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

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Abstract

Purpose – *This study aims to evaluate the effect of Alpha-Stim Anxiety, Insomnia and Depression (AID) cranial electrotherapy stimulation (CES) on anxiety, depression and health-related quality of life for primary care social prescribing service patients with anxiety symptoms.*

Design/methodology/approach – *Open-label patient cohort design with no control group. A total of 33 adult patients (average age 42 years) completed six 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).*

Findings – *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).*

Practical implications – *Alpha-Stim AID can be delivered through a primary health-care social prescribing service and most patients will use as prescribed and complete treatment course. Alpha-Stim AID CES may be an effective anxiety and depression treatment for people with anxiety symptoms. The widespread roll-out of Alpha-Stim AID in health-care systems should be considered.*

Originality/value – *To the best of the authors' knowledge, this is the first study to respond to the UK's National Institute for Health and Care (NICE) request for the collection of real-world data to understand better Alpha-Stim AID in relation to people's treatment uptake, response rates and treatment completion rates (NICE, 2021).*

Keywords *Alpha-Stim, Service delivery, Quality of life, Primary care, Social prescribing, Cranial electrotherapy stimulation, Anxiety, Co-morbidity, Depression*

Paper type *Research paper*

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Introduction

Anxiety disorders (generalised anxiety disorder [GAD], phobias and panic disorders) are common and have a 13.6%–28.8% lifetime prevalence, with up to 33.7% of the general population experiencing an anxiety disorder during their lifetime (Bandelow and Michaelis, 2015; Michael *et al.*, 2007). GAD is the most common anxiety disorder and is defined as excessive and difficult-to-control anxiety or worry about issues in peoples' lives, everyday

activities or life events (APA, 2013). This anxiety and its effects can impair functioning and reduce well-being and quality of life (Locke *et al.*, 2015; Kessler *et al.*, 2012; Wittchen *et al.*, 2011).

Pharmacotherapy used for anxiety disorders with evidence of effectiveness includes selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), benzodiazepines, buspirone and tricyclic antidepressants (TCAs) (Bespalov *et al.*, 2010; Muntingh *et al.*, 2016). Meta-analysis shows that SSRIs and SNRIs are effective in treating anxiety disorders (Jakubovski *et al.*, 2019). However, adverse side effects, which can include nausea, fatigue, weight gain, tremors, sexual dysfunction, insomnia and gastrointestinal problems, mean the medication is not an acceptable option for some people (Bandelow *et al.*, 2017); for example, between 18% and 30% of people stop using SSRIs (Mochcovitch *et al.*, 2017). In addition, there can be a high risk of relapse (Culpepper, 2009), withdrawal effects can be long-lasting and severe (Davies and Read, 2019), and benzodiazepines are only recommended for severe anxiety symptoms and for less than four weeks of use, due to risk of dependence and withdrawal issues (NICE, 2019a).

Psychotherapy is recommended for anxiety disorders and can be effective, but as it is delivered over multiple sessions over a period of several weeks or months, it is costly and lengthy, with non-response rates of 60%–66% (Gyani *et al.*, 2013; Griffiths and Griffiths, 2014; NICE, 2019b). In addition, some people do not find psychotherapy to be an acceptable option due to cultural beliefs, mobility issues, travel costs or work or caring responsibilities (Bandelow *et al.*, 2017). Therefore, it is important that patients have a choice of treatment options for anxiety that best suit their lives, needs and concerns.

Cranial electrotherapy stimulation (CES) treatment can be offered in addition to pharmacological and psychotherapy/psychological treatment or as a standalone alternative treatment for various psychological disorders (Kirsch *et al.*, 2019). CES is a non-invasive method of applying a pulsed low-intensity electrical current through the head to cause an effect in the brain (Nardone *et al.*, 2014). CES has few side effects for users and was initially introduced to induce sleep and relaxation (Guleyupoglu *et al.*, 2013). It has subsequently been used for treating anxiety, depression, insomnia, post-traumatic stress disorder (PTSD) and pain (Kirsch *et al.*, 2019); however, there is a lack of compelling evidence from well-designed studies for beneficial effects (Brunyé *et al.*, 2021). A systematic review and meta-analysis examined the efficacy of CES for patients who reported anxiety symptoms and found CES significantly reduced anxiety symptoms with moderate effect sizes and patients tolerated CES well (Ching *et al.*, 2022).

