



Randomised controlled trial on the use of acupuncture in adults with chronic, non-responding anxiety symptoms

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► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/acupmed-2014-010524>).

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Received 17 January 2014

Accepted 17 December 2014

Published Online First

16 January 2015

ABSTRACT

Background A group of adults can be identified with chronic non-responding anxiety symptoms who have repeatedly accessed treatments through their GP, such as cognitive behaviour therapy, bibliotherapy and medication, but with no effect. These patients make heavy use of health service resources with no beneficial outcome. This study aims to test the effect of an acupuncture formula of three specific acupuncture points, suggested in a previous pilot study.

Method 40 participants from a psychiatry waiting list were randomised into one of two groups: group 1 (n=25) received 10 weeks of acupuncture at PC6, HT7 and LR3, and group 2 was a waiting list control group. The waiting list group (n=15) then received acupuncture. Both groups were followed up for 10 weeks after treatment. The outcome measure was the State and Trait Anxiety Inventory.

Results 36 patients completed the study, with two dropouts in each group. State anxiety scores in the acupuncture group decreased from 57.7 (SD 13.1) to 38.8 (12.0); scores in the waiting list control group decreased from 61.5 (11.6) to 60.6 (11.7). The difference was highly significant ($p<0.0001$). Similar changes were seen for trait anxiety scores. The control group showed similar statistically significant improvements when they received acupuncture. The improvements were maintained after 10 weeks of follow-up in each group.

Conclusions Acupuncture is a promising intervention for patients with chronic anxiety symptoms that have proven resistant to other forms of treatment.

INTRODUCTION

Anxiety is an increasing problem worldwide.¹ The 2009 WHO World Mental Health Survey found that anxiety disorders are consistently the most prevalent form of a mental health disorder, with

a lifetime prevalence of approximately 12% and a 12 month incidence averaging approximately 11% across surveys.² There is a general trend for women to suffer with anxiety disorders to a greater degree than men.³ Anxiety in the UK affected 16.8% of the population in 2004.⁴ A 2014 YouGov survey of 2300 adults in the UK showed that 19% felt anxious a lot or all of the time, 61% experienced anxiety daily and 48% stated that anxiety had stopped them from doing something.⁵ The use of complementary and alternative medicine (CAM) as a treatment option for anxiety, and acupuncture specifically in this instance, has been identified as a growing trend within the western world,^{6,7} with some reports suggesting that those individuals with psychiatric conditions are more likely to use CAM than those without a psychiatric medical history.⁸ Despite this trend, there is, as yet, no evidence to suggest that compliance with CAM is superior to that with conventional management.⁹

A group of patients with particularly chronic anxiety, unresponsive to the usual interventions and making continuous heavy demands on health service resources, was identified during the weekly multidisciplinary team meeting held by the Haverfordwest Community Mental Health Team, in 2007. As a possible solution, a novel approach was offered, in the form of a course of acupuncture specifically for anxiety. A systematic review⁷ previously showed the potential benefit of acupuncture, and a pilot study by the author in a group of four patients demonstrated a promising improvement in symptoms.¹⁰ The acupuncture treatment used was based on the author's literature review,¹¹ the aim of which was to identify the most



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To cite: Errington-Evans N.
Acupunct Med 2015;**33**:
98–102.

frequently used points and effective treatment regimen. Three points, PC6, HT7 and LR3, used bilaterally, were identified. The regimen was a 30 min session delivered once weekly for 10 weeks. GV20 was also widely reported but, on discussion with a number of (non-participating) patients during development of the research protocol, it was considered unacceptable to this particular population, citing the fact that the point looked painful and they did not like the fact that they would be unable to see the acupuncture site during treatment.

The aim of this study was to examine whether the use of acupuncture at points PC6, HT7 and LR3, used bilaterally, during a 30 min treatment session per week, for 10 weeks, is effective in the reduction of both state and trait anxiety symptoms in a population of patients with chronic anxiety unresponsive to other treatments.

This study was approved by the local research ethics committee (Ref 11/WA/0056) and Hywel Dda University Health Board R&D department (Ref HD/10/073).

METHOD

A randomised controlled trial was conducted comparing 10 weeks of acupuncture (group 1) with a 10 week waiting list control group (group 2). The control group (group 2) then received acupuncture, and both groups were followed-up 10 weeks after the end of their treatment. Anxiety symptoms were evaluated at baseline, and at 10 and 20 weeks in both groups, and at 30 weeks in group 2 (ie, 10 weeks after the end of their acupuncture, giving the same post-intervention data as group 1). The study design is shown in figure 1.

