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Effects of Acupuncture as a Treatment for Hyperventilation Syndrome: A Pilot, Randomized Crossover Trial

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ABSTRACT

Background: Sustained and subtle hyperventilation can result in a wide variety of symptoms, leading to a chronic condition that has been termed hyperventilation syndrome (HVS). Treatment options include physiotherapy, in the form of breathing retraining (BR), but additional approaches aim to reduce the anxiety that is recognized as being a frequent component of this condition.

Objectives: The aim of this study was to evaluate whether acupuncture is an appropriate treatment for HVS to reduce anxiety, and whether a crossover trial is an appropriate study design to evaluate acupuncture in this condition.

Design: A single-blind crossover trial was carried out comparing the effects of 4 weeks (30 minutes twice weekly) acupuncture and BR on patients with HVS.

Subjects: Ten (10) patients diagnosed with HVS were recruited to the trial and randomized into two groups. Both groups received acupuncture and BR with a washout period of 1 week.

Outcome measures: The primary outcome measure used was the Hospital Anxiety and Depression (HAD) Scale. Other outcome measures used were the Nijmegen questionnaire and Medical Research Council Dyspnea scale.

Results: The results showed statistically significant treatment differences between acupuncture and breathing retraining, in favor of acupuncture. Reductions were found in the HAD A (anxiety) ($p = 0.02$) and Nijmegen (symptoms) ($p = 0.03$) scores. There was no statistical evidence of any carryover effects. However, when graphically examining individual anxiety scores, in those who received acupuncture first, there was a reduction in anxiety levels which persisted through the washout period, suggesting that there may have been some carryover effect from this treatment.

Conclusions: This study suggests that acupuncture may be beneficial in the management of HVS in terms of reducing anxiety levels and symptom severity. However, there may be some carryover effect, after acupuncture treatment, which went undetected because the small sample size. This preliminary study provides the basis for a larger, sufficiently powered and methodologically sound trial.

INTRODUCTION

Hyperventilation has been defined as breathing in excess of metabolic requirements and is associated with a reduction of arterial carbon dioxide, leading to a respiratory alkalosis and a range of physical symptoms.[1] Hyperventilation syndrome (HVS) is a term that was originally used to provide a clinical diagnosis for patients presenting with dis-

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turbed breathing associated with diverse symptoms.[2] Anxiety was a core component in the original description of HVS, but the relationship of hyperventilation to anxiety is not simple and hyperventilation can occur without anxiety.[3] HVS is a controversial diagnosis,[4] but it continues to be used by clinicians and authors.

Physiotherapy is one of the treatment options frequently offered to patients with HVS and generally consists of a combination of advice, education, and specific breathing retraining techniques (BR). It is currently unclear which components of the physiotherapy treatment is most effective for HVS.[5–7] Physiotherapists and others are now beginning to explore therapies such as acupuncture as adjunctive treatments in the management of HVS. Although a systematic review has reported that acupuncture has been used with some success in patients with respiratory conditions,[8] there is no objective evidence to support its use in the treatment of HVS. A small uncontrolled acupuncture study by Levashov[9] did find reductions in subjective symptoms and respiratory minute volume, but any mechanisms were not discussed by the authors. It is well documented that acupuncture influences centers within the brain (e.g., limbic system), and this could affect emotional factors.[10] Acupuncture may therefore help HVS by reducing the anxiety component of the condition.

The aims of this preliminary, uncontrolled, randomized study were (1) to establish whether acupuncture could be an appropriate modality in reducing anxiety in the treatment of HVS, when compared to standard physiotherapy breathing retraining; and (2) to establish whether a crossover design was appropriate for investigating the effects of acupuncture and BR.

