Cost-effective rehabilitation and care after hip fracture

PhD dissertation

Jonas Ammundsen Ipsen
Oktober 2024

Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding

Department of Regional Health Research, University of Southern Denmark, Odense

Content

Supervisors

Main supervisor

Inge Hansen Bruun, PhD

Associate Professor, Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding, & Department of Regional Health Research, University of Southern Denmark, Odense

Co-supervisors

Bjarke Viberg, MD, PhD

Professor, Department of Orthopaedic Surgery and Traumatology, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding, & Department of Orthopaedic Surgery and Traumatology. Odense University Hospital, Odense, & Department of Clinical Research, University of Southern Denmark, Odense

Eva Draborg, PhD

Associate Professor, DaCHE – Danish Centre for Health Economics, Department of Public Health, University of Southern Denmark

Assessment Committee

Chair of committee

Liza Sopina, PhD

Associate Professor, DaCHE - Danish Centre for Health Economics, University of Southern Denmark SDU

National assessor

Michael Skovdal Rathleff PhD, dr.med

Professor, Department of Health Science and Technology, Aalborg University, and Centre for General Practice at Aalborg University.

International assessor

Hans Olav Melberg, PhD

Professor, Department of Community Medicine, Faculty of Health Sciences, University of Tromsø, The Arctic University of Norway

Funding

Novo Nordisk Foundation - grant number NNF210C0068702

National Association of Physiotherapists

William Demant Foundation

Lillebaelt Hospital.

This thesis is the sole responsibility of the author identified. It does not reflect the views of the Novo Nordic Foundation or other funders. The funders had no role in the study designs, data collection, analysis, interpretation or report writing. The studies included in the thesis were completed independently of the administering organisation and funders.

Acknowledgements

To my three supervisors, Bjarke, Inge and Eva, thank you for believing in me and accompanying me on this academic journey. Thank you for your supervision, your time and always being available for discussions. You opened your networks to me, gave me opportunities to fail and to learn, and challenged me every step of the way. For this, I will forever be grateful.

To my fellow PhD students at Kolding and Odense Hospital and DaCHE, thank you for your company and support. Special thanks go to Signe, Henriette, Stefan, Trine, Morten, Louise, Amalie and Anna – I exploited your knowledge and experience whenever I had the chance. Thank you for allowing me to do so. I have thoroughly enjoyed having each and every one of you as a colleague.

Particular thanks must go to Lars Tobiesen Pedersen, my fellow PhD colleague in the Rehabilitation for Life trial. More than anyone else, Lars has challenged my views and beliefs and has been a friend and confidant from the day we both started our PhD journey. I appreciate your feedback, support and company immensely.

To the decision-makers and data managers at Lillebaelt Hospital and the six municipalities in the catchment area: Kolding, Vejle, Middelfart, Fredericia, Vejen and Billund – thank you! Together we managed to build a very unique dataset. I hope we can continue this cooperation in the future.

For all the clinicians in hospital and municipalities, thank you with your commitment it was possible to change patients course of rehabilitation and care.

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I would also like to thank my co-authors, Charlotte Abrahamsen, Birgitte Nørgaard, Charlotte Suette and Jan Abel Olsen, for their support and contributions. Their input improved the studies presented in this thesis.

To Jan and Hans Olav, thank you for hosting my research stay at the Department of Community Medicine in Tromsø; it was a very special and rewarding time for my family and me.

To Trine Kjær, thank you for facilitating contact with Jan, and for all the feedback, support and intellectual contributions you made to the works presented in this thesis.

Last, but not least, to Henriette – the most important reason for my success – thank you for encouraging me to go back to university and for being there and supporting me throughout my PhD. You, more than anyone, have seen the ups and downs and helped me get back on track.

To Christian, Aviaja and Anker, thank you so much. You have had to endure long and boring talks at the dinner table and, at times, tolerate a father whose mind was elsewhere. You have reminded me of what is important and helped me retain some balance when I was most busy.

List of studies

The thesis entail three published manuscripts and one manuscripts under review.

Study I

Ipsen JA, Pedersen LT, Draborg E, Bruun IH, Abrahamsen C, Viberg B. Cost-Effectiveness of Physical Rehabilitation and Care of Older Home-Dwelling Persons after Hip Fracture: A Systematic Review and Narrative Synthesis. J Rehabil Med. 2022 Nov 24;54:jrm00351. doi: 10.2340/jrm.v54.3421. PMID: 36314360; PMCID: PMC9709712.

Study II

Ipsen JA, Viberg B, Pedersen LT, Draborg E, Bruun IH. Informal care after hip fracture: prospective cohort. BMC Geriatr. 2024 May 17;24(1):436. doi: 10.1186/s12877-024-05040-y. PMID: 38760708; PMCID: PMC11100116.

Study III

Ipsen JA, Pedersen LT, Viberg B, Nørgaard B, Suetta C, Bruun IH. Rehabilitation for life: the effect on physical function of rehabilitation and care in older adults after hip fracture-study protocol for a cluster-randomised stepped-wedge trial. Trials. 2022 May 7;23(1):375. doi: 10.1186/s13063-022-06321-w. PMID: 35526010; PMCID: PMC9077959.

Study IV

Ipsen JA, Olsen JA, Viberg B, Pedersen LT, Bruun IH, Draborg E Rehabilitation and care after hip fracture: A cost-utility analysis of a stepped-wedge cluster randomised trial. In review at Journal of Rehabilitation Medicin.

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Summary

The overall aim of this thesis was to contribute new evidence on post-surgical rehabilitation and care following hip fracture and identify possibilities for improved Cost-effectiveness.

Study I was a systematic review with a narrative synthesis that summarised and described the evidence base around post-surgical rehabilitation and care courses after hip fracture comparable to a Scandinavian healthcare system. Three cost-utility analysis matched the in- and exclusion criteria. The three interventions were heterogen in content and when their interventions started after the hip fracture surgery. They used the same health care sector perspective but did not measure the same costs or indirect costs as informal care. Hence the three analysis were too heterogen for synthesised comparisons and firm conclusions.

Study II was a prospective cohort study using the Rehabilitation for Life cohort and explored how often, to what extent, and when patients received help from informal caregivers following hip fracture. Of the 244 patients, 90% reported receiving informal care. The median total amount of informal care was 32 hours; at the twelve-week follow-up, 36% still received informal care. In conclusion informal care is very prevalent after hip fracture and should be measured as a cost.

Study III was the study protocol for the Rehabilitation for Life trial, and described the design, methods and conduct of this trial.

Study IV was a cost-utility analysis with a limited societal perspective comparing the cost per QALY between Rehabilitation for Life and usual rehabilitation and care after hip fracture. The usual rehabilitation and care was the cost-effective approach.

The findings of this thesis have provided new insights into patients' need for rehabilitation and care and identified an approach that is slightly better but costly compared to usual rehabilitation and care after a hip fracture. **Study I** established that the evidence base on rehabilitation and care after hip fracture was limited and heterogeneous and highlighted the need for more comprehensive measurements of cost. **Study II** demonstrated the extensive role played by relatives in meeting a patient's need for care after hip fracture, providing a strong argument for including measurements of informal care after hip fracture. **Study III** provided an in-depth description of the Rehabilitation for Life intervention. **Study IV** compared and ranked the costs and effects of Rehabilitation for Life and usual rehabilitation and care after hip fracture. Rehabilitation for Life had a small but statistically significant additional effect on patients' quality of life, but at a higher cost.

Dansk resume

Formålet med afhandlingen var at udbygge den sundhedsøkonomiske evidensbase for genoptræning og pleje af ældre efter hoftebrud og identificere mulige veje til øget omkostningseffektivitet.

Studie I var et systematisk review med en narrativ syntese af omkostnings- og effektanalyser med kvalitetsjusterede leveår som udfald. Tre analyser matchede ind- og eksklusionskriterierne. Interventionerne var forskellige og startede på forskellige tidspunkter efter hoftebruds operationen. Analyserne målte forskellige omkostninger selvom de anvendte det samme perspektiv og ingen af dem målte indirekte omkostninger som pårørende hjælp. Evidensen var både for begrænset og for heterogen til samlede konklusioner eller anbefalinger omkring omkostningseffektiv genoptræning og pleje efter hoftebrud.

Studie II var et fremadskuende kohorte studie på Træning for Livet kohorten. I studiet opgjordes antallet af patienter, der modtog hjælp fra pårørende, hvor meget hjælp de modtog, og hvornår de modtog hjælp efter et hoftebrud. I alt angav 90% af de 244 patienter, at de modtog hjælp fra deres pårørende. Medianen af den totale mængde af pårørende hjælp var 32 timer. Ved tolv ugers opfølgningen svarede 36% af patienter af de modtog hjælp fra deres pårørende. Konklusionen var derfor, at pårørendes hjælp er meget normalt efter et hofte brud, og at pårørendes hjælp bør måles som en omkostning.

Studie III var en studie protokol, der beskrev designet af Træning for Livet herunder intervention sammenlignet med vanlig genoptræning og pleje efter hoftebrud.

Studie IV var en omkostnings- og effekt analyse hvori omkostninger blev indsamlet i et begrænset samfundsperspektiv. Effekt blev målt i kvalitets justerede leveår og det primære udfald var den inkrementelle forskel i omkostninger og effekt mellem Træning for Livet og vanlig genoptræning og pleje. Træning for Livet lidt bedre og væsentligt dyrere end vanlig genoptræning og pleje.

Fundene der præsenteres i afhandlingen kaster nyt lys på ældres behov for genoptræning og pleje efter et hoftebrud og peger på en lidt mere effektiv organisering, der dog vil medfører øget omkostninger. **Studie I** beskrev, at evidensen for omkostnings-effektiv genoptræning og pleje efter hoftebrud var begrænset og understregede behovet for bredere måling af omkostninger efter hoftebrud. **Studie II** viste at stort set alle patienter modtager hjælp fra pårørende efter et hoftebrud og understreger nødvendigheden af at måle pårørendes pleje som en omkostning efter hoftebrud. **Studie III** indeholder en detaljeret beskrivelse af Træning for Livet og vanlig genoptræning og pleje efter hoftebrud. **Studie IV** sammenlignede og rangerede Træning for Livet og vanlig genoptræning og pleje på omkostninger og effekt og estimerede hvilken tilgang, der var omkostningseffektiv fra et begrænset samfundsperspektiv.

Abbreviations

QALY – Quality Adjusted Life Year

ICER – Incremental Cost-Effectiveness Ratio

CEAC – Cost-Effectiveness Acceptability Curve

LMM – Linear Mixed Regression Model

Background

01.01 Do we need cost-effective rehabilitation and care after hip fractures?

01.01.01 Patients

As approximately 6,500 patients over the age of 65 sustain a hip fracture each year in Demark, this is the most common form of trauma requiring surgical intervention (1, 2). The implications of a hip fracture are severe; nearly one-quarter of such patients die within the first year following the incident, while a significant number of survivors are unable to regain their former level of functional independence, and many need long-term care at home (3-5). It is therefore understandable that patients describe a hip fracture as a life-shattering trauma (6). Consequently, the regaining of independence in everyday activities emerges as a critical recovery goal, highlighting the indispensable role of timely and effective rehabilitation and systematic care (7).

01.01.02 A costly fracture

The economic burden associated with hip fractures is substantial, with costs of hospitalisation, rehabilitation and care estimated to reach approximately 604 million euros annually in Denmark. However, these figures fail to capture the full spectrum of associated costs : notably, indirect costs such as informal caregiving were not included (2). Informal care is prevalent in Scandinavia and is estimated to represent a value equivalent to 2–4% of the Gross Domestic Product (GDP) in Sweden and the Netherlands (8-10). A vital trade-off is likely missed by not measuring informal care, as this leads to the underestimation of the true economic impact of a hip fracture and, ultimately, erroneous budgeting, which can have consequences for treatments offered in the future. Thus, accurate estimates of cost and effects are

vital to ensure the prioritisation of interventions that offer the greatest effect for the resources invested.

01.01.03 The healthcare system

Denmark's healthcare operates under a universal single-payer system funded through taxation and comprising three financially independent sectors: hospitals, municipalities and private praxis. This ensures that all rehabilitation and care services following hip fracture are available to patients at no cost (11, 12). The system also accounts for informal caregiving, in that the municipal assessment of care needed is adjusted according to relatives' ability and willingness to deliver informal care (13, 14).

The healthcare budget is fixed in the short term, so an increase in service levels for some patients will reduce the resources available to others until demand diminishes. However, with a slight increase in hip-fracture rates and expected increased prevalence due to the ageing population, a decrease in demand seems unlikely (15).

01.01.04 Prioritisation of rehabilitation and care after hip fracture

Historically, prioritisation has been politically unpopular as it inevitably results in disappointment for some. However, as the increase in healthcare costs exceeds the change in Gross Domestic Product (GDP), and with a demographic shift towards an ageing population, the healthcare system faces escalating demands and rising costs and prioritisation is inevitable (16-19). Ideally, prioritisation favours interventions that offer the greatest health benefits compared to resource consumption. However, it is not known which approach to rehabilitation and care following hip fracture has the

better effect and at what costs; hence, scarce resources may be allocated to less cost-effective approaches.

01.02 Patients clinical pathway following hip fracture

01.02.05 Hip fracture surgery

Patients who sustain a hip fracture begin their treatment in the emergency ward, where they are screened and the diagnosis established. They are then transferred to the operating room, where they receive one of three surgical treatments (arthroplasty, sliding hip screw or intramedullary nail). The choice of surgical technique depends on the location and type of the fracture. While the economic impact of choosing a specific surgical procedure is limited, due to uniform hospital reimbursement rates, the different options carry different time and material costs. Arthroplasty, often required for femoral neck fractures that compromise blood flow to the caput femoris, involves cementing a joint component in place, eliminating the need for the fracture to heal. Conversely, femoral neck, intertrochanteric or subtrochanteric fractures with preserved blood flow are typically addressed with internal fixation techniques, such as intramedullary nails or sliding hip screws. These methods stabilise the fracture and allow natural bone healing. Arthroplasty is more time-consuming to perform and involves higher acquisition costs for materials. The rehabilitation and care costs associated surgical technique has to my knowledge not been assessed after hip fracture.

01.02.06 Post-surgical pathway

Post-operatively, patients are transferred to the ortho-geriatric ward, where they begin rehabilitation. An orthopaedic surgeon and a geriatrician assess each patient and 92% of patients are mobilised within 24 hours (15). Nurses are responsible for

monitoring vital signs and overall patient condition throughout the patient's hospital stay. On weekdays, a physiotherapist actively engages with the patient, facilitating mobility by providing walking aids and instruction in specific exercises. At weekends, however, patients are not seen by a physiotherapist. During their hospital stay, the patient spends about 99% of their time sitting or lying (20). Discharge is coordinated with the patient's home municipality, to which referrals for further rehabilitation and reports on medical stability and care needs are forwarded.

01.02.07 **Post-discharge pathway**

Municipal service levels are regulated by the Health and Service Act (21, 22). Under these regulations, municipalities have autonomy in fulfilling their obligations. On discharge, at least 95% of patients with hip fractures are referred to municipality-based rehabilitation programmes (15). These programmes typically begin one to two weeks after the patient leaves the hospital and last between four and twelve weeks, with one or two sessions weekly, depending on individual rehabilitation goals and a therapeutic assessment (23, 24). Rehabilitation content following hip fracture is poorly described and rarely includes information on intensity or progression (24).

01.02.08 **Respite stay**

Patients whose rehabilitation and care needs extend beyond what can be offered in their own homes are admitted to a municipal rehabilitation and care facility for a time-limited respite stay. During this stay, nurses monitor the patient's medical stability, and physiotherapists exercise with the patients daily, with the ultimate goal of enabling them to return to their own homes (25-30).

01.02.09 Recommendations for post-surgical rehabilitation and care

In 2019, the Danish regions issued new guidelines recommending systematic, early initiation of post-surgical rehabilitation and care for eight to twelve weeks after hip fracture (7). In 2021, Dyer et al. (31) synthesised evidence on rehabilitation after hip fractures, advocating early in-hospital rehabilitation and structured exercise regimes lasting twelve weeks or more, in line with clinical guidelines from the Danish regions and others (7, 32). Thus, this indicates a discrepancy between usual post-surgical rehabilitation and national or international recommendations.

Dyer et al. (31) also noted that such extensive rehabilitation may not be more effective than the standard care for all hip fracture patients and could lead to substantial cost increases if universally applied. From a financial perspective, no definitive answers have been found, and the impact of these recommendations on patient health-related quality of life and associated costs remains unknown (3, 10).

