

Evaluating the effectiveness of community-delivered hearing rehabilitation and health education intervention on social isolation and functioning among Chinese adults with hearing impairment: study protocol for a randomized controlled trial

Jiamin GAO, Yuying ZHANG, Xiaqing JIANG, Zhenjing FU, Haochen JIANG

Submitted to: JMIR Research Protocols
on: July 10, 2024

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript.....	5
Supplementary Files.....	30
Figures	31
Figure 1.....	32
Figure 2.....	33
Multimedia Appendixes	34
Multimedia Appendix 1.....	35
Multimedia Appendix 2.....	35
CONSORT (or other) checklists.....	36
CONSORT (or other) checklist 0.....	36

Evaluating the effectiveness of community-delivered hearing rehabilitation and health education intervention on social isolation and functioning among Chinese adults with hearing impairment: study protocol for a randomized controlled trial

Jiamin GAO¹ PhD; Yuying ZHANG² BEc; Xiaqing JIANG² MM; Zhenjing FU² BM; Haochen JIANG³ PhD

¹School of Sociology Beijing Normal University Beijing CN

²School of Government Beijing Normal University Beijing CN

³School of Economics and Management Fuzhou University Fuzhou CN

Corresponding Author:

Jiamin GAO PhD

School of Sociology

Beijing Normal University

No. 19 Xijiekouwai Street, Haidian District

Beijing

CN

Abstract

Background: Hearing impairment (HI) is a common sensory deficit with considerable impacts on social well-being (SWB) in adults. Evidence on the effectiveness of auditory rehabilitation and hearing health education on the social domain of hearing-impaired individuals' health are scarce.

Objective: This study aims to test the feasibility and efficacy of providing free hearing aids or a combined offline and online hearing health education intervention on social isolation and functioning among Chinese adults with HI.

Methods: This study is a three-arm, single-blinded, randomized controlled trial (RCT) with a follow-up at 24 months after the baseline study. A total of 417 participants aged 18 and above with some degree of HI will be recruited and randomly assigned to two intervention groups and one control group. Free hearing-aid provision as well as a hearing health education program which is combined with online and offline lessons will be implemented in two interventions groups, respectively. The control group will not receive any intervention. The primary outcomes include social isolation and functioning in society. The secondary outcomes include social engagement, a sense of mastery, self-efficacy, psychological resilience, chronic diseases, life satisfaction, hearing health literacy and hearing care utilization.

Results: None.

Conclusions: The findings of this study will provide evidence for the impact and cost-effectiveness of a community-based auditory or hearing health education intervention on SWB among Chinese adults with HI, which may contribute to promoting hearing health and reducing adverse health consequences in an aging society. Clinical Trial: Chinese Clinical Trial Registry ChiCTR2200062148. Registered 25 July 2022, <https://www.chictr.org.cn/showproj.html?proj=174741>

(JMIR Preprints 10/07/2024:64115)

DOI: <https://doi.org/10.2196/preprints.64115>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

✓ **No, I do not wish to publish my submitted manuscript as a preprint.**

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in the JMIR Publications

No. Please do not make my accepted manuscript PDF available to anyone.



Original Manuscript

Protocol

Jiamin GAO, Ph.D.¹; Yuying ZHANG, B.Econ.²; Xiaqing JIANG, M.Mgt.²; Zhenjing FU, B.Mgt.²; Haochen JIANG, Ph.D.³

¹School of Sociology, Beijing Normal University, Beijing, China.

²School of Government, Beijing Normal University, Beijing, China.

³School of Economics and Management, Fuzhou University, Fuzhou, China.

Corresponding Author:

Jiamin GAO, Ph.D.

School of Sociology, Beijing Normal University. No. 19 Xijiekouwai St. Haidian District, Beijing, P.R.China, 100875.

E-mail: gaojiamin@bnu.edu.cn

Phone: +86-13910276139

Fax: +86-13910276139

Evaluating the effectiveness of community-delivered hearing rehabilitation and health education intervention on social isolation and functioning among Chinese adults with hearing impairment: study protocol for a randomized controlled trial

ABSTRACT

Background: Hearing impairment (HI) is a common sensory deficit with considerable impacts on social well-being (SWB) in adults. Evidence on the effectiveness of auditory rehabilitation and hearing health education on the social domain of hearing-impaired individuals' health are scarce.

Objective: This study aims to test the feasibility and efficacy of providing free hearing aids or a combined offline and online hearing health education intervention on social isolation and functioning among Chinese adults with HI.

Methods: This study is a three-arm, single-blinded, randomized controlled trial (RCT) with a follow-up at 24 months after the baseline study. A total of 435 participants aged 18 and above with some degree of HI will be recruited and randomly assigned to two intervention groups and one control group. Free hearing-aid provision, as well as a hearing health education program which is combined with online and offline lessons, will be implemented in two interventions groups, respectively. The control group will not receive any intervention. The primary outcomes include social isolation and functioning in society. The secondary outcomes include social engagement, a sense of mastery, self-efficacy, psychological resilience, chronic diseases, life satisfaction, hearing health literacy and hearing care utilization.

Results: Participants were recruited for hearing tests in September 2022, during which baseline results were collected through in-person interviews. Follow-up interviews were conducted in September 2024. The primary analysis will use analysis of variance (ANOVA), linear mixed-effects modeling (LMM), structural equation modeling (SEM) and cost-effectiveness analysis.

Conclusions: The findings of this study will provide evidence for the impact and cost-effectiveness of a community-based auditory or hearing health education intervention on SWB among Chinese adults with HI, which may contribute to promoting hearing health and reducing adverse health consequences in an aging society.

Trial registration: Chinese Clinical Trial Registry ChiCTR2200062148. Registered 25 July 2022, <https://www.chictr.org.cn/showproj.html?proj=174741>

Keywords: Hearing impairment; Social isolation; Functioning; Community-delivered hearing interventions; Randomized controlled trial

Introduction

Background

Hearing impairment (HI) significantly impacts the health and wellbeing of adults, especially for the middle-aged and elderly. Globally, approximately 1.57 billion people had some degree of HI in 2019, with nearly 30% suffered from disabling HI and most were aged ≥ 45 years [3]. HI is associated with various negative consequences, including declines in physical and cognitive functions, increased depression and anxiety, and heightened risks of frailty, hospitalization and mortality [4-9]. Unaddressed HI often leads to significant withdrawal from the social domain of life and poor performance of functioning in society.

Social well-being (SWB), not only encompasses one's ability to establish healthy relationships and engage meaningfully with social networks, but also represents a subjective evaluation of personal life circumstances and functioning in society [10]. World Health Organization (WHO) identifies SWB is a crucial element for overall health and has prioritized worldwide to enhance social connections to fight against social isolation which is often regarded as a common reflection of poor SWB [11]. Social isolation, defined as an objective absence or paucity of contacts and interactions between a person or within a social network [12, 13], is associated with HI and often considered as a potential pathway to adverse health outcomes related to HI [14]. Communication difficulties or mental fatigue attributed to HI as well as the increased cognitive load required to compensate for auditory deficits often discourage social interactions among those HI [15-17].