The precise mechanisms of action of CES remain unclear. It has been suggested that the effects could be related to modulation of the central and peripheral nervous system, which alters resting state and limbic system activation, which then increases cortical alpha-based activity and the release of neurotransmitters and hormones (Brunyé *et al.*, 2021; Ching *et al.*, 2022). In addition, CES is associated with changes detected by electroencephalography (EEG) from delta (0.1–3.5 Hz) and beta (12.5–30 Hz) frequencies to more relaxing alpha frequencies (8–12 Hz) (Kennerly, 2004) and increased theta activity in the left frontal region (Kim *et al.*, 2021).

Alpha-Stim anxiety, insomnia and depression (AID) device is manufactured by Electromedical Products International Inc., it can be purchased directly by the public in the UK, and other countries; approximate cost is £600 (Electromedical Products International Inc., 2022). Alpha-Stim AID 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 has been suggested that it may have similar effects to skilled practice of meditation/mindfulness (Morriss *et al.*, 2019). It is easy to use, and is Conformite Europeenne (CE) marked for intended purpose (Griffiths *et al.*, 2021). The

Alpha-Stim AID CES is a mobile phone-sized device that is connected via soft pad clips to both earlobes and used for up to an hour a day. It has been found to reduce anxiety by 32% (Barclay and Barclay, 2014). A systematic review found that Alpha-Stim AID reduces symptoms of anxiety and depression and is safe without serious side effects (Shekelle *et al.*, 2018). Open-label with no control group design studies in primary care, nurse-led services for university students and in an Improving Access to Psychology Treatment (IAPT) service, reported significant improvements in anxiety, depression and quality of life for patients experiencing anxiety symptoms (Griffiths *et al.*, 2021; Morriss *et al.*, 2019; Royal *et al.*, 2022). These studies found Alpha-Stim AID to have few minor side effects (a few participants report mild tingling sensation at skin contact point and slightly dizziness sensation), that it was safe, can be used if a person is on an anxiety medication, well-tolerated and acceptable, and that users will use it in line with the required treatment instructions.

In March 2021, the National Institute for Health and Care Excellence (NICE) published guidance on Alpha-Stim AID (MTG56) (NICE, 2021). This study responds to the request in this guidance for collecting real-world data to understand better Alpha-Stim AID in relation to people's treatment uptake, response rates and treatment completion rates (NICE, 2021). In this project, Alpha-Stim AID was offered through a UK primary care social prescribing service to patients who reported symptoms of anxiety and assessed outcomes in terms of usage of the device and impact on anxiety, depression and health-related quality of life.

Methods

Design

The study had an open-label patient cohort design with no control group. Pre- and post-intervention assessments with participant self-report measures were collected.

Ethics approval

Ethical approval was granted by the review panel of the NHS Trust leading the study and by the NHS primary care provider consortium. All participants provided informed written consent.

Medical records

Following informed consent, demographic information (gender, date of birth) was extracted from clinical records containing routinely collected data.

Setting

Participants were recruited through a social prescribing service. A general practice (GP) patient is referred to a primary care-based social prescribing link worker (SPLW), who assesses their needs and goals (what matters to them) and provides practical and emotional support. SPLW makes appropriate links and referrals to health care and community-based resources and services to facilitate behaviour change to healthier lifestyles (NHS England, 2021).

