



RESEARCH ARTICLE

The experience of using Alpha-Stim AID cranial electrotherapy stimulation (CES) for symptoms of anxiety

[version 1; peer review: awaiting peer review]

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Abstract

Background:

Alpha-Stim AID is a self-administered, 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) primary care social prescription service to patients with symptoms of anxiety. This study explored the experience and impact of using Alpha-Stim AID cranial electrotherapy stimulation (CES) through in-depth interviews.

Methods:

Out of a sample of 57 using Alpha-Stim AID, fifteen participants consented to be interviewed. The age range of the participants was 26–65 years (M = 46.6); 10 (67%) were female and 5 (33%) male. Data were analysed using thematic analysis.

Results:

There was 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.

Conclusions:

It is important to identify anxiety symptoms and offer patients choice of treatment options. The results support the use of Alpha-Stim AID as a treatment option for people with symptoms of anxiety. Access to Alpha-Stim AID should not be restricted by being able to afford to buy it. An appropriately designed randomised control trial (RCT) is required.

Keywords

Social prescribing, primary care, general practice, Alpha-Stim, cranial electrotherapy stimulation, anxiety

Open Peer Review

Approval Status *AWAITING PEER REVIEW*

Any reports and responses or comments on the article can be found at the end of the article.

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Background

Anxiety is a common psychiatric disorder associated with fear, nervousness, apprehension, and panic, and physical responses such as cardiovascular, respiratory, and gastrointestinal (Martin, 2003). Anxiety disorders (generalised anxiety disorder [GAD], phobias, and panic disorders) have a 13.6% to 28.8% lifetime prevalence in Western countries (Michael *et al.*, 2007). The most common anxiety disorder is GAD, defined as excessive and difficult-to-control anxiety or worry about life events or activities (APA, 2013), which can impair activities of daily living and reduce quality of life (Locke *et al.*, 2015).

Individuals with anxiety will commonly experience comorbidity; over three quarters of people with an anxiety disorder have an additional chronic disease (Kessler *et al.*, 2010; Merikangas & Swanson, 2010). There is a strong and unique association between anxiety disorders and physical health disorders, and the presence of both may result in a greater level of disability (Sareen *et al.*, 2005). People with anxiety disorders often experience somatic symptoms (poor sleep, low energy levels, fatigue, headaches, pain, chest pain, shortness of breath, and gastrointestinal issues) and many individuals with anxiety disorders present to primary care with these somatic complaints rather than seeking help for anxiety symptoms (Wittchen *et al.*, 2002; Wittchen & Hoyer, 2001).

Anxiety disorders are associated with fewer healthy behaviours (Hearon *et al.*, 2014) and increased healthcare utilisation across multiple healthcare settings (Horenstein & Heimberg, 2020). High rates of healthcare use among individuals with anxiety disorders may partly be due to poor recognition of somatic symptoms as anxiety-related and a subsequent lack of effective anxiety treatment (Horenstein & Heimberg, 2020). Anxiety symptoms can often be detected when more in-depth primary care patient assessment is undertaken, such as in social prescribing services (NHS England, 2021).

Medication is used as a treatment for anxiety disorders, including selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine uptake inhibitors (SNRIs), benzodiazepines, buspirone, and tricyclic antidepressants (TCAs) (Bespalov *et al.*, 2010). While there is evidence of effectiveness for some (Muntingh *et al.*, 2016), compliance can be an issue due to adverse side effects, which can include nausea, fatigue, weight gain, tremors, sexual dysfunction, insomnia, and gastrointestinal symptoms (Bandelow *et al.*, 2017). There can be a high treatment dropout, for example, the dropout rate of SSRIs is between 18% and 30% (Mochcovitch *et al.*, 2017). Medication prescription may be associated with a high risk of relapse (Culpepper, 2009) and benzodiazepines are only recommended for severe anxiety symptoms and short-term use (two to four weeks) due to dependence and withdrawal issues (NICE, 2019a).

Psychotherapy is recommended for anxiety and can be effective, but is costly and lengthy: delivered over multiple sessions over a period of time, with non-response rates of 60-66% (Gyani *et al.*, 2013; Griffiths & Griffiths, 2014; NICE, 2019b). Uptake and attendance in psychotherapy can be affected by mobility issues, travel costs, or work or caring responsibilities (Bandelow *et al.*, 2017). It is important for alternative home-based treatment options to be available to enhance patient choice of treatment.

Cranial electrotherapy stimulation (CES) is a non-invasive treatment method involving the application of pulsed low-intensity electrical current to the head to cause changes in the brain (Nardone *et al.*, 2014). CES can significantly reduce anxiety symptoms and patients tolerate CES well (Ching *et al.*, 2022). In a RCT with 115 participants diagnosed with anxiety disorder using the Alpha-Stim AID (Anxiety, Insomnia and Depression) CES there was a 32% reduction in anxiety (Barclay & Barclay, 2014). A review that examined five randomized, double-blind placebo-controlled studies found that Alpha-Stim AID reduces symptoms of anxiety; it concluded that Alpha-Stim AID is safe, based on an absence of any serious side effects (Shekelle *et al.*, 2018).