It was decided that participants could miss up to two continuous weeks from the acupuncture treatment over the study period. The choice of 2 weeks was arbitrary, based more on trying to ensure attendance rather than any scientific rationale. Sickness,

forgetfulness and mental health issues could result in participants being removed from a study, despite the fact that this population has difficulty making and keeping appointments.^{12–14} Making this small adjustment seemed a practical and pragmatic decision.

Participants

Forty participants identified from the waiting list for psychology interventions were recruited by invitation letter. Each had already proven themselves resistant to all routine interventions offered by their GP and frontline mental health services (ie, advice, medication, bibliotherapy and cognitive behaviour therapy). The research took place over a 50 week period, with recruitment occurring up until the cut off point where the participant had only 30 weeks available (to allow for randomisation to the treatment or control group).

The waiting list was almost 12 months and, as such, these individuals were unlikely to see the psychologist before the research was concluded. To maintain confidentiality, the psychologist reviewed the waiting list for those individuals with anxiety conditions and sent letters of invitation to potential participants, requesting permission for the researcher to contact them directly. It was explained that their position on the waiting list would not be affected by participation.

The participants' original referrers (usually their GP) was contacted, in writing, to ensure that they knew no reason why the participant should be excluded from the study. Then, participants were contacted directly, by letter, with an information sheet explaining the study, aims and objectives (see online supplementary appendix 1). Once the participants were entered into the research programme, each individual completed the consent form (see online supplementary appendix 2). Participants were randomly allocated a number by the researcher using a random number generator (<http://stattrek.com/Tables/Random.aspx>), which then assigned them to group 1 or group 2. Participants completed the State and Trait Anxiety Inventory (STAI).

In the treatment group, 52% of participants were women, and in the control group, 60% were women. Mean age in the treatment group was 42.08 years compared with 45.2 years in control group ($p=0.42$). Data were not collected for duration of symptoms but all participants were recruited specifically for the reason that they were resistant to all GP lead care and firstline secondary care.

Sample size

Sample size was obtained pragmatically through the available population on the waiting list and time constraints.

Inclusion and exclusion criteria

An individual met the inclusion criteria if they were still experiencing anxiety symptoms following GP lead care, as well as firstline secondary care (ie, advice,

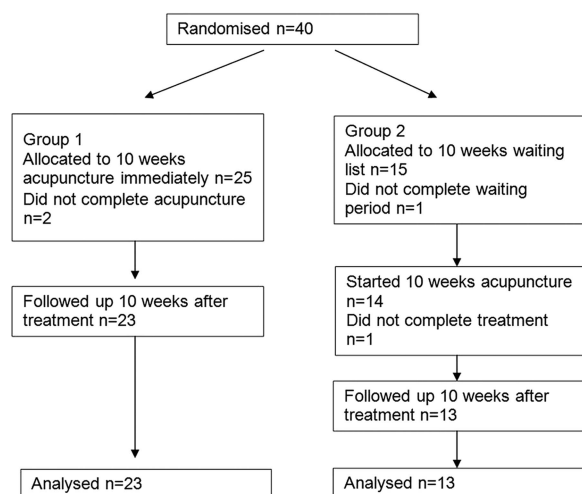


Figure 1 Research process flowchart.

medication, bibliotherapy and cognitive behaviour therapy). Participants were excluded from the study if they had a phobia of needles, haemophilia or lack of capacity.

Outcome measure

The outcome measure was the STAI, which is validated for this population and sensitive to changes in anxiety over time.¹⁵ Higher scores indicate greater anxiety, with a range of 20–80. Normal scores for the working age population are state 35.72 (SD 10.4) and trait 34.89 (SD 9.19) for men, and state 35.2 (SD 10.61) and trait 34.79 (SD 9.22) for women. Participants in the study had statistically significant increases in their state and trait anxiety ($p<0.001$) scores compared with ‘normal scores’.

Acupuncture treatment

The treatment programme consisted of 10 sessions over a maximum of 12 weeks, 30 min per treatment session. The points selected were PC6, HT7 and LR3, used bilaterally, for the systemic effect. The needles used were ‘Classic Plus’ (Wujiang Jiachen Acupuncture Devices Co Ltd, Jiangsu, China) sterile acupuncture needles, 25 mm×0.25, copper handle, individually packed, with guide tube. All acupuncture in the study was completed by the author. Each needle was inserted to the standard depth and stimulated until *de qi* was achieved. This was maintained throughout the duration of the session. Participants could sit or lie supine, and were told that they could fall asleep if they wished. The treatments were conducted in the physiotherapy department. Once the needles were inserted, the participant was left alone, with repeated discreet checks that *de qi* was maintained throughout the treatment. Conversation was kept to a minimum to ensure that the changes could be more directly attributable to the acupuncture. If the participant was asleep, they were allowed to remain asleep until the end of the treatment.