Alpha-Stim AID intervention

Alpha-Stim AID is a mobile phone-sized device worn via a neck lanyard delivering small electric currents via soft pads conducting through metal clips to the earlobes. Light activities can be performed whilst it is in use, but the person is advised not to drive a vehicle. Once the participants provided informed consent to try the Alpha-Stim AID (CE marked as a class IIa medical device), the devices were sent by tracked postal service or

given to participants by their SPLW with instructions on how to use them. They were advised to use it once a day for an hour for six weeks at level 1 (2 bars on screen) (0.5 Hz, 100–500 μA, 50% duty cycle, biphasic asymmetrical rectangular waves).

The SPLW showed the patient how to use the Alpha-Stim AID CES device, outlined how to obtain support while using it and how to return it. In addition, SPLWs could be contacted to ask questions about the device and its effects. Patients remained on any prescribed medication and continued other medical or psychological interventions. Following six week's use, they were required to return the Alpha-Stim AID.

Inclusion/exclusion

Informed consent to the study and agreement to return Alpha-Stim AID equipment at the end of the study was required. The inclusion criterion was the patient reporting anxiety symptoms. The exclusion criteria were implantation with a pacemaker or an implantable cardioverter device, or pregnancy.

Procedure

Patients were referred to a SPLW by their GP and the SPLW then identified if the patient had anxiety symptoms. Patients were selected if they met inclusion/exclusion criteria and they were then provided with information about the treatment and evaluation. Informed consent was sought and required to begin treatment. Patients could withdraw consent or stop treatment at any point without the need to provide a reason. Following informed consent, participants were required to fill in the three self-report questionnaires. This was completed at three time points: baseline (pre Alpha-Stim AID use), week 3 (during Alpha-Stim AID use) and week 6 (post Alpha-Stim AID use). In total, 33 data sets from 84 individuals approached were suitable for use in the research, see Figure 1, the participant flow diagram.

