

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

NCT Number: NCT05393349

Unique Protocol ID: UW 19-574

Document Description: Study Protocol and Statistical Analysis Plan

Document Date: 2019-08-20

a) Project Title:
'Home sweet home' programme: Empowering the patient and caregiver for early and safe discharge of patients with geriatric hip fractures - A randomized controlled Trial

b) Introduction:
Health care consequences of hip fracture

The global incidence of geriatric hip fractures is projected to increase by more than 250% in the next twenty-five years⁽¹⁾. Local data showed that there was a steady increase from 3500 to more than 4500 hip fractures per year from 2000 to 2011⁽²⁾. Nevertheless, the consequence of hip fractures is serious and costly. Ten percent of patients have a contralateral hip fracture, 30% of patients are readmitted for other acute reasons, 25% need long term care, 10-25% die within 1 year and almost 50% have residual functional disabilities⁽⁹⁻¹²⁾.

Geriatric hip fracture clinical pathway decreased preoperative length of stay

Since 2006, hip fracture pathway has been implemented in Hong Kong West Cluster. Table 1 shows the care map of the geriatric hip fracture clinical pathway (GFH). The implementation of GFH resulted in a decreased preoperative length of stay, decreased surgical site infection, decreased pressure sore, decreased 30-day and 12-month mortality rate⁽³⁾.

High dependency of patients upon discharge

However, according to our data⁽⁴⁾, a significant number of patients still required an extended length of stay, which is defined as more than 28 days in a rehabilitation hospital. Table 1 shows the deficiency of current care. More than 60% of patients were discharged back to home. However, 39% and 51% of patients had severe and moderate dependency respectively upon discharge from rehabilitation hospital (Modified Barthel Index 0-60 and 61-90 respectively). Current training provided to those patients and their caregivers were brief and inadequate. The lack of a trained caregiver affects the decision to return home and patients may need settlement in nursing homes. Moreover 12% had readmission within 28 days of discharge, with repeated fall accounts for the majority.

The patients were referred to geriatric day hospital after discharge from the convalescent hospital. However, the waiting time for geriatric day hospital was 2 months. During this interval, the patients were discharged home taken care of by the caregivers. The caregivers were unsupported and inadequately trained for the job.

Patient and caregiver empowerment for hip fracture patients in Hong Kong

Patient empowerment has been used in patients with stroke and other geriatric conditions. There are only scarce studies focussing on geriatric hip fractures which required special care in terms of ambulation, transfers and activities of daily living training. So far prospective randomized studies are lacking. Lofgren et al⁽⁵⁾ showed patient empowerment resulted in shortened length of stay and earlier return to previous living by comparing two hospitals.

In Hong Kong, the elderly hip fracture patients returning home are often taken care of by domestic helpers or family members. Caring for older patients after hospital discharge is challenging and many of their caregivers lack the confidence to do so. Hence, we opine that caregivers need special attention as well. Lin studied the caregivers' burden of hip fracture patients in Taiwan⁽⁶⁾. The caregivers experienced moderate burdens. Caregivers who were unable to access other resources for help experienced a higher burden.

There has been an increasing trend for patient and caregiver empowerment programme. Hendrix et al⁽⁷⁾ investigated the effects of an individualized caregiver training program on self-efficacy in home

care and symptom management. Results revealed a significant increase in self-efficacy after the training in the treatment group. However, their study focused on cancer patient only. Coleman et al⁽⁸⁾ tested whether an intervention designed to encourage older patients and their caregivers to assert a more active role during discharge could result in decreased rehospitalization rates. He showed the adjusted odds ratio comparing rehospitalization of intervention subjects with that of controls was 0.52 at 30 days, 0.43 at 90 days, 0.57 at 180 days. Intervention patients reported high levels of confidence in obtaining essential information for managing their condition, communicating with members of the healthcare team, and understanding their medication regimen. Their patient population are heterogenous and include various medical and orthopaedic patients.