Compared to social isolation, functioning in society is a broader and more comprehensive measure for assessing one's capacity to interact with others, contribute to various societal roles, and actively engage in meaningful activities, including but not limited to work, education, family life and community involvement. The International Classification of Functioning, Disability and Health (ICF), provides a framework for assessing functioning within society across three levels: body or body part, the whole person, and the whole person in a social context, corresponding to its definition of functioning encompassing all body functions, activities and participation [18]. Activity limitations and participation restrictions, which measured functions from individual and societal perspectives, are referred to a person's capacity in a standard environment and performance in a usual environment with a healthy condition. The validation of the ICF application for adults with HI and in audiological or rehabilitation research has been examined internationally [19, 20], demonstrating a positive association between hearing loss and decline in mobility, self-care or the ability get along with others [4, 21, 22]. Despite evidence supporting HI as a modifiable risk factor for social health, the efficacy of HI interventions on enhancing SWB requires further research [23, 24]. Previous studies either have shown mixed results with little consistency in the significance and magnitude of the effective of hearing intervention on social isolation or functioning [15, 25-27], or utilize small sample size, non-randomized controlled trial to

identify the causal relationships between hearing intervention and improvements in SWB [15, 28, 29]. Moreover, few interventional studies have further discussed and tested the possible mechanistic pathway through psychosocial or supportive factors, and evidence regarding developing countries is scarce.

Conceptual framework and interventions

Both the ICF and stress-buffering model provide insights into how adult-onset HI affects SWB and the effectiveness of auditory interventions. The ICF describes the bidirectional association among impairments, activity limitations and participation restrictions. Besides, functioning can be viewed as the outcome of interactions between health conditions and contextual factors which include external environmental factors (e.g., supportive environment or social attitudes) and internal personal factors (e.g., coping style and psychological resources) [18]. The ICF reveals that the ideal interventions should consider a holistic approach combining with physical, personal and environmental factors. The stress-buffering model, derived from the stress process paradigm, posits that social and coping resources can buffer (mediate or moderate) the impacts of stressors like HI on health and well-being by altering one's appraisal and coping behaviors toward a stressor or threat [30, 31]. Empirical studies support the potential psychological resilience to mediate the relationship between functional HI and SWB[16].

Intervention strategies typically focus on individual or environmental approaches. Individual strategies such as audiological training, skill development, and health education aim to utilize residual hearing through individual tailored intervention and improve communication and coping skills for hearing-impaired persons or their communication partners (CPs). Skill development and health education are person-centered approaches that can be widely promoted and applied at the community level. Either an appropriate use of hearing aids or assistive devices to compensate for auditory loss, development of self-management skills for HI, or the application of positive communications, are often considered potential effective skill-developing interventions. Educative interventions in the hearing rehabilitation context are to empower adults with HI and their CPs to adapt to hearing deficits and improve help-seeking behaviors. Hearing health education involves the dissemination of knowledge about the nature of hearing and hearing loss, communication strategies, the promotion of hearing devices or assistive technologies use, and the enhancement of psychosocial resources. Environmental strategies center on enhancing support systems within micro- and meso-environments, such as family and community, by providing information and guidance to the significant others and help them better understand the challenges faced by adults with HI, as well as fostering active communication skills, awareness and access for hearing healthcare.

In response to the WHO's guidelines on integrated person-centered ear and hearing care (IPC-EHC), we initiated the HISEA (Hearing Impairment and Social Outcomes Evaluation in Adults) project to conduct hearing interventions that targeted the social isolation and functioning of HI persons in Guangdong Province, China. This community-delivered intervention aligns with the China Disability

Action Plan (2021-2025), which emphasize the importance of promoting public awareness on hearing prevention and care through health education as well as treat HI through rehabilitative services. Figure 1 presents a diagram illustrating how the interventions developed in HISEA align with the ICF and stress-buffering framework.

Study aims and hypotheses

This full-scale randomized controlled trial (RCT) aims to evaluate the feasibility and efficacy of a community-delivered hearing aid provision and hearing health education program in improving social health among hearing-impaired adults in China. The key outcomes are reducing social isolation and enhancing societal functioning. among hearing-impaired adults in China. Additionally, it seeks to determine if psychosocial factors and social support buffer the HI-SWB linkage as well as the effects of hearing interventions on social health.

We hypothesize there will be positive effects after the long-term interventions of HAU and HHE on hearing-impaired older adults' social health, and strengthened psychological well-being could be potential pathways.

Methods

This protocol was developed and is reported according to the Standard Protocol Items for Interventional Trials (SPIRIT) [32, 33].

Ethical Considerations

Ethics approval and protocol amendmentsThe study was approved by the Chinese Ethics Committee of Registering Clinical Trials (ChiECRCT, Reference number: ChiECRCT20210561). The trial is registered on ClinicalTrials.gov (registration number: ChiCTR2200062148; date of registration: 25 July 2022). If there are any changes to the protocol, we will report to the ChiECRCT and inform the subjects. A formal amendment to the protocol will be submitted to and approved by the ethics review committee before implementation.Consent and confidentiality

During the enrollment session, pParticipants receive detailed information about the study during the enrollment session and are required to provide d written informed consent prior tobefor undergoing the auditory examination. Regardless of their inclusion in subsequent studies, participants received compensation consisting of 30 yuan in cash and a gift of daily necessities for their participation in the hearing tests. In the follow-up survey, respondents will also receive 30 yuan (≈USD\$4.2) in cash after completing the questionnaire.

Each respondent is assigned a personal identification number, which serves as a unique identifier for correlating the participants' identification details with information A personal identity (ID) number is given to each respondent, which acts as the unique link for matching the participants' identification

information with trial-related to the trail, thereby safeguarding information, to ensure confidentiality. No further identifiable features will be included in the data analysis process.

Feasibility study

Prior to the initiation of the full-scale RCT, a feasibility study was undertaken. This study involved a comprehensive review and evaluation of the overall implementation plan by community social workers and audiologists to ascertain its feasibility from a healthcare professional perspective. Additionally, a cohort of 28 hearing impaired adults was recruited from Zhaoqing City, Guangdong Province, for the purposes of conducting hearing checks and baseline interviews. During this process, we evaluated the participants' willingness to engage in the study, confirmed their comprehension of the survey questionnaires, and assessed their readiness to participate in health education initiatives or to wear hearing aids over a long period, should they be assigned to the treatment groups. We made some adjustments to the questionnaire based on the feedback from the respondents. The preliminary results validated the feasibility of our intervention study.

Study design and setting

A three-arm, single-blinded RCT with a 24-month follow-up period will be conducted. A total of 435 eligible participants were randomly assigned in a 1:1:1 ratio to a control group, a hearing aid use (HAU) group, or a hearing health education (HHE) group. The HAU group will receive hearing aids and follow-up instructions. Due to the budget constraints, the audiological rehabilitation intervention predominantly used hearing aids free provided by the Audiology Department of Guangdong Provincial Cultural Sports and Rehabilitation Assistive Devices Center for People with Disabilities (GPSRC), which affiliated to the China Disabled Persons' Federation (CDPF). Individuals diagnosed with disabling HI and classified as a person with hearing disability are eligible to apply for complimentary hearing aids and fitting services from the local CDPF departments. Since the number of hearing-disabled adults who were eligible for hearing-aid fitting was limited at in one site at the timepoint of baseline survey and intervention, a total of 139 persons with disabled HI were randomly selected from four sites with similar socioeconomic and cultural conditions. The selection was based on the list provided by GPSRC, which maintains records of hearing-disabled persons in Guangdong Province. The HHE group will undergo both offline and online educational interventions, while no interventions are planned for the control group which is similar to a natural setting. A sample of 278 adults diagnosed with some degree of HI was randomly selected and assigned into the HHE group and control group from Hualong County in Guangzhou, Guangdong based on its roster. For the HAU group, participants were prescribed hearing aids at baseline (T0) and received reinstruction on the use of hearing aids 12 months after T0. For the HHE group, participants were required to participate in an offline hearing education at T0, followed by an online educational intervention at 6 months after T0 and an offline information intervention at 12 months after T0. The primary outcomes are changes in social isolation and functioning, assessed at baseline and 24 months.