Health service-based Alpha-Stim AID studies with an open label cohort and no control group design indicated positive outcomes. A study in primary care NHS patients experiencing anxiety symptoms reported significant improvements in anxiety, depression, and quality of life (Griffiths *et al.*, 2021), as did a study set in an NHS Improving Access to Psychology Treatment (IAPT) service with patients diagnosed with GAD (Morris *et al.*, 2019). Providing Alpha-Stim AID through a nurse-led primary care clinic to university students with a diagnosis of anxiety or depression delivered improvements in anxiety and depression symptoms (Royal *et al.*, 2022). These studies indicate that Alpha-Stim AID is safe, well-tolerated, and acceptable to the majority of patients, and the majority of patients will conform to the required treatment protocol.

The Medical Research Council (MRC) recommend using qualitative methods to capture people's experience and feedback of an intervention (Moore *et al.*, 2015). Qualitative research has been undertaken regarding a different form of electrical treatment: transcranial direct current stimulation (tDCS) (Gordon *et al.*, 2021; Grycuk *et al.*, 2021); which while not the same as CES, shares similar characteristics including being a non-invasive brain stimulation given via a

portable device that administers weak electrical currents to the brain. Grycuk *et al.* (2021) explored the experiences and perceptions of tDCS for patients with schizophrenia through interviews with 12 participants and evidenced motivations, concerns, factors reducing fear, experience, and perceived effects. Acceptability, side effects, outcomes, and barriers and facilitators to engagement for patients having tDCS for binge eating disorder have also been successfully investigated (Gordon *et al.*, 2021). In addition, qualitative approaches have been an effective approach to understanding the experience of patients with anxiety and the use of medication (Bosman *et al.*, 2016) and psychotherapy (Pedersen *et al.*, 2020).

Prior to recommending Alpha-Stim AID for adoption, the United Kingdom's (UK's) National Institute for Health and Care (NICE) stated the need for collection of real-world data to better understand issues around people's treatment preferences, treatment completion rates, and impact on quality of life (NICE, 2021). There is no research to date that has explored the experiences and impact of using Alpha-Stim AID through in-depth interviews. This study takes a qualitative approach to examine and understand the experience and impact of using Alpha-Stim AID for patients with symptoms of anxiety.

Methods

Design

This was a qualitative approach employing semi-structured interviews with patients experiencing symptoms of anxiety, who used Alpha-Stim AID for six weeks. The interview questions chosen were informed by the research literature and the data were analysed together.

Ethical approval

Ethical approval was granted by the review panel of Northamptonshire Healthcare NHS Foundation Trust, whose researchers led the study, and approved by the NHS primary care provider consortium; reference: IFAS009. 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, which is where a general practice (GP) patient is referred to a primary care-based Social Prescribing Link Worker (SPLW), who assesses their needs and goals, provides practical and emotional support, and makes appropriate links and referrals to healthcare and community-based resources and services; seeking to facilitate behaviour change to healthier lifestyles (NHS England, 2021). The participants were part of a group who had originally taken part in a project funded by East Midlands Academic Health Network's (EMAHSN) 'Innovation Pipeline' funding stream.

Participants

Participants were identified as having symptoms of anxiety by SPLWs and asked if they would like to try using the Alpha-Stim AID for the management of their anxiety. In total 57 participants agreed to try the Alpha-Stim AID. The inclusion criteria for participants were patients: 18 years or over; under the care of SPLWs; and reporting symptoms of anxiety. Patients were excluded if they: lacked the capacity to consent; experienced seizures; or had a pacemaker/any other implanted electrical device.

Of the 57 participants who used the Alpha-Stim AID, 15 were interviewed: the age range was 26–65 years ($M = 46.6$, $SD = 12.0$); 10 (67%) were female and 5 (33%) were male. All participants reported ethnicity as 'White British'. The reasons given for the use of the Alpha-Stim AID, and frequency of use are presented in [Table 1](#).

Alpha-Stim AID intervention

Once the participants provided informed consent to try the Alpha-Stim AID (marked as a class IIa medical device by Conformite Europeene [CE]), they were sent it or given it by their SPLW with instructions on how to use it. They were advised to use it once a day for an hour for six weeks, and to use the device at level 1 (2 bars on screen) (0.5 Hz, 100-500 μ A, 50% duty cycle, biphasic asymmetrical rectangular waves). Alpha-Stim AID is a mobile phone-sized device worn via a neck lanyard which delivers small electric currents via metal clips (which are soft pad covered) attached to both earlobes. Light activities can be performed whilst in use, but the person is advised not to drive a vehicle. SPLWs could be contacted to ask any questions about the device and its effects. Patients remained on any prescribed medication they were taking and continued any other medical or psychological interventions. Following 6 weeks' use they were required to return the Alpha-Stim AID.

Table 1. Participants' use of Alpha-Stim AID.

