Ear Science Institute Australia &
Ear Sciences Centre, UWA
Suite 1, Level 2
1 Salvado Rd, Subiaco
Western Australia 6008
Tel: 08 64570541
www.earscience.org.au

Patient Information

Impact of Hearables & Behavioural Activation to Improve Mental Distress and Social Isolation in Hearing Impaired Older Adults

Investigators
Dona Jayakody (Primary), Osvaldo P. Almeida, Leon Flicker, Simon Gilbody, David Ekers, Michelle Trevenen, Suzanne Robinson, Simone Pettigrew, Marshall Makate, Melanie Ferguson, Hema Patel, Matthew Zimmermann, Kathryn Stewart, Andrew H. Ford

Introduction
Age-related hearing loss is common and currently, one in six Australians have a disabling hearing loss. Treatment can be relatively simple but traditional hearing aids are expensive and, not always indicated for mild to moderate hearing loss. Personal sound amplification products (PSAPs or 'hearables') offer a simple, cost-effective alternative to conventional hearing aids.

Hearing loss can adversely affect someone's quality of life and contribute to feelings of loneliness, social isolation and even depression. A number of psychological therapies can be helpful in these situations, but few focus on the social isolation and mental distress that is commonly associated with hearing loss.

Behavioural activation (BA) is a relatively simple psychological intervention that addresses these factors and can be delivered in-person or via the internet. The proposed randomised, controlled clinical trial will test if hearables and behavioural activation improves mental health outcomes in older adults with hearing loss.

The aims of the study
The aim of this trial is to determine if treatment of mild to moderate hearing loss with hearables and/or BA improves mood, quality of life, psychosocial function and reduces symptoms of depression in individuals over the age of 65 with mild depressive symptoms.

Personal Sound Amplification Device
PSAPs are electronic devices that can be worn over the ear or in the ear. They are able to process and amplify sound signals, and the more expensive brands are able to imitate features of hearing aids. Many also have voice control, smartphone integration, and built-in algorithms that provide additional functionalities. PSAPs have been particularly popular with people who have mild hearing loss or need to improve their hearing in certain situations only. They can also be purchased over the counter and users are able to adapt their devices to suit their preferences throughout the day.

Behavioural Activation
When feeling low, a person's motivation to do things may decrease. In the case of this study due to loss of hearing, some people may find they end up giving up hobbies or activities they used to enjoy and may not participate in social conversations due to feelings of embarrassment and frustration. This can lead to a further decline in mood. One of the ways of overcoming depression and low mood is by changing behaviour, and gradually increasing activity levels. The BA program within this study aims to encourage participants to

Ear Science Institute Australia &
Ear Sciences Centre, UWA
Suite 1, Level 2
1 Salvado Rd, Subiaco
Western Australia 6008
Tel: 08 64570541
www.earscience.org.au

increase their engagement in activities and social conversations best suited to their environment with the aim of improving mental wellbeing.

Who should participate in the study?

We require the assistance of men and women who are:

- Aged 65 and older
- Experiencing some symptoms of low mood and depression
- Are currently not using hearing aids or Hearable devices
- Competent in written and spoken English
- Willing to provide consent for participation
- Who have mild to moderate hearing loss that impacts on their function and quality of life

What will I be asked to do?

If you agree to participate a member of the research team will contact you to arrange a time and date for you to attend the Ear Science Institute Australia Clinic to complete and sign a consent form confirming your participation and a brief screening assessment if you agree. This might take up to 40-45 minutes of your time. You will be given the opportunity to ask any questions you may have. We will then go through the responses to your assessment to find out if our study could be potentially helpful for you.

If you are eligible to participate and with the support of a research officer, you will be asked to complete baseline and hearing assessments. In addition, you will also be asked to complete a cost-effective questionnaire which may take up to a further 20 minutes to complete. The cost-effective questionnaire outlines questions which may require you to detail out of pocket expense in relation to medication, time and travel if known. In total all baseline assessments including questionnaires should be complete within 90 minutes. Following this you will randomly be assigned (by chance, like the toss of a coin) to one of four groups:

Group 1 – Hearing Amplification only (PSAPs)

Those assigned to group 1 will be gifted with PSAPs as part of the trial. The PSAPs will be fitted by a member of the research team and a follow up appointment will be made in order to program the device based on user experience. If you are assigned to this group, you will also be asked to complete a diary noting down the length of time spent wearing the devices per day. You should aim to wear the device for 8 hours per day if possible, over a 12-week period. This can be broken down to 4 hours in the morning and four hours afternoon/evening. Participants will then be asked to complete follow up assessments at 12 and 26 weeks. An opportunity to complete a condensed version of the BA program following completion of the 26-week trial period will be provided to all participants in this group.

