

# Designing an RCT of acupuncture for depression—identifying appropriate patient groups: a qualitative study

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**Background.** Acupuncture is a popular complementary therapy choice for depression in the UK but the evidence base lags behind its usage. Further effectiveness trials are required; however, these need based on appropriate design for a complex intervention on a heterogeneous group of people.

**Aim.** To identify subgroups of patients with depression who could be the focus of effectiveness trials.

**Methods.** Qualitative research using in-depth interviews in UK primary care. In-depth interviews with 30 participants from three stakeholder groups: 10 acupuncture patients and 10 acupuncturists—to examine the reasons why acupuncture is used for depression and 10 physicians—to elicit who would be acceptable to refer into a trial of acupuncture for depression. Interviews were transcribed and analysed using a Framework approach.

**Results.** The data have highlighted that the acceptability of particular treatments for depression is influenced by the individuals' illness career within their social context. In addition, the plausibility and associated acceptability of depression treatments are also closely tied to an individuals' explanatory model of their condition. Seven patient subgroups were identified who could potentially find acupuncture of particular interest and on which effectiveness trials could be focused.

**Conclusions.** We have identified the main reasons why people seek acupuncture for depression and the circumstances in which physicians would be willing to refer for depression were it to prove effective. We have also set out a number of potential patient subgroups who may be particularly interested participating in a randomized controlled trial of acupuncture for depression.

**Keywords.** Acupuncture, complementary therapies, depression, qualitative research.

## Introduction

Depression is one of the most common reasons for consulting in primary care.<sup>1</sup> The burden of this illness is expected to be second only to heart disease by 2020.<sup>2</sup> The benefits of integrating acupuncture into primary care, where patients are keen to have a wider range of treatment options,<sup>3,4</sup> have been highlighted.<sup>5</sup> Of the main complementary therapies, acupuncture is the most often used for common mental health problems including depression.<sup>6</sup> A UK survey of 9408 respondents found that psychological problems were the second most common reason for seeking help from an

acupuncture practitioner with respondents wanting most help with feeling anxious, stressed and depressed.<sup>7</sup> Systematic reviews of acupuncture for depression<sup>8,9</sup> have suggested that high-quality effectiveness research is required to inform policy decisions on health care provision. Trials have largely focused on individuals with mild-to-moderate depression levels and considered acupuncture as an alternative to antidepressants or used an explanatory design involving theoretically inappropriate acupuncture treatment for comparison purposes. These studies have had a number of methodological and design limitations. Furthermore, the generalizability of these studies to the

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primary care context and to acupuncture as it practised in the UK is poor. With research findings indicating that acupuncture is a complex intervention<sup>10</sup> and that it would be more meaningful to investigate it as such,<sup>11</sup> our overall aim was to conduct a pilot study of acupuncture for depression in line with Medical Research Council guidelines.<sup>12</sup> These guidelines propose a stepwise approach with the first phases of research focussing on understanding the nature of the problem and determining how the intervention may potentially be of benefit. In this paper, we discuss our research findings in relation to patients' reasons for using acupuncture and consider patient groups for whom a referral may be of particular interest and who would be the focus of effectiveness trials.

## Methods

### *Design, participants and setting*

Differing perspectives on acupuncture and depression care were explored among three stakeholder groups. As we were interested in examining which depression patients might be interested in acupuncture, we needed to understand the reasons why some patients select to use acupuncture. This was achieved through in-depth interviews with 10 acupuncture patients and 10 professional acupuncturists who were members of the British Acupuncture Council (the lead professional body for traditional Chinese medicine acupuncturists in the UK). In addition, we were also interested to uncover which patient groups GPs would be willing to refer for acupuncture (or at least refer into an effectiveness trial); therefore, we also interviewed 10 medical practitioners.

