Scientific Research Publishing

Open Journal of Depression, 2022, 11, 80-92
https://www.scirp.org/journal/ojd
ISSN Online: 2169-9674
ISSN Print: 2169-9658

Alpha-Stim AID Cranial Electrotherapy Stimulation (CES) for Anxiety Treatment: Outcomes in a Community Healthcare Service

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How to cite this paper: Griffiths, C., Joseph, L., Caesar, D., Lakkappa, B., Leathlean, C., & da Silva, K. (2022). Alpha-Stim AID Cranial Electrotherapy Stimulation (CES) for Anxiety Treatment: Outcomes in a Community Healthcare Service. *Open Journal of Depression, 11,* 80-92.
https://doi.org/10.4236/ojd.2022.114007

Received: September 12, 2022
Accepted: November 18, 2022
Published: November 21, 2022

Abstract

Background: Symptoms of anxiety disorders are highly common and can have a severe impact on people's lives; they are typically treated with psychotherapy and/or anti-anxiety medication. These treatments are not suitable for, acceptable to, or effective for everyone. Alpha-Stim AID is a cranial electrotherapy stimulation (CES) device with evidence of effectiveness in treating symptoms of anxiety. In this study, Alpha-Stim AID was offered through a United Kingdom (UK) universal community healthcare provider, Intermediate Care Team (ICT) community healthcare service to patients who reported signs of anxiety. **Objective:** The aim of this paper is to present feasibility findings and outcomes on anxiety, health status, and quality of life. **Methods:** Open-label patient cohort design, with no control group. Participants were adults who reported symptoms of anxiety and were under the care of universal national health service (NHS) Intermediate Care Team (ICT) community healthcare service in the United Kingdom (UK). Pre- and post-intervention assessment used participant self-report measures: generalised anxiety disorder (GAD-7) and health related quality of life (EQ-5D-5L). The three ICT staff members who offered the Alpha-Stim AID to patients completed a questionnaire on their experience. **Results:** Eighteen patients used the Alpha-Stim and completed outcome measures. GAD-7 scores significantly improved from 13.9 (SD = 4.3) to 7.3 (SD = 5.7) ($p < 0.001$), with a large effect size of 0.88. Analysis of EQ-ED-5L health index score conversions indicated perceived quality of life increased from 0.31 (SD = 0.25) to 0.48 (SD = 0.28) at end ($p = 0.036$), with a small effect size of 0.12. EQ-VAS scores at baseline improved from 49.2 (SD = 24.0) to 64.4 (SD = 26.2) at the end ($p = 0.05$), with a small effect size of 0.12. **Limitations:** There was no control

group, and the intervention was adjunct to existing treatments. **Conclusions:** Alpha-Stim AID CES can be offered through a UK NHS Trust Intermediate Care Team (ICT) community healthcare service and can have a significant positive impact on symptoms of anxiety, quality of life, and health status in patients who report experience of anxiety symptoms. Roll-out through community mental health providers to people with experience of anxiety symptoms is feasible. An appropriately designed and sufficiently powered randomised controlled trial of Alpha-stim for anxiety is required.

Keywords

Alpha-Stim, Community Care, Cranial Electrotherapy Stimulation, Service Delivery, Anxiety, Depression, Quality of Life, Co-Morbidity

1. Introduction

Anxiety disorder symptoms are highly prevalent and are associated with a high burden of illness; they can have a severe effect on people's quality of life, wellbeing, and ability to function (engage in activities of daily living, socialise, work, etc.) (Kessler et al., 2012; Wittchen et al., 2011). Generalised anxiety disorder (GAD) is the most common psychiatric disorder in older adults (Bandelow et al., 2017). Anxiety disorder symptoms are highly underrecognized and undertreated; less than a third of people get appropriate treatment (Bandelow et al., 2017).

The United Kingdom's (UK's) National Institute for Health and Care (NICE) guidance for management of generalised anxiety disorder (GAD) symptoms is a three-step progressive process: 1) provide education and active monitoring; 2) individual guided self-help, or psychoeducational groups; and 3) an individual high-intensity psychological intervention or drug treatment (choice guided by patient preference) (NICE, 2019b). There can be long wait times for individual high-intensity psychological intervention, and therefore medication may be given in advance of patients accessing psychotherapy (Clark et al., 2018).