01.02.10 How can rehabilitation and care be changed?

Eliminating the post-discharge wait for rehabilitation and developing a rehabilitation course with standard content in term of exercises, progression and intensity and duration will ensure that patients receive a standardised and evidence-based minimum rehabilitation after hip fracture (31). However, due to the divided healthcare system in Denmark, these changes need to start in hospital and continue in the municipality, which calls for a complex intervention, changing how post-surgical rehabilitation and care are delivered.

01.03 Rehabilitation for Life

The hypothesis for the Rehabilitation for Life trial was that poor mobilisation and reduced activity during and after hospitalisation increased fatigue and led to loss of muscle mass, affecting patients' physical function levels. This risk is particularly acute for older hip-fracture patients who may also be grappling with post-surgical pain and the emotional impact of their injury (33, 34). To counteract loss of muscle mass and function, rehabilitation and care should commence promptly, with a particular focus on improving patients physical function by increasing muscle mass and strength (35). However if patients are to exercise faster and harder they need to be medically stable and have effective pain management, as uncontrolled pain or complications such as infections hinders exercise (36).

Thus the aim of the rehabilitation and care trial was to test if a continuous and standardised course of resistance exercise combined with systematic care, aimed at empowering patients and used in hospital and municipal settings, was more effective in restoring physical function measured using the Timed up and Go test and Cumulated Ambulation score compared to usual rehabilitation and care after hip fracture (37). An exploratory outcome was to assess if the intervention was cost-effective compared to usual rehabilitation and care after hip fracture.

01.03.11 Methods

The Rehabilitation for Life (RFL) trial was designed as a stepped-wedge, cluster-randomized clinical trial utilizing a 1:1 allocation ratio. This design involved dividing the participating municipalities into six clusters. Initially, all clusters contributed data as a control group (38). Subsequently, every three months, one cluster transitioned to implementing the intervention (39, 40).

Patient

The trial targeted community-dwelling patients 65 years of age or older with non-impaired cognitive function living in any one of the six municipalities in Lillebaelt Hospital's catchment area.

Intervention development

The Rehabilitation for Life Intervention involved rehabilitation, care and empowerment components (37).

Rehabilitation

The rehabilitation component was developed based on the recommendations from the Danish regions (7). The progressive resistance exercise regimes was made in cooperation with physiotherapist from the hospital and the municipalities to meet the requirements and practical concerns I both sectors. For instance, the same exercise equipment were not available across municipalities and heterogeneity in patient's physique necessitated alternative exercises and progression and regression procedures were described.

Care

The care component was based on the experiences from a local research program (41). In this project standardised and coordinated measurement of vital signs and infections counts targeted older institutionalised hip fracture patients reduced readmission rates. This intervention was adapted to match the needs of the community dwellings hip fracture patient by introducing one visit from one municipal nurse, who would measure infections counts and vital signs, three days after dischrage. This day was chosen to avoid false positive infections counts due to the

antibiotics administered during the surgery. Follow-up visits was completed if needed. A fourteen day open admission meant municipal nurses could confer with doctors in the hospital and start treatment in the patient's own home.

Empowerment

The Empowerment orientated components was chosen based on hip fractures patients desire for increased involvement and knowledge of their own course of post-surgical recovery (42). Tools such as an exercise dairy, a recovery timetable and a digital application was made to support patients. Physiotherapist and nurses in hospital and municipalities participated in workshops where they were introduced to the intervention and how to engage with patients to facilitate empowerment. These workshops aimed to create a collaborative and empowering environment through dialogue and ensuring patient involvement throughout the post-surgical course of rehabilitation and care. Knowledge sharing between sectors was completed using a videoconference between physiotherapist in hospital, municipalities and the patient.

The Rehabilitation for Life intervention and the usual rehabilitation and care were described using the Template for Intervention Description and Replication (TIDIER) (43). The TIDIER describing the Rehabilitation for Life intervention and the usual rehabilitation and care are presented in Figure 1, used in Study III.

	Rehabilitation for life	Usual rehabilitation and care
Why	Continuous and progressive rehabilitation as well as early detection of critical illness and complication during and after hospitalisation will improve the older adults' physical performance and decrease mortality. Knowledge empowers older adults and facilitates a change in mindset among health professionals.	Activity-based rehabilitation restore and maintain the activities of daily living. Older adults' need to regain functions creates motivation.
What	25 rehabilitation sessions with a physiotherapist over 12 weeks of these 5 within 2 weeks from discharge are planned. A virtual meeting between physiotherapist in the primary and secondary sectors and older adults is conducted in the 2 rehabilitation sessions after discharge. The suitcase contains knowledge and equipment the older adults need to take responsibility and perform daily exercises. Health professionals participate in a workshop. Early detection of critical illness and complications performed day 3 after discharge.	Older adults' general amount of rehabilitation is approximately 1–2 rehabilitation sessions a week for 6–8 weeks. Care has to be prescribed.
Who provide	Physiotherapists, nurses, and social- and health assistants.	Physiotherapists, nurses, and social- and health assistants.
How	Face to face, virtual meetings, and app	Face to face.
Where	Ortho-geriatric ward, the patients' home, and in the rehabilitation centres.	Ortho-geriatric ward, the patients' home, and in the rehabilitation centres.
When and how much	*Weeks 1–2 after discharge:* - Five training sessions with a physiotherapist, duration up to 60 min. -One virtual meeting duration 30 min. -Vial measurements, duration up to 45 min. If necessary, one follow-up meeting with the municipal emergency nurse assessment, duration up to 45 min. Week 3 to week 12 after discharge: 2 weekly rehabilitation session with a duration up to 45 min is planned.	*During admission*: rehabilitation in the ortho-geriatric consist of a daily session with a physiotherapist duration of 30 min. *Week 1 after discharge:* -1 rehabilitation session duration up to 45 min. *Weeks 2–8 after discharge:* -1 or 2 weekly sessions of rehabilitation duration 45 min.
Tailoring	Patients with a CAS score ≥ 4 receive rehabilitation at a rehabilitation centre. Progression follows the national guidelines [7].	The patients rehabilitate at home or at a rehabilitation centre, pending on an individual assessment.

Figure 1 TIDIER describing Rehabilitation for Life and the usual rehabilitation and care

01.03.12 Cost-effectiveness of Rehabilitation for Life

The intervention was expected to be more resource demanding due to the greater number of rehabilitation sessions and nurse visits, and the enhanced communication required between healthcare sectors. However, as soon as patients had achieved a Cumulated Ambulation Score (CAS) of four or above, rehabilitation was to be offered in group sessions, where one physiotherapist could supervise several patients at the same time (7, 44), thus reducing the cost of exercise sessions. However, it remains unclear whether the Rehabilitation for Life intervention achieved poorer, better or the same outcomes relative to resource consumption than the usual programme. Therefore, an exploratory outcome was included to compare the costs and effects of the intervention to usual rehabilitation and care.

01.04 Health economic evaluations

01.04.13 Cost-utility analysis

Different types of economic evaluation have been designed, each with its own characteristics and purpose (45). A cost-utility analysis design enabled the comparison and ranking of the effect of competing treatments on patients' quality and length of life expressed in quality-adjusted life years (QALY) and associated costs (45, 46). This makes it possible to identify the treatment option that provides the most health for resource consumption, as demonstrated in this formula calculating the incremental cost-effectiveness ratio (ICER) (45, 46):

$$ICER = \frac{Cost(intervention) - Cost(control)}{QALY\ gain(intervention) - QALY gain(control)} = \frac{\Delta cost}{\Delta QALY}$$

A unique feature of the QALY is its comparability, underlined by the saying "A QALY is a QALY is a QALY". Hence, this outcome can offer the opportunity to pool and compare effects across cost-utility analyses as suggested by Bagepally et al. (47).

01.04.14 Calculating and reporting the ICER

As specified in the equation above, two measures are needed to calculate the ICER: difference in incremental cost and utility. However, as costs rarely follow a normal distribution, uncertainty of the ICER is estimated using a non-parametric approaches as boothstrapping in which observations are typically reproduced by 1000 bootstraps (48, 49). The bootstrapped pairs can then be presented visually on an ICER plane using a scatter plot, where the incremental effect is plotted on the *x*-axis and incremental costs on the *y*-axis (50, 51). The ICER plane consists of four quadrants and should be interpreted as follows: results in the northwest quadrant (NW) indicate

that the intervention is more costly and less effective than the comparator, suggesting that the intervention should not be adopted. Those in the southeast quadrant (SE) indicate that the intervention is less costly and more effective than the comparator, suggesting that it should be adopted. Results in the northeast or southeast quadrants require decision-makers to weigh the trade-offs between health gains and costs, Figure 2.

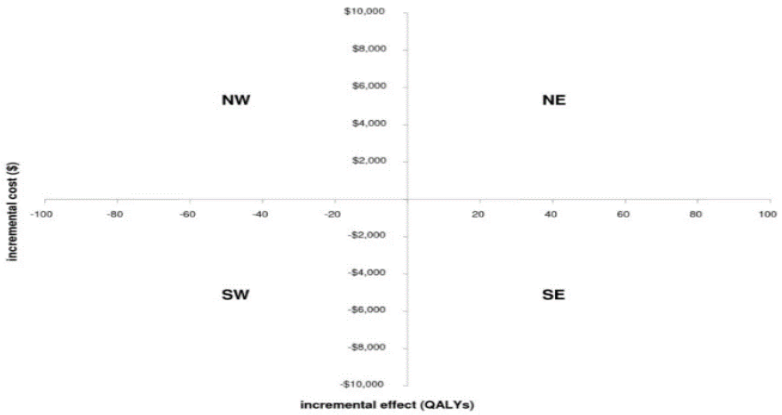

Figure 2 Example of an incremental cost-effectiveness ratio plane (ICER plane)

The ICER can be assessed against a willingness-to-pay threshold representing society's willingness to pay for additional health benefits (52). However, most thresholds were established many years ago and have not been adjusted for inflation; for instance, the United States threshold was established in 1983 and has not been adjusted since (53). Moreover, willingness to pay varies between countries, even for the same disease (54, 55). Therefore, to rely too heavily on thresholds or use them as clear-cut rules for decision-making, considering the inflation of treatment costs and salaries may not make sense in all cases (17, 56, 57). In the Danish literature, 20,000 € and 50,000 € per additional QALY are thresholds

commonly used (58, 59). However, Denmark has no official national threshold; willingness to pay is determined on a case-by-case basis. Setting a threshold in this context is, therefore, somewhat arbitrary.

01.04.15 Designing a trial-based cost-utility analysis

Designing a high-quality, trial-based cost-utility analysis that can be harmonised with other studies and pooled requires close cooperation between all stakeholders in the trial, including researchers, those conducting the trial and health economists, as inaccurate planning may result in biased estimates (60, 61). For instance, to ensure the validity of the cost estimate, it is important to select a sufficiently broad perspective (62). A perspective that is too narrow may misrepresent the value of an intervention, making it appear cost-effective although this may not be the case under a more inclusive perspective (63, 64). Such misrepresentations often stem from failing to account for trade-offs. While it is ideal to include all possible costs, practical constraints can require the focus to be tailored to the specific research question at hand (45, 63-65).

Discounting

Discounting is a fundamental aspect of health economic evaluations, especially critical when projecting long-term costs and effects. This process helps adjust future costs and health outcomes to their present values, based on the understanding that the value of costs and benefits generally diminishes over time (66, 67).

Measuring hospital costs

Hospitals are reimbursed for services delivered according to the Diagnosis-Related Group (DRG). These data are reported to the Danish National Patient Registry and can be accessed by the Danish Health Data Authority (68). The Danish Health Data Authority services and manages several of the large health registers, which also include the National Register of Pharmaceutical Sales, in which patients using prescription medication are registered, and the National Health Service Register, which contains contacts and reimbursements for general practice and other healthcare professionals (69). The Danish National Patient Registry, the National Register of Pharmaceutical Sales and the National Health Service Register are considered complete and commonly used in national surveys and research (59, 70, 71).

Measuring municipal costs

Services delivered by the municipalities are accessible through Statistics Denmark (72). However, the indicators on rehabilitation have only covered all 98 municipalities since 2022 and the indicators may not be complete. For instance, Statistikbanken, which is run by Statistics Denmark, is unable to assess the number of people 67 years or older who received municipal rehabilitation in the Southern Denmark Region in 2022 due to the lack of accuracy in records of services given (73). Alternatively, the municipal time registrations for each service delivered to each patient can be used. However as registration practices differ between municipalities, the time registrations needs to be extracted and validated by each municipality.

Informal care

Unlike formal care, informal care is not recorded in registries and, thus, can only be measured directly through questionnaires or diary surveys completed by patients or their caregivers. However, consensus is lacking on the most appropriate method (74). To determine how best to capture informal care, given the cognitive impairments that affect patients' recall abilities post-fracture, two different measurement methods were pilot-tested with twelve patients (75, 76). Data on the use of informal care was collected in telephone interviews with patients every two weeks for twelve weeks. As a memory aid, all patients received a diary in which they were asked to report the number of hours delivered by informal caregivers. In the telephone interview, the data collector asked:

"Have you, after your hip fracture, received help from relatives for activities you did not require help with before the hip fracture? For instance, showering or getting dressed.

If YES, *try and recall the last week, how many hours of help did you receive."*

To cover both weeks the amount of help reported was multiplied by two.

In addition all patients was equipped with a diary in which they were asked to record the amount of informal care received as hours per week (45, 77). During admission, all patients received verbal instruction in how to fill the diary, table 2**.**

Table 2. informal care diary	
	Time spent
Week 2	Hours: Minutes:

Week 3	Hours:	Minutes:
Week 4	Hours:	Minutes:
Week 5	Hours:	Minutes:
Week 6	Hours:	Minutes:
Week 7	Hours:	Minutes:
Week 8	Hours:	Minutes:
Week 9	Hours:	Minutes:
Week 10	Hours:	Minutes:
Week 11	Hours:	Minutes:
Week 12	Hours:	Minutes:

Pilot testing informal care measurement

To collect informal care, we needed a measure that could be easily disseminated within a relatively short time between follow-ups, and was accepted and feasible for the patients. Identifying an existing questionnaire or cost diary that met these requirements was not successful. Hence, inspired by the cost diary proposed by Goossens, M. E et al. 2000 (80) and the four informal care questions from the Caregiver Indirect and Informal Care Cost Assessment Questionnaire (78). The two-question method combined with a simple cost diary was developed and pilot-tested in an iterative process involving twelve patients.

Initially, four patients tested the questions and diary, and based on their feedback, the question and diary used were developed. Eight new patients then tested the updated question and diary for twelve weeks, receiving phone calls every two weeks. These patients reported the questions were simple and easy to understand; they all preferred reporting informal care per phone, and only one had filled the diary,

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but only for the first four weeks. Based on these results the developed measure was considered feasible and used.

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Aim

The overall aim of this thesis was to contribute new evidence on how post-surgical courses of rehabilitation and care following hip fracture can be organised to increase cost-effectiveness. To achieve this aim, four studies were planned and completed.

Study I aimed to describe the current evidence base by systematically searching and synthesising cost-utility analyses focused on rehabilitation and care interventions after hip fracture.

Study II aimed to assess the amount of informal care patients received after hip fracture to identify a potential trade-off between formal and informal care.

Study III aimed to provide an in-depth description of the methodology and delivery of the Rehabilitation for Life trial.

Study IV aimed to compare and rank the cost-effectiveness of rehabilitation and the Rehabilitation for Life intervention and usual rehabilitation and care.

Methodological considerations

The methodology of each study is described in the manuscripts presented in the thesis appendices. Hence, this section will focus on the methodological considerations for each study.

The PhD project relation to the Rehabilitation for Life trial, was to assess the cost-effectiveness of the trial. Thus, the studies were completed, so the findings of study I shaped or expanded studies II, III, and IV. For example study I identified a lack of knowledge of the extent and value of informal caregiving after hip fracture. Study II, therefore, was completed to inform on the extent of informal care after hip fracture. A second finding was that none of the cost-utility analysis included in study I utilised a perspective wide enough to capture indirect costs as informal care. Thus, the associated costs for the family and friends of the patient and potential replacement costs for society are missing in cases where informal caregivers aren't available. It was therefore decided to expand the measurement of cost in study III and utilise the broader limited societal perspective in study IV.