We used a criterion sampling method,<sup>13</sup> constructing a sampling frame for each stakeholder group, with the aim of recruiting a balanced sample capturing diversity across key criteria (maximum variation sampling).<sup>14</sup> For patients with depression, our sampling criteria were age (at least one person from every decade of life between 20 and 70) and gender (equal numbers of men and women). Our patient sample included negative cases (individuals who had used acupuncture but had not found it to be effective or experienced temporary bad reactions) and other ethnic groups. Four of the 10 study patients had been treated by SS or HM but were not interviewed by their acupuncturist. We did not screen for depression as this would have limited the study to current sufferers. Instead, we allowed patients to self-select as having been depressed, which facilitated the inclusion of a wide range of differing perspectives on depressive illness and its treatment. Three participants had at some point received a diagnosis of bipolar disorder and one participant had never been diagnosed with depression because she did not wish to have a mental health

problem entered onto her medical records. The physician sample was comprised of nine GPs and one psychiatrist with a particular interest in the management of depression in primary care. A GP with experience of referring patients to acupuncture specifically for depression was also a key informant. The psychiatrist interview was one of the first to be conducted and was used to pilot and develop the physician topic guide. For GPs, we sampled across gender, location of practice (whether urban, rural or inner city based) and years since qualified. For acupuncturists, we balanced across gender, style of acupuncture, where they trained and years since qualified.

Participants were recruited opportunistically through professional and social networks in order to complete the study within the allotted time frame. This method proved to be more effective than advertisements in clinics for patients and helped to facilitate access to medical doctors and who may be more likely to agree to take part in research if the inviting researcher is known to them.<sup>15</sup> Fieldwork took place between September 2004 and February 2005. Interviews varied in length, with patient interviews tending to have taken longer than other stakeholders, the shortest being 25 minutes and the longest being 90 minutes. All interviews were conducted by SS, an acupuncture practitioner, except one participant who was interviewed by HM, as she had previously been SS's patient. Interviews took place in GP surgeries, acupuncture and complementary therapy clinics or university offices.

Interview topic guides were developed for each stakeholder group to ensure similar questions were posed to all participants within each group and that key topics were covered. Participants were encouraged to explore their own agendas when these were within the broad scope of the topic guide or had relevance for future effectiveness research on acupuncture. All participants were questioned about their experiences and views of managing depression with acupuncture and other complementary or conventional approaches. Respondents' explanatory models of illness<sup>16</sup> were explored in order to better understand why a particular intervention (be it medication, psychological therapy, acupuncture or another intervention) was thought to be more credible or preferred over another.

### *Data analysis*

Interviews were audiotaped and transcribed verbatim. Analysis was conducted by SS using the Framework approach.<sup>17</sup> Utilizing Atlas/Ti software for data management, data were indexed and charted in three thematic matrices (one for each stakeholder group) to enable comparisons within individual cases and between participants across *a priori* (those which were essentially driven by the questions on the topic guide) and emergent themes (including higher order constructs).

TABLE 1 *Acupuncture for depression—therapeutic niches*

Patient subgroups on which to test effectiveness of acupuncture for depression who may have a particular interest	Stakeholder group who identified the therapeutic niche
1. An alternative or adjunctive treatment to antidepressants or psychological interventions for those who have not fully responded to them	Patients, GPs, acupuncturists
2. Women trying to conceive, pregnant and breastfeeding women	Patients
3. Polypharmacy patients	GPs
4. An alternative to antidepressants for those who would prefer not to use them. Reasons included unwanted side effects and ideological opposition to using them—the idea of medication being used to suppress important and genuine emotional responses to life's circumstances	Patients, GPs, acupuncturists
5. An alternative treatment for individuals who are unable or unwilling to engage properly with talking therapies or who would prefer not to use them	Patients, GPs
6. To provide extra support for those coming off medication	Patients, acupuncturists
7. Individuals with concomitant pain conditions or somatic problems, e.g. fibromyalgia, irritable bowel syndrome, migraine, arthritic pain, menopause	Patients, GPs, acupuncturists

