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The effect of the "Empowerment Network for Auditory-Cognitive Training (ENACT) Program" on auditory perception and function, cognitive function and health-related quality of life of persons living with mild cognitive impairment

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Title

The effect of the "Empowerment Network for Auditory-Cognitive Training (ENACT) Program" on auditory perception and function, cognitive function and health-related quality of life of persons living with mild cognitive impairment

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Abstract

Background: Hearing loss is highly prevalent among older adults. Its deleterious effects on functional well-being, mood status, social isolation and health-related quality of life have been widely reported. The impact in persons living with mild cognitive impairment would be even more undesirable, as hearing loss would further deprive the cognitive stimulation and thereby catalyst the conversion to Alzheimer's disease.

Objectives: To develop an Empowermernt Network for Auditory-Cognitive Training (ENACT) Program to enhance the auditory and cognitive function of persons living with mild cognitive impairment (PLwMCI), and to conduct the process and outcome evaluation on the initial effects.

Methods: This is a pilot mixed method study, comprising a randomized controlled trial and a post-trail qualitative interview. A total of 62 participants will be recruited from two community center. The inclusion criteria include mild cognitive impairment accordingly to the Petersen's criteria; with at least one-side hearing impairment as defined by a score of 2- or 3- digit test greater than the norm value on the integrated Digit-in-Noise (iDIN test); has a smartphone to access the online training materials; not received formal cognitive and auditory training in the past 6 months. After the baseline outcome evaluation, they will be randomized to receive the 12-week ENACT program or the usual care control. The nurse-led ENACT program comprises three phases including i) goal-oriented health counseling phase, ii) the peer-assisted group-based auditory-cognitive training phase, and iii) the family engaged active-communication training phase. The outcome evaluation on hearing function, perceived benefit of auditory training, the cognitive function and HRQoL will be assessed at baseline, 12th and 18th week. Qualitative interview with the PLwMCI, their family members and the peer health coach will be conducted to solicit their experience in the process.

Significance: The findings will provide important insights on the feasibility, clients' perception and preliminary effect of an innovative care approach to tackle dual functional loss in PLwMCI with hearing loss.

Key issues to be addressed

Prevalence of hearing loss among older adults

Hearing loss is a prevalent chronic health condition and has been reported to increase loneliness, social isolation, and depressive symptoms, and thus affect an individual's functional performance and quality of life [1-3]. According to the report by the World Health Organization (WHO) in 2021, hearing loss affects 20% of the global population. It is estimated that 1.16 billion people worldwide now live with mild hearing loss, 430 million live with moderate to severe impairment, and 30 million with profound or complete hearing loss in both ears. [4] It is also projected that by 2050, 1 in every 4 people (2.5 billion) will have some degree of hearing, with 1 in 14 (700 million) of moderate or higher severity. [4] Hearing loss is especially prevalent among elderly population. The global prevalence of moderate or higher grades of hearing loss increases from 12.7% at the age of 60 years to over 58% at 90 years. [4] Notably, among all the people with hearing impairment, 62·1% were older than 50 years. [5]. In Hong Kong, 66.2% of older adults aged 70 years and above suffer from hearing impairment. [6]

2. The impact of hearing loss on the cognitive function of persons living with MCI

Age-related hearing loss is identified as a key risk factor for cognitive impairment and dementia. A recent meta-analysis showed that people with hearing loss are 44% more likely to have mild cognitive impairment (MCI) than those without hearing loss. [7] Substantial evidence showed the high conversion rate from MCI to Alzheimer's Disease or dementia, which is regarded as a costly health condition associated with high level of disability among older adults. [8-9] Indeed, people with MCI is more vulnerable to the impact of hearing deprivation, as the reduced sensory input would further reduce the cognitive stimulation and hamper their abilities for social and everyday life engagement.[10-11] Underpinned by the 'Use it or Lose it' phenomenon for managing cognitive decline, MCI complicated with hearing loss would set off a vicious cycle to result in a multiplying effect on functional decline, depression and poor health-related quality of life (HRQoL).[10] As such, an integrated care approach would be needed to tackle this cluster of functional impairment.

