

Official Title: 'Home Sweet Home' Programme: Empowering the Patient and Caregiver for Early and Safe Discharge of Patients With Geriatric Hip Fractures

Brief Title: Geriatric Hip Fractures Caregiver Programme

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WRITTEN INFORMED CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Title of Study: 'Home sweet home' programme: Empowering the patient and caregiver for early and safe discharge of patients with geriatric hip fractures – A randomized controlled trial

Subject No.: _____

**Caregiver Empowerment
Programme**

We would like to invite your participation in the captioned research study. Participation in research study is wholly voluntary and it will **absolutely put no effect** on your future treatment.

Aim of Study:

The incidence of geriatric hip fracture is projected to increase in the future as the world population ages. According to our data, a significant number of fracture hip patients still required an extended length of stay after surgery, which is defined as more than 28 days in a rehabilitation hospital. Inadequate training and support provided to those patients and their caregivers was the main reason of high dependency of patients upon discharge. We aim to investigate the effect of the patient empowerment programme to patients on the functional outcome and readmission rate.

Details:

We aim to recruit around 140 elderly patients suffering from hip fracture who requires surgical treatment. You are being invited to participate in this study because you are suffering from a hip fracture and has received operative treatment. Rehabilitation has started in Queen Mary Hospital and will be continued in rehabilitation hospital in our cluster.

If you agree to participate in this study, you will be randomly assigned to one of the rehabilitation strategies. Apart from the above randomization, you will receive equal standard treatment and aftercare. The study is independent of your fracture treatment. Treatment of the fracture is entirely the responsibility of your attending physician and will be following the treatment standard of Queen Mary Hospital and other rehabilitation hospitals in our cluster.

Your participation in the study will take around 1 year with 4 study-related visits, at rehabilitation hospitalization, post-operative 1-month, 6-month and 1 year respectively. During each study visit, you need to complete the questionnaire. Your fracture recovery and functional outcome will also be assessed.

Risks and inconveniences:

If you are allocated to the experimental group, a carer needs to be identified from your family and attends at least 2 to 4 training sessions during the rehabilitation period. Each session last around half an hour. The main content is to teach the caregiver techniques to assist the patient in daily activities, e.g. walking, dressing and toileting, etc. There is no potential risk associated with this study.

Benefit:

You will not receive any personal benefit from participating in this study. However, finding of this study is going to benefit future patients.



Data Security & Confidentiality:

You have the rights of access to personal data and publicly available study results, if and when needed. 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 office (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 consenting to participate in this study, you expressly authorize:

- the principal investigator and his research team and the ethics committee (Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster) responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
- the relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

This study has been critically evaluated by the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster (HKU/HKWC IRB). This study was planned and will be implemented in accordance with strict international guidelines and stipulations for patient protection (Declaration of Helsinki). For inquiries, please call 22553923.

For more information concerning this research, please contact named below at any time during the study or after its conclusion:

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1. I have read the above study information and consent forms and taken the time to thoroughly consider the situation. The purpose and procedures of the study have been explained to me.
2. I understand that all the collected medical information associated with this study, will be read and processed anonymously by authorized personnel.
3. Of my own will, I would like to take part in this research study.

I confirm that I fully understand the above-mentioned and agree to participate in the captioned study:

Name of subject

Signature of subject

Date

Name of witness
(if applicable)

Signature of witness

Date

Name of the investigator
conducting consent

Signature of the investigator
conducting consent

Date