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Clinical effectiveness and cost minimisation model of Alpha-Stim cranial electrotherapy stimulation for generalised anxiety disorder in IAPT services

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Background

Cranial electrotherapy stimulation (CES) was first utilised to induce sleep and relaxation using bursts of small electric currents applied to the head in the 1900s (Guleyupoglu et al., 2013). Since then improvements have taken place in electrode placement, use of battery driven devices and understanding of dose, frequency of treatment and waveform that is required to improve anxiety symptoms. Single courses of CES are associated with changes in electroencephalography (EEG) from delta (0–3.5 Hz) and beta (12.5–30 Hz) frequencies to more relaxing and alerting alpha frequencies (8–12 Hz) (Kennerly, 2004). Cortical and subcortical brain activation on fMRI have been demonstrated in people with high levels of anxiety (Feusner et al., 2012) and increases in plasma beta endorphins, adrenocorticotrophic hormone and cortisol (Liss and Liss, 1996; Shealy et al., 1998) after a single 20 min CES treatment.

A recently published systematic review identified five randomised controlled trials (RCTs) with 198 participants for anxiety disorders comparing active CES to sham CES (Shekelle et al., 2018). It concluded that there was low quality evidence of the effectiveness of CES for anxiety and depression symptoms in people with anxiety disorders at the end of treatment as well as evidence that CES does not cause serious side effects. A randomised controlled trial in 115 volunteers with a primary anxiety disorder showed the effectiveness of 5 weeks of active CES versus sham CES on anxiety and depression symptoms at the end of treatment (Barclay and Barclay, 2014). However, there have been no studies of the maintenance of clinical improvement or cost effectiveness of CES in treatment seeking patients with GAD who had not responded to second-line treatment as recommended by NICE (2011).

The study

The aim of this research was to determine:

1. The proportion of patients treated with CES in IAPT services who reach the clinical threshold for remission (GAD-7 score of 7 or less; Spitzer et al., 2006), reliable improvement and recovery after treatment at 12 weeks.
2. The proportion of patients treated with CES in IAPT services who maintain the clinical threshold for remission (GAD-7 score of 7 or less), reliable improvement and recovery at 24 weeks.
3. If there are significant changes over 24 weeks in generalised anxiety, depression, insomnia, social adjustment and quality of life.
4. If the cost of CES offsets the cost of psychological treatment and other treatment over 24 weeks.

Methods

Consecutive sample of 161 eligible patients with GAD waiting for individual cognitive behaviour therapy (CBT) selected from two publicly-funded services in England. They received 60 min per day Alpha-Stim CES for 6–12 weeks. Primary outcome was remission on the GAD-7 scale at 12 and 24 weeks. Cost effectiveness was examined using a cost minimisation model of direct health costs.

Results

Only 22% of potentially eligible patients agreed to take in the study. All 161 participants started CES treatment and 112 (69.6%) completed at least 6 weeks treatment. Of the 49 (30.4%) participants who withdrew from treatment by 12 weeks, nine (5.6%) could not find the time to complete the treatment, four (2.5%) withdrew because of no improvement, four (2.5%) withdrew because of side effects (two with headaches and insomnia, one with nausea and one with a strange feeling after use), two (1.2%) withdrew because they felt better, and 30 (18.6%) gave no reason. Eighty-one (50.3%) completed follow ups to 12 weeks and 72 (44.7%) to 24 weeks.

Of 161 patients recruited, 72 (44.7%) and 77 (47.8%) achieved remission on the GAD-7 at 12 and 24 weeks respectively with 122 (75.8%) receiving at least 6 weeks CES. Mean (sd) GAD-7 score at baseline significantly improved from 15.77 (3.21) to 8.92 (5.42) and 8.99 (6.18) at 12 and 24 weeks respectively ($p < 0.001$). 80 (49.7%) participants required further individual CBT. CES provided a saving of £540.88 per patient (95% CI −£327.12, £648.69).

Limitation

Participants were not randomised and there was no control group. Only 48 (29.9%) participants completed every assessment.

Discussion

This study shows that in moderate to severe treatment seeking patients with GAD, nearly 45% of patients achieved remission and 63% reliable improvement in their self-rated anxiety symptoms with Alpha-Stim CES treatment. These improvements were maintained for a further 12 weeks after CES was completed whether or not patients received iCBT in addition. Most of the improvement with CES was seen in the first 4 weeks. It had a moderate effect size. Remission rates are lower than reported for iCBT in routine IAPT services in the UK (Radhakrishnan et al., 2013); however our sample had substantially higher scores than routinely reported for IAPT services (NHS Digital 2019). Approximately 50% of patients on the waiting list for iCBT received iCBT, thereby enabling the NHS IAPT services to treat other patients on the waiting list for iCBT.

Alpha-Stim CES was well tolerated with only six (4%) patients stopping it because of side-effects and four (3%) because they were not making any progress. Compared to a standard course of iCBT (eight sessions or longer), Alpha-Stim CES reduced costs of care by £540 or more per patient and it was also cost effective.

Conclusion

In patients with generalised anxiety disorder not responding to low intensity psychological treatment, 6–12 weeks daily Alpha Stim CES may be effective after treatment and 3 months later, thereby reducing the need for individual CBT and saving health costs.

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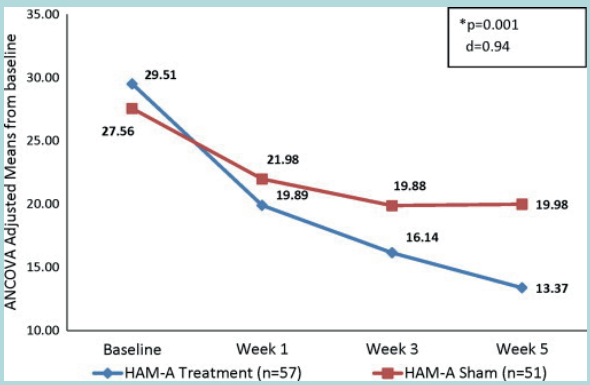

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