3. Current state-of-art in tackling cognitive and hearing loss

Research evidence on tackling the dual cognitive and hearing impairment is very limited. Although previous studies indicated that tackling hearing loss may have a secondary benefit on improving cognitive function and delay the onset of dementia, [12-13] a more integrated care approach to optimize both hearing and cognitive function may be needed for individuals who already developed cognitive decline. In fact, cognitive training is a standard evidence-based care to managing MCI. It is timely to explore how the management of hearing loss can be integrated to cognitive training to tackle the dual impairment.

For hearing loss, auditory rehabilitation measures include hearing technology (hearing aids, cochlear implants, and implantable aids), sign language and sensory substitution, and rehabilitative therapy (e.g. total communication approach).[4] Hearing aid is a non-invasive intervention shown to improve communication, cognition, and quality of life among older adults with cognitive impairment or dementia.[14-15]. However, several barriers still exist, including limited care accessibility, compliance issue and potential social stigmatization [16-17]. In Hong Kong, the waiting time for specialty consultation and obtaining a hearing aid need about 21 – 97 weeks. [18] Besides, self-ageism by the older adults who regard hearing and memory loss as a normal part of aging deter their motivation for

prompt care seeking. [19] Other than hearing aids, a wide variety of assistive listening devices (ALDs) including frequency modulation (FM) systems, infrared system, hearing induction loop, self-fitting hearing aids and personal sound amplification product emerged to address the communication needs for hearing loss, [20-22] However, the availability and perceived relevance of such care approach are also hampered by the similar reasons as those for hearing aids to affect the uptake rate.

Auditory training, in fact, is regarded as a more behavioral intervention to strengthen the skills and ability of older adults in receiving, understanding, interpreting and responding to hearing stimuli. The training adopted a progressive approach to develop structured content to provide training on sound awareness, sound discrimination, sound identification and sound comprehension. Structure training and counseling techniques are incorporated deliberately to improve the auditory perception of an individual, and secondary effect on cognitive functional improvement is reported [25-29]. Moreover, communication strategies are integrated as an important part of auditory training to improve the ability of an individual in interacting with the environment and social network. More specifically, total communication approach is recommended which provides sensory substitution for oral-aural communication by using visual/tactile communication. [20] Total communication consists of formal signs, natural gestures, fingerspelling, body language, listening, and speechreading, which were demonstrated to bring about good effects on the social engagement and functional performance of people with hearing loss [23-24].

To address the dual care needs for PwMCI and hearing impairment, it may be possible to integrate auditory training to cognitive training, as both of them are activity-based and focusing on increasing the attention and working memory of an individual to engage in the auditory-communication process. Moreover, auditory instruction is one of the core mediums in delivering cognitive training activities. It is highly possible to integrate the auditory training curricular to the corresponding administration process. To tackle the enhanced support need of individuals with dual functional impairment to engage in an integrated training protocol, strategies including goal-oriented approach and peer support can be integrated to optimize the empowerment network. Including family members in the training is also important, as the auditory-communication process in everyday life would take place in the social interactional context.

Aim and Objectives

1) To develop the Empowerment Network for Auditory-Cognitive Training (ENACT) Program to enhance the auditory and cognitive function of persons living with mild cognitive impairment (PLwMCI).

2) To evaluate the preliminary effects of the ENACT program on the auditory perception, auditory function, cognitive function, subjective memory complaint and health-related quality of life of PLwMCI.

3) To evaluate the experience of PLwMCI and their primary caregiver when engaged in the ENACT program.

4) To evaluate the experience of the peer health coach when assisted in delivering the ENACT program.