Most studies on patient and caregiver empowerment had shown a positive result⁽⁷⁻¹⁰⁾.

Our proposed study focusses on empowering hip fracture patients and their caregivers in all aspects in terms of ambulation, transfers and activities of daily living training. To our knowledge, the impact of empowerment on hip fracture patients and their caregivers has not been studied in Hong Kong and the aim of the project is to study if those fracture hip patients can be benefited from empowerment program in terms of functional outcomes.

c) Aims and Hypotheses to be Tested:

We would investigate the effect of empowerment to fracture hip patients and those caregivers on the functional outcomes and readmission rate.

Primary hypothesis: Patient and caregiver empowerment improves the patient's functional recovery in terms of Modified Barthel Index and EQ-5D-5L questionnaire.

Secondary hypothesis: Patient and caregiver empowerment decrease readmission rate, length of stay and decrease secondary fracture at 1 year

d) Plan of Investigation:

(i) Subjects

All patients admitted to a university hospital between 1 July 2019 to 30 June 2020 with acute intertrochanteric fracture, neck of femur fracture or subtrochanteric fracture and received operations for fracture fixation/femoral head replacement were recruited. The inclusion and exclusion criteria are listed below:

Inclusion criteria:

1. ≥60 years of age
2. Suffered from acute intertrochanteric fracture, neck of femur fracture or subtrochanteric fracture and received operations for fracture fixation/femoral head replacement
3. Patients who are ambulatory, with or without walking assistance

Exclusion criteria:

1. Pathological fracture
2. Non-operative treatment
3. Bedbound/chair bound patients
4. Patients who were readmitted to acute hospital from convalescent hospital due to acute medical conditions.

Caregivers can be patient's relatives, friends or domestic helper who can commit to visiting the patient at least two days per week during the early discharge period.

(ii) Methods

The goal of the intervention is to improve the geriatric hip fracture care by empowering the patient

and the caregiver. The intervention consists of three main areas which directly corresponds to the contents the patients and caregivers expressed as most needed in interviews we conducted during hip fracture patients follow up:

1. Knowledge of the disease
2. Confidence and skill in self-care management
3. Support in the post-discharge period

After the patients received their hip fracture surgery, they will stay in the acute hospital for around 4 days and then transfer to convalescent hospital when their physical condition stabilizes. The patient will be recruited during this period. The patient and caregiver empowerment programme intervention commence after the patient is admitted to the convalescent hospital. It consists of the following improvements:

Set realistic discharge goals

A predicted Modified Barthel Index on discharge can be calculated based on patients' demographics and premorbid conditions. The in-charge doctor can help patients and caregivers set the rehabilitation goal on admission to convalescent hospital.

Early identification of discharge date and caregiver

Adults are goal-focused, and they focus on relevant education that supports their existing goals. Early identification of discharge date sets a timeframe for them to achieve the rehabilitation target. From hospital registry 2016 data the mean length of stay in convalescent hospital is 19 days and this will be set as a reference. Early identification of the caregiver allows caregiver education to commence early.

Performance exposure, positive appraisal, and mastery experience

Currently, patient education takes place only during predefined therapist training sessions. There is no training session dedicated to caregiver education. Discharge teachings are not standardized. The contents may be delivered in a rushed, last-minute method without careful planning or individualization of content based on the patient's specific learning needs.

In this programme, additional training sessions will be given the patient and caregivers by the therapists. Caregivers have an opportunity to do tasks under guidance. A non-threatening atmosphere during training with constructive feedback facilitates learning. Caregivers are given enough time and guidance until tasks are successfully demonstrated, and care issues solved.

Put the patient and caregiver in charge of their own education

This means giving them access to the information whenever they seek for it. In this programme, orthopaedic surgeon, geriatrician, physiotherapists, occupational therapists, and nurses will make videos (each 3-5 minutes long) which are available to the patients and caregivers during both the hospitalization period and after discharge. They will complement the therapists' training sessions and allow revision of the contents by the patients and caregivers anytime. The patients and caregivers will be asked to complete an assessment after they view the videos to reinforce the knowledge they learn in the videos.

