

Clinical effectiveness and cost-effectiveness analysis of home-based rehabilitation following hip fracture surgery: Study protocol

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ABSTRACT

Background: Hip fracture incidence has risen significantly with population aging. Postoperative rehabilitation plays an important role in patient recovery. Home-based rehabilitation promotes continuous care. However, evidence of clinical outcomes and cost-effectiveness is needed.

Objectives: To investigate the clinical effectiveness and cost-effectiveness of home-based rehabilitation compared with facility-based rehabilitation as the usual rehabilitation scheme after hip fracture surgery.

Materials and methods: This study was a quasi-experimental design with cost-effectiveness analysis. One hundred and four participants were recruited (52 participants per arm). Both groups received interventions for 8 weeks, either at the patient's home or at the hospital. Outcome variables included physical performance, ability to perform daily activities, fall efficacy, and quality of life. These outcomes were evaluated at baseline, postintervention, and at the 6-month follow-up. Moreover, we performed a cost-effectiveness analysis after the 6-month follow-up period.

Results: The outcome variables would be evaluated and compared between groups and time points at baseline, after the 8-week intervention, and at the 6-month follow-up. The changes in clinical outcomes would be examined and reported for both between- and within-group comparisons. The cost-effectiveness at the 6-month follow-up would be specified as the incremental cost-effectiveness ratio (ICER), while also considering parameter uncertainty.

Conclusion: Home-based rehabilitation following hip fracture surgery was expected to enhance functional recovery, quality of life, and cost-effectiveness. Moreover, this intervention could help solve patients' problems related to accessibility and continuing care.

Introduction

The incidence of hip fracture has dramatically increased in an aging society, including Thailand.¹ The incidence of hip fracture in Thai elderly individuals is approximately 140.9 patients per 100,000 person-years.² Its complications not only lead to physical problems such as embolism, delirium, or pressure ulcers but also lead to economic problems at the household and national levels.^{3,4}

Rehabilitation after hip fracture surgery is very important for enhancing functional recovery and independent living.⁵ However, despite health insurance coverage, access to facility-based rehabilitation services remains challenging for some patients due to limited mobility, transportation difficulties, and caregiver constraints. Home-based rehabilitation is a way to increase accessibility of continuous postoperative rehabilitation.⁶ Several studies have proposed home-based methods as the standard of practice. However, the effectiveness of home-based rehabilitation is still controversial compared with that of facility-based programs.^{5,7,8}

In addition to clinical outcomes, health economic evaluations are needed for health policy decisions. Previous studies have demonstrated that the cost-effectiveness of home-based rehabilitation compared with usual or standard care remains inconclusive due to the diverse health system contexts and evaluation perspectives across countries.⁹

In Thailand, the National Health Security Office (NHSO) advocates home rehabilitation after hip fracture surgery.^{10,11} The fragility hip fracture has been considered a condition requiring intermediate care, i.e., intensive rehabilitation. However, a specific rehabilitation protocol for hip fracture, especially a home-based program, has not been established. Additionally, the cost-effectiveness of the policy had

never been determined. Therefore, the objectives of this study were to investigate the clinical effectiveness and cost-effectiveness of home-based rehabilitation after hip fracture surgery.

Materials and methods

Study design

This study was a quasi-experimental alongside health economic evaluation design (Thai Clinical Trials Registry (TCTR) Identifier: TCTR20250527001). Assessors were blinded, whereas physiotherapists and participants could not be blinded due to the context of the rehabilitation program. Additionally, the group allocation could not be randomized because of the nature of the health insurance scheme and the convenience of the participants and caregivers.

Study setting

The participants were recruited from the hospital after hip fracture surgery. Then, they were assigned to two groups, home-based and facility-based rehabilitation, based on their own preferences. The characteristics considered important prognostic indicators, including age, sex, type of fracture, type of operation, comorbidities, cognitive level, and time to rehabilitation, were exhaustively recorded to monitor the equivalence of participants in each group. For the home-based rehabilitation group, the rehabilitation was delivered to their homes. The facility-based group received the rehabilitation program as outpatients in the physical therapy section.