MATERIALS AND METHODS

It was recognized that recruitment for this study might prove to be difficult. In a crossover design, participants act as their own controls, thereby minimizing within-subject variability and thus reducing the number of people who need to be recruited. A single-blind randomized, crossover trial was conducted with consecutive willing patients who were recently diagnosed with HVS and referred for physiotherapy treatment to Southampton General Hospital between May and November 2003. Diagnosis was based on a combination of physician clinical judgment, elimination of alternative diagnoses through specific investigations, and symptom reproduction during a hyperventilation provocation test.[11] All participants were asked to complete a health questionnaire prior to entering the trial to ensure there were no contraindications to acupuncture treatment. Written informed consent was obtained from all participants subsequent to Ethical Committee approval (ethics number 034/03/t) and prior to data collection.

Because this was a pilot study, a sample size calculation was not performed. A convenience sample of 10 participants was recruited. Inclusion criterion: patients recently diagnosed with HVS and referred for standard physiotherapy by a consultant respiratory physician. Newly diagnosed patients with HVS were considered appropriate for the trial to reduce the chances of them having already received any BR or acupuncture for their condition. Exclusion criteria were the following: (1) patients who did not wish to receive acupuncture treatment; (2) patients who were receiving other conventional or complementary therapy for their HVS; and (3) patients with conditions for which acupuncture treatment was contraindicated (e.g., active infection, epilepsy, cardiac pacemaker, and areas of broken skin). Although only a relative contraindication, women who were pregnant or planning to become pregnant during the trial were excluded. Because of the potential adverse effects of stimulating some of the acupuncture points during pregnancy, it was considered ethically appropriate to exclude these patients.[12]

All patients who fulfilled the criteria were invited to participate in the trial by the researcher and were given an information leaflet. All participants were acupuncture naive and had not received acupuncture or BR treatment previous to this trial. Those willing to take part attended the hospital for assessment. Baseline assessments consisted of the Hospital Anxiety & Depression (HAD) scale[13] and the Nijmegen hyperventilation questionnaire.[14] Because each participant would receive both treatments, randomization using random number tables was carried out to allocate the order of treatment (i.e., Group A: acupuncture followed by BR or Group B: BR followed by acupuncture).

In group A, the participants attended twice a week for 4 weeks and received eight acupuncture treatments. At the end of the 4-week period, outcome measures were taken. A 1-week "washout" period followed. This washout period was chosen because there was no evidence prior to this study that suggested any long-term effects of either BR or acupuncture in this population. Participants in group A were then asked to attend twice a week for a further 4 weeks and received BR. At the end of this period, final outcome measures were taken. In group B the participants attended at the same time intervals receiving BR for the first 4 weeks and acupuncture in the second 4-week period. Although blinding is desirable to eliminate experimenter bias, in this study it was not possible to blind either the participants or the intervention therapist. Therefore, a respiratory nurse who was blinded to the group allocation carried out baseline and outcome assessments. A senior clinical physiotherapist (with 12 years' experience in respiratory physiotherapy and 5 years experience using acupuncture in respiratory care) carried out both interventions.

A traditional Chinese medicine (TCM) approach to acupuncture would mean the use of individualized treatment programs for each patient. However, most physiotherapists are not trained in TCM, so to make this study applicable to physiotherapy, a standardized point prescription was used.