Research Plan & Methodology

1) Setting and subjects

The pilot randomized controlled trial will be conducted in two elderly community centers of a non-government organization in Hong Kong. The target population is the persons living with mild cognitive impairment (PLwMCI) who have hearing impairment. MCI is defined by a score of 19-26 out of the 30 on the Montreal Cognitive Assessment (education adjusted), the presence of subjective memory complaint and preserved daily activity function. [30] Hearing impairment is identified by the integrated Digit-In-Noise (DIN) test developed by L Wong with the results of 2- or 3-digit results greater than the norm value to indicate hearing loss. [31] Other inclusion criteria include: i) available of primary caregiver in the family, ii) have smart phone to receive online training materials, iii) not receive formal cognitive or auditory training in the past 6 months, iv) no other sensory impairment, and v) consent to participate. Upper confidence limit approach is used to estimate the sample size for this pilot trial. Based on the method by Sim and Lewis, [32] a total of 62 subjects are required for this two-arm study to allow the most accurate variance estimation for intervention of small to medium standardized effect size (0.2-0.6) at 80% power and 5% level of significance, with an estimated 10% attrition. SNOSE method will be used to allocate the participants to the ENACT program or control group in an 1:1 allocation ratio. A total of 127 individuals will be recruited (62 PLwMCI, 62 primary caregivers and 3 peer health coaches). For the qualitative study to explore the engaging experience in ENACT, a purposive subsample of 12 participants and their family caregivers, who completed the ENACT will be recruited. Besides, all the health coach will be interviewed for their experience of engage in the ENACT program.

2) Study interventions

The 12-week Empowerment Network on Auditory-Cognitive Training (ENACT) Program aims to offer combined auditory and cognitive training to the PLwMCI with hearing loss. A person-centered approach is used to not only engage the PLwMCI in combined auditory-cognitive training, but also to empower them and their significant others to maintain better communication, social interaction and social engagement in everyday life. Empowerment network refers to the use of collaborative and partnership approach between the nurse, family member and peer health coach to optimize and sustain the training effects of ENACT program. The ENACT Program comprises of three phases as follows:

i) Goal-oriented health counseling phase (1^{st} – 2^{nd} week) – A nurse consultation will be conducted in the center with the aim to identify the participants' experience of living with the hearing and cognitive impairment, particularly on how it affects their daily living, social engagement, coping and adaptation. Education on how such functional decline set up a vicious cycle of further impairment will be given to motivate self-directed goal setting. An agreeable action plan with consideration of the clients' preference and resource will be developed. On the followed week, the nurse will conduct a telephone visit to follow up the action plan implementation and give additional support if needed.

ii) Peer-assisted group-based auditory-cognitive training phase (3^{rd}-8^{th} week) – This phase is led and conducted by the nurse with the focus to provide combined group-based auditory and cognitive training (group size = 6) with support from the trained peers. The content for the six sessions is developed according to the hierarchy of auditory skills proposed by Erher which comprises four level of increasing difficulty including sound awareness, sound discrimination, sound identification and sound comprehension. Activities proposed by the Cognitive Symptom Management and Rehabilitation Therapy (CogSMART) on working memory training, attention bias motivation, and cognitive interpretive training are integrated in planning the auditory training activities to achieve the dual benefit.[33] To better secure the participants' confidence and motivation in learning, the training will be commenced with low difficulty level with lower level auditory training, and progressively to incorporate more cognitive training activities and higher level auditory training. A total of 2-3 trained peer health coach will join the group session to facilitate the practice. Home exercise in format of audio-scripts and online response grid are developed, so that the health coach can better engage the participants via their preferred social platform such as WhatsApp's or WeChat for two times before the next group session. Each qualified health coach has received 12- hour training which covers

effective communication with persons with auditory-cognitive impairment, instructions to administer auditory and cognitive training activities, and motivational strategies for older adults.

iii) Family engaged active-communication training phase (9^{th} – 12^{th} week) – This phase is to empower the PLwMCI and their primary caregivers on active communication strategies in the presence of hearing loss. The content is developed according to Active Communication Education (ACE Program) which developed for adults with hearing loss. [34] This phase will comprise 2 bi-weekly training sessions for the PLwMCI and 2 online training sessions with the involvement of the primary family caregivers. The online session is needed as effective communication take places in interactional and interpersonal context. The importance and strategies for the family to engage the PLwMCI in everyday decision-making and activity will also be highlighted.

In the 2^{nd} and 3^{rd} phase, the nurse will continue to monitor the goal attainment of the PLwMCI and make additional health counseling and goal adjustment accordingly.

