

Alpha-Stim AID Cranial Electrotherapy Stimulation (CES) for Anxiety in Chronic Breathlessness: A Qualitative Exploration of Feasibility, Usability, and Acceptability

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Abstract

Background: Anxiety is common in people living with chronic breathlessness. Cranial Electrotherapy Stimulation (CES) with the Alpha-Stim Anxiety, Insomnia, Depression (AID) has evidence of effectiveness in the treatment of anxiety disorders, but little is known about its feasibility, usability, and acceptability for people living with anxiety associated with chronic breathlessness. **Aim:** To explore individuals' experiences of using Alpha-Stim AID to manage their anxiety associated with their breathlessness. **Methods:** Participants were recruited from two hospices, with advanced chronic respiratory disease and breathlessness and anxiety, and followed either a Set Dose Regime (SDR) or a Personalised Dose Regime (PDR). Semi-structured interview with 15 participants who had used Alpha-Stim AID (SDR and/or PDR) daily for eight weeks were analysed thematically using the predefined domains of feasibility, usability, and acceptability. **Results:** *Feasibility:* the Alpha-Stim AID was readily integrated into daily routines, providing a valued hour of calmness and fostering adherence to Alpha-Stim AID use. *Usability:* most participants reported benefits including reduced anxiety, improved mood, better sleep, and subtle mindset shifts such as cognitive reframing, although a minority reported limited impact. *Acceptability:* The device was perceived as simple to use and intuitive and associated with no or mild transient side effects, with PDR enhancing comfort, perceived control, and engagement. **Conclusions:** Alpha-Stim AID is a low-burden, well-tolerated adjunctive intervention for anxiety in people with breathlessness, with potential benefits extending beyond symptom relief. Future research should explore long-term effects, the mechanisms underpinning mind-

set change, and strategies for optimising personalizing dosing regimens.

Keywords

Anxiety, Chronic Breathlessness, Cranial Electrotherapy Stimulation, Alpha-Stim AID, Acceptability

1. Introduction

Breathlessness, or dyspnoea, frequently occurs in people with progressive respiratory illnesses such as Chronic Obstructive Pulmonary Disease (COPD) and Interstitial Lung Disease (ILD) (Bonini & Fiorenzano, 2017; Kupper et al., 2016; O'Donnell et al., 2020). For those who suffer from breathlessness, the impact includes physical limitation, fatigue, and avoidance of activities (Hanania & O'Connell, 2019). Breathlessness is associated with reduced functionality, high levels of use of clinical services and hospital admissions, poor prognosis, and increased mortality (Sethi et al., 2023). Breathlessness can also have a significant negative psychological impact on those experiencing it. Individuals frequently report fear, helplessness, social withdrawal, and panic during breathless episodes (Gysels et al., 2007; Willgoss & Yohannes, 2013). Anxiety and depression are highly prevalent and widespread for those who experience breathlessness (Rahi et al., 2023; Willgoss & Yohannes, 2013; Pumar et al., 2014). For example, Kunik et al. (2005) found in their sample of individuals who had a chronic breathing disorder that 80% of patients screened using the PRIME-MD had symptoms of depression, anxiety, or both, with 65% given a formal diagnosis of an anxiety and/or depressive disorder.

There is a bidirectional relationship between anxiety and breathlessness: living with a physical health condition can be a source of anxiety (psychologically and physiologically), and anxiety can exacerbate breathlessness (Storer et al., 2024). Anxiety also increases the perception of breathlessness and vice versa (Bailey, 2004) by increasing focus on bodily sensations, causing negative thoughts about breathing, and affecting how people interpret what their bodies are telling them (von Leupoldt & Dahme, 2007). Conversely, breathlessness can trigger anxiety or panic responses, resulting in a vicious cycle in which fearful anticipation exacerbates respiratory distress and breathlessness, and this exacerbated breathlessness then increases fear and anxiety (Livermore et al., 2008).

People who experience significant breathlessness are offered a range of symptomatic treatment options depending on their diagnosis and stage of the disease. This includes pharmacological intervention such as low-dose opioids (e.g., morphine) (Barnes et al., 2016; Ekström et al., 2015). Non-pharmacological strategies are also utilised, such as breathing retraining, inspiratory muscle training, hand-held fan therapy, and mindfulness techniques (Burge et al., 2024; Hanada et al., 2020; Sciriha et al., 2021). However, anxiety in people with breathlessness appears

less well recognised and specifically addressed (Ouellette & Lavoie, 2017). There is an intertwined relationship between anxiety and breathlessness in patients with an advanced respiratory disease, and anxiety cannot be separated from breathlessness, meaning there is a requirement for holistic support for patients with anxiety related to breathlessness (Bleazard et al., 2025). Interventions such as Cognitive Behavioural Therapy (CBT) can reduce anxiety, particularly when combined with other supportive approaches (Yohannes et al., 2017). Pharmacological treatments, including Selective Serotonin Reuptake Inhibitors (SSRIs), may also be beneficial when distress is clinically significant (Maurer et al., 2008). However, in advanced disease populations, some medications, such as benzodiazepines, carry significant risks including respiratory suppression, sedation, and dependence (Baldwin et al., 2013). Given the limitations of interventions for those with advanced diseases, but the need for holistic support, a tailored, multifaceted approach is recommended for the management of their anxiety.