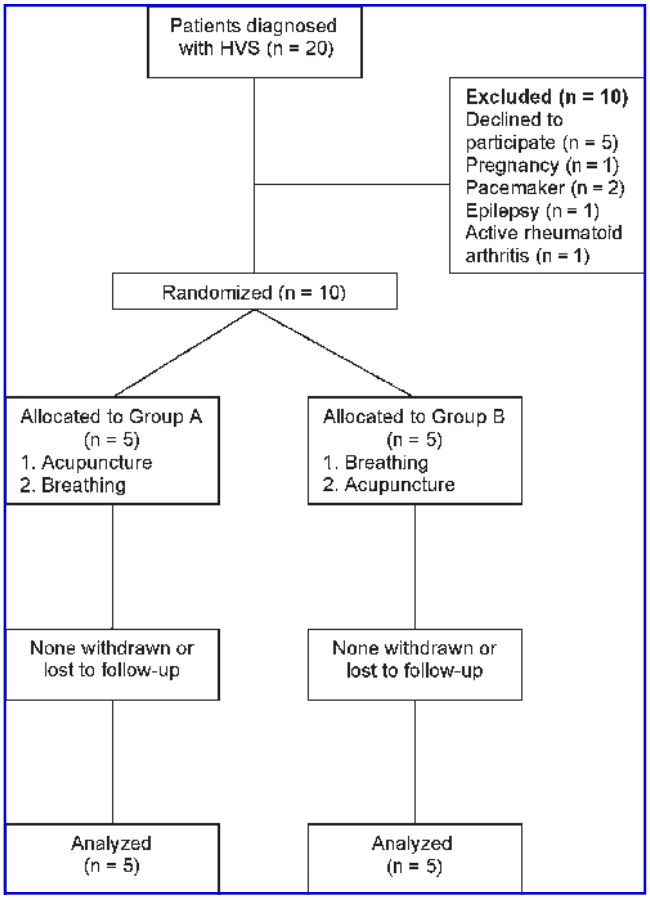

FIG. 1. Consort diagram of trial.

The choice of a Western approach to acupuncture was pragmatic and does not imply that it would be more beneficial than a TCM approach. The points used were Colon 4, Liver 3, and Stomach 36. Combinations of these points have been used in studies of acupuncture for anxiety[15] and have been examined in studies investigating the deactivation of the limbic system and activation of serotonergic responses, which may be the mechanism by which acupuncture works for anxiety and depression states.[16,17] Sterile, single-use acupuncture needles were used (40 mm long × 0.25-mm diameter) from Noma (Complex Homeopathy) Limited (Southampton, United Kingdom). Each needle was inserted into the acupuncture points and *de qi* (needling sensation associated with acupuncture) was elicited by manipulation of the needles. Each participant was treated bilaterally and had a total of six needles inserted for the duration of the treatment. A draining technique was used and the needles were left for a period of 30 minutes. The practitioner returned to check on the participant at regular intervals during the intervention.

Standard BR was provided in the form of breathing control and relaxation techniques. Participants were taught breathing control by asking them to place one hand on their upper abdomen and to concentrate on abdominal movements.[18] Participants were instructed to allow the abdomen to rise on inspiration and fall on expiration. They were encouraged to slow the rate of breathing. Once this was mastered, participants were advised to continue with this technique for as long as they could during the session. Participants were also guided through a relaxation session during this time.[19] BR sessions lasted approximately 30 minutes in total. Participants were advised to continue to practice the breathing technique at home at regular intervals during the day.

Outcome measures

The primary outcome measure was the HAD scale. This is a validated scale[20] used to identify anxiety and depression disorders among patients in nonpsychiatric hospital clinics. It is divided into an anxiety subscale (HAD-A) and a depression subscale (HAD-B), both containing seven intermingled items. Scores of 0–7 indicate anxiety and depression to be within normal range, 8–10 are deemed borderline, and 11–21 are deemed abnormal.[13] These authors are unaware of any consensus as to the minimal clinically important change on this scale. The secondary outcome measure was the Nijmegen questionnaire. This is a validated screening tool, which has been shown to have 95% effectiveness in distinguishing "hyperventilators" from "normals."[14] Scores of 23 and above are deemed indicative of hyperventilation.

Table 1. Baseline Characteristics and Baseline Data for the Two Groups as Means (Standard Deviations)

Variable	*Group A* (n = *22*) *Acupuncture/BR*	*Group B* (n = *5*) *BR/Acupuncture*
Age (years)	53 (12.3)	47 (13.7)
Gender (M/F)	2/3	3/2
HAD Scale Anxiety score	14 (8)	12 (8)
HAD Scale Depression score	8 (2.5)	8 (10)
Nijmegen score	32 (12.5)	26 (9.5)
Symptom duration (years)	2 (1.67)	1 (0.75)

HAD, Hospital Anxiety and Depression.
Standard deviations are in parentheses.