Participants

Eligible participants are adults aged ≥ 18 years with adult-onset audiometric HI, without significant cognitive impairments or neurological conditions. Participants are prescreened via telephone and in-person visits conducted by community workers and confirmed with some degree of HI through audiometric assessment by professional audiologists. The eligibility criteria are as follows:

Inclusion criteria

- a. **Age: 18 years or older.** Individuals aged ≥ 18 at the time of recruitment are eligible for the trial. This age range meets the needs of this study by targeting adult-onset HI. Besides, given that adult-onset HI is more prevalent in middle-aged and older adults, individuals who developed hearing loss after the age of 55 are preferentially included.
- b. **Residency.** Community-dwelling within the sites for the duration of the study.
- c. **Audiometric hearing impairment.** Participants must have adult-onset audiometric hearing impairment with a four-frequency (0.5, 1, 2, and 4 kHz) PTA hearing threshold ≥ 21 dB HL and ≤ 90 dB HL in a better hearing ear (ranging from mild, moderate, severe to profound hearing loss according to the WHO 2021 grades of hearing loss[2]). These grades of hearing loss indicate the level at which individuals are likely to benefit from the use of hearing aids or other amplified devices.
- d. **No significant diagnosed or self-reported history of dementia or neurological impairments.**
- e. **Communication.** Fluent in Chinese or Cantonese with basic word recognition skills.
- f. **Willing to participate, be randomized, and adhere to the protocol.** Participants must be willing and able to consent to engage in the study, be willing to participate in the interventions and commit to adhering to the study protocol until the end of the trial (24 months after the baseline survey).

Sample size calculation and recruitment

Sample size calculations are based on the expected effects of the hearing aid intervention on the primary outcome: an individual's functioning in society measured by the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0), which was developed within the ICF conceptual framework [34]. We estimate that a sample size of $N = 222$ (111 in each group) provides 85% statistical power with a 5% significance level to detect a standardized effect size of 0.404 for the difference between the HAU group and the control group in the mean change from baseline in the functioning score at the 24-month follow-up [25]. Since there is little evidence evaluating the effects of hearing aid use on social isolation using the Lubben Social Network Scale (LSNS), or the effectiveness of hearing health education on functioning and social isolation, we will assign HHE group the same sample size as the HAU group and the control group. To account for a 20% drop-in (uptake of hearing aids in the control group) and dropout (discontinuation of hearing aid use in the hearing intervention group) rate, a total of 435 individuals are included. This comprises 121 individuals in the HAU group, 158 in the HHE group, and 156 in the control group, respectively. Recruitment activities are conducted in communities and villages ($n=8$) from Guangzhou, Shanwei, Chaozhou and other areas in Guangdong Province, China. The recruitment of participants commenced on 1st September 2022 and was completed on 31st September 2022. Oral informed consent is obtained through prescreening, and written informed consent is presented by the investigator to the participant before the hearing screening. Hearing screening and assessment will be undertaken by an audiologist following a standardized procedure (see Table 1).

Table 1 Schedule of enrollment, interventions, and assessments.

Timepoint	Study period														
	Enrollment- T_1			Allocation T_0			Post- allocation T_1			Post- allocation T_2			Close-out T_4		
	-30 to -1 d			Day 0			6-month			12-month			24-month		
	T^a	T^b	C	T^a	T^b	C	T^a	T^b	C	T^a	T^b	C	T^a	T^b	C
Enrollment															
Eligibility screen	×	×	×												
Informed consent	×	×	×												
Demographics	×	×	×												
Health history	×	×	×												
Visual status	×	×	×												
Allocation				×	×	×									
Interventions															
Hearing aids provision				×						×			×		
Hearing health education					×			×			×			×	
Assessments															

Socio-demographics				×	×	×							×	×	×
Hearing outcomes															
Pure-tone audiometry				×	×	×									
HHIA score				×	×	×							×	×	×
Self-reported hearing				×	×	×							×	×	×
IOI-HA score													×		
Hearing-related health literacy				×	×	×							×	×	×
Communication ability					×	×							×	×	×
SWB (primary outcome)															
LSNS-6 score				×	×	×							×	×	×
WHODAS 2.0 score				×	×	×							×	×	×
ISE score				×	×	×							×	×	×
SEAQ score				×	×	×							×	×	×
Secondary outcomes															
GSE score				×	×	×							×	×	×
PMS score				×	×	×							×	×	×
CD-RISC score				×	×	×							×	×	×
EQ-5D-5L score				×	×	×							×	×	×
SWLS score				×	×	×							×	×	×
Covariates															
Lifestyle behaviors				×	×	×							×	×	×
Chronic diseases				×	×	×							×	×	×

Randomization, allocation and masking

After confirming eligibility and informed consent, participants are randomly stratified by HI severity and the field site to ensure balanced distribution of participants. Randomization is performed by an independent statistician who is not involved in data collection, management or analysis using a computer-generated random number sequence to assign participants to either treatment or control group[35]. Allocated interventions will not be modified unless participants voluntarily withdraw for personal reasons. Due to the nature of the interventions, complete blinding of participants and facilitators are not feasible. However, we minimize the potential biases by blinding participants to the study hypothesis, employing standardized protocols for training and tools for measurement, and masking field staff to allocation details.

Study interventions

The community-delivered interventions are developed based on the conceptual framework of ICF and stress-buffering model. For HAU group, it mainly targets at addressing HI as a stressor or physical impairment and improve personal resources for managing HI. For HHE group, it aims to eliminate or minimize the social effects of HI through enhancing hearing-impaired adults with personal and social resources on awareness, acceptance, adaption and support for HI.

Hearing rehabilitation intervention: hearing aid use group (HAU)

Participants in the hearing rehabilitation intervention treatment group are fitted with bilateral or unilateral hearing aids. The hearing aids are fitted to participants in accordance with the protocol established by the hearing aid manufacturer and the guidelines launched by CDPF with professional audiologists. Instructions on the usage of hearing aids, the proper insertion of the aids and batteries, and a comprehensive, step-by-step guide on their utilization and maintenance, are also provided. Materials for self-management and adaptation strategies are also explained and provided after the fitting services. To improve hearing aid compliance, support is offered after fitting (1 month later) to ensure that each participant is progressing with their hearing aids. In addition, a WeChat group has been established for HAU participants and audiologists to address sporadic needs from hearing aid users, such as battery replacements, cleaning, or proper storage of hearing aids. Unscheduled interim visits are necessary for troubleshooting or repairing malfunctioning hearing aids or addressing other related issues if the problem cannot be resolved through online or telephone communication. Postintervention reinstruction on the use of hearing aids is conducted 12 months after the fitting through telephone communication and the dissemination of digital materials via the WeChat group.

Hearing health education intervention (HHE)

The HHE intervention group is developed based on the Health Education Services Standard of the *National Basic Public Health Service Standard (third edition)* issued by the National Health Commission of the People's Republic of China, which provides guidance for health education for community-dwelling residents[36]. It targets hearing-impaired participants, their CPs or family members, community residents and hearing-health related community workers (i.e., social workers, local staff of CDPF and civil affairs). The objectives of HHE include improving awareness, knowledge and literacy of hearing health among individuals, families and communities, developing communication strategies and skills for hearing-impaired adults and their CPs or family members, as well as creating a supportive family and community environment that promotes social inclusion and accessibility to hearing health care services.

