Effectiveness of internet-based self-help cognitive behavioural therapy (CBT-I) in reducing insomnia symptoms among the adult population: A randomized controlled trial

(consent form and information sheet)

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THE EDUCATION UNIVERSITY OF HONG KONG
DEPARTMENT OF PSYCHOLOGY

CONSENT TO PARTICIPATE IN RESEARCH

Effectiveness of internet-based self-help cognitive behavioural therapy (CBT-I) in reducing insomnia symptoms among the adult population: A randomized controlled trial

I _____ hereby consent to participate in the captioned research of The Education University of Hong Kong (EdUHK) and the Baptist Oi Kwan Social Service (BOKSS), which supervised and conducted by Dr. Chan Ka Shing, Kevin and Dr. Lam Chun Bun, Ian (EDUHK), and Ms. Poon Fung Oi, Scarlet (BOKSS) who are staffs of EDUHK and BOKSS.

I understand that information obtained from this research may be used in future research and may be published. However, my right to privacy will be retained, i.e., my personal details will not be revealed.

The procedure as set out in the **attached** information sheet has been fully explained. I understand the benefits and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without negative consequences.

Name of participant _____

Signature of participant _____

Date _____

INFORMATION SHEET

Effectiveness of internet-based self-help cognitive behavioural therapy (CBT-I) in reducing insomnia symptoms among the adult population: A randomized controlled trial

You are invited to participate in a project of The Education University of Hong Kong (EdUHK) and the Baptist Oi Kwan Social Service (BOKSS), which supervised and conducted by Dr. Chan Ka Shing, Kevin and Dr. Lam Chun Bun, Ian (EDUHK), and Ms. Poon Fung Oi, Scarlet (BOKSS) who are staffs of EDUHK and BOKSS. Your participation in the project is voluntary. You have every right to withdraw from the study at any time without negative consequences. All information related to you will remain confidential, and will be identifiable by codes known only to the researcher.

The introduction of the research

The purpose of this study was to evaluate the efficacy of a self-help cognitive behavioral therapy program for insomnia. Cognitive behavioral therapy is widely used by medical practitioners in the West to treat various diseases, including insomnia. Adults with symptoms of insomnia were invited to participate in the study.

The methodology of the research

You are free to decide whether to participate in this study. If you decide to participate, you can still withdraw at any time without giving any reason, and your withdrawal will not affect the services you receive, nor will it affect your future relationship with Baptist Oi Kwan Social Services. The study will last for 10 weeks. If you decide to participate in this study, you will need to attend 6 treatments (approximately 45 to 60 minutes each) and complete 3 pre-treatment and post-treatment assessments of approximately 20 minutes. All treatments will be completed through the "Re:Fresh E-platform".

Scheduler:
1st assessment → treatment* (six weeks) → 2nd assessment → 3rd assessment (after four weeks)
*Due to study design, eligible participants may have to wait approximately 10 weeks before receiving treatment.

The study will enroll approximately 210 participants. All participants will be randomly assigned to an intervention group or a waitlist control group to complete online self-help cognitive behavioral therapy for insomnia. The intervention group will complete assessments before treatment (T1), after treatment (T2), and 4 weeks after treatment (T3). The alternate control group will complete assessments at the same time as the intervention group (ie, at T1, T2, and T3) and receive the same treatment after all assessments are completed. Participants in the intervention group will complete six 45- to 60-minute weekly online sessions through the Re:Fresh electronic platform. Each session will include key CBTI elements, including sleep hygiene education, stimulus control, sleep restriction, relaxation training and cognitive therapy. Lessons include major therapy sessions, quizzes, and assignments in written or video format. Course materials will be presented interactively to promote engagement. Assessments will be conducted in the form of a questionnaire on the Re:Fresh electronic platform and each assessment is expected to take 20 minutes to complete.

Participants who complete the research will each receive a $200 gift certificate, which will be distributed in two installments. They will also have the opportunity to participate in the group. The data collected will provide valuable information on the research question. Cognitive behavioral therapy may improve your insomnia and quality of life, but it's not guaranteed. The information collected in this project may increase our knowledge on the treatment of insomnia.

The potential risks of the research (State explicitly if none)

When receiving psychotherapy, side effects are rare. If you experience any discomfort during treatment, you should notify the research team immediately. As this treatment is self-help, the Risks and Disadvantages of Participation is that there will be no face-to-face support from healthcare professionals. During the treatments, you may recall personal experiences that may cause discomfort or unpleasant situations, but will not cause you serious and long-term harm.

Cognitive behavioral therapy is safe and has a long history. It is very popular in both public and private clinics in Hong Kong, and side effects due to participation in this study are unlikely to occur. If you do have any accident, please remember to notify the research team immediately. The research team will decide whether to allow you to continue participating in the study on a case-by-case basis. There are no compensation arrangements for casualties in this study.

Describe how results will be potentially disseminated

All personal information collected during the study will be kept strictly confidential. Your personal data will be transmitted to the server of Baptist Oi Kwan Social Service. The online information you provide will only be used for this study. The online personal data obtained from the research will be destroyed after the first document is published, and the research data that does not contain personally identifiable information will be stored on the "Re:Fresh E-platform" server for a long time.

If you would like to obtain more information about this study, please contact Mr. Chan Ka Long at telephone number 3751 5493.

If you have any concerns about the conduct of this research study, please do not hesitate to contact the Human Research Ethics Committee by email at hrec@eduhk.hk or by mail to Research and Development Office, The Education University of Hong Kong.

Thank you for your interest in participating in this study.

Dr. Chan Ka Shing, Kevin, Dr. Lam Chun Bun, Ian (EDUHK), and Ms. Poon Fung Oi, Scarlet (BOKSS)
Investigators