Interview dynamics were reflected on introspectively,<sup>18</sup> and transcripts examined and compared with each other to explore the influence of researcher's professional role and social relationship to respondents. Special attention was paid to the disclosure of therapeutic failure as participants may have wished to present themselves, or their experiences of acupuncture, in a positive light to the acupuncturist interviewers. Descriptive accounts of preliminary analysis were checked by JA (who is neither an acupuncture practitioner nor had any previous interest in Complementary and Alternative Medicine research). During this process, the themes were problematized and any preconceptions were challenged. Any inconsistencies within themes were discussed with SS, this process resulted in some themes being merged or recategorized. While each stakeholder group was analysed separately, the study findings were considered as a whole. The analytic process allowed us to identify from which group of stakeholders a particular patient subgroup had emerged.

## Results

The findings can be described within two interrelated themes—'illness career and depression' and 'explanatory models of illness'. Patient subgroups who might find acupuncture of interest and on whom an effectiveness study could be based are highlighted within the discussion for each theme and are summarized in Table 1.

### *'Illness career' and depression*

Symptoms of depression and how they are treated must be examined in the context of an individuals' illness career. These symptoms need to be understood in the context of previous experience of symptoms and illness, in addition to previous experiences of service provision and certain treatment options for both depression and other non-depression-related symptoms. This theme was particularly important for all three stakeholder groups and impacted on which patients

they felt would be open to participate in a trial of acupuncture and for whom this was felt to be appropriate.

Physicians, patients and acupuncture practitioners were aware of individuals for whom the standard treatments for depression within primary care (namely medication or 'talking therapies') were neither effective nor entirely acceptable.

In terms of effectiveness, for those who had suffered with depression for many years or who had tried other interventions with only limited success were appreciative that there were further unexplored avenues to try, and GPs could see the benefits of being able to offer another form of intervention to these individuals (Patient group 1).

We're only giving people two options really to go for one or the other, so they're aren't any other ... there's no other choices ... I can think of patients who I would recommend [acupuncture] to, those are sorts of patients who have had all kinds of medications and have had counselling and are still coming and saying they've still got all kinds of problems and I think definitely they'd be a place for them to say, you know, acupuncture has been tried would they like to try it (Female GP 4).

In essence, acupuncture (and indeed other forms of complementary and alternative therapy), if effective, could provide another potential treatment choice within what is currently a relatively limited 'care bundle' and might be of particular interest to those individuals for whom conventional therapies have been largely ineffectual.

In addition, there are obvious cases where drug treatments are inappropriate due to medical contraindication, including during pregnancy or polypharmacy. For example, one participant in the sample had used acupuncture because she wanted to conceive (Patient group 2), and it was inadvisable to continue using her medication. Physicians did highlight that in the context

of co-morbidity, and if effective, acupuncture might provide a useful alternative to antidepressants for patients who were already taking a number of different medications (Patient group 3):

there is increased risks of using antidepressants in certain groups and certainly there is a huge number of medications people are taking anyway and in the elderly for example. So using an alternative modality of treatment such as acupuncture would to my mind would be a very useful choice. If I've got a patient who I'm struggling to think well actually could you really have another medication—I know you're taking 13 in the morning ... But also the risk associated with the side-effects and the interactions that medication will have, it creates a more comfortable and potentially safer treatment than treating with an antidepressant (Male GP 10).

However, among those for whom the diagnosis of conventional therapies may be seemingly appropriate and potentially effective, all three stakeholder groups were aware that for some depression patients one or more of the conventional therapies are unacceptable. Respondents felt that this was likely to be due to an interplay of factors including the stigma associated with certain treatments, previous negative experience of the treatment option, more generalized views relating to feelings towards certain treatments and, linking with the second theme, that the treatment option did not fit within the patients' explanatory model of depressive illness. Each of these will be discussed in turn.

*Stigma associated with treatment for depression.* As would be expected, the accounts of those with a history of depressive illness were peppered with statements relating to the stigma associated with mental health problems and the associated treatments.

