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Acupuncture for Depression: Exploring Model Validity and the Related Issue of Credibility in the Context of Designing a Pragmatic Trial

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SUMMARY

Introduction: Evaluating care that is not credible to its practitioners or patients will result in a gap between evidence and practice and the potential value, or harm, of the intervention may be underestimated. Our aim was to develop a pragmatic trial that would have better model validity and credibility than trials to date in this clinical area. **Methods:** In-depth interviews; a nominal consensus technique and five arm pilot trial conducted in UK primary care using counseling and usual general practitioner (GP) care as comparisons for acupuncture. **Findings:** Patients with long standing, severe illness that had not responded, or partially responded to conventional treatments may be interested in using acupuncture and participating in a trial. Using a database method to recruit, pilot trial patients were mostly severely depressed (87.5%); chronically ill (60% with 3+ previous episodes), with high levels of comorbidity, and medication use. Acupuncture was as credible to pilot trial participants as usual GP care and more credible than counseling: most patients (62.5%) preferred to be allocated to acupuncture, rating it more highly at baseline than counseling or usual GP care as potentially able to benefit their depression ($P = 0.002$). Disparities were identified in the working models of acupuncturists and counselors that suggest inherent differences between interventions in terms of the process and intended potential outcomes of therapy, as well as the interaction between patients and therapists. **Conclusion:** The Medical Research Council (MRC) framework with its phased, mixed method approach has helped to develop research that has better model validity than trials to date in this field. The next phase of research will need to involve acupuncture and counseling practitioners to help researchers to develop realistic and credible care packages for a full-scale trial, where patients are likely to be severely and chronically ill.

Introduction

Intervention credibility is of fundamental importance to researchers designing experimental evaluations: if the care provided in the intervention under investigation is not credible to practitioners who provide care, or the patients receiving it, then the research may underestimate its potential benefits or harm. Equally, if the comparator arm(s) is not thought to constitute credible care then researchers may be accused of attempting to exaggerate the effects of the intervention by choosing a therapeutically weak comparison.

Acupuncture is an example of a traditional medicine where researchers argue that the concept of model validity, in the context of an experimental evaluation, is of equal importance as internal or external validity [1]. To have good model validity, an intervention should have good credibility with practitioners and patients; and also strong model congruity: the diagnosis, treatment, and outcomes should be a good "fit" [1], thus credibility is a central tenet of the model validity concept. Evaluating credible outcomes is one aspect of model validity that should not be overlooked and attempts have been made to design studies with relevant patient reported outcome measures (PROMS) [2,3]. Although, in some instances, even such measures do not always capture what is of greatest importance to the patients or study participants [4]. For certain interventions (including acupuncture), this is of particular importance when the desired outcome for the patients may not be limited to medically defined measures of disease.

Depression is set to become the second leading cause of lost disability-adjusted life years by 2020 (see 5:250–1) [5]. This illness affects many people's lives, either directly or indirectly, and the

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economic burden to society is considerable [6]. It is of paramount importance that new and more effective treatments are identified that can better meet the needs of patients [7–10], for whom the illness is usually a chronic, recurring, and debilitating problem [11]. There have already been a substantial number of trials of acupuncture for depression, most conducted in China, that have mainly focused on the short-term benefits of specific treatment protocols and techniques. This type of research has resulted in an evidence base that has weak model validity [1,12], and poor credibility among acupuncture practitioners (in Western contexts) because it does not reflect clinical practice [12]. Additionally, it is debatable whether protocol acupuncture evaluations would constitute "best practice" or achieve optimal results as such treatment does not take into account the patient's changing needs and allow for modifications to be made—as would normally happen in routine clinical practice (in Western contexts). Furthermore, one of the strengths of Chinese medicine acupuncture is that, in theory at least, because of a conceptualization of therapeutic effects resulting from a bodily re-education or learning process [13], the treatment can potentially help to prevent future illness recurrences, as well as alleviate current problems. It is thus disappointing that the research to date has focused only upon symptom alleviation rather than this in addition to the potential for prevention [14]. Although preventative treatment trials are more costly, an intervention that offers protective benefits would have considerable social and economic benefits, as estimates suggest only 20% of individuals suffer only one illness episode with the mean number of lifetime episodes being four [15].