Table 2. Scores for Anxiety, Depression, and Hyperventilation Before and After Each Intervention for the Whole Sample Expressed as Mean (Standard Deviations)

	Pre BR	*Post BR*	*Pre Acu*	*Post Acu*
HAD Scale Anxiety score	9.8 (3.8)	8.6 (3.6)	12 (4.4)	8 (3.4)
HAD Scale Depression score	7.1 (3.8)	6.2 (2.9)	7 (3.7)	5 (2.7)
Nijmegan score	28 (5.2)	27 (4.3)	31 (6.8)	24 (5.5)

BR, breathing; Acu, acupuncture; HAD, Hospital Anxiety and Depression.
Standard deviations are in parentheses.

Data analysis

All data were entered into SPSS (version 12.0; SPSS Software Inc., Chicago, Illinois), which was also used to calculate descriptive statistics. Data were transferred to SAS to compare interventions using an analysis-of-variance approach in which treatment effects, carryover effects (i.e., whether the effects from the treatment in the first period affected the outcomes from the second treatment period) and period effects (i.e., whether the participants' condition and their ability to respond to treatment remained stable across both periods of treatment) were assessed as recommended by Senn.[21] The study is reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement.

RESULTS

During the data collection period, 20 consecutive HVS patients attending for physiotherapy were invited to participate in this study. Of these, 5 were found to be ineligible (pregnancy, pacemaker [2], epilepsy, and active rheumatoid arthritis) and 5 declined to participate (Fig. 1). Ten patients were recruited (5 male, 5 female) and all completed the trial. Table 1 shows baseline characteristics for the two groups. The baseline scores for both groups are presented in this table. As expected, the results from the Nijmegen questionnaire at baseline show that symptom scores were high. All 10 participants had Nijmegen scores of >23 at baseline (≥23 being positive for hyperventilation). HAD anxiety scores were also high, with 9 of 10 of the sample having a clinically relevant score for anxiety (i.e., ≥11) at baseline. Despite being newly diagnosed, the mean length of time that participants in this study had been symptomatic was 2 years (range 6 months to 5 years), which reflects a high level of chronicity within the sample. Table 2 shows the results for the HAD and Nijmegen scores presented for the whole sample pre- and post-BR, and pre- and post-acupuncture. After each intervention there was some reduction in the anxiety scores, although this was more marked after acupuncture. Nijmegen scores were found to rise a little after BR, but were reduced after acupuncture (although still positive for hyperventilation). The individual changes in HAD anxiety and Nijmegen scores for each group are depicted in Figures 2–5. The analysis of variance approach showed no evidence of any carryover effect, but a statistically significant period effect was noted for both HAD anxiety and Nijmegen scores. When graphically examining individual anxiety scores for group A, who received acupuncture first (Fig. 2), there was a reduction in anxiety levels. However, after the washout period these scores remained almost identical to those after the acupuncture treatment, suggesting that there may have been some carryover effect from the acupuncture. A similar pattern was found with the Nijmegen scores for group A (Fig. 4) in that pre-BR treatment the Nijmegen scores were almost identical to those postacupuncture treatment. In Figure 3, any carryover effect is not evident after BR. It is possible that the small sample size meant that any carryover effect might have passed undetected on statistical analysis. It is unclear, therefore, whether the treatment differences that were found were simply caused by a carryover effect. The period effect suggests that the participants responded differently, or their condition changed, from the first treatment period to the second. The analysis was therefore modified to take this period effect into account when assessing treatment effect. There were statistically significant treatment effects for anxiety scores and Nijmegen scores (Table 3). In view of the potential carryover effect, a between-patient comparison was carried out looking only at the data obtained from period 1 of the study. An independent-samples *t* test indicated that there were no statistically significant differences between acupuncture and BR (Table 4).