Cranial Electrotherapy Stimulation (CES) is an established form of Non-Invasive Brain Stimulation (NIBS) which aims to relieve symptoms in conditions such as chronic pain, anxiety, or depression (Kumar et al., 2007). The Alpha-Stim Anxiety, Insomnia, Depression (AID) is a NIBS device. In the United Kingdom (UK), the National Institute for Health and Clinical Excellence (NICE) has stated that Alpha-Stim AID shows promise for managing anxiety disorders (NICE, 2021). The Alpha-Stim AID delivers microcurrent electrical stimulation through ear-clip electrodes, typically at 0.5 Hz with a modulated waveform, designed to influence central nervous system activity by causing changes in the brain from beta and delta frequencies that are associated with stress, to alpha frequencies associated with relaxation (Kennerly, 2004; Kim et al., 2021; Patel et al., 2022). CES has very few side effects and is used to induce sleep and increase relaxation (Guleyupoglu et al., 2013). Its portability, safety profile, and ease of use increase acceptability and usability in clinical and home-based treatments (Griffiths et al., 2023a; Royal et al., 2022).

CES can be used alongside pharmacological or psychological treatments or as a standalone intervention (Kirsch et al., 2019). Evidence suggests CES is well tolerated and can reduce anxiety symptoms, with moderate effect sizes reported in adults (Ching et al., 2022; Barclay & Barclay, 2014). Patients have described Alpha-Stim AID as easy to use, readily integrated into daily routines, and beneficial for overall well-being (Griffiths et al., 2023a; Shekelle et al., 2018). Alternative interventions need to be explored for those with advanced illnesses and breathlessness, where pharmacological burden (and its side effects) and patient vulnerability may limit safe treatment options and CBT is not available or accessible. Alpha-Stim AID offers a low-cost alternative and something that can be self-administered by the patient at home. Previous research on the use of Alpha-Stim AID as an intervention has focused primarily on anxiety symptoms alone, and no studies to date have examined its use with advanced illness breathless patients to help with their anxiety. The present study looks to address this gap and aims to explore patients' perspectives on the feasibility, usability, and acceptability of the Alpha-Stim

AID to manage their experiences of anxiety associated with their breathlessness.

2. Method

2.1. Design

A qualitative research design was implemented. One-to-one semi-structured interviews were undertaken with participants to examine their perspectives and perceptions of the Alpha-Stim AID in relation to feasibility, usability, and acceptability. Questions were designed to explore feasibility (practicality of use), usability (ease of operation and support needs), and acceptability (perceived benefits and tolerability) of the Alpha-Stim AID device. For this research, informed by Rothstein et al. (2016), these factors were defined in the following ways. *Feasibility* was the question of how the application and implementation of the Alpha-Stim AID was achieved, accounting for how it was incorporated into patients' treatment. *Usability* was whether the Alpha-Stim AID functioned in the way it should, and if it enhanced outcomes for those using it (including perceived impact). *Acceptability* was whether the service users liked the device, and how it worked.

2.2. Participants and Procedure

Following HRA ethical approval, patients who attended the Help With Breathlessness (HWB) service at two hospices were screened for eligibility and approached by the research team for informed consent to participate in an interventional scoping study. Recruitment of participants took place between January 2024 and July 2025. All participants who used the Alpha-Stim AID during this period ($n = 16$) were approached to be interviewed, and all but one person agreed to be interviewed. Eligibility for inclusion included: being aged 18 years or above; diagnosis of advanced chronic lung disease (including COPD, ILD, or Pulmonary Fibrosis of any aetiology); currently receiving hospice care at one of the two selected sites; a score of two or more for question two on the "Integrated Palliative care Outcome Scale" (IPOS) for shortness of breath; a score of two or more on question three on the IPOS for anxious or worried; capability of giving oral and written informed consent to the study; and an estimated prognosis of >3 months at the time of recruitment. Exclusion criteria comprised: implantation with a pacemaker, cochlear implant, or an Implantable Cardioverter Device (ICD); neurological conditions, e.g., brain neoplasm, cerebrovascular events, epilepsy, neurodegenerative disorders, or prior brain surgery; currently pregnant or planning a pregnancy; involvement with any other clinical trial at the time of consent; current or previous episodes of psychosis or mania; and a diagnosis of current substance use disorder or dependence. Participants could choose to be in the intervention group or control group, and those in the intervention group were interviewed after 8 weeks about their experiences of using the Alpha-Stim AID.

Participants received an Alpha-Stim AID, with instructions on its use. The intervention for initial participants recruited was a set dose and time regime (set dose regime: SDR) of a single 60-minute session per day in their own home at a

current of 100 μA . This dose and/or duration of treatment could be modified at day 3 and/or day 5 in response to side effects. Later, participants who joined the study were instructed to personalise the dose and duration (personalised dose regime: PDR). These participants were asked how long they were prepared to use the Alpha-Stim AID (up to a maximum of 60 minutes). The dose (μA) at which the person starts to notice some dizziness (the room going round rather than feeling faint), buzzing or nausea was established (up to a maximum of 500 μA). The dose for the intervention was 50 microamp (one setting) below that. This dose and/or duration of treatment was then reviewed and modified if needed at day 3 and/or day 5 in response to side effects. Thereafter, patients could adjust their dose and duration as side effects allowed. In clinical practice in mental health contexts, the PDR has usually been established after 2 - 3 days and remains consistent thereafter. The treatment period for all participants was 8 weeks.