Participant	Reason for use	How often used Alpha-Stim AID	When used it	Level used at
P1	Anxiety and panic attacks	Every day	Different times of day, predominantly mornings	Level 1 only
P2	Anxiety	Every day initially, reduced to once every 2 days, then once every 3 days	Before bedtime	Level 1 only
P3	Anxiety and depression	Every day	Before bedtime	Twice increased – didn't like feeling, returned to level 1
P4	Anxiety	Every day initially, then sporadically	Around mid-day	Level 1 only
P5	Anxiety and depression	Initially every day, then 3-4 times a week dependent on mood	No set time, when felt low mood	Level 1 only
P6	Anxiety, stress and panic attacks	Every other day initially, then every day	In the morning	Tried higher level, felt dizzy, returned to level 1
P7	Anxiety and panic attacks	Used when felt overwhelmed	Before bedtime	Tried higher level, experienced headache, returned to level 1
P8	Anxiety and panic attacks (has PTSD)	Every day	In the evening	Level 1 only
P9	Anxiety and depression	Every day	In the morning	Tried it at top level (5), no effect at any level
P10	Anxiety (has OCD)	Every day (2 times a day)	Early afternoon, and before bedtime	Level 1 only
P11	Anxiety (has PTSD)	Sporadically initially, then every day	Before bedtime	Level 1 only
P12	Anxiety	Every day	In the evening after work	Level 1 only
P13	Anxiety	Every day	Before bedtime	Level 1 only
P14	Anxiety (has PTSD)	Every day (2 times per day)	In the morning (20 mins after awake), 1 hour before bedtime	Tried higher level, experienced memory loss, returned to level 1
P15	Anxiety and depression	Every day	In the evening	Level 1 only

Procedure

Patients who completed 6 weeks use of the Alpha-Stim AID were contacted and asked if they would undertake an interview. Those who gave oral informed consent to this were phoned at a prearranged time and interviewed. The interviews followed a semi-structured format. Interviews lasted between 13.52 minutes and 50.07 minutes ($M = 30.57$, $SD = 9.33$). They were recorded on a digital audio recorder, and then were transcribed verbatim. Once transcribed and anonymised, the recordings were deleted. NVivo 13 (a qualitative data analysis software package) was used for supporting data analysis. Data were collected between November 2021 and August 2022.

Data analysis

The ontological and epistemological positionings were critical realism; this is ontologically realist based on the assumption that there is an external reality, independent of human minds, and epistemologically relativist, i.e., different methods produce different perspectives on reality, and reality is a finite subjective experience (Denzin & Lincoln, 2005). A critical realist approach therefore is grounded in the assumption that data are informative of reality, but

that data need to be interpreted to enable access to underlying structures embedded in it (Willig, 2012). As there were no studies exploring experiences of using an Alpha-Stim AID, thematic analysis was seen to provide the best methodological framework, as theories can be applied flexibly (Braun and Clarke, 2006), without any a priori theoretical assumptions (Willig, 2001). Thematic analysis enables the researcher to interpret the patients' experiences as well as the situations and contexts within which they arise.

The thematic analysis was data-driven and inductive (to explore experiences, perspectives and meanings of the participants in relation to Alpha-Stim AID) and focused on the semantic level to capture explicitly expressed meaning (Braun and Clarke, 2021). The six-phase guide advocated by Braun and Clarke (2006) was implemented and comprised: (i) familiarisation with the data, through transcription, reading and noting initial analytical observations; (ii) generating initial codes from important features in the data; (iii) searching for themes – coherent and meaningful patterns relevant to the research question; (iv) reviewing the themes, assessing for consistency and ensuring that they reflected the whole data set; (v) defining and naming themes; and (vi) writing up coherent accounts of the data, utilising excerpts to capture the essence of the theme. Thematic networks (Attride-Stirling, 2001) were used as a heuristic in the thematic analysis, and not a separate method, to present the themes generated and illustrate their relationships, through the development of global, organising and basic themes.

Coding was undertaken by two members of the research team. To ensure rigour of the coding and strength of the interpretation and theorising, a third member of the research team reviewed and provided feedback on the analysis and findings. Analysis of the data was supported by an individual with lived experience of anxiety, who undertook initial reading and coding of a proportion of the interviews (phases i and ii of thematic analysis), and assisted with reviewing the themes and assessing them for consistency, and naming and defining the themes (phases iv and v of thematic analysis). Verbatim quotes were reported to promote verifiability (Silverman, 2015). To promote credibility and confirmability of the research, and to make sure that the findings were the experiences of those interviewed, Shenton's (2004) strategies (credibility, transferability, dependability, and confirmability) for ensuring trustworthiness were followed.

Results

Based on the narratives of the participants, three global themes were developed, and associated organising and basic themes created. Figure 1 presents the thematic network that was developed, of the different levels of themes.

Users' engagement - enablers and obstacles

This global theme is made up of two organising themes (*Enablers* and *Obstacles*). This global theme represents the different factors that support or hinder engagement with and use of the Alpha-Stim AID.

Enablers

This organising theme is made up of five sub-themes.

Accessible, easy to use, go-to device

The device was easily accessible, could be used as and when required.

P1: The fact that, it's there, it's by my bed, I could just use it if I'm having a rubbish day. I could just sit in my bed and do it while I'm lying there. I haven't got to go anywhere.

P7: I think with medication, obviously, it takes a while for it to work, whereas the, the Alpha-Stim is instant ... in regards to like talking therapy that takes a while also I think. Just because obviously, it's instant.

Alpha-Stim AID offered an element of psychological support, from the knowledge it could be accessed at any time.

P6: I think knowing that I've got something that I could go to, if I was feeling particularly anxious – I knew I could go to it, and it made me feel better ... it just helped knowing it was there and I could come home and use it.

The Alpha-Stim AID was simple and easy to use.

P5: It is good because it is simple to use, I understood how to use it. Press the button and it just went and I didn't feel negative about it.

