Scientific Research Publishing

Psychology, 2024, 15, 645-663
https://www.scirp.org/journal/psych
ISSN Online: 2152-7199
ISSN Print: 2152-7180

A Qualitative Study Exploring the Experience and Value of the Cranial Electrical Stimulation (CES) Device Alpha-Stim AID for a Social Prescribing Service Patients with Symptoms of Anxiety

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How to cite this paper: Griffiths, C., Walker, K., Willis, A., Smart, D., Galvin, S., Macmillan, H., & Terry, D. (2024). A Qualitative Study Exploring the Experience and Value of the Cranial Electrical Stimulation (CES) Device Alpha-Stim AID for a Social Prescribing Service Patients with Symptoms of Anxiety. *Psychology, 15,* 645-663.
https://doi.org/10.4236/psych.2024.155040

Received: April 18, 2024
Accepted: May 21, 2024
Published: May 24, 2024

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. **Methods:** This study explored the experience and impact of using Alpha-Stim AID and social prescribing service through in-depth interviews. Out of a sample of 30 using Alpha-Stim AID, thirteen participants consented to be interviewed. The age range of participants was 27 - 68 years (M = 50.67, SD = 13.27); eight (62%) were female and five (38%) were 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. Themes that emerged offered insights into the welcomed addition of Alpha-Stim AID to anxiety treatment and its ease of use, how Alpha-Stim AID had positive impacts, the benefits of social prescribing service, and how improvements gained enabled engagement in socialising, activities, and further mental health recovery. **Conclusions:** It is important to identify anxiety symptoms and offer patients a choice of treatment options beyond medication. The results support the use of Alpha-Stim AID as a treatment option for people with symptoms of anxiety using social prescribing services.

Keywords

Social Prescribing, Primary Care, General Practice, Alpha-Stim, Cranial Electrotherapy Stimulation, Anxiety

1. Introduction

Generalised anxiety disorder (GAD) is a common psychiatric disorder associated with fear, nervousness, apprehension, panic, and physical responses (cardiovascular, respiratory, and gastrointestinal) (Martin, 2003). Anxiety disorders such as GAD have a 13.6% to 28.8% lifetime prevalence in Western countries (Michael et al., 2007). GAD is 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 physical 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 lifestyle 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 commonly 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). Around 20% of prescribed antidepressants are not collected from pharmacy (Xing et al., 2011). Medication prescription may be associated with a high risk of relapse (Culpepper, 2009) and benzodi-

azepines 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 it is costly and lengthy; it is 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 of psychotherapy sessions 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 options and 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 chemical mediators such as norepinephrine, serotonin, and GABA (γ-aminobutyric acid) and changes in brain electrical activity similar to that produced by meditation (decreases in higher frequency alpha and beta waves, which are associated with stress and arousal) (Bystritsky et al., 2008; Nardone et al., 2014; Schroeder & Barr, 2001, Zaghi et al., 2010). 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 CES there was a 32% reduction in anxiety (Barclay & Barclay, 2014). A review that examined five randomised, 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 indicate 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 (Morriss 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). A qualitative study of the experience of Alpha-Stim has found support for the acceptability, useability, and positive impact of Alpha-Stim AID (Griffiths et al., 2023). These studies indicate that Alpha-Stim AID is safe, well-tolerated, and acceptable to the majority of patients, and that the majority of patients will conform to the treatment protocol.

Social prescribing is a relatively new and innovative service model, developed mostly in the UK that has been promoted as a way of supporting the sustainability of the health system (Costa et al., 2021). Social prescribing is the provision of a service that engages with and links patients in primary care to different sources of support within the community. It operates as a non-medical, social referral (that can be provided alongside medical referral and treatment) as a means of improving health and wellbeing (Bickerdike et al., 2017). Social prescribing

works on the premise that health is determined synergistically by biological, social, economic, psychological, and environmental factors, it aims to work with patients in a holistic way and to facilitate health self-management (Costa et al., 2021). Social prescribing evolves around the creation of referral pathways to community-based resources, which are utilised to connect individuals who have health, social or practical needs, with accessible local providers of services and support (Pilkington et al., 2017).

