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Effectiveness of active communication education to improve hearing aids adherence

Submission date
14/07/2023

Recruitment status
No longer recruiting

Registration date
18/07/2023

Overall study status
Completed

Last Edited
17/10/2024

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Untreated age-related hearing loss has a negative effect on communication, quality of life and how daily activities are performed. In addition, it is associated with a higher mortality rate, cognitive deterioration, dementia, depression and a deterioration in physical function. ARHL is one of the top five causes of disability-adjusted life-years in people over 70 worldwide. Traditional treatment for ARHL is adherence to the use of hearing aids. However, this adherence to historically low. Recent reports in the UK indicate that around 18% of people give up on using hearing aids. In developing countries like Chile, this rate is around 30%. Auditory rehabilitation programs, such as the Active Communication Education (ACE) have demonstrated efficacy in improving hearing aid adherence. Studies conducted in countries like Australia, Sweden and Chile, have demonstrated the positive impact of the ACE program on communication strategies, social engagement, and hearing aid use.

Who can participate?
Eligible participants were older adults (≥65 years) who had received hearing aids in at least one ear in the last five years through the Chilean public health system in the Metropolitan region and in the Valparaíso region, without cognitive impairment (≥ 22 on the Chilean version of the Mini-Mental State Examination [MMSE]). Participants who had lost their hearing aids or experienced technical issues with them were excluded.

What does the study involve?
The intervention group participated in the Chilean adaptation of the ACE program, which comprised six weekly 90-minute sessions. The control group participated in a social intervention designed especially for this study and administered by a speech therapist. Both interventions had the same frequency, duration, and number of participants

What are the possible benefits and risks of participating?
Participants will receive additional information and counseling about their hearing problem and their hearing aids, learn new communication strategies, meet other people with hearing loss, and learn about their hearing loss. As a potential benefit, participants could improve their hearing skills, activities of daily living and overall quality of life.The present study does not contemplate adverse effects or risks, direct or indirect.

Where is the study run from?
The present study is conducted by the Pontificia Universidad Católica de Chile who is the lead institution, together with the Universidad de las Américas as a secondary institution.

When is the study starting and how long is it expected to run for?
January 2019 to September 2022

Who is funding the study?
This work was financed by the National Commission for Scientific and Technological Research (CONICYT in Spanish), the Fund for Encouraging Scientific and Technological Development (FONDEF in Spanish), and the Government of Chile's Ministry of Health (MINSAL in Spanish) through the Fund for Health Research and Development (FONIS in Spanish, SA18I0138 and FONIS SA20I0120).

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
FONIS SA18I0138

Study information

Scientific Title
Effectiveness of Active Communication Education (ACE) to improve hearing aids adherence and successful adaptation for older adults using hearing aids in Primary Health Care Centers (PHCs): a multicenter, triple-blind randomized clinical trial

Acronym
CH-ACE

Study objectives
The implementation of the linguistically and culturally adapted version of the "Active Communication Education" program in primary health care centers (PHCs) leads to long-term changes in hearing aid adherence among older adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 04/06/2019, Scientific Ethical Committee, Southern Metropolitan Health Service (Av Santa Rosa #3453, San Miguel, Santiago, 8930821, Chile; +56 2 2576 3637; veronica.rivera@redsalud.gov.cl), ref: 23-25042019

2. approved 23/05/2019, Scientific Ethical Committee, South-West Metropolitan Health Service (Av Concha y Toro #3459, Interior, Puente Alto, Santiago, 8150215, Chile; +56 2 2576 5163; comiteeticocientifico@ssmso.cl), ref: NO2886

3. approved 09/10/2018, Scientific Ethical Committee - Faculty of Medicine of the Pontificia Universidad Católica de Chile (Diagonal Paraguay #383, Torre 11, Piso 1, Local 4, Santiago, Santiago, 8320000, Chile; +56 2 2354 8173; cecmeduc@uc.cl), ref: 180405001

Study design
Multicenter double-blind randomized parallel design clinical trial with masked outcome assessment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Age-associated hearing loss in older adult users of hearing aids implemented in the Chilean public health service.