Psychotherapy can be effective for anxiety but is costly (costly in terms of providing psychotherapy and attending appointments) and lengthy (multiples sessions over a period of time), with non-response rates of 60% - 66% (Gyani et al., 2013; Griffiths & Griffiths, 2014). Medication treatments for anxiety symptoms include selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), benzodiazepines, buspirone, and tricyclic antidepressants (TCAs) (Bespalov et al., 2009). These can reduce symptoms of anxiety; however, not all people respond, and patient acceptability and compliance can be compromised due to adverse effects; for example, weight gain, increased rates of falls, increased fracture rates, gastrointestinal and sexual difficulties, insomnia, and severe headaches (Anderson et al., 2012; Gafoor et al., 2018; Lingam & Scott, 2002). In some cases, withdrawal effects can be long-lasting and severe (Davies & Read, 2019). Benzodiazepines are only recommended for severe an-

xiety symptoms and only short term prescription (two to four weeks) due to dependence and withdrawal issues (NICE, 2019a).

Combing psychotherapy and medication can be effective for some people (Bandelow et al., 2017). However, some people do not respond well to either medication or psychotherapy and some people do not wish to try either because of medication side effects or difficulties in attending psychotherapy sessions due to mobility issues, travel costs, or work or caring responsibilities (Bandelow et al., 2017). Therefore, it is important to be able to offer alternative home-based treatment options and to enhance patient choice of treatment.

An alternative anxiety treatment is the Alpha-Stim AID (anxiety, insomnia, and insomnia) device made by Electromedical Products International Inc., which can be purchased directly by the public in the US, UK, and other countries (Electromedical Products International Inc., 2022). Alpha-Stim AID cranial electrotherapy stimulation (CES) uses very low voltage current to potentially induce changes to electrical activity of the brain, from stressful (beta and delta) frequencies to more relaxing (alpha) frequencies (Kennerly, 2004). It may have similar effects to skilled practice of meditation/mindfulness (Morriss et al., 2019). The Alpha-Stim AID is a mobile phone sized device connected via soft pad clips to both earlobes, for up to an hour a day. It is easy to use, and is CE marked for intended purpose (Griffiths et al., 2021). NICE has confirmed that people using Alpha-Stim AID have a low risk of side effects (NICE, 2021).

A randomised controlled trial (RCT) demonstrated the efficacy of the treatment versus sham (Barclay & Barclay, 2014). A systematic review identified five RCTs with a total of 198 participants and found that it is a safe (does not cause serious adverse events) form of CES that improves anxiety and depression symptoms over six weeks treatment in people experiencing anxiety with depression (Shekelle et al., 2018). A study with an open cohort design with no control set in a UK National Health Service (NHS) Improving Access to Psychology Treatment (IAPT) service with 161 patients diagnosed with GAD showed the Alpha-Stim to be a cost-effective anxiety disorder treatment that reduces anxiety and depression symptoms and improves health related quality of life (Morriss et al., 2019). The study showed that Alpha-Stim can be delivered through NHS IAPT services, is acceptable to patients, and patients will conform to the required treatment protocol.

Social prescribing services in the UK receive referrals from GPs and seek to address holistic health and wellbeing needs by asking "what matters to you?" and linking to appropriate services and support (Department of Health, 2006; NHS England, 2016). Alpha-Stim CES has been delivered through a UK based primary care social prescribing service and evaluation of outcomes found it to be effective in reducing anxiety and depression symptoms and improving health related quality of life; it was found that Alpha-Stim AID was acceptable to most patients, most used as instructed and returned it following use (Griffiths et al., 2021). Delivering Alpha-stim through a nurse led primary care clinic to univer-

sity students with a clinical diagnosis of anxiety or depression was found to be acceptable and feasible; improvements in anxiety and depression symptoms were found, and it was calculated to be cheaper than treatment through a general practitioner (GP) (Royal et al., 2022).