One main aim of our research was to design a trial where therapeutic integrity is not compromised by the trial's design and the therapy provided has good credibility with practitioners/care providers. The research program was organized around a PICO (patients; intervention; comparison; outcomes) structure [16]. In relation to patients we sought to identify particular patient groups, within the context of UK primary care where most depression is treated, for whom acupuncture could provide additional benefits and would have high credibility as such individuals might be more amenable to using the intervention, and participating in a trial. For the acupuncture intervention the main challenge was to find a way to "standardize" acupuncture care, and to define and delineate the parameters of treatment appropriately, while maintaining credibility and without compromising therapeutic integrity. In regard to the comparator arm we sought to identify which interventions would be credible comparisons; could be of most interest to stakeholders; and would prove feasible, and practical. Finally, in relation to outcomes, we sought to understand the perspectives of those giving and receiving acupuncture care to identify its potential consequences (positive and negative), and to identify or develop appropriate measurement instruments, or methods, to capture these.

Methods

The research program consisted of three studies, the methods of which are summarized here as they have been described in detail elsewhere [17–19]. The purpose of the interview and consensus studies was, primarily, to obtain knowledge to inform the design of the pilot trial/process evaluation [20,21]. The design was guided by the Medical Research Council (MRC) framework for evaluating complex health care interventions [22], where pretrial preparatory research involves an iterative research process [23].

In-Depth Interview Study

The in-depth interview study used a criterion sampling method [24] to capture diversity (maximum variation sampling) across key criteria. Thirty-three interviews were conducted with participants from three stakeholder groups: physicians (nine GPs and one psychiatrist), patients who had used acupuncture for depression ($n = 10$), and acupuncture practitioners ($n = 13$). The patient sample included three negative cases (individuals who had not found acupuncture to be effective or had observed negative reactions to the intervention). Topic guides were developed for each stakeholder group. Interviews were transcribed and analyzed using a framework approach [25]. A reflexive analytic approach [26] was used to consider the impact of researcher's interests on the study, using the Framework approach to identify a potential therapeutic role for traditional acupuncture as a depression intervention in the UK primary care context; to find out what interventions GPs would be most interested in as comparisons in an experimental evaluation; to explore the acupuncture treatment process in depression; and to better understand the changes and outcomes that were perceived to result from receiving acupuncture

Consensus Study

The aim of the consensus study was to define and delineate the parameters of acupuncture care to be evaluated in a trial by identifying which aspects were perceived by practitioners to be of crucial importance therapeutically. In order to give equal weighting to each practitioner, a nominal group technique [27] was used that involved an electronic rating followed by a face-to-face meeting and a further electronic rating. Fifteen participants, all members of the British Acupuncture Council (the leading professional body), were selected for participation on the basis of their experience and training across a range of acupuncture styles used in the United Kingdom. Components, identified from the literature and based on researchers' (SS and HM) combined clinical knowledge, were added to or eliminated by participating practitioners, and rated in two rounds. Eight of the practitioners took part in a face-to-face meeting (between the two ratings) where a structured discussion about each component took place. Practitioners attending this meeting developed a list of "guiding principles of treatment" for depression. Components or items for which there was "group support" in the second and final round (those rated as appropriate in the range 7–9 by at least 75% of the participants) were used to develop a practitioner's log, to simplify and standardize reporting of acupuncture care in the trial.

Findings from these two preparatory studies were used to inform the design of the pilot trial. It was important to test the findings in a pragmatic intervention setting from this preliminary work, on which the patient group, intervention protocol, comparator intervention, and outcome measures were decided using a pilot randomized controlled trial (RCT).

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Pilot Trial

Potentially eligible patients were recruited from primary care, screened for depression, and randomized to one of five groups. The rationale behind the complex five arm design was to better understand what might constitute an optimum therapy regime for trial patients recruited from primary care. All five groups continued to receive usual care. Two groups were allocated to receive acupuncture, either a 12 or 24 session maximum allowance, and two groups were allocated to similar maximum durations of nondirective counseling. Patient preferences were ascertained at baseline with each of the intervention types being rated on a seven point scale according to whether it was thought likely to be of benefit for depression. All participants were randomized regardless of these preferences in a fully randomized preference design [28]. Data collection was by postal questionnaires. The Beck Depression Inventory (BDI) II [29,30] was the primary outcome measure. A range of secondary outcome measures were used (e.g., the SF 36 pain subscale, EQ-5D, and W-BQ12 well being questionnaire) recorded at 3, 6, and 9 months. Monthly tracking, using a short questionnaire (to minimize the burden of participation), was conducted at other months for a period of 9 months.