The HHE intervention comprises three parts. Part A is an interactive face-to-face session consisting of a hearing health lesson and counseling for hearing-impaired participants and community workers. Brochures for participants and their CPs/family members, and posters for community health education

boards are provided. The hearing health lesson is taught by the program coordinators with a written lesson plan and prepared with easily accessible teaching materials, such as paper-based visual aids or slides. Part B is an internet-based educational section that aims to reinforce the content covered in Part A through the use of the WeChat public account. It is conducted 6 months after the baseline survey targeted for hearing-impaired adults and their CPs. Part B consists of a 2-week online information support program delivering knowledge on hearing health and its consequences, positive skills and strategies for interacting with hearing-impaired adults, hearing prevention and rehabilitation guidance, and social support for adults with HI through textual, image and video formats. All interventional-related information is disseminated through the WeChat public account registered by the research team. To ensure the accessibility and reach of online information support, the research team set up a check-in task and regularly remind procedure. Part C is an offline information provision conducted 12 months after the baseline survey with the purpose of reinforcing content in Part A and Part B. Hearing health educational pamphlets are designed for all the intervention objectives and are delivered to them accordingly. The content presented in the lessons, brochures, posters, a WeChat public account and pamphlets is based on and adapted from the WHO Hearing Report (2021) and other relevant publications[37, 38]. During the design phase of the intervention, the HHE intervention settings were discussed and deliberated with experienced audiologists, community workers and community-dwelling adults with HI who would not participate in the study. It is deemed acceptable for hearing-impaired adults and their CPs in the community.

Control group

No interventions are provided for the control group considering the current situation of the hearing impairment rehabilitation:

Firstly, the prevalence of hearing aid utilization in China is notably low, and there is a lack of healthcare awareness among rural older adults experiencing HI. A population-based survey carried out between 2014 and 2015 across four provinces in China, including Guangdong, revealed that the estimated prevalence of hearing aid acquisition among rural older adults with hearing loss is 4.2%. The reasons for not having a hearing aid within this group included “not understanding its function”, “not being able to afford it”, and “not needing it” [39]. According to the China Health and Retirement Longitudinal Study 2018 data, only 3% of older adults in rural areas with subjective hearing loss self-reported experience of using hearing aids [40]. Both sets of data indicate that the resonate the natural setting for the control group.

Secondly, the policy context in Guangdong Province requires the attainment of a disability status qualification prior to the application for government-subsidized hearing aids, potentially discouraging older adults with HI from initiating the application process. The government offers subsidized hearing aids at institutions specifically established to provide services related to assistive devices for individuals

with hearing disabilities. However, it is essential for these individuals to actively secure an official assessment to obtain a disability certificate, which is a prerequisite for applying for the subsidized hearing aids. The process of obtaining disability status may be associated with social stigma, which could inhibit individuals from applying despite the availability of government subsidies. Therefore, the number of disabled individuals seeking these hearing aids remains relatively low.

Taking these two points into consideration, we have opted not to intervene with the older adults in the control group. Participants who are eligible for the control group are required to engage in both the baseline and follow-up surveys.

Outcome measures

This study investigates the 24-month impact of HAU and HHE interventions on social isolation, functioning and engagement among adults with HI, and to further explore the buffering role of psychosocial factors in these outcomes. The detailed outcomes are listed as follows:

Primary outcome measures

1. *Social isolation*, assessed by the abbreviated 6-item Chinese version of the Lubben Social Network Scale (LSNS-6), which has been recognized as a good tool to screen for social isolation among community-dwelling adults by several cross-national and cross-cultural validation studies [41, 42]. The LSNS-6 evaluates one's perceived social network or support received from family and friends
2. *Functioning*, measured by WHODAS 2.0, evaluating an individual's health-related functioning and disability across six life domains within the ICF framework [34]. WHODAS 2.0 is a cross-culturally valid tool that reflects a person's ability to participate in daily life activities (personal perspective: cognition, mobility, and self-care) and to engage with their environment (social perspective: getting along, life activities, and participation).
3. *Social engagement*, determined through a subjective assessment using the 6-item Index of Social Engagement (ISE) which describes an individual's self-evaluation of both social involvement and autonomy is used to capture subjective social engagement [43], and objective evaluations via the 10-item Social Engagement and Activities Questionnaire (SEAQ).

Secondary outcomes

Hearing health outcomes

1. *Hearing handicap* is measured by the Hearing Handicap Inventory Screening Questionnaire for Adults (HHIA). Participants' self-reported hearing status is also collected to reflect subjective HI. For the HAU group, the International Outcome Inventory for Hearing Aids (IOI-HA) will be employed during the follow-up period to verify the treatment effects of hearing aid use.
2. *Hearing-related health literacy* is measured through a set of nine questions developed by the research team based on the Knowledge, Attitude, and Practice theory. The 9-item assessment

evaluates the respondents' understanding (e.g., information on hearing health, preventive measures, and awareness of available hearing healthcare), attitudes (e.g., beliefs and attitudes toward hearing health care, willingness to prioritize and engage in hearing health activities), and behaviors (e.g., regular hearing check-ups, protection from loud noises, the use of hearing aids if needed) related to hearing health [44]. The content and validity of the 9-item questionnaire were evaluated by five experts in hearing and health education.

3. *Communication ability* is measured in the follow-up survey using the 10-item Self-Assessment of Communication (SAC), a self-report questionnaire designed to assess the impact of hearing loss and hearing intervention outcomes [45].

Psychosocial and health-related outcomes

4. *Self-efficacy* is assessed by the 10-item Chinese version of the General Self-Efficacy Scale (GSE). It has been identified as a good tool for measuring self-efficacy in community-dwelling adults [46].
5. *A sense of mastery* is measured by the 7-item Chinese version Pearlin Mastery Scale (PMS). In addition to self-efficacy, mastery serves as another psychological resource that may help mitigate the impact of stressors on wellbeing. PMS has been regarded as a well-validated measure commonly used in studies to examine adults' health and well-being outcomes [47].
6. *Psychological resilience* in the HHE group is evaluated using the 2-item Connor-Davidson Resilience Scale (CD-RISC). The 2-item CD-RISC has demonstrated good validity and reliability in the elderly or Chinese general population [48].
7. *Quality of life* includes both a subjective and an objective measure. Health-related quality of life is measured by standard tests such as the EuroQol-5 Dimensions-5 Levels (EQ-5D-5L), and the subjective well-being is measured by the 5-item Chinese version of the Satisfaction with Life Scale (SWLS).

Covariates

Socio-demographic factors (age, sex, residency, marital status, education, income status and employment), lifestyle behaviors (smoking, drinking), and health conditions (visual status, diagnosed with hypertension, diabetes or any other cardiovascular diseases, and self-reported health) of the eligible participants are collected during the baseline survey.

Statistical analysis

The intent-to-treat principle will be used during the impact analysis. The differences between the control and intervention groups in terms of primary and secondary outcomes will be evaluated through analysis of variance (ANOVA) and linear mixed-effects modeling (LMM). Multiple methods such as weighting, matching and imputation will be used to handle the problem of missing data and sample attrition. Additionally, a nonparametric bias-corrected case resampling bootstrap method, structural equation

modeling or interaction analysis will be used to further explore the buffering effect of psychosocial factors. Heterogeneity analysis will be applied to investigate whether the intervention effects are robust across subgroup samples, such as participants with different levels of objective hearing loss.

The cost-effectiveness analysis will be based on the costs of the HAU or HHE interventions and their effects on improving health-related quality of life, as measured by EQ-5D-5L. EQ-5D-5L is designed to measure generic quality of life in terms of mobility, self-care, usual activities, pain/discomfort and anxiety/depression [49]. Previous literature has employed this multi-dimensional construct of quality of life to evaluate the effect of hearing interventions [50-53].