There is a lack of information on outcomes from delivering through community healthcare services. NICE guidelines state that Alpha-Stim AID shows "promise" for managing anxiety disorders; however, due to concerns over insufficient good-quality evidence, NICE has not recommended the adoption for routine treatment (NICE, 2021). Prior to recommendations for adoption, the NICE recommended the collection of real-world data to better understand issues around people's treatment preferences, treatment completion rates, short and long term efficacy as well as impact on quality of life (NICE, 2021). Implementation studies are required in healthcare settings to check that the efficacy seen in RCTs is replicated in routine clinical practice (Medical Research Council, 2000; NICE, 2018).

The overall purpose of this study is to determine the feasibility, acceptability and impact on participant reported anxiety symptoms, health related quality of life and health status of the Alpha-Stim AID. This is the first study to seek to report these factors from a Intermediate Care Team (ICT) community healthcare service delivering Alpha-Stim AID for anxiety in a United Kingdom (UK) universal national health service (NHS).

2. Methods

2.1. Design

Open-label patient cohort design with no control group. Pre- and post-intervention assessment with participant self-report measures. Three members of staff offering the Alpha-Stim AID to patients were interviewed

2.2. Setting

UK NHS community universal healthcare provider in England. NHS community health trusts deliver physical and mental health care, support, rehabilitation, and treatment for children, adults, and older adults through locally based and outreach services; they typically offer access to physical and psychological therapies and treatment, physical and mental health assessment, employment support, personalised and trauma-informed care, and medicines management (NHS England, 2021). The specific service from which patients were recruited is known as Intermediate Care Team (ICT) which is an enhanced home based assessment, care, support, and treatment service commissioned for 17 days input (but may see patients for a longer period), used to facilitate discharges from hospitals, allow people to remain in their homes rather than care homes, and prevent inpatient admissions. This is achieved by a multidisciplinary team of physiotherapists, nurses, occupational therapists, and reablement assistants. Patients are usually older adults, often have co-morbid diseases, can have mobility issues,

and have a high level use of health and social-care services.

2.3. Inclusion/Exclusion Criteria

Inclusion: 18 years or over; under the care of ICT community health services; signed consent form; and patient reported symptoms of anxiety. Exclusion: lack of capacity to consent; experience of seizures; and have a pace-maker of any other implanted electrical device.

2.4. Alpha-Stim Intervention

Electrical current is delivered by Alpha-Stim AID (CE marked medical device) (0.5 Hz, 100 - 500 μA, 50% duty cycle, biphasic asymmetrical rectangular waves), a mobile phone sized device delivering small electric currents via soft pad conducting clips to the earlobes. The person wears the device via lanyard hung around their neck, enabling light activities to be performed whilst in use. All participants were recommended 60 min per day of Alpha-Stim CES treatment at a current of one hundred micro amps (level 1: 2 bars on the device display), 7 days per week for 6 consecutive weeks. Patients were given printed instructions and shown how the device works. Support was provided if required. Patients remained on any physical or medical health medication they were currently taking.

2.5. Procedure

Patients were reviewed to see if they reported signs of anxiety. Patients were selected if they met inclusion/exclusion criteria. Patients were provided with information about the treatment and evaluation, informed consent was sought and required to begin Alpha-Stim treatment; patients could withdraw consent and stop using the Alpha-Stim at any point without need for providing a reason. Measures of anxiety and health related quality of life were collected at baseline and 6 weeks. An Alpha-Stim usage questionnaire was completed.

2.6. Consent

Participants provided informed consent to use Alpha-Stim and allow evaluators to collect outcome measures, and access NHS patient data for analysis and publication of anonymised group results. The project was reviewed and approved by the NHS Trust provider.

2.7. Measures

The Generalised Anxiety Disorder-7 (GAD-7) is a seven-item self-report measure of GAD (Spitzer et al., 2006). A score that is rated as 0 - 4 represents no or minimal anxiety, 5 - 9 mild anxiety, 10 - 14 moderate anxiety, and 15 - 21 severe anxiety. The GAD-7 has good sensitivity and specificity for GAD and is moderately good at screening three other anxiety disorders: panic disorder, social anxiety disorder, and post-traumatic stress disorder (PTSD) (Kroenke et al., 2007). It has good internal consistency shown by Cronbach's Alpha value of $\alpha =$

0.92 (Kroenke et al., 2007).