The pilot trial included a qualitative process evaluation whereby participants were invited to provide written feedback about trial participation and acceptability of measures taken, as open ended questions within the follow-up questionnaires. Practitioner's logs were completed by acupuncturists and counselors to provide a record of therapy provision, describe adverse events, and to explore therapist's views on participation, acceptability of interventions, and the utility of the log. Deviations to protocol were allowed, if thought necessary by therapists, who were asked to record these in the log. Standard descriptive statistics were used to describe any differences observed across the arms of the trial. The qualitative data from the process evaluation were analyzed using content analysis [31].

Combining qualitative and quantitative methods, as the MRC guidelines recommend is not straightforward because of their epistemological and ontological differences [32,33]. We have therefore employed a pragmatic reflexive approach, based on Hammersley's subtle realism. Subtle realism shares with naïve realism the idea that research investigates independent and knowable phenomenon but differs because it postulates that there is no direct access to these phenomenon. It shares with relativism the assumption that reality is only knowable through socially constructed meaning [34,35]. In line with this essentially reflexive approach, consideration was given to whether there was convergence, complementarities, or disparities [36,37] within and between the various study findings to enhance research comprehensiveness. Three main methods for integrating data from mixed methods research have been described by O Cathain et al. [38]. The method used here was similar to the "following a thread" approach [39]. The interview study and consensus technique were first analyzed separately—in order to design the pilot trial. Once the pilot trial had been completed, the findings of the two other preparatory studies were used to help interpret the results of the pilot study. The thread that has been followed here is that of credibility, which would help us achieve our aim of developing a full-scale trial with high model validity.

Findings

Findings are described under relevant PICO headings.

Patients

A number of topics/themes are discussed below, which all relate to credibility. These are: help seeking with acupuncture for depression, GP referral to acupuncture for depression, characteristics of trial patients, trial intervention preferences, and comparative uptake and usage patterns.

Help Seeking with Acupuncture—Why Some Patients Might like It, and Others Not?

Acupuncture's credibility was, according to interview study findings, related to personal experience of using it, illness history, previous experience of using depression interventions, and patient's explanatory models of illness. For example, in one case a patient who had ruled out psychological therapies because of their perceived lack of credibility, stopped using acupuncture after only four treatments—because it did not appear to have much impact on his illness, and, being a bodily focused intervention, he doubted its capacity to help with mental problems, which were thought to be located in his brain. Medication, which he reported had exacerbated his illness, was thought to be more appropriate because it simply made more sense to him.

In contrast to this patient, other patients preferred using acupuncture to medication, because they had experienced positive outcomes from it, valued the holistic approach that concentrated on other health problems as well as their depression, and, in some cases, felt that medication had resulted in emotional disturbances or "blunting". Their experiences of using medication had led to negative feelings about it, which contrasted with their impressions and experiences of acupuncture.

GP Referral to Acupuncture for Depression—Which Patients Might Want to Try It?

Interview study findings suggested that patients who had tried conventional treatments with partial or limited success, or had positive experiences of complementary and alternative medicines (perhaps because of a positive previous experience), might be more likely to be interested in using acupuncture for depression. Moreover, the diagnosis of depression was potentially anxiety provoking because it carried considerable stigma, and, the nature of the illness itself might result in heightened anxiety levels, especially when the diagnosis was first offered by a physician. This suggested to patients that some individuals, particularly those experiencing depression for the first time, might initially be more comfortable using a depression intervention that was "tried and tested" or at least recommended by their GP. It seemed unlikely that GPs could provide such reassurances because with the exception of one key informant, the GPs in our sample did not associate acupuncture with depression. However, they considered acupuncture had good credibility with patients in a general sense and seemed open to the possibility it could be helpful for

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depression sufferers, particularly where other more commonly used treatments had not been wholly successful.

In terms of trial recruitment, it was the case that referring patients to an acupuncture intervention remained problematic for some general practitioners—as one of the three practices that were approached to participate in the pilot trial did not agree to recruit depressed patients. The reason given was they felt they had lost credibility with their patients on a previous project where they had been required to refer patients to an evaluation of acupuncture for irregular menstrual bleeding. Acupuncture for depression was evidently also not thought to be a straightforward referral by these doctors.

