

1. Research Consent Form

Title of the Study: Lay-led Brief Cognitive Behavioural Therapy for Insomnia (CBT-I) Group for Older Adults in Hong Kong: A Pilot Study

NCT Number: [To be assigned]

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Organization/Affiliation: Department of Social Work and Social Administration, The University of Hong Kong



Department of Social Work and Social Administration, The University of Hong Kong
Pilot Study on the Effectiveness and Feasibility of the “ReFrame-R” Project
Information sheet

You are invited to participate in the pilot study of the “*ReFrame-R*”, a research study conducted by the Department of Social Work and Social Administration at University of Hong Kong. Before deciding, please make sure you understand the study’s purpose and what participation involves. Read the information below carefully, and if you wish, discuss it with friends, relatives, or professionals. Please contact the research team if you have any questions or need more details.

PURPOSE OF THE STUDY

In recent years, intergenerational communication and family relationships in Hong Kong have faced many challenges, affecting the mental health of both young and older generations. This study aims to test the “*ReFrame-R*”, a program specially designed for older adults to enhance their communication competence and strengthening their sense of family role boundaries. We hope to evaluate the effectiveness and feasibility of this project.

STUDY OVERVIEW

This study adopts a pilot randomized controlled trial design to evaluate the effectiveness of intergenerational communication training. We will invite a total of 40 older adults to participate in this research. After providing consent and complete the baseline assessment, participants will be randomly assigned into two groups by computer: 20 to the training group and 20 to a control group.

ELIGIBLE PARTICIPANTS

You will be invited to participate if you meet all of the following: 1) aged 60 or above; 2) primarily Cantonese-speaking; 3) maintain regular contact with adult children; 4) able to comprehend Traditional Chinese; 5) have no known history of autism spectrum disorder, intellectual disability, schizophrenia or related psychotic disorders, bipolar disorder, Parkinson’s disease, or dementia; 6) have no mild or greater depressive symptoms; and 7) have no communication difficulties.

PARTICIPATION AND WITHDRAWAL

Your participation is voluntary and your decision will be respected. If you choose to participate, you will receive this information sheet and will be asked to sign a consent form. You can choose to stop at any time without negative consequences.

PROCEDURES

If you agree to participate, you will be randomly assigned (1:1 ratio) to either the training group or the control group. If assigned to the training group, you will attend 4 weekly sessions of “*ReFrame-R*” intergenerational communication training (90-minute per session). Sessions are led by trained counsellors or nurses, with topics including intergenerational communication competence and family role boundaries. Participants in this group will receive a booklet containing communication tips and brief logs to record family interactions. Control group participants will receive the same intergenerational communication booklet for self-study.

The research team will provide a weekly individual consultation (approximately 10 minutes) to troubleshoot difficulties and reinforce home practice.

You will be invited to complete assessments at three time points: baseline, Week 4, and Week 6. Each assessment takes about 10 minutes and will be conducted by a research assistant. You will be asked about your family relationships and mental health.

POTENTIAL RISKS / DISCOMFORTS

The procedures employed in this study have no known risks.

POTENTIAL BENEFITS

Participation in this project is free of charge. This pilot study aims to evaluate the effectiveness and feasibility of the “*ReFrame-R*” training program. The core of the training is to guide participants in rethinking their roles within the family. By improving intergenerational communication, we aim to help older adults build stronger emotional connections with their family members (in particular, their children). We anticipate that acquiring these communication competence and respecting family role boundaries may enhance older adults’ self-efficacy and a sense of meaning; however, this cannot be guaranteed.

PRIVACY AND CONFIDENTIALITY

Any information obtained in this study will be kept strictly confidential. Only members of the research team and authorized personnel from oversight or regulatory bodies will have access to identifiable information for the purpose of verifying that the study is properly conducted and reviewing results. Data collected in this study will be used for research purposes only. No personal information (including contact information) will be shared or disclosed to any individual or party outside of the research team, except as required by those authorized oversight bodies. Participants will not be identified in any report and publications resulting from this study. All data will be stored on password-protected computers managed by the research team. Records containing personal identifiers will be retained for five years after the first publication of this study; thereafter, identifying information will be permanently removed and anonymous data will be kept on an online depository (osf.io).

ETHICAL APPROVAL

This study has been reviewed and approved by the Human Research Ethics Committee of the University of Hong Kong (HREC ref: EA260121).

QUESTIONS AND CONCERNS

If you have any questions or concerns about the research, please contact Dr. Branda Yee-Man Yu at HKU: Tel: 3917 3914, email: branda.yu@hku.hk. If you have questions about your rights as a research participant, contact the Human Research Ethics Committee, HKU (Tel: 3917-5267, email: hrec@hku.hk).

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I, _____ (name), on this _____ day of _____ (month), _____ (year), was fully informed about this study by a research assistant from the Department of Social Work and Social Administration, The University of Hong Kong. I have read and understood the information above, and I agree to its contents. I also consent to use my personal data for the purposes described. I have had the opportunity to ask questions and my questions have been answered to my satisfaction.

I understand that my participation is voluntary and that I may withdraw at any time without giving any reason, and that withdrawal will not affect my access to other services, medical care, or legal rights.

I also agree to the following:

☐ The researchers may contact me in the future to provide information about other research projects.

☐ If I withdraw from this study, the researchers may continue to use the research data I provided prior to my withdrawal.

☐ I also permit the Human Research Ethics Committee and relevant statutory bodies, to the extent permitted by applicable laws and regulations and without infringing my privacy, to directly access my research records to verify the study data.

Participant: _____ Name: _____ Date: _____ / _____ / _____

Witness: _____ Name: _____ Date: _____ / _____ / _____