Provide a collaborative, supportive experience that allows patients to check in on their progress

A weekly assessment of patient's functional progress by nurse and therapist will be done. It will be recorded on a chart shown to the patients and their caregivers, along with the predicted

Modified Barthel Index and discharge goals. The patient and caregiver can see their progress and get positive reinforcement to perform better.

Implementing a patient discharge checklist to ensure patients' and caregivers' engagement in the discharge process

The discharge checklist includes followings such as:

- Caregiver instruction on bed mobility, transfer, ambulation and walking aids
- Red flags signs to seek help after discharge
- Phone contact of our nurse consultant will be given to the patients and caregivers on discharge. They can seek for help or clarification when they face difficult caring issues at home.

(iii) Study design

The is a prospective study and a randomised controlled trial will be conducted in Hong Kong west cluster. The subjects are those patients with fracture hip. Patients will be recruited according to inclusion and exclusion criteria. After recruitment, patients will be randomised.

Randomization

The block randomization method will be used to allocate subjects randomly to the intervention group and control group using blocks of four (AABB, ABAB, ABBA, BAAB, BABA, and BBAA). The patients are randomly assigned to 2 study groups when they are in the acute hospital: patient and caregiver empowerment group or control group that will receive standard rehabilitation care. The assessors who are measuring the key outcome measure are unaware of the study arm allocation. Due to the study intervention, the patients and caregiver cannot be blinded to the study group allocation.

Enrolment of participants

The participating study sites will identify all eligible patients (i.e. who meet all of the inclusion and none of the exclusion criteria). The assessment of eligibility will be performed by the investigator or a Study Coordinator, who will approach each potential study patient and inquire about their interest and eligibility in participating in this study. This inquiry will include screening questions to confirm eligibility as well as a description of the study and responsibilities for participating.

If the patient wishes to participate, a member of the research team will go through the informed consent process, which will explain the purpose of the study, the procedures, the risk/benefits, alternatives to participation, and data protection. Each patient choosing to participate will sign and date an Informed Consent Form. A copy of the signed Informed Consent Form will be placed into the patient's medical record, the Investigator Site File or the patient binder and one copy will be handed over to the patient.

All patients with written informed consent will be allocated to a unique patient trial number. The date of informed consent and the recruitment information is entered in the study database. The recruitment period will be up to 12 months, during which 122 patients are planned to be enrolled.

Primary and secondary outcome

Primary outcomes:

- Functional scores (Modified Barthel Index and EQ-5D-5L) at first follow up visit (3 months postop).

Secondary outcome:

- Cumulative readmission rates at 1 month, 6 months and 1 year
- The length of stay in convalescent hospital
- Subsequent injury with fractures within 1 year

Study procedure

The schedule of all follow-up visits including data to be collected at each visit is shown in Table 2 below.

Premature study termination

Patient participation in the study may end prematurely for one of the following reasons:

1. Patient withdrew informed consent
2. Protocol violation
3. Unknown/lost to follow-up
4. Death
5. Other

(iv) Data processing and analysis

The comparison will be performed between the intervention group and the control group. Patients will be assigned to the intervention group or control group by block randomization method. Data on patient demographics, diagnosis, comorbidities and functional scores from two groups will be abstracted from hospital records as baseline data. Modified Barthel Index and EQ-5D-5L will be recorded at discharge and on follow up as primary outcomes. Cumulative readmissions within 1 month, 6 months and 1 year of discharge, the length of stay in convalescent hospital and subsequent injury with fractures will be captured as secondary outcomes.