Analysis

The primary endpoint was change in STAI state and trait scores in the acupuncture (group 1) and waiting list control (group 2) over the first 10 weeks of the study. Analysis was conducted using SPSS (V.22). The analysis included only those who provided complete data. Group means (SDs) were calculated to estimate the response of the control group to acupuncture and changes during follow-up in both groups. A secondary analysis was conducted of changes from immediately before to immediately after acupuncture in both men and women, combining the two groups. Significance was set at $p=0.05$.

RESULTS

Forty participants were recruited (45% men), aged 19–64 years. Fifteen participants were randomised to

Table 1 Baseline characteristics of the two groups

	Group 1	Group 2
Gender (M:F)	12:13	6:9
Age (years) (mean (SD))	42.1 (10.4)	45.2 (13.9)
Duration of symptoms (weeks) (mean (SD))	14.3 (8.3)	15.1 (11.1)

the waiting list control group (group 2). Four participants (two from each group) withdrew from the study because of symptom progression or other personal reasons. This withdrawal did not have an effect on the overall baseline characteristics of the groups. One participant offered a reason for withdrawal, being that the acupuncture did not have enough traditional emphasis compared with previous acupuncture they had received. There were no adverse effects reported. Baseline characteristics of the two groups are shown in [table 1](#).

The STAI results showed that the treatment and control groups were matched at baseline (week 0) for both state ($p=0.63$) and trait ($p=0.80$) anxiety scores. Comparing STAI scores of men and women, there was no statistically significant difference between baseline scores ($p>0.05$). As shown in [table 2](#), there were marked reductions in mean state anxiety scores over weeks 0–10 in the acupuncture group (18.9 (SD 8.6), 95% CI 15.39 to 22.41) compared with the waiting list group (0.8 (SD 7.4), 95% CI -3.2–4.82). The difference was highly significant ($p<0.0001$). Similarly, the reduction in mean trait anxiety score in the acupuncture group (21.9 (SD 14.3), 95% CI 16.06 to 27.74) was significantly ($p<0.0001$) greater than the reduction in group 2 (-1.2 (SD 2.5), 95% CI -2.56 to 0.16).

[Figures 2](#) and [3](#) show that group 2, after receiving acupuncture, scored significant reductions in mean state (22.0 (SD 9.0), 95% CI 17.11 to 26.89) and trait (21.4 (SD 9.1), 95% CI 16.45 to 26.35) anxiety scores, which were similar to those shown by the acupuncture group. The mean scores in both groups remained at similar values at follow-up, 10 weeks after acupuncture. There was no statistically significant difference between groups 1 and 2 at the post acupuncture STAI or the 10 week follow-up STAI ($p>0.05$).

Table 2 Mean (SD) state and trait anxiety scores on the State and Trait Anxiety Inventory for the acupuncture (group 1) and waiting list (group 2) groups

	Week 0	Week 10	Week 20	Week 30
State anxiety				
Group 1	57.7 (13.1)	38.8 (12.0)*	36.8 (14.2)	
Group 2	61.5 (11.6)	60.6 (11.7)	38.6 (10.3)	35.2 (10.1)
Trait anxiety				
Group 1	64.4 (11.4)	42.5 (15.1)*	40.8 (17.1)	
Group 2	64.0 (9.3)	65.2 (9.1)	43.8 (11.8)	39.8 (13.2)

Acupuncture group treated weeks 0–10; waiting list group treated weeks 10–20.

*Between groups difference in changes, $p<0.0001$.

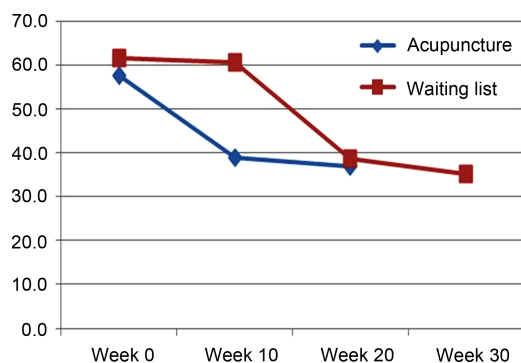


Figure 2 Mean state anxiety scores in the acupuncture and waiting list groups.

DISCUSSION

This study showed that 10 sessions of acupuncture, using PC6, HT7 and LR3 bilaterally, had a statistically significant effect on both state and trait anxiety scores compared with a waiting list control group. The reductions in anxiety scores in the control group were also statistically significant when they received acupuncture. In both groups, the changes persisted for 10 weeks of follow-up. No differences between baseline scores or response to acupuncture were identified between men and women.

