Alpha-Stim-D

Participant Information Sheet (Version 1.3 Date 04/06/2020)

We would like to invite you to take part in our research study

- You are being invited to take part in a research study involving a medical device for the treatment of depression.
- Before you decide we would like you to understand why the research is being done and what it would involve for you.
- Please take time to read the information carefully. Talk to others if you wish.
- Ask us if there is anything that is not clear or if you would like more information**.**

Contents

1 What is the purpose of the study?

- Every year depression affects 1 in 6 people. Many people with depression do not consider anti-depressant medication or therapy to be helpful, or easily accessible.
- We want to find an alternative way to help people with depression who may prefer not to use medication or have not benefitted from anti-depressant medication or psychological treatment.
- We are testing the effectiveness of device called Alpha-Stim AID for the treatment of depression. It has been available to purchase in the UK since 1998. The study will help to determine whether the device should be made available on the NHS for patients with depressive symptoms.

2 What is Alpha Stim AID?

- The Alpha-Stim AID device is manufactured by a company called Electromedical Products International, and is distributed in the UK by a company called The Microcurrent Site Limited**.**
- Alpha-Stim AID works by changing the brain's electrochemical signals by sending electric currents through ear clips that are attached to your ear lobes.
- Your moods and emotions are controlled through electrochemical signals in your brain. If these signals are not working properly the hormones and neurotransmitters that regulate your emotions can become unbalanced.
- Some people tell us that they do not experience any sensation (they don't feel anything) when using the device but that they do experience an improvement in their symptoms of depression. So if you don't feel anything it doesn't mean that the device isn't working.

If you have any questions about this study, please talk to the Lead Researcher Shireen Patel on **0115 8231434**

- Alpha-Stim AID is convenient because it can be used at home whilst you are carrying out activities such as resting, reading or watching TV.

❖ More information about Alpha-Stim AID can be accessed on https://www.alpha-stim.com/

3 Why have I been asked to take part?

- We are asking people with depression who have not found anti-depressants or therapy helpful to take part in this study.

4 Do I have to take part?

- It is up to you to decide whether or not to take part.
- If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your medical care.

5 What will happen to me if I agree to take part?

If you agree to be contacted by us:

- We will call you to answer any questions you have about the study. If you are still happy to participate, we will ask you to complete a participant consent form.
- This can be completed online or posted out to you.
- **If you decide to participate:**
- Once we receive the consent form we will arrange a time for when we can ask you some questions about your physical and mental health and your use of health services.
- We will first ask some questions to determine if you are eligible for the study, if, based on your answers, we find that you are, we will ask you some further questions.
- This interview is expected to last around 1-2 hours. We can arrange to do this over the telephone or via video-calling whichever is most suitable to you. Should you incur any travel costs as a result of the study you will be reimbursed.
- If the answers you provide indicate that you are not eligible to participate, with your consent, we may inform your GP if your responses raise any concerns about your well being.

What happens next:

- We will then randomly allocate you to one of two groups. The process of determining which group you are allocated to will be completely random and like tossing a coin you will have a 50/50 chance of which group you are allocated to.
- One group will receive the active Alpha-Stim AID device. The other group will receive a device that looks exactly the same and you will not be able to tell the difference. The difference is that the second device will not send any currents. We will do this because we want to see if the active device is effective in reducing the symptoms of people using it compared to people who are using a device which does not send any current.
- With your consent we will provide your name and address details to Microcurrent Site Limited (distributers for the device in the UK) so that they can post out the device to you. The information will be provided over the phone to ensure safeguarding of your data. They will keep your details on a secure password protected database until the end of your study participation.
- You will be sent a link of a training video showing you how to use the device. If you have any questions please contact your GP surgery.
- A nurse or Health Care Assistant (HCA) from your GP surgery will call you within 72 hours after you receive the device to ask if you have any further questions or concerns.

What else will I need to do:

- You will be advised to use the device for 60 minutes at a time every day for 8 weeks in your home at a time convenient for you. You will be asked to write down some information about your use of the device. After a maximum of 10 weeks from when you receive the device it must be posted back to the Company in the SAE provided.
- We will ask all participants to complete a set of questionnaires 4, 8 and 16 weeks after the first interview. These can be completed over the phone or via video-call, whichever is most suitable for you.
- The questions will be similar to the ones we ask you at your interview and will ask about your physical and mental health and use of health services so that we can compare any changes.