The United Kingdom's (UK's) National Institute for Health and Care (NICE) stated the lack of and need for further collection of real-world data on Alpha-Stim AID to better understand issues around people's treatment preferences, treatment completion rates, and impact on quality of life (NICE, 2021). Delivering Alpha-Stim AID through social prescribing services has potential, but there is a lack of research investigating whether this is viable and acceptable by patients. This study takes a qualitative approach to examine and understand the experience and impact of using Alpha-Stim AID and social prescribing services for patients with symptoms of anxiety.

2. Method

2.1. Design

A qualitative approach was taken, employing semi-structured interviews. Interview questions were informed by previous CES qualitative research (Griffiths et al., 2023; Patel et al., 2023; Grycuk et al., 2021). Questions were developed to explore: "compliance with instructions provided"; "usage"; "was it useful and why?"; "would you use it again?"; "if you stopped using it why?"; "how did using Alpha-Stim make you feel?"; "impact of using the Alpha-Stim"; and "impact of social prescribing service".

2.2. Approval

Approval was granted by a review panel of the NHS social prescribing service. All participants provided informed written consent. The study was delivered in accordance with the Declaration of Helsinki.

2.3. Setting and Participants

Participants were recruited from a social prescribing service. Through this service, patients work with social prescribing link workers (SPLWs), who provide support, both practically and emotionally; they make appropriate referrals to community-based support and resources and offer intervention/treatment options.

Participants were identified by SPLWs as having symptoms of anxiety and after discussions with a clinician, were offered the use of an Alpha-Stim. Inclusion criteria: 18 years or over; under the care of SPLWs; and reporting symptoms of anxiety. Exclusion criteria, those who: lacked the capacity to consent; experienced seizures; or had a pacemaker/any other implanted electrical device. All

participants were fully informed about the purpose of the study, what it entailed, and given an opportunity to ask questions.

In total from a group of 30 participants, 13 were recruited for an interview. All were offered an interview and the 13 were those who agreed to be interviewed. The age range of participants was 27 - 68 years (M = 50.67, SD = 13.27); eight (62%) were female and five (38%) were male. Participants reported ethnicity as "White British" (n = 11, 84%), "White Irish" (n = 1, 8%) and Other (n = 1, 8%).

2.4. Alpha-Stim AID Intervention

The device provided was an Alpha-Stim AID (Conformite Europeenne [CE] marked as a class IIa medical device). Participants were given this by their SPLW with verbal and written instructions for how to use it. Usage of the device was set at once a day, every day, for one hour, for a period of six weeks. Participants were advised to use the device set at level 1 (2 bars on device's screen) (0.5 Hz, 100 - 500 μA, 50% duty cycle, biphasic asymmetrical rectangular waves). Alpha-Stim AID is the size of a mobile phone, worn via a neck lanyard. It delivers small electric currents via conducting liquid soaked soft pad covered metal clips, which are secured to the earlobes. Patients could contact the SPLW during the six-week period they used the Alpha-Stim if they required any support. Patients remained on any prescribed medication and continued any medical or psychological interventions that were in place. After they had used the Alpha-Stim AID for six weeks they were required to return it.

2.5. Procedure

All interviews were completed one-to-one via the telephone. Interview lengths ranged from 15.14 to 48.33 minutes (M = 29.39, SD = 11.37). Interview questions were on the process, experience, use of, problems with, and impact of using Alpha-Stim AID and the social prescribing service. Semi-structured design allowed for verification of answers and follow-on questions. The interviews were recorded and then transcribed verbatim and anonymised; following this all recordings were securely deleted. To support the analysis, NVivo 16 software was used.