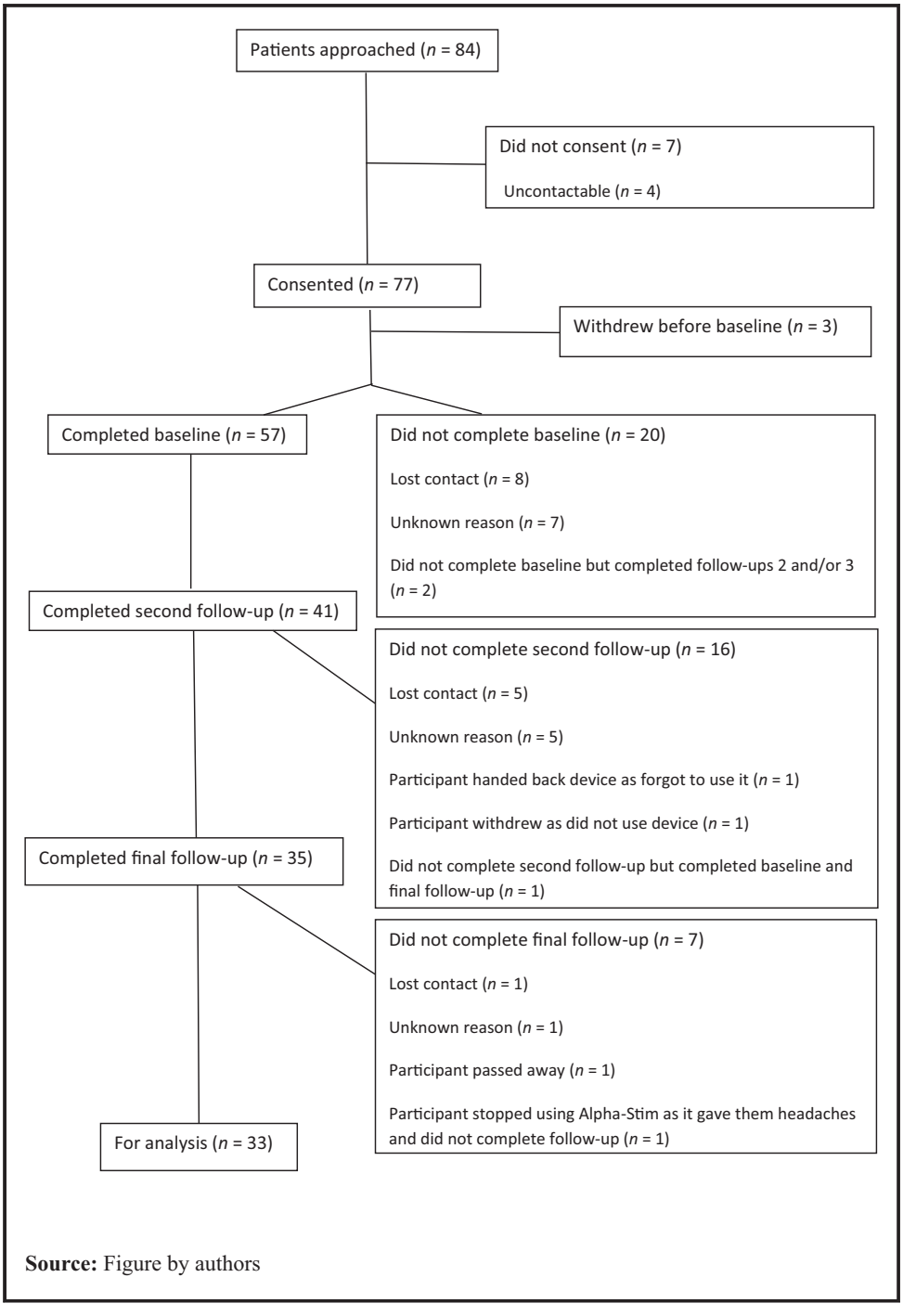
Measures

The Generalised Anxiety Disorder-7 (GAD-7) is a seven-item self-report measure of GAD (Spitzer *et al.*, 2006). A score of 0–4 represents no or minimal anxiety, 5–9 mild anxiety, 10–14 moderate anxiety and 15–21 severe anxiety. Remission is defined as a score of 7 or less, and reliable improvement is defined as a reduction of 5 points (Kroenke *et al.*, 2007; Spitzer *et al.*, 2006). 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 PTSD (Kroenke *et al.*, 2007). It has good internal consistency, shown by Cronbach's Alpha value of $\alpha = 0.92$ (Kroenke *et al.*, 2007).

Patient Health Questionnaire-9 (PHQ-9) is a self-report measure of depression; it has good sensitivity and specificity for major depression as well as good internal consistency (Kroenke *et al.*, 2001); scores for depression severity are: 0–4 none, 5–9 mild, 10–14 moderate, 15–19 moderately severe and 20–27 severe (Kroenke *et al.*, 2007). Remission is defined as a score of 9 or less, and reliable improvement is a drop of 6 points (Richards and Borglin, 2011).

European Quality of Life Five Dimension (EQ-5D-5L) (EuroQol Group, 1990; van Hout *et al.*, 2012) is a five-item and visual analogue scale (VAS) self-rated measure of health-related quality of life and overall health status. It is a standardised measure of health developed by EuroQol group to provide a simple, standardised measure for a clinical appraisal (EuroQol Group, 1990). The descriptive system comprises five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each of which is measured within five 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

Figure 1 Participant flow diagram



Source: Figure by authors

describing a participant's holistic health state. Each health state can be assigned an index score based on societal preference weights for the health state. Health state index scores 1 = the value of full health, with higher scores indicating higher health utility. In addition, EQ VAS is a subjective measure of a participant's current health, ranging from 0 (meaning the worst health imaginable) to 100 (best health imaginable). The EQ-5D-5L demonstrates good construct validity and is sensitive to change in patients with depression and anxiety

(Peasgood *et al.*, 2012). The EQ-5D-5L is a validated, generic, preference-based measure of health status, widely used in national health surveys in the UK and worldwide and in clinical trials of health interventions (Brooks and Group, 1996; Herdman *et al.*, 2011) and EQ-5D is recommended by NICE to estimate health state utility weights for quality-adjusted life year (QALYs; NICE, 2019c).

