



The University of Hong Kong

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

Informed Consent

You are sincerely invited to participate in the feasibility study on a Cognitive Behavioral Therapy for Insomnia (CBT-I) Group conducted by the Department of Social Work and Social Administration, The University of Hong Kong. Before consenting to participate, carefully read the information below, and if needed, you may discuss with family, friends, or professionals. If anything is unclear or if you need more information, please contact the research team.

You are invited to participate in a brief in-person group for CBT-I consisting of four sessions. The group will be led by trained Emotional Support Assistants, with each session lasting approximately 1.5 hours and expected to be completed within a 4 weeks. CBT-I is an evidence-based, non-pharmacological treatment that improves sleep quality by reconstructing thoughts and habits. It has been validated as a first-line treatment for both short-term and long-term insomnia. This brief CBT-I group will cover treatment components such as sleep hygiene, stimulus control, cognitive restructuring and relaxation exercises. You will be invited to complete questionnaires regarding your sleep habits, attitudes, and pre-sleep state, which will take about 10-15 minutes.

PURPOSE OF THE STUDY

In Hong Kong, middle-aged individuals and older adults face a variety of mental health challenges, particularly concerning insomnia. This pilot study will include CBT-I treatment components such as sleep hygiene, stimulus control, cognitive restructuring and relaxation exercises, but will not incorporate sleep restriction. The aim of this study is to evaluate the effectiveness of the brief CBT-I group in improving insomnia and to assess the feasibility of future implementation without the sleep restriction component.

INCLUSION CRITERIA

The inclusion criteria for the study are as follows: participants must be aged 45 or older, experiencing existing symptoms of depression and insomnia, and capable of providing informed consent for their participation in the study. Participants will be excluded if they have a known history of intellectual disabilities, schizophrenia spectrum disorders, bipolar disorder, Parkinson's disease, or dementia. Additionally, individuals assessed to be at active suicidal risk will not be eligible for participation. Those who experience significant difficulties in communication will also be excluded from the study.

PARTICIPATION AND WITHDRAWAL

Taking part in this study is completely voluntary. You can withdraw at any time without consequences. If you choose to participate, you will need to sign a consent form and will receive a copy of this informed consent and a signed consent form for your records.

PROCEDURE

You will be invited by the partnering organizations of the Jockey Club Holistic Support Project for Elderly Mental Wellness (JC JoyAge) to participate in a brief in-person group for CBT-I, consisting of four sessions. The group will be held at the centres of the partnering organizations, with each session lasting approximately 1.5 hours and expected to be completed within 4 weeks. The sessions will cover four treatment components: sleep hygiene, stimulus control, cognitive restructuring, and relaxation exercises, all facilitated by trained Emotional Support Assistants. Emotional Support Assistants are peer supporters aged 45 or above who are trained to provide mental health-related services to individuals of similar age who are struggling with depressive emotions. They have completed approximately 98 hours of basic training and have received CBT-I training from psychologists affiliated with JC JoyAge. After each session, you will be encouraged to incorporate the skills learned into your daily life and share your experiences or challenges in the following session. In the first session of the group, you will be invited to fill out a questionnaire regarding your sleep habits, attitudes, and pre-sleep state. In the final session, you will also be invited to complete the same questionnaire, along with an additional feedback form about the group. These questionnaires will take about 10-15 minutes to complete.

ANTICIPATED BENEFITS

The study anticipates improving the quality of your sleep, and you may gain knowledge and techniques for enhancing your sleep through participation in the group. While the intervention is grounded in evidence-based psychotherapy, individual benefits may vary and depend on your active participation and efforts. Therefore, the study cannot guarantee that you will benefit, and regardless of the intervention outcomes, the organization does not assume any legal liability.

PRIVACY AND CONFIDENTIALITY

If you agree to participate in this study, the research team and personnel from regulatory bodies may review your personal information to ensure the correct implementation of the study and analyze the results. Any information obtained in this study will be used solely for research purposes, and personal information will be kept strictly confidential and not disclosed to third parties. Your name and other private information will not appear in any reports related to this study. All personal data will be stored on computers accessible only to the research personnel, and your personal information will be stored separately from other data. Records containing personal identifiers will be retained for five years after the first publication of this study; thereafter;

05. Research Consent Form (Formative Evaluation)

identifying information will be permanently removed and anonymous data will be kept on an online depository (osf.io).

RIGHTS OF RESEARCH PARTICIPANTS

If you would like to learn more about your rights as a research participant, please contact the Human Research Ethics Committee, HKU (Tel: 3917-5267; Email: hrec@hku.hk). If you have any questions about the research, please feel free to contact Ms Wong (Tel: 3917-3913; Email: lonniw@hku.hk) or; Dr. Branda Yu, The University of Hong Kong (Tel: 3917-3914; Email: branda.yu@hku.hk)

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Consent form

I confirm that I fully understand the above information and agree to its contents. I have had the opportunity to ask questions for clarification, and my questions have been satisfactorily answered.

I understand that my participation is voluntary, and I can withdraw at any time without providing any reason, without affecting my existing and future legal rights.

Please tick the appropriate box ✓:

- ☐ I **agree** to participate in the *Lay-led Brief Cognitive Behavioural Therapy for Insomnia (CBT-I) Group: A Pilot Study* and **agree** to provide information for program evaluation and research purposes.
- ☐ I **do not agree** to participate in the *Lay-led Brief Cognitive Behavioural Therapy for Insomnia (CBT-I) Group: A Pilot Study* and **do not agree** to provide information for program evaluation and research purposes.

Name of participant

Date

Signature

Date of Preparation :

HREC Reference Number : EA260143