Characteristics of Pilot Trial Patients

Details of pilot trial participants are shown in Table 1. To summarize: pilot study participants, including 34 women and 6 men, were mostly (87.5%) severely depressed (BDI of >28) and chronically ill (60% with 3+ previous episodes), with high comorbidities (82.5% had other health problems and 42% had 5+ other health problems). It is notable that only three out of 40 individuals were experiencing their first episode of depression. Nearly 50% of participants (19/40) were not working with 15/40 being signed off work by their GP. As such these patients may be economically disadvantaged and may be somewhat different from the type of acupuncture patient that is normally seen by acupuncturists working in private practice.

Intervention Usage and Patient Preferences

Pilot trial participants had relatively high levels of medication use: 70% had used depression medication and 62.5% had used medication for problems other than depression in the 4 weeks prior to baseline. Of the 40 patients with depressive symptoms recruited into the trial, 72% had previously used counseling and 17% had previously used acupuncture; however, 62.5% expressed a preference to be allocated to acupuncture. Acupuncture was rated more highly than counseling or usual GP care as potentially able to benefit depression ($P = 0.002$, using a Friedman test). However, there was little evidence that the distribution of expectation that acupuncture will help the depression differed by the allocation group ($P = 0.272$ using a Kruskal–Wallis test). Similar results were observed for the expectation that counseling will help or GP will help with the depression ($P = 0.634$ and 0.436, respectively).

Intervention

From the in-depth interview and consensus study research we ascertained that to be a credible evaluation for practitioners the therapeutic approach would need to be holistic, in part because patients often seek help initially for other illnesses in private clinical practice, and frequently suffer from comorbidities, which influences the treatment strategy. The Chinese medical diagnosis and *qi* paradigm were considered of paramount importance to practitioners with Chinese medical theories being used to explain and

Table 1 Baseline characteristics of participants according to group allocation

	Acupuncture 12 sessions n = 6	Acupuncture 24 sessions n = 6	Counseling 12 sessions n = 6	Counseling 24 sessions n = 6	Usual GP care n = 16	Total n = 40
Mean BDI score (SD)	44.17 (11.3)	38 (12.29)	43.16 (6.43)	39 (10.6)	37.18 (8.90)	39.53 (9.7)
Mean (SD) age in years	39.33 (14.56)	45.67 (16.8)	36.83 (13.74)	44.17 (22.92)	37.63 (12.46)	41
Experienced three episodes or more	2	3	5	2	12	24
Mean (SD) age in years of first depression episode	24.83 (17.00)	29.5 (15.15)	16.25 (1.89)	27.2 (27.56)	21.15 (11.17)	23.4 (15.3) (n = 34)
No. of females	6	4	5	4	15	34
Other health problem(s)	6	5	4	5	13	33
Five or more other health problems	2	4	0	4	7	17
Medication for depression (4 weeks)	5	4	4	5	10	28
Previously used counseling	5	4	2	5	13	29
Previously used acupuncture	2	1	0	2	2	7
Prefer acupuncture	4	3	3	3	12	25
Prefer counseling	0	0	1	0	0	1
Prefer usual care	0	0	0	0	1	1
Any of the above	2	3	2	3	3	13
Mean (SD) expectation will help depression (1 = least help, 7 = most help)						
Acupuncture	6.17 (1.33)	5.2 (1.30)	4.8 (1.64)	4.83 (1.33)	4.8 (1.15)	5.1 (1.3) (n = 37) *P*-value = 0.272
Counseling	4.33 (1.76)	4.17 (1.17)	5.00 (1.22)	4.00 (1.79)	4.73 (.88)	4.5 (1.3) (n = 38) *P*-value = 0.634
Usual care	4.17 (2.71)	4.83 (1.47)	3.67 (1.63)	4.00 (1.41)	3.27 (1.79)	3.8 (1.8) (n = 39) *P*-value = 0.436

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"empower" patients, by reframing depressive illness in Chinese medical terms to destigmatize it. The implication of these findings for an experimental evaluation is that practitioners would like to use Chinese medical constructs when discussing the treatment strategy with their patients, and, that a protocol approach, with treatment that is prespecified (according to the illness label of depression) would not suffice as treatment would need to be "holistic" and patient focused rather than based on a specific disease.

