Alpha-Stim AID cranial electrotherapy stimulation (CES) for anxiety treatment: anxiety, depression and health-related quality of life outcomes in primary healthcare social prescribing services

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Alpha-stim device and possible mechanims of action



Alpha-Stim AID CES

A cranial electrotherapy stimulation (CES) device which uses very low voltage current to induce changes to electrical activity of the brain, from stressful rhythms to relaxing rhythms. It has similar effects to skilled practice of meditation/mindfulness. It is shown on EEG machines to increase Alpha brain waves (related to relaxation and calmness) and reduce Beta waves (related to excitement and stress). Delivered by a mobile phone sized device and connected via clips to the earlobes, for up to an hour a day.

Conclusion

Alpha-Stim AID can be delivered through a primary healthcare social prescribing service and most patients will use as prescribed and complete treatment course. This present study shows that the use of the device may lead to relatively quick improvement, aligning with other findings (Morriss et al., 2019). Most of the improvements in anxiety and depression with Alpha-Stim AID was seen in the first 3 weeks. Alpha-Stim AID CES may be an effective anxiety and depression treatment for people with anxiety symptoms. Alpha-Stim AID can currently be offered to patients by NHS services. Business as usual models are emerging. Commissioning of Alpha-Stim is problematic with the current focus on medication and talking therapies to address anxiety. NICE states: 'Alpha-Stim AID shows promise for managing anxiety disorders' and have recommended a RCT design to provide required evidence.

Introduction

Anxiety disorders are the most common mental disorders, typically treated with psychotherapy and medication. These treatments are not suitable for, acceptable to, or effective for everyone. Alpha-Stim AID is a safe cranial electrotherapy stimulation (CES) treatment with evidence of effectiveness in treating anxiety disorders (Ching et al., 2022) and has been reviewed by National Institute for Health and Care Excellence (NICE). Three previous Alpha-Stim studies suggest that community-based patients' depression and anxiety symptoms can be treated with Alpha-Stim AID through the NHS (Griffiths et al., 2021; Morriss et al., 2019; Royal et al., 2022).

In this project Alpha-Stim was offered in primary care through social prescription liaison workers (SPLWs) to patients who reported symptoms of anxiety.

Aims

This is the first study to respond to National Institute for Health and Care's (NICE) [MTG56] request for real-world data to understand better understand Alpha-Stim AID anxiety treatment in relation to people's treatment uptake, response rates, and treatment completion rates (NICE, 2021). This study explored the experience and impact of using Alpha-Stim AID.

Results

Reliable improvement and remission rates respectively were 53.39% and 33.3% for GAD-7; 46.7% and 29.5% for PHQ-9. There was a significant improvement in GAD-7 and PHQ-9 with large effect sizes. EQ-5D-5L results showed significant improvements in health-related quality of life. Perceived quality of life increased by 0.17 on the health index score; with the intervention adding 1.68 quality-adjusted life years (QALYs).

Analysis of interviews provided support for the acceptability and useability of Alpha-Stim AID. Most participants described a positive impact in their lives and would recommend it to others. Themes that emerged offered insights into how people used the Alpha-Stim and their experiences of the effects.



Methods

Open-label patient cohort design with no control group. Thirtythree adult patients (average age 42 years, 61.3% females, 35.5% males and one participant identified as 'other') completed 6 weeks of Alpha-Stim AID use. Pre- and post-intervention assessment with participant self-report measures: Patient Health Questionnaire (PHQ-9), Generalised Anxiety Disorder (GAD-7), and European Quality of Life Five Dimension (EQ-5D-5L). Fifteen participants consented to be interviewed. Interview data were analysed using thematic analysis.

Limitations

The study was not an RCT: there was no control group. Followup data collection was at end of treatment point, with no later follow-up data collection was undertaken.

Funding

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Future

An Alpha-Stim AID RCT is being set up which may meet the recommendation of NICE guidance [MTG56] for an appropriate RCT. A project is under way to test business-as-usual deployment of Alpha-Stim AID in primary care through a social prescription service to patients who report symptoms of anxiety.

References

Griffiths, C., da Silva, K., Jiang, H., Walker, K., Smart, D., Zafar, A., Deeks, S., Galvin, S. & Shah, T. (2023). Alpha-Stim AID cranial electrotherapy stimulation (CES) anxiety treatment: anxiety, depression, and health-related quality-of-life outcomes in primary healthcare social prescribing services. Mental Health Review Journal. Vol. Ahead-of-print. https://doi.org/10.1108/MHRJ-11-2022-0068 Griffiths, C., Walker, K., & Jiang, H. (2023). The experience of using Alpha-Stim AID cranial electrotherapy stimulation (CES) for symptoms of anxiety. *F1000 Research*. Published prior to review: (10.12688/f1000research.128323.1) https://doi.org/10.12688/f1000research.128323.1 Griffiths, C., da Silva, K., Leathlean, C., Caesar, D., Joseph, L. & Lakkappa, B. (2022). Alpha-Stim AID cranial electrotherapy stimulation (CES) for anxiety treatment: outcomes in a community healthcare Journal service. Open of Depression, 11, https://www.scirp.org/journal/paperinformation.aspx?paperid=121330 Griffiths, C., Leathlean, C., Smart, D., Zafar, A., Hall, C-L, & Deeks, S. (2021). Alpha-Stim cranial electrotherapy stimulation (CES) for anxiety treatment: outcomes in a United Kingdom (UK) primary

care practice. Open Journal of Psychiatry, 11, 3. https://doi.org/10.4236/ojpsych.2021.113015

Ching, P. Y., Hsu, T., Chen, G., Pan, C. C., Chu, C. S., and Chou, P. H. (2022), "Efficacy and tolerability of cranial electrotherapy stimulation in the treatment of anxiety: A systemic review and meta-analysis", *Frontiers in Psychiatry*, Vol. 13 No. 899040, pp. 1-13

Morriss, R., Xydopoulos, G., Craven, M., Price, L., and Fordham, R. (2019), "Clinical effectiveness and cost minimisation model of Alpha-Stim cranial electrotherapy stimulation in treatment seeking patients with moderate to severe generalised anxiety disorder", *Journal of Affective Disorders*, Vol. 253, pp. 426-437

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