Interventions
The experimental group will take part in the Chilean adaptation of the ACE program, which will comprise six sessions, one a week, lasting 90 minutes each. In the first session, the program, its rules, and how it works will be described. The participants in each group will introduce themselves and tell their hearing loss story. They will also talk generally about hearing in old age and the national public policy charged with supplying hearing aids. In the second session, the communication needs of the participants will be analyzed and strategies to resolve the communication problems identified by the members of the group will be discussed. In the third session, anticipatory communication strategies, as well as maintenance and repair techniques and explanations, will be dealt with, as well as how these could be applied and reinforced in everyday situations. The fourth session will deal with understanding speech in noisy environments, identifying everyday situations with these characteristics and how to overcome them. In the fifth session, communication with difficult speakers and useful strategies for these cases will be tackled. The sixth session will deal with difficulties with hearing other sources of sound, such as telephones, televisions, and doorbells. The usefulness of lip-reading will also be discussed and strategies for how to recognize the viseme associated with the expressive facial movements of certain sounds will be looked at.

The control group will receive a group intervention created especially for this study as a placebo, carried out by a speech therapist. This intervention will last the same amount of time and have the same weekly frequency as the experimental intervention. It will have a structured form, a traditional/demonstrative approach, and a passive-receptive methodology. During the first session, the functions of hearing aids and how national public policies aimed at people with hearing loss work will be explained. In the second session, age-related hearing loss and the existing rehabilitation options will be dealt with. The third session will involve a presentation on the main biological changes associated with aging and which specialists to consult in each case. The fourth session will include a presentation on the main changes and cognitive difficulties that can arise as a result of aging and how these affect communication. In the fifth, auditory self-care

related to noise exposure and hygiene will be dealt with. The sixth session will involve a review of the topics dealt with in previous sessions, providing guidelines on when to consult a speech therapist or specialist doctor.

Randomization will be carried out in stratified blocks per region using Stata v.16 software. Blocks of six candidates will be used for four possible assignment combinations. The control group will be made up of 60 subjects – 36 from the Metropolitan Region and 24 from the region of Valparaíso. The experimental group will be made up of 54 subjects – 34 from the Metropolitan Region and 20 from the region of Valparaíso.

Intervention Type
Behavioural

Primary outcome(s)
Adherence to hearing aid use is measured using Question I of the Spanish version of the International Outcome Inventory for Hearing Aids (IOI-HA) at baseline, immediately after the intervention, 6 months post-intervention, and 12 months post-intervention.

Key secondary outcome(s))
1.Successful adaptation measured using Question 1 and Question 2 of the Spanish version of the International Outcome Inventory for Hearing Aids (IOI-HA) at baseline, immediately after the intervention, 6 months post-intervention, and 12 months post-intervention
2. Generic quality of life measured using Chilean version of WHOQOL-BREF questionnaire at baseline, immediately after the intervention, 6 months post-intervention, and 12 months post-intervention

Completion date
14/09/2022

Eligibility

Key inclusion criteria
1.Seniors with hearing loss fitted with a hearing aid in at least one ear in the last five years implemented through the Chilean public health system.
2. A normal cognitive state, as shown by a score of ≥ 22 in the Chilean version of the Mini Mental State Examination (MMSE).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit

100 years

Sex
All

Total final enrolment
114

Key exclusion criteria
1. Loss or technical malfunctioning of the hearing aid.

Date of first enrolment
01/10/2019

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Chile

Study participating centre
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Pasaje Huara 5379, San Joaquín, Región Metropolitana
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Sponsor information

Organisation
Agencia Nacional de Investigación y Desarrollo

ROR
https://ror.org/02ap3w078

Funder(s)

Funder type
Government

Funder Name
Agencia Nacional de Investigación y Desarrollo

Alternative Name(s)
Agencia Nacional de Investigación y Desarrollo de Chile, National Agency for Research and Development, Government of Chile, Chilean National Agency for Research and Development, Agencia Nacional de Investigación y Desarrollo de Chile (ANID), ANID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the informed consent approved by the three ethics committees that

endorsed the study explicitly stated that the data would be used only for the purposes of the present research and that access would be authorized only for the research team, during the conduct of the research and up to 3 years after its completion.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/10/2024	17/10/2024	Yes	No
Protocol file			18/07/2023	No	No