Study population and sample recruitment

Participants were recruited from Bhumibol Adulyadej Hospital, a tertiary hospital in Bangkok. The patients were referred to the rehabilitation department

after surgery. They were then invited to participate if they met all criteria. A physical therapist recruited participants and screened them according to the inclusion and exclusion criteria.

The inclusion criteria included patients aged more than 50 years who underwent hip fracture surgery for the first time. A postoperative duration of less than 3 months was considered. Patients with both intra- and extracapsular hip fractures were recruited. Each subject had to be accompanied by their own caregiver.

Participants were excluded if they had pathological bone conditions such as sarcoma or disease-related fractures; cognitive decline indicated by The Montreal Cognitive Assessment score (MoCA-Thai) of 24 or lower (adjusted for education)¹² (assessed by the physical therapist who was the recruiter); inability to ambulate at least 10 meters independently or with assistance prior to the fracture; neurological or other disorders affecting mobility; medical issues that restricted physical activity; infectious diseases or poorly controlled chronic illnesses; advanced osteoporosis; or malnutrition defined by the European Society of Clinical Nutrition and Metabolism as a weight loss exceeding 5% over the past six months.¹³

The study protocol was explained to the patients and their caregivers, and a participant information sheet was also provided. The information included rationales, objectives, study procedures, and details of the interventions used in this study. If patients chose to participate, they signed an informed consent form. Then, the baseline assessment appointment was scheduled.

Assessors

Three physical therapists who had more than three years of experience in the geriatric musculoskeletal field were the assessors in this study. They were trained to use all measurement tools. The intra-rater and inter-rater reliability tests were conducted to confirm their consistency of measurement. The intraclass correlation coefficient (ICC) cut-off was set at more than 0.75 (good reliability). All assessors were blinded to the group allocation of all participants. Additionally, all measurements were performed at appointment dates in the hospital. However, if the participants could not attend the appointment in the outpatient clinic, they were evaluated at home regardless of group allocation.

Variable studied

Physical performance was the main outcome in this study. It was evaluated using the Short Physical Performance Battery (SPPB), which has been shown to have high intra- and intertester reliability (ICC=0.88-0.92).¹⁴ The SPPB is used to assess physical performance in older adults and comprises three components: balance, lower extremity strength, and gait speed. The balance assessment included standing with feet together, in semi-tandem, and in tandem positions. Gait speed was evaluated by measuring the time required to walk 2.44

meters, while lower extremity strength was assessed by the time taken to rise from a chair and sit down five times. Total scores ranged from 0 to 12, with higher scores indicating better physical function (0=poor function; 12=excellent function).¹⁵

Fall efficacy was assessed via the Falls Efficacy Scale-International (FES-I). This assessment is commonly used to assess fear of falling. There are 16 activity items related to daily living. Participants rated their fear of falling in each activity on a scale of 1-4 points.¹⁶ FES-I has been proven to have moderate test-retest reliability (ICC=0.72) in patients with hip fractures.¹⁷

Quality of life was evaluated using the EuroQol-5 dimensions scale (EQ-5D-5L). The EQ-5D-5L has two parts. Part I includes five domains assessing health status: mobility, self-care, pain, anxiety and depression, and usual activity. Participants rated their score based on the severity in each domain. In addition, they rated their health status score on a visual analog scale in Part II.¹⁸

Ability in daily living activities was measured by the Barthel index (BI). Ten activities, including feeding, moving from wheelchair to bed and returning, personal toilet, getting on and off the toilet, self-bathing, ability to walk, stair climbing, dressing, controlling bowels and controlling the bladder, were evaluated. The assessor rated the score as 0, 5, 10, or 15 based on independent performance in the activity, with a maximum score of 100 points (a high score indicates independent living).^{19,20} The BI has been proven to have moderate intertester (ICC=0.71) and high intratester reliability (0.97).¹⁹

The cost-effectiveness analysis was conducted from a societal perspective and included all costs related to hip fracture rehabilitation. The incremental cost-effectiveness ratio (ICER) was used for the cost-effectiveness analysis.²¹ The ICER formula is as follows:

$$\text{ICER} = (\text{CostA} - \text{CostB}) / (\text{QALYA} - \text{QALYB})$$

Cost A: Cost of intervention (Home-based rehabilitation)

Cost B: Cost of comparator (Facility-based rehabilitation)

QALY A: Quality-adjusted life year of the intervention (Home-based rehabilitation)

QALY B: Quality-adjusted life year of the comparator (Facility-based rehabilitation)

The cost variables were collected as follows:

1. **Direct medical costs** were calculated as the unit cost of rehabilitation services per visit and multiplied by the number of visits.