EQ-5D-5L (EuroQol Group, 1990; van Hout et al., 2012) is a 5-item self-rated measure of health related quality of life and overall health status. It is a standardised measure of health developed by EuroQol group with the aim to provide a simple, standardised for clinical appraisal (EuroQol Group, 1990.). The descriptive systems comprises of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which are measured within 5 levels (no problems, slight problems, moderate problems, severe problems and extreme problems). The digits from the five dimensions are combined to create a five-digit number describing a participants' holistic health state and there is a Visual Analogue Scale (VAS) of health status. Each health state can be assigned an index score based on societal preference weights for the health state. Health state index scores generally range from less than 0 (where 0 is the value of a health state equivalent to dead; negative values representing values as worse than dead) to 1 (the value of full health), with higher scores indicating higher health utility. It is recommended by NICE to estimate health state utility weights for quality-adjusted life year (QALYs) (NICE, 2018). The EQ-5D-5L is a validated, generic, preference-based measure of health status, widely used in national health surveys in the UK and clinical trials of mental health interventions (Brooks & Group, 1996; Herdman et al., 2011). EQ-5D-5L demonstrates good construct validity and is sensitive to changes in patients with depression and anxiety (Peasgood et al., 2012).

2.8. Medical Records

Demographic information (gender, date of birth) was extracted from clinical records containing routinely collected data. Analysis was conducted using an anonymised database.

2.9. Statistical Analysis

Analysis of change from baseline to post-course treatment scores and correlational analysis was carried out using appropriate statistical tests. Data were analysed using the statistics software package SPSS® Statistics v28. All tests were 1-sided, at a 5% level of statistical significance.

3. Results

3.1. Participant Characteristics

The sample comprised of 11 (61%) females and seven males (39%); age range from 66 to 100 with a mean of 79 years. Baseline EQ-5D-5L crosswalk data values indicated participants had a holistic health index of 0.31 (max = 1). See **Table 1**.

3.2. Analysis of Change

GAD-7 remission is defined as 7 points or less, reliable improvement is defined as a reduction in 5 or more points from baseline. Nine participants (52.9%)

Table 1. Baseline characteristics of participants (n= 18).

Variable	Mean ± SD (Min - Max)
ED-5D-5L health index value	0.31 ± 0.25 (−0.07 - 0.65)
EQ-VAS	49.17 ± 23.96 (10 - 100)
GAD7	13.89 ± 4.27 (6 - 21)

achieved reliable improvement. Out of the 16 patients with a baseline GAD-7 of more than 7, 12 patients (75%) achieved remission.

There were no outliers in the dataset, as assessed by inspection of a boxplot for values greater than 1.5 box-lengths from the edge of the box. The difference scores between the baseline and post intervention GAD-7 were not normally distributed, as assessed by Shapiro-Wilk's test ($p = 0.027$). Due to the small sample size ($n = 18$), as well as lack of symmetry and normal distribution, a Wilcoxon Signed-Rank Test was used to analyse the differences between pre and post GAD-7 scores. The test revealed a statistically significant decrease in GAD-7 ($Z = -3.42$, $p < 0.001$) from baseline ($M = 13.89$, $SD = 4.27$) to 6 weeks ($M = 7.29$, $SD = 5.58$). Out of 18 participants, 16 reported reduced anxiety symptoms, two stayed the same, and none reported increased anxiety symptoms after the intervention.

Table 2 illustrates the descriptive data for each of the five EQ-5D-5L dimensions as well as the mean health digit (calculated according to each dimension) and corresponding health index at baseline and week 6. The data is somewhat consistent with Devlin et al. (2017), indicating that the lowest satisfaction scores were observed for pain/discomfort and mobility level.

Additionally, Wilcoxon Signed-Rank Tests were used to analyse the differences between pre and post intervention EQ-5D-5L dimensions. The tests revealed a statistically significant improvement in self-care and anxiety/depression, as well as on a self-rated health satisfaction which increased by 12%. Additionally, the overall health index score improved, but result was just outside significance level.