01.05 Study I

The systematic review was preplanned and registered at the PROSPERO database. When planning the systematic review, the possibility of conducting a scoping review to provide a more comprehensive description of the evidence base was discussed (81). However, an important consideration for Study I was to include studies with the potential to be pooled into a meta-analysis and a systematic review methodology was, therefore, considered more appropriate (47, 79). Chapter 20 of the Cochrane Handbook, which is regularly updated, makes recommendations on the inclusion of economic evidence but does not consider the possibility of pooling economic

evidence (80). Hence, the review was designed to adhere to guidance in the series "*How to prepare a systematic review on health economic evaluations for informing evidence-based health care decisions: a five-step approach" (81-84),* which presents and discusses in depth how to prepare and report a systematic review of health economic evaluations. In addition, Bagepally et al. (51) describe and discuss methods for harmonising findings across cost-utility analyses to obtain a pooled estimate of the incremental net benefit where a positive or negative value directly indicates the cost-effectiveness of an intervention. Applying Bagepally's methodology would be an exciting contribution to the literature. However, given the limited size and heterogeneity of the evidence base, this is a project for the future, perhaps when the systematic review needs to be updated, and more cost-utility analyses in the field have been published.

An awareness of the potential risk of publication bias, as identified in audits completed by the authors of Chapter 20 of the Cochrane Handbook, is essential (82): The authors found that clinical trials published with an economic evaluation systematically report effects higher than those published with no economic assessment, possibly indicating that economic evaluations with positive findings are more likely to be published (85).

01.05.16 **Strength and Limitations**

A concern in any review is the risk of missing relevant studies. This can occur as a result of too narrow search criteria, a poor search strategy or if the wrong databases are searched (86, 87). Poor searches are a very common problem that occur in upward to 92% in some samples of systematic reviews (86). To mitigate the risk of making errors in the search a research librarian was conferred. To avoid missing studies indexed in some but not other databases the search was completed in

several databases with different indexations and journals. The in- and exclusion criteria was established in discussion and reflected the aim of doing a meta-analysis or descriptive comparison on the QALY outcome. Overall the search was considered thorough and systematic. This has reduced the risk of missing relevant studies but not ruled out the risk.

In retrospect an alternative to the narrative synthesis might have been to broadening the inclusion criteria and include other types of cost-effectiveness analysis. This would have provided a more complete pictures of the cost and effect of various rehabilitation and care interventions. However, the drawback of widening the inclusion criteria is an increased heterogeneity in effect measure which makes interpretations more difficult.

Another important step of performing a systematic review is in the selection of studies. To avoid deselecting relevant studies this should be done by a minimum of two persons independent of each other (88). The level of agreement between reviewers in this review was 0.82 in the title and abstract selection and 0.86 in the full text selection. In two cases studies was discussed with the third author. In both cases the studies was excluded as a QALY outcome was missing.

Study I was completed using a predefined analysis plan. i) synthesised using a meta-analysis, ii) descriptive statistics, iii) narrative synthesis.

The narrative synthesis are typical used when statistical comparison are limited due to heterogeneity (89, 90). In these cases, the narrative synthesis can be used to analyse and describe variation within and between studies using an textual approach

(89). It is an analyses that has been associated with reduced transparency why clear reporting on for instance data transformations are particular important (91).
Given the amount of heterogeneity between studies the narrative syntheses was used, and to increase transparency reporting were done following guidelines designed specifically for comparisons of health economic evaluations (81-84).

01.06 Study II

Study II was an exploratory study completed to target a knowledge gap identified in study I where none of the included studies measured informal care. Informal care is widespread in Denmark, and municipalities actively account for it when assessing patients' need for formal care (13, 14, 92-95). Various studies have reported that informal caregivers to hip-fracture patients experience a substantial caregiver burden, thus highlighting a potential trade-off between formal and informal caregiving (93, 96).

01.06.17 Strength and limitations

Design

An important limitation of Study II was that it was an exploratory study, and all participants participated in the stepped-wedge cluster randomised trial. Stepped-wedge cluster-randomised designs are vulnerable to temporal confounding where changes over time, such as changed service levels, health practices, seasonal effects or societal trends, can affect whether patients receive informal care and how much (97). An example could be budget cut-backs forcing municipalities to reduce service levels. Another limitation associated to the stepped-wedge design is the carry–over effect where the intervention can have a systematic impact on the amount of informal care received (98). It is unlikely these limitations will affect if

patients receive informal care or not. However it can have affected the amount of informal care they reported to receive. Hence, the estimates on the amount of informal care should be considered minimum estimates.

Generalizability

Generalizability was another limitation, as participants was recruited for the same trial they belonged to the same sub-group and there were more patients who withdrew from the trial or did not wish to inform on informal care. Hence the findings are not representative to the entire hip fracture population. A dropout analysis assessing differences between participants and those how withdrew consents will be included in the primary outcome article of the Rehabilitation for Life Trial. However the patients who withdrew their consent were similar to those who did not withdrew their consent.

Regression analysis

The exploratory regression analysis was performed using a step forward approach were candidate covariates were chosen based of hypothesis presented in the statistical analysis plan (99, 100):

- Persons which are well mobilised at discharge from hospital employ less help from informal caregivers
- Patient with low need of help with basic activity of daily living receive less help from informal caregivers
- Patients with higher perceived health may have less need for informal care
- Patients living alone receive less help from informal caregivers
- Type of surgery may affect peoples' need for help from informal caregivers
- Help from informal caregivers may diverge between municipality of residence

The variables differentiating patients on a 95% level of statistical significant were carried forward (101). This variable selection procedure is very common approach easy to implement and a p-value of <0.05 is a clear and easy decision rule (100, 102). However, it is also an overly data-driven approach, and a p-value of 0.05 is a very conservative decision rule that may increase the risk of ruling out important variables. Thus, it has been suggested to apply a higher thresholds ranging from 0.15-0.50 (100, 101). Given the very limited sample size and only 25 patients being non-recipients of informal care overfitting the logistic regression was a concern and the reason the p-value of < 0.05 was chosen. The findings of the logistic regressions should therefore be interpreted with caution to these limitations.

Measuring informal care

Several limitations were associated with the development of the informal care measurement method. Other instruments inspired the questions and diary used; however, a proper validity and reliability test was not completed. Hence, though it was pilot tested, there is uncertainty about the generalizability, reliability and validity. An important consideration was that even though patients were introduced to the diaries in the hospital, they did not use them, and the risk of them going missing was present. Hence, I would probably not use them again. Using one gatekeeper question and one follow-up question worked well. However, the recall period may have led to positive recall. Such a phenomenon was observed by Dalziel et al. (71), who found that patients with follow-ups every two weeks tended to have a positive recall. In contrast, patients with a one-year recall period remembered less. No one optimal recall period exists and must be decided on the characteristics of what is observed and its intent (103). Based on the experience gained from measuring informal care in this thesis, a less frequent time point and a longer follow-up might

have been preferred. For instance, once a month for six months would have been consistent with the other costs measured. Given that the older population is becoming more accustomed to text messages, this might also be a feasible and much less resource-demanding way of measuring informal care. Testing the clinometric properties of the informal care questions on an adequate sample is an important next step.

01.07 Study III

When I started this PhD, the Rehabilitation for Life programme was already planned; however, the trial's methodology and intended deliveries had not been described in depth, and no economic evaluation was planned. By writing the study protocol, I was able to obtain an in-depth understanding of the trial, map potential trade-offs, and plan how the various costs could be measured within the trial's parameters.

01.07.18 Strength and Limitations

Deviations clinical trial registration and Study III

There are deviations between the clinical trial registration and study III. These deviations was mainly the result of human error where the two registrations wasn’t aligned. Thus reducing transparency. The study protocol are the updated version of the two. To increase transparency deviations will be reported and discussed in the primary outcome article assessing the effect of the intervention on the two primary outcomes and secondary outcomes.

The trial had two primary outcomes; Timed Up and Go (TUG) eight weeks post-surgery and the CAS 30 day post-surgery. The choice of two outcomes was to

assess potential differences in the timing of effect onset. With the CAS score, the aim was to assess if the organisational changes of continuous rehabilitation and care meant more patients reached independence in basic mobility (CAS=6) faster. With TUG it was assessed if the intervention had a superior effect on patient's level of physical function compared to usual rehabilitation and care. Thus, it is important to be aware that the CAS score reflects the short-term effects and that TUG assesses the longer-term effects. In the primary outcome article, TUG will be weighed higher in the conclusion.

Secondary follow-up was completed twelve weeks, twenty-six weeks and fifty-two weeks post-surgery. The twelve week follow-up was completed to assess the add-on effect of four additional weeks of rehabilitation. This was chosen as the guideline states approximately 50% of patients has a need for a twelve weeks course of rehabilitation (7). The twenty six weeks and fifty-two weeks follow-up was completed to assess effectiveness in longer terms.

Exercise is generally considered positive for patients and progressive resistance exercise has been found to be feasible in-hospital after hip fracture (104). However, following harms is one way to ensure patient safety and it can potentially affect costs and effects. The data collection on costs and utility lasted six months and twelve months, respectively; hence, any costs associated with harm are likely captured in study four. In addition the trial followed falls and pain every two weeks throughout the intervention.

Study design

Due to the complexity of the Rehabilitation for Life intervention, a change in clinical practice was required across hospital and municipalities. Thus, a cluster randomisation procedure extended with a stepped-wedge crossover sequence was adopted, which involved assigning the patient to a treatment arm depending on their address within the municipality (39, 40). In this design, all clusters would contribute to the intervention arm and adopt the intervention (38).

The cluster-randomised, stepped-wedge design comes at a cost in terms of increased complexity, longer recruitment periods and reduced statistical power compared to simpler, and often statistically stronger, cluster-randomised parallel trials (39, 105, 106). The increased complexity is caused by the need to ensure a balanced randomisation between treatment arms and the inherent risk of secular time trends (97). For instance, once the intervention is introduced, health professionals may start to assimilate it ahead of schedule, or implement changes in policy that dilute or enhance the effect attributed to the intervention (38, 97, 106). These secular trends may become a problem particularly in interventions where the effect takes time to materialise (97), as is the case with most exercise interventions. Thus, it is generally recommended that the stepped-wedge design be used in the following three scenarios: i) when other possibilities are not feasible, ii) when the intra-cluster correlation is high (as the stepped-wedge design is then statistically stronger than parallel designs), iii) if the intention is to implement an intervention across all clusters (39, 97, 107). As the rehabilitation for Life trail intended to implement the intervention and we had to complete several workshops that had to be planned months in advance, the stepped wedge design was a practical design that matched the logistical challenges in municipalities. These logistical challenges

was among other to book large enough conference rooms and ensuring the health professional who was to deliver the intervention all was at work.

Blinding

A recent Cochrane review has questioned the importance of blinding in clinical trials, finding no difference in treatment effects between blinded and unblinded clinical trials (99). It has also been argued that blinding is less important in explanatory trials (100, 101). However, while randomisation reduces selection bias and confounding, it does not protect against biased outcomes assessment. Therefore, unblinded trials should be interpreted with caution (108).

Physical rehabilitation and care interventions are inherently visible, which typically precludes the possibility of concealing group assignment, for both patients and clinicians (109). Furthermore, I participated extensively in the trial, played a significant role in data collection and conducted all the analyses presented in this thesis. Aware of the risk of unconscious bias due to the lack of blinding, I implemented various strategies to mitigate this risk. i) To obscure clues that might reveal whether participants were in the control or intervention groups, identifiable variables were systematically removed from datasets. ii) The analytic approach was planned before any study began. iii) To increase accountability and transparency, statistical analysis plans for all studies were registered and made publicly available. The systematic review was registered with PROSPERO (ID: CRD42021281984) and outlined the study's objectives, methods and anticipated analyses. The statistical analysis plan for studies on informal caregiving and the cost-utility analysis were made publicly available on my SDU PURE profile (99).

Despite these efforts, it is not possible to eliminate all risk of bias.

Data collection

To reduce the risk of missing data and intra-rater variation, data collection was centralised to a small team of just four researchers (110). This approach was adopted to maintain consistency and reliability across the multiple assessment points. Initially, the possibility of employing a local data collector in each participating municipality were discussed. However, this approach was ultimately deemed impractical and potentially biased: specifically, it was deemed impossible to ask the physiotherapists who conducted the rehabilitation sessions also to perform outcome measurements, as this might compromise the impartiality of the data (111, 112). An alternative strategy could have involved outsourcing the data collection process to each municipality, instructing them to hire independent data collectors who were not affiliated with the trial. This approach would have offered the significant advantage of blinding the researchers to the data collection process.

Intervention implementation

The lack of blinding may also have constituted a problem for the implementation of the intervention in the hospital. All patients, regardless of randomisation, were recruited from the same orthogeriatric ward. Thus, in-hospital physiotherapists had to navigate between delivering the usual rehabilitation in one room and a more extensive exercise programme in the next. In addition, both physiotherapists and nurses were asked to deliver the intervention in an empowerment-orientated approach that helped the patient gain control. In retrospect, it may be questioned if health professionals could have been empowerment-orientated in one room and not in the next. Hence, with the exception of physical reminders in the form of the trolley, the difference between the intervention and control in hospital may have been limited. Designing the trial as a cluster-randomised parallel study in two catchment

areas (one control and one intervention) would have increased the likelihood of measuring the difference associated to variation in approaches. Alternatively, a cluster crossover design could have been used (113), which differs from regular cross-over designs by crossing the entire cluster at the same time (113).

01.08 Study IV

When the cost-utility analysis was planned, the Rehabilitation for Life trial had already started to recruit patients. Hence, the analysis was designed within the parameters of the trial, and the sample size was dependent on the number of patients recruited for the trial.

01.08.19 Strength and limitations

The benefit of running a cost-utility analysis alongside a trial is that resources can be shared. For instance, the follow-up conducted once every two weeks to supervise the conduct of the trial was also used to collect data on informal care and transport to and from rehabilitation. However, there are also disadvantages: for instance, in this cost-utility analysis, the sample size and the balance between treatment arms were not optimal.

Generalisability

To complete study IV, additional ethical approvals had to be obtained and extra written consent had to be collected from 75 patients already recruited. However, 19 of these had already retracted their consent or died. Thus, they couldn't be contacted. This imbalanced the mortality rates in favour of the control when, in fact, there was no difference in mortality between groups. Thus, the groups did not reflect the actual outcome on mortality. Hence, it was decided to exclude patients who died

before the six-month follow-up in the intervention and control. The impact was likely distributed equally as the mortality rates were equal between groups. However, it reduces the generalisability of findings to a sub-group of patients with lower mortality risk.

Another important limitation was the number of patients discharged to a respite stay. The municipalities that transitioned from control to intervention early had more respite stay places per capita than the municipalities that transitioned from control to intervention later. Therefore, there was a higher proportion of patients in the intervention group who were admitted to a respite stay. This imbalance had a major impact on the costs related to the intervention. Therefore an unplanned sub-analysis was completed to assess the cost-effectiveness of the intervention on patients discharged to their own home. The finding of the sub-analysis are therefore further limited to a physically fitter subgroup of patients.

Study design

Due to the stepped-wedge, cluster-randomised design of the Rehabilitation for Life trial and the repeated measurements taken for each patient, a statistical model designed for dependent data and capable of factoring time trends was used. The benefit of the linear mixed-regression model is its ability to predict health outcomes on an individual cluster level, factoring both within- and between-cluster variation with interactions between treatment allocations over time and the models ability to account for missing data (114-116), thus reducing statistical uncertainty.
The predicted utility of each patient at each time point was extracted from the model and be used to calculate the mean QALY gain under the assumption that utility was stable between follow-ups. An alternative method of calculating QALY would have

been to use the mean utility at each follow-up, however this calculation do not account for time trends or within-cluster variation and will inherently require some reflection on imputation strategies for missing data. Both possibilities were discussed with an experienced biostatistician, and given the trial's stepped-wedge cluster-randomised design and the multiple measurements of each participant, it was clear that the more complex linear mixed regression model was the appropriate choice of method. The mixed regression model are however not without limitations. Among other the model is complex, it can be over fitted resulting in biased results. This can especially be a problem with small samples and too few clusters. Additionally there are several assumptions that must be fulfilled to avoid biased results. Thus to ensure the integrity of the model assumptions and its fit was rigorously checked. In addition experienced biostatisticians routinely was consulted.

Hospital and municipality costs

The municipal time registrations represent actual resource consumption and include registrations not normally reported as responses to emergency calls. Hence, the municipal data collected in this thesis likely represent some of the most complete measurements of municipal services delivered.

A challenge when using the DRG rates is that they do not allow for cost comparisons at a micro level, for instance, by including variations in surgical material costs. However, for this cost-utility analysis, which focused predominantly on post-surgical treatment, the DRG rates were deemed an appropriate valuation tool, following national recommendations (117).