2.6. Data Analysis

Critical realism was ontological and epistemological positioning for this study. Realism assumes that there is an external reality, independent of human minds, with reality seen as a finite subjective experience (Denzin & Lincoln, 2005). A critical realist approach assumes that the data is informative and a representation of reality, but this needs to be interpreted to identify and understand underlying structures embedded in the data (Willig, 2001, 2012).

Thematic analysis (TA) (Braun & Clarke, 2021) was used to analyse the data. The analysis was inductive, and data driven, to gain an insight into the understanding, perspectives, and experiences of participants in relation to the impact

of social prescribing and Alpha-Stim AID. Themes were developed on the semantic level to capture explicitly expressed meaning (Braun & Clarke, 2021). The six steps were followed to analyse the data and comprised: 1) Familiarisation with the data through reading and re-reading; 2) Generating initial codes; 3) Development of themes—identification of coherent and meaningful patterns relevant to the research question; 4) Reviewing the themes across and within interview data for consistency; 5) Defining and naming themes; 6) Writing up an account of the data (Braun & Clarke, 2006, 2021). Verbatim quotes were identified, selected, and included to promote verifiability (Silverman, 2000, 2015), and trustworthiness of the analysis, following strategies (Shenton, 2004) in order to enable credibility and confirmability.

3. Results

A content analysis of participants' practical usage of the Alpha-Stim AID was undertaken, based on a series of direct questions. Table 1 presents the findings from this, with some exemplar quotes.

Table 1. Practical usage of the Alpha-Stim AID.

Usage of Alpha-Stim	Yes *n* (%)		No *n* (%)	
Did you use it every day?	3 (25%)	P3: Yes, *I tried to use it every day.* P7: *I used it religiously*	10 (77%)	P6: *In the beginning I did, for I think about a week or just over a week, and then I reduced it, because it was actually giving me headaches.* P13: *I have ADHD, which is one of the reasons I have anxiety. So, I'm not always very good at remembering to do things.*
Did you use it for 6 weeks?	7 (54%)	P2: *Six weeks all together.* P3: *I think it was just over 6. Just over 6 weeks*	6 (46%)	P5: *I used it for about three weeks. And then it stopped, I couldn't feel it.* P9: *I probably used in total for about three weeks. The effects from it is still working to this day.*
Did you keep to 2 bars?	8 (62%)	P8: *Two bars. I basically stayed at two bars all the way through.* P11: *I didn't fiddle at all with it, no, I just left it exactly as it was, you know configured.*	5 (42%)	P2: *I did increase it a couple of times… it made me feel a little bit giddy in the head so I put it back down again.* P6: *No, I just felt it wasn't working on a lower setting*
Did you have any practical problems using the Alpha-Stim?	0 (0%)		13 (100%)	P4: *I picked it up very quickly and knew exactly what to do. From my point of view, it, no, I didn't have any issues at all* P12: *No, it's very simple.*
Did the Alpha-Stim stop working?	3 (25%)	P3: *The last evening I used it, it didn't seem to work properly.* P8: *It did once, all of a sudden when I went to use it, it was fine, again, I don't know whether it was me, or whether it was the machine.*	10 (77%)	P1: *No, it was fine.* P11: *No, not that I'm aware of. It just does its thing in the background. It's very foolproof.*

The thematic analysis resulted in the identification of themes and subthemes that were captured in two main global themes—"*Usability and usage of Alpha-Stim*" and "*Perceived impact and outcomes experienced*". All the themes are presented in Figure 1 below.

3.1. Usability and Usage of Alpha-Stim

This global theme captured usability and usage of the Alpha-Stim AID and factors that promoted its use, satisfaction with device, the quality of the experience, how it was used, and facilitators and barriers to its use.

3.1.1. A Preferred Option to Medication

Participants expressed that they wanted and liked having an alternative to taking medication, or if they were already on medication, having access to an additional type of intervention that was not taking more medication.

