationship (Paterson and Britten, 2003). Observational methods may be better suited to understanding how the relationship is developed in practice.

Outcome measures, including acupuncture's broader effects

While the BDI and HADS seemed to provide an adequate measure of depression, for some patients the benefits of acupuncture extended to more than just a change to the depression itself. For example, in the case series, comments of patients in the 10-week questionnaire included, "I have learnt a great deal about depression and how to combat the same" and "the acupuncture was really worthwhile." We could usefully investigate what patients mean by these and

other broader effects where changes go beyond simply the alleviation of symptoms, possibly involving changes in personal and social identity and new coping strategies (Paterson and Britten, 2003).

We suggest a mixed-method approach to understanding and measuring broader effects. First, we can gain more of an understanding by using structured in-depth interviews with practitioners and patients. Second, we can use a literature review in identifying well-validated outcome measures that might assess these broader effects (Fitzpatrick et al., 2001). These outcome measures would ideally need to be tested on acupuncture patients in routine care before being used in a clinical trial alongside more conventional outcome measures such as BDI and HADS.

Treatment protocol for a clinical trial

In this case series, the acupuncture was delivered by practitioners who practiced within the broad rubric of TCM, which is characterized by a detailed diagnosis followed by individualized treatment to reflect considerable patient variability. In terms of defining an appropriate intervention within a clinical trial, we need to consider the constraints on treatment and how broad or narrow they should be. In a pragmatic trial, it is possible to define the acupuncture by reference to the characteristics of the practitioner only, as was done in a recent trial of acupuncture for back pain (Thomas et al., 1999). However, the more scope there is for practitioners to practice what they normally do, the more likely they will use a raft of modalities, as occurred for example in this case series, where 2 patients received flower remedies. It can be argued that such variability of treatment may muddy the waters, making it more difficult to associate any change with acupuncture.

Therefore, a challenge in designing an acupuncture trial is to develop a treatment protocol for the acupuncture intervention that has credibility within both the acupuncture community and the scientific establishment. This will mean a protocol that combines sufficient standardization to allow replicability, along with the necessary flexibility to accommodate a legitimate treatment repertoire for the expected patient variability (Schnyer and Allen, 2002). Using the clinical literature and expert opinion, a quantitative consensus method (Black et al., 2001) could be used to draw up an appropriate trial protocol for the treatment of depression. Such a protocol could also be tested with a representative sample of acupuncturists in order to assess it for comprehensiveness and acceptability.

CONCLUSION

In this study we utilized a focus group with 6 participants with experience of depression and a prospective case series of 10 patients who received acupuncture treatment for their depression. Through this study, we have developed some

useful data on patients with depression, and have a better understanding of the complexity of research in this area. It is clear that further research is required to address a number of methodological challenges before proceeding with a clinical trial of acupuncture for patients with depression.

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