Usual care will be provided to the control group which mainly covers the social activities offered by the affiliated center. The participants are requested not to join any activities relating to cognitive training or auditory training before the post-test data collection.

3) Data collection

The study will comply with the Declaration of Helsinki. The nurse will assess the baseline outcomes of the participants with the following validated measures before randomization. Another RA who has no information about the group assignment will conduct the post-test measure at the 12^{th} and 18^{th} week after the commencement of the intervention.

i) *A battery of cognitive assessment* will be used to evaluate various domains of cognition of the PLwMCI, including the Cantonese version of the Alzheimer's Disease Assessment Scale–Cognitive subscale (ADAS-Cog) for global cognition,[35] the digit span-forward and backward test for attention and working memory, and Trail-Making Test Part A and B for complex attention, executive function and task switching. Multiple assessments are essential for detecting subtle cognitive changes.
ii) The Glasgow Hearing Aid Benefit Profile [36] will assess the self-perceived benefit of auditory training.
iii) The Revised Hearing Handicap Inventory for the Elderly [37] to assess the perceived hearing loss.
iv) The Short-From 12 Survey to measure the overall HRQoL as well as the physical and mental health.

Upon the completion of the ENACT Program, interviews will be conducted to the participants and their family caregivers in a dyadic format. Focus group interview will be conducted to health coach. The interviews will be audiotaped with the consent of the participants. Interview guides with open-ended questions are used to guide the interviews.

4) Data analysis

Data will be analyzed on an intention-to-treat basis. Skewed variables will be transformed before subjected to analyses. Baseline characteristics between the two arms of participants will be compared using t test, chi-square test or Fisher's exact test, as appropriate. Generalized Estimating Equation will be used to compare the differential changes on the health outcomes of the PLwMCI and family caregivers across the baseline, 12^{th} week (T2) and 18^{th} Week (T3) between the two study arms, with adjustment for a set of priori control variables including age, sex, educational level and other comorbidity burden. For the qualitative data, the audio-taped interview for the participants, the family caregivers and the health coach will be transcribed verbatim by the RA. The PI will carefully review the transcribed content. Inductive thematic analysis will be used to code the data on the overall perception and perceived acceptability of ENACT. The coded units will be sorted into categories and subcategories and analyzed for recurrent themes and pattern. Within-case and across-cases analyses in each group of participants (PLwMCI, caregivers, health coach) will be conducted, and followed by cross-group analysis. Data credibility will be further maintained by conducting an audit trail.

5) Handling and storage of personal data and study data

Personal data will be stored during and after the study. Personal identifiable data (e.g., name and address) would be saved in secured computer with restricted access. USB device would not be used for participants' information nor personal data storage. Personal identifiable data would not be recorded on data collection forms and electronic files. A subject code will be used instead. Hardcopies of data sheet and consent form will be stored in locked cabinets in the Department. To protect participants' privacy, all research data would be handled in line with University policy in handling/storage/destruction of patients' medical records. They would be locked in cabinets where the department keeps patients' confidential information. The study will follow University policy. Only study investigators and research assistants involved in the study will have access to the data. PI will take the responsibility for its safekeeping. All personal and study data will be kept for five years after the study and will be destroyed according to the University and HA guidelines on handling confidential data.

6) Major ethnical issues

The study follows the Declaration of Helsinki on medical protocol and ethics. Ethics approval will be obtained from the HKU/HA HKW Institutional Review Board (HKU/HA HKW IRB). Participants are voluntary to join the study. A written informed consent, which will include the research title, purpose, explanation of the research, and the procedures of the study, will be obtained from each eligible participant. Risks and benefits are also explained clearly to the participants. Participants have the right to withdraw from the study at any time. They will be protected from discomfort and harm during the study. Further, anonymity and confidentiality of the participants will be strictly protected.