2. **Direct non-medical costs** included transportation, paid caregiver, and informal care costs incurred during the rehabilitation period. Transportation costs were valued using actual public transport expenses or government rates for private transportation. Paid caregiver costs were based on actual payments, excluding family-provided

care. Informal care costs were estimated from time spent by family members or friends on patient care activities and valued using gross national income (GNI).

3. **Indirect costs** associated with productivity losses were excluded from the base-case analysis in accordance with the Thai Health Technology Assessment guidelines, as health outcomes were captured using quality-adjusted life years (QALYs).²¹

Study conduct

The demographic data were recorded. Baseline clinical outcome data, including the SPPB, FES-I, EQ-5D-5L, and BI scores, were assessed. After completion of the intervention at 8 weeks, these assessments were re-evaluated. Finally, the follow-up period at 6 months after hospital discharge was set for assessing the long-term effect of each intervention arm. The same outcome measures were monitored. Furthermore, participants and caregivers reported costs incurred during the intervention period for the cost-effectiveness analysis (Figure 1).

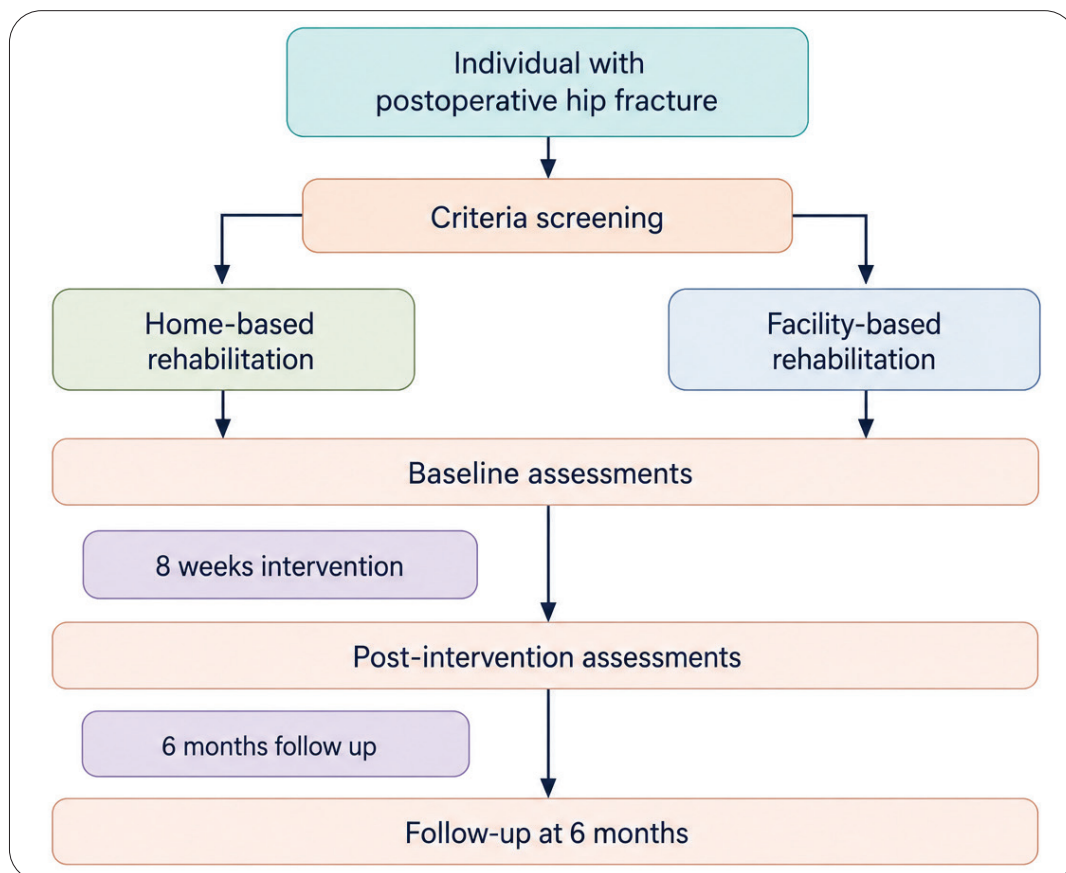


Figure1. Flow diagram of the study.