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Discounting

Discounting was not applied in study IV. In studies where long-term projections or extrapolations of data beyond the observed time points are necessary, discounting is essential. However, in this study, extending the analysis beyond the one-year mark was not deemed to provide additional meaningful information. Because the health outcomes and associated costs were captured within the one-year period with no difference in effect after one year, making longer-term projections unlikely to influence conclusion.

Ethics

Patients in the Rehabilitation for Life programme were assessed for eligibility, and informed consent was obtained within 72 hours of surgery. In cases where cognitive function was medically unresolved, decisions on inclusion or exclusion were made in dialogue with nurses and physiotherapists at the hospital and with the patient's next of kin. Before obtaining consent, patients received written and oral information on the trial. The principles of the Helsinki Declaration were followed (118). The Regional Ethics Committee of Southern Denmark (S-20200070) approved Rehabilitation for Life and the works presented in this thesis. Datas were collected and stored with approval from the Danish Data Protection Agency (20-21854).

Main results

01.09 Study I

This was a systematic review of cost-utility analyses comparable to the Scandinavian health care system with a narrative synthesis. In the review, 1,493 studies were identified across nine databases, with 502 duplicates and 953 studies excluded during the screening of titles and abstracts. Three cost-utility analysis met the inclusion criteria. They assessed different rehabilitation or care interventions initiated at various post-operative time points. One high-quality study found that a comprehensive geriatric assessment was more cost-effective than coordinated care following hip fracture. The other two studies, both of moderate quality, did not demonstrate the cost-effectiveness of the rehabilitation interventions compared to usual rehabilitation protocols. In all three analyses, the cost measures used were insufficient to fully capture the healthcare sector perspective, and the studies included different costs to the same perspective.

01.09.20 Main finding

The main finding was that evidence on the cost-effectiveness of physical rehabilitation and care following hip fracture was limited and heterogeneous. Only one high-quality study was found, suggesting that decision-making in this area is often based on inadequate cost-effectiveness information. Informal care was not measured in any of the studies included; thus, its role in post-surgical rehabilitation and care remains unmeasured and unknown.

01.10 Study II

This was an exploratory prospective cohort encompassing the Rehabilitation for Life population. The study included 244 participants, with a median age of 78 years (range 74–84); 66% were women, and 51% lived alone. Of the 244 patients, 90% received informal care, the median of the amount of informal care was 32 hours (range 12–66). At the twelve-week follow-up, 36% of patients still received informal care, with the amount reduced to a median of 7 hours (range 4–17), figure 4.

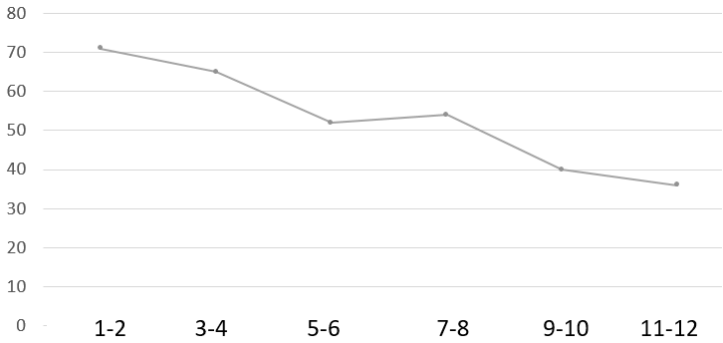

Figure 4 percentage of patients receiving informal care at the follow-up completed once every two weeks

Of the 244 patients, 45% were highly dependent on informal care. These high-dependence patients received six times more help than those with low dependence with medians of 66 hours and 11 hours respectively and they had poorer health and poorer physical function at discharge from the hospital.

01.10.21 Main finding

The main finding was that 90% of patients received informal care following a hip fracture, and 36% still reported receiving informal care at the twelve-week follow-up. These findings underscore that patients rely substantially on informal care after a hip

fracture. Given the prevalent yet under-researched nature of informal care, further investigation is necessary. These findings also highlight the importance of considering the impact of healthcare decisions on informal caregivers, suggesting a need for policies that support these essential care-providers.

01.11 Study III

The research protocol for the Rehabilitation for Life trial was published to document its rationale, methodology and planned analyses, aiming to enhance transparency and prevent poor research practices such as selective reporting (119). This publication also aimed to inform the broader research community about the ongoing trial, helping to minimise the risk of research duplication and waste. Several deviations between clinical trial registration and study protocol has been identified. The study protocol are the updated registrations.

01.12 Study IV

This analysis compared the costs and effects of the Rehabilitation for Life intervention with the usual rehabilitation and care protocols to determine which treatment option offered most utility to resources consumed.

The Rehabilitation for Life intervention resulted in a small but statistically significant QALY gain of 0.02 (95% Confidence Interval (CI) 0.00; 0.05), this came at a marginal cost increase of €4,224 (95% CI €722; €7,727). The incremental cost per QALY gained was estimated at €159,990. Ninety-six per cent of the bootstrapped observations fell in the northeast corner of the ICER plane, suggesting that while the intervention provided slightly better outcomes, it did so at a higher cost. The probability of the intervention being cost-effective than usual rehabilitation and care

was about 5% at a willingness-to-pay threshold of €20,000, increasing to 9% at a €50,000 threshold.

The exclusion of patients discharged to respite care increased the QALY gain to 0.03 (95% CI 0.01; 0.06) and decreased the incremental costs to €2,586 (95% CI €674; €5,847); the incremental cost per QALY was €67,531. The probability of the intervention being cost-effective at the €20,000 threshold was approximately 18%, rising to 38% at the €50,000 threshold. The ICER planes and CEAC with respite-stay patients included and excluded are presented in Figures 5 and 6. Both figures are also reported in Study IV.

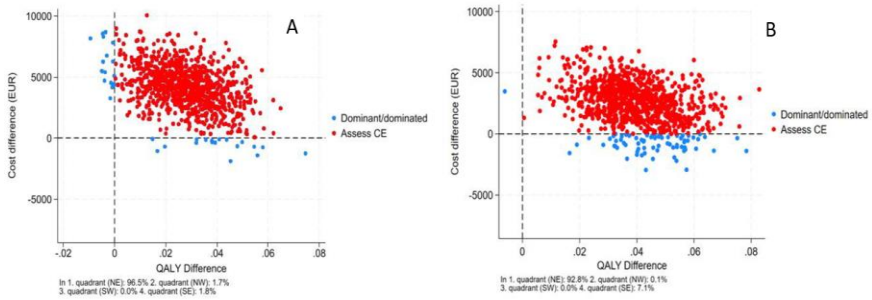

Figure 5 ICER plane (A) – patients in respite stay included; (B) – patients in respite stay excluded

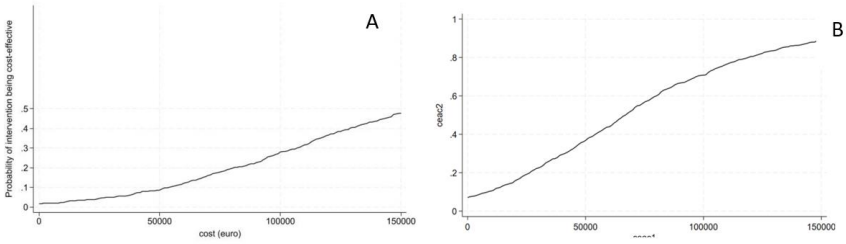

Figure 6 CEAC (A) – patients in respite stay included; (B) – patients in respite stay excluded

The major cost drivers were respite stays (difference €4,751), rehabilitation (difference €505), general practitioner (difference €336), waiting time (difference €992) and informal care (-€482).

01.12.22 **Main finding**

The main finding was that usual rehabilitation and care was the most cost-effective approach. If interventions were only offered to patients discharged directly to their own homes, the benefits increased and costs decreased. The generalisability of finding limited and mainly representative to a healthier sub-group of patients after hip fracture. Thus study findings should be interpreted with respect to generalisability.

Discussion

The overall aim of this thesis was to contribute new evidence on how post-surgical rehabilitation and care programmes following hip fracture can be organised to increase their cost-effectiveness. In this thesis, usual rehabilitation and care was the most cost-effective course. Whereas implementing the Rehabilitation for Life intervention would likely lead to increased costs, and limited additional utility gains for the patient.

01.13 Rehabilitation

In 2021, Dyer et al. (20) synthesised the evidence on rehabilitation after hip fracture. The authors recommended early in-hospital rehabilitation and structured exercise regimes with a minimum of twelve weeks or more duration. This recommendation is in line with recommendations from other clinical guidelines (7, 32). Dyer et al. (31) stated that this may not be superior to usual rehabilitation for all patients after a hip fracture and that the long-term provision of rehabilitation to the entire hip fracture population could be costly (31). From an economic perspective, there is no finite answer. The findings presented in this thesis are not enough to conclude on the potential cost and effect of offering rehabilitation standardized in duration after hip fracture (10). The findings are however contributions to an area where evidence are limited. Including the cost-utility presented in this thesis there are now three cost-utility analyses evaluating rehabilitation interventions for community-dwelling patients after hip fracture (120, 121). Heterogeneity between these three are present, but they point in the same direction. Taraldsen et al. (64) evaluated the cost-effectiveness of a late-phase exercise regime. Milte et al. (63) evaluated the cost-effectiveness of individualised nutritional exercise and nutritional intervention. In both cases, the intervention had limited or no additional benefits. Taraldsen et al. (64) and

Milte et al. (63) found their interventions cost-neutral. However, this is not fully representative, for instance transportation is inevitably associated with costs. The only question is if it is the public, patient or informal caregiver that cover them. The Rehabilitation for Life trial was the only of the three cost-utility analysis to identify a statistically significant QALY gain compared to usual rehabilitation. However the statistical power may have been affected by limitations in the underlying trials study design and are only representative to patients with lower mortality risk. The QALY gain presented in these three cost-utility analyses differed little, ranging from -0.00 to 0.02. Of the three interventions, Rehabilitation for Life was the most costly. However comparing the cost between the three is not straightforward, as their perspectives differed, and they did not measure the same costs from a healthcare sector perspective (120, 121). For instance, the cost-utility analysis presented in this thesis was the only one to measure the direct cost of transport and respite stay and the indirect costs of waiting time and informal care. Had the same costs been measured equally across all three cost-utility analyses, the cost difference between studies would likely have been less (120, 121).

The three interventions; study IV, Taraldsen et al (120) and Milte et al (121) were all more comprehensive including more rehabilitation. However, there are multiple indications that patients do not benefit equally from the same standardised rehabilitation: Parsons et al. (122) reported that pre-fracture quality of life for 4,720 English hip-fracture patients varied depending on the type of surgery and patient-specific characteristics such as age, comorbidities, pre-fracture mobility and pre-fracture residence. A high Body Mass Index has also been associated with decreased physical activity (123, 124); living together with a partner and receiving

social support have been associated with higher levels of physical activity (125, 126). Patient's activation level at discharge has been associated with functional mobility three and six month's post-fracture (127). Patients' personality traits have been associated with adherence to rehabilitation (128), while poor health literacy has been associated with a poorer quality of life following hip fracture (129, 130). Moreover, patients' rehabilitation needs can change, and it may be necessary to adjust the content and duration of rehabilitation programmes accordingly (131, 132). Health equity is defined as the absence of unfair, avoidable or remedial differences among and within patient groups and is achieved when everyone can obtain their full health potential (133). Equity in rehabilitation could, for instance, be obtained by diverting resources to improve utility for the more exposed and frailer hip fracture patients. If this approach is feasible and politically tolerable, personalizing interventions more to match patients' needs may pose a road to increased utility.

01.14 Respite stay

Patients admitted to respite care following hip fracture typically have rehabilitation and care needs that exceed what can be delivered in their own homes (134). During their stay patients receive daily rehabilitation and are monitored on a day-to-day basis by community nurses, regardless of the group they are randomly allocated to. Thus, it is unlikely the Rehabilitation for Life intervention would result in an additional effect. It was decided to include patients discharged to a municipal respite stay as the intervention was intended for all patients living in their own homes, and at the time of randomisation it was not known whether patients would be discharged to a respite stay or not.

Respite stays are very resource demanding and given the large variation in the municipalities policies, it may be necessary to assess which patients benefit from a respite stay and what optimal length of a stay might be. This however are beyond the scope of this thesis.

01.15 Care

At least two cost-utility analyses have assessed the cost-effectiveness of orthogeriatric care after hip fracture (135, 136). The analysis conducted by Prestmo et al. (135) demonstrated the cost-effectiveness of orthogeriatric care by admitting patients to an orthogeriatric ward and offering comprehensive geriatric assessment to patients. A comprehensive geriatric assessment involves a systematic evaluation of a patient's complete health profile and based on these assessments, tailored interventions are implemented, targeting each patient's specific needs (137, 138). This approach led to increased QALY gain at a lower cost compared to the usual in-hospital post-surgical care (135). A cost-utility analysis by Alexander et al. (136) assessed the cost-effectiveness of delivering dedicated care at a geriatric fracture centre compared to standard care. Geriatric fracture centres are facilities for patients sustaining a fragility fracture. Here patients receive standardised and comprehensive orthogeriatric care for medical and surgical complications (139-141). Treating hip-fracture patients at a geriatric fracture centre produced the same QALY gain at a lower associated cost (136). Thus, orthogeriatric care approaches may be an organisation of post-surgical care that will be cost-neutral or cost-saving and have and equal or better effect on patients utility. Orthogeriatric care is, to my knowledge, already the standard care approach in Danish hospitals after hip fracture.

01.16 Informal care

It is important to acknowledge that relatives of patients have no formal obligation to provide informal care in Denmark! However, as 90% of hip-fracture patients report receiving informal care, and the amount of care delivered by relatives exceeds that delivered at home by the municipalities, the importance of informal care cannot be underestimated (142). A systematic review of qualitative studies on the relatives of hip-fracture patients reports that relatives want to help their loved ones despite finding the task intense and frustrating (143). A source of frustration is that most relatives have no experience in providing care and do not feel recognised or supported by health professionals in fulfilling this role (143). This finding is supported by another qualitative study that highlights the point of discharge after a hip fracture as a time of particular tension, when both patients and relatives feel frustrated and unprepared for their new roles as care-recipients and caregivers respectively (144). Discharge should not be a stressful event, feared by patients and relatives (42). Hence being an informal caregiver has positive and negative consequences but, for some, the burden leads to physical and psychological morbidity (93, 145-147) and can become particularly heavy if the patient suffers from dementia (148). Martin-Martin et al. (149) tested the effectiveness of teaching handling techniques and ergonomics to informal caregivers of hip-fracture patients. The intervention reduced the emotional distress felt by the informal caregivers. Relatives' experiences at discharge can, therefore, be improved. Less stressful and coordinated discharge aligns with the aims of the upcoming Danish reform of care of the elderly, in which additional support to relatives is addressed as a point requiring attention (150). However if the findings can be reproduced in other health care systems are unknown and beyond the scope this thesis.

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It is important to reflect that not all patients have an informal caregiver and that patients with no informal caregiver may have other or more extensive needs for formal care.

Conclusion

This PhD thesis comprised four studies that explored different aspects of cost-effectiveness of rehabilitation and care following hip fracture to provide insights into a potentially more cost-effective organisation of the rehabilitation and care programme.

Organising the post-surgical course of rehabilitation care per the Rehabilitation for Life intervention will likely result in slightly higher utility gain but at a higher cost. Hence, usual rehabilitation and care was the cost-effective approach. A sub-analysis excluding patients admitted to respite stays indicates a slightly higher utility in favour of the intervention and a statistically insignificant difference in cost. However, these findings should be interpreted in light of the study's limitations in generalisability statistical power.

Informal caregiving was found to be very prevalent after hip fracture, and the amount of help patients received from informal caregivers care exceeded the amount of formal care provided by municipalities. Thus a trade-off may exist between formal and informal care after hip fracture. Which warrant further research.

The evidence base on costs-effectiveness of rehabilitation and care interventions remain limited and there is a need for more evidence. Hence, researchers are strongly recommended to measure and report cost-effectiveness. This will increase the evidence base and, thus, decision-makers' ability to direct resources more efficiently, ensuring that the greatest number of patients can benefit from the most effective treatments available.

Future perspectives

01.17 Rehabilitation for Life

Before the Rehabilitation for Life trial, rehabilitation and care programmes after hip fracture were heterogeneous and poorly described across municipalities (24). Now, all hip-fracture patients in the catchment area of Lillebaelt Hospital discharged to own home receive an equal standard of rehabilitation and care that meets national and international recommendations. However, in its current form the Rehabilitation for Life intervention increased costs and had limited additional utility gains compared to usual rehabilitation and care.