Statistical analysis

Data were analysed using the statistics software package SPSS® Statistics v28. Data screening confirmed the data set met all the requirements of the general linear model. Following descriptive analysis, one-way repeated measures ANOVAs were conducted to determine whether there were statistically significant improvements for the mental health assessments between baseline, week 3 and week 6. Frequencies and percentages were used to determine reliable improvement and remission rates. The average EQ-5D-5L digit calculated within each dimension was combined at baseline and post-intervention to create comparative five-digit health states. These digits were converted into the corresponding holistic health index scores to calculate QALYs. A one-way repeated measure ANOVA was conducted on each participant's converted health index score at the three time points to assess significant improvement. Pearson's correlations were used to determine the relationship between the three scales and EQ subscales. ANCOVA was used to test whether Alpha-Stim AID usage acted as a significant covariate of any improvement observed.

Results

Participant characteristics

Of the 77 participants who agreed to participate, 33 (42.9%) completed six weeks of treatment, baseline, three and six-week assessments. Their average age was 41.97 years (SD = 10.58), 61.3% were females, 35.5% males and one participant identified as "other". As illustrated by Table 1, participant mean baseline scores were in the "severe" range for GAD and the "moderately severe" range for depression (Spitzer *et al.*, 2006; Kroenke *et al.*, 2001). Baseline EQ-5D-5L crosswalk data values indicated participants had a low average holistic health index and EQ VAS score; however, the dispersion was high.

GAD-7 and PHQ-9

There were no outliers in the data, as assessed by inspection of a boxplot. The Shapiro–Wilk test found both the GAD-7 and PHQ-9 measures to be normally distributed ($p > 0.05$) at baseline, week 3 and 6. Mauchly's test of sphericity indicated that the assumption of sphericity had not been violated, χ^2 (2) = 0.98, p = 0.694.

The reduction in GAD-7 scores were statistically significant, F(2, 64) = 24.60, $p < 0.001$, a large effect size was observed: partial $\mu 2$ = 0.435. Thus, 44% of the improvement in GAD-7 score was attributed to the intervention. Post hoc analysis with a Bonferroni adjustment revealed that there was a decrease in GAD-7 scores from baseline (M = 15.52, SD = 3.84)

Table 1 Baseline characteristics (n = 57)

Variable	*Mean ± SD (min–max)*
GAD-7	16.05 ± 4.43 (4–21)
PHQ-9	17.54 ± 5.42 (7–27)
EQ health index	0.41 ± 0.35 (−0.35 to 0.88)
EQ VAS	46.82 ± 25.45 (0–95)

Source: Table by authors

to week 3 (M = 10.73, SD = 5.72), a statistically significant mean decrease of 4.79, 95% CI [2.75, 6.83], $p < 0.001$, and from baseline to week 6 (M = 10.15, SD = 5.05). Reliable improvement and remission rates for GAD-7 at the end of the study were 53.39% and 33.3%, respectively.

The PHQ-9 Mauchly's test of sphericity indicated that the assumption of sphericity had not been violated, χ^2 (2) = 0.95, p = 0.429. The reduction in PHQ-9 scores were statistically significant at all time points during the intervention, $F(2, 32) = 32.56$, $p < 0.001$, with a large effect size, partial $\mu 2 = 0.503$. The large effect size confers that the intervention accounted for 50% of the improvement in PHQ-9. Post hoc analysis with Bonferroni adjustment revealed that there was a decrease in PHQ-9 scores from baseline (M = 16.85, SD = 4.66) to week 3 (M = 11.67, SD = 6.37), a statistically significant mean decrease of 5.18, 95% CI [3.05, 7.32], $p < 0.001$; and from baseline to week 6 (M = 11.00, SD = 5.97), a statistically significant decrease of 5.71, 95% CI[3.25, 8.45], $p < 0.001$. Reliable improvement and remission rates for PHQ-9 at the end of the study were 46.7% and 29.5%, respectively.