The guiding principles of treatment developed by practitioners attending the consensus study face-to-face meeting are shown in Box 1.

Box 1. Guiding principles of acupuncture treatment for depression (from the consensus study meeting)

- To facilitate the empowerment of the patient.
- De-stigmatizing and transforming the depression label into something meaningful for the patient in terms of their experience.
- Helping the patient to understand the causes of depression.
- "Lifting" the patient, easing the process, and helping the patient gain a sense of perspective.
- Facilitating a patient's connection with the authentic self.
- Facilitating the "progression" of the patient.
- ACHIEVE ALL OF THE ABOVE BY DIRECTLY AFFECTING A PERSON'S QI*
- Bringing in the "whole of themselves and their experiences" to do this.

*Capitalized because it was viewed as the most important and defining guiding principle.

Data from the pilot trial practitioner logs suggested that from their perspective acupuncture was thought to be a suitable or credible intervention for the trial population. Practitioners commented in their logs that the intervention would likely to be of benefit to the patients they were treating. There were only two minor protocol deviations in the pilot trial with one of the trial practitioners recommending ergonomics and stretching exercises suggesting acupuncturists were generally satisfied that with the flexibility they were given, and believed they could potentially achieve something useful for patients, while recognizing these might be challenging cases where on-going support was required.

Comparison

In terms of identifying credible comparisons for acupuncture, the interview study indicated that GPs in particular would be most interested in pragmatically useful comparisons such as antidepressants and psychological therapies.

The interview study suggested that patients would be more likely to initiate and continue with treatment if they perceived it offered potential or real benefits. For some interview study patients counseling was perceived as worthwhile but for others it was not. There were some concerns raised about brief National Health Service (NHS) counseling interventions being off putting as patients felt they would not be able to achieve much in such a short time and such minimal care would not be appropriate under the circumstances. Interview study patients who had prematurely terminated counseling also described how they felt that counselors might not be able to address the problems that had given rise to their depression, when these problems were to do with circumstances beyond their control. However, counseling was the only feasible type of psychological therapy to use as a comparison, and nondirective counseling was used in the pilot—as it had been suggested (via consultations with service managers for psychological therapies) that counseling would have broad applicability and might suit a wider range of primary care patients than other types of psychological therapy. We recruited two counselors who together designed a nondirective counseling protocol. The pilot study showed that despite its wide usage it is possible to recruit sufficient individuals from primary care who are not currently receiving counseling and would like to take part in a trial.

Therapy Initiation and Attendance

Table 2 compares the therapy initiation rates, rates of good attendance at therapies, and trial attrition rates by type of intervention. High attrition rates were observed across all three types of intervention (acupuncture, counseling, and usual care), but this was greatest among those allocated to counseling, where uptake was poorest, especially in the 12 session allocation group. Counseling had a lower therapy initiation rate, compared to acupuncture, and lower rates of "good attendance." In the 12 session group, only one patient used full allowance of 12 sessions of counseling compared with three patients for acupuncture—although attendance in the 24 session group was better than acupuncture (three counseling patients used their maximum allowance compared with no acupuncture patients). Drawing conclusions about attendance patterns on the basis of such small numbers (six in each group) is unwise but it is likely that patient's prior experiences of counseling had influenced their views about its potential to be of benefit and resulted in different rates of therapy initiation and usage. Additionally, acupuncture and counseling involve different therapeutic processes, which may in turn influence usage patterns. While the

Table 2 Showing therapy uptake, attendance, and complete trial follow up—at every month—for the trial duration

	Acupuncture intervention N = 12	Counseling intervention N = 12	Usual general practice care N = 16	χ^2 (*P*-value)
	N (%)	N (%)		
Used therapy	10 (83)	8 (67)		0.13 ($P = 0.72$)
Good attendance (50% or more of the allowance)	7 (58)	6 (50)		0.05 ($P = 0.82$)
Complete trial follow-up	6 (50)	3 (25)	7 (44)	0.78 (0.68)

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P-values suggest that there are no differences between the groups, these analyses are likely to suffer from insufficient power. However, regarding the credibility of the acupuncture intervention, it appears that this was at least as credible as counseling in terms of initial uptake and was very similar to usual GP care as measured by trial completion.

