THANK YOU for taking part in the Alpha-Stim-D Trial!



We highly value your participation in the Alpha-Stim-D Trial, without your contribution we would have been unable to conduct this important research looking at an alternative treatment for depressive symptoms. Your involvement enabled us to complete the trial on time despite an initial six month delay due to the Covid-19 pandemic. We recognise that this trial took place during a challenging time for most of us, and we acknowledge that it may have been difficult for you as an individual. We really appreciate your support throughout.

To thank you for your time and valuable contribution towards the trial we would like to provide you with a summary of our key findings.



What was the Alpha-Stim-D Trial?

The Alpha-Stim-D trial was a clinical trial to see whether the Alpha-Stim AID device could help patients in Primary Care with their depressive symptoms.



Why did we do the Alpha-Stim-D Trial?

During the Covid-19 pandemic, the number of people who reported experiencing depressive and anxiety symptoms reached a record high. Despite this, current treatments for depression (medication or talking therapies) are not always helpful. People can find medication ineffective or experience side-effects. Similarly, talking therapies are not appropriate for everyone, and they can have very long waiting lists. As a result, we felt it was important to investigate an alternative treatment for depressive symptoms.



What did we do in the Alpha-Stim-D trial?

From September 2020 to January 2022, we recruited 236 participants aged 16 and above from 25 GP surgeries across Berkshire, Buckinghamshire, Derbyshire, Leicestershire, Lincolnshire, Northamptonshire, Nottinghamshire and Oxfordshire. You were all randomised in an equal 50/50 split to either receive an active or inactive Alpha-Stim device.

We asked you to use the device for an hour every day for 8 weeks and to complete some questionnaires about your health 4, 8 and 16 weeks after you received the device. Our aim was to see whether those of you who received the active device showed a greater reduction in depressive symptoms compared to those who received the inactive device. If the active device was shown to be effective, we hoped to be able to provide it as part of routine NHS care. We also contacted some of you who had kindly taken part in the trial to share your experiences of using the Alpha-Stim AID device.



What did we find?

Overall both groups, regardless of the device they had showed a decrease in depressive symptoms over the 4 months of the trial. There was no significant difference based on which device you used, which means that no evidence was found to show the effectiveness of the device for depressive symptoms.

However, we were pleased to hear that 73% of you used the device for at least half of the recommended time (minimum of 28 hours over 8 weeks), and a large majority in each group kindly completed follow-up questionnaires. Thank you once again for taking the time to complete these follow-ups. Only 17 (7%) of you reported side-effects, such as headaches, tinnitus or dizziness.



In the interviews, some of you highlighted that the device was easy to use and incorporate into daily routine, as it was portable and discreet:

"It's like, very compact as well. So, like if you did need to go for a walk or if you need to go shopping or whatever, you could just walk with it in your pocket." "It's very straightforward isn't it, you turn it on, it does its job, you put it back in its box. So yeah, it was very straightforward."

Those of you who took part in an interview also expressed that you appreciated an alternative to medication and that the device allowed some time in the day to relax.

"Antidepressants are extremely nasty drugs, so if there's something that's if it's only an hour a day and it means you don't have to take medication or something like that, then I think that's acceptable." "So, the trial, you know, when I was using it, just that bit of respite that it gave was fantastic. You can't. put a price on that... And that's what the device gave me, even if it was only for an hour or two hours... it gave me some peace and some respite from the tension.

What next?

More research needs to be done to see if using the device differently (e.g., changing the device settings) could provide benefits, as well as whether the device could help with mental health difficulties such as anxiety. Although no plans are currently in place, we would like look into this further and we will get back to you if you would like to hear further or be involved in future projects.



Thank you!!

A huge thank you to all 236 of you for taking part in the trial. Also, a big thank you to those who took the time to share their invaluable personal experiences of using the device. The successful completion of the Alpha-Stim-D trial was largely because of the involvement and commitment from everyone who kindly took part in the trial.

If you would like more details about the trial:

- > Full report: https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(23)00007-X/fulltext
- > Podcast episode: https://thelancetpsychiatry.buzzsprout.com/1391365/12130777-richard-morriss-on-cranial-electrostimulation-therapy-for-depression
- > Please contact us at <u>alpha-stim-d@nottingham.ac.uk</u> or call us (Shireen: 07929852271, Clem: 07929852207, Priya: 07790988203) if you have any questions or would like additional information.



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