Pearson's correlation coefficients indicated statistically significant correlations between PHQ-9 and GAD-7 at baseline (r = 0.834), after three weeks (r = 0.824) and after six weeks (r = 0.741), all $p < 0.001$.

EQ-5D-5l

Table 2 illustrates the descriptive data for each of the five dimensions as well as the mean health index and VAS at baseline, weeks 3 and 6. From baseline to week 6, quality of life increases with an improvement of 0.17. Measured across 10 years, this intervention adds 1.68 QALYs.

Data screening permitted the use of a one-way repeated measure ANOVA to determine whether there was a statistically significant difference in participants' EQ dimensions, as well as their health index score and VAS at the six-week data point. The improvement was statistically significant for two EQ dimensions ("usual activity" and "anxiety/depression"), for the health index score and the VAS score. A large effect size was observed for "anxiety/depression" and medium effect sizes for "usual activity", health index score and EuroQol visual analogue scale (EQ-VAS) scores. Post hoc analysis with a Bonferroni adjustment revealed an improvement from baseline to weeks 3 and/or 6 but not between weeks 3 and 6.

Table 3 illustrates the data collected from the EQ-5D-5L tool and broken down by level 1 (patients reported no issues on the dimension), level 2 (patients reported mild to moderate levels of issue) and level 3 (patients reporting severe to an extreme level of issues). The greatest improvement was observed in the "anxiety/depression" dimension, with severe/extreme levels of reported anxiety and depression dropping by 29.1% by the end of the intervention. In terms of "usual activity", reporting of no problems (level 1) did not

Table 2 Means and standard deviations within each dimension across time with corresponding mean variation, significance and effect size

EQ-5D-5L dimension	*Baseline* M (SD)	*Week 3* M (SD)	*Week 6* M (SD)	F	p	$\mu 2$
Mobility	1.81 (1.06)	1.63 (1.04)	1.66 (0.90)	1.00	0.374	
Self-care	1.94 (1.22)	1.88 (1.07)	1.56 (0.80)	2.179	0.132	
Usual activity	2.88 (1.45)	2.34 (1.36)	2.19 (1.03)	4.223	0.019*	0.120
Pain/discomfort	2.44 (1.29)	2.53 (1.34)	2.16 (1.08)	2.45	0.110	
Anxiety/depression	3.25 (1.11)	2.53 (1.16)	2.69 (0.93)	8.99	< 0.001*	0.225
Health index score	0.46 (0.36)	0.55 (0.37)	0.63 (0.26)	6.150	< 0.001*	0.166
EQ-VAS score	51.69 (22.19)	58.78 (20.77)	62.56 (20.60)	3.956	0.024*	0.113

Note: *Significant at $p < 0.05$ level
Source: Table by authors

Table 3 Percentage of participants reporting levels 1 to 3 on EQ-5D-5L by dimension and time

EQ-5D-5L dimension	*Baseline*	*Week 3*	*Week 6*
Mobility			
Level 1	49.1	60.5	54.3
Level 2	40.3	25.6	40.0
Level 3	10.6	13.9	5.7
Self-care			
Level 1	43.9	41.9	57.1
Level 2	45.6	50.1	42.9
Level 3	10.5	7.0	–
Usual activity			
Level 1	21.2	27.9	25.7
Level 2	45.6	46.5	60.0
Level 3	33.2	25.6	14.3
Pain/discomfort			
Level 1	31.6	34.9	31.4
Level 2	54.4	46.5	54.3
Level 3	14.0	18.6	14.3
Anxiety/depression			
Level 1	1.8	16.3	5.7
Level 2	49.1	60.4	74.3
Level 3	49.1	23.3	20.0

Notes: Level 1 consists of responses where no problems are reported. Level 2 indicated responses reporting a mild to moderate level of issues on a given dimension, and level 3 refers to severe to extreme issues reported.
Source: Table by authors

change over time; however, the level of severe/extreme issues dropped by 18.9%. No statistically significant changes were observed in the "pain/discomfort", "self-care" and "mobility" dimensions, although the trends showed improvement over time.