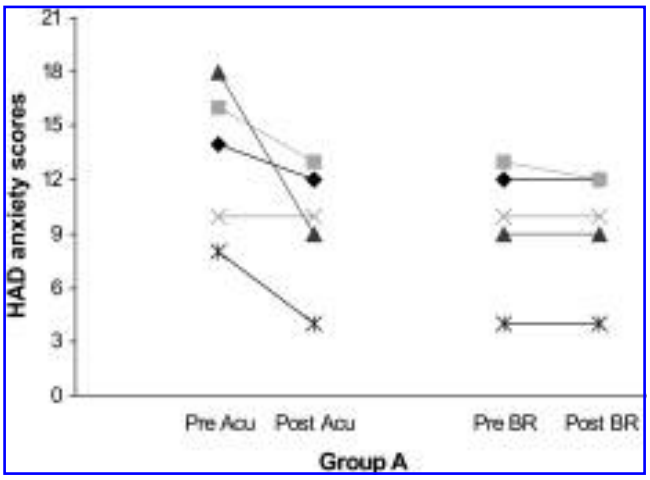

FIG. 2. Group A individual Hospital Anxiety and Depression Scale anxiety scores pre and post each intervention.

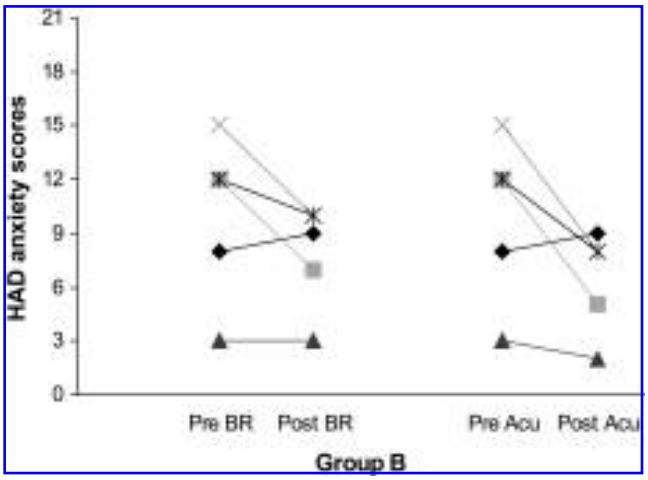

FIG. 3. Group B individual Hospital Anxiety and Depression Scale anxiety scores pre and post each intervention.

DISCUSSION

BR is a standard therapy for patients with HVS. This practice is supported by experimental findings on its effects in hyperventilation and anxiety disorders.[5,6,22–24] The role of acupuncture for anxiety disorders has been previously studied and found to result in statistically significant improvements in anxiety levels.[24–28] The role of acupuncture specifically for HVS has been less well studied, with only one publication specifically in this area.[9] This study was written in Ukrainian, and the full text is not available in English translation. However, the abstract suggests that the primary outcome measures employed were physiologic, with no mention of anxiety. The preliminary study presented here suggests that acupuncture may have a beneficial effect on anxiety levels in patients with HVS when compared to the BR. There were statistically significant treatment effects found in anxiety scores and symptom severity after acupuncture treatment. There was also a reduction in anxiety scores after BR, which did not reach statistical significance, but this may have been because of the small sample size providing insufficient power.

Statistical analysis of the Nijmegen and HAD anxiety scores revealed negative mean differences, indicating that symptom scores tended to be lower after acupuncture. No previous studies employing the Nijmegen score as an outcome measure for acupuncture have been identified. Previous studies of BR for HVS have found statistically significant improvements in Nijmegen scores.[5,23] However, these studies employed larger sample sizes and a longer intervention period.