In total, 15 participants were recruited. Initially, 11 participants were recruited as part of the SDR group and were interviewed. Of these, 3 then used the Alpha-Stim AID again, but employing the PDR. These individuals were interviewed a second time to include questioning about the personalised dose. A further 4 new participants were recruited, employing only the PDR, and were then interviewed.

Of the participants, 8 (53.3%) were female and 7 (46.7%) were male. The age range of participants was 51 years to 77 years ($M = 64.86$, $SD = 7.62$). For ethnicity, 12 (80%) identified themselves as White British, 2 (13.3%) as Indian, and 1 (6.6%) as British Asian. Participants reported their diagnosed illness(es) as: COPD ($n = 5$, 33.3%); COPD and emphysema ($n = 2$, 13.3%); COPD and alpha-1 antitrypsin ($n = 1$, 6.7%); idiopathic pulmonary fibrosis ($n = 2$, 13.3%); interstitial lung disease ($n = 2$, 13.3%); sarcoidosis of the lungs ($n = 1$, 6.7%); emphysema ($n = 1$, 6.7%); and bronchiectasis ($n = 1$, 6.7%).

In total, 18 interviews with 15 participants were undertaken over the phone (3 participants did 2 interviews). Interview times ranged from 22.36 - 44.12 minutes ($M = 31.35$, $SD = 5.44$).

2.3. Data Analysis

Thematic analysis was undertaken (Braun & Clarke, 2006, 2021). Interviews were coded using a priori topical codes according to the three assessment areas of feasibility, usability, and acceptability as defined above. Interviewing continued iteratively alongside analysis until saturation was reached. By the fifteenth interview, data analysis indicated repetition across categories, with no novel codes or concepts emerging. The research team collectively judged that the data had achieved adequate information power and thematic completeness to address the study aims. NVivo was used to organise and analyse the data. A 6-step process as advocated by Braun and Clarke (2006, 2021) was followed, and the steps followed are presented in Table 1.

This process was completed with attention to the guidance on the principles of Credibility, Transferability, Dependability, and Confirmability, following guidelines by Shenton (2004). A proportion of transcripts were independently double-

coded by a second researcher, and the resulting coding frameworks were compared to assess consistency and interpretive alignment. Discrepancies were discussed and resolved through consensus, leading to the refinement of code definitions where appropriate. A third researcher subsequently reviewed the final codes, supporting data extracts, and thematic structure to ensure that themes were firmly grounded in the data. This process of double-coding, peer debriefing, and independent verification enhanced the credibility, dependability, and confirmability of the findings.

Table 1. Process and steps followed for TA.

Step	Process	How implemented
1	Familiarisation with the data.	Data were transcribed, read, and re-read, and initial codes were noted.
2	Generation of initial codes.	Interesting features across the data set were coded, and data relevant to each code were collated.
3	Search for and identification of themes.	Codes were collated into potential themes, and data relevant to them were gathered.
4	Review themes.	Themes were assessed, combined, refined, separated, and discarded accordingly.
5	Defining and naming themes.	Operationalisation of each theme and subtheme and development of clear working definitions that capture the essence of each theme.
6	Write and produce the report.	The overall learning from the qualitative data analysis was written up, summarizing the themes and illustrating these with noteworthy quotes.

2.4. Reflexivity

The lead interviewer (a forensic psychologist and health researcher) has extensive experience working across forensic and non-forensic mental health settings, including projects exploring alternative and adjunctive interventions such as Alpha-Stim AID, physical activity, transcranial Direct Current Stimulation (tDCS), and digital health tools. This background provided valuable contextual understanding of participants' experiences but also the potential for pre-existing assumptions regarding the effectiveness of such approaches. To minimise researcher bias, reflexive practices were embedded throughout the study. These included maintaining a reflexive journal, regular debriefing with the wider research team to challenge interpretations, and ongoing discussion of emerging codes and themes to ensure that findings were grounded in participants' narratives rather than researcher expectations.

3. Results

A range of themes and subthemes were developed that were associated with "Feasibility", "Usability" and "Acceptability". These are presented in **Figure 1**.

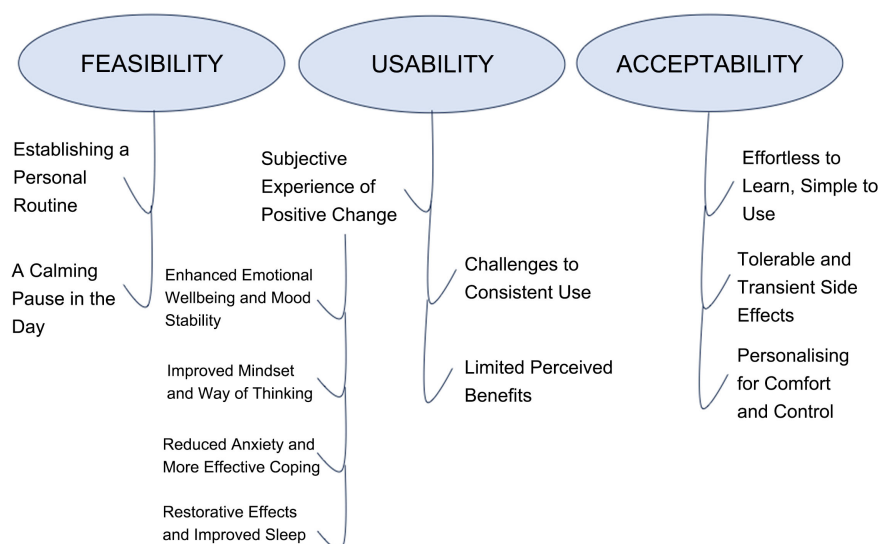


Figure 1. Themes and subthemes related to feasibility, usability, and acceptability of the Alpha-Stim AID.