01.18 Supporting informal caregivers

A notable finding of this thesis was the extent to which patients rely on care from relatives. This may reflect the trend of responsibilities increasingly shifting from hospitals to community care, leading to faster patient discharge from hospital (151, 152). This shift has seemingly extended to informal caregivers, who now bear more responsibility for the day-to-day care of their loved ones (94). This hypothesis is supported by findings by Statistics Denmark who report that people living with partners start receiving formal care at a higher age than persons living alone (95). This underscores a need for policies to support informal caregivers, and aligns with the recommendations in the Danish reform of the care of the elderly that advocate for increased support to be given to patients' relatives.

01.19 Incorporating economic evaluation in trials

The number of economic evaluations is increasing in health studies and they are popular among decision-makers (153). Thus, this tendency will likely continue. However, a high-quality economic evaluation requires planning, accurate

measurements of cost and benefit, and a stringent and transparent analysis plan (154). Thus, it may be better to plan the economic evaluation alongside the trial and incorporate it as a secondary or exploratory outcome. Reporting the economic outcomes in the same paper as the clinical outcomes will also make it easier for the reader to understand the different costs and consequences associated with an intervention, potentially leading to greater impact and interest from a broader audience.

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Appendices

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I. Ipsen, J. A., Pedersen, L. T., Draborg, E., Bruun, I. H., Abrahamsen, C. & Viberg, B. Cost-Effectiveness of Physical Rehabilitation and Care of Older Home-Dwelling Persons After Hip Fracture: a Systematic Review and Narrative Synthesis. 24. Nov. 2022, I: Journal of Rehabilitation Medicine. 54, jrm00351.

II. Ipsen, J. A., Viberg, B., Pedersen, L. T., Draborg, E. & Bruun, I. H. Informal care after hip fracture: prospective cohort. 17. maj 2024, I: BMC Geriatrics. 24, 1, s. 436

III. Ipsen, J. A., Pedersen, L. T., Viberg, B., Nørgaard, B., Suetta, C. & Bruun, I. H. Rehabilitation for life: the effect on physical function of rehabilitation and care in older adults after hip fracture—study protocol for a cluster-randomised stepped-wedge trial, 7. maj 2022, I: Trials. 23, 375.

This study are under review at the *"Journal of rehabilitation medicine"*
IV. Ipsen, J.A., Olsen, J.A., Viberg, B., Pedersen L.T., Bruun, I. H., Draborg, E. Rehabilitation and care after hip fracture: A cost-utility analysis of stepped-wedge cluster randomized trial.

V. Supplementary and statistical analysis plan for each study.

J Rehabil Med 2022; 54: jrm00351

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REVIEW ARTICLE

COST-EFFECTIVENESS OF PHYSICAL REHABILITATION AND CARE OF OLDER HOME-DWELLING PERSONS AFTER HIP FRACTURE: A SYSTEMATIC REVIEW AND NARRATIVE SYNTHESIS

Jonas Ammundsen IPSEN, PT, MScPT[1,2], Lars T. PEDERSEN, MScPH[1–3], Eva DARBORG, PhD[4], Inge H. BRUUN, PhD[1,2], Charlotte ABRAHAMSEN, PhD[2,5] and Bjarke VIBERG, PhD, MD[2,5]

From the [1]Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding, [2]Department of Regional Health Research, University of Southern Denmark, Odense, [3]Department of Health Education, University College South Denmark, Esbjerg, [4]Danish Centre for Health Economics, Department of Public Health, University of Southern Denmark, Odense and [5]Department of Orthopaedic Surgery and Traumatology, Lillebaelt Hospital, University Hospital of Southern Denmark, Denmark, Kolding

Objective: **To provide a systematic review of the literature and knowledge base of cost per quality-adjusted life year of physical rehabilitation and care of older persons after hip fracture.**

Material and methods: **A research librarian assisted in searching 9 databases (14 May to 27 May 2021), with exclusion of studies on cognitively impaired or institutionalized individuals. A stepwise selection process was conducted by 2 authors, study quality was assessed using Drummond et al.'s checklist, and comparison between different countries was assessed using Welte et al.'s checklist.**

Results: **Three studies were included, which employed 3 different interventions initiated at 3 different postoperative time-points. One high-quality study demonstrated that comprehensive geriatric assessment was cost-effective compared with coordinated care. The other 2 studies did not find the interventions studied to be cost-effective, and both studies were deemed to be of moderate quality.**

Conclusion: **The body of evidence on the cost-effectiveness of physical rehabilitation and care after hip fracture is limited and heterogeneous, with only 1 high-quality study. Thus, stakeholders perform decision-making with a limited knowledge base of the cost-effectiveness of physical rehabilitation and care. We recommend researchers to assess cost-per-QALY.**

Key words: systematic review; quality-adjusted life year; quality of life; cost-effectiveness; rehabilitation; care; costs; hip fracture.

Accepted Oct 12, 2022; Epub ahead of print Oct 31, 2022

J Rehabil Med 2022; 54: jrm00351

DOI: 10.2340/jrm.v54.3421

Correspondence address: Jonas Ammundsen Ipsen, Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Denmark, Kolding. E-mail: Jonas.Ammundsen.Ipsen@rsyd.dk

LAY ABSTRACT

Hip fractures have severe consequences for older persons and, after surgery, patients need physical rehabilitation and care to recover. Physical rehabilitation and care vary greatly in terms of effectiveness and cost. It is not known what kind of physical rehabilitation and care contribute most to health relative to their costs. This systematic review provides the first comprehensive description of the cost-effectiveness of physical rehabilitation and care of older persons after hip fracture. Nine databases were searched, and 3 economic evaluation studies were identified. One economic study identified comprehensive geriatric care as cost-effective compared with usual coordinated care. The other two studies consisting of an intervention of additional 10 weeks of physical rehabilitation initiated 4 months after discharge and an intervention physical rehabilitation and nutrient management proved not cost-effective compared to usual rehabilitation and care. In conclusion, the number of studies published in this field is very limited and further research is necessary.

Hip fracture is the most common surgically treated trauma (1) and is associated with life-changing consequences for older home-dwelling persons, who experience reduced quality of life (QoL), physical function and mobility, as well as increased dependency on others (2, 3). After hip fracture, the most important goal for this patient group is to recover and regain independence (3). However, many patients do not regain their QoL or independence even a year after surgery (2, 4).

Physical rehabilitation and care are key interventions in facilitating recovery and improving QoL after hip fracture, and are routinely offered as individual or multifaceted interventions. The effectiveness of physical rehabilitation and care can vary greatly depending on the setting and content of the intervention (5–7).

A systematic review including 112 studies estimated the total world wide global cost per person in the first year after hip fracture as US$43,669. Physical rehabilitation and care was the second-largest driver

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of cost in this estimate, accounting for US$12,020 per person (8) and with 1.6 million expected yearly hip fractures world wide (Johnell O, Kanis JA (2006) An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporos Int 17(12):1726–1733) hip fractures has a significant impact on healthcare resources consumption.

Prioritizing healthcare services based on cost-effectiveness is critical to the efficient utilization of resources (9). Thus, the cost-effectiveness of physical rehabilitation and care interventions is important in determining whether one intervention generates better, equal or worse outcomes than another, based on their relative consumption of resources. In addition to determining the relative impact physical rehabilitation and care interventions have on persons, cost-effectiveness estimates must also take into account the setting and content of each intervention. Economic evaluations are demanded by stakeholders and have a great potential for expanding the knowledge base, but, to our knowledge, no systematic reviews of studies assessing the economic dimensions of physical rehabilitation and care after hip fracture have been published. Therefore, the aim of this systematic review was to provide an overview of the literature and knowledge base of cost per quality-adjusted life year (QALY) of physical rehabilitation and care after hip fracture for persons aged 65 years and older.

METHODS

Protocol and registration

The systematic review was reported according to the updated Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (10) and conducted in adherence with the article series "How to prepare a systematic review on health economic evaluations for informing evidence-based healthcare decisions: a five-step approach" (11–14). The protocol was registered with PROSPERO (ID: CRD42021281984) and is accessible at https://www.crd.york.ac.uk/PROSPERO/

Design

A systematic review and meta-analysis were originally planned; however, the number of studies found was limited and heterogeneous regarding both when the interventions were initiated after surgery and the content of physical rehabilitation and care. Therefore, a narrative analysis was conducted instead. It was thus planned to conduct an exhaustive, comprehensive search for quantitative studies and to discuss the results in depth in order to elucidate the effect of the interventions (15).

Eligibility criteria

The research question was developed based on the population, intervention and outcome (PIO). The study populations was compromised of older home-dwelling persons (65 years or older). Interventions comprised physical rehabilitation and care programmes targeting improvement in the person's physical functioning after hip fracture, which were mono- or multi-faceted, such as, but not limited to, physiotherapy, exercise and care interventions targeted improvement of the persons level of physical function after hip fracture (16, 17). The outcome measured was cost per quality-adjusted life year (QALY) in studies conducted in healthcare systems utilizing a single payer healthcare system comparable to those used in the Nordic countries (17, 18). Studies assessing interventions that targeted older persons with severe cognitive impairments, such as progressed dementia, or persons who were permanently institutionalized were excluded.

Information sources

Nine databases were selected based on their content descriptions at the University of Southern Denmark Library: MEDLINE, Embase, CINAHL, Cochrane Library, Scopus, the Health Technology Assessment (HTA) database of the Centre for Review and Dissemination, International HTA database, EconLit, and Academic Search Premier. All databases were deemed relevant by all authors and were searched from the date of inception.

Search strategy

Keywords were identified, assessed and arranged according to the PIO model. The search strategy was adapted to each database to account for differences in MeSH terms, indexation and matrix. All authors approved the keywords for each database. Grey literature in conference abstracts was searched. The search strategies are shown in Appendix S1.

A single author (JAI) performed all searches, during the period 14–27 May 2021.

Study selection

Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org, and a stepwise study selection process was conducted. Duplicates were removed, and 2 authors (JAI and LTPE) independently screened the remaining studies' titles and abstracts. Next, both authors (JAI and LTPE) independently performed full-text screenings for final inclusion. In both steps (screening of title and abstract and full text), disagreements were resolved by consensus, which occasionally involved all authors (JAI, LTPE, ED, IHB, CA and BV).

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Data extraction

A single author (JAI) completed a data extraction form, based on the form developed by Wijnenn et al. (14), which was subsequently verified by all authors. The form comprised 13 items relating to general study characteristics and 18 items relating to study methods and outcomes. The completed data extraction forms are available in Appendix S2.

The following data were extracted: first author, year of publication, year of trial, funding source, competing interests, publication type, setting, person characteristics, intervention type, control intervention, study eligibility criteria, study perspective, type of economic evaluation, analytical method, time-frame, discount rates for costs and effects, inflation rate, type and category of costs, data source of resource use, methods for identifying resource use, assumptions for measurement of resources, costs reported or converted currency, data source of effects, methods of measuring effects, methods of valuation of effects, effects, incremental cost-effectiveness ratio (ICER), analyses of uncertainty (e.g. sensitivity analyses), outcome(s) of sensitivity analyses and authors' conclusions.

Disagreements were resolved through discussion and consensus between all authors.

Quality assessment

Quality assessment was performed using the commonly used checklist developed by Drummond et al., which was designed to appraise the quality of economic evaluations (9). The checklist was formatted as a table, with 1 axis showing each checklist criterion and the other axis presenting each economic evaluation, as suggested by Watts et al. (19). Each criterion was assessed as "Yes", "No" or "Can't tell". The criteria for "Yes" are described in Appendix S3. Two authors (JAI and LTPE) independently assessed the studies and subsequently compared their findings. Disagreements were resolved by discussion between the 2 authors, and unresolved disagreements were discussed with an experienced health economist (EUD).

Transferability of studies

Welte et al.'s decision chart was used to assess the transferability of the study findings (20). The decision chart is practical in use and consists of 3 general knockout criteria and 14 specific criteria (14, 21, 20). To meet the first and second general criteria, the physical rehabilitation and care intervention and the comparator must be compatible with the decision country. To meet the third general criterion, the study must be of acceptable methodological quality, which was appraised by applying Drummond et al.'s checklist (20). The specific criteria assess relevance on a 4-point scale, ranging from "very high" to "very low" (20). Correspondence must be deemed "very high" or "high" to assume an unbiased cost-effectiveness ratio (CER) (20). As Welte et al.'s (21) decision chart requires a comparison between 2 countries, we pragmatically chose one Nordic country (Denmark) as reference country to compare study countries against. The assessment of transferability was conducted by 1 author (JAI), who conferred with an experienced health economist (ED). Disagreements were resolved by discussion.

Data synthesis

A narrative synthesis summarizing and interpreting the findings of the individual studies was conducted. To compare costs from studies completed in different years and currencies, the reported currency was converted to euros using the mean conversion rate for the trial completion year, based on historical conversion rates (22). Furthermore, costs were forward discounted from the trial completion year to 2021 using the national discount rate from Denmark of 3.5% and the equation $P = Fn/1+R$ (P = present value; F=future value; n=number of years; R=interest rate) (9, 23) Table 3.

RESULTS

Study selection

The search located 1,493 studies, of which 502 duplicates were removed. After title and abstract screening, 953 studies were excluded, and, after full-text screening, 35 studies were excluded. Three studies remained and were included in this review. Two trial protocols currently recruiting were identified (24, 25), although as no results were available at the time of data extraction, these studies were not included. The study selection process and reasons for exclusion are shown in Fig. 1.

Study characteristics

The 3 included studies were trials that applied a healthcare perspective encompassing the use of physical rehabilitation and care services in the primary and secondary sectors (26–28). The studies displayed heterogeneity in how costs were collected, valued and in QoL preference weights used (26–28). Two studies were based on trials completed in 2010 (26, 28) and 1 study was based on a trial completed in 2014 (27). One study was conducted in Australia (26) while 2 were conducted in Norway (27, 28). The interventions consisted of different types of physical rehabilitation and care, and were initiated at different postoperative timepoints. The study characteristics are shown in Table I.

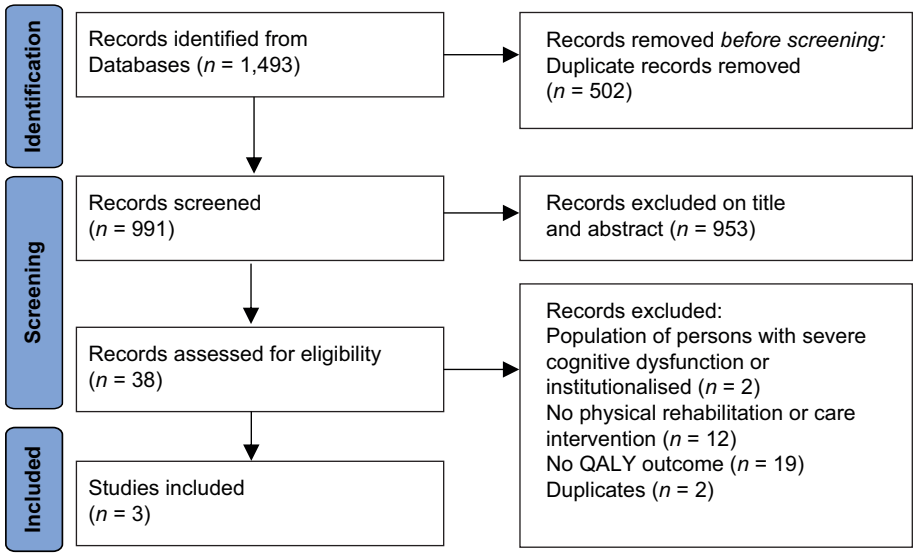

Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart. QALY: quality-adjusted life years.