Data collection and management

Data collection forms and procedures for data management are available upon request. All the data will be collected through a structured paper questionnaire. Trained enumerators will conduct face-to-face interviews with each eligible participant and complete the forms. Double-blind data entry will be performed to input the baseline and follow-up data into electronic form for quality assurance purposes. All information collected during the trial will be kept in strict confidence. Participant details will be stored on a secure password-protected computer disk and mobile hard disk drive. The confidentiality of the intervention objectives during qualitative interviews will be safeguarded by assigning a unique identification code to electronic sound files and transcripts of the interviews. The information will be known only to the qualitative researcher and appropriate members of the research team. The PI and data analysis personnel will have access to the final trial dataset. According to Good Clinical Practice guidelines, data will be archived for a period of 10 years after finalizing the study with participants' informed consent. To enhance protect participant confidentiality, any quotes published will be anonymous. After finalization, the key file containing information linking participants' names and contact details, will be destroyed once the project team no longer needs to contact the participants further for study purposes.

Monitoring

Data monitoring

The study is subject to local regulations. The principal investigator is responsible for developing, implementing and maintaining the quality assurance and control of all the research. During the period of sample recruitment, interim analysis will be provided strictly confidentially, which may include analyses of data from other comparable trials. Through these interim analyses, the PI will determine if the interventions or potential mechanisms have been proven, or if they differ from the expectations. The PI will decide whether to modify the trial. Unless this situation occurs, the research staff will remain unknown during the interim analysis.

Adverse events

Adverse events will be collected and recorded after informed consent and this procedure will continue until the end of the study. For those who report an adverse event after submitting the signed informed consent but before the trial intervention, the event will not be considered as an adverse event related to our intervention. Serious adverse events will be reported to the ethics review committee.

Auditing and inspecting

The PI will allow study-related audits and inspections by the ethics review committee of the documents pertaining to the research. The PI will guarantee the capability to conduct inspections of applicable study-related facilities.

Results

Trial status

The project was funded in July, 2019. The current protocol is version 3, dated January 15, 2025. The recruitment of participants and collection of baseline data began on September 1st and ended on September 30, 2022. A total of 435 participants were recruited and assigned to a random group at baseline. A follow-up survey was conducted after 24 months in September 2024, which included 397 participants. Figure 2 displays the flow diagram of the HISEA trial. Until this version of protocol, the intervention effects have remained unknown.

Preliminary results

Table 2 shows the socio-demographic characteristics of the sample at baseline. The mean age of the participants in RCT is 71.59 years [SD=9.55], with 43.09% of the sample identifying as female.

Table 2 Baseline sample characteristics.

Variables	Control group	Hearing health education group	Hearing aid use group	Total
Age ^a	74.82±9.29	71.44±6.51	67.02±11.75	71.59±9.55
Sex				
Male	56□35.90%□	56□35.67%□	75□61.98%□	247□56.91%□
Female	100□64.10%□	101□64.33%□	46□38.02%□	187□43.09%□
Education				
Illiterate	43□27.74%□	27□17.20%□	30□25.21%□	100□23.20%□
Primary school	86□55.48%□	94□59.87%□	61□51.26%□	241□55.92%□
Middle school	26□16.77%□	36□22.93%□	28□23.53%□	90□20.88%□

Variables	Control group	Hearing health education group	Hearing aid use group	Total
or higher				
Marital status				
With spouse	116 [75.32%]	95 [67.14%]	88 [76.52%]	298 [72.86%]
No spouse	38 [24.68%]	46 [32.86%]	27 [23.48%]	111 [27.14%]
Self-rated economic status				
Fair	115 [74.68%]	109 [70.32%]	24 [20.00%]	248 [57.81%]
Poor	39 [25.32%]	46 [29.68%]	96 [80.00%]	181 [42.19%]
Self-rated health				
Good	76 [48.72%]	149 [94.90%]	52 [42.98%]	277 [63.82%]
Fair	65 [41.67%]	7 [4.46%]	46 [38.02%]	118 [27.19%]
Poor	15 [9.62%]	1 [0.64%]	23 [19.01%]	39 [8.99%]
Chronic disease				
No	22 [20.00%]	39 [27.08%]	70 [61.40%]	131 [35.6%]
Yes	88 [80.00%]	105 [72.92%]	44 [38.60%]	237 [64.40%]
N	156	158	121	435

Note: ^a Mean and standard deviation are reported.

DISCUSSION

Anticipated main findings

We anticipate a significant positive effect of interventions on reducing social isolation and enhancing functioning outcomes, along with several psychological pathways which contribute to these main results.

Comparison to prior work

This randomized controlled trial assesses the impact of two interventions—provision of free hearing aids and a hearing health education program on social connections and functioning among community-dwelling Chinese adults with HI. The design of this RCT is partly similar to the ACHIEVE RCT conducted in the United States, which commenced in 2017. The ACHIEVE trial implemented a three-year hearing intervention that included audiological counselling and provision of hearing aids, alongside a control intervention on successful aging health education. A notable distinction in our study's design is the inclusion of a control group that receives no intervention, as well as the specificity of our health education to hearing-related topics. While the ACHIEVE trial primarily targeted cognitive outcomes, it also assessed some mental health and well-being outcomes [54]. In contrast, our study is specifically oriented towards social functioning. Furthermore, secondary analysis of ACHIEVE data indicated no significant association between the three-year interventions—either hearing aid provision or health

education—and health-related quality of life [55]. Our research will help examine the effectiveness of these interventions among older adults with HI within a different sociocultural context. Our use of WHO-DAS II as a generic measure in hearing-impaired population is similar to another 12-month hearing aid intervention research conducted in the USA [56].

Currently, among the completed RCTs concerning community hearing intervention rehabilitation in China, two studies exhibit similarities to our community interventions. One of these studies conducted a 20-month hearing aid intervention [51], while the other implemented a 3-month hearing aid combined with health education intervention [57]. Both studies used a two-arm design and assessed a range of outcome variables, with secondary outcomes including quality of life and social isolation. Our intervention design is characterized by a more complex three-arm intervention design and a larger sample size, which is anticipated to yield more robust evidence regarding the long-term effects of hearing interventions. To our knowledge, this will be the first RCT to evaluate the efficacy of community-delivered hearing rehabilitative and supportive interventions—both hearing aid and health education—on older adults' SWB in the context of Chinese aging society.

Strengths

This study highlights two main strengths. First, the study makes a theoretical contribution by integrating the WHO's ICF and IPC-EHC frameworks, in conjunction with the stress process model. The WHO frameworks facilitate a focus on both individual and environmental factors in the design of interventions, emphasizing social isolation and functional outcomes, which distinguishes this research from traditional studies that primarily address quality of life and cognitive functions. Within the context of the stress process model, the deterioration of hearing deterioration is conceptualized as a chronic can be considered as a chronic stressor, which may that can exert have both direct and indirect influenceseffects on psychosocial distress , potentially leading to depression[58]. Thus, the psychological pathway outlined in our hearing intervention aims to provide empirical support for the application of the stress model in the management of chronic diseases such as hearing loss, offering a detailed explanation of the role of stress within the model in relation to different health consequences. Alterations in auditory capability may necessitate long-lasting adjustments in behaviors and attitudes, giving rise to secondary stressors in other life domains (Corna et al., 2009). Evidence demonstrated that resources in coping like self-esteem and mastery can buffer the relationship between hearing loss and social well-being by influencing the process of older adults' perception, appraisal and coping when facing the declines in hearing status (J. Gao et al., 2023; L. I. Pearlin et al., 1981; Turner & Roszell, 1994).

Second, the interventions are community-oriented, which aligns with China's policy setting on hearing rehabilitation and health promotion. Currently, China's Action for Promoting Hearing Health in the Elderly mainly conducts activities based on communities, such as popularizing knowledge about hearing health, screening and public health initiatives. Besides, both online and offline elements are

blended in the interventions, which provides more convenient and efficient support and meet with current digital health trends. The findings of this study may provide valuable insights for healthcare and social workers to enhance well-being among older adults through auditory interventions.

Limitations

Despite these strengths, the trial faces several limitations.