3.1. Feasibility

3.1.1. Theme: Establishing a Personal Routine

Participants consistently described how they established a regular and personally meaningful routine around using the Alpha-Stim AID. This was related to “*Feasibility*” and its implementation as participants integrated its use into their daily lives in a way that felt manageable and sustainable alongside any other treatments they had in place.

Evening use was the most common time for using the Alpha-Stim AID. For many, this time of day aligned with rest, relaxation, or the completion of daily tasks, making it a convenient moment to engage with the device:

“It was part of a good routine for me that I liked. My hour in the evening, where I could chill. I just like going on it. And it means other people give me peace while I am on it.” (P4, SDR)

Others found the device complemented their existing health routines, such as scheduled times for taking medication:

“I would always do it at about the same time every evening, before I then took my morphine tablets.” (P1, SDR)

The routine implementation of Alpha-Stim AID was frequently described as calming or comforting; several participants highlighted that they felt it had a positive impact on sleep:

“Generally, I would do it an hour before bedtime because my sleep is horrendous... it seemed to relax me about 80 percent more than what I would normally. I was getting, on average, a solid three hours of sleep.” (P9, SDR)

Flexibility was important for some, with participants appreciating the fact that they could fit Alpha-Stim AID around their day as needed:

“It was a matter of having time and doing it when I wasn’t going to be disturbed.” (P12, PDR)

Across accounts, the ability to establish a personal, individualised routine helped make Alpha-Stim AID a feasible and sustainable treatment option. For many, it evolved into a “*habit*” (P10, PDR), giving them a sense of control and predictability around managing their anxiety.

3.1.2. Theme: A Calming Pause in the Day

Using the Alpha-Stim AID device for many was therapeutic and provided a dedicated time or period of calmness within their day. Having this “*calming pause*” was associated with the concept of feasibility, as it not only encouraged regular use of the Alpha-Stim AID but was low-burden and easily embedded at a chosen time. Participants consistently described their Alpha-Stim AID session as a quiet, restful hour that brought about a noticeable sense of relaxation.

“I was sitting there not moving about. So, I had a full hour of quiet time.” (P11, SDR)

Several participants appreciated the opportunity to stop, sit, rest, and take a step back from their usual responsibilities, distractions, or activities. This “*pause*” seems to be restorative:

“It allowed me to relax for an hour, if that makes sense. Because normally, I’ve just been doing something or another, and this gave me the opportunity to take an hour out of my day, and just sit and do nothing and just chill.” (P5, SDR)

The act of pausing itself was welcomed. Several participants were uncertain as to whether the calm they experienced stemmed from the Alpha-Stim AID directly or more so from the act of having an hour of quiet and stillness when using it.

“I don’t know whether it was relaxing me, or whether it was just because what I was doing was relaxing.” (P1, SDR)

Others described the experience as akin to meditation, which facilitated time and space to reflect, refocus, or simply let go of anxious thoughts:

“The Alpha-Stim gives you that time to focus on something different too. It’s a sort of form of meditation if you like. You are actually setting aside time for a form of meditation.” (P13, PDR)

For some, this hour became a protected part of their day and gave them an opportunity to take their minds off their illness, refocus, and even generate feelings of hope for their future:

“Instead of sitting there feeling sorry for yourself, for that hour you were just focused on something else... it brought a bit of sunshine and hope... it brought hope back into my life.” (P13, PDR)

Overall, this daily session became more than a treatment; it was a meaningful ritual that helped many participants slow down, refocus, pause, and ultimately feel more at ease.

3.2. Usability

3.2.1. Theme: Subjective Experience of Positive Change

The theme of “*Subjective Experience of Positive Change*” sits within “*Usability*”, reflecting how the device functioned as intended, and how its use was associated

with perceived emotional, psychological, and physical benefits that enhanced participants' overall sense of well-being. While some participants expressed uncertainty about how or why it helped, many discussed a range of positive effects that they perceived resulted from using the Alpha-Stim AID.

1) Sub-Theme: Enhanced Emotional Wellbeing and Mood Stability

Several participants described how they experienced improvement in mood and emotional state. These changes tended to be subtle but created a sense of calm, contentment, or psychological improvement that contrasted with the stress and anxiety associated with their chronic illness and breathlessness. Participants talked about feeling “*less agitated*”, “*chilled*”, or “*peaceful*”, (P2, SDR) which was different from how they typically felt. This emotional shift, even if temporary, was often described as welcome, significant, and enjoyable:

“I just felt so chilled that it was unbelievable. It was lovely.” (P4, PDR)

While it wasn't always clear how these benefits were achieved, it was perhaps due to psychological factors that participants felt calmer and more emotionally balanced. Rather than simply feeling good in the moment, participants also believed this enabled them to better manage their day ahead:

“I just felt better, calmer... like I could carry on with my day without feeling worked up.” (P4, SDR)

Overall, the emotional well-being and mood stability experienced appeared to be an important part of the perceived value and acceptability associated with using the Alpha-Stim AID.