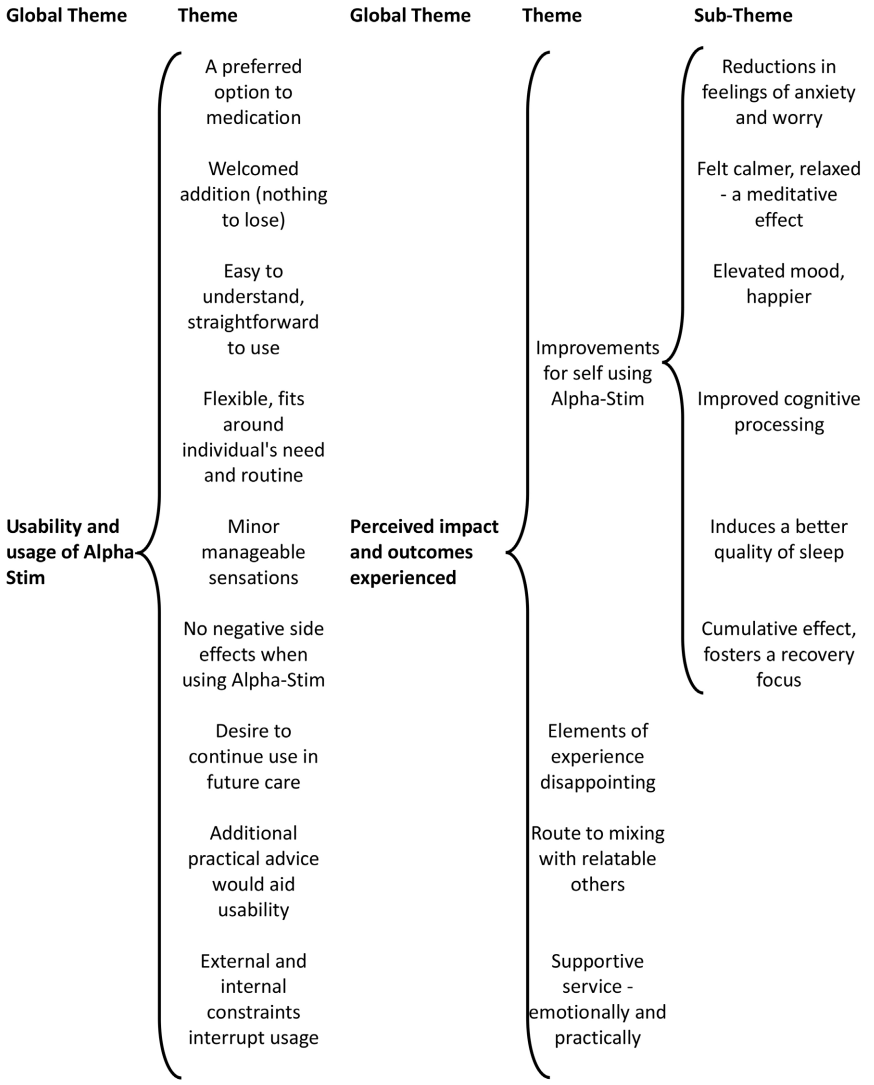

Figure 1. Themes for individuals' experience and impact of social prescribing and Alpha-Stim AID.

P6: *It has a value in the fact that it's alternative and different…rather than just saying well, this is the traditional medicine, this is what we use, you know, because pills don't solve everything.*

For one of the participants, they had experienced problems with medication, and so the Alpha-Stim option was preferred.

P1: *I've struggled to come off medication for quite a few years and I've had help from a doctor etc., and I have found that has been quite frightening at times, very inhibiting and I just found that it* [*Alpha-Stim*] *was just such a major breath of fresh air to me.*

There was a feeling that the default position of medical professionals was recommending medication first. However, participants were keen for an alternative to this default position.

P5: *Alpha-Stim it's not taking another pill. I don't like when I go to the doctors, they go take this, and will prescribe this and then is it working?—We will double the dose then. So, something that's possibly going to work, but it's non medicated, you're not sticking anything in your body.*

3.1.2. Welcomed Addition (Nothing to Lose)

The majority of the participants stated how the option of the Alpha-Stim was welcomed, e.g., "*I jumped at the chance of trying it*" [P9]. Participants felt that this offered them some hope in finding something that could work—"*It gives you the feeling of hope and optimism*" [P1], a valuable addition in their lives. Some had initial reservations and scepticism; however, several felt they had nothing to lose.