No prohibitive reactions or side effects

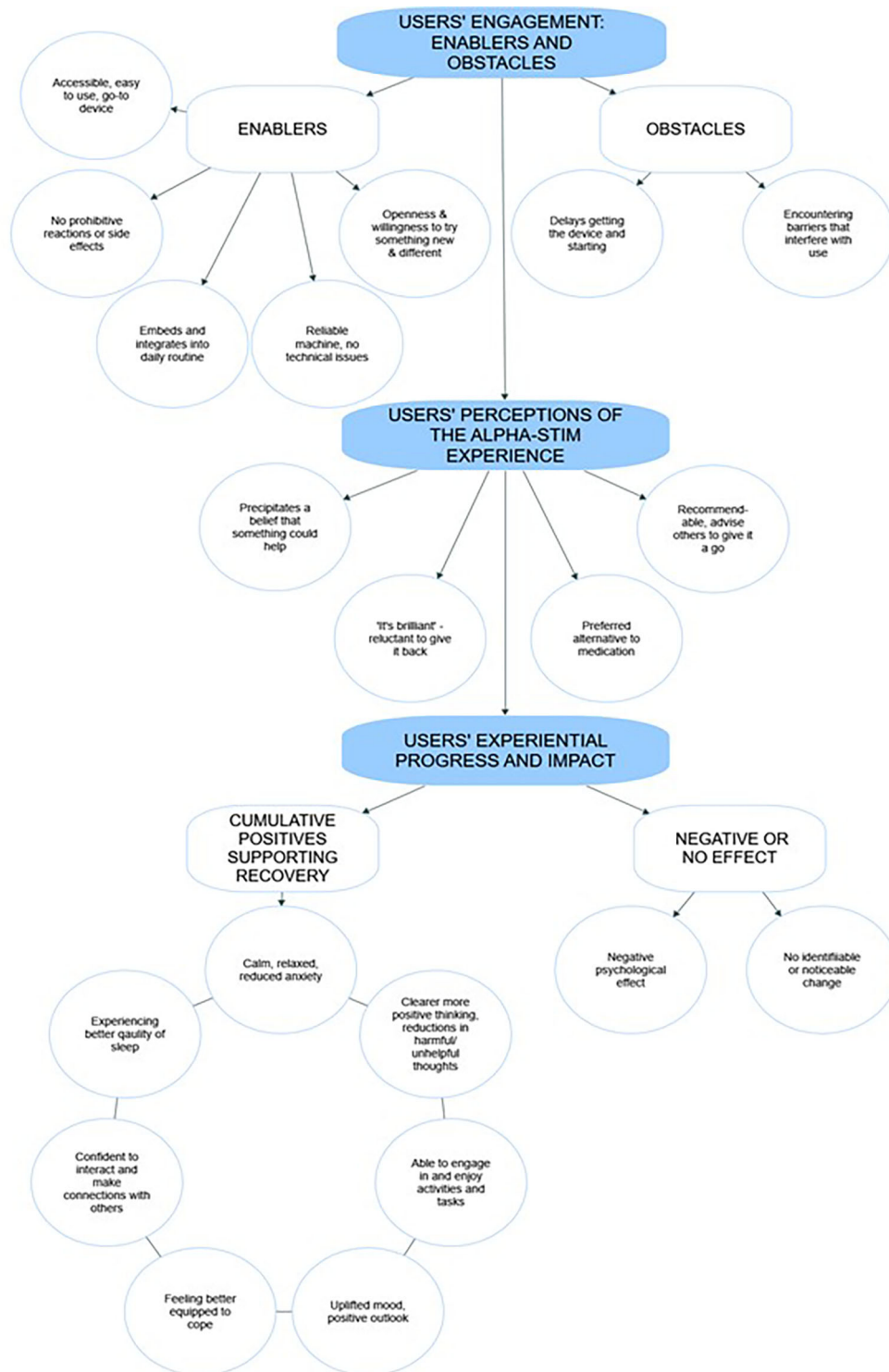


Figure 1. Thematic map of themes exploring experiences of Alpha-Stim AID.

Most participants reported no side effects using the Alpha-Stim AID: feeling little, or no physical sensations whilst using it.

P10: The first time I used it I felt a little bit [of tingling], but the more I used it, the more I didn't feel anything after that. It just calmed me, seemed to calm me down to a really good level without having any side effects.

A few experienced side-effects, but these were all manageable and could be tolerated, so were not prohibitive for use.

P4: Just a little shock. Like an electric shock, I suppose. It wasn't an electric ... you felt there was like a sting, really. It doesn't mean I can't use it because of that.

P9: It was a bit, sort of like pin pricks in my ear lobes ... but it wasn't, too bad. And it wasn't all the time, it was just every now and then.

A couple of participants reported that they experienced feelings of dizziness, but this did not prevent its use. One participant reported how it was not 'bothersome, more like a very relaxed dizziness' [P7], whereas for another it was only initially a problem.

P12: The first couple of times I used it I felt quite dizzy. You know like when you're on a boat? Just dizzy, in my head. Just a bit dizzy. That went after probably about the third time I was using it, that had gone.

Embeds and integrates into daily routine

Alpha-Stim AID could easily be embedded and integrated into daily routines.

P1: The thing is good – as well, it's the fact it's, it's something you have to do every day. It's like, it's, it's sort of a habit that I've done, that I've hooked into.

Participants developed a regular time as part of their routine, for some it was at the start of the day:

P6: I used it routinely in the morning, and I picked that just because I thought it would help me through the day.

Whereas others found it better fitted into their evening and bedtime routine:

P3: I tend to use it in the evening, when I'm just sitting at home, sitting at home relaxing, and then after I've used it, I'm tired and sleepy.