Deviations to the person-centered approach and referrals to other types of psychological therapy in the pilot trial suggested there may be an element of dilution should counseling be restricted to the person-centered approach in a full-scale trial. However, it may be that overall, when compared with other types of psychological therapies, this approach offers a wider range of applicability to primary care patients as the therapy is by definition tailored to the patient and the therapy process may be less demanding cognitively than other methods such as cognitive behavior therapy. There was only one patient for whom the intervention was thought to be inappropriate at the initial assessment because the patient's depression, which was thought to result from work-related stress was now resolved and both the patient and counselor saw no need for counseling. Counselors' views about the potential for the intervention to be of benefit can be seen in Box 2, which shows that 12 sessions, were not thought likely to be sufficient in some cases. Prematurely terminating therapy might have harmful consequences for some individuals due to expected (on the part of the trial counselor who saw all but one of the patients) initial illness deterioration, which was considered part of the treatment process.

Box 2. Counselors' views about the potential of nondirective counseling to help clients and opinions about therapy provision

- Counseling may help her become more forward looking, build confidence and self esteem, and deal with unresolved stress from recent traumatic events.
- May benefit from emotional support and time and space to explore feelings and thoughts associated with loss, transitions, mortality, and a traumatic assault (Counselor 1).
- Quite optimistic despite extent of client's difficulties. Highly motivated, intelligent, psychologically minded, and good emotional connection.
- Client has little psychological mindedness. Current distress seems to stem mainly from an abusive childhood. Twelve sessions may be too few.
- Severely depressed, 24 sessions may be of great help in this regard.
- May find counseling challenging, trust issues, is aware she may feel worse before she feels better.
- Client might find person centered counseling challenging and might get worse before getting better, in this respect I expect 24 sessions might be needed.
- Counseling might enable client to put painful incidents and relationships behind her—client offered and accepted a further six sessions as she was not in an appropriate state to end as planned (initially allocated to 12 sessions).

Outcomes

A credible evaluation means measuring credible outcomes that are good fit to the model and expected by practitioners and patients receiving care—for both the intervention under investigation and comparison. In order to be a fair evaluation great care must be taken when selecting measurement instruments, particularly if the interventions have a different therapeutic focus and range of effects. Equally, if the intervention under investigation is expected to result in a wide range of improvements (as may be the case with acupuncture) while the therapeutic focus of the comparison intervention(s) is narrower it may be important to identify and quantify any additional benefits from the intervention under investigation.

The interview research highlighted how acupuncture patients often sought help initially for other health problems and discovered during the course of treatment that their depression symptoms were improving. Patients receiving acupuncture, and for whom it was perceived to be effective, commented on observing a greater sense of physical and psychological well being after treatment than they had with conventional therapies, and that medication reduction or discontinuation, which was evidently a reason for help seeking initially for some, partly because of concerns about dependency, was also highly valued as an outcome. In view of these findings, attempts were made to investigate broader outcomes resulting from acupuncture including whether the intervention could help with bodily pain, with well being, and with quality of life.

There was evidence in the pilot study, based on the counselor's log, that counseling patients in the pilot used the intervention to provide additional support to help with discontinuation, making measurement of medication use important in a full-scale trial to draw comparisons between the different types of care.

Intriguing disparities were identified between acupuncturist's and counselor's logs in the pilot trial, where therapists recorded the main symptoms and problems, from the patient's/client's perspective—see Table 3. Responses suggested the therapeutic focus for the two types of care may be subtly different, and that patients and practitioners working with them have different expectations of what the interventions can potentially treat—which might impact on interactions between patient and therapist and on therapy outcomes. Counselors reported physical health issues but their work appears to focus more on psychological and emotional problems, trauma, and relationship/work issues, whereas acupuncturists mentioned mental and emotional health but additionally described a wide range of physical health problems including: respiratory, circulatory, and digestive disturbances, arthritis, headaches, menstrual problems, and heart conditions. There was also more of a focus on physical symptoms such as tiredness and energy with acupuncture than counseling. These findings, which showed convergence with the interview study in relation to acupuncture being potentially at least, of greater physical benefit than counseling, have implications for outcome measurement in a full-scale trial.