Table I. Study characteristics

Study id	Study	Study completion year	Number of persons control/ intervention	Perspective	Effect measure	Preference weights	Country	Intervention summary
1	Milte, R. 2016	2010	99/76	Healthcare sector perspective	A-QOL	Australian general population weights	Australia	Exercise was performed 3 times per week and progressed every 14 days by trial physiotherapists. Dietary strategies included dietary counselling focusing on timing, size, and frequency of meals, recommendations of nutrient-rich foods and recipes, referral to community meal programmes, and provision of commercial oral nutritional supplements or commercial protein powders as deemed appropriate. The intervention lasted 10 weeks with weekly visits. The control group received usual rehabilitation.
2	Taraldsen, R. 2019	2014	73/70	Healthcare sector perspective	EQ-5D-3L	English tariffs	Norway	Persons received a home-based programme, starting 4 months post-surgery. The programme consisted of 2 exercise sessions per week and lasted 10 weeks. Each session had a duration of approximately 45 min and was supervised by physiotherapists. The control group received usual rehabilitation.
3	Prestmo, A. 2015	2010	199/198	Healthcare sector perspective	EQ-5D-3L	English tariffs	Norway	Intervention persons received comprehensive geriatric care in a geriatric ward with an emphasis on comprehensive medical assessment and treatment, initiation of rehabilitation through mobilization. Number of staff per bed was higher in the geriatric ward. Control received usual rehabilitation at the orthopaedic ward.

A-QOL: Assessment of Quality of Life (A-QOL) instrument; EQ-5D-3L: Euroqol five dimension three level (EQ-5D-3L) questinaire.

Milte et al. (26) assessed a 10-week individualized nutrition and exercise intervention initiated shortly after discharge after hip surgery. QoL outcomes were measured using the 5-dimension assessment of quality of life instrument (AQoL-4D) with preference weights for the general Australian population. Data collection was carried out weekly by trial staff. The questionnaire was used in combination with registry data encompassing the use of medical and pharmaceutical benefit schemes. The study's time-frame was 6 months. Costs were adjusted to a 2010 consumer price index (trial year) and valued to accepted unit costs from the Australian National Hospital Cost Data Collection and cost of visits from allied healt professionals were taken from rebates specified by Department of Veterans Affairs.

Taraldsen et al. (27) assessed the outcomes of a 10-week, late-phase exercise programme initiated 4 months after discharge after hip surgery. QoL outcomes were measured using the EQ-5D-3L with English preference weights. Administrative registers, municipal person records and the Norwegian Directorate of Health were used to collect data on the use of healthcare services. Valuation of costs was based on fee-for-service information in Norwegian kroner

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(NOK) and reported in 2012 euros using the mean exchange rate from 2012. The study's time-frame was 8 months.

Prestmo et al. (28) assessed the outcomes of a comprehensive geriatric assessment (CGA) at a geriatric hospital ward compared with usual care at an orthopaedic ward. QoL was measured using the EQ-5D-3L with English preference weights. Data on the use of healthcare services was obtained through administrative systems, municipal patient records, the Norwegian Patient Register and the Norwegian Health Economics Administration. Costs were valued using published costs or local experts and municipal websites in NOK and presented in 2010 euros based on the mean exchange rate from 2010. The time-frame of the study was 12 months.

Quality assessment

The study by Prestmo et al. (28) was determined to be of high quality, while the studies by Taraldsen et al. (27) and Milte et al. (26) were of moderate quality.

None of the studies achieved "Yes" ratings for all criteria, as they did not account for different time-frames or include all costs relevant to the healthcare perspective. Milte et al. (26) and Prestmo et al. (28) disclosed differential timing, though a comparison was deemed unfeasible due to their respective time-frames of 6 and 12 months. Taraldsen et al. (27) did not disclose their reasons for not adjusting for differential timing. The studies were heterogeneous in the costs included in the healthcare sector perspective, as, for instance, only 1 study, by Milte et al. (26), included use of medication in calculation of costs.

The studies' included costs are detailed in Appendix S4.

Milte et al.'s study (26) was assigned ratings of "No" for 3 additional criteria. First, the study had an insufficient description of the comparator. Without knowledge of the contents and settings of usual physical rehabilitation and care in Australia, it was not possible to assess the comparative intervention. The second "No" was assigned for reporting an ICER estimate based on a minor statically insignificant difference in effect, which was inappropriate. The third "No" was due to the discussion, which did not reflect these concerns regarding the ICER estimate.

Taraldsen et al.'s study (27) was assigned "No" ratings on 2 additional criteria. First, the ICER was estimated and reported based on a small statistically insignificant difference in effect. Secondly, there was no reporting of an ICER plane or cost-acceptability curve, and the cause for not reporting an ICER plane was undisclosed, thus making the interpretation less transparent to the reader.

Table II. Quality assessment of studies using Drummonds Checklist

Economic evaluation	Research question well defined?	Comprehensive description of alternatives?	Effectiveness of programme established?	Important and relevant costs and consequences each alternative identified?	Costs and consequences for measured accurately and appropriately?	Costs and consequences valued credibly?	Costs and consequences adjusted for differential timing?	Incremental analysis of costs and consequences performed?	Allowance made for uncertainty in estimates?	Presentation and discussion of study results include all issues of concern to users?
Milte, R 2016	Yes	No	Yes	No	Yes	Yes	No	No	No	No
Taraldsen, K. 2019	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No
Prestmo, A. 2015	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes

Table III. Summary of findings regarding the cost-effectiveness of rehabilitation of older home-dwelling persons after hip fracture

Study id	Economic evaluation	Intervention effect	Control effect	Difference in QALY gain (95% CI)	Intervention costs, €	Control costs, €	Cost difference (95% CI)	Cost per QALY (€/QALY)
1	Milte, R. 2016	0.155	0.139	0.02 (–0.027, 0.059)	21.551,86	21.268,93	€ 206,39 (–2,928.98, 3,468.72)	€ 13.471,14
2	Taraldsen, K. 2019	0.73	0.73	0	26.219	25.976	€ 242.9 (– 6.82, 6.75)	–
3	Prestmo, A. 2015	0.52	0.45	0.09 (0.02, 0.16)	37.213,52	40.743,44	€ –3.528,00 (–8,808.14; 1,989.34)	€ –49.145,53

QALY: quality-adjusted life year; 95% CI: 95% confidence interval.

Prestmo et al.'s study (28) received "Yes" ratings for the remaining criteria.

The quality assessment of the 3 studies is shown in Table II.

Transferability

Milte et al. (26) fulfilled the first and third general knockout criteria. However, the second criterion was not fulfilled, as the description of usual physical rehabilitation and care was too general to adequately assess the content and setting of the comparator. Correspondence in practice variation was deemed "low", as the mean length of stay of 16 days was considerably longer than usual practice in Nordic countries (26, 29). In addition, correspondence was "low" in 3 specific criteria. First, the inclusion of weekly social visits with the control group and the longer length of stay did not correspond well to procedures in Nordic countries. Secondly, the lack of a description of usual physical rehabilitation and care made direct comparisons between countries impossible. Thirdly, it is unknown how Australian QoL preferences compare with a Nordic population. As Danish and English QoL preferences do not equate, we cannot assume high correspondence between Australian and Nordic populations (30). Thus, the ICER estimate was considered biased.

Taraldsen et al. (27) met all 3 knockout criteria, and the correspondence between Norway and Nordic countries was deemed "high" (27). The healthcare perspective was narrower than recommended, although it is the most commonly used perspective in western countries (31). The ICER estimate was thus rated as unbiased.

Prestmo et al. (28) fulfilled the 3 general knockout criteria, and the correspondence between Norway and Nordic countries was deemed high. As the healthcare sector perspective was narrow, but the most commonly used, the ICER estimate was rated as unbiased (31).

The completed transferability decision charts are shown in Appendix S5.

Findings

Milte et al. (26) detected a difference in QALY gain of 0.02 (95% confidence interval (95% CI) –0.027, 0.059; intervention group 0.155 vs control group 0.139) (26), but the difference was not statistically significant. The mean total cost difference was €206.39 (95% CI –2,928.98, 3,468.72; intervention group €21,551.86 vs control group €21,268.93). Assuming the difference between groups was a true difference, the incremental cost per QALY was estimated as €13,471.14.

Taraldsen et al. (27) reported no difference in QALY gain between the groups (intervention group median 0.73 vs control group median 0.73) (27). The mean total cost difference was €51, 3 (95% CI –6.82, 6.75; intervention group €26,219 vs control group €25,976).

Prestmo et al. (28) demonstrated a statistically significant difference in QALY gain of 0.09 (95% CI 0.02, 0.16; intervention group mean 0.52 vs control group mean 0.45) (28). The total cost difference was –€3,528.00 (95% CI 2928.98, 3468.72; intervention group €37,213.52 vs control group €40,743.44). The incremental cost per QALY was –€49,145.53.

A summary of the studies' findings is shown in Table III.

DISCUSSION

This systematic review presents the findings of 3 primary studies assessing different physical rehabilitation and care interventions compared with usual physical rehabilitation and care after hip fracture (26–28). Two of the studies showed that the interventions were not cost-effective, while the third study found the intervention to be cost-effective. Prior to this study PROSPERO (ID: CRD42021281984), the protocol was registered in Open Science Framework and remained unchanged during the review, except for the omission of a meta-analysis due to heterogeneity between studies.

The narrative synthesis revealed pronounced heterogeneity between studies, which is similar to a previous systematic review assessing the global cost of fragility hip fractures.which reported significant heterogeneity between studies affecting the credibility and accuracy of the results (31).

Prestmo et al. (28) demonstrated that CGA, including physical rehabilitation and care at a geriatric ward was more effective and less costly compared with usual care at an orthopaedic ward. In contrast, a Swedish study by Lofgren et al. (32), comparing coordinated rehabilitation and care at a geriatric ward with usual rehabilitation and care at an orthopaedic ward for hip fracture patients detected no difference between programmes in QoL. The difference between these 2 studies in the effect on

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QoL might be explained by differences in interventions (28, 32). CGA appears to be more comprehensive than coordinated rehabilitation; however, the descriptions were vague (28, 33). An additional explanation might be found in population differences, as Lofgren et al. (32) included persons living in nursing homes. Milte et al. (26) and Taraldsen et al. (27) did not find 2 different physical rehabilitation and care interventions to be cost-effective compared with usual physical rehabilitation and care in the primary sector. This may indicate that the content and scope of physical rehabilitation and care are important factors in improving persons' QoL.

None of the included studies found their interventions to be more resource-demanding than usual physical rehabilitation and care (26–28). In 2 of the studies, this was probably due to fewer persons in the intervention group being admitted to nursing homes (27, 28). If nursing home admissions remain lower in the long term it might have implications for the cost-effectiveness ratio. This is potentially supported by an Australian study by Cameron et al. (34), which identified accelerated rehabilitation, including components of CGA, early mobilization and discharge programmes as less costly and as effective at recovering patients' level of function as conventional rehabilitation. However as Prestmo et al. (28) followed persons for only 12 months and Taraldsen et al. for 8 months, it was not impossible to assess the long-term implications of the interventions (26–28). Thus, this should be assessed in future studies with a longer follow-up period, which, if feasible, are powered to the high mortality and drop-out rate of frail older persons.

Two of the included studies, by Taraldsen et al. (27) and Prestmo et al. (28), were conducted in a healthcare system organized in a primary sector (municipalities) and a secondary sector (hospital). In the study by Taraldsen et al. (27) the intervention imposed an increased and decreased use of municipal rehabilitation. In the study by Prestmo et al. (28) the intervention increased hospital cost and decreased the use of municipal care. Thus, in both studies the stakeholders paying the intervention were not the ones receiving the benefits. Based on the limited number of studies available, it was not possible to assess the significance of this potential barrier for implementation of new and more effective physical rehabilitation and care interventions.

Applying a narrow healthcare sector perspective in cost-effectiveness studies increases the risk of underestimating true resource use (9, 35). The 3 studies in this review included different costs in their assessments using the healthcare sector perspective (26–28). For example, Milte et al. (26) included the cost of social visits to the control group, while Taraldsen et al. (27) included the cost of psychiatric care in hospital, and Prestmo et al. (28) included the cost of hospital stays post-discharge. This indicates an overly narrow perspective of the minimal requirements of the healthcare sector. In contrast, the societal perspective is more feasible in older persons after hip fracture, as it includes the costs of informal care. Informal caregivers have been estimated to deliver a mean of 39.5 h of care per week in the first 6 months after hip fracture, and 36% of informal caregivers report a high perceived burden of care (36, 37).

Strengths and limitations

A strength of this systematic review was the very broad search performed in cooperation with a research librarian (13). To further exhaust the search, reference lists and grey literature were searched, though no additional relevant studies were identified. An additional strength was the study selection process, which was carried out independently by 2 researchers. Furthermore, study quality was assessed using a well-established checklist developed by Drummonds et al. (9), and 2 reviewers performed the assessment independently (19, 38).

Healthcare reimbursement schemes and the content of usual physical rehabilitation and care can bias or prevent credible comparisons of outcomes and costs between countries. Thus, the current review systematically assessed the transferability of study findings to a Nordic context using the Welte decision chart (20). This was carried out by a single author, and to reduce the risk of biased assessment, an experienced health economist advised in this process. A second assessor would have reduced the risk of assessor influence; however, it is not considered likely that a second accessor would have altered the assessment of transferability.

CONCLUSION

The evidence base of the cost-effectiveness of various physical rehabilitation and care interventions after hip fracture is limited and heterogeneous. Only 1 of 3 interventions was shown to be cost-effective. The studies used the same healthcare sector perspective, but did not include all relevant costs, and the interventions differed in content and were initiated at different postoperative time-points. This prevented pooled effect size estimates and clear recommendations for physical rehabilitation and care of older home-dwelling persons after hip fracture. Based on the findings of this systematic review, future economic evaluations should employ broader perspectives and a plan for longer follow-up to capture the long-term implications of physical rehabilitation and care. The inclusion of only 3 economic evaluations underscores the need for more economic research studies to sup-

port healthcare decision-making and prioritization, and highlights a gap in the current knowledge base.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge funding provided by the research council at Lillebaelt Hospital, the Association of Danish Physiotherapists, and the Novo Nordic Foundation. The contents of the published materials are solely the responsibility of the Administering Institution of Lillebaelt Hospital and the individual authors identified and do not reflect the views of the research council or the Novo Nordic Foundation. The funders of the study had no role in the study design, data collection, data analysis, data interpretation or writing of the report. The systematic review was completed independently of the administering organization and donors.

The authors have no conflicts of interests to declare.

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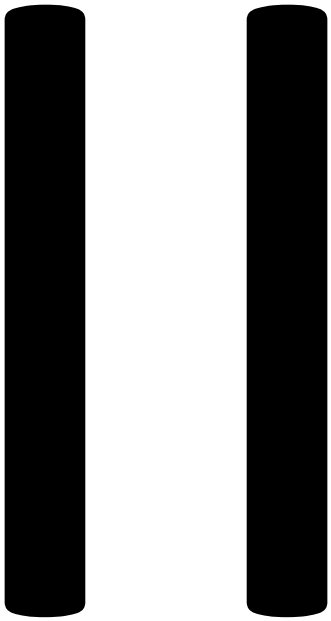

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RESEARCH

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Informal care after hip fracture: prospective cohort

Jonas Ammundsen Ipsen[1,2*], Bjarke Viberg[3,4,5], Lars T. Pedersen[1,2,6], Eva Draborg[7] and Inge Hansen Bruun[1,2]

Abstract

Background Hip fracture is very common and it has life-shattering consequences for older persons. After discharge the older persons need help with even basic everyday activities from formal and informal caregivers. In Scandinavia formal care are well-developed however the presence of informal caregivers likely reflect on the amount of formal care and wears on the informal caregivers. This study explore how often and how much informal care (IC) older persons receive after hip fracture.

Method We contacted 244 community-dwelling older persons every two weeks the first twelve weeks after discharge after hip fracture and asked them if they received care from family and/or friends and how much. We used non-parametric statistics and level of significance was 95%.

Results The proportion of older persons receiving IC was 90% and the median amount of IC was 32 hours (IQR 14-66). The number of older persons who received IC was highest the first four weeks after discharge and so was the amount of hours of IC. The older persons that were high-dependence on IC received a median of 66 (IQR 46-107) hours compared to the low-dependent of 11 hours (IQR 2-20).

Conclusion IC is very frequent, especially the first two to four weeks after discharge. The median IC was 32 hours from discharge to the 12-week follow-up. However, this figure tended to rise for persons with, among other, reduced functionality and those residing with a partner.

Implications With respect to local differences, the findings in this study are likely applicable to other Scandinavian countries. We strongly suggest that the variation in older person need for informal caregiver be given consideration in the prioritisation of resources.

Trial registration This prospective cohort study of informal care, was part of a cluster-randomised stepped-wedge clinical controlled trial. Written consent was obtained required by regional ethics committee S-20200070. Data was collected in accordance with the Danish Data Protection Agency (20-21854).