Participants could use it while continuing with other tasks and activities, thereby reducing disruptions.

P10: It's not, it's only an hour, and you can still ... it's not intrusive, you can still do other things ... so you don't have to sit still ... you can still go about your routine and your daily life with that, you know, it's not a problem.

Reliable machine, no technical issues

Participants all found that the Alpha-Stim AID was reliable.

P1: It never stopped working, it's very reliable.

P5: The Alpha-Stim never stopped working, there were no technical issues with it.

P12: The Alpha- Stim always worked, it never stopped, and it was always completely reliable – you could guarantee that it was working and ready to use at any point.

Openness and willingness to try something new and different

Engagement with and use of the Alpha-Stim AID was furthered by individuals' willingness and openness to try something new.

P2: Yeah, I know everyone is different but it's always worth a try. Like I thought maybe it's not, maybe it is ... but I tried it. I tried it and it worked.

P8: I am open to trying something a bit different. I just want to help myself really. So, I'm trying anything.

For several participants, their willingness and openness came from having tried other interventions with no or little success.

P13: I'm willing to sort of give anything a try if I am honest with you. I have literally tried CBT, I've tried the pills I've tried CAMHS, and I have tried every, everything been offered to me before. I am willing to give it a try.

There was a feeling of 'nothing ventured nothing gained'.

P10: My thoughts were, if it didn't, I haven't lost anything by at least trying it and giving it a go ... if I hadn't had tried it, I would've regretted it ... so I thought, giving it a try is the least I can do and hopefully it'll work. If it doesn't, it doesn't, and I haven't lost anything by that.

Obstacles

Obstacles were not widespread; however, there were two identified in a minority of the narratives, which formed two themes.

Delays getting the device and starting

Three of the participants experienced delays in the process of getting started due to supply and communication issues, that were successfully resolved:

P7: It wasn't easy to receive to begin with, because there wasn't many about so I had to wait for one to become available, so it took a bit longer than you would have liked.

Encountering barriers that interfere with use

Factors were identified that resulted in participants delaying using it, or a temporary or permanent stoppage of use. These obstacles were practical:

P12: I didn't use it like I was supposed to. So, it was a timing thing. I was just really busy ... so it was really just kind of life getting in the way that stopped me using it.

Or they involved having other priorities:

P7: Obviously, having children. Not so much priorities but obviously, I had to. Yeah, it was more of just being around the children really, not being able to actually sit and relax and use it.

Or they were to do with time.

P4: I just felt you know having to sit there for an hour, finding time really. And I'm quite [a] fidgety person. You know it is time-consuming doing it. You know you sit there, having to peel them off, put them on ... it's just time-consuming.

Or they were to do with psychological barriers:

P8: I didn't use it for a while when it was sent to me ... probably a bit of anxiety, probably, I just don't know, it was just left in its box on my table, sitting in front of me and I was looking at it every day.

Some of the patients wanted to use it longer than the 6-week loan, but the cost of the Alpha-Stim AID was prohibitive.

P5: Once that goes back, I am going to be lost ... if I could afford it, I would but with the disability, with the money I get, I ... there is no way I would be able to afford it. But I will be lost without it.

Users' perceptions of the Alpha-Stim AID experience

This global theme is made up of four sub-themes capturing the participants' perceptions and opinions.

Precipitates a belief that something could help

Being given this opportunity, and trying something different, precipitated a belief and hope that they had something that would help.

P15: It gave me a belief that it would help me, thought it would help me, not be so stressed and depressed.

P1: But I mean the great thing with the Alpha-Stim is it gives you hope. I try not to go into these things going, it's magic, it's going to make me better. But it's just because you know, you hope that it might, it might not make you better, but it might help you on the way. And I feel that's what it's done.

P5: It just gives you positive thoughts. That there is something in life which is actually there to help you. And it's the thought that you know, it's out there and you [are] getting to try it.

Participants felt that the device added value to their lives, that they wanted to keep it and were reluctant to give it back.

P8: Because I don't want to let it go and I want to get the best benefit I could over the last few days. I like the Alpha-Stim. I don't want to give it back ... [SPLW's name] got me an extra week or two.

'It's brilliant' – reluctant to give it back

Across the narratives, the experience of the Alpha-Stim was simply described as brilliant, e.g., *'I think it's incredible, it's brilliant'* [P1]; *'It was brilliant, to be honest. It's brilliant'* [P2]; *'The instrument itself is brilliant'* [P5].

The device added value to their lives, supporting them so much, that they wanted to keep the Alpha-Stim, and were reluctant to give it back.

One participant bought one.

P3: Because I am going to invest. I've chatted with my family and my friends, and they've all seen the difference that it's made to me. So yeah, I'm going to be getting one.

Preferred alternative to medication

Participants preferred Alpha-Stim AID as an alternative to medication for treating their anxiety.

P8: Well, I was really interested because it's not medication ... I do take medication, but I don't like to take medication. So, this was a lot more helpful for me because it isn't medication. I liked having an alternative to medication.

P15: I prefer to try something that's not tablets. More natural than tablets.

P6: I do like the fact that it is a non-medicated intervention and is very safe.

P4: The main thing was a replacement for medication ... I think with, with not going down the chemical route of prescription drugs. Having the freedom of having something where you can just sit there, and you need to just try. [Alpha-Stim] can mean that you perhaps don't go down the medication route, which is, you know, a positive thing.