2) Sub-Theme: Reduced Anxiety and More Effective Coping

Anxiety relief was another prominent feature of participants' narratives. Many perceived that the device helped them manage their anxiety linked to their breathlessness and “*stay on an even keel*” (P2, SDR). While the mechanism behind these effects was often unclear to participants (with some wondering if the benefits were psychological), the impact was very much valued. Participants reported how they felt a measured reduction in their anxiety.

“It eased off on my anxieties... I just felt better.” (P4, PDR)

“I had at least 25% less anxiety.” (P13, PDR)

For some, and linking to the theme “*A Calming Pause in the Day*”, simply knowing that they had a dedicated time each day to slow down and focus seemed to reduce anticipatory worry. These sessions often became part of participants' coping mechanisms, offering both structure and reassurance.

“It's just that little bit of time to yourself, and you know it's coming every day... I found that comforting. I felt more in control.” (P4, PDR)

Participants also described using the device to manage moments of acute anxiety, especially when linked to breathlessness or the fear of it. The Alpha-Stim AID provided a non-pharmacological option that helped to break the cycle of panic, even if the effect was short-term.

“Before, I'd start to panic when I couldn't get a breath, and that made it worse. But with this, I just sat down with it, and it calmed me down.” (P2, SDR)

This ability to manage the feedback loop between breathlessness causing anxiety, and anxiety then causing breathlessness, gave participants a greater sense of control over their responses to their physical symptoms of breathlessness, helping them feel less overwhelmed.

3) Sub-Theme: Restorative Effects and Improved Sleep

Participants identified improvements in sleep and rest as a positive outcome. The device appeared to support relaxation in the evenings, helping participants to unwind and settle their minds before going to bed. This was particularly noted by those who had previously struggled with insomnia or poor-quality sleep due to their anxiety or medical condition.

“I have trouble sleeping because of my disease and anxiety. I go to sleep and then I wake up after about an hour and a half, an hour wide awake. I can't go back to sleep. But when I was on that [Alpha-Stim], I slept and slept, you know, every night—it was a good night.” (P2, SDR)

Participants did not always attribute these changes directly to the device itself but seemed to associate its use with deeper or more consistent rest/sleep. Participants discussed how using the Alpha-Stim AID had a calming effect, which then led to them having a better night's sleep overall.

“I would do it an hour before bedtime because my sleep is horrendous... finding it really difficult to lie down because of my breathlessness, so it seemed to relax me about 80 percent more than what I would normally. I was getting more solid sleep.” (P9, SDR)

These restorative effects of sleep reinforced participants' motivation to continue using the device but, more importantly, contributed to an overall sense of improved well-being.

“Five days in, I would think to myself, this is working for me, this is helping me relax...great quality sleep, and the more sleep you get, the better you feel, so it's all about a circle for me.” (P14, PDR)

4) Sub-Theme: Improved Mindset and Ways of Thinking

As well as the emotional and physical effects experienced, several participants described a shift in thinking, such as in how they thought about themselves, their illness, and their ability to cope. Using the device was sometimes perceived as enabling them to have some “*mental space*” or the ability to focus more. For some, the device provided a routine that promoted reflection or offered a period of distraction from difficult thoughts. Others highlighted the importance of belief—about the device and/or the possibility that change could happen for them.

“The Alpha-Sim, because it makes you sit and think for an hour... You have got to believe in something, I think, and I think once you believe in something, it changes the way you look at things and changes the way you go about things, and I think that's what's helped.” (P13, PDR)

One participant described how the device helped them adopt a calmer mindset when faced with breathlessness, thereby avoiding the panic that would typically arise.

“During use of the machine... my mindset was different. I could sit and do my

breathing exercises, and I felt that it made a difference.” (P9, PDR)

These changes were not always easy to attribute or articulate but were nevertheless meaningful. Some described more general shifts in perspective, such as renewed “*curiosity*” (P13, PDR) about their condition, or a shift in “*frame of mind*” (P2, SDR), and how this changed the way they looked at things.

“Whether it’s the machine or the way you think, I don’t know... but it changed how I looked at things.” (P13, PDR)

Overall, this theme highlights the broader changes in thinking, mindset, and reframing that some participants experienced, which seemed to extend beyond symptom relief to a sense of hope and possibility.

3.2.2. Theme: Challenges to Consistent Use

A minority of participants did not use the Alpha-Stim AID consistently due to personal, contextual, or practical factors. This was not because of dissatisfaction with the device itself and amounted to only occasionally missing sessions. The challenges were often related to competing priorities, ill health, or “*life getting in the way*” (P5, SDR). For some, life events (e.g., a bereavement in the family for P1, SDR) or emotional strain created a temporary inability to use the device, despite a willingness to continue. Others described physical illness or exhaustion as reasons for missing sessions:

“Over Christmas, I was so poorly... I just couldn’t lift my head up off the pillow, let alone think about anything like that.” (P2, SDR)

For some individuals, day-to-day pressures interfered with using the Alpha-Stim AID. Participants mentioned forgetting to use it, e.g., “*I completely forgot*” (P11, SDR); or prioritising other responsibilities:

“I just ran out of time... I’m studying as well at the moment... so I didn’t do it at all” (P5, SDR).