Keywords Informal care, Hip fracture, Care, Prospective

*Correspondence:
Jonas Ammundsen Ipsen
jonas.ammundsen.ipsen@rsyd.dk
Full list of author information is available at the end of the article

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Background

Hip fracture is the most common surgically treated trauma and it has life-shattering consequences for older persons [1, 2]. Upon discharge to home, older persons face challenges with basic activities such as walking or getting dressed, incurring an increased need for assistance [1, 2]. To meet this need, older persons receive formal care from healthcare professionals and/or informal care (IC) from family or friends [3–6].

The United Nations Economic Commission for Europe Standing Working Group on Ageing warns that without adequate support the negative influence on the physical and mental health of IC providers can increase demands and costs of health care [7]. Compared with other member countries of the United Nations, Scandinavian countries have a universal healthcare system in which the public is obliged to provide care and family and friends are not bound to provide IC [7, 8]. However, in contrast, the Scandinavian countries have the highest prevalence of informal caregivers in Europe [9]. Thus, informal caregivers likely want to take care of their older relatives despite the duty of the public health care system. This, in combination with an increased focus on resource scarcity, can have increased the healthcare system's dependency on informal caregivers when frail older persons are discharged to their own homes after hip fractures [10, 11].

In Sweden, Finland and Denmark, 13-16% of the population are informal caregivers, and Danish and Norwegian older persons with high needs for formal care also receive significant amounts of IC [11–14]. Denmark, Sweden, Norway and Finland all have a high prevalence of IC, and in all four countries, there are recommendations on the inclusion of informal caregivers in meeting patients' need for help [11, 14–18]. There are likely differences in how these recommendations are employed between countries. Nevertheless, all four countries have a healthcare system divided in sectors with partly autonomous municipalities and hospitals. Thus, healthcare professionals, patients and informal caregivers across Scandinavia likely face similar challenges to coherent care when discharging patients after hip fractures.

Although IC is probably common among older persons after hip fracture in Denmark, the frequency and amount of this IC have not been assessed before in a Scandinavian country. Filling this knowledge gap is important as it provides insight into the burden of IC on family and friends after hip fracture. Thus, this study aimed to quantify the frequency and amount of IC received by home-dwelling persons aged 65 and older after hip fracture.

Methods

Study design

This study, a prospective cohort study of informal care, was part of a cluster-randomised stepped-wedge clinical controlled trial ('Rehabilitation for Life') [19]. Reporting followed the guidelines for Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).

Setting

The cohort encompassed one catchment area (one hospital and six municipalities serving a mixed rural and urban population). The responsibility for providing care, which is offered free of charge, is shared between hospital and municipalities. Municipalities regularly assess whether the amount of care is sufficient or requires an increase or decrease with regard to the older person's needs; this can ultimately become a lifelong service [20, 21].

Participants

Inclusion criteria were community-dwelling persons aged 65 years or older after hip fracture treated at a one hospital in Southern Denmark. Exclusion criteria were inability to speak or understand Danish, discharge to permanent residence in nursing homes, progressed dementia, and refusal to participate in the trial, refused to participate in this study or having short life expectancy.

Outcomes

The primary outcome was the number and percentage of older persons receiving IC from time of discharge to follow-up at 12 weeks.

The secondary outcome was the median total number of hours of IC from discharge to 12-week follow-up.

The biweekly change in frequency and number of hours of IC was explored with and without inclusion of the older persons with missing information.

Variables

Informal care: the proportion of older persons receiving assistance from informal caregivers from time of discharge to 12-week follow-up.

Amount of informal care: the aggregated number of hours of IC the older persons received from informal caregivers from time of discharge to 12-week follow-up.

Biweekly change in frequency and amount of IC: the number of older persons receiving IC and the median number of hours of IC in weeks 1-2, weeks 3-4, weeks 5-6, weeks 7-8, weeks 9-10 and weeks 11-12.

Demographic characteristics: age, gender, body mass index (BMI), living arrangement (i.e., alone, cohabiting

or other), and physical status classification using anesthesiologist's pre-surgery validation American Society of Anaesthesiologists (ASA) levels one being the best. The ASA score assess patient's overall health based on five classes [22]. In this study, the ASA score was dichotomised as ≤2 or above 2.

Type of operation: categorised as arthroplasty, sliding hip screw or intramedullary nail.

Mobility: New Mobility Score (NMS) was a clinician-applied 0-9 score measured at discharge. A higher score indicates better mobility [23].

Basic mobility: Cumulated ambulation score (CAS) was a clinician-applied 0-6 score measured at discharge. Higher score indicated better basic mobilisation [24].

Activities of daily living: Barthel-20 was measured on a scale from 0-20, at discharge, to assess a patient's need for assistance. Higher score indicate lesser need for help [25].

Overall health: EuroQol five-dimension five level VAS-score was a standardised questionnaire, used to assess the patient's overall health status from 0-100. Higher score equal superior health [26].

Pain: Pain in the operated leg was measured using the four-point Verbal Rating Scale (VRS): 1–no pain, 2–slight pain, 3–moderate pain, 4–severe pain [27].

Data collection and source

The older persons recorded the amount of IC received as the number of hours in a diary, Supplementary 1 [28, 29]. The data was collected by telephone interviews and home visits every two weeks from discharge to 12-week follow-up. The older persons were instructed to only record the new need for IC caused by the hip fracture and only the amount of time they received IC. For instance, if an informal caregiver provides help for bathing or grocery shopping as part of a longer visit, only the time the patient received care was to be recorded. Patients who did not fill in the diary were asked to estimate the hours of IC the previous week and to include both weeks; the estimate was multiplied by two. A Rehabilitation for Life trial physiotherapist collected demographic characteristics, type of surgery, NMS, CAS, Barthel-20, EuroQol five-dimension five-level VAS-score and VRS in the hospital on the day of discharge. Demographic characteristics and types of surgery were collected in the medical journals. NMS, CAS, Barthel-20, EuroQol five-dimension five-level VAS-score, and VRS were questionnaires the patients filled out in the hospital on the day of discharge. The physiotherapist read the questionnaires aloud for older persons with impaired vision.

Sample size

The study size was determined from the number of participants in the Rehabilitation for Life trial [19].

Statistical methods

Descriptive statistics for continuous variables were presented with medians and interquartile (IQR) due to non-normal distribution, while categorical variables were presented with frequencies and percentages. Group comparisons for continuous variables were performed using Wilcoxon's rank sum test, and Pearson's χ^2 was used for categorical variables**.** The proportion of variance explained by variables differentiating recipients of IC from non-recipients and older persons' high and low dependence at a 95% statistically significant level. The proportion of variance explained was assessed with McFadden pseudo-R2 and reported as the odds of receiving IC and high dependency, respectively. We used mono- and multivariate logistic regressions depending on the number of variables identified, differentiating persons receiving and not receiving IC and the high and low dependent persons at a statistically significant level. The statistically significant level was 95%. All statistical analyses were performed with StataCorp. 2019 (*Stata Statistical Software: Release 17*. College Station, TX: StataCorp LLC).

Drop out analysis

As not all older persons responded to the phone calls, an analysis between the older persons with complete and incomplete follow-up on discharge and demographic variables was completed.

Sub-analysis

Due to large IQR ranges of the median amount of IC, the median amount of IC from time of discharge to 12-week follow-up was used to create low and high dependence groups of older persons.

Results

From September 2020 to April 2023, 1.114 older persons were screened for study eligibility after hip fracture; of these 789 were excluded, leaving 244 older persons for inclusion (Fig. 1). The median age of the cohort was 78 (74-84) years; 66% were female, and 51% lived alone (Table 1).

Number and percentage of older persons receiving IC

Of the 244 included older persons, 219 (90%) received IC. The median number of hours per week of IC from time of discharge to 12-week follow-up was 32 (14-66). Except for type of surgical treatment (p=0.049), at the baseline variables included in this study, the older

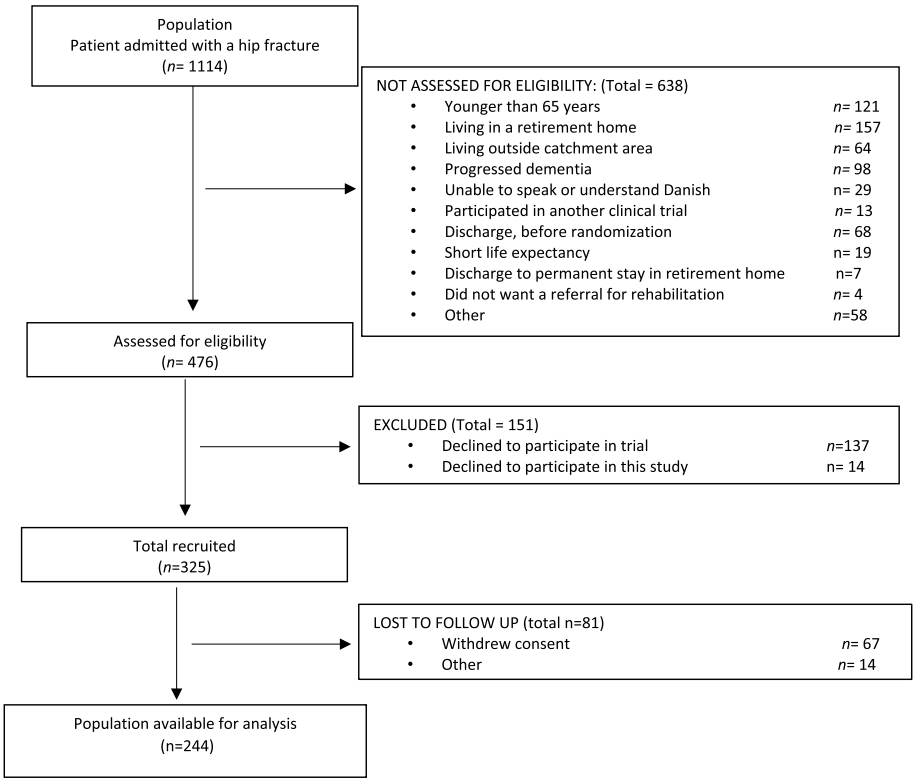

Fig. 1 Flow chart of the inclusion process

persons who received IC were similar to older persons who did not receive IC (Table 1).

Biweekly change in frequency and amount of IC

The number of older persons receiving IC and the number of hours of IC were highest in the first two to four weeks after discharge and declined over time. However, after twelve weeks, a third of the older persons still received informal care (Table 2). Approximately five to ten per cent of the older persons did not report on IC at each biweekly follow-up, and excluding older persons with missing information increased the biweekly amount of IC; the change has been visualised in Supplementary 2.

Drop out analysis

Of the 244 older persons, 63 (26%) had incomplete follow-up (Table 3). The older persons with complete follow-up received a median amount of IC of 28 (13-62) hours whereas the older persons with incomplete follow-up received a median of 14 (3-67) hours. Compared to the older persons with complete follow-up, the older persons with incomplete follow-up were older (p=.030), more frequently lived alone (p=.006), had higher ASA score (p=.026), surgically treated using intramedullary nails (p=.010), had poorer gait function (p= .000), had poorer basic mobility (p=.000), had poorer ability to perform activities of daily living (p=.001) and had poorer overall health (p=.005).

Sub analysis

High and low dependence on IC

Of the 244 older persons, 110 (45%) had high dependence on IC (≥32 hours of IC) (Table 4). Older persons with high dependency received a median of 66 (46-107) hours of IC per week, and older persons with low dependency received a median of 11 (2-20) hours of IC. The two groups differed significantly from each other: compared with older persons with low dependency, the older persons with high dependency more frequently lived with a partner (p=.000), were more often surgically treated using intramedullary nail (p=.001), had poorer basic mobility (p=.019) and perceived their ability to perform basic activities of daily living as poorer (p=.040).

Variance analysis

Receiving IC

Univariate regression analysis did not indicate that the type of surgery increased the odds of receiving IC, and the proportion of variance explained was 1% (OR 1.12, 95% CI 0.701-1.818, R2 .016). No other variables

Table 1 Demography percentage and hours of IC of the cohort and recipients and non-recipients of IC

Variables	No IC *n*= 25 (median IQR)	IC *n*=219 (median IQR)	Cohort *n*= 244 (median IQR)
Hours of informal care	0	32 (14-66)	27 (11-57)
Female *n* (%)	15 (60%)	146 (73%)	161 (66%)
Age	77 (70-83)	79 (74-84)	78 (74-84)
BMI	24 (21-28)	24 (21-28)	24 (21-28)
Living alone *n* (%)	13 (52%)	111 (51%)	124 (51%)
ASA score ≤ 2 *n* (%)	11 (44%)	121 (55%)	132 (54%)
Operation type *n* (%)[a]			
Arthroplasty	7 (28%)	75 (34%)	82 (34%)
Sliding hip screw	11 (44%)	48 (22%)	59 (24%)
Intramedullary nail	7 (28%)	95 (44%)	102 (42%)
NMS score	2 (1-4)	2 (1-3)	2 (1-3)
CAS score	6 (4-6)	5 (4-6)	6 (4-6)
Barthel-20	15 (10-18)	15 (11-17)	15 (11-17)
Overall Health	50 (33-75)	60 (50-75)	60 (50-75)
Pain operated leg			
No pain	3 (12%)	28 (13%)	31 (13%)
Slight pain	6 (24%)	54 (24%)	60 (24%)
Moderate pain	9 (36%)	87 (40%)	96 (40%)
Severe pain	7 (28%)	50 (23%)	57 (23%)

IQR Interquartile range, *BMI* Body mass index, *ASA* American Society of Anaesthesiologist Physical Status Score, *NMS* New Mobility Score, *CAS* Cumulated Ambulation Score

[a] marked variables differentiated the groups at a 95% significant level

differentiated recipients from non-recipients at a statistically significant level.

High dependency of IC

The univariate regression demonstrated that the odds of high dependence on IC increased by 135% if the patient was surgically treated using intramedullary nails. The type of surgery explained 4% of the difference between the older person's high or low dependence on IC (OR 2.35 95% CI 1.295-4.236 R2 .04). Living with a partner increased the risk of being high dependent on IC by 194% and explained 5% of the proportion of variance (OR 2.94 95% CI 1.742-4.959 R2 0.05). Neither basic mobility (OR 0.83 95% CI 0.688, 1.009 R2 0.01) nor the ability to perform ADL activities (OR 0.93 95% CI 0.875, 1.000 R2 0.01) differentiate older persons with high dependence and low dependence at a 95% significance level. The multivariate regression included type of surgery, living arrangement, CAS and Barthel-20 score and combined these four variables explained 10.4% of the proportion of variance between older persons high or low dependent on IC. A table of the variance analysis are available in Supplementary 3.

Discussion

Key result

In this study, IC was very common, with 90% of the participants receiving IC with a median amount of 32 hours of IC in the 12 first weeks after discharge. The frequency and number of hours of IC were highest during the first two to four weeks after discharge and gradually declined over time. Sub-analysis demonstrated that the older persons high dependent on IC (≥32 hours) comprised 45% of the cohort; they received a median number of 66 hours of IC and were generally characterized as having poorer health and physical function at discharge compared to the older persons in the low dependent group. The variables of type of surgery and living with a partner explained 10% of the variance between the persons with high and low dependence on IC. Approximately one in four of the older persons did not have complete follow-up, and the older persons with complete follow-up differed from those with incomplete follow-up in having better health and physical function at discharge.

