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TITLE:

Acupuncture as a complex intervention for depression:
a consensus method to develop a standardised treatment protocol
for a randomised controlled trial

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Abstract (249 words)

Objective

To standardise a complex intervention by defining the characteristic (specific) components of treatment for a randomised controlled trial of acupuncture as an intervention for individuals who have been diagnosed with depression using a consensus method.

Methods

A nominal group technique was used. Potential components of the acupuncture intervention were generated from the literature, experts, and participants. These were categorised as constant or variable, the latter including active management techniques (such as providing relevant explanations), auxiliary techniques (such as auricular acupuncture), and other aspects of patient care (such as offering lifestyle and dietary advice), all of which were underpinned by defined theoretical frameworks. Participants were selected on the basis of their experience and training, to encompass a diverse range of styles of traditional acupuncture practice in the UK, and all rated components in two rounds.

Results

Fifteen practitioners rated 52 variable components in the first round and 55 in the second. There was group support for 16 active management components, three auxiliary techniques and five areas of life-style support, all driven by eight theoretical diagnostic and treatment frameworks. For the 39 components that were rated twice, group support

increased between rounds from 75% to 79% (z=-2.2, p=0.03), while the absolute average deviation from the median dropped from 1.04 to 0.83 (z=-2.5, p=0.011).

Conclusion

Standardising the characteristic components of a complex intervention for a randomised controlled trial of acupuncture for depression using a consensus approach is feasible. The method can be generalised to other clinical situations and other treatment modalities.

Introduction

Randomised controlled trials are regarded as the most rigorous method of comparing the impact of two interventions. In complex interventions built up from a number of inter-related components delivered by a therapist, defining the precise nature of the intervention can be problematic. An intervention can be described as "complex" when there is "difficulty in defining precisely what, exactly, are the 'active ingredients' and how they relate to each other". (1) The Medical Research Council has identified defining the intervention as "the most challenging part of evaluating a complex intervention", yet it gives little advice on how this should be done. Nevertheless, knowing the precise components of treatment within a randomised controlled trial is essential in order to know what it is that is being evaluated and to what one can attribute change to, therefore enabling the results of a trial to be more easily interpreted or replicated.

There has been a tendency in acupuncture research to attempt to simplify the complex nature of the intervention and focus on particular components that can then be treated as the 'active' ingredients of the therapy. In some trials, a particular group of acupuncture points is delivered to each patient in the same way at each treatment session. In other trials there may be an individualised treatment strategy but each patient receives the same initial treatment at every session throughout the trial (2) or the same treatment for a month at a time, with changes based on reassessment (3) There is a theoretical advantage here in that the tighter the specification, the easier the interpretation of the results of trials, so that one can identify more precisely to what one can attribute the outcome to. The disadvantage of these studies is their low ecological validity when

compared to normal practice, with the implication or poor generalisability. Should the outcome of a trial with a tightly specified intervention be negative for acupuncture, then interpretation might be problematic. There will be a "negative conundrum": was it that that acupuncture didn't work, or was the integrity of the intervention compromised to the extent that the treatment was simply inadequate? At the other end of the spectrum is the loosely specified trial protocol. This has the advantage that it may be more readily generalised to routine care. The downside is that if acupuncture practitioners incorporate additional therapeutic modalities into a treatment, such as herbs, nutritional supplements, massage and manipulation, only some of which are underpinned by Chinese medical theory, it will be less clear what one can attribute change to. In terms of the interpretation of a negative trial, the conundrum in this case is whether acupuncture really doesn't work, or if there is a dilution effect due to some components being less effective than others, such that the outcome underestimates the potential impact. There remains a challenge to manage this trade off between a tightly and a loosely defined intervention (see Figure 1).

Insert Figure 1 about here.