A sense of being normal actually I think is possibly the top of the list. I don't have to spend the rest of my life being on anti-depressants and therefore having a sort of mental health stigma hanging around my neck. I mean that may not be applicable to somebody who's never been depressed before or who's having one episode, but certainly as a long-term sufferer that's probably the top of the list to think that I don't actually have to carry on taking tablets but acupuncture is so, you don't have to go to a doctor, you know, it's like you don't have the mental health bit' (Female patient 2, aged 48).

Because acupuncture was not associated with the treatment of depressive illness to the same degree that medication and psychotherapy were, it appeared—

albeit among a very limited sample—to carry less stigma.

*Personal experience of conventional treatments for depression.* Individual's views on the appropriateness and acceptability of treatments for depression are obviously influenced by their own personal experiences of those treatments. Throughout the patient accounts, there was evidence of dissatisfaction with both counselling and medication.

they did offer me counselling at the surgery and I went once and I just thought, and she said to me during a conversation, once anyway, I think it's all caused by where you are and as soon as you move away from that the situation will be much better. I thought well I'm stuck there until I get re-housed, so nothing is going to change, so I thought I can't see how she's going to help me really and I just thought she isn't going to be any help and I'll just have to sort it out myself and I just didn't go back again, ... I don't think that everything can be solved just by talking and listening, ... But I only went once, so it wouldn't be fair to give a true guide on it, that was just me, it doesn't mean everybody though (Female patient 7, aged 38)

It appears that the personal experiences of using medication had influenced patients' views about its safety, and a number of patients commented on the potential 'dangers' of medication referring to the possibility of becoming dependent on drugs, their perceived 'toxicity' to the body, and also their unwanted side effects (Patient group 4).

Because I didn't feel, as soon as I started taking them I didn't feel like myself anymore. I constantly wanted to shake my head as if I wanted to clear it. It was like having a hangover all the time, but you hadn't had a drink, just that once removed feeling and I felt drugged. I just felt drugged, I didn't feel like myself anymore, and whereas before I'd still been getting up in the morning, you know, because I'd been feeling really anxious and I felt really anxious in the mornings, but I knew that if I got up and started doing things in the house and stuff like that, then it would pass and it would be okay. But when I started taking those things, I didn't even feel like getting up, which I thought was really backwards, if you understand and I kept thinking I must keep going for 3 weeks, people kept saying it takes 3 weeks for it all to balance out and start working properly. But I couldn't, it was horrible, I would rather have been, you know, tearful and sobbing half the time but at least the other half of time I knew I felt okay (Female patient 1, aged 47).

*Generalized views relating to treatments for depression.* GPs commented on the fact that certain patients were resistant to trying counselling or psychotherapy and thought acupuncture might hold some appeal for them. The level of personal disclosure required for acupuncture was thought to be less than psychotherapy; although the territory it covered was similar, it was thought to be less emotionally demanding (Patient group 5).

I think people would value an alternative to counselling ... the idea of sitting down and talking about their feelings and emotions to people, for many people it's not an easy thing to do again in my practice population, so even counselling, you know, people think counselling is universally attractive to people. In my experience it's not (Male GP 1).

Acupuncture practitioners believed that one of the main reasons people sought help, if they came specifically for depression and were using antidepressants, was to reduce or come off medication (Patient group 6)—this was associated with generalized views relating to feeling 'reliant' on medication:

those are the people who come for depression, usually because they don't want to go on the medication, are on the medication and don't like being on the medication, are on the medication and found it useful but don't want to stay on it forever, have been told by their doctor they need to come off it, love being on it and are scared to come off it, maybe acupuncture will help them, all the permutations of that (Female acupuncturist 6).

Others were ideologically opposed to antidepressants (Patient group 4) because they felt that they suppressed genuine emotions resulting from real social problems.

the drug syndrome is a symptom of modern life ... drugging people keeps a lid on it and I think in certain respects it serves certain aspects of society to do that ... it's like giving people happy pills isn't it, well it's not giving them, it's numbing down ... and I'm not for numbing down, I'm for keeping alive. So I think those options (alternatives to medication) should be there (Female patient 1, aged 47)

Among the patient stakeholders, part of the dissatisfaction with drug therapy was the lack of time and attention given by GPs that was associated with this intervention.