Some participants discussed technical or mechanical and reliability issues, such as batteries running out or the device cutting off mid-session for an unexplained reason, which, while not insurmountable, still disrupted their intended daily routine:

“No, it was one or two days when the battery was down... there was a lull for two or three days.” (P10, SDR)

“There were a few times... it had switched itself off... I had to go back on it again” (P13, PDR).

Taken together, these examples show how usability is not solely about whether a device is *functional*, but whether it can be *integrated* into people’s lives. Temporary disruptions due to factors such as ill health, other priorities, or life events all influenced daily use and engagement. As such, supporting consistent use may require flexibility, reminders, or adaptations to work around unpredictability and competing priorities in participants’ health and daily lives.

3.2.3. Theme: Limited Perceived Benefit

While most participants experienced benefits from using the Alpha-Stim AID,

some reported little or no noticeable change in their wellbeing, despite using and engaging with the device as instructed. For some, usability in terms of physically using the machine was not problematic, but in terms of impact and outcomes, they felt they experienced no benefits. Participants described feeling “*neutral*” or unaffected by using the Alpha-Stim AID; this makes it difficult to see any rationale or benefit in continuing to use it:

“*It didn't make any difference at all to me as far as my anxiety was concerned*” (P5, SDR).

One participant initially followed the SDR and then implemented the PDR; however, they found no effect from either.

“*Unfortunately, I couldn't get the tingle in my ears... it (PDR) didn't seem to have any effect whatsoever... When I used it before, without the personalised dose, it didn't help my anxiety then either.*” (P6, PDR)

3.3. Acceptability

3.3.1. Theme: Effortless to Learn, Simple to Use

A key aspect of “*Acceptability*” noted by all participants was that the Alpha-Stim AID device was straightforward to operate and integrate into daily life. Participants repeatedly emphasised that setting up and using the device was easy, required minimal effort, and didn't feel like a burden. As such, this simplicity enhanced their engagement with it. Participants described the Alpha-Stim AID as “*simple*” (P4, SDR), “*intuitive*” (P8, SDR), or “*self-explanatory*” (P9, SDR). One participant simply reported, “*It was very easy to use*” (P6, SDR), while another described, “*Once it was on, I didn't think about it anymore*” (P1, SDR). The design was praised for its straightforwardness: “*No problems at all. It was quite straightforward*” (P6, SDR).

For some, the Alpha-Stim AID became a habitual task.

“*I would put the machine on and just let it do its thing. That was it, really.*” (P7, SDR)

“*It just becomes... habitual by using it on a daily basis.*” (P10, PDR)

Overall, the lack of technical or procedural complexity helped facilitate the use of the Alpha-Stim AID. The ease with which participants were able to use it supports its perceived acceptability as part of their treatment plan.

3.3.2. Tolerable and Transient Side Effects

In addition, “*Acceptability*” was achieved through participants overwhelmingly reporting that they experienced either no side effects or minor, short-lived, manageable side effects such as mild physical sensations, none of which interfered with their continued use.

The majority of participants simply stated they experienced no side effects whatsoever, and that the device was comfortable and unobtrusive. For example, one noted, “*It wasn't uncomfortable. It wasn't unpleasant*” (P1, SDR). Where sensations were noticed, they were typically described as mild, fleeting, and short-term.

“At first, I had a bit of a ‘muzzy’ head... but it didn’t last long. It was just like a few seconds or a minute.” (P2, SDR)

Participants who were on the PDR were often able to self-manage any discomfort by adjusting settings as per their instructions, reinforcing the fact that side effects were tolerable and could be eliminated.

“On the highest setting I did get a small amount of dizziness... but that was then sorted by reducing to level 5.” (P15, PDR)

In the few cases where side effects were slightly more intense, they were still perceived as something that would pass and were not prohibitive.

“Made me dizzy and made me a bit nauseous... but it wasn’t a lasting effect.” (P13, PDR)

Overall, the minor, short-lived nature of these sensations, and the participants’ ability to accommodate or adapt to them, contributed to the “*Acceptability*” of the Alpha-Stim AID. Even participants who initially experienced side effects typically concluded that this did not outweigh its continued use and perceived benefits.

3.3.3. Theme: Personalising for Comfort and Control

Personalised Dose Regimes (PDR) (implemented by seven participants) were perceived as acceptable because they enabled users to tailor the intensity of the Alpha-Stim AID to suit individual needs and tolerances. Participants described this as a process of trial and error to find a setting that was both detectable and comfortable, generally settling on a level that felt “*right*” for them.

“I started at 6 and then tried 7 and 8, but it was just far too much... I was getting some dizziness and was advised to move it down to 5... It was a bit of trial and error of how I was feeling, but I felt I got to the right point.” (P15, PDR)

The ability to personalise the dose and adjust the settings themselves gave users a sense of control over their experience, which in turn seemed to increase their confidence in using the device and its potential benefits.

“I get it to the right level, and then that makes me feel in control and less anxious. In control, yes.” (P10, PDR)

Many participants described finding the right level and dose as having a therapeutic benefit, including increased relaxation, reduced anxiety, and improved well-being once they had calibrated the device to their preference. Personalisation was not only about physical comfort but also about enhancing the effectiveness; this was observed by P4, who experienced both the SDR and PDR.