For some, using the Alpha-Stim AID meant they were able to stop using medication:

P3: But the Phenergan it was, I don't really want to take [it], I don't really want to take more chemicals I don't want to take more meds. Since using the Alpha-Stim, I haven't taken a single one Phenergan, because I haven't needed it.

Recommendable, advise others to give it a go

All participants would recommend Alpha-Stim AID based on their positive experiences.

P5: It's brilliant, and I'd recommend it to anyone that was struggling.

P2: I would recommend it to other people, definitely, hundred percent.

P3: I have suggested [name] try it. She suffers with mental health, and she's been put on, I think it's called Propranolol for anxiety, and I said you want to see if you can go on, try this machine. See if you can get on a trial, see if you can use it. I said because it's really worked and I've noticed a difference, she said yes, I've noticed a difference in you as well.

One participant found the Alpha-Stim AID did not work for them, but they would still recommend people try it.

P9: I'd recommend it to people who are thinking about doing it, do it, because it might work. Just because it doesn't work for me, you know, not everything works for everyone. But some things do for some people, some things work. Yeah, I think it's a good idea.

Users' experiential progress and impact

Outcomes in terms of impact, progress and recovery were divided into both positive and negative.

Cumulative positives supporting recovery

This organising theme is made up of seven basic interlinked themes (Figure 1). The seven themes represent different positive outcomes experienced: reduced anxiety, clearer thinking and better thought processes, socialising more, engaging in activities, better sleep, positive outlook, and better coping. How these are interlinked and the order in which they are experienced is individualised. Some participants felt the Alpha-Stim AID reduced their anxiety, this increased their ability to do things they enjoyed, and in doing so they felt better and more positive about themselves. Others felt the Alpha-Stim AID improved their sleep, as a result they were better able to cope, and they felt this then reduced their anxiety. A combination of interlinked factors produced positive outcomes.

Calm, relaxed, reduced anxiety

The majority of patients felt they experienced a positive impact; their anxiety was reduced and more manageable:

P1: My anxiety is going down; I've gone out in the garden. I'm not worried about it ...

P14: I noticed a change, in, in some of my anxiety levels. I think it has reduced the severity of that constant feeling of anxiety.

P15: I have not so much depression, stress and anxiety.

Several of the participants reported the Alpha-Stim AID had a relaxing effect, which helped with anxiety.

P4: I did feel a lot calmer I think, with it, I think when I used it, I didn't get so anxious. I felt calmer in myself, I didn't sort of race, or I felt a little bit more sort of on an even keel.

P3: You've got into that better cycle I think of feeling more relaxed, less anxious, therefore able to sleep. So, then the next day you feel better ... I've lost the anxiety so I can engage more and enjoy being with my friends ... because I'm not as anxious ... my mood is at a better level.

Experiencing better quality of sleep

Several participants talked about the positive effect on their sleep, including improved sleep:

P12: After about a week or two my sleep had really improved. I think the sleep had a really big impact and it's definitely the most successful thing I think I've found from using the Alpha-Stim. And I think that's really been quite life-changing.

Longer sleep was commented on:

P2: I found it, well actually [it] helped me sleep as well. Instead of maybe about two or three hours sleep a night and napping in the daytime I sleep maybe about six hours now [at night].

Less broken sleep was seen too:

P5: Now I am getting a little more sleep to what I was having ... waking up less during the night.

There was more ease getting off to sleep:

P14: I think it's made it easier for me to go to sleep ... it used to take me longer before I could settle down to sleep.

Better quality sleep was also observed:

P8: I feel I'm getting a better quality of sleep since the Alpha-Stim.

P3: It makes me want to sleep ... the only way I can describe it is that I'm getting a better quality, I sort of slept well, but I think I got a better quality of sleep, which helped anxiety ... the more sleep, the more, better quality of sleep I'd had, was resulting in a better mood and lower anxiety.

One participant compared their sleep when using the Alpha-Stim AID and when not, and was convinced better sleep could be attributed to it.

P13: I even thought, is this psychological? Am I thinking it's working because I want it to work. So, I stopped using it for three days, and noticed my sleep pattern wasn't as good again. So, I put it back on, and I thought no, it's not psychological. It really is working.

Clearer more positive thinking, reductions in harmful/unhelpful thoughts

This theme is about improvements in thought processes, including the removal of negative thoughts.

P12: I used to be very bad for, 'it's the end of the world', 'something's wrong' or 'I'm useless' and all that, those kind of horrible thoughts. They've definitely improved.

P5: Before I started taking that [Alpha-Stim], I was feeling suicidal and everything. Now those thoughts yeah, those thoughts are going. I have even stopped hearing voices in my head. That's calmed that down, I still have those days. I have calmed down.

Several participants reported changes in their 'mindsets', being able to think more clearly, utilising positive self-talk, 'taking their thoughts to court' [P3], or generally thinking more rationally and in a helpful way.

P2: Is it about the way I'm thinking. I don't sort of automatically go into a panic meltdown mode. It's hard to describe really. It's like I'm able to talk to myself and get over that. Where, I would try to talk to myself before and I wouldn't, I'd just come back inside. So, it is helping the way that I am thinking. The Alpha-Stim helps with my mindset.

P6: It just stopped me overthinking and stopped my thoughts racing. I'm able to stay calm, which then helps me look at things more practically rather than just go into a downward spiral, which I did last time. I think it helps my emotions. I'm not as erratic, not thinking the worst and then you go the other way.