Participants were requested to use the Alpha-Stim AID daily. Data from the participant usage questionnaire indicated that 47% of participants used the device daily through the 6-week intervention, 33% reported using the device "virtually" every day, and 20% of participants used the device half of the days, a third of the days or once a week. These categories were analysed as a covariate for GAD-7 improvement. The ANCOVA results were non-significant in both cases, indicating that failure to adhere to daily treatment did not have a significant detrimental impact on improvement.

3.3. Correlations

Higher GAD-7 at baseline significantly correlated with higher QL-Mobility ($r = 0.575$, $p = 0.013$) and higher QL-AD scales ($r = 0.468$, $p = 0.050$). Furthermore,

Table 2. Mean and standard deviation within each dimension across time with corresponding mean variation, significance, and effect size.

EQ-5D-5L DIMENSION	Baseline	Week 6	*Z*	*p*	*r*
	mean (SD)	mean (SD)			
Mobility level	2.50 (1.15)	2.29 (1.21)	−0.962	0.366	
Selfcare level	3.00 (1.28)	2.29 (1.31)	−2.428	0.015*	0.143
Usual activity level	3.78 (1.11)	3.24 (1.56)	−1.469	0.142	
Pain/discomfort level	2.50 (1.15)	2.00 (0.94)	−1.612	0.107	
Anxiety/depression level	3.28 (0.96)	2.59 (0.87)	−2.360	0.018*	0.139
Health index score	0.31 (0.25)	0.48 (0.28)	−2.10	0.036	0.124
QL-VAS	49.17 (23.97)	64.38 (26.20)	−1.96	0.050*	0.115

* Significant at $p < 0.05$ level. Each dimension is scored between 1 – no problem to 5 – extreme problem.

higher scoring on GAD-7 was reaching significance with the poorer QL-health index ($r = -0.462$, $p = 0.062$).

3.4. Staff Experience Questionnaire

The three members of staff offering the Alpha-Stim AID to patients were interviewed. They were asked about their experiences offering Alpha-Stim to patients; providing instructions for use; any feedback they had; impression of the effect of Alpha-Stim on patients; Alpha-Stim as an alternative to medication; would they like to continue offering Alpha-Stim to patients; how would they see the availability of Alpha-Stim in their service working; problems or issues; and advice for other clinicians looking to offer Alpha-Stim to their patients.

Experiences were generally positive. Staff felt reassured about evidence of effectiveness and safety, and liked its simplicity of use:

> "The alpha stim does not cause any side effects it's quite a safe device."
> "It was quite simple and clear, it was straight forward, there was not any technical difficulties … the use guidance was also quite simple … You just had to press one button and that's it, you put the pads on the ear lobes that's it, finished nothing else."

In terms of their impression of the effect of Alpha-Stim on patients there were both positive and negative comments:

> "The patient was referred to us only because her anxiety levels had gone high and had COPD as well, when I went to her, at follow-up, for the review, the patient was a different person altogether, she looked very well and that what really surprised me the difference."
> "The patients were quite happy, we had a couple of patients who requested the machine even after the study, they were quite impressed with the ma-

chine, they wanted the machine."

Many patients were in their 80's and 90's:

"There are patients who were not able to use the machine due to other issues, like dexterity so they can't clip it to their ear or their can't remember to use it, because of that they have not been able to use it as much as they should have. Those [who] have contractions in their fingers, they cannot coordinate to clip it on, they need someone to physically do it for them. However, if there are any reasons why they cannot use it, we should try to sort that out, like, may be liaising with their carers to be prompts to get the patients to use it."

There were some tips as to how patients could be encouraged to use the device more regularly:

"When the carers go in, they can just ask 'have you used the machine today?' so it's like a prompt, a daily prompt, will be really good for patients."
"App [reminder] on smartphone can help … Also can be synchronized with Heart rate monitor [use]."

The staff considered offering Alpha-Stim as an alternative to medication to treat anxiety:

"Absolutely, if it works for any patient that would be better than medication because we have an issue with patients not taking their medication, and some of our patients are on too much medication, which gives them side-effects, so anything that can reduce their anxiety is very welcome."
"Not enough evidence has been generated yet as replacement of standard practices."