A useful approach in standardising the components of a complex intervention can be derived from the Medical Research Council's categorisation of "constant and variable components". (1) The "constant" components of treatment can be understood as fixed for all practitioners, all patients and every treatment. The "variable" components can be understood as treatment functions and processes applied flexibly for each patient, yet always driven by accepted theoretical considerations, with principles that can be replicated to produce the same intended outcome. (4)

Our aim in this study was to involve practitioners in defining the parameters of a flexible standardised protocol for use in a pragmatic trial of acupuncture as an intervention for patients diagnosed with depression, with acupuncture provided as an adjunct to usual GP care. We limited our study to the components within this protocol that were seen by professional acupuncturists in the UK as specific to, and 'characteristic' of, acupuncture; these being the "therapeutic interactions or strategies that are theoretically derived, unique to a specific treatment and believed to be causally related to outcome". (5) . Our intention for the final protocol was that it would provide practitioners with sufficient flexibility in their treatment options in order to match expected patient variability, yet with sufficient detail provided for replication.

Methods

A consensus method to identify components

For our primary method we used the consensus process known as the Nominal Group Technique (6), which involves an initial electronic rating followed by a face-to-face meeting and then a further rating. Ideally, a formal consensus method gives equal weight to the views and ratings of each participant with less risk that individuals or sub-groups might dominate. Not all of our participants were able to attend the meeting that we had arranged, so while we used the decisions at the meeting to improve our range and description of components, data from all participants was used in the final analysis. Our final results were based on all participants, not just those who attended the meeting.

In this approach we aimed to elicit acupuncturists' opinions to determine what they judged might be the essential characteristic features of 'good practice' for the treatment of depression. A consensus method is especially appropriate where there is no rigorous research, as is the case for acupuncture and depression where the literature consists of case-based clinical experiences along with small and poorly conducted trials. (7-10) This type of consensus approach is frequently used to develop clinical guidelines in conventional medical contexts where the literature-based evidence is inadequate. In the field of acupuncture a variation in this method has been used to determine a protocol for elbow pain. (11)

Participants in the consensus process

Acupuncturists were invited to participate on the basis of their educational, clinical and research background, with the intention that their views reflected the diversity of the acupuncture profession in the UK.(12) We selected participants on the basis of having a working familiarity with Traditional Chinese Medicine (TCM) and interest and/or experience in research, or interest and/or experience in treatment of depression. We invited 17 acupuncturists, of whom two declined at the outset because of other commitments, giving us a sample of 15 participants.

Identifying potential components of a treatment protocol

The two co-authors drew up an initial list of potential components based on their clinical experience, on interviews that one of us (SS) had conducted with two internationally respected acupuncturists, and on the limited research literature on

acupuncture for depression at the time. (7;8) (Incidentally, two systematic reviews were published soon after our data was collected. (9;10)) We also ensured that we had the requisite range of components required for subsequent reporting, in line with the STRICTA guidelines. (13) All participants were sent an initial pack that included a plan of investigation, a paper on the difference between pragmatic and explanatory clinical trials, and a questionnaire with a provisional list of potential components of acupuncture, with a view to them being assessed for applicability in a protocol for an RCT based on their experience of what is effective. It was assumed that patients had received a conventional medical diagnosis of depression, acupuncture was to be provided as an adjunct to usual GP care, and that eligibility for the trial was broad with regard to the severity and chronicity of this diagnosis. In the questionnaire we asked participants to identify, from the list of components, the ones that they deemed appropriate for a protocol specific to acupuncture, including active management, auxiliary treatments and prescribed self help activities, as well as the underlying theoretical and diagnostic frameworks. There were options for participants to extend this list of potential components and include others not already identified. Not reported here, were responses from participants on "constant" components (as defined above) including the number and frequency of sessions and the background and minimum experience of practitioners providing treatment within a trial. Excluded from the questionnaire were components of treatment not specific to acupuncture, such as listening skills and empathy.