Intervention

To ensure a fair comparison, participants in both groups received the same standardized rehabilitation domains, including strengthening exercises, weight-bearing training, functional training, and education. This approach allowed any differences in outcomes to be attributed to the rehabilitation setting rather than differences in training dosage.

Home-based rehabilitation group

The home-based rehabilitation group received progressive strengthening exercises, weight-bearing exercises, balance training, functional mobility training, and education on complication prevention. The program was designed based on an intensive literature review and confirmation by an expert panel. The physiotherapists who delivered this program were trained before providing

it in participants' homes. The home environment was assessed and adjusted. The home visit plan was once a week for 8 weeks. Moreover, the participants received a booklet containing information and education about their condition and rehabilitation plan during the first visit.

1. Progressive strengthening exercises. The strengthening program targeted lower-limb muscles, specifically the plantar flexors, knee extensors, hip abductors, and hip extensors. The exercise intensity was progressively increased through added resistance, with each session consisting of 8-12 repetitions per set, 3 sets per day, for a minimum of five days per week. A trained caregiver supervised the exercises for safety.

2. Weight-bearing and balance training. The weight-bearing and balance training program comprised activities such as standing balance, forward stepping, sideways

stepping, and forward lunges. The program was tailored to each participant's abilities, with all exercises performed throughout the intervention period. Participants who could complete the required repetitions and timing at a given level progressed to the next level of difficulty.

3. Functional training. The program incorporated transfer activities tailored to each individual's daily needs, including various home-based tasks such as moving from supine to sitting, transitioning from sitting to standing, walking, and climbing stairs.

4. Education. Patient education covered guidance on home modifications to prevent recurrent falls and enhance the safety of mobility and transfers. It also focused on preventing complications such as wound infections, delirium, and dislocations while supporting improvements in daily activities and overall mobility. The information was included in the booklet for the subject.

Facility-based rehabilitation group

The facility-based rehabilitation group was conducted at the outpatient rehabilitation clinic. Physiotherapists providing care in the hip fracture rehabilitation clinic delivered the program. The program followed the usual care standard in the setting and included functional and weight-bearing training, strengthening exercises, and home program education. The participants were scheduled for appointments once per week for 8 weeks.

1. Strengthening exercise. The strengthening exercises targeted lower extremity muscles, specifically the hip abductors, hip extensors, knee extensors, and plantar flexors. The prescribed routine involved 10-15 repetitions per set, 2-3 sets per day, performed 3-5 days a week. The exercises were conducted under the supervision of the physical therapist or the caregiver to ensure safety.

2. Functional and weight-bearing training. Ambulation training included bedside activities such as transferring from supine to sitting, sitting to standing, standing, and walking, tailored to each participant's functional ability. Additionally, weight-bearing exercises such as functional reach, standing squats, and forward stepping were incorporated.

3. Education. The education program aimed to provide patients with guidance on proper transfer techniques, the use of gait aids, and the prevention of complications such as dislocation.

Sample size calculation

Sample size calculation was conducted using the G*power program. Based on a previous study, the effect size of the home-based and facility-based comparison was 0.72 and 0.56 for daily activity and mobility outcomes, respectively.⁵ In this study, we focused on physical performance, which contained mobility outcomes; therefore, the effect size applied was 0.56. Other parameters were set as a two-tailed test, a 0.05 probability of error, and 80% power. Then, the total sample size required was 82 participants (41 participants

in each arm). However, a 20% dropout rate. Finally, 104 participants were recruited (52 participants per group).

Safety

All physical therapists involved in the study were trained in adverse event prevention and management. Serious adverse events prompted immediate guidance to participants and caregivers regarding hospital treatment, with coordination between the research team and hospital personnel.