P12: *It was, I was sceptical because it sounded a bit wacky. I've never heard of it before, so I was a bit sceptical. But I was, you know, I was willing to give it a try. I just figured I've got nothing to lose, really.*

3.1.3. Easy to Understand, Straightforward to Use

All the participants commented on how easy it was on a practical level to use the Alpha-Stim. It was described as "*very straightforward, self-explanatory*" [P9]; "*idiot proof*" [P5]; "*foolproof*" [P11]; and "*easy to use*" [P3].

P6: *The machine was pretty straightforward. I mean the machine is as easy to use, a simple thing, you literally just put on your ear and connect it to your lobes…*

3.1.4. Flexible, Fits Around Individual's Need and Routine

Participants found the Alpha-Stim was something they could embed into their daily routine.

P11: *I tried to do it at same time every night. I stick the Alpha-Stim on, and then just wind down. Part of my routine and winding down. I set the time, because I have a time every night to take my drugs. So, it all ties together.*

For others, they liked the flexibility of not having to use it at the same time, that it could fit in with and around their other commitments.

P8: *I think the flexibility of using the Alpha Stim…you can use it anytime in*

the day, depending on circumstances, that's been a huge benefit.

3.1.5. Minor Manageable Sensations

Participants reported that while using the Alpha-Stim that they experienced some "unusual" sensations. However, these sensations were all described as being minor and not unbearable, such as: "*Slight tingly, fuzzy feeling on my ears*" [P3]; "*A kind of lightheaded kind of feeling*" [P4]; "*It sort of tingles, you can sort of feel the electrodes*" [P6]; "*A semi-spaced head*" [P12] and "*Giddy feeling*" [P2]. All the sensations were manageable; either they were short-term and not long lasting, or they could be controlled by the individual themselves through how they utilised the device. They did not prevent use of the Alpha-Stim.

P5: *It was just like grabbing hold of electric fence. Just a little pulse every now and again… it was all manageable sensations really. Well, you're in control of it. You've got the nought to five thing, you decide at which setting you put it.*

3.1.6. No Negative Side Effects When Using Alpha-Stim

Participants did not report any significant negative side effects while using the Alpha-Stim or after having used it which prevented use. This was in comparison to other treatment tried, particularly medication, which was associated with negative side effects.

P1: *I experienced no side effects, and in fact I wouldn't mind buying one if I could have one it may be a great help to me, with some medications as you're probably aware can cause parkinsonism and dystonia in some people.*

P11: There were no negative side effects with Alpha-Stim. Well, none, I'm aware of. That was a big thing for me. I did want to know I was doing the right thing.

For the participants who felt they did not achieve the outcomes they had hoped for from the Alpha-Stim AID, their anxiety was not made worse.

3.1.7. Desire to Continue Use in Future Care

Several of the participants talked about wanting to carry on using Alpha-Stim after the initial six weeks and perhaps again in the future. They saw the Alpha-Stim as advantageous as part of their ongoing treatment.

P1: *So that Alpha Stim for me would be a fantastic bonus in the future. I think it's just amazing, and I'd just really like to borrow it again. I do still need the machine I think it would be very advantageous for me.*

Several of the participants intended to, or already had bought their own Alpha-Stim AID for future use. This demonstrates a commitment to the continued engagement with this treatment.

P9: *I've actually been out and bought myself one…I thought, okay, well, if this is working, maybe if I find my own one, then I have got it with me all the time. I feel it is something that I feel actually will be a real benefit to have long term and keep as part of my ongoing treatment.*

3.1.8. Additional Practical Advice Would Aid Usability

A minority of participants felt they would have benefitted from more guidance

about the Alpha-Stim AID, such as more information about how it works, and the chance to ask questions.