First round rating of components of treatment protocol

A summary of the feedback on the provisional list of components was returned to participants along with a new questionnaire containing identified components for the trial protocol. In this first rating round of the consensus process, the questionnaire was sent to all fifteen participants, who were asked to rate the "appropriateness" of potential components on a nine-point scale (from 1 indicating "extremely inappropriate" to 9 indicating "extremely appropriate"). Questionnaires were returned electronically or by post. There were options for amending the wording of components or suggesting new ones. These collective data were analysed and fed back to each participant, as well as their confidential individual ratings.

Second rating of components of treatment protocol

The second round of rating took place in two stages: first at a face-to-face meeting with eight of the participants, and second a few weeks later electronically for those who could not attend. Prior to the meeting, participants were sent a revised questionnaire with feedback, and a two page synopsis of preliminary findings from interviews with thirteen acupuncture practitioners about their work with depression (eleven having been conducted by the co-authors for another study). The one day meeting was held in London in March 2005 and chaired by one of the authors (HM) and observed by the other (SS) who recorded key discussion points. Neither HM nor SS took part in the voting. The participants identified the style(s) of acupuncture that they practised. Following discussion and using a revised questionnaire, participants again rated components they judged should be included in the protocol. It was agreed by the group that components rated by at least 75% of participants in the 7 to 9 range were defined as having "group support". Each component was discussed in turn, and possible reasons

for variability in ratings were explored. Divergent views were encouraged, and there was scope to revise the wording of components where there was perceived ambiguity or lack of clarity, to move components from one category to another, or to generate new components. There was no pressure to establish agreement. The eight participants at the meeting confidentially re-rated all components, with the option of changing their previous ratings on the basis of the opinions aired. Likewise the remaining seven participants subsequently rated the same components electronically.

Analysis

The combined ratings for each component were analysed for their central tendency, both the mean and the median. Components with medians in the 7 to 9 range were defined as "appropriate" for the protocol, in the 4 to 6 range as having equivocal support, and in the 1 to 3 range as not being supported by the group. The components rated by 75% or more of participants as appropriate in the 7 to 9 point range were defined as having "group support" and on this basis were included in the final protocol. As a surrogate measure of the extent of agreement, and one that has been used elsewhere (14), we calculated the concentration of ratings for each component using the average absolute deviation from the median. To compare the changes between the first and second round ratings of components rated twice, we used the Wilcoxon Signed Ranks Test for paired data.

Results

The practitioners

Of the fifteen practitioners, nine were female; seven were from the London and surrounding areas. They reported practising a range of styles of acupuncture; see Table 1, where we compare these data with those of the most recent national survey of British Acupuncture Council practitioners**.** (12)

Insert Table 1 about here.

Rating components of the protocol

The group rated components in two rounds; the numbers and categories of components rated in each round are presented in Table 2. The final wording of the sixteen treatment active management components, all of which were awarded more than 75% of individual ratings in the 7 to 9 range (and medians of 9), are presented in Table 3. The auxiliary techniques, areas of life-style support and theoretical diagnostic and treatment frameworks that achieved the minimum 75% ratings in the 7 to 9 range for inclusion in the treatment protocol are presented in Table 4. Auricular acupuncture and *Ah Shi* acupuncture were re-considered as potential auxiliary treatments rather than theory-driven frameworks, but only the former received group support. Other auxiliary techniques not adopted included cupping, electro-acupuncture, *gua sha*, Chinese herbal medicine, plum blossom needle, and journal work. Various prescribed self-help activities did not receive group support, including stretching exercises, Tai Qi, Qi Gong, meditation, breathing exercises, cognitive therapy and moxa (for home use). Advice in the areas of meditation and relationships were not supported as lifestyle components.

The theoretical components that did not achieve this level of support included: Six Divisions (Stages), Four Levels, Three Burners (*Jiaos*), Channel based acupuncture, Stems and Branches, Japanese meridian therapy, Japanese Manaka style acupuncture, Trigger point acupuncture, and *Ziwu liuzhi* therapy.

Insert Tables 2, 3 and 4 about here.