They (GPs) don't understand. My GP wasn't giving me enough time and he wasn't listening to me and stuff, you know, when you're in with the acupuncturist, you know yourself, you have a good

half an hour and my GP was five minutes (Male patient 3, aged 24)

Part of the attraction of such new interventions for depression is that acupuncture can provide the time and attention aspect, while being seen to be a physical treatment (avoiding the stigma associated with treatments of depression which focus on 'the mind'), which may be less challenging to participate in than psychological therapies.

### *Explanatory models of illness*

What is considered an appropriate treatment for depression is inevitably allied to what individuals see as the cause of the symptoms. For example, one patient who felt that acupuncture had made little or no difference to his depression did not consider it to be a plausible intervention. He strongly saw depression as a physical dysfunction of the brain, while acupuncture was focussing on the treatment of his body. Not surprisingly, psychological interventions were also dismissed by this respondent, who preferred to use medication. Likewise, with patients with concomitant painful or somatic symptoms who considered their depression to be a direct consequence of the other conditions they were experiencing. For such patients where the origin of their depressive symptoms is thought to be due to physical rather than psychological causes, treating this with medication aimed at altering brain chemistry or psychological therapy makes little sense. Among these patients, acupuncture appeared to be a more credible intervention—as it was characterized as an individualized whole-person approach, which attempts to address a range of problems in unison (Patient group 7).

For some patients, considering the whole body removed the emphasis of the consultation from the 'mind' or mental state. It was easier to talk about physical symptoms because they were simpler to describe than emotions, feelings and mental states, as well as less stigmatizing:

I was kind of 10 minutes into this history and he (the acupuncturist) very gently stopped me and said, you know, I really appreciate you telling me this stuff, that's absolutely important but can I ask you some other questions and he said, how's your stomach, how's your digestion? and I thought, right but it was key for me in that it wasn't asking me how I felt in here in my head, it was asking me about my body ... it took the focus off my head into my body which was a joy ... the complete opposite I guess of the cognitive therapy. (Female patient 5, aged 38).

The fact that acupuncture was not part of the conventional mix of therapies made it more appealing to

individuals with personal or cultural values that were congruent with an 'alternative' or culturally different approach.

My dad always thought that Eastern medicine, because for some reason he had more faith and hope in Eastern medicine and he thought he's always tried like homeopathic medication and thought that's more natural (Male patient 3, aged 24).

## Discussion

### *Summary of main findings*

While many people with depression are turning to complementary and alternative therapies, evidence relating to their effectiveness for depressive conditions remains unclear. This paper presents the preliminary developmental work for the development of a pilot RCT of acupuncture for depression. Using qualitative methods, our analysis has uncovered two broad themes, which have provided insights into why certain subgroups of depression sufferers may be particularly interested in a new intervention, namely acupuncture, for depression. Within the two broad themes, we have identified seven patient subgroups who could be the focus of an effectiveness trial of acupuncture for depression and who may have a particular interest in this form of therapy.

Our data have highlighted that the acceptability of particular treatments for depression is influenced by the individuals' illness career—that is previous experience of ill-health and their subsequent treatments experienced within their social context. In addition, the plausibility and associated acceptability of depression treatments are also closely tied to an individuals' explanatory model of their condition. Therefore, only therapies that are seen to address what they see as the root cause of the symptoms are likely to be viewed as potentially effective. These generalizable traits contribute to some individuals with depression finding orthodox treatments both acceptable and effective; however, there are many cases who remain dissatisfied with conventional options and would be receptive to testing new treatment options, an example of which is acupuncture.