“Using the new dose was better—everything used to fade away. All my troubles would go into the background.” (P4, PDR)

In contrast, some participants, while on the SDR, questioned the intensity of the stimulation and expressed uncertainty about whether it had been sufficient. This uncertainty potentially undermines the acceptability of the device.

“I would like to try it with more power. I had a feeling, you know, I’ve had experience with a TENS (machine)... and I wonder if some more power would have made a difference.” (P3, SDR)

4. Discussion

Following TA of the interview data, themes were developed that were associated with “*Feasibility*” “*Usability*” and “*Acceptability*”. The Alpha-Stim AID was identified as something that could be embedded in individuals’ routines and, for most, provided a calming period of “*time out*” for them. It was perceived as having a positive impact on the majority of the participants. The device was easy to use, associated with having no or tolerable and manageable side effects, and benefited individuals further when a personalised regimen was implemented.

The feasibility of the Alpha-Stim AID has been found in other patient groups in primary care, community, and mental health settings, demonstrated through the successful integration of the device into daily schedules with minimal disruption, thereby facilitating adherence (Griffiths et al., 2023a; Royal et al., 2022). Integrating the Alpha-Stim AID into daily routines to manage anxiety and breathlessness enhances adherence and effectiveness, in line with Self-Regulation Theory, which suggests that individuals are more likely to adopt and maintain health behaviours that are compatible with their existing routines, and that foster perceptions of control (Leventhal et al., 2003). Individuals are more likely to use the Alpha-Stim AID when it does not disrupt daily life, when it can be embedded into existing daily habits, and when it requires little cognitive effort, and this enhances perceived control (Judah et al., 2018; Divine & Astill, 2025).

A clinically relevant factor regarding the feasibility of Alpha-Stim AID use was how it created an “*enforced*”, but positively experienced, period of rest, during which users had a “*pause*” in their day, which involved relaxing and engaging in a calming routine, a possible mechanism of action identified by Morriss et al. (2023). This structured downtime was found to be restorative and thus something that contributed to reductions in individuals’ anxiety and breathlessness. This aspect of Alpha-Stim AID use closely resembles principles of scheduled rest and mindfulness, which reduce anxiety and enhance self-regulation by lowering sympathetic nervous system arousal and promoting restorative processes (Zeidan et al., 2010; Keng et al., 2011). Using the Alpha-Stim AID facilitated a habitual, routine, and structured period of calm, and in doing so reduced anxiety, and this may be achieved through mechanisms similar to those described in behavioural activation (BA). BA targets and breaks negative behavioural cycles by encouraging individuals to engage in scheduled, pleasurable, or soothing activities, which over time reinforce positive emotional states (Jacobson et al., 2001). When used regularly, Alpha-Stim AID offers a calming, structured activity that can be embedded into daily routines, which promotes emotional regulation and increased perceptions of control—a key principle in BA.

Regarding “*Usability*”, participants described a positive impact they associated with their Alpha-Stim AID use. While these changes were not universally experienced or sustained across all areas of functioning, participants consistently reported experiencing benefits, such as moments of calm, improved mood, reduced anxiety, and/or better sleep. This had a meaningful and positive impact on their

well-being. These findings align with those from a systematic review by Chung et al. (2023), who found that CES use was associated with improved management of symptoms of anxiety, depression, and insomnia when used as a form of treatment for psychiatric symptoms in patients; they highlighted the usability and efficacy specifically of the Alpha-Stim AID. Similarly, Griffiths et al. (2023b) reported that patients using social prescribing services who used the Alpha-Stim AID reported meaningful improvements; half of the participants showed reliable reductions in anxiety symptoms, with one-third achieving remission. In addition, depression was reduced and health-related quality of life improved. Taken together, these outcomes suggest that regular Alpha-Stim AID use may benefit broader psychological and functioning factors.

Our research also found that some participants described subtle shifts in how they thought about and responded to their anxiety and associated breathlessness, suggesting that Alpha-Stim AID use may support changes in individuals' mindsets and their patterns of thinking. To date, research studies of Alpha-Stim AID have generally examined outcomes related to changes in symptoms (e.g., anxiety, depression) and not changes that may occur in mindset or thinking patterns. Griffiths et al. (2023a), through a qualitative examination, suggested that users may experience a shift in how they relate to anxiety (e.g., increased calmness or emotional control), but these effects have not been systematically studied. This makes the exploration of mindset change and thinking patterns a novel contribution to the literature, and something that future research should examine in more detail. The changes in thinking observed in the current study may relate to the routine of participants setting aside time to use the device and creating what we termed "*A Calming Pause in the Day*". For some, this time was used for reflection, while others found it gave them a break from negative thought patterns. Participants also talked about how using the Alpha-Stim facilitated "cognitive reframing", i.e., looking at things in a different, more positive or helpful way, giving them a sense of belief in the potential for personal change. This perhaps reflects the core concepts of hope theory (Snyder, 2002), in which renewed belief in your capacity to effect change (agency thinking) and the identification of ways to achieve it (seeing possible ways forward) are central to promoting hope. Through this lens, Alpha-Stim AID may operate not simply as a tool for managing their symptoms but also as offering psychological support to facilitate a shift in mindset, encouraging users to embrace possibility and personal change.