The impact of the consensus process

Direct comparisons can be made between the both first and second ratings of components for the whole group as well as for those who did and did not attend the meeting, see Table 5. We found that the mean of the percentages of components rated in both rounds with "group support", i.e. rated by the whole group in the 7 to 9 range, increased by 4% (p=0.03) with a increased convergence between participants (p=0.011). For participants who attended the face-to-face meeting, there was not a significant increase in the percentage rated 7 to 9 (2%, p=0.54) but there was an increase in convergence of ratings (p=0.009). For participants who did not attend the group meeting, there was both an increase in components with group support (5%, p=0.009) as well as increased convergence (p=0.011).

Insert Table 5 about here.

Discussion

Defining the characteristics of treatment

In this study we have tackled the most challenging part of evaluating a complex intervention(1), developing a trial protocol with defined components of an acupuncture treatment for depression. Our main finding is that it is feasible to define these by involving a group of experienced acupuncturists from varying backgrounds in a consensus process. Harnessing their collective knowledge and experience has provided data that represents what the majority of acupuncturists in the UK are likely to regard as essential for treating depression in the context of a clinical trial.

Our evidence suggests that a range of the active management processes (Table 3) are integral to a course of treatment, because they are characteristic of, and specific to, acupuncture and underpinned by theoretical considerations. These findings reinforce the evidence of Paterson and Dieppe (5) for whom specific components extended to diagnostic processes that are interwoven with treatment on a session-by-session basis, and include discussions between practitioner and patient based on underlying Chinese medical concepts focusing on a such areas as a patient's sense of balance, self-identify, willingness to change, self-limiting behaviour and attitudes. Our data is also consistent with data from acupuncturists treating low back pain, where the therapeutic processes beyond needling were explored within a trial. (15)

The implication of defining these theory-driven active management processes as specific to acupuncture is that false negative results may occur for two reasons (see Figure 2). If, for example, patients in the true acupuncture arm are provided without active management processes, then the acupuncture will be sub-optimal and the

treatment effect underestimated. However, if patients in the control arm receiving sham acupuncture are provided with any of these theory-driven active management processes, then the control will be super-optimal and overestimate the treatment effect. In this context it may be helpful for researchers designing clinical trials of acupuncture who wish to control for "non-specific effects" to clearly state the components of treatment for which they aim to control. Our findings support the view that acupuncture is a complex intervention, with many variables involved in treatment and with the potential for interactions between components of care.

Insert Figure 2 about here

The influence of the consensus process

There is evidence that the consensus process resulted in an increase in agreement on the number of components receiving group support, as well as an increase in the concentration of that support over the two rounds of voting (Table 5). Asking participants to rate a theoretical model of acupuncture, when they had no personal experience of using it, presented them with a difficult decision. In the group discussions, the majority expressed a desire to be inclusive about components and styles of practice. Interestingly, there were differences in the level of inclusivity between meeting attendees and non-attendees, with the former having a much more inclusive first round of ratings (83% compared to 68%), but the latter showing significantly increasing support for more components (see Table 5).

The wider relevance of the approach

This study has relevance beyond the treatment of patients diagnosed with depression and beyond the modality of acupuncture. The principles can be applied where there is a coherent professional practice yet research evidence is thin, for example throughout the field of complementary medicine and also in conventional medicine where the intervention is complex. This method of defining the scope of a complex intervention is dependent on the decisions made at the outset about selection of participants and provision of relevant information. Involving clinicians in a process of identifying and selecting perceived essential components of an intervention will lead to a trial intervention that has clinical integrity and is likely to be acceptable to those implementing it. The intervention can also be properly defined on the basis of relevant theory, such that interpretation and replication are facilitated.

Conclusions

In preparation for an acupuncture trial of depression, we have used a consensus method to identify those components likely to be essential to the intervention to be incorporated into a standardised protocol for a randomised controlled trial. These components include active management processes, diagnostic and treatment frameworks, auxiliary techniques and areas of self-help, all characteristic of, and specific to, acupuncture. The method can be generalised to other clinical situations where complex treatment modalities are employed.