P8: I have got all these thoughts that stop me going to sleep, and since using the Alpha-Stim I still have them, but that's still the same, but they're not so intense. I have managed to get rid of that intensity of those thoughts and things like that. And so, I'm getting to sleep better.

Confident to interact and make connections with others

The theme is about changes in ability, desire and confidence to socialise with others.

P12: I think there's been an improvement ... I was always kind of afraid to ask to meet up with my friends, like there was always something niggling in my head like: "Oh... don't do it." Now I'm definitely more confident with that.

P6: Whereas usually, I'd have caught up with my sisters, and I wasn't wanting to do that. But I think once my mood improved, I was able to go and see them. From using the Alpha-Stim, I felt better in myself, and it meant that I would talk to family and socialise.

P5: Well, it must have helped me to be able to go out and socialise because I have just asked [SPLW's name], he has just helped me get a, some voluntary work.

P8: I have started this group, the Kins, Kintsugi group. It's just a wellbeing group. So, I've been offered group therapy throughout the years, and I've always turned it down. But not this time.

P3: And then just being with my friends and actually speaking with them sitting with a cup of coffee, just chatting with them. And not, just not constantly looking around me. It is almost impacting on my anxiety; I've lost the anxiety so I can engage more and enjoy being with my friends.

Able to engage in and enjoy activities and tasks

Anxiety prevented engaging in day-to-day activities and tasks. Following a reduction in anxiety, individuals reported an ability to take on and undertake tasks they previously hadn't.

P1: I've just gone, wow, I've been doing the washing up, doing the garden, being tidying up, you know, washing stuff.

P15: More, well, I have had more showers. If I didn't, if I weren't going out, I wouldn't bother before. But it's hard though. But I am taking a bit more care of myself.

Participants were able to do and enjoy activities which were previously meaningful and important to them.

P3: I've got back into some of the stuff that I enjoy doing, but I'd stopped doing because I just had no interest in it. You know, I've started reading books again, and crocheting and doing cross stitch. It's just enabling me to do things that I enjoy that then make me feel better.

Alpha-Stim AID acted as a catalyst, changing a negative cycle of experiencing poor mental health into a positive cycle:

P2: I was almost in a cycle of, this black cloud, that I couldn't do anything, and because I wasn't doing anything that obviously didn't make me feel good. But I've now changed that cycle to I feel better in myself, so I can do more stuff, and that then makes me continue to feel better. Alpha-Stim kind of kicked me off for the starting-to-do stuff, and now I seem like I can do more.

Feeling better equipped to cope

Participants noted they felt more equipped to manage and cope: 'I'm feeling a lot more equipped, well equipped to deal with things' [P1]; 'I'm able to cope a lot better with things' [P2]; 'I am able to just cope with things that are normal day-to-day' [P10]; 'I'm probably like, finding it easier to cope with things' [P8]. Participants reported reductions in OCD behaviours, feelings of sadness, breakdowns, and anxiety; through this, participants felt they could then cope and manage better.

P12: It is a good tool to help with my anxiety. I think it was good for me as someone who just needed to be brought down to a level where I could cope and manage with whatever life throws at me.

P14: There's been subtle or marginal improvements. Or even with the ability to cope with daily living, which in itself would be ... could be seen as an improvement in quality of life also, as it's making the days more manageable

Uplifted mood, positive outlook

Participants experienced a noticeable improvement in how they were feeling.

P1: I feel probably more positive at the minute.

P2: I don't feel so harmful towards myself anymore. I've got a lot more energy. Just, well, happy that I can actually go out by myself as well. It's just a lot happier.

P6: It did improve my mood, and it made me want to get up and do the normal thing. My mood felt better, and I didn't have so much of the depression, so because of that I am more likely to do things around the house and look after myself.

P12: Normally I would stress [over mistakes made] and really overthought the whole situation. That's a good example of how I've changed. I've almost just let go of the stress ... and have a bit more of a brighter outlook.

Negative or no effect

This organising theme is made up of two sub-themes representing where the Alpha-Stim AID was deemed to have no effect or a negative effect.

No identifiable or noticeable change

Only two participants reported no differences in anxiety, mood, sleep, wellbeing, or any mental health symptoms.

P11: And part of me wants to profess to having some sort of really positive or significant result from the use of it. But I'm not conscious, at least, of any significant, or any sort of change in my overall state.

For two other participants, whereas they reported positive impacts, they felt there were one or two areas where they would have liked to have experienced benefit but didn't; for example, finding the Alpha-Stim AID did not help with their sleep: 'it made no difference to sleep at all' [P15], or their mood: 'I don't think it had much of an impact on my mood' [P13].

Negative psychological effects

This theme was only evident in the narratives of the two individuals who experienced no effects: there was a negative psychological effect as their high expectations of the device being something that would help them did not materialise. They had the realisation that this was another thing that had not worked, and they would still be experiencing anxiety.

P9: I don't know if it made me a bit worse. Cause, I was, I was expecting it to be good, and sort me out. But it's just another thing that doesn't work for me. It's more that you were thinking: "Oh hopefully this can help." And then, of course it hasn't, and that has been difficult.