The staff explained that they would like to continue offering Alpha-Stim to patients:

"We are making sure that a patient's anxiety is under control, if they have this device it may have an effect on hospital admissions for COPD patients."
"I would love to continue to offer it to patients because I have seen that it can help reduce anxiety."

The staff considered the need to offer the Alpha-Stim again:

"Patients are quite happy, their anxiety has gone down by a considerable amount, they are quite happy to use the machine, but we may have to still continue with it."

Staff offered feedback on incorporating into their service:

"It should become a known structured procedure."
"Rather than prescribing the usual medications for anxiety, the GP could prescribe the Alpha-Stim."

Very few problems or issues were reported:

"Some people said that they can feel a mild tingling sensation, but it doesn't bother them, they are quite happy to use that."
"When the team has been very busy, it has been tricky to say, you are taking time to [offer] the Alpha-Stim, you know when the whole team is stretched to its limits, you feel like, that this is not the priority now."

Staff provided advice for other clinicians looking to offer Alpha-Stim to their patients:

"This device was explained to each GP practice, how to obtain the device and the evidence."
"I would say it that we should try to give everybody a chance to try it."

4. Discussion

The results show that Alpha-Stim AID CES can be successfully delivered through a UK universal national health service (NHS) Intermediate Care Team (ICT) community healthcare service. This indicates the applicability in other community based healthcare services. Findings indicate that most people in this patient group will use the Alpha-Stim AID as required (daily or virtually every day) for a 6-week period; and that it can be effective in reducing anxiety and improving quality of life a and health status in this patient group.

The feedback from staff offering the Alpha-Stim was generally positive. Staff felt reassured about evidence of effectiveness and safety, and appreciated its simplicity of use. They highlighted the importance of offering Alpha-Stim as an alternative to using medication and the need to identify and offer support for those who could not use themselves or who needed reminders to use regularly. Staff related how they saw signs and benefits of a reduction in anxiety in some of their patients following the use of Alpha-Stim.

The significant improvements in anxiety align with published RCT findings and service based study results (Barclay & Barclay, 2014; Shekelle et al., 2018; Morriss et al., 2019; Griffiths et al., 2021; Royal et al., 2022). This current study's positive remission and reliable improvement rates add to evidence from three other NHS service based Alpha-Stim studies (Morriss et al., 2019; Griffiths et al., 2021; Royal et al., 2022). These positive results indicate Alpha-Stim AID's potential in reliving anxiety by offering to patients through various NHS services.

Participants perceived overall rating of their health related quality of life and health status increased, Alpha-Stim AID's benefits in terms of anxiety and effective sleep may have influenced this (Shekelle et al., 2018). The findings revealed a statistically significant improvement in EQ-5D-5L dimension of "self-care" potentially indicating that the reduction in anxiety has positive effect on real-world functioning. In addition, a statistically significant improvement in anxiety/depression EQ-5D-5L dimension was found, indicating a positive effect on mental health/well-being.

Limitations

There was no control group: the design was not a randomised controlled trial. Treatment with Alpha-Stim AID was open label and adjunct to any existing anxiety or other treatments. Long-term effects could not be reported, there was no follow-up data collection point beyond end of treatment. The sample was over-represented by females (61%) and so results are less generalisable to males; however, this reflects the higher proportion of females who are diagnosed with anxiety in the general population.

5. Conclusion

The implementation and use of the Alpha-Stim AID were found to reduce symptoms of anxiety and improve health status, and be feasible and acceptable to staff and patients. The availability of the Alpha-Stim AID through the NHS is currently very limited. The results support the availability of Alpha-Stim AID as a treatment option for people with symptoms of anxiety. Alpha-Stim AID could be offered as a treatment option freely available to people with symptoms of anxiety, rather than just those who can afford the cost of the device. An appropriately for designed and powered RCT on effectiveness of Alpha-Stim AID for anxiety symptoms compared to cognitive behavioural therapy (CBT), anti-anxiety medication or combination of both is required (NICE, 2021).

Acknowledgements

The authors wish to thank the patients and staff involved.

Conflicts of Interest

No other authors have any conflicts of interests to declare.

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