CLINICAL TRIAL PROTOCOL

I. ADMINISTRATIVE INFORMATION

1. 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.

2. Protocol Version

The present protocol corresponds to the initial version from 2019 (v1.2019). The study officially commenced on 15/01/2019 upon receiving funding and concluded on 14/09/2022 when the final technical and financial report was submitted to the funding agency.

3. Funding

The authors declare that they have no conflicts of interest. 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 XV Fund for Health Research and Development (FONIS in Spanish, 2018, SA18I0138).

4. Roles and Responsibilities

Research Team

- Anthony Marcotti Fernández (AMF)[1, 2]: principal investigator, study design, management of ethical and institutional permissions and approvals, fieldwork coordinator in the Metropolitan Region, storage and data protection.
- Eduardo Fuentes López (EFL)[3]: study design, data analysis.

- Sebastián Rivera Retamal (SRR)[4]: study design, fieldwork coordinator in the the Valparaiso Region, intervention coordinator.
- Bernardita Alvear Veas (BAV)[5]: recruitment of subjects, implementation of the allocation sequence, assignment of subjects to control and experimental groups.

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II. INTRODUCTION

1. Background and rationale

Hearing loss is a prevalent condition among older adults, with a higher likelihood as individuals age (Goman & Lin, 2016; Homans et al., 2017; Rigters et al., 2018; Sharma et al., 2020). Untreated age-related hearing loss (ARHL) can negatively impact communication, quality of life and daily activities (Gopinath et al., 2012). ARHL is one of the top five causes of disability-adjusted life-years (DALYs) in people over 70 worldwide (Kassebaum et al., 2016). The conventional treatment for ARHL is the use of hearing aids, however, it often encounters challenges in terms of low adherence rates (Dillon et al., 2020) leading to a substantial number of potential users not using them (Bainbridge & Ramachandran, 2014). Adherence to hearing aids is influenced by personal factors like motivation and perceived benefit, and external factors such as cost and counseling (Knudsen et al., 2010).

Auditory rehabilitation programs, such as the Active Communication Education (ACE) (Hickson et al., 2007a) have demonstrated efficacy in improving hearing aid adherence. Implemented in several countries (Cardemil et al., 2014; Hickson et al., 2007a; Öberg, 2017a; Rivera et al., 2020; Watson et al., 2021a), ACE

involves group sessions led by speech therapists for adults with hearing loss and their partners. These sessions address common communication difficulties and aim to the communication abilities of people with hearing loss in everyday life. 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.

In countries such as Brazil (Ministério da Saúde, 2009), Colombia (Ministerio de Salud y Protección Social, 2013) and Chile (Ministerio de Salud, 2013), where public policies provide free hearing aids, it's crucial to identify factors associated with adherence, perceived benefit and success with hearing aids due to high rates of discontinued use (Fuentes-López et al., 2019). Programs like ACE can enhance the effectiveness of these public policies by addressing rehabilitation needs. By implementing programs like ACE, both developed and developing countries can improve outcomes for individuals with hearing loss, especially in regions where auditory rehabilitation services are limited.

Primary health care centers (PHC) are considered ideal settings for delivering the ACE program due to their easy accessibility, geographic integration within the community, and focus on promoting individual well-being while involving significant others. Therefore, this study aims to evaluate the effectiveness of the ACE program in improving adherence, perceived benefit, and success with hearing aids at PHCs.

2. Objetive

The aim of this study is to assess whether the implementation of the linguistically and culturally adapted version of the "Active Communication Education" program in primary health care centers (PHCs) will result in sustained improvements in hearing aid adherence among older adults.

3. Trial Design

A multicenter, double-blind, randomized parallel design clinical trial with blinded outcome assessment will be conducted.

III. METHODS

1. Study setting

The research setting will be primary health care centers of the Chilean public health system (Centros de Salud Familiar - CESFAM). The following establishments will participate:

- CESFAM UC Madre Teresa de Calcuta. Circunvalación 1815, Puente Alto, Región Metropolitana, Chile.
- CESFAM Carol Urzúa. Mendoza 855, San Bernardo, Región Metropolitana, Chile.
- CESFAM Santa Teresa de los Andres. Pasaje Huara 5379, San Joaquín, Región Metropolitana, Chile.
- CESFAM Barón. Blanco Viel 661, Valparaíso, Región de Valparaíso

2. Eligibility criteria

The eligibility criteria for participants in this research will be as follows: (1) seniors aged 65 and above who have experienced hearing loss and have been fitted with a hearing aid in at least one ear within the past five years through the Chilean public health system; (2) participants must demonstrate a normal cognitive state, which will be determined by scoring ≥ 22 on the Chilean version of the Mini Mental State Examination (MMSE). The exclusion criteria for participants in this study will be as follows: (1) individuals who have experienced loss or technical malfunctioning of their hearing aid.