### *Strengths and limitations of this study*

The sampling strategy we utilized facilitated the capture of a wide and diverse range of views and experiences; however, our participants may not be typical cases. For example, doctors who took part may have been motivated by their interest in depression or alternative medicine; as such, they may not be representative of the GP population as a whole. Likewise, we are aware that we only included those people with current or previous depression who had chosen to try

acupuncture. While there are potential problems with this approach, we felt that this sampling strategy would achieve the aims of the study, which were to identify subgroups of patients who could be included in a pilot trial of acupuncture for depression. The inclusion of negative cases was particularly useful in this regard and did alert us to the fact that while acupuncture will not be an acceptable treatment to all patients with depression, we wanted to identify those groups for whom it was likely to be acceptable in order to enhance our trial design, which we achieved through the identification of a number of potential 'therapeutic niches' for acupuncture to be tested as an intervention for depression in primary care.

Reflexivity is key to the quality of research of this nature.<sup>19</sup> In this case, attention was paid to the potential impact of researcher's professional role and prior social relationship to respondents. It was felt that using social and professional networks to gain access to potential respondents in order to invite them into the study assisted with recruitment and did not appear to have impeded disclosure. It is impossible to discount the fact that two of the researchers may, because of their own experiences of using acupuncture to treat depression, have held certain views about its potential benefits or role in depression care, which have influenced the study. However, 'preconceptions are not the same as bias, unless the researcher fails to mention them'.<sup>19</sup> Efforts were made to explore the impact of researcher's views on data collection, and a non-acupuncture practitioner had a substantial role in data analysis and interpretation.

### *Comparison with existing literature*

The concepts of illness careers and explanatory models are well defined in the understanding of the experience of illness,<sup>20–22</sup> particularly in relation to mental health problems.<sup>23</sup> In this instance, they have helped understand what might constitute appropriate treatment for people with depression and to explain why acupuncture might be potentially of interest or not.

The majority (62%) of patients who use a complementary therapy do so after they have already sought help from conventional medicine.<sup>24</sup> Our findings would seem to support the aforementioned survey data in that it was readily apparent that personal experiences of using counselling and medication had led to patients wanting to try something else in addition to or instead of National Health Service depression treatments.

The study findings resonate with those of other researchers who have explored why patients seek acupuncture in general. For example, a large-scale survey with a qualitative component found that the 'preferred aspects of care' valued by acupuncture patients included not only relief of presenting complaints but also the 'expanded effects of care including improvements in physiological and psychosocial adaptivity ...

and feeling more able to guide their own lives and care for themselves'.<sup>25</sup> Our findings also reinforce the evidence of a UK survey and interviews with ongoing acupuncture patients that identified that 'patients valued the holistic style of treatment offered'<sup>26</sup> and of qualitative research where the perceived 'whole-person effects' of acupuncture treatment were a characteristic feature of the intervention.<sup>27</sup>

We found that patients often were reluctant to disclose to their GP their desire to, or in fact, the reality of stopping their prescribed medication for depression. We also found that patients were far more concerned about the safety of medication than doctors or other health professionals. These findings lend support to research conducted on behalf of the Concordance Fellowship,<sup>28</sup> which identified discrepancies between patients and GPs views about antidepressants, particularly in relation to difficulties in discontinuing with them and the problems this might pose for patients, and demonstrated that patients felt pressed for time in depression consultations.

#### *Implications for clinical practice and future research*

Most acupuncture patients in our sample had mentioned the fact that they had used it to their GP, but some had not. This finding supports survey research that suggested patients' disclosure of complementary therapy usage to their GPs is relatively poor (<50%).<sup>24</sup> Our study may thus be of particular interest to health professionals wishing to better understand the potential therapeutic role for acupuncture as an intervention for depression. Should it prove effective, the patient subgroups we have highlighted may welcome a referral from their GP or relevant health professional.

The findings from this study have proved useful to help direct the research to patient groups where the intervention may be most welcomed. This study was intended as a springboard for further research into the effectiveness of acupuncture for depression, which is currently underway. This study was not designed to consider the acceptability of acupuncture as an intervention for depression more generally—this will be considered in the context of an RCT, through examination of response rates, uptake of the intervention and attrition.

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## Declaration

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