First, the design of a one-time follow-up study presents challenges in evaluating the short-term effects of interventions, as well as their impacts beyond a 24-month period. Duration of intervention and follow-up are selected based on the following considerations: (1) Prior research has consistently shown significant findings regarding the short-term effects of hearing aid interventions; however, the medium- to long-term effects remain ambiguous, and adherence to the prolonged use of hearing aids is notably low. Our primary interest lies in investigating these medium- to long-term effects; (2) Given that the measurement tools used in both the baseline and follow-up questionnaires are fixed, we intend to extend the interval between the two measurements to mitigate potential learning effects; (3) Additionally, the constraints imposed by the project's duration and funding are considered.

Second, there is a lack of subjective measures in our survey questionnaire. To address this gap, we conducted qualitative interviews after the RCT. A subset of older adults with HI from intervention groups were inquired about their satisfaction with the use of hearing aids, their experience in health education activities, and their assessments of the health education materials. Additionally, we gathered feedback from communication partners and community workers who interact with participants during the interventions.

Third, the provision of free hearing aids may raise concerns regarding the social approval effect. Previous research on hearing aid interventions has typically involved the distribution of free devices [51, 59, 60]. In instances where there is a financial burden associated with acquiring commercial hearing aids, selection bias may arise, as economically disadvantaged older individuals may find it more challenging to participate in such interventions. The Chinese government has established a range of welfare policies aimed at supporting individuals with disabilities and the elderly, which include not only rehabilitation services, but also living subsidies for disabled individuals, long-term care insurance, and elderly care subsidies. Within this welfare framework, hearing aids do not represent a unique benefit. Therefore, we contend that the social approval effect remains within a manageable scope and is unlikely to compromise the reliability and validity of the RCT. Future research could also compare the intervention effects of paid hearing aids with those of free hearing aids.

Fourth, the interventions are conducted at different sites, which may result in geographical and selection biases. Nevertheless, the comparable socioeconomic and cultural contexts of these sites are expected to alleviate such biases. There was no pilot study due to the time and budget constraint; however, given that the social and demographic characteristics of the feasibility study site closely

resemble those of the formal trial sites, we believe this limitation does not pose a significant threat to the research design.

Fifth, our reliance on self-reported measures of social isolation and functioning may introduce measurement bias, which we will address through the use of validated tools, cross-validation, and multisource evaluations.

Lastly, although the sample size was determined using standard calculation methods, it remains relatively small, which affects its representativeness and the external validity. Randomization in a small sample may not completely eliminate the preexisting differences either. Therefore, we will further employ matching techniques or other econometric methods during the statistical analyses.

Dissemination Plan

The results of the study will be disseminated through peer-reviewed publications and national and international conference presentations to publicize and explain the research to key audiences. Dissemination authorship will be fulfilled by the research team's efforts. Information regarding public access can be seen on the Chinese Clinical Trial Registry website.

Future directions

This trial is poised to provide early insights into the feasibility, acceptability, and effectiveness of community-delivered rehabilitation interventions aimed at mitigating the social impacts of HI. The findings will inform future improvements in hearing healthcare and community-based health practices.

Acknowledgements

Authors' contributions. JG is the program leader. JG conceptualized and designed the field trial and drafted the manuscript. YZ is the program coordinator. YZ edited the manuscript and participated in questionnaire design, data management and statistical analysis after the final data collection. XJ and ZF are research assistants and participated in participant allocation, drafting the hearing health education materials, and data collection. XJ, ZF and HJ provided support in the field trial. All authors were involved in critical revision of the manuscript and approved the final version.

Funding. This work was supported by National Social Science Foundation of China (No. 19CRK009). Funders played no role in study design; data collection, management, analysis, and interpretation of data; manuscript drafting and revision; and the decision for the publication.

Other Acknowledgements. The authors would like to thank the Guangdong Provincial General Services in Developing & Supplying Aids for the Disabled and Hualong Disabled Persons' Federation for their assistance in participants recruitment and data collection. We also thank the co-authors for their important contributions and are grateful to all the participants for sharing their views

and experiences in this study. The authors also thank the National Social Science Foundation of China and Beijing Normal University for funding and sponsoring.

Data Availability

The data sets generated and analyzed during this study are not publicly available due to the confidentiality agreement reached with the participants, but are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Abbreviations

CPs communication partners

HAU hearing aid use

HHE hearing health education

HI hearing impairment

ICF International Classification of Functioning, Disability and Health

RCT randomized controlled trial

SWB social well-being

Multimedia Appendix

Multimedia Appendix 1: peer review report

Multimedia Appendix 2: SPIRIT checklist

References

1. Hickson, L., L. Worrall, and N. Scarinci, *A randomized controlled trial evaluating the active communication education program for older people with hearing impairment*. Ear and hearing, 2007. 28(2): p. 212-230.
2. Organization, W.H., *World report on hearing*. 2021: World Health Organization. 252.
3. Haile, L.M., et al., *Hearing loss prevalence and years lived with disability, 1990–2019: findings from the Global Burden of Disease Study 2019*. The Lancet, 2021. 397(10278): p. 996-1009.
4. Chen, D.S., et al., *Association of hearing impairment with declines in physical functioning and the risk of disability in older adults*. Journals of Gerontology Series A: Biomedical Sciences and Medical Sciences, 2015. 70(5): p. 654-661.
5. Lin, F.R., et al., *Hearing loss and cognitive decline in older adults*. JAMA internal medicine, 2013. 173(4): p. 293-299.
6. West, J.S., *Hearing impairment, social support, and depressive symptoms among US adults: A test of the stress process paradigm*. Social Science & Medicine, 2017. 192: p. 94-101.

7. Contrera, K.J., et al., *Association of hearing impairment and anxiety in older adults*. Journal of Aging and Health, 2017. 29(1): p. 172-184.
8. Tian, R., et al., *Association between hearing loss and frailty: a systematic review and meta-analysis*. BMC geriatrics, 2021. 21(1): p. 333.
9. Genther, D.J., et al., *Association of hearing loss with hospitalization and burden of disease in older adults*. Jama, 2013. 309(22): p. 2322-2324.
10. Keyes, C.L.M., *Social well-being*. Social psychology quarterly, 1998: p. 121-140.
11. Organization, W.H., *Summary report on proceedings minutes and final acts of the International Health Conference held in New York from 19 June to 22 July 1946*. Official Records of the World Health Organization, 1948(2).
12. de Jong Gierveld, J., T. van Tilburg, and P.A. Dykstra, *Loneliness and Social Isolation*, in *The Cambridge Handbook of Personal Relationships*, A.L. Vangelisti and D. Perlman, Editors. 2006, Cambridge University Press: Cambridge. p. 485-500.
13. Veazie, S., et al., *Addressing social isolation to improve the health of older adults: a rapid review*. 2019.
14. Mick, P., I. Kawachi, and F.R. Lin, *The association between hearing loss and social isolation in older adults*. Otolaryngol Head Neck Surg, 2014. 150(3): p. 378-84.
15. Ellis, S., S. Sheik Ali, and W. Ahmed, *A review of the impact of hearing interventions on social isolation and loneliness in older people with hearing loss*. European Archives of Oto-Rhino-Laryngology, 2021. 278(12): p. 4653-4661.
16. Gao, J., H. Hu, and H. He, *Functional Hearing Impairment, Psychological Resilience, and Social Well-Being Among Chinese Older Adults in Low-Income Households*. Journal of Speech, Language, and Hearing Research, 2023. 66(6): p. 2141-2154.
17. Alattar, A.A., et al., *Hearing impairment and cognitive decline in older, community-dwelling adults*. The Journals of Gerontology: Series A, 2020. 75(3): p. 567-573.
18. Organization, W.H., *Towards a common language for functioning, disability, and health: ICF. The international classification of functioning, disability and health*, 2002.
19. Karlsson, E., et al., *Validation of the Brief International Classification of Functioning, Disability and Health (ICF) core set for hearing loss: an international multicentre study*. International Journal of Audiology, 2021. 60(6): p. 412-420.
20. Granberg, S., et al., *The ICF core sets for hearing loss project: International expert survey on functioning and disability of adults with hearing loss using the international classification of functioning, disability, and health (ICF)*. International Journal of Audiology, 2014. 53(8): p. 497-506.
21. Lin, T.-C., M. Yen, and Y.-C. Liao, *Hearing loss is a risk factor of disability in older adults: A systematic review*. Archives of Gerontology and Geriatrics, 2019. 85: p. 103907.
22. Dai, W.-w., J.-m. Gao, and X.-y. Zheng, *Social participation restriction and its related factors among Chinese older adults with hearing disability*. 听力学及言语疾病杂志, 2020. 36(7): p. 985-989.
23. Bott, A. and G. Saunders, *A scoping review of studies investigating hearing loss, social isolation and/or loneliness in adults*. International Journal of Audiology, 2021. 60(sup2): p. 30-46.
24. Huang, A., R. O'Sullivan, and J. Lubben, *HEARING AND VISION LOSS: EPIDEMIOLOGIC AND INTERVENTION IMPLICATIONS FOR SOCIAL ISOLATION, LONELINESS, AND MOOD DISORDERS*. Innovation in Aging, 2023. 7(Suppl 1): p. 161.
25. McArdle, R., et al., *The WHO-DAS II: measuring outcomes of hearing aid intervention for adults*. Trends in Amplification, 2005. 9(3): p. 127-143.
26. Weinstein, B.E., L.W. Sirow, and S. Moser, *Relating hearing aid use to social and emotional loneliness in older adults*. American Journal of Audiology, 2016. 25(1): p. 54-61.
27. Yamada, Y., B. Švejdíková, and H. Kisvetrová, *Improvement of older-person-specific QOL after hearing aid fitting and its relation to social interaction*. Journal of communication disorders, 2017. 67: p. 14-21.