3. 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.

4. Outcomes

The primary outcome measure of this study will be the adherence to hearing aid use, which will be assessed using Question I of the Spanish version of the International Outcome Inventory for Hearing Aids (IOI-HA). This assessment will be conducted at baseline, immediately after the intervention, and at 6 and 12 months post-intervention. The secondary outcome measures will include successful adaptation, evaluated using Question 1 and Question 2 of the Spanish version of the IOI-HA, as well as the assessment of generic quality of life using the Chilean version of the WHOQOL-BREF questionnaire. These assessments will be conducted at baseline, immediately after the intervention, and at 6 and 12 months post-intervention.

5. Sample Size

The sample size was estimated based on a similar previous study that included patients with hearing loss who participated in an ACE program in a hospital in Chile (Cardemil et al., 2014). The study utilized the International Outcome Inventory for Hearing Aids (IOI-HA) questionnaire and found that 80% of the intervention group and 40% of the control group used hearing aids for more than 8 hours. Considering these differences in proportions of hearing aid use, a one-tailed test with $\alpha=0.05$, and a power of 80% required $n=36$ patients per group. To account for a loss of 10%, it was necessary to recruit at least 40 individuals per center, for at least 80 participants in the two different regions of Chile.

6. Recruitment

The list of beneficiaries of the GES program "Bilateral Hearing Loss in individuals aged 65 and older requiring the use of a hearing aid", along with their respective contact information, will be extracted from the database of each participating CESFAM. Since the number of individuals benefiting from the GES program may vary among different CESFAMs, as well as the number of subjects who may be excluded based on certain exclusion criteria, the sample selection will

be conducted using block sampling. To accomplish this, all subjects referred to the GES program at each participating facility will be enumerated, and through a random number generator based on software, subjects to be contacted will be selected. The contacted subjects will be briefly and simply explained about the study and invited for an informational interview if they require further details. In the event of obtaining incorrect or nonexistent contact information for a subject, or receiving a negative response regarding interest in participating in the study, this procedure will continue until the required number of subjects is reached.

7. Allocation

We will randomize participants in the future using computer-generated stratified blocks per region, with each block consisting of six candidates and allowing for four possible assignment combinations. The same researcher (BAV) will be in charge of recruitment, generating the allocation sequence and assigning the subjects to the control and experimental groups.

8. Blinding

Firstly, none of the study participants will have knowledge, either before or during the study, regarding their assigned group. Therefore, they will be completely blinded. Secondly, to prevent bias from therapists who will administer both the placebo program and the rehabilitation program, they will also be blinded. All therapists will be trained in the application of both programs, with prior information that one program is a placebo and the other is the actual intervention, but they will not know which is which. As mentioned earlier, to prevent unmasking by therapists and/or study participants, the programs will have identical characteristics in terms of the number of participants, session quantity and duration, and general content coherent with an auditory-communicative rehabilitation program. However, they will vary in modality, methodological approach, and specific content. Thirdly, the data analysis for the groups and subgroups will also be blinded. The investigators responsible for data analysis will not know which intervention was implemented in each group until the final stages of analysis. This process will be monitored by the

same investigator responsible for group assignment, who will maintain a detailed record of this information.

9. Data management

The data collection and administration of assessment instruments will be carried out by professionals who have been duly trained for these purposes. All collected documents, questionnaires, protocols, and assessment tests will be promptly archived in folders designated exclusively for this purpose and immediately delivered to the responsible investigator for data collection (BAV). This investigator will be responsible for the recruitment tasks, group assignment, and maintaining masking of the other investigators. Furthermore, this same investigator will assign an alphanumeric code to each set of documents for every participating subject in the study. The documents will be organized in a digital database where the only identifier will be the previously assigned code, and they will be handed over to the responsible investigator.

10. Statistical methods

We will conduct exploratory data analysis to identify outliers and assess the distribution of all variables. Descriptive statistics will be summarized with the mean and standard deviation for normally distributed continuous variables, and the median and 1st and 3rd quartiles for non-normally distributed variables. For categorical variables, we will report the absolute and relative frequencies. The success of randomization will be evaluated by comparing the two groups for any significant differences. We will apply the Fisher exact test for categorical variables and utilize either parametric or non-parametric tests for continuous variables based on their distribution.