P3: *I…maybe needed a little more information to hand, to answer questions. I would've preferred to have been able to have a better explanation of how it works, and how it has the potential to work.*

It was suggested that being shown how to use it would have been beneficial.

P8: *Maybe if there was a workshop or something like that, because I wasn't too sure what to expect. It's all very well, going from the book, but sometimes to actually see someone who's actually doing it…I would have understood a lot more.*

3.1.9. External and Internal Constraints Interrupt Usage

Some participants reported certain factors got in the way, preventing their consistent use of the Alpha-Stim. These were both external and internal factors. For example, external factors cited included life in general, other priorities or needs that require attention such as caring for relatives, time constraints, and being away on holiday.

P1: *I was busy, I wasn't, I didn't deliberately not use it, but I just, I've got an elderly mother that I help, and sometimes I was exhausted, at the end I just tried to get off to sleep.*

Other constraints were internal. This included one person who suggested psychologically they felt the time was not right, or others who suggested it was due to forgetting or laziness.

P10: *Just totally forget. Because like if somebody come round I'd forget and such.*

P11: *Basically, it's my own laziness.*

3.2. Perceived Impact and Outcomes Experienced

This global theme was developed to collate the impact of both the Alpha-Stim and the social prescribing service. It is represented by various themes that include what individuals perceived as useful, helpful, positive and of benefit to them. There is also reference to where the impact was not as positive as would have been hoped for.

3.2.1. Improvements for Self Using Alpha-Stim

This theme is represented by six sub-themes of improvements participants perceived.

1) Reductions in feelings of anxiety and worry

Several participants had a notable reduction in feeling anxious, others said that they were coping better and not feeling so stressed.

P4: *I don't feel as anxious and stressed as I used to, I live in a very unpredictable household, that can put me into a negative mindset, a stress, anxiety, trigger them very quickly and very easily. I'm finding that I'm sort of getting better at not reacting with anxiety.*

Participants perceived that it aided the prevention of the worry associated with their anxiety.

P3: *A lot of little things like every day, things that I would've spent a lot of time worrying about, how to do best, and am I able to do it. Whereas I don't seem to have anywhere near as much problem now. So, my anxiety's decreased, so usual worries just weren't there.*

2) Felt calmer, relaxed—a meditative effect

Participant's talk about how the Alpha-Stim enabled them to feel calmer and more relaxed.

P3: *It just helped me to feel a bit calmer. So, most days, I used it every day. So, I noticed from the very first time using it that it made me feel a bit calmer. I have more of a calmness and less racing thoughts.*

P1: *I think it helped me to probably slow some of my breathing down. I think it creates a feeling of warmth in the body and I also think it creates a feeling of calm, of peace, and I think it helps you to slow down.*

Undertaking the process of physically using the Alpha-Stim created a routine of "actively relaxing"; for example, it was used during a quiet time that was created, or as part of some individual time out; it meant sitting down on your own, when not rushing around doing other things.

P4: *It's given me the hour of being able to de-stress, and that's my time to, everybody to leave me alone, let me come down and wind down for sleep. It also seems to have helped me with being calmer, more relaxed in situations, not so reactionary.*

3) Elevated mood, happier

Participants expressed experiencing a positive impact on their mood, for example: "*I feel, my mood feels elevated*" [P1]; "*I think it's had a positive impact on my mood*" [P3]; and "*I feel more optimistic*" [P4].

P6: *I think actually, it's improved my mood. I feel more content, generally. I think it had a positive impact that way. It made me feel happier… it sort of saved the mood swings.*

4) Improved cognitive processing

The participants discussed how they felt their cognitive functioning had improved. For some this comprised thinking more clearly, slowing their thinking, or reductions in overthinking or intrusive thoughts.