Source of funding
Seed Fund, HKU

Section VIII: deliverables (250 words – pls state when and where the initial findings will be submitted for outside funding)

As the purpose of this application is to develop evidence to strengthen the design of a full-scale trial on applying an integrated auditory and cognitive training to empower the PwMCI and their significant other to manage their hearing loss, the research evidence relating to the process and outcome evaluation will be disseminated to the clinical collaborators in three flagship non-government organization including the Young Women's Christian Association, the Tung Wah Groups Hospital and St. James Settlement in Hong Kong. In addition, this project will need to conduct community-based screening for older adults with MCI and hearing loss. By using the screening tool developed by Professor Lena Wong (Co-I), we would expect to provide screening for about 200 individuals who are at late middle age or above. Through providing training to the peer health coach, the PI's team will build the capacity for the affiliated NGO to better support the aged care service for dual hearing and cognitive impairment. All these ground work would enhance the research track record of the investigator team for the corresponding future grant submission.

The team will also make an attempt to invite oversea collaboration through the PI's engagement in the research network on hearing loss in the University of Pittsburgh (School of Nursing) to conduct a parallel study in USA. Two manuscripts will be generated to present the outcome and process evaluation of this pilot study, and the targeted journal will be Lancet Longevity and International Journal of Nursing Studies. These are Q1 journal in gerontology and nursing with very good readership in the field.

Based on the pilot study findings, a full-scale study will be submitted to the General Research Fund 2025/26

The following pathway will be used to optimize the planning of the full-scale trial and the subsequent knowledge translation.

1) Schedule a scientific forum and research fact sheet to disseminate the fidelity and preliminary effects of ENACT program for managing the dual hearing and cognitive loss among the community-dwelling soon-to-be old and older adults.
2) Conduct a discussion forum with the aged service to solicit their opinion and idea about the ENACT. A journey-mapping approach will be used to discuss the details on subject eligibility, goal-oriented health counselling, integrated auditory and cognitive training, dyadic active communication training, and health coach training and engagement.
3) Create a web-link and host in the HKU School of Nursing website disseminate the a project objectives, ENACT and preliminary results to the health care providers and public through the Hong Kong College of Gerontological Nursing, Hong Kong Association of Gerontology, and the Sau Po Centre on Aging and to collect their feedbacks and opinion on the ENACT program for tacking dual hearing and cognitive impairment.
4) To conduct a webinar to disseminate the findings to the clinical and academic network of the overseas collaborators and invite cross-country full-scale trial.
5) To disseminate the results of the pilot-scale mixed method study in the international conference hosted by the Gerontological Society of America, the International Association of Gerontology and Geriatric, and the British Society of Gerontology.
6) The pilot study research protocol and the pilot study findings will be submitted for publication in international referred journals in nursing and gerontology.

Declaration of related research work

This is a new submission and the research proposal has not been submitted for other funding.

The investigator team has conducted ground work to inform the current proposal development.

1) The PI and Dr. Chen Feng have conducted a territory-wide survey (N=4000) to identify the high prevalence of self-reported hearing loss among older adults, and this problem is strongly associated with cognitive decline and impaired health-related quality of life.

2) The PI has previously adopted strength-based, exercise-based, and cognitive-based interventions to improve the cognitive and health outcomes of persons with mild cognitive impairment. The experience will be incorporated to develop the ENACT program of the current application.

3) The Co-I (Professor Lena Wong) has developed a valid and reliable screening test on hearing loss among older adults with cognitive decline. The test will be used for screening in this application. The Co-I also has expertise in auditory training.

Pathway to impact

1. The screening results on the co-existing cognitive and hearing impairment will be disseminated to the public through the press media (including but not limited to newspaper scripts, TV programme, KE platform) to increase the public awareness of this geriatric problem in Hong Kong.

2. The initial experience of conducting this pilot ENACT program will be disseminated to the flagship nongovernment organization who are providing aged care service and dementia preventive care in Hong Kong. The stakeholders' view will be solicited to enhance the program design for future empirical testing

3. The toolkit developed for the ENACT program including communication passport, auditory training manual, active communication module for persons with MCI, the communication manual for family with PLwMCI will be shared with the aged care service stakeholders.

4. Based on the experience of using iDINT , the test will be made available to the aged care stakeholders for early detection of hearing and cognitive decline.

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