Harms

The study was monitored for adverse events, particularly falls. Physical therapists trained both participants and their caregivers until they could safely perform the prescribed tasks. Safety measures included using a gait belt during ambulation, transfers, and training activities. All exercises were always carried out under caregiver supervision, and participants were advised not to attempt any activities or exercises not instructed by a physical therapist, as this could increase the risk of falls or injury.

Statistical analysis

The SPSS software (IBM SPSS Statistics V18.0 for Windows, SPSS Inc., USA) was used for data analysis. Age, sex, type of fracture, type of operation, comorbidities, cognitive level, and time to rehabilitation were presented with descriptive statistics, which included means with standard deviations (SDs) for continuous data and frequencies for categorical data.

In case of any difference between groups at baseline, the multivariable-adjusted ANCOVA models would be applied, considering the baseline outcome measures and relevant demographics as covariates. For outcomes measured repeatedly over time, linear mixed-effects models were used, including fixed effects for group, time, and the group-by-time interaction, with baseline values and potential confounders as covariates.

To test for normal distribution, the Shapiro-Wilk test was used. In addition, outcome comparisons between groups were analyzed using a two-way mixed ANOVA. However, the Mann-Whitney U test was used when the data violated the assumption of normality. The statistical significance level was set at 0.05.

For the cost-effectiveness analysis, the ICER was used for the health economic evaluation. The cost-effectiveness threshold was set at 160,000 Baht/QALY.²¹ Furthermore, probabilistic sensitivity analysis (PSA) was investigated for uncertainty of ICER.

Results

This section outlines the outcome variables to be reported and the planned analytical approach for each. The demographic and clinical characteristics of participants in the home-based and facility-based rehabilitation groups, as listed in Table 1, would be reported. Baseline comparability between groups would be

examined using statistics appropriate to each variable's distribution.

As presented in Table 2, the outcome variables would be assessed and compared between groups and times at baseline, post 8-week intervention, and 6-month follow-up. Between-group and within-group changes in physical performance (SPPB), fall efficacy

(FES-I), quality of life (EQ-5D-5L), and ability in daily living activities (BI) would be analyzed according to the statistical plan and then reported. Cost-effectiveness at the 6-month follow-up would also be presented as the incremental cost-effectiveness ratio (ICER), with parameter uncertainty addressed.

Table 1. Independent demographic variables.

Variable	Values
Age	Years
Sex	Male/Female
Types of fracture	Intracapsular/Extracapsular fracture
Types of operation	Internal fixation/Hemi hip arthroplasty/Total hip arthroplasty
Comorbidities	Number of comorbidities
Cognitive level	Score of Montreal Cognitive Assessment (MoCA)
Time to rehabilitation	Days

Table 2. Outcome variables.

Outcome variables	Period of assessment			Assessment
	Baseline	Post 8-week intervention	Follow up 6 months	
Physical performance (main outcome)	X	X	X	SPPB
Fall efficacy	X	X	X	FES-I
Quality of life	X	X	X	EQ-5D-5L
Ability in daily living activities	X	X	X	BI
Cost-effectiveness			X	ICER

Discussion

This study aims to evaluate and compare the clinical effectiveness and cost-effectiveness of home-based and facility-based rehabilitation. The study recruited 104 individuals who had undergone post-hip fracture surgery. Then, they were divided into two groups, including home-based and facility-based rehabilitation, regarding their context of health insurance scheme and transportation to receive rehabilitation. The study monitored outcomes including physical performance, fall efficacy, quality of life, ability in daily living activities, and cost-effectiveness.

Some differences were observed between home-based and facility-based rehabilitation. Home-based rehabilitation included actual environmental adjustments, as the therapist could directly evaluate and advise the home setting. The facility-based group received the home adjustment recommendation without actual evaluation by the clinician. Previous studies suggest that environmental adjustment is an important factor in enhancing functional recovery and minimizing secondary falls because many hip fracture patients fall into an inappropriate environment.²² However, rehabilitation at the participant's home might have some limitations compared with the facility-based

group in terms of space, personnel, and equipment for rehabilitation.