P3: *I do wonder if somehow the Alpha-Stim has helped with this by clearing my thoughts…the Alpha-Stim has kind of cleared my head a bit…before using this Alpha-Stim I would not wake up with a very clear head at all.*

One of the participants commented they felt that they had an improved memory, noting this in relation to their spelling and grammar. Another person felt there were improvements in their concentration, which was helpful day-to-day.

P13: *The first time I used it I felt that I was kind of concentrating on what I was doing a lot more. I'm getting more things done. I think I'm being a little bit less inattentive than I have been of late.*

5) Induces a better quality of sleep

Some participants perceived that use of the Alpha-Stim was associated with a better quality of sleep: not waking so frequently, quicker sleep initiation, and improved duration.

P4: *And getting a better quality sleep, because I don't get a good quality of sleep…normally I would wake up anywhere from five to nine times a night. I've noticed that I am not waking up as frequently, and I'm also having deeper dreams…in terms of the sleep I do get, it just feels a bit better quality.*

P5: *It helped me get off to sleep quicker. I did find in the middle of the night if I had got up and gone to the loo and come back and pop it back on and it would help you get back off to sleep again.*

P8: *I think I was getting an extra two* [*hours sleep*], *normally I would sleep for three hours, but I was getting an extra couple of hours…that's great for me*

P3: *Well, I thought it was kind of just helping me fall asleep…it was maybe helping me fall into a deeper sleep. I've been sleeping much better.*

6) Cumulative effect, fosters a recovery focus

This sub-theme represents how participants experienced cumulative or knock on effects following use of the Alpha-Stim AID. This could be described as a domino effect, or a causal sequence. Individuals talk about how the improvements in anxiety enable them to engage with and do other beneficial activities.

P2: *It has calmed my anxiety. I felt more organised…calmer…less anxiety. So that makes me feel better, and when I feel better, I can get out in the garden and definitely my mood feels elevated.*

P13: *I think that's all kind of tied in with how I say I'm feeling better. I've been feeling kind of less hopeless and depressed. I get a knock-on effect that, feeling slightly better, and then I can concentrate more, I can do more things, and because of that, that then makes me feel better in myself.*

P1: *I think along with my own determination pushing myself out there…it's helped with sleep and self-esteem…I think I am more cheerful, I think I am more wanting to socialise a bit more now, I am wanting to do things differently.*

3.2.2. Elements of Experience Disappointing

Some found that the Alpha-Stim AID simply did not have any effect.

P11: *I am quite disappointed that it didn't make a difference…I just felt exactly the same.*

3.2.3. Route to Mixing with Relatable Others

Through the social prescribing service, access was given to different groups, and these were found to provide a mechanism for meeting with others and making friends which aided the recovery process.

P1: *I think it's just really seeing people I've never met before, it is nice to meet new people…it makes you feel quite lucky, and it's nice to meet people sometimes like that and make you feel a bit better.*

A key factor was engaging with people who were in same situation. This is about mixing with those with shared understanding and meaning and who could

all relate to one another. It offers a feeling that you are not alone in this.

P12: *Meeting people that I felt quite comfortable with, really helped with my social anxiety as well. Because meeting other people who are like in the same boat as me was quite helpful.*

3.2.4. Supportive Service—Emotionally and Practically

This theme is about the service itself being supportive and as such an aid to recovery. Participants suggested the SPLWs had genuine concern for them and a desire to help.

P1: *The person* [*SPLW*] *was quite concerned about me, she had met me a couple of times and I'd been quite sort of open about myself, and I think she was genuinely wanting to support me. I think that they are very caring people.*

Participants talked about being able to talk to the SPLW, and in doing so get emotional support.

P5: [*SPLW*] *she's quite good at listening and watching. I think* [*SPLW's name*] *has been very helpful. She's sort of quite pleasant to talk to. She's very intuitive. And very empathetic and listens and wants to help, which is nice.*

In addition, the participants felt that the SPLWs were also able to offer practical support. This could include introducing them to different community groups and getting them set up at various groups/activities e.g., the gym, wellness clinics, or walking groups, as well as other practical support with issues like financial difficulties or housing problems.