Group 2 – Behavioural Activation only

If you are assigned to the Behavioural Activation program, you will be provided with a specifically designed self-help workbook. The workbook is about maintaining mental well-being in older people. Through an 8-stage program, It outlines relevant information about depression and low mood and how to recognise depressive symptoms and take action to improve your mood. In particular, the booklet outlines how to monitor activities, keep a balance between activities and recognise the connection between activity and mood.

The 8 stage program is designed for you to complete over a 12 week period, 1 stage at a time with the last two stages of the workbook being completed together (Stages 7 & 8).Participants assigned to this group will receive a telephone call or attend a face to face appointment on a weekly basis with the study's behavioural therapist to review the principles of the program, offer help with the workbook if needed and answer any

Ear Science Institute Australia &
Ear Sciences Centre, UWA
Suite 1, Level 2
1 Salvado Rd, Subiaco
Western Australia 6008
Tel: 08 64570541
www.earscience.org.au

questions. They will also be given the opportunity to do this face to face – which ever method is suited best to the participant.

The approximate duration of these telephone sessions will be 30-45 minutes. You will then be asked to complete follow up assessments at 12 weeks and 26 weeks. Participants in this group will be provided with PSAPs at 12 weeks and requested to use them as per participants in group 1.

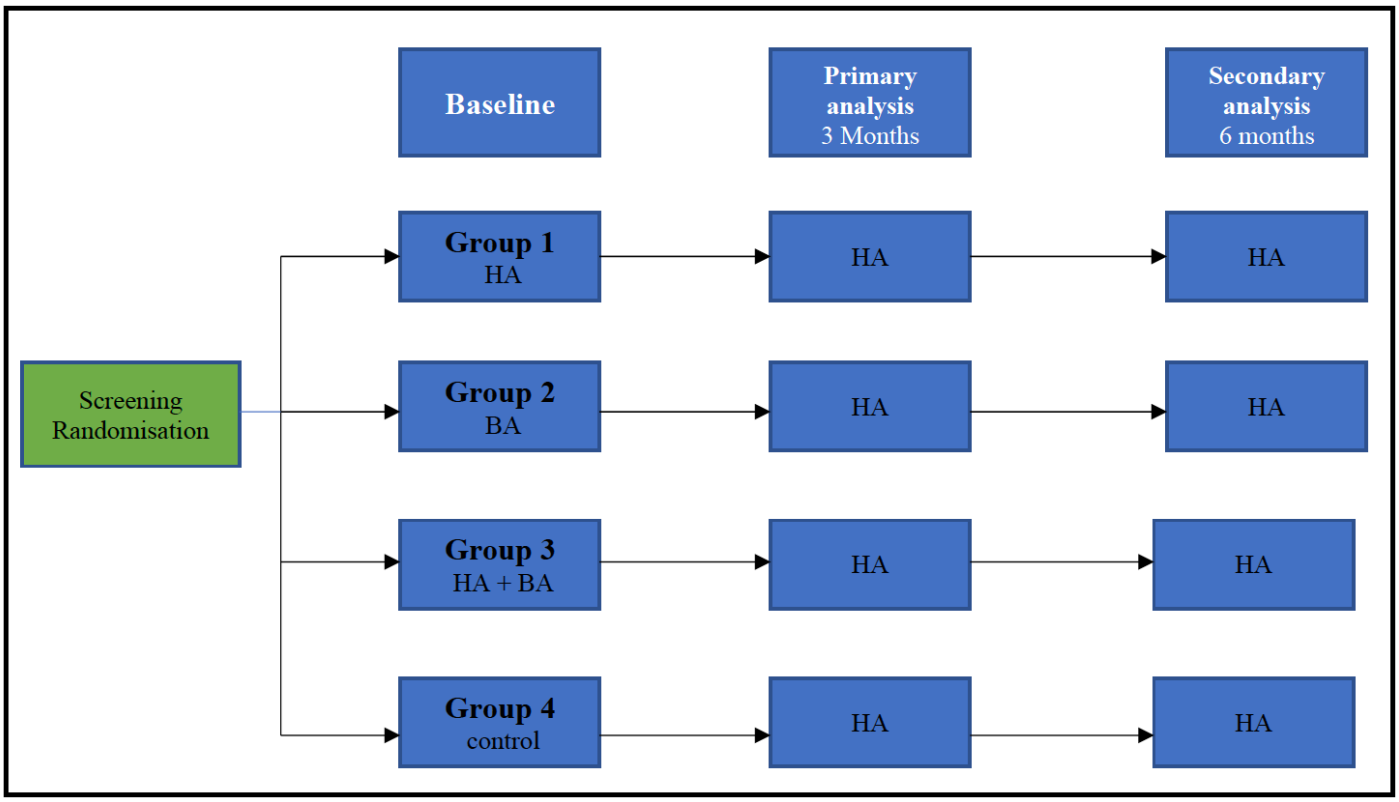
Group 3 – Hearing Amplification and Behavioural Activation