Participants in this study had significantly higher STAI scores than scores given in the STAI manual¹⁵ for the 'normal' population. No limits have been established for STAI to categorise anxiety as mild, moderate, severe or extremely severe, or to exclude anxiety altogether. Anxiety is a subjective sensation, which one patient would describe as overwhelming when others would describe it as a minor concern. STAI is designed to show how an individual feels at a point in time, and is sensitive to changes that occur between that time and the following assessment. The scores for both state and trait anxiety decreased by approximately a third in both groups in this study following acupuncture treatment.

Previous studies have provided little or no explanation for their process of point selection, or use a justification such as practitioner experience.^{7 11} This

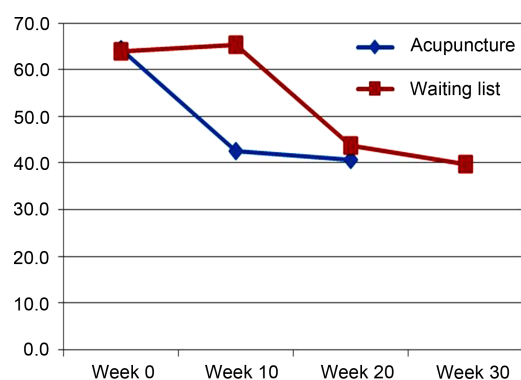


Figure 3 Mean trait anxiety scores in the acupuncture and waiting list groups.

study aimed to offer a more objective transparent rationale for point selection, with the purpose of suggesting a standardised protocol in the treatment of conditions within the anxiety spectrum. Our results show that these points can be used as an effective acupuncture treatment for anxiety.

Other clinical trials have not explicitly recruited participants with chronic unresponsive anxiety, as was done in this study. In patients with clinical anxiety, Pilkington's review¹⁶ found three published trials which suggested that acupuncture was no different from drug treatment. This was disputed by subsequent studies which found that acupuncture was an effective treatment for anxiety.^{17 18} Black *et al*¹⁹ found no effect of auricular acupuncture compared with sham or untreated controls. Thus while the results of this study support the majority of the trial evidence, further research is required.

While not formally collected or analysed, there was a significant amount of qualitative information that was provided during the study. It is recommended that future studies formally collect and collate this information to allow for a greater breadth of data development. Anecdotal evidence, in the form of certain comments, changes in participant status and specific feedback from family and friends of the participants was volunteered. Several participants obtained jobs, despite having been unemployed for several years, and some family members voluntarily came to the department specifically to report changes that had occurred. A further outcome not formally assessed, but generally reported by participants, was that those who suffered with insomnia or generalised disturbed sleep found they were sleeping better.

A further example of the benefits of acupuncture is that several of the participants requested to be taken from the psychology waiting list, and other individuals felt that they were now going to be able to engage more completely. Prior to the acupuncture, a number of participants had felt as though psychology was a pointless referral, as they had little or no expectation of it having a successful outcome. Following the acupuncture, as they had already felt some degree of progress, they now felt that the psychology referral could help them continue to improve. In contrast, there were two participants who felt that they had 'wasted time' participating in the acupuncture research.

Limitations

As with all acupuncture research, there are some issues with the design. Point selection was based on a frequency based analysis, ascertaining the most commonly used points, treatment frequency and dosage used by the greatest number of practitioners. Despite this, the fact remains that most of those practitioners chose points without an objective peer reviewed evidence base. Also, the information sheet may have unwittingly introduced bias by presenting acupuncture

in a positive manner. The lack of blinding is another limitation, which could be circumvented by incorporating blinded assessors and statisticians. To reduce bias, STAI was completed by the individual without the researcher or any other individual present. Withdrawal of four patients introduces the possibility of bias from missing data.

CONCLUSION

This study suggests that acupuncture, using a standardised approach, is an effective tool in the management of patients who present with anxiety symptoms that have proven resistant to a number of other routine interventions.

Summary points

- ▶ 40 patients with chronic anxiety that was resistant to all conventional treatments were randomised to acupuncture or a waiting list control group.
- ▶ There was a significant reduction in anxiety after acupuncture, which lasted at least 10 weeks.

Funding The study was supported by the Hywel Dda Health Board; £10 000 was provided through the local R&D committee to cover staffing and administration costs.

Competing interests None.

Ethics approval The study was approved by Dyfed Powys Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

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Acupunct Med 2015 33: 98-102 originally published online January 16, 2015

doi: 10.1136/acupmed-2014-010524

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