In terms of depression outcomes it is notable that very few people who participated in the pilot trial achieved remission: 4/40 at 3 months; 8/40 at 6 months; and 5/40 at 9 months—across all intervention groups. Also of interest is the fact that none of the

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Table 3 Main symptoms as reported in therapist's logs

"Main symptoms and problems from the patient's perspective using their own words if possible"	
Acupuncture	Counseling
Depression and anxiety, Irritable Bowel Syndrome, lack of appetite, stomach cramps, tension headache, heavy menstrual bleeding, prone to thrush, viruses and cystitis, nightmares since childhood	Work-related stress. Anxiety, panic attacks, loss of appetite "head all over the place"
Depression, low self esteem, relationship problems, tearfulness, lost her "spark"	Number of significant losses, transitions and ill health problems, several serious operations, victim of violent assault, carer of wife with Alzheimer's, given up hobbies and feels isolated
Can't cope with stress, introverted, "always tired," "headaches"	Extreme anger, low mood, feelings of unhappiness, wants to come off antidepressants
Death of wife in 1976 precipitated high levels of stress and a stroke, agoraphobia after stroke, talks a lot and very fast, heart problems, angina and irregular heartbeat, poor sleep, occasional bad migraine	"Can't cope with life," "Zero self esteem," "Sometimes I hate myself" "I cut myself to blot everything out and focus on the pain." Episodic anxiety, depression, alcohol abuse, aggression, eating problems, self-harm, self-destructive spending sprees, very low self esteem
Very tired and weepy, doesn't sleep, over-worrying, some anxiety	Work and relationship stress, now unemployed following forced redundancy, feels lost.
Thinks that depression started when she was 10, hid in her bedroom as a teenager, any difficulty in life sends her into a depressive state, poor sleep, long-term sciatica and similar problems, constipation—does not get feeling of bowel movement, night sweats	Extreme anger and stress, history of physically abusive relationships, daughter as a result of rape, troubled relationships, low self esteem
Depression for 6–7 years, using antidepressants on and off since 1999, relationship and work stress, left husband and remarried, alternates between feeling happy and sad for no reason	Severe depression, anxiety, panic attacks, insomnia, violent temper, suicidal thoughts, self-harms to relieve pain
"I am the door mat" Very tired, feels overwhelmed by responsibilities, no time for herself, terrific pain from arthritis (spine, hips, knees), frozen left shoulder	"Life in general is too much for me", Husband's cruelty hard to endure, agoraphobic since separation from husband in 1976
Depression, poor health is having impact on self-image, university studies, and work ambitions. Sinusitis, poor immunity, eczema, hay fever, painful menstruation since menarche, sensitive digestion, food intolerances	Currently depressed as a result of troubled upbringing, family relationships and a rape 5 years ago, experiences traumatic flashbacks, irritability, feels angry, resentful, guilty, "want to be normal again"
Severe depression from age 15, like stepping into a black hole when it comes on. Severe back pain following car accident, which makes depression worse, not as mobile as before, diagnosed with COPD and emphysema	

12 patients allocated to acupuncture care worsened from baseline during the course of the trial whilst 4/12 in the counseling group worsened and 4/16 in the usual care group worsened.

Discussion

Summary of Findings

Preparatory research was conducted to inform the development of a full-scale trial of acupuncture for depression where the intervention under investigation, and comparison(s) could have good credibility with patients and therapists. A pilot trial has indicated that it is feasible, using a database method, to effectively recruit individuals from primary care into a study where acupuncture is compared with counseling and usual GP care. However, the majority of patients who might want to participate in the research are likely to be severely depressed, have a long history of illness, suffer with multiple health problems, and prefer acupuncture to counseling or usual GP care. The majority are likely to be using antidepressants and have used counseling previously. While patients showed improvements in depression scores, very few participants achieved remission over the course of the pilot trial. The preparatory research has also suggested discrepancies in therapeutic focus and treatment processes between acupuncture and counseling with acupuncture being more focused on physical problems. It was observed that counseling is expected, in some cases, to result in illness deterioration during the initial treatment phase and suggests the process of therapy may be different and possibly slower than acupuncture where there is no expectation of deterioration. The fact that a larger proportion of patients deteriorated from baseline in the counseling group as compared with acupuncture, where no patients worsened from baseline, may be a chance finding but it may also be indicative of different therapeutic processes.

Strengths and Weaknesses of the Research

The main strength of this research is that stakeholder's views and opinions were systematically investigated in a program of preparatory research, and the findings can be used to inform the design of full-scale clinical trial that has relevance to the UK primary care context, and has good model validity. In the field of acupuncture research, particularly in the area of depression [12], this represents a major step forward.