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Figure 1: Trade off between a tightly and a loosely defined complex intervention which has been evaluated in a trial with a positive outcome.

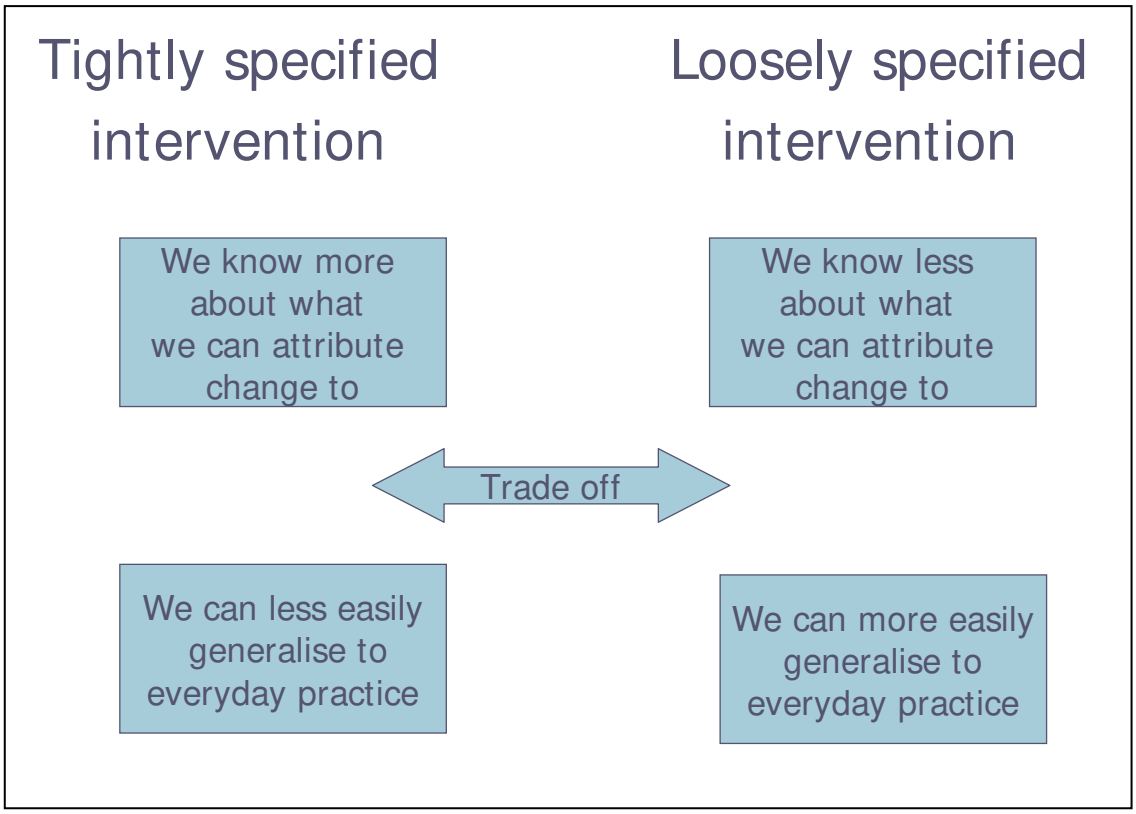


Table 1: "Styles of acupuncture" as self-reported by participating practitioners compared to a year 2000 survey of British Acupuncture Council (BAcC) members.

	Participants in consensus process (N=15)	**BAcC membership responding to 2000 survey (N=860)***
	%	%
TCM	93	67
Five Elements	67	57
Eight Principles	73	28
Japanese	13	7
Other	20	9
Don't know	0	4

* Source: White E 2000

Table 2 Numbers and categories of variable components that are characteristic of traditional acupuncture as a treatment for depression that were rated by 15 acupuncturists.