A participant usage survey indicated that the majority of participants were mostly compliant with usage instructions (six participants using the device every day and five virtually every day, 79%). A total of 14 of the 33 participants completed the usage survey. Descriptives of usage are presented in Table 4.

The frequency of use categories was analysed as a covariate between PHQ-9 and GAD-7 improvement. The ANCOVA results were non-significant for PHQ-9 and GAD-7, indicating that failure to adhere to daily treatment did not have a significant detrimental impact on improvement.

Costs. The EQ-5D-5L health index conversion scores indicated that the improved quality of life is equivalent to 1.7 QALYs (life year gains) across a span of 10 years (EuroQol Research Foundation, 2023). The cost per QALY threshold stipulated by NICE for England and Wales ranges between £20,000 and £30,000 (GOV.UK, 2020). Cost modelling has estimated a per-person treatment cost of £70 (GBP) for a course of Alpha-Stim, inclusive of all staff and *ad hoc* costs (NICE, 2021). This present study concluded an estimate of staff time costs and postage costs of (£62 [GBP]) and device cost of £100 (GBP) per single patient cycle. The cost of device is estimated as £600 (GBP) (with six uses of six weeks consumables), and each device was estimated to have a six use life (due to damage, lack of ability to clean to an acceptable level for re-use and non-return). This indicated an estimate of £162 per patient. Thus, the intervention is highly cost-effective, as the price per QALY is well below the stipulated thresholds.

Discussion

This study showed that Alpha-Stim AID can be provided to patients through a primary health-care social prescribing service. When offered, the majority of patients will choose

Table 4 Descriptives from the usage survey

Usage	n *(%)*
Frequency of use	
Every day	6 (43)
Virtually every day	5 (36)
Most days	1 (7)
Half the time	1 (7)
A couple of times	1 (7)
Routinely used at set time	
Yes	12 (86)
No	2 (14)
Anxiety reduced	
Yes	8 (57)
No	2 (14)
Don't know	1 (7)
No answer	3 (21)
Was it useful	
Yes	9 (64)
No	3 (21)
Don't know	2 (14)
Use it again	
Yes	8 (57)
No	1 (7)
No answer	5 (35)

Source: Table by authors

Alpha-Stim AID as an alternative form of treatment and use it as per instructions. Alpha-Stim AID can be effective in reducing anxiety and depression, and increasing health-related quality of life and health status in patients with symptoms of anxiety. The outcomes add evidence to support the effectiveness of Alpha-Stim AID in reducing anxiety and depression reported by published RCTs and health service-based studies (Barclay and Barclay, 2014; Shekelle *et al.*, 2018; Morriss *et al.*, 2019; Griffiths *et al.*, 2021; Royal *et al.*, 2022).

The results from the current study for the depression and anxiety remission and reliable improvement rates add to evidence from three other NHS service-based Alpha-Stim studies, suggesting 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). However, compared with the GAD-7 anxiety assessment, a lower percentage of participants achieved PHQ-9 depression symptom reliable improvement and remission. This perhaps indicates that Alpha-Stim is less beneficial in terms of treating symptoms of depression than symptoms of anxiety, which an RCT of Alpha-Stim AID for depression also reported (Morriss *et al.*, 2023).

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 three weeks. The time course of response of SNRIs and SSRIs is around two to four weeks to significant benefits, respectively; but it may take longer than three weeks to achieve most of the improvement (Jakubovski *et al.*, 2019).

The results indicated statistically significant improvements on two of the five dimensions measured by the EQ-5D-5L: "ability perform usual activity" and "anxiety/depression". Levels of severe/extreme issues in the ability to perform usual activities dropped by 18.9%, and the severe/extreme levels of reported depression and anxiety dropped by 29.1%. These findings indicate the positive impact of Alpha-Stim AID on mental health, well-being, recovery and real-world functioning, factors highly valued by people in their everyday lives.