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A weakness of the research is the reliance solely on self-report outcome measures including the BDI, which was selected as the main outcome measure.

Our research would have been improved by a follow up with pilot trial therapists, sharing with them the clinical results, and seeking their views and opinions about optimizing therapy provision in a full-scale trial. It would have been useful to bring in other acupuncturists and counselors to comment on therapy provision and whether the care provided in the pilot was representative and the working models of trial therapists reflected their own perspectives on intervention mechanisms. Interviews with pilot study patients could more fully explore their experiences of receiving different interventions, their reasons for using or not using interventions, and to obtain a better understanding about reasons for such high levels of trial attrition.

Comparison with Existing Literature

The literature suggests that the 12 session allocation may have been undertreating patients. Zhang et al. report, in a recent systematic review of acupuncture trials for depression, [40] that the number of acupuncture treatment sessions for the 20 trials included in the review ranged from 24–60, albeit with treatment provided over a much shorter time duration (4–12 weeks), mainly because acupuncture is implemented on a daily basis in China rather than weekly or biweekly. The implication of this, in the light of our own research findings, is that a longer, and possibly a more intense initial therapy regime, may achieve better outcomes– should similar patients be recruited into a full-scale trial to the pilot. National Institute for Clinical Excellence (NICE) guidelines [41], which employ a stepped care approach based on severity, recommend that patients with severe depression are offered high-impact psychological interventions typically of 16/20 sessions duration. Counseling is not recommended for the type of patients that were recruited into the pilot trial by NICE although person-centered or nondirective counseling is, according to the CORE database, by a considerable margin, the most widely employed therapeutic intervention for depression across all settings (primary, secondary, tertiary, and specialist NHS care) [42]. As such non directive counseling represents a useful/credible pragmatic comparison for acupuncture provided that depression severity/illness history are given due consideration when designing a full-scale trial.

While our research identified disparities between counselors and acupuncturists, Launso and Skovgaard (2008) [43] have more systematically investigated differences in the working models of conventional doctors and alternative practitioners, in the course of trying to bring therapists and doctors together to help multiple sclerosis sufferers. A tool was developed to make the differences more visible—based on an IMCO (intervention, mechanism, context, and outcomes) model. This tool could be of value for developing trials with good model validity. Model validity is important because differences between interventions can be exaggerated by the design of a trial, which can introduce an inherent bias and favor one intervention over another—for example, by measuring outcomes that are more likely to result from one intervention, or, by stopping therapy before one of the interventions has had a proper chance to work—because the process of therapy is different and takes longer. A better understanding of the differences between acupuncture and counseling, some of which have been identified by this research, will help to develop a fair evaluation comparing the two therapies in relation to alleviating depression and any protective benefits they might offer. It may be that the two types of intervention are equal in terms of depression but acupuncture, with its bodily focus, can help with other health problems—at the same time as treating depression.

Implications of the Research for Further Study and Practice

Preparatory research for a full-scale trial is not expected to influence practice, nevertheless this research has highlighted that acupuncture may be an acceptable and credible form of treatment for depression, particularly for individuals who have not responded to other interventions.

It must be acknowledged that most of the patients who took part in the pilot trial were complex cases, with long illness histories. Care provision in a trial must be appropriately geared up to offer support to these individuals as there is little point in evaluating an incomplete therapy process. Prematurely terminating care in a trial may ultimately undermine the intervention's credibility as a potentially useful one for illness sufferers, or mislead service commissioners into concluding the treatment is only partially effective. Our research exploring model validity and credibility has revealed disparities in therapeutic processes between acupuncture and counseling. Careful thought must be put into the design of an experimental evaluation so that it does not inherently favor one intervention over another because differences between the two interventions will be exaggerated. For counseling patients, there is a chance, according to our preparatory work, that they may worsen during the initial treatment phase. Thus inadequate therapy provision has more serious implications than for acupuncture as it is ethically questionable to involve patients in research where there is a possibility their condition could deteriorate as a result of research participation.

Before proceeding to trial, further research and consultation is required, involving acupuncture practitioners, and counselors to allow them the chance to reflect on research findings from the preparatory studies and provide input about what sort of care provision and courses of therapy would be appropriate and credible for a similar patient population in a full-scale trial.

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Conflict of Interest

The authors have no conflict of interest.

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