Those assigned to this group will be gifted with PSAPs and undergo the BA program (as outlined under groups 1 & 2) and complete follow up assessments at 12 & 26 weeks

Group 4 - Control

If you are in the control group you will complete all initial and follow up assessments (baseline, 12 & 26 weeks) and be provided with PSAPS after 12 weeks. You will be provided the opportunity to complete a condensed version of the BA program following completion of the 26-week trial period.

All eligible participants within the study, including those that choose to withdraw will be entitled to retain their PSAPs and will not need to return these to the research team.



Cost of participation in the study

Participation in the study will be at no cost to you.

Ear Science Institute Australia &
Ear Sciences Centre, UWA
Suite 1, Level 2
1 Salvado Rd, Subiaco
Western Australia 6008
Tel: 08 64570541
www.earscience.org.au

Are there any risks?

None of the study procedures are harmful, but you may find answering the questionnaires and participating in the assessments tiresome. Please feel free to complete the questionnaires and assessments in sections, rather than at one sitting and do not hesitate to ask the study team member for a break if needed.

Some of the questions address sensitive issues and some people may find them intrusive and potentially upsetting. Please do not hesitate to contact the investigators at any point to discuss any concerns that you may have regarding your participation in the study. In the unlikely event that you might become distressed during the study period, please contact your GP for assistance. Dr Dona Jayakody and Dr Andrew Ford from the study team can also be contacted on dona.jayakody@easrcience .org.au (08 6457 0548).

Withdrawal from the trial

Your decision to participate in this study is voluntary and you can withdraw at any time without reason. Should you choose to withdraw please notify a member of the study team by calling them on 08 6457 0548 quoting "the hearables trial". Rest assured your participation or non-participation will not affect your care. Data collected until the point of withdrawal will be used for the purpose of evaluation only unless you advise us otherwise. You are also able to retain your hearable device and will not be required to return these back to us.

How your personal information will be handled

We encourage you to nominate a GP or register with one if you don't have one. The last page of the questionnaire offers the provision to record your GP contact details. By doing so, you are consenting to the study team releasing the contents of our clinical assessments to your GP so that your GP can use this information to optimise your medical care. **Please be advised that if our assessments suggest that you may be experiencing symptoms that place you at clinically significant risk, we may have to initiate a clinical referral for further assessment as a result of our duty of care towards you.**

The data we collect from you will be handled in strict confidence and in compliance with all privacy laws (in Australia, this is the Privacy Act 1988). Your name will not appear on study documents and only duly authorised persons in the study team will have access to your data. Your name will not appear on any publications arising from this study.

The collected data will be stored on an electronic database on the university's institutional Research Data Store (IRDS drive). UWA servers have firewalls which are protected by confidential, individual password logons to prevent unauthorised access. Hard copy documents will be stored in locked filing cabinets in the trial co-ordinator's secure office in order to safeguard personal information on the grounds of Royal Perth Hospital and Ear Science Institute of Australia. The trial co-ordinator will store keys securely in her locked offices. In accordance with the WA Health Research Governance Policy and Procedures and UWA code of conduct for the practice of responsible research, information collected from consenting participants will be stored in the current authorised location (UWA – W.A. Centre for Health and Ageing or ESIA) for at least the minimum period of 15 years after publication of research findings.

Results of the trial

Upon completion of the study analysis a copy of the results and published journal article will be sent to all participants. This can also be obtained by contacting the study team on 08 6457 0548

Ear Science Institute Australia &
Ear Sciences Centre, UWA
Suite 1, Level 2
1 Salvado Rd, Subiaco
Western Australia 6008
Tel: 08 64570541
www.earscience.org.au

Further information & Responsible Investigator

Dr Dona Jayakody - Ear Science Institute Australia, 1 Salvado Road, Subiaco WA 6008
Ph: 08 6457 0548
Email: dona.jayakody@earscience.org.au

Approval to conduct this research has been provided by the University of Western Australia, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time. In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics Office at the University of Western Australia on (08) 6488 3703 or by emailing to humanethics@uwa.edu.au

All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.