Data analysis will be performed using the Statistical Package for Social Science (SPSS) software. Baseline data, primary outcomes and secondary outcomes of the intervention group and control group will be compared. Chi-square test will be used for categorical variables. For continuous variables, the normal distribution will be determined by the Kolmogorov–Smirnov test. Independent *t*-test will be used for comparing average values of normally distributed continuous variables, while the Wilcoxon rank sum test will be used for comparing median values of abnormally distributed variables. The difference will be considered significant only if $p < 0.05$.

Binary logistic regression will be used to determine predictive factors for primary and secondary outcomes. Multivariate analysis will also be performed to verify independent predictive factor for outcomes. Odds ratios and 95% confidence intervals will be used for association estimation.

Power analysis

According to past records, the mean Modified Barthel Index at postoperative 3 months is about 80, with a standard deviation of about 20. The expected difference between the intervention group and control group will be 10 points. With a statistical power of 0.8 and the level of significance of 0.05 using the two-sided independent *t* test, the number of subjects in each group will be estimated to be 64, based on the computation with the G*Power 3.1.9.2. With an estimation of attrition of about 10 percent of the recruited subjects, a total sample of 140 will be needed.

Hospital registry data showed in 2017 this cluster had received 373 hip fracture patient admission. 337 were included in the clinical pathway, of which 292 were transferred to convalescent hospital for rehabilitation after hip fracture surgery. 201 patients were discharged back to home with caregivers after completion of rehabilitation. We should be able to complete the recruitment of

140 patients within 1 year.

Data Collection

The senior research assistant will not only coordinate among different disciplines, but he or she will also collect data through the electronic record system. Any missing or unclear data will be verified by direct assessment of the medical record itself by tracing the medical record file.

Data Store

All materials pertaining to the investigation will be monitored and kept in closed archives by the CI responsible for documentation. All investigators will maintain all source data together with related documentation for a maximum period of time permitted by the hospital, institution or relevant setting.

Confidentiality

Confidentiality of the data and subject records will be maintained by investigators' compliance with local legislation, regulatory restrictions and ethical considerations. The investigators will remove all patient identifiers except for subject numbers, gender and date of birth. All study personnel involved is bound to secrecy.

[Word Count: 3527]

e) Existing Facilities:

Department of Orthopaedics and Traumatology, Queen Mary Hospital had a good track record of running the geriatric hip fracture pathway since 2004. A team of professionals including doctors and therapists with experience in hip fracture patient care were present in our centre who can materialize this programme. We have technicians and audio-visual facilities who are ready to record the videos. Trial recording of one video (hip fracture treatment) had been performed. A schedule and content for videos taking and training sessions have been planned. On the other hand, SPSS is available for data processing.

f) Justification of Requirements:

- 1) An experienced Senior Research Assistant is responsible for coordinating between disciplines (doctor, nursing, physiotherapist, occupational therapist), monitoring the project within the 2-year study period and also responsible for guiding the research clinics such as preparing study questionnaires and study materials, filming and editing training video. He/she is also required to ensure the data efficacy and perform data analysis.
- 2) A Senior Research Assistant is responsible for running the research clinic during the 2-year study period and required for the following work:
 - a. **Screening** of potential study subjects
 - b. Monitoring of all the geriatric hip fracture patients for the timeframe mentioned above in 3 hospital including **Queen Mary Hospital, Fung Yiu King Hospital and MacLehose Medical Rehabilitation Center**
 - c. **Demographic data completeness monitoring**
 - d. Monitoring and audit of the **functional scores**