	Active management components specific to acupuncture	Theoretical diagnostic and treatment frameworks	Auxiliary techniques related to acupuncture theory	Prescribed self-help related to acupuncture theory	Life-style support related to acupuncture theory
Components in the first rating round (electronic)	16	20	5	5	6
Components in the second rating round (both face-to-face and electronic round)	17	20	10	1	7
Components rated as appropriate by 75% of acupuncturists: final selection	16	8	3	0	5

*Table 3: Active management components that are implemented in ways specific to acupuncture and receiving "group support"**

	Variable components related to the process of treatment
1	Take your patient's case history, including current orthodox medical diagnosis and treatment, and undertake traditional acupuncture diagnostic assessments, by asking questions, palpating, observing, smelling and hearing.
2	Identify your patient's patterns of disharmony from within your normal repertoire of traditional acupuncture diagnostic frameworks
3	Implement your treatment strategy based on your traditional acupuncture diagnosis, to be applied flexibly at each treatment on an individual patient basis.
4	In devising your treatment strategy, draw on diagnostic and treatment approaches that are integral to one or more of the following theoretical frameworks, see Table 4.
5	Determine group of acupuncture points for needling, to be adapted as necessary at subsequent sessions, drawing on relevant theoretical considerations.
6	Select acupuncture needles of an appropriate length and gauge, based on relevant theoretical considerations.
7	Insert acupuncture needles to an appropriate depth, obtaining de qi where required, based on relevant theoretical considerations.
8	Use appropriate needling techniques, based on relevant theoretical considerations.
9	Retain needles for an appropriate period of time, based on relevant theoretical considerations.
10	Integrate relevant auxiliary interventions into the treatment strategy, the rationale for each being based on relevant theoretical considerations (for options, see Table 4).
11	Integrate relevant life-style support into the treatment strategy, the rationale being based on relevant theoretical considerations (for options, see Table 4).
12	Use relevant explanations to provide for your patient any necessary information about their condition, their traditional acupuncture diagnosis, the aims and methods of the acupuncture treatment, and their prognosis.
13	Devise with your patient a treatment plan that covers the number and frequency of treatments, based on theoretical considerations as well as on their needs and availability and within the maximum number of treatments funded.
14	Elicit and interpret patients' reactions to acupuncture treatment, whether positive and negative, reassuring patients where relevant, and incorporating this information into the ongoing treatment process.
15	Discuss and agree with your patient reasonable expectations of treatment progress and outcomes, in the context of other treatments that they are receiving
16	Make a judgment about the potential limitations acupuncture and, where appropriate, encourage patients to seek additional help from their GP or other health professionals, especially where there are concerns about the seriousness of the symptoms.

* "Group support" was defined as when 75% of participants rated the component in the range 7 to 9.

Table 4: Components (except active management components) with "group support" (n=15) in the second (and final) round, i.e. those with more than 75% of participants rating the components as appropriate in the range 7 to 9

	Median	Average absolute deviation from the median (ADD)[1]	Percentage rated 7 to 9
Auxiliary Techniques			
Moxibustion	9	0.4	93%
Auricular acupuncture	9	1.07	80%
Acupressure massage	8	1.2	80%
Lifestyle support			
Advice about diet	9	0.36	93%
Advice about exercise[2]	9	0.38	93%
Advice about rest	9	0.57	93%
Advice about relaxation	9	0.71	93%
Advice about work	9	0.79	93%
Theoretical and diagnostic frameworks			
Pathogenic Factors	9	0.27	100%
Five Elements: Shen and Ko Cycles	9	0.33	100%
Eight Principles	9	0.33	93%
Zang Fu Syndromes	9	0.4	93%
Qi Blood & Body Fluids	9	0.47	93%
Five Elements – Blocks[3]	9	0.87	93%
Five Elements – Causative/Constitutional Factor[4]	9	0.93	93%
Eight Extra Vessels	9	0.87	87%

Notes:

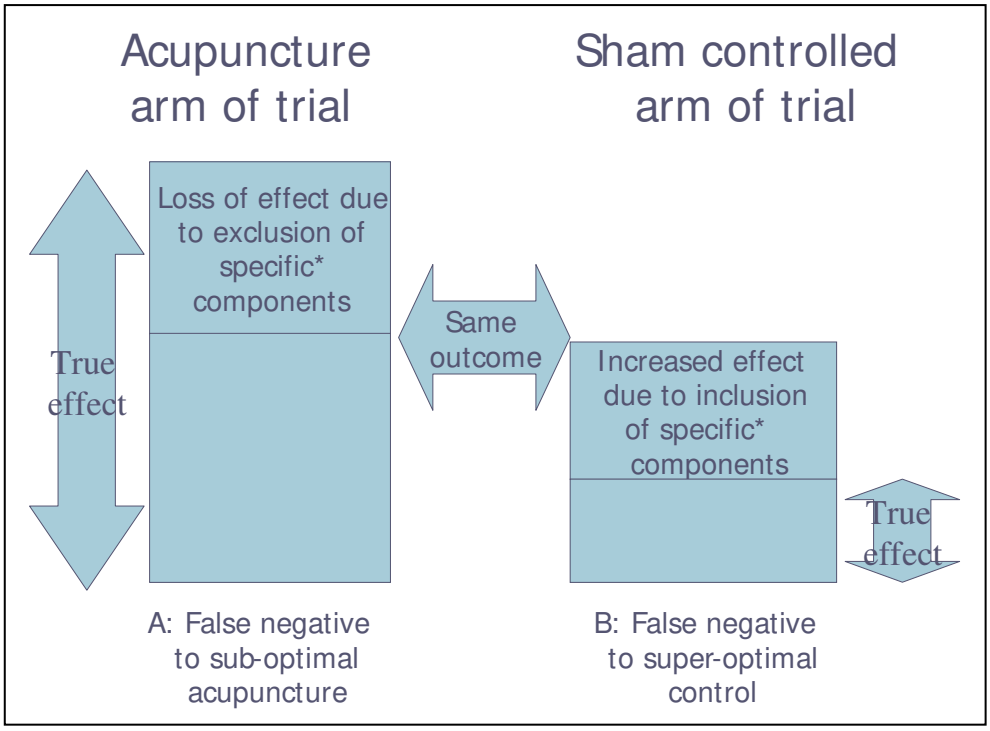
[1] ADD = Average Absolute Deviation from the median is a measure of the concentration of the individual ratings, an indication of the level of consensus
[2] Exercise includes: Physical exercise, Tai Qi, Qi Gong, Stretching exercises, and Breathing exercises
[3] Five Elements – Blocks include: Entry Exit, Husband Wife, Possession and Aggressive Energy
[4] Five Elements – Causative/Constitutional Factor, the factor is the one that predisposes an individual to disharmony

Table 5: Impact of the consensus process: first and second round ratings for all 39 components that were rated twice by all participants

	Mean of percentage of components rated from 7 to 9 (a measure of "group support")		Mean of components' average absolute deviations from the medians (a measure of group consensus)	
Ratings of the 39 components by:	First round ratings	Second round ratings	First round ratings	Second round ratings
All participants (n=15)	75%	79%[1]	1.04	0.83[3]
Participants who attended the meeting (n=8)	83%	85%	0.87	0.57[4]
Participants who did not attend the meeting (n=7)	68%	73%[2]	1.12	0.91[5]

Significant changes in rankings of the 39 components between first and second rounds (Wilcoxon Signed Ranks Test):
[1] z = - 2.2, p = 0.03
[2] z = - 2.6, p = 0.009
[3] z = - 2.5 p = 0.011
[4] z = - 2.6, p = 0.009
[5] z = - 2.6, p = 0.011

Figure 2: Two possible reasons for false negative outcomes from sham-controlled trials, A: due to sub-optimal acupuncture, and B: due to super optimal sham acupuncture.



* Specific that is to all components of acupuncture treatment underpinned by theoretical considerations, not just the needling alone.