To assess adherence before and after the intervention, we will employ Fisher's exact test. Additionally, a proportions test will be used to compare intra-group hearing aid usage for 8 hours or more. Ordinal regression models will be utilized to determine the effect size on adherence (categories from Question 1 of the

IOI-HA) between the pre- and post-intervention scenarios. Multilevel ordinal models will be employed to estimate the effect of ACE on hearing aid adherence (different answers to Question 1 of the IOI-HA) at different time points (baseline, immediately post-intervention, and after 6 to 12 months post-intervention). Multilevel models are chosen to account for the correlation of measurements from the same individual over time. For dichotomized hearing aid use for 8 hours or more, multilevel logistic models will be used.

Regarding the perceived benefit of hearing aids, proportion tests and Fisher's exact test will be conducted to assess the perceived benefit before and after the intervention for each group. A proportion test will also be applied to compare inter-group perceived benefits after 6 and 12 months since the intervention. Negative binomial regression models will be used for the secondary outcome of success with hearing aids, establishing the effect size through relative risk (RR) considering the repeated measurements.

Furthermore, we will explore whether age, gender, economic income, pure-tone audiometry (PTA), depressive symptoms (Yesavage Scale), cognitive state (MMSE), years of education, and living situation modify the effect of ACE on adherence to hearing aid use (Question 1 from IOI-HA), perceived benefit (Question 2 from IOI-HA), and success with hearing aids. All analyses will be conducted using STATA statistical software version 17 (StataCorp, College Station, Texas).

IV. ETHICS

1. Research ethics approval

This protocol was reviewed and approved by the following Scientific Ethical Committees:

- 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
- 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
- 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

2. Consent

For the specific purposes of this study, an informed consent form was developed, reviewed, and approved by the Ethics Committees that authorized the protocol. The informed consent form includes the following sections: background of the principal investigator, study objective, research procedures, clarification of benefits, risks, costs, coverage of damages, and compensations, statement of confidentiality of information, clarification of voluntary participation, and an invitation to address any doubts before making a decision. The document is attached as an annex/other document in the corresponding section of the application platform. The informed consent form stipulates that the principal investigator or a delegated representative must be present to address any questions that may arise from the subjects after reading the informed consent form. Additionally, an institutional

representative from each CESFAM designated for this purpose, acting as a notary, must also be present for the informed consent form's signing process.

3. Confidentiality

All documents requiring tabulation will be handled anonymously using the pre-assigned alphanumeric codes. Tabulators will only have access to this anonymized information. Physical documents will be safeguarded and stored for a period of 3 years after the study's completion, under the exclusive responsibility of the Principal Investigator (AMF). These data will be stored in a locked cabinet located at the Audiology Laboratory of the Speech-Language Pathology Program in the Department of Health Sciences at Pontificia Universidad Católica de Chile, San Joaquín Campus, located at Av. Vicuña Mackenna 4860, Macul, Santiago. This study intends to present the obtained results in scientific journals and conferences; however, the names of the subjects, as well as other sensitive information as defined by Chilean Law 19.628 on the protection of privacy, will never be disclosed.

4. Risk-benefit analysis

During the course of this study, patients enrolled in both the control and experimental groups may benefit from receiving additional information and counseling regarding their hearing issues and proper use of hearing aids. They will also gain knowledge about new communication strategies for individuals with hearing problems and have the opportunity to learn from the experiences of other participants with hearing loss in their respective groups. Furthermore, both patients in the control and experimental groups, as well as their accompanying individuals, may benefit from participating in a group intervention program. Group-based audiological rehabilitation programs have been shown to reduce the psychosocial impact of hearing loss, such as the psychological and social functioning of an individual. Additionally, the information obtained from this study will be valuable in further understanding the participants' hearing issues and may potentially benefit others with the same condition.

Among the potential benefits for participants in the experimental group, expected outcomes include improvements in emotional aspects and auditory functionality, expectations of improvement, health-related quality of life, and self-perception of difficulties, general communicative functionality, and psychological well-being, as well as adherence to hearing aid use. Upon completion of the study, participants will be unmasked, provided with feedback on the results, and informed about the benefits obtained, both for the control and experimental group patients. While the control group may have been deprived of these benefits during the study, they will also be offered the opportunity to receive the ACE-based auditory intervention. This study does not present any risks, whether physical, psychological, or social, to the participants.

V. REFERENCES

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