The mechanisms behind the perceived effects of acupuncture and BR are still unclear. Nonspecific placebo effects have been suggested for both[28–31] because of considerable patient–practitioner interaction. In this study, the same amount of time was allocated for each treatment session during both interventions. However, during BR the clinician was guiding the participant throughout the session, whereas during acupuncture the clinician left the participant unattended for short periods during each session. The participants therefore received more attention during the BR. However, acupuncture involves the insertion of needles, which may itself be a powerful placebo.[31]

In this study, we compared acupuncture to the standard therapy for HVS (i.e., BR) and found some effect. Future studies need to establish whether this effect is specific to acupuncture by comparing it to an acupuncture placebo. This study used a crossover design to provide greater statistical power with a small patient sample. Although no carryover effect was demonstrated statistically, the validity of the tests for carryover has been questioned.[21] When the individual anxiety scores were plotted in graphic form (Figs. 2 and 3), it was evident that there may have been some carryover effect that went undetected. This suggests that it is not ap-

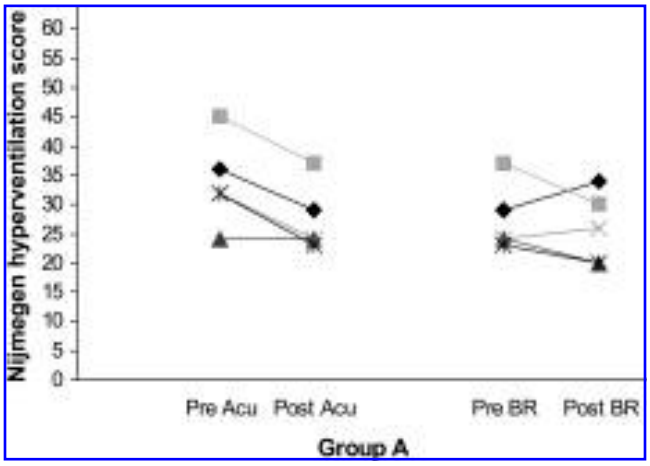

FIG. 4. Group A individual Nijmegen scores pre and post each intervention.

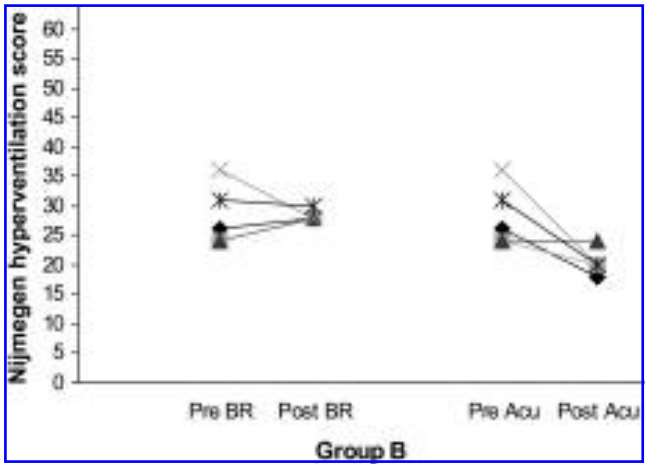

FIG. 5. Group B individual Nijmegen scores pre and post each intervention.

Table 3. Differences Between HAD Scale Scores and Nijmegen Scores After Acupuncture and Breathing Retraining

Variable	*Carryover effect* p *value*	*Mean difference*	*95% Confidence intervals*	p *value*
HAD Scale Anxiety	0.26			
Treatment (A–B)[a]		−0.6	−1.12 to 0.08	0.02
Period (1–2)		0.8	0.28 to 1.32	0.01
HAD Scale Depression	0.19			
Treatment (A–B)[a]		−1.1	−2.51 to 0.31	0.11
Period (1–2)		0.3	−1.11 to 1.71	0.64
Nijmegan	0.38			
Treatment (A–B)[a]		−3.9	−6.09 to −0.51	0.03
Period (1–2)		4.7	1.91 to 7.49	0.01