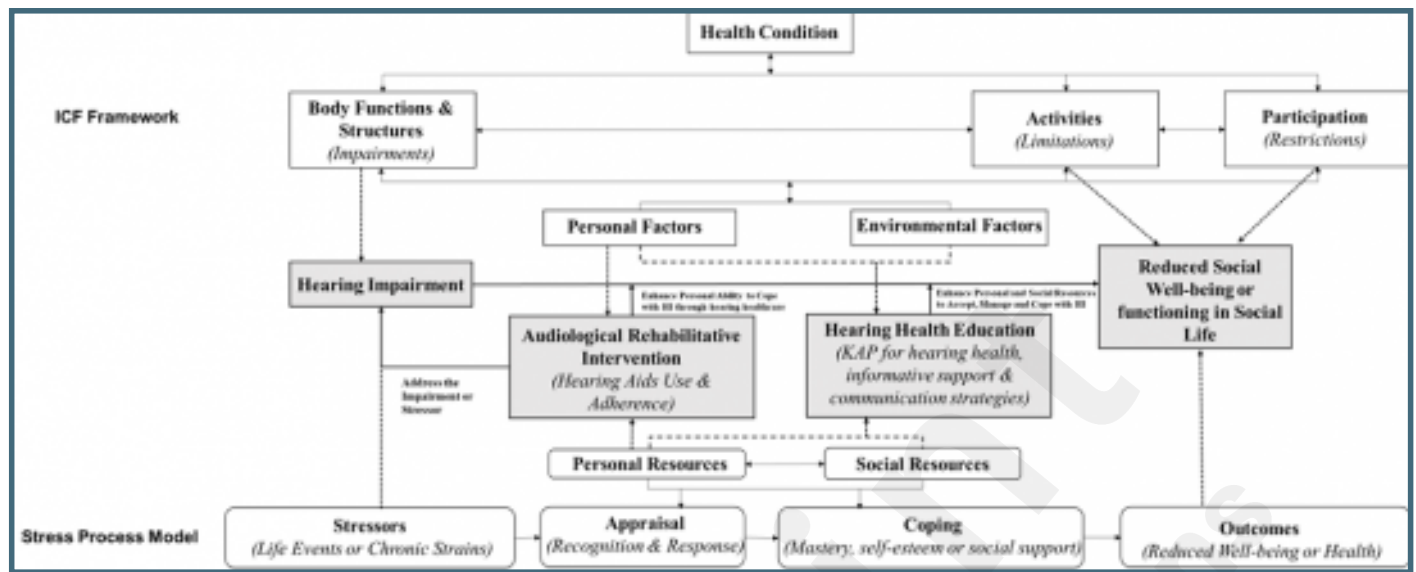
28. Jarvis, M.-A., et al., *The effectiveness of interventions addressing loneliness in older persons: an umbrella review*. International Journal of Africa Nursing Sciences, 2020. 12: p. 100177.
29. Hoang, P., et al., *Interventions associated with reduced loneliness and social isolation in older adults: a systematic review and meta-analysis*. JAMA Network Open, 2022. 5(10): p. e2236676-e2236676.
30. Pearlin, L.I., et al., *The stress process*. Journal of Health and Social behavior, 1981: p. 337-356.
31. Wheaton, B., *Models for the stress-buffering functions of coping resources*. Journal of health and social behavior, 1985: p. 352-364.
32. Chan, A.-W., et al., *SPIRIT 2013 statement: defining standard protocol items for clinical trials*. Annals of internal medicine, 2013. 158(3): p. 200-207.
33. Chan, A.-W., et al., *SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials*. Bmj, 2013. 346.
34. Üstün, T.B., *Measuring health and disability: Manual for WHO disability assessment schedule WHODAS 2.0*. 2010: World Health Organization.
35. Randomness and Integrity Services Ltd. *True Random Number Service*. Available from: <https://www.random.org>.
36. China, N.H.a.F.P.C.o.t.P.s.R.o., *National Basic Public Health Service Specification (Third Edition)*. 2017.
37. Wu, H., *Full Life Cycle Management of Hearing Health - Otology Experts Discussing Deafness and Auditory Medicine*. 2021: Shanghai Science and Technology Press.
38. Zhou, H., *Hearing Rehabilitation Guide*. 2020: People's Health Publishing House.
39. He, P., et al., *Hearing Aid Acquisition in Chinese Older Adults With Hearing Loss*. American Journal of Public Health, 2018. 108(2): p. 241-247.
40. Strauss, J.A., G. Yang, and Y. Zhao, *China Health and Retirement Longitudinal Study*.
41. Lubben, J., et al., *Performance of an abbreviated version of the Lubben Social Network Scale among three European community-dwelling older adult populations*. The Gerontologist, 2006. 46(4): p. 503-513.
42. Chang, Q., et al., *Validation of an abbreviated version of the Lubben Social Network Scale ("LSNS-6") and its associations with suicidality among older adults in China*. PloS one, 2018. 13(8): p. e0201612.
43. Mor, V., et al., *The structure of social engagement among nursing home residents*. The Journals of Gerontology Series B: Psychological Sciences and Social Sciences, 1995. 50(1): p. P1-P8.
44. Saunders, G.H., et al., *Development and evaluation of a questionnaire to assess knowledge, attitudes, and behaviors towards hearing loss prevention*. International journal of audiology, 2014. 53(4): p. 209-218.
45. Schow, R.L. and M.A. Nerbonne, *Communication screening profile: Use with elderly clients*. Ear and Hearing, 1982. 3(3): p. 135-147.
46. Wang, Y., T. Jiang, and F. Zhou, *The Chinese version of the self-efficacy scale for daily life activities among older adults: translation, validity and reliability*. Geriatric Nursing, 2023. 54: p. 46-53.
47. Pearlin, L.I. and C. Schooler, *The structure of coping*. Journal of health and social behavior, 1978: p. 2-21.
48. Davidson, J.R., & Connor, K. M., *Connor-Davidson Resilience Scale (CD-RISC) Manual*. 2017.
49. Herdman, M., et al., *Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)*. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation, 2011. 20(10): p. 1727-36.
50. Watson, J., et al., *Randomised controlled feasibility trial of an active communication education programme plus hearing aid provision versus hearing aid provision alone (ACE To HEAR)*. BMJ Open, 2021. 11(4): p. e043364.
51. Ye, X., et al., *Effects of providing free hearing aids on multiple health outcomes among middle-*

