Official title of the study:

**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**

Date of document:
9th July 2024

**Upon the initial registration of this study on March 18, 2025, Version 1 was designated as the updated file. The first amendment application for the consent form was submitted on April 24. Following approval by the ethics committee, the revised version will be uploaded. **

**School of Nursing, LKS Faculty of Medicine,**
**The University of Hong Kong**

# 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

## Information Sheet
## (Participant and primary family caregiver)

You are invited to participate in a project entitled "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", which is conducted by the School of Nursing, LKS Faculty of Medicine, The University of Hong Kong. Before you decide, it is important that you understand why the research is done and how you will be involved. Please read the information carefully and discuss it with relatives, friends and your family doctor if you wish. Ask if there is anything unclear of if you wish to obtain more information. Take time to decide whether you wish to participate in the research.

**Project 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

**Purpose of the Study**
The overall aim of this project is to

i) developing the Empowerment Network for Auditory-Cognitive Training (ENACT) Program to enhance the auditory and cognitive function of persons living with mild cognitive impairment (PLwMCI),
ii) evaluating 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,
iii) evaluating the experience of PLwMCI and their primary caregiver when engaged in the ENACT program,
iv) evaluating the experience of the peer health coach when assisted in delivering the ENACT program.

**Nature of Participation**
Individual will be invited to participate in this study.
The criteria of the participant: 1) Montreal Cognitive Assessment (MoCA) score of 19-26, 2) the presence of subjective memory complaint and preserved daily activity function, 3) hearing loss of 2- or 3-digit results greater than the norm value by the integrated Digit-In-Noise (iDIN) test, 4) available of primary caregiver in the family, 5) have smart phone to receive online training materials, 6) not receive formal cognitive or auditory training in the past 6 months, 7) no other sensory impairment, and 8) consent to participate.

The criteria of the primary family caregiver: 1) 18 years old or above, 2) Primary caregiver in the family of the participant, 3) Have smart phone to receive online training materials, 4) Consent to participate.

**Participants Selection**

Individual will be invited to participate in this study with the criteria including: 1) Montreal Cognitive Assessment (MoCA) score of 19-26, 2) the presence of subjective memory complaint and preserved daily activity function, 3) hearing loss of 2- or 3-digit results greater than the norm value by the integrated Digit-In-Noise (iDIN) test, 4) available of primary caregiver in the family, 5) have smart phone to receive online training materials, 6) not receive formal cognitive or auditory training in the past 6 months, 7) no other sensory impairment, and 8) consent to participate.

**Data Collection Procedure**

After obtaining informed consents, the research assistants will start data collection based on validated questionnaires and interviews. Validated questionnaire is expected to take 30 minutes in NGOs. After collection of the above baseline data, you will be randomly assigned to Program A or Program B according to a computer generated sequences of equal opportunities. After being assigned to either of the program, you will not be able to request to change to another plan. If you could not attend/complete all activities, you are still treated as participants of the study and will not be terminated. The post-test data collection will take place at the 12th and 18th week thereafter.

Program A includes 3 parts in 12 weeks:

1) Goal-oriented health counseling by nurse,
2) Peer-assisted group-based auditory-cognitive training,
3) Family engaged active-communication training: 2 bi-weekly training sessions for the PLwMCI and 2 online training sessions with the involvement of the primary family caregivers.

Program B:

1) Mainly covers the social activities offered by the affiliated center.

Participants in Program A may also be invited to a semi-structure interview. Each interview will last for around 1 hour in NGOs. The interview content will be recorded in an anonymous manner, and the recording data will be collected at the University of Hong Kong to facilitate subsequent data analysis.

**Cost and Payment of the Study**

You will not be charged for participating in the Study. Also, you will not receive any rewards from the Study.

**Funding/Sponsor**

The study is funded by Seed Fund, HKU.

**Risks and Benefits**

The assessment will not cause any pain, discomfort, or harm to you. You will have a better understanding of the project.

**Anonymity and Confidentiality**

All the information which is collected about you during the course of the Study will be kept strictly anonymous and confidential. The collected data will be locked up in a secure location and only the researcher can access to them. All the data will be destroyed five years after the study.
Under the laws of Hong Kong [in particular the Personal Data (Privacy) Ordinance, Cap 486], you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or her officer (Tel no.: 2827 2827) as to the proper monitoring

or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.
By signing the written informed consent form, you are authorizing the Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) and the regulatory authority(ies) will be granted direct access to your study data for data verification. For enquiries relating to your rights as study subjects, please contact the HKU/HA HKW IRB at:

- Secretary: 2255 4086 / hkwirb@ha.org.hk
- Address: Room 901, 9/F, Administration Block, Queen Mary Hospital, 102 Pokfulam Road, Hong Kong

**Voluntary Participation/Withdrawal**
You are voluntary to participate in this study. Your decision to participate or not will be respected. You have the right to ask any questions, refuse or withdraw from the Study at any time and without giving a reason. Your decision of participating in this study will not affect the quality of present or future services you receive in the community. If you withdraw, the data collected before withdrawal will be destroyed if we do not have your consent. You may also state in the consent to allow the researcher to continue using the data collected from you for your research purposes after your withdrawal. You will be given enough time to consider whether to participate in this study. Your participation will not be terminated unless force majeure (things we cannot control), for example, the outbreak of pandemic; under such circumstances, the research staff will make appropriate arrangements (e.g., suspending the Study till the pandemic situation gets better or migrating the Study to online), and your participation remains valid and will not be terminated.

Please sign the attached consent form if you agree to participate. After signing, a copy of this participant information sheet and signed consent form will be given to you for retention.

**Inquiry**
For any questions or enquiries, please feel free to contact the research team:

Prof. YU Doris Sau-Fung, Professor, Chair (Research)
School of Nursing, LKS Faculty of Medicine, The University of Hong Kong (Tel: 3917 6319)

***You are cordially invited to participate in this study.***

**School of Nursing, LKS Faculty of Medicine, The University of Hong Kong**

**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**

**Informed Consent**
**(Participants and primary family caregivers)**

This is to certify that I, _____, consent to participate in the above study. I understand that the information obtained from this study may be used in future research and may be published. However, I will not be in any way identifiable. I have been given a detailed account of the project and have had opportunities to ask questions which have been explained to my satisfaction. I understand that my participation is entirely voluntary, and I have the right to withdraw from the study at any time and will not affect the quality of services I received in the community.

If I request to withdraw from the study, I *agree/*disagree the researcher to continue using the data collected from me for research purposes after my withdrawal.

I understand that my identity will be handled confidentially. I also agree Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) and the relevant statutory bodies to directly review my research data to verify the relevant clinical research data, subject to the appropriate regulations and legislation and without infringing my privacy. For enquiries, please contact the HKU/HA HKW IRB at:

- Secretary: 2255 4086 / hkwirb@ha.org.hk
- Address: Room 901, 9/F, Administration Block, Queen Mary Hospital, 102 Pokfulam Road, Hong Kong

| Name of Participant | Signature | Date |
|---|---|---|
| Name of Caregiver | Signature | Date |
| Name of Research Assistant | Signature | Date |

**After signing, a copy of the participant information sheet and signed informed consent form will be given to me for retention.