This present study's sample had higher GAD-7 and PHQ-9 baseline scores (GAD-7 average was in the highest "severe anxiety" range and PHQ-9 in the second highest "moderately severe" range) than reported by patients seeking help for anxiety and depression from IAPT services in the corresponding geographical area (NHS Digital, 2022). This indicates the potential high level of need for anxiety and depression identification and treatment in patients seen by social prescribing services.

This study found that a primary health-care social prescribing service can set up and deliver the Alpha-Stim AID treatment and collect patient assessment measures. Primary care social prescribing services are well-placed to deliver this treatment as social prescribing is a universal service across the UK and seeks to get an in-depth understanding of patients' holistic needs, issues and goals (NHS England, 2021). In addition, primary care services have extensive experience with other medical devices, such as the transcutaneous electrical nerve stimulation (TENS) unit used to manage pain, as well as blood pressure monitoring devices, which are given to and retrieved from patients; they can apply processes and experience of these devices to the supply of Alpha-Stim AID. Alpha-Stim AID devices have the potential to be distributed by post direct to a patient's home, therefore, preventing the stigma and barriers of attending an IAPT clinic or psychiatric service. Offering via home, online or phone based services can make the treatment more accessible for some people, such as those with transport, mobility or disabilities issues.

Alpha-Stim AID treatment was acceptable to most patients; most used the device as instructed and returned it following use, aligning with other findings (Griffiths *et al.*, 2021; Morriss *et al.*, 2019; Royal *et al.*, 2022). This intervention may offer an alternative solution to those experiencing anxiety symptoms who have failed to respond to medication or psychotherapy or find medication side effects or factors related to psychotherapy unacceptable.

Individual and system level cost-benefit analysis is required to understand the potential savings that could be derived by the wider implementation of Alpha-Stim for people with symptoms of anxiety. To better target people who are likely to benefit, further research is required to investigate why some people respond, and others do not: what factors determine response. Mechanisms of action studies are required, and there is a need for an appropriately powered RCT on effectiveness for anxiety: a RCT comparing Alpha-Stim AID with individual cognitive behavioural therapy (CBT), medication or both (NICE, 2021).

Limitations

There was no control group or randomisation to another treatment. Only 33 out of 57 participants who began treatment (58%) completed treatment and every assessment, indicating a high participant drop-out. A survey was not conducted from those who dropped out, a lack knowledge of the reasons for drop out is a limitation. Only 14 of the 33 participants completed the usage survey, which limits the knowledge of usage and results related to frequency of use. Treatment with Alpha-Stim AID was open-label and adjunct to any existing anxiety or other treatments or therapies, which were not recorded or reported. Additional diagnosis was not recorded or reported. 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 present with anxiety symptoms. This study collected outcome measures at three weeks and at the end of the treatment point, with no later follow-up data collection; it is recommended that future studies use a 12- and 24-week follow-up data collection point.

Conclusion

This study's findings provide further evidence that Alpha-Stim AID may be clinically effective against anxiety and depression symptoms when offered through health-care services for patients with anxiety symptoms. This study developed an effective SP service based pathway and delivery by SPLWs. Addressing anxiety and depression symptoms through a social

prescribing service potentially reduces demand on primary care, secondary care and IAPT services, and, therefore, may reduce health-care costs.

Consideration needs to be given as to when a patient is offered Alpha-Stim AID, it is less costly than a course of face-to-face psychotherapy and more convenient as it is delivered at home, and it has fewer side effects than anti-anxiety medication. However, it may require more staff time to support its use than to provide medication, and there are more convenient forms of psychotherapy than face-to-face, such as online psychotherapy. The current availability of Alpha-Stim AID in universal health-care systems is very limited. The results support the wider availability of Alpha-Stim AID through primary care as a treatment option for people with anxiety symptoms. Many people cannot afford the cost of the device for themselves, and making it freely available through a universal health-care provider (possibly through personal health budgeting), would address this issue.

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