- e. **Scheduling** the follow-up visits
 - f. **Input of all the data of hospital stay and related material** into computer
 - g. **Trace medical record file** if there is unclear or incomplete data which are not available in the electronic medical record system
 - h. **Trace all deaths** of the patients under investigation through the hospital authority medical record system
 - i. **Basic statistical analysis** on all study parameters
- 3) Publication cost to cover the cost of publishing results of the proposed project
 - 4) Travel and subsistence to support attendance at local and international conferences for dissemination of research findings (registration, preparation of material, travel & accommodations, etc.)
 - 5) Audit fee to cover cost of independent accounting auditing
 - 6) 10 iPads will be acquired at convalescent hospitals (2 in FYKH Orthopaedic Ward, 1 in FYKH Physiotherapy Department, 1 in FYKH Occupational Therapy Department, 2 in MMRC Orthopaedic Ward, 1 in MMRC Physiotherapy Department, 1 in MMRC Occupational Therapy and 2 in Community Nursing Department) to allow easy access of the training videos by patients and relatives.
 - 7) 2 LED flat soft light panels will be acquired for high-quality filmmaking
- g) Impact on People's Health and Health Services as well as Plan to Disseminate Research Findings to End Users:
- 1) Analysis of the demographics of geriatric hip fracture patients in the study period can outline the general status of this group of patients.
 - 2) The change in any fracture types can guide our strategy on implants and prosthesis in the coming years.
 - 3) coming years.
 - 4) The causes of fall can help us to enhance the present fall prevention program.
 - 5) If empowerment program is proven to be effective in functional outcomes and readmission rate of elderly patients after hip fracture, this care model in our hospital can be set as an example to all other hospitals in Hong Kong or even in China. With the ageing population problem coming, this can help to plan the future direction of our fragility fracture care and ease the foreseeable heavy burden coming from the geriatric patients.
 - 6) The concept of fracture empowerment to patients and those caregivers can be further expanded to other musculoskeletal diseases.
 - 7) Useful data generated by this small study may lead to a full-scale study in the future and aim to prevent subsequent fragility fractures.
- h) Key References:

1. Gullberg B, Johnell O, Kanis JA. World-wide projections for hip fracture. *Osteoporos Int.* 1997;7(5):407-13.
2. Liu SK, Ho AW, Wong SH. Early surgery for Hong Kong Chinese elderly patients with hip fracture reduces short-term and long-term mortality. *Hong Kong Med J.* 2017;23(4):374-80.
3. Lau TW, Leung F, Siu D, Wong G, Luk KD. Geriatric hip fracture clinical pathway: the Hong Kong experience. *Osteoporos Int.* 2010;21(Suppl 4):S627-36.
4. Lau T. Queen Mary Hospital Clinical Pathway on Geriatric Fracture Hip Annual Report. Hong Kong: Queen Mary Hospital; 2017.
5. Lofgren S, Hedstrom M, Ekstrom W, Lindberg L, Flodin L, Ryd L. Power to the patient: care tracks and empowerment a recipe for improving rehabilitation for hip fracture patients. *Scand J Caring Sci.* 2015;29(3):462-9.
6. Lin PC, Lu CM. Hip fracture: family caregivers' burden and related factors for older people in Taiwan. *J Clin Nurs.* 2005;14(6):719-26.
7. Hendrix CC, Landerman R, Abernethy AP. Effects of an individualized caregiver training intervention on self-efficacy of cancer caregivers. *West J Nurs Res.* 2013;35(5):590-610.
8. Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. *J Am Geriatr Soc.* 2004;52(11):1817-25.
9. Tearl DK, Hertzog JH. Home discharge of technology-dependent children: evaluation of a respiratory-therapist driven family education program. *Respir Care.* 2007;52(2):171-6.
10. Lindberg L, Ekstrom W, Hedstrom M, Flodin L, Lofgren S, Ryd L. Changing caring behaviours in rehabilitation after a hip fracture - A tool for empowerment? *Psychol Health Med.* 2017;22(6):663-72.
11. Wong TM, Leung FKL, Lau TW, Fang C, Chan FHW, Wu J. Effectiveness of a Day Rehabilitation Program in Improving Functional Outcome and Reducing Mortality and Readmission of Elderly Patients With Fragility Hip Fractures. *Geriatr Orthop Surg Rehabil.* 2018;9:2151459318759355.