[a]Adjusted for period effect.
HAD, Hospital Anxiety and Depression.

propriate to use a crossover design for acupuncture studies. It remains uncertain whether any effects of acupuncture or BR persist beyond the cessation of the therapy and whether any apparent treatment difference detected could therefore simply be caused by a carryover effect. Studies that have examined the long-term effects of BR have usually encouraged patients to persist with the breathing techniques after the formal training period has ceased.[32] The effect of acupuncture upon anxiety appeared to be immediate. It is not known whether a longer intervention period would result in any longer effect. The dose–response to acupuncture or BR remains to be established, and further piloting is required. It appears that a two-arm prospective trial with a long-term follow-up period would be ideal to examine these effects.

The limitations of a cross-over design include being only of use when examining a chronic condition, and when there are no long-term effects from the treatment being evaluated. HVS fulfills the first criterion of chronicity. In studies examining acupuncture for other chronic conditions causing breathlessness and anxiety, the effect of acupuncture was considered to be transitory.[33,34]

Any long-term effects of BR are generally poorly reported, and the two studies that have noted such effects[22,35] involved continued use of BR. No studies have been identified that found any long-term effects of BR if participants ceased to use these techniques. In this study, participants were advised not to use their BR techniques during the second treatment period.

Although no statistically significant carryover effects were detected, there did appear to be a significant period effect for some of the outcome variables including HAD anxiety and Nijmegen scores. This could be because of variability in the stability of the participants' condition from the first treatment period to the second. Alternatively, it could be argued that participants' initial enthusiasm meant that the first treatment offered was more valued. Although the statistical analysis was modified to adjust for the period effect, the significant treatment effects observed should be considered with caution. HVS is a chronic condition, but patients will often volunteer for clinical trials when their condition is more obvious or exacerbating. It may therefore have been better to have a "run-in" period during which participants' symptoms and anxiety levels were monitored to ensure that their condition was stable, prior to entering the trial. In view of the potential carryover effect, the recommended analysis on data from period 1 only was carried out to assess for differences between the two treatment techniques.[36] No statistically significant differences were found between the outcomes of both techniques. However, it is important to note that this analysis meant that the sample size was halved, thereby substantially reducing power. The two groups were not balanced for severity of symptoms, age, or co-morbidities because the initial analysis was meant to be a within-subject comparison. Baseline scores for both groups were compared statistically using a Mann–Whitney test, and no statistically significant differences were found between the groups.

Table 4. Comparison of Scores After Period 1 of the Study Using an Independent *t* Test

Variable	*Mean difference*	*95% Confidence interval of difference*		p *value*
		Lower	*Upper*	
HAD Scale Anxiety score	1.8	−2.9	6.5	0.40
HAD Scale Depression score	1.2	−3.0	5.4	0.54
Nijmegan score	−1.0	−8.2	6.2	0.72

HAD, Hospital Anxiety and Depression.

The primary outcome in this study was anxiety as assessed using the HAD scale. Although this is a commonly used validated tool, there are issues surrounding the analysis of the data generated. Different authors have treated HAD scale data as being dichotomous, categoric, or continuous. However, because it was originally devised to detect the presence or absence of clinically significant anxiety, it may not be the ideal tool for assessing response to interventions. Future studies could include additional measures of anxiety, such as the State Trait Anxiety Inventory.[37]

CONCLUSIONS

These results suggest that there may be a beneficial effect of using acupuncture for the treatment of HVS, in terms of reducing anxiety levels and hyperventilation symptoms. However, a crossover design may not be the most appropriate in this patient group. A significant period effect was detected, and there may well be some carryover effect after acupuncture treatment that went undetected because of the small sample size. This preliminary study provides the basis for a larger, sufficiently powered, and methodologically sound trial (i.e., a two-arm randomized controlled trial) investigating the effects of acupuncture in the treatment of HVS.

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