Physical performance, which was measured by the SPPB, was the main outcome in the study. The SPPB specifically represents lower-extremity performance. Magaziner *et al.* used the SPPB as the outcome to evaluate patients post-hip fracture in their study.²³ Interestingly, they reported no statistically significant difference in physical performance between groups receiving home-based rehabilitation compared with those receiving the standard of care. However, they detected a smaller, meaningful difference.²³ The barrier in this study might be illness and hospitalization of patients that limit continuation of the intervention. Additionally, the protocol for both groups was unclear. We expected our study to provide further evidence to clarify rehabilitation protocols and the actual effect of home-based rehabilitation on physical performance. In addition, we anticipated a change score exceeding 1 point based on the Minimal Clinically Important Difference (MCID) findings of Perera *et al.*'s study.²⁴

The Falls Efficacy Scale-International (FES-I) was used to assess the fear of falling. Lee *et al.* also used the FES-I to measure outcomes. However, they reported

that only clinical change was significant, with no significant difference between usual care and home-based rehabilitation.²⁵ The small sample size might be a limitation in their study. In this study, we expected a difference of 6.0 points in the FES-I score, according to the MCID.²⁶

For quality of life, Taraldsen *et al.* used the EQ-5D-5L to compare home-based care with usual care. No statistically significant difference was observed between the two treatment protocols.²⁷ Furthermore, information on the MCID in the EQ-5D-5L has not been established. However, in addition to evaluating quality of life with the EQ-5D-5L, we also determined cost-effectiveness in our study.

Ability in daily activities was measured by the BI. It was evaluated at baseline, post 8-week intervention, and follow-up period. We expected the change score to surpass 9.8 points according to the study by Unnanuntana *et al.*²⁰

Regarding cost-effectiveness, previous studies have shown heterogeneous outcomes when comparing home-based programs with usual care. Differences in the health reimbursement system context were one of the factors influencing cost-effectiveness evaluation.^{9,28-29} Moreover, previous studies included only the payer perspective, and only one was conducted from a societal perspective.⁹ The societal perspective was very important among hip fracture patients because their family members had to take approximately 39.5 hours per week to care for patients. Therefore, our study investigated health economic outcomes from a societal perspective.^{30,31}

The results of this study would provide a comprehensive understanding of the effectiveness of home-based rehabilitation after hip fracture surgery from both clinical and economic perspectives. Therefore, we expected that the results would be important information for policy decision makers. Thus, evidence-based guidelines for rehabilitation programs after hip fracture surgery in Thailand could be established.

Limitations

This study might have several limitations. Firstly, the study design and implementation could be influenced by the specific characteristics of the participating settings and participants, which might limit the generalizability of the findings. Secondly, variations in adherence to and implementation of the intervention might affect interpretation of the study outcomes. Finally, as this is a protocol describing a planned study, the findings might depend on the successful implementation of the proposed methodology and follow-up procedures.

Conclusion

This study protocol describes a structured approach to evaluating the effectiveness and economic value of home-based rehabilitation. The findings are expected to provide evidence to inform clinical practice and

support the development of appropriate postoperative hip fracture rehabilitation strategies.

Ethical approval

Mahidol University Central Institutional Review Board (COA No. MU-CIRB 2025/107.0304) approved the research protocol. Written informed consent was obtained from all participants.

Declaration of generative AI and AI-assisted technologies

During the preparation of this manuscript, the authors used ChatGPT (OpenAI) to assist with language editing, grammar checking, and improving the manuscript's clarity and readability. The authors reviewed and edited all AI-assisted content and took full responsibility for the accuracy, originality, and integrity of the final manuscript. ChatGPT was not used to generate research data, conduct statistical analyses, or make scientific interpretations or conclusions.

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Conflict of interest

The authors declare no conflicts of interest.

CRediT authorship contribution statement

Rapeepat Jitmal: conceptualization, methodology, investigation, writing-original draft, review and editing, visualization, project administration; **Mantana Vongsirinavarat:** conceptualization, methodology, supervision, writing-review and editing, project administration; **Wanlop Kunanusornchai:** methodology, supervision, writing-review and editing; **Pattara Leelahavarong:** methodology, writing-review and editing, supervision; **Piyaporn Pramuksun:** methodology, writing-review and editing, supervision.

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