School of Nursing – The University of Hong Kong

Subject Information Sheet

You are invited to participate in a research. This is a study conducted by the School of Nursing of 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 friends, relatives and your family doctor if you wish. Ask if there is anything unclear or if you wish to obtain more information. Take time to decide whether you wish to participate in the research.
A total number of 60 participants will be recruited from the community centers operated by two non-governmental organizations in Hong Kong.

Study Title:

The feasibility and preliminary effects of an empowerment-based cognitive behavioural therapy for insomnia on sleep, cognitive function and health-related quality of life in persons with mild cognitive impairment: A mixed-method pilot study

Purpose of the Study:

The purpose of this study is to determine the feasibility of an empowerment-based cognitive behavioural therapy for insomnia in MCI persons and to examine the preliminary effects of the empowerment-based cognitive beyavioural therapy for insomnia on sleep, cognitive outcomes and health-related quality of life. and thereby to inform the development of effective interventions in the future to improve sleep and cognitive function of persons with mild cognitive impairment.

Participants Selection:

Adults who are of Chinese ethnicity, fifty years of age or above, living in the community, with mild cognitive impairment, have poor sleep quality and able to communicate will be invited to participate in this study. People with confirmed dementia, impaired communication and sleep disorders with organic cause like sleep apnoea or restless legs syndrome or due to medical problems using hypnotics and other medications known to affect sleep like steroids and anxiolytics are excluded.

Nature of Participation:

Your participation is absolutely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you refuse to participate, you don't have to give a reason. The treatment and care that you are receiving will not be affected. If you decide to take part in the study, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of treatment and care you receive in present and future. You will be updated timely of new information that may be relevant to your willingness to continue the participation in this study.

Procedure:

A research assistant (RA) will visit you once at the community center of non-governmental organization. During the visit, he/she will verbally explain the details regarding this study with the supplement of this information sheet. If you agree to participate, you have to sign an informed consent form prior to the data collection. The RA will also provide you a copy of the signed informed consent form.

Participants will be screened by the RA for cognitive function and activities of daily living. Eligible participants will be invited to join the study. The RA will have a face-to-face interview at the community center with the participant to collect the baseline data, including demographics, sleep quality and patterns, cognitive function as well as the quality of life. The interview will take about 30 minutes. The RA will provide an Actiwatch for participants to wear at bedtime to observe the sleep pattern for a consecutive seven-day period.

The RA will ask the participant to extract one of the sealed envelopes of the group according to the randomly assigned numbers by the computer. Participants will be distributed to either the intervention or control group, and will receive the following care:

For participants in intervention group, there will be six face to face sessions (90 minutes per session) in small group format and two 30-minute individual sessions will be scheduled over eight weeks, with the individual sessions arranged in the 4th and 7th week, and this is then followed by two bi-weekly telephone follow-ups. The session will cover topics about sleep hygiene and relaxation, sleep restriction, stimulus control and cognitive therapy. RA will provide continuous support through telephone calls (and two bi-weekly calls). He/she will monitor participants' adherence to the recommended behaviours and will provide methods to resolve the barriers encountered in real life settings.

For participants in control group, participant will receive standard care in the community centers during the study period. You are required to consent not to participate in any structured cognitive training activities provided in the centers during the study period.

No matter participants are in intervention group or control group, the RA will make an appointment with the participants to repeat the assessment on sleep quality and patterns, cognitive function as well as the quality of life at immediate and 3 months post-intervention. The face-to-face interview will be conducted by the RA at the community center and will take about 30 minutes. Similarly, the RA will provide an Actiwatch for participants to wear at bedtime to observe the sleep pattern for consecutive seven-day period.

A total of 10 participants, with 3-4 participants from each intervention group, will be invited to take part in a qualitative interview to obtain more in-depth comments about the feasibility and acceptability of the intervention.

Alternative treatments if person opts for not joining the study

All persons will receive appropriate and standardized treatment in the community. There will be no difference between study participants and other persons in terms of treatment arrangement. Your participation will not affect your present or future care and treatment received from the hospital or in the community.

Cost and payment of the study

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

Risk and Benefits:

The assessment will not cause any pain, discomfort or harm to you. The major potential benefit is that the result could allow healthcare professionals to have a better understanding of how cognitive behaviour therapy affecting the sleep quality and cognition in persons with mild cognitive impairment. Accordingly, effective interventions can be formulated in the future.

Compensation and treatment for study related injury

When there is any mental or physical discomfort raised during the study period, our research team will provide or refer appropriate treatment to you. You will not give up your legal rights by signing this form.

Anonymity and Confidentiality:

All the information which is collected about you during the course of the research 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 kept for 5 years. The data will be destroyed according to the University guidelines on handling confidential data after the aforesaid storage period.

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 his 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 Research Ethics Committee (REC) and the regulatory authority(ies) will be granted direct access to your study data for data verification.

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 medical care you receive in the hospital and community. If you withdraw from the study, the data collected up to your withdrawal will be continuously used without your request to destroy.

Please sign the attached consent form if you agree to participate in this study. 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:

Principal Investigator:

Dr. Li Polly Wai-chi, Assistant Professor, School of Nursing, The University of Hong Kong (Tel: 3917 6686) or email: pwcli@hku.hk.

If you have questions related to your rights as a research participant, please contact the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) at 2255 4086.

You are cordially invited to participate in this study.

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Informed consent

Study Title:

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I hereby agree to participate in the above studies. I understand that the information obtained in the study will be used for future research and maybe published in academic literature.

I also know that if I disagree with the information obtained in the public study, I can continue to participate in the study. However, all personal data is kept strictly confidential and will not be made public. I understand all the benefits and risks associated with this study.

The researcher has explained the study to me in detail and asked me to ask questions and get a satisfactory reply. If I am involved in this study and cause any physical discomfort or emotional fluctuations, the researcher will treat or refer to my treatment. I will not waive any legal rights by signing this consent form.

I hereby sign this consent form to prove that all the information provided by me is correct. I understand that participation in this study is voluntary and I may withdraw this consent at any time without any reason, without affecting my current and future treatment.

I understand that my identity will be treated confidentially. I also allow the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster and the relevant statutory bodies to directly check my research data to verify the relevant clinical research data, subject to the appropriate regulations and legislation and without infringing my privacy.

Participant signature	Participant name	Date
**Proxy signature	**Proxy name	Date

**Relationship between proxy and participant

Research assistant signature	Research assistant name	Date

** Proxy signature is required if indicated.

After signing, I will receive a copy of the participating academic research materials page and signed informed consent for reservation.