P4: [*SPLW*] *are putting us in touch with somebody to help us with housing, because where we live is not suitable for, our needs.*

4. Discussion

This study qualitatively examined through in-depth interviews the experience of individuals with symptoms of anxiety who were receiving support from a social prescribing service and used the Alpha-Stim AID for six weeks. Findings provide support for acceptability, useability, and positive outcomes. The themes that emerged offered insights into the welcomed addition of Alpha-Stim AID to anxiety treatment and its ease of use, how Alpha-Stim AID had positive impacts, the benefits of social prescribing service, and how improvements gained enabled engagement in socialising and activities, and subsequent further mental health recovery.

Participants found engagement with the Alpha-Stim AID was enabled through the useability of the device, in that it was accessible, easy to use, generally 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; Griffiths et al., 2023; 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 welcomed and 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, improvements in mood and cognitive functioning, and increases in feelings of calmness and relaxation—some expressing it was akin to feelings experienced when meditating. This supports evidence from qualitative Alpha-Stim AID research (Griffiths et al., 2023) and quantitative research, which found Alpha-Stim AID significantly reduces anxiety symptoms (Barclay & Barclay, 2014; Griffiths et al., 2021; Griffiths et al., 2023; Morriss et al., 2019; Royal et al., 2022; Shekelle et al., 2018). Participants in this study linked benefits gained to the process of using Alpha-Stim AID, that this created a specified time for relaxation each day, which aligns with conclusions of other Alpha-Stim AID research (Morriss et al., 2023).

Participants reported improvements in sleep quality: less waking during nighttime sleep, easier sleep initiation, and better sleep 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), and qualitatively evaluated Alpha-Stim AID (Griffiths et al., 2023).

The Alpha-Stim AID was associated with breaking negative cycles of mental illness and promoting positive cycles of mental health, well-being, and mental health recovery. The Alpha-Stim AID was a catalyst beyond the initial impact it had on anxiety, mood, cognitive functioning, and sleep; enabling individuals to engage with and participate in other activities that aided with their recovery, enabling a holistic mental health recovery. Social prescribing provided emotional and practical support and opportunities for social and community engagement, so that people experiencing benefits due to Alpha-Stim AID could engage in activities aiding further mental health recovery.

Participants described changes in their thoughts and thought processes. 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, enabling self-esteem, a sense of achievement, optimism, and hope. 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; Griffiths et al., 2023; Morriss et al., 2019; Royal et al., 2022; Shekelle et al., 2018). Those who did not experience a positive impact, experienced disappointment 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 possibility of 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 outcomes, and why some people experience benefits and some do not.

It was reported by some of the participants that they could have benefitted from further support in relation to the use of the Alpha-Stim AID, this may have improved adherence to its daily use. This could be initiated through offering initially face-to-face workshops/groups to set up and try the Alpha-Stim with others through the support workers. The use of peer support workers might also be helpful over the period of using the Alpha-Stim, or through the creation of a peer support group comprising other users of the Alpha-Stim as a way of monitoring, encouraging, supporting, and aiding individuals. Peer support in mental health recovery can instil hope, improve engagement, quality of life, self-confidence, and integrity and may reduce the burden on the health care system (Shalaby & Agyapong, 2020).

Due to recruitment having taken place though NHS primary care social prescribing services in a single county of the UK, generalisability to other settings is reduced. The majority of 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.

5. Conclusion

It is important to identify anxiety symptoms and offer patients a choice of treatment options. The results support the use of Alpha-Stim AID as a treatment option for social prescribing patients 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 would address this inequality of healthcare treatment. 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). A future study could investigate the value peer support and group training in the use of Alpha-Stim to see if they improve patient experience, adherence to protocol and outcomes.

Acknowledgements

We would like to thank the healthcare workers and social prescribing services for their support.

Funding

Funding for the Alpha-Stim AIDs was provided by Electromedical Products International, Inc., but study design, analysis, interpretation, and reporting was independent of the funder.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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