School of Nursing – The University of Hong Kong

Subject Information Sheet

You are cordially invited to participate in this 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 your relatives, friends and family doctor if you wish. Feel free to ask if there is anything unclear or if you wish to obtain more information. Please take time to decide whether you wish to participate in the research. A total number of 268 participants will be recruited from two regional hospitals in Hong Kong.

Study Title:

An internet-based cardiac rehabilitation enhancement (i-CARE) intervention to support self-care of patients with coronary artery disease (CAD): A mixed-method study

Purpose of the Study:

The purpose of this study is to evaluate the effects of i-CARE on self-care behaviours, blood pressure, waist-to-height ratio, cholesterols, functional status, health-related quality of life (HRQoL), cardiovascular events and mortality of CAD patients and explore the experience of patients in engaging in the i-CARE intervention.

Participants Selection:

Adults with confirmed diagnosis of CAD, living in the community, owning a smartphone with internet access, able to communicate in Cantonese and type in Chinese or English will be invited to participate in this study. People who are enrolled to a structured centre-based or home-based cardiac rehabilitation programme in the past year, with psychiatric problems, impaired cognitive functioning (i.e. Abbreviated Mental Test ≤ 6) and terminal disease with life expectancy < 1 year are excluded.

Nature of Participation:

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

Procedure:

Firstly, participants will be screened by the nurse for health status. Eligible participants will be invited to join the study. A research nurse 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 data collection. The research nurse will also provide you a copy of the signed informed consent form.

The research nurse will then conduct a face-to-face interview to collect participant's baseline data, including demographics, self-care behaviours, blood pressure, waist-to-height ratio, cholesterols, functional status and health-related quality of life. Participants are required to fast for at least 8 hours before cholesterols testing, which will be measured by a validated point-of-care machine (blood sample is collected via a finger prick). The research nurse 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 allocated to one of the treatment groups (intervention group or control group).

For participants in the intervention group, they will receive a 12-week i-CARE intervention. Firstly, the research nurse will conduct a face-to-face orientation session in the hospital. The session will last for about 1.5 hours. The research nurse will first highlight the crucial role of participants themselves in managing the disease and assist them to understand the links between their self-care behaviours and health consequences. A subsequent interactive skill-building session, including techniques of blood pressure, heart rate and blood glucose measurements, will be included to ensure participants acquire the skills required for self-monitoring. The nurse then will introduce the mobile application, assist the participants to register an account and personalise the setting according to their individualized risk profile and preferences. Moreover, a pedometer will be provided to each of the participants. The nurse will teach the participants how to use the pedometer and synchronize the daily step counts to the mobile application.

The mobile application used in this study includes three key user interfaces: a self-monitoring dashboard, the interactive self-care modules and the chat room. For the self-monitoring dashboard, it is a personalized interface that allows participants to select relevant parameters for regular self-monitoring according to their own risk profile, including blood pressure, heart rate, lipid profile and blood glucose. Participants can customize the application features on receiving notifications and motivational messages. The input data will be presented in a graphical format to visually demonstrate the changes over time. The interactive self-care modules will cover the following topics: 1) CAD, its symptom monitoring and management, 2) medication management, 3) personalized risk factor control, 4) healthy diet, 5) activity and exercise, and 6) stress management. A variety of interactive features, such as the use of audio-visual format with animations and illustrations and self-care tips sharing from peer will be included to improve knowledge acquisition of participants.

The chat room will serve as a platform to facilitate interactions between the nurse and participants. The nurse will initiate chatting with participants weekly, so as to identify any problems or barriers that the participants encountered in their daily practice of self-care behaviours and advise resolving methods correspondingly. Participants are also welcomed to initiate chatting with the nurse regarding disease management. The nurse will offer advice and counselling accordingly during office hours.

Upon completion of the 12-week i-CARE intervention, the research will invite 30 participants in the intervention group to take part in an in-depth interview to explore their engagement experiences. The interview will be audiotaped, and the recorded data will be kept by the University for the sole purpose of data analysis. The

audiotaped record will be anonymized.

For participants in the control group, they will receive conventional care as arranged by the hospital during the study period.

Regardless of the status of group assignment, the research nurse will make an appointment with all the participants at 3 months and 6 months after baseline data collection to repeat the assessment on self-care behaviours, blood pressure, waist-to-height ratio, cholesterols, and health-related quality of life. For self-reported measures (self-care behaviours and health-related quality of life), participants in the intervention group can access to the online questionnaires via the URL link shown in the pop-up reminder message in the mobile application, whereas participants in the control group will receive the URL link via text message or WhatsApp sent by the research nurse. Other parameters, including blood pressure, waist-to-height ratio and cholesterols will be measured in hospital. Cholesterols will be measured by a validated point-of-care machine (blood sample is collected via a finger prick) or via blood taking at hospitals.

Alternative treatments if person opts for not joining the study

All persons will receive appropriate and standardized treatment in the community and healthcare settings. 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 monetary rewards from this study.

Risk and Benefits:

The assessment includes blood-taking procedure that may cause mild discomfort to you. Although the blood taking process is involved; there is no known major risk of blood taking, so it is quite safe. The major potential benefit is that the result could allow healthcare professionals to have a better understanding of how internet-based cardiac rehabilitation programme affecting the self-care behaviours, biomarkers, physiological, anthropometric, clinical parameter and self-reported health outcomes in persons with coronary artery disease. Accordingly, effective interventions can be provided as regular service in the future to support patients in disease management.

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:

Dr. Li Polly Wai-Chi, Assistant Professor, School of Nursing, The University of Hong Kong (Tel: 39176686) or email: pwcli@hku.hk

Dr Wong Chi-Wing, Associate Consultant, Department of Medicine and Geriatrics, Pok Oi Hospital (Tel:24868985)

If you have questions related to your rights as a research participant, please contact the New Territories West Cluster Clinical and Research Ethics Committee (NTW CREC) at 2468 6118

You are cordially invited to participate in this study.

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Informed consent

Study Title:

An internet-based cardiac rehabilitation enhancement (i-CARE) intervention to support self-care of patients with coronary artery disease (CAD): A mixed-method study

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 New Territories West Cluster Clinical and Research Ethics Committee (NTW CREC) 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

Research assistant signature	Research assistant name	Date

After signing, I will receive a copy of the information sheet and signed informed consent.