- aged and older adults with hearing loss in rural China: a randomized controlled trial.* BMC medicine, 2022. 20(1): p. 124.
52. Joore, M.A., et al., *Response shift in the measurement of quality of life in hearing impaired adults after hearing aid fitting.* Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation, 2002. 11(4): p. 299-307.
 53. Metselaar, M., et al., *Self-reported disability and handicap after hearing-aid fitting and benefit of hearing aids: comparison of fitting procedures, degree of hearing loss, experience with hearing aids and uni- and bilateral fittings.* European archives of oto-rhino-laryngology : official journal of the European Federation of Oto-Rhino-Laryngological Societies (EUFOS) : affiliated with the German Society for Oto-Rhino-Laryngology - Head and Neck Surgery, 2009. 266(6): p. 907-17.
 54. Lin, F.R., et al., *Hearing intervention versus health education control to reduce cognitive decline in older adults with hearing loss in the USA (ACHIEVE): a multicentre, randomised controlled trial.* The Lancet, 2023. 402(10404): p. 786-797.
 55. Huang, A.R., et al., *A Hearing Intervention and Health-Related Quality of Life in Older Adults: A Secondary Analysis of the ACHIEVE Randomized Clinical Trial.* JAMA Network Open, 2024. 7(11): p. e2446591-e2446591.
 56. McArdle, R., et al., *The WHO-DAS II: measuring outcomes of hearing aid intervention for adults.* trends in amplification, 2005. 9(3): p. 127-43.
 57. Qiong, W., et al., *Effectiveness evaluation of a community-based rehabilitation intervention on communication function of older adults with hearing impairment: a randomized controlled trial.* Journal of Shandong University (Health Sciences), 2024. 62(11): p. 96-104.
 58. Kramer, S.E., et al., *The association of hearing impairment and chronic diseases with psychosocial health status in older age.* Journal of aging and health, 2002. 14(1): p. 122-37.
 59. Fuchten, D., et al., *Assessing the feasibility of a randomised controlled trial examining the effect of hearing aids on cognitive decline in elderly individuals: a study protocol.* BMJ Open, 2023. 13(12): p. e074176.
 60. Chen, Y., et al., *Hearing intervention for decreasing risk of developing dementia in elders with mild cognitive impairment: study protocol of a multicenter randomized controlled trial for Chinese Hearing Solution for Improvement of Cognition in Elders (CHOICE).* Trials, 2023. 24(1): p. 767.

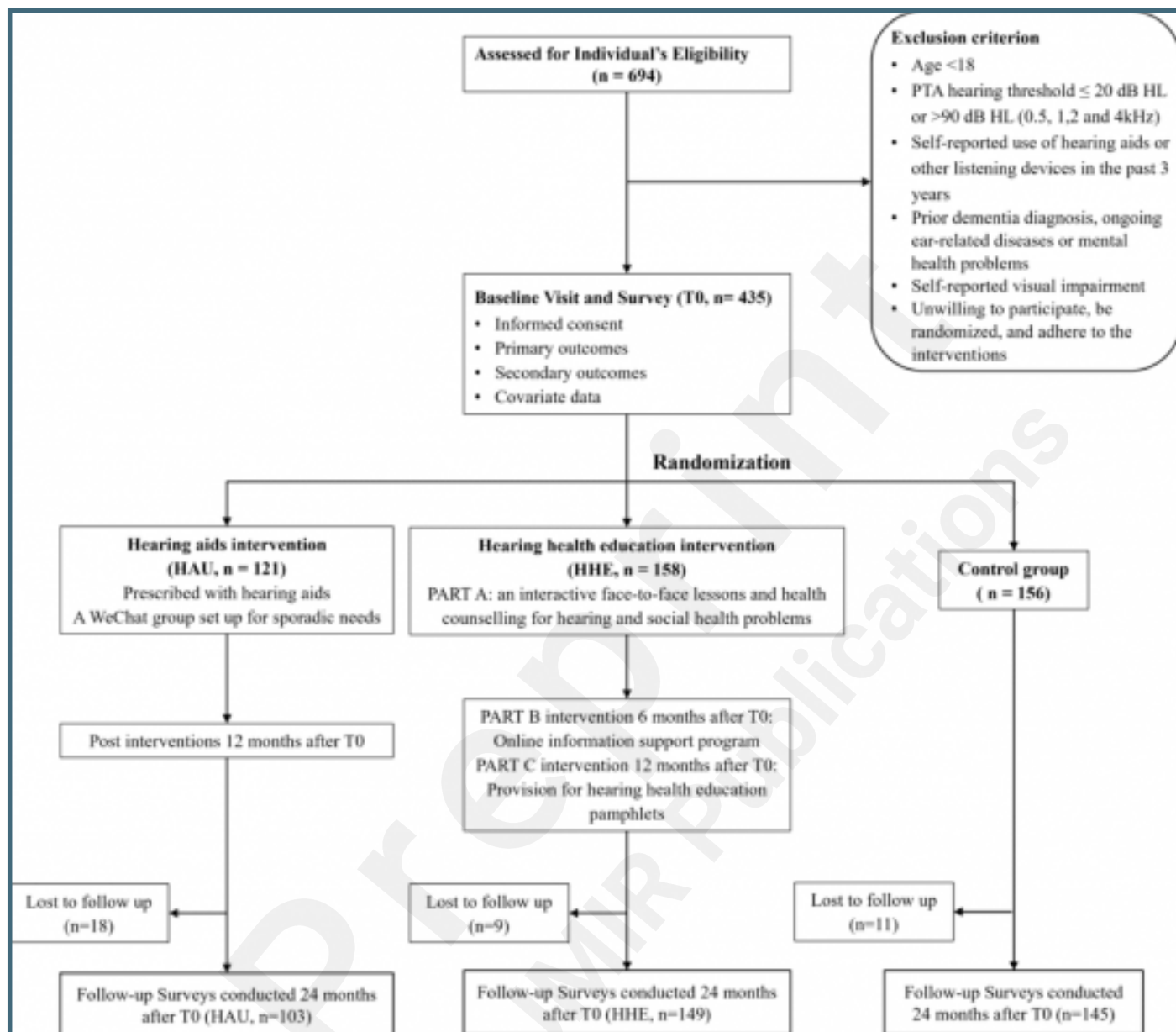
Supplementary Files

Figures

Theoretical framework of HISEA developed based on the ICF and stress-buffering model.



HISEA study flow diagram developed using SPIRIT/CONSORT.



Multimedia Appendixes

Peer review report.

URL: <http://asset.jmir.pub/assets/63ea511e45c80436dba219b5ab03a572.pdf>

SPIRIT checklist.

URL: <http://asset.jmir.pub/assets/775b0dbdfba497d11bd8fff62e92cb61.docx>



CONSORT (or other) checklists

CONSORT EHEALTH V1.6.

URL: <http://asset.jmir.pub/assets/d0ea7ab720cc073224fe7008489c7ebc.pdf>