Discussion

This is the first research to qualitatively examine through in-depth interviews the experience and feedback of individuals with symptoms of anxiety who have used the Alpha-Stim AID. It provides support for acceptability, useability, and positive outcomes. The themes that emerged offered insights into what worked well, positive experiences, engagement, and beneficial outcomes; and what did not work well, barriers to using the device, and lack of impact (in a couple of cases).

There were fewer prior feelings of uneasiness about receiving Alpha-Stim AID treatment and less discomfort reported than has been reported for using tDCS (Gordon *et al.*, 2021; Grycuk *et al.*, 2021). Participants found engagement with the Alpha-Stim AID was enabled through the useability of the device, in that it was accessible, easy to use, reliable, could be embedded into their daily routine, and did not have any adverse side effects preventing use; these factors promoted treatment compliance. The findings add to and align with evidence of useability, feasibility, ease of use, and lack of side effects found in other studies (Barclay & Barclay, 2014; Griffiths *et al.*, 2021; Morriss *et al.*, 2019; Royal *et al.*, 2022; Shekelle *et al.*, 2018). Medication side-effects can cause treatment failure (Sundbom & Bingefors, 2013); and the lack of Alpha-Stim AID side effects meant that some participants perceived the Alpha-Stim AID as a preferred alternative to medication.

Positive impact was experienced by the majority of the participants, who associated positive benefits with using the Alpha-Stim AID. The participants described reductions in their anxiety and panic attacks, and increases in feelings of calmness and relaxation. This supports evidence from quantitative research, which found Alpha-Stim AID significantly reduces anxiety symptoms (Barclay & Barclay, 2014; Griffiths *et al.*, 2021; Morriss *et al.*, 2019; Royal *et al.*, 2022; Shekelle *et al.*, 2018). Participants reported improvements in sleep quality and duration. This finding is aligned to studies that have quantitatively measured CES and its impact on sleep (Kirsch & Gilula, 2007; Kirsch *et al.*, 2019; Wagenseil *et al.*, 2018). The positive experiences described by the participants were interlinked, giving insight into factors related to experiencing wellbeing and a good quality of life. The Alpha-Stim AID was associated with breaking negative cycles of mental illness and promoting positive cycles of mental health, well-being, and recovery. Further research could investigate how Alpha-Stim AID is directly and/or indirectly linked to these factors through its effects on anxiety, sleep, thoughts, or mood.

Participants described changes in their thoughts and thought processes: a mindset shift. Some reported a reduction in harmful and unhelpful thoughts (which are known to be associated with distress), and an increase in their ability to make connections with other people and to participate in activities. Some participants reported cognitive reframing (Robson & Troutman-Jordan, 2014) which enabled them to shift their mind-set to look at situations and experiences from a constructive perspective and find more constructive ways of perceiving ideas, events or situations. This seemed to be a key recovery factor and linked to self-reflection and greater resilience.

Some participants experienced no effect following the use of the Alpha-Stim AID, and it is not effective for all people (Barclay & Barclay, 2014; Griffiths *et al.*, 2021; Morriss *et al.*, 2019; Royal *et al.*, 2022; Shekelle *et al.*, 2018). Those who did not experience a positive impact, experienced psychological distress due to the failure of hopes that it would work. Practitioners need to be aware of this and prepare patients for this potential outcome and ensure that patients receive ongoing support, and to suggest other solutions for their anxiety. Patients need to be informed of possible treatment not working and trajectories before the initiation so they know that they may need to try a number of options until an effective treatment is found (Toledo-Chávarri *et al.*, 2020). Further research could be conducted to understand factors that influence impact, and why some do and some do not experience benefits.

Strengths and limitations

Due to recruitment having taken place through NHS primary care social prescribing services in a single county of the UK, generalisability to other settings is reduced; however, the sample was drawn from both rural and urban areas. All participants reported as being White British, limiting generalisability to other ethnic groups. Participants self-selected, which can introduce bias, as their experiences and perceptions may differ from those who did not wish to be, or felt unable to be interviewed. There was a relatively small sample size limiting generalisability; however, the sample size was deemed appropriate for an in-depth interview study, as saturation often occurs at around 12-15 participants in relatively homogeneous groups (Guest *et al.*, 2006). A larger proportion of the participants were female and so results are less generalisable to males; however, this reflects the larger percentage of females presenting to primary care who report symptoms of anxiety.

Conclusions

It is important to identify anxiety symptoms and offer patients a choice of various treatment options. The results support the use of Alpha-Stim AID as a treatment option for people with symptoms of anxiety. In many countries people can buy and use Alpha-Stim AID themselves and some private clinicians prescribe use, but the awareness of this device is low, and cost is prohibitive for many (around £600 GBP) (Electromedical Products International Inc., 2022). Availability through free-to-access universal healthcare systems such as the UK's NHS exists in only a couple of areas. An appropriately designed and powered RCT on the effectiveness of Alpha-Stim AID for anxiety symptoms compared to cognitive behavioural therapy (CBT), anti-anxiety medication or a combination of both is required (NICE, 2021). If Alpha-Stim AID is an effective treatment for anxiety, then access should not be restricted by being able to afford to buy it.

Authors' contributions

All authors contributed to the design of the study and interpretation of results. All co-authors contributed to critically revising the manuscript, read and approved the final manuscript, and agree to be accountable for all aspects of the work.

Data availability

The datasets generated and analysed during the current study consisting of the transcripts of patients' interviews are not publicly available due to confidentiality and privacy for participants, but the data collection tools are available from the corresponding author on reasonable request.

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