We will also ask your thoughts about the device. This will take approximately 45 minutes. You will receive a £10 gift voucher for completing the final questionnaire.

- We may ask some people who take part in the study if they would like to be interviewed again. This interview is optional and will allow you to share your study experience. The interview will take place within 12 months from your initial interview. We may use anonymised quotes in reports or training materials arising from this interview.

6 What are the possible benefits of taking part?

- The questionnaires and interview you complete as part of the research will allow you to think about your symptoms and emotions and how these have changed over the research period.
- We cannot promise the study will help you but the information we get from this study may help patients in the future to get treatment that helps them manage their symptoms.

7 What are the possible disadvantages and risks of taking part?

- Some of the questions we will be asking will enquire about symptoms including emotions such as feeling anxious or low.
- Whilst most people do not mind answering these questions, some people may feel upset. It is important that we ask these questions and find out if treatment can improve these symptoms. Many people find that talking or sharing concerns can be helpful.
- If used correctly the Alpha-Stim AID device has minimal side effects and without the risk of negative effects such as addiction.
- The most common side effects are mild headaches and mild skin irritation on the earlobes.

8 What if there is a problem?

- If you have any concerns or the side-effects persist inform your GP surgery or the research team who will support you. If you have immediate worries for your safety please dial 999, or call 111 for a non-emergency number that can direct you to the best medical care. More information can be accessed at: https://www.nhs.uk/NHSEngland/AboutNHSservices/Emergencyandurgentcareservices/Pages/NHS-111.aspx
- If you have concerns about any aspects of this study for the entire duration of your participation you should ask to speak to the lead researcher, Shireen Patel, who will do their best to answer your questions. Their contact details are at the end of this information sheet. If you remain unhappy and wish to complain formally, you may contact the NHS England complaints team. They can be contacted on 0300 311 22 33.
- Any safeguarding concerns or issues of distress will be managed in line with our standard operating procedures.
- Alpha-Stim AID devices are covered by product liability insurance from the manufacturers. You will be able to claim if you are injured through using the device.

9 What will happen if I withdraw from the study?

- Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected.
- If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

10 Will my taking part in the study be kept confidential?

- We will follow ethical and legal practice and all information about you will be handled in confidence.
- If you join the study, we will use information collected from you during the course of the research. This information will be kept strictly confidential, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named below) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.
- You can find out more about how we use your information and to read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx
- The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. The research team will not access medical records or extract any data from them, access to medical records by the sponsor may be required for auditing/monitoring purposes. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. Your contact information will be kept by the University of Nottingham for 12 months after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies(unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it.
- All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.
- In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.
- The only time that we would break confidentiality and inform your GP is if we felt that we need to share information to protect your safety or the safety of others or if there is an indication that an alternative form of treatment may be more appropriate for you. We will tell you if we do this.

11 Involvement of the General Practitioner (GP):

- With your written consent, we will send a letter to your usual doctor informing them that you are taking part in this study.

12 What will happen to the results of the research study?

- The results will be publicised through the extensive arrangements for dissemination locally within the University and local NHS services (through road shows, websites, and conferences) as well as publication in peer reviewed journals, local, national and international scientific conferences.
- We will also send all participants a summary of the findings. The results will be published at the end of the study which is expected to be the end of 2022.

13 Who is organising and funding the research?

- The research study is being organised by the University of Nottingham in partnership with the University of Leicester.
- This study is funded by National Institute for Health Research (NIHR), Applied Research Collaboration (ARC) East Midlands and with funding from NHS organisations and Electromedical Products International.

14 Who has reviewed the study?

- All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity.
- This study has been reviewed and approved by East Midlands Leicester South Research Ethics Committee. The project has also been reviewed by the Health Research Authority. The Research and Innovation team within University of Nottingham have also undertaken review in accordance with University policies and procedures.
- We also developed the project with patient and public involvement and engagement (PPI/E) representatives.

15 Further information and contact details

If you have any queries or would like to talk more about the study you can contact:

Lead researcher
Shireen Patel
Tel: 0115 82314 34
NIHR ARC East Midlands
IMH Building
University of Nottingham
Nottingham
NG7 2TU

Chief Investigator
Professor Richard Morriss
Tel: 0115 8230427
NIHR ARC East Midlands
IMH Building
University of Nottingham
Nottingham
NG7 2TU

This study is funded by the National Institute for Health Research (NIHR) Applied Research Collaboration East Midlands (ARC EM). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY
NIHR | National Institute for Health Research