A minority reported that Alpha-Stim AID had a limited impact in relation to anxiety, mood, or sleep; however, they all reported feeling relaxed and calm whilst using the machine (their "*pause*" for the day). Although clinical trials and evaluations have found that Alpha-Stim AID may be effective for reducing symptoms of anxiety, depression, and insomnia, the evidence highlights that there is variability in individual responses. A meta-analysis comprising 11 randomised controlled trials found a moderate overall effect size in anxiety reduction for individuals, reporting stronger effects for those with primary anxiety disorders compared

to those with secondary anxiety; this suggests that responsiveness to treatment may be condition/diagnosis specific (Ching et al., 2022). In a pilot study with individuals with Generalised Anxiety Disorder (GAD), 50% of participants showed meaningful improvements in their symptoms, while the remaining participants experienced limited or no benefit or withdrew from the study due to side effects (Bystritsky et al., 2008). This suggests that its impact may depend on a range of factors such as diagnosis, individual expectations, treatment duration, engagement, and consistent use of the device as part of a daily routine.

All the participants described how the Alpha-Stim AID was “easy” and “simple” to set up and use. There were only a few reports of any problems with the mechanics or actual functioning of the Alpha-Stim AID. In health interventions, particularly those involving devices or digital technologies, ease of use, as a key component of usability, is critical to both engagement and adoption. When users perceive a device as intuitive, simple, and not burdensome, they are more likely to accept it and start using it, maintain engagement over time, and utilise it in ways that support therapeutic benefit (Sekhon et al., 2017).

This study found that participants reported either no, mild, transient, and/or manageable side effects associated with using the Alpha-Stim AID, and any experienced were not prohibitive of continued use. Alpha-Stim AID research consistently demonstrates minimal risk of adverse impact for different populations and across different contexts/settings (Ching et al., 2022; Barclay & Barclay, 2014). NICE (2021) reported that Alpha-Stim AID was a low-risk intervention for those diagnosed with anxiety disorder, with no associated serious side effects, and that any reported, such as dizziness, headache, or nausea, were mild, transient, and could generally be resolved by adjusting the level of CES via settings on the Alpha-Stim AID. This is in contrast to anxiety medication, which for many can have serious and prohibitive side effects, including nausea, indigestion or other gastrointestinal disturbances, jitteriness, fatigue, sexual dysfunction, sedation, cognitive impairment, and withdrawal symptoms (Melaragno, 2021).

“Acceptability” of the device was also influenced by the “Personalised Dose Regime” (PDR) as it allowed users to tailor the level of CES of the Alpha-Stim AID to suit their own individual needs and what they could tolerate. This gave individuals a sense of control over their treatment and its implementation, and increased confidence in the device and the potential benefit it may have for them, which not only enhances comfort for them, but also fosters a greater sense of autonomy and control over treatment and the management of their anxiety and breathlessness. However, it is unclear whether the PDR or the stimulation of the alpha waves was associated with the perceptions of effectiveness, suggesting that undertaking an RCT with a sham condition is needed to unpick mechanisms and causations. In addition, future research could also explore how personalised dosing impacts clinical outcomes and individuals’ adherence to Alpha-Stim AID use over time, and identify best practices and guidance for dose adjustment, so that benefits are maximised and discomfort or adverse effects are minimised.

5. Limitations

A limitation of this research is the self-selected participants who self-opted into the intervention group of a scoping study, which may limit the generalisability of the findings. Self-selected patients may also have been those more likely to have had a positive experience of Alpha-Stim, introducing potential bias. In qualitative research, sample size determination lacks a fixed rule, but data collection typically ends upon achieving saturation and obtaining satisfactory information, with a minimum sample size of ten often considered sufficient (Creswell, 2013; Polit & Beck, 2006). Due to small sample sizes, generalisability of qualitative research findings is normally not an expected attribute (Leung, 2015); this present study focused on the credibility, transferability, dependability, and confirmability of the data (Shenton, 2004). Participants were also recruited from a single service, and their experiences may not reflect those of individuals from other settings or with different clinical profiles. Using semi-structured interviews is reliant on self-report, which can be influenced by recall or social desirability bias. These participants may also have been more motivated or engaged than typical service users, and this could influence their perceptions of feasibility, usability, and acceptability. Additionally, participants' experiences were captured at a single point following an 8-week intervention, so longer-term perspectives and potential changes over time were not investigated.

6. Conclusion

The Alpha-Stim AID is a feasible, usable, and acceptable intervention for most individuals experiencing anxiety and breathlessness. Participants were generally able to embed its use into daily routines, creating a calming period of time during which they could relax and reflect. The majority experienced meaningful benefits, reporting reduced anxiety, improved mood, better sleep, and subtle shifts in mindset, such as cognitive reframing, suggesting psychological benefits beyond symptom relief. The device was intuitive, easy to use, and associated with minimal side effects, which promoted engagement and facilitated self-management. Future research should explore long-term outcomes, the mechanisms of mindset changes, which different factors may influence the efficacy of the Alpha-Stim AID, and strategies for optimising personalised dose regimes. Overall, Alpha-Stim AID shows promise as a low-burden, safe adjunctive treatment for supporting symptom management and psychological well-being for those with breathlessness and anxiety.

Conflicts of Interest

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

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