Interpretation

During data collection, we were aware that older persons can be struggling with several diseases. During the pilot test, we learned that many of them failed to fill or incompletely fill their diaries [1, 30–32]. To mitigate this, we collected data via telephone interviews every two weeks, and non-responders to the telephone call were contacted twice on two separate days before a missing data point was accepted (i.e., a total of four telephone calls were performed). As a result, three out of four had complete

Table 2 Number of recipients and hours of informal care at each time point for the population and recipients of IC

	Week 1-2 *n*=221	Week 3-4 *n*= 234	Week 5-6 *n*=226	Week 7-8 *n*= 232	Week 9-10 *n*=216	Week 11-12 *n*=235
Receiving IC *n* (%)	157 (71%)	151 (65 %)	117 (52%)	126 (54%)	87 (40%)	84 (36%)
Cohort hours of IC median (IQR)	8 (0-27)	4 (0-14)	1 (0-7)	2 (0-8)	0 (0-4)	0 (0-4)
Recipients hours of IC median (IQR)	14 (8-28)	10 (4-20)	7 (4-16)	7 (4-18)	6 (3-15)	7 (4-17)
Missing *n*	23	10	18	12	28	9

Table 3 Drop-out analysis between the older persons with complete and incomplete follow-up on baseline with demographics

Discharge	Complete follow-up *n*=180 Median (IQR)	Incomplete follow-up=64 Median (IQR)
Hours of IC	28 (13-62)	14 (3-69)
Female	120 (67%)	41 (64%)
Age[a]	78 (73-83)	80 (76-85)
BMI	24 (21-27)	23 (21-26)
Living alone[a]	82 (46%)	42 (65%)
ASA[a]	105 (58%)	27 (42%)
Operation type *n* (%)[a]		
Arthroplasty	69 (38%)	13 (21%)
Sliding hip screw	45 (25%)	14 (22%)
Intramedullary nail	66 (37%)	36 (57%)
Gait (NMS)[a]	2 (2-4)	2 (1-3)
Basic mobility (CAS)[a]	6 (4-6)	4 (3-6)
Barthel-20[a]	15 (12-17)	13 (9-16)
Overall Health[a]	60 (50-80)	50 (45-70)
Pain operated leg		
No pain	22 (12%)	9 (14%)
Slight pain	48 (27%)	12 (19%)
Moderate pain	75 (41%)	22 (34%)
Severe pain	36 (20%)	21 (33%)

IQR Interquartile range, *BMI* Body mass index, *ASA* American Society of Anaesthesiologist Physical Status Score, *NMS* New Mobility Score, *CAS* Cumulated Ambulation Score

[a] marked variables differentiated the groups at a 95% significant level

Table 4 Sub-analysis of the older person's high or low dependence on IC

Variable	<32 hours of IC *n*=134 median (IQR)	≥32 hours of IC *n*=110 median (IQR)
Hours of IC	11 (2-20)	66 (46-107)
Female	86 (64%)	75 (68%)
Age	78 (73-83)	79 (75-84)
BMI	24 (21-28)	24 (21-27)
Living alone[a]	84 (63%)	40 (36%)
ASA score ≤2	68 (51%)	64 (58%)
Operation type *n* (%)[a]		
Arthroplasty	51 (38%)	31 (28%)
Sliding hip screw	40 (30%)	19 (17%)
Intramedullary nail	42 (32%)	60 (55%)
Gait (NMS)	2 (1-4)	2 (1-3)
Basic mobility (CAS)[a]	6 (4-6)	5 (3-6)
Barthel-20[a]	15 (12-17)	14 (11-16)
Overall Health	60 (50-75)	60 (50-75)
Pain operated leg		
No pain	19 (14%)	12 (11%)
Slight pain	36 (27%)	24 (22%)
Moderate pain	48 (35%)	48 (44%)
Severe pain	31 (23%)	26 (23%)

IQR Interquartile range, *BMI* Body mass index, *ASA* American Society of Anaesthesiologist Physical Status Score, *NMS* New Mobility Score, *CAS* Cumulated Ambulation Score

[a] marked variables differentiated the groups at a 95% significant level

follow-up, and none of the older persons with incomplete follow-up missed more than three follow-ups. Hence, we believe that the frequency of older persons receiving IC in this study is accurate.

The older persons in this study received a median of 32 hours of IC after discharge after hip fracture. To the best of our knowledge IC after hip fracture has not been quantified in health care system comparable to the Scandinavian before and the studies that have been conducted in Scandinavia have been of other populations' than older persons after hip fracture [15, 33–36]. A study from the Netherlands have found that informal caregiver delivered a 39.5 hours of IC per week the first six months after hip fracture [36]. This difference might be due to the Netherlands' mixed solidarity healthcare system where family and friends have an obligation to deliver IC [7]. Another key difference was that this study asked explicitly for the new need for IC after hip fracture and only asked the older persons to indicate the time they received IC. Given the very limited evidence, we can only recommend more research within this field.

Regarding the number of hours of IC, the sub-analysis of the older persons with missing information demonstrated that the older persons with incomplete follow-up had a lower median number of hours of IC and that their demographic and discharge characteristics more closely resembled those of persons highly dependent on IC. Thus, if all participants had a complete follow-up, the median number of hours of IC would likely have been higher. Hence, we recommend that the median amount of IC estimates be interpreted as minimum estimates, considering the older person's physical level of function, as our estimates will likely best fit the proportion of older persons who were physically better at discharge after hip fracture. This finding was in line with Mathiowertz et al. 1994 [37] who argued that non-responders were often the most functionally limited persons. Mathiowertz et al. 1994 [37] found that the patients who lost levels of physical function were more inclined to have caregivers responding on their behalf.

Surgical procedure with intramedullary nail was associated with receiving IC, being highly dependent on IC and having incomplete follow-up. To our knowledge, these associations have not been identified before. However, because surgical approaches are planned with consideration of fracture type and location, recommendations

of one procedure over another are likely ill-advised. The sub-analysis exploring the proportion of variance explained by type of surgery and living arrangement indicate a statically significant association to high dependence of IC and explained 4% and 5%, of variance between groups respectively. In a general context this may not be a great deal of variance explained, however it may indicate that it is possible to identify those with high dependence at discharge and prioritise resources accordingly. This however is beyond the scope of this study.

Based on the result of this study, informal caregiving is very common, and in our opinion, it is a positive matter that family and friends of patients want to take of their loved ones. Nevertheless, studies have shown that providing informal care wears on the caregivers with associations of increased morbidity, social isolation, and reduced quality of life [38]. This is, of course, not ideal, as caregivers should not become sick or worn out due to providing care for a loved one. Hence, we may need to consider if more support or a larger formal service level is needed, for patients with a high dependence on IC.

Strength and limitations

This study has several strengths. First, due to the study's novelty, a pilot test was completed in advance to identify and overcome potential challenges to obtaining an unbiased measure of IC [28, 39]. The data collection procedure was developed and feasibility tested in an iterative process involving 12 older persons who were followed for 12 weeks after discharge after hip fracture. Another clear strength of this study is the use of diaries and telephone calls to reduce missing information and recall bias.

An important limitation was the assumption that the amount of IC during the week the phone call was completed was representative of the previous week. As IC decreased over time it was probable that the older person received more IC in week three than in week four. Hence this assumption has potentially reduced the amount of IC. Another limitation is the size of the study population. With 244 older persons included, we did not have sufficient power to detect small differences.

Generalizability

Generally, the Scandinavian countries are considered fairly homogenous [40]. Thus, and with respect to local differences, the results of the present study are probably applicable to other Scandinavian countries, but not necessarily to other countries directly. An important consideration for the generalizability of this study is the sample size. We included community dwelling and cognitively unimpaired older person, hence presented results are mainly representative for the healthier part of the hip fracture population.

Conclusion

This study demonstrates that even though family and friends of older persons after hip fractures are not bound to deliver IC, the vast majority choose to do so. This was especially the case the first two to four weeks after discharge, and twelve weeks after discharge, a third of the older persons still received IC. We believe that this study was the first to quantify the older person's need for IC after hip fracture in Scandinavia. Hence, we highly recommend more research within this area and the inclusion of IC in future health economic evaluations involving older persons after hip fracture. Furthermore, we believe the findings in the study emphasize the need to consider the impact of prioritisation on informal caregivers, at least to older people's high dependence on IC. However, this will require additional resources.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12877-024-05040-y.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Acknowledgements

Data management was provided and REDCap was hosted by OPEN, OPEN, Open Patient data.

Authors' contributions

All authors meet the criteria for authorship stated in the Uniform Requirements for Manuscripts. Submitted to Biomedical Journals: Study concept and design: JAI, BV, ED and IHB. Acquisition of Data: JAI, LTP and IHB. Analysis and Interpretation: JAI. Drafting of the manuscript: JAI supported by BV, ED, LTP and IHB. Critical revision and approved of the final version of the manuscript for important intellectual content: JAI, BV, LTP, ED and IHB.

Funding

Open access funding provided by University of Southern Denmark The authors gratefully acknowledge funding provided by the research council at Lillebaelt Hospital, The Association of Danish Physiotherapists, and the Novo Nordic Foundation. The contents of the published materials are solely the responsibility of the Administering Institution of Lillebaelt Hospital and the individual authors identified and do not reflect the views of the research council or the Novo Nordic Foundation. The funders of the study had no role in the study design, data collection, data analysis, data interpretation or writing of the report. The study was completed independently of the administering organization and donors.

Availability of data and materials

Data can be made available on reasonable request to corresponding author.

Declarations

Ethics approval and consent to participate

Assessment of eligibility and informed consent were obtained up to 72 hours post-surgery. In cases where cognitive function was medically unresolved, decisions on inclusion or exclusion were made in dialogue with nurses and physiotherapists at the hospital and with the patient's next of kin. Prior to obtaining written consent, patients received written and oral information and all participants gave informed written consent to participating in the study. All experimental protocols were performed in accordance with the Helsinki

declaration and was approved by the Administering Institution of Lillebaelt Hospital, the Regional Ethics Committee of Southern Denmark (S-20200070) and the Danish Data Protection Agency (20-21854).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding, Denmark. [2]Department of Regional Health Research, University of Southern Denmark, Odense, Denmark. [3]Department of Orthopaedic Surgery and Traumatology, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding, Denmark. [4]Department of Orthopaedic Surgery and Traumatology, Odense University Hospital, Odense, Denmark. [5]Department of Clinical Research, University of Southern Denmark, Odense, Denmark. [6]Department of Health Education, University College South Denmark, Esbjerg, Denmark. [7]Department of Public Health, DaCHE - Danish Centre for Health Economics, University of Southern Denmark, Odense, Denmark.

Received: 20 September 2023 Accepted: 2 May 2024
Published online: 17 May 2024

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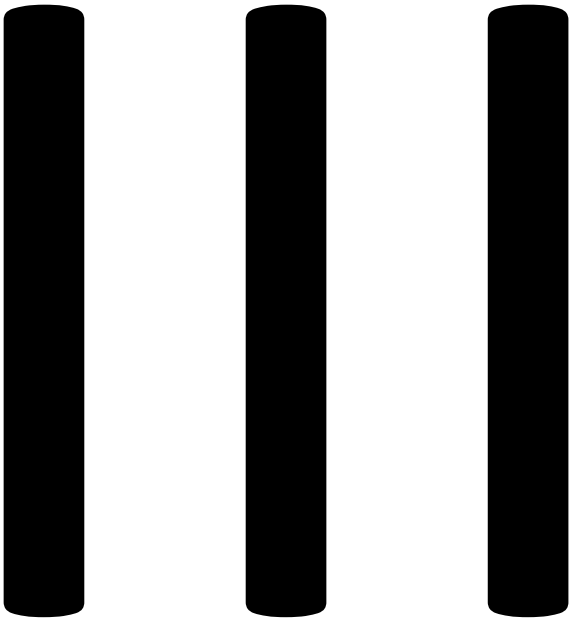

Trials

STUDY PROTOCOL

Open Access

Rehabilitation for life: the effect on physical function of rehabilitation and care in older adults after hip fracture—study protocol for a cluster-randomised stepped-wedge trial

Jonas Ammundsen Ipsen[1,2*], Lars T. Pedersen[1,2,3], Bjarke Viberg[4], Birgitte Nørgaard[5], Charlotte Suetta[6,7] and Inge H. Bruun[1,2]

Abstract

Background: A hip fracture is a serious event for older adults, given that approximately 50% do not regain their habitual level of physical function, and the mortality rate is high, as is the number of readmissions. The gap in healthcare delivery, as separated into two financial and self-governing sectors, might be a contributing cause of inferior rehabilitation and care for these patients. Therefore, we aim to assess the effect of continuous and progressive rehabilitation and care across sectors for older adults after hip fracture.

Methods/design: The project is designed as a stepped-wedge cluster randomised controlled trial. The study population of patients are older adults 65 years of age and above discharged after a hip fracture and healthcare professionals in primary and secondary care (municipalities and hospitals). Healthcare professionals from different sectors (hospital and municipalities) will be engaged in the empowerment-orientated praxis, through a workshop for healthcare professionals with knowledge sharing to the older adults using a digital health application (app). The rehabilitation intervention consists of 12 weeks of progressive resistance exercises initiated 1–2 days after discharge. To improve communication across sectors, a videoconference involving the patient and physiotherapists from both sectors will be conducted. On day, 3 after discharge, an outreach nurse performs a thorough assessment including measurement of vital signs. A hotline to the hospital for medical advice is a part of the intervention. The intervention is delivered as an add-on to the usual rehabilitation and care, and it involves one regional hospital and the municipalities within the catchment area of the hospital. The primary outcome is a Timed Up and Go Test 8 weeks post-surgery.

Discussion: Using a stepped-wedge design, the intervention will be assessed as well as implemented in hospital and municipalities, hopefully for the benefit of older adults after hip fracture. Furthermore, the collaboration between the sectors is expected to improve.

Trial registration: The study is approved by the Regional Scientific Ethics Committees of Southern Denmark (S-20200070) and the Danish Data Protection Agency (20-21854). Registered 9 of June 2020 at ClinicalTrials.gov, NCT04424186.

*Correspondence: Jonas.Ammundsen.Ipsen@rsyd.dk
[2] Department of Regional Health Research, University of Southern Denmark, Odense, Denmark
Full list of author information is available at the end of the article

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Keywords: Hip fracture, Rehabilitation, Care, Between sectors, Empowerment, Physical function, Stepped-wedge cluster randomised controlled trial

Administrative information

Please see Table 1.

Background and rationale

A hip fracture is a serious event for older adults since approximately 50% do not regain their habitual level of physical function thus, acquiring new or additional need for care [1, 2]. Furthermore, when compared to an age-matched group, the 1-year mortality increases threefold and the quality of life is reduced [2, 3]. The 30-day readmission rate after a hip fracture is as high as 16–19% [4, 5].

For older adults, it is well-known that poor mobilisation and reduced activity during and after hospitalisation trigger loss of muscle mass that moreover is associated to increased mortality [3]. To reduce mortality, early detection of illness and sufficient pain management has been identified as important [6, 7]. Insufficient pain management is associated to an increased risk of complications, morbidity, and mortality and also impedes physical activity [8]. Nevertheless, continuous and progressive rehabilitation, as well as the detection of critical illness and complications, is lacking across the sectors in a healthcare system divided into two financial and self-governing sectors.

In Denmark, the average length of stay is 5–7 days for hip fracture patients [7]. Rehabilitation in the primary sector must be initiated within 7 days after discharge. However, usual care does not include systematic assessment including vital signs measurement. Furthermore, various exercise regimes are used depending on the sectors, and the regimes are usually not specified in terms of intensity or progression. Communication and cooperation between sectors are also lacking, although the older adults express a need for increased involvement [9].

To impede functional decline and lower mortality and readmission rates, continuous and progressive rehabilitation and care across sectors are needed. This study introduces an empowerment-orientated praxis focusing on continuous rehabilitation and care, as well as optimised communication and cooperation between sectors.

Objective

This study aims to assess the effect of continuous and progressive rehabilitation and care across sectors for older adults following a hip fracture.

Trial design

The protocol describes a cluster randomised stepped-wedge trial. It has a superiority design, a 1:1 allocation ratio, and the time interval for each step is set to three months, as illustrated in Fig. 1. The study protocol follows the Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) checklist (see Additional

Table 1 Administrative information

Title	Rehabilitation for life: the effect on physical function of rehabilitation and care in older adults after hip fracture—study protocol for a cluster-randomised stepped-wedge trial
Trial registration	ClinicalTrials.gov Identifier: NCT04424186
Protocol version	Protocol version number 1 date 10.11.2020
Funding	The project is funded by the National Association of Municipalities, the Region of Southern Denmark, the Novo Nordisk Foundation, the Association of Danish Physiotherapists, and the Research Council of Lillebaelt Hospital - University Hospital of Southern Denmark, Denmark.
Author details	1. Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark 2. Department of Regional Health Research, University of Southern Denmark 3. Department of Health Education, University College South Denmark 4. Department of Orthopaedic Surgery and Traumatology, Lillebaelt Hospital, University Hospital of Southern Denmark 5. Department of Public Health, University of Southern Denmark, Denmark 6. Department of Geriatric and Palliative Medicine, Bispebjerg and Frederiksberg Hospitals, University of Copenhagen, Denmark 7. Department of Medicine, Herlev and Gentofte Hospitals, University of Copenhagen, Denmark
Name and contact information for the trial sponsor	Kolding Hospital a part of Lillebaelt Hospital - University Hospital of Southern Denmark. Main phone number: +45 76 36 20 00
Role of sponsor	The contents of the published materials are solely the responsibility of the sponsor, Lillebaelt Hospital, and the individual authors identified and do not reflect the views of funders. Neither funders nor sponsor will have a role in the study design, data collection, data analysis, data interpretation, or writing of the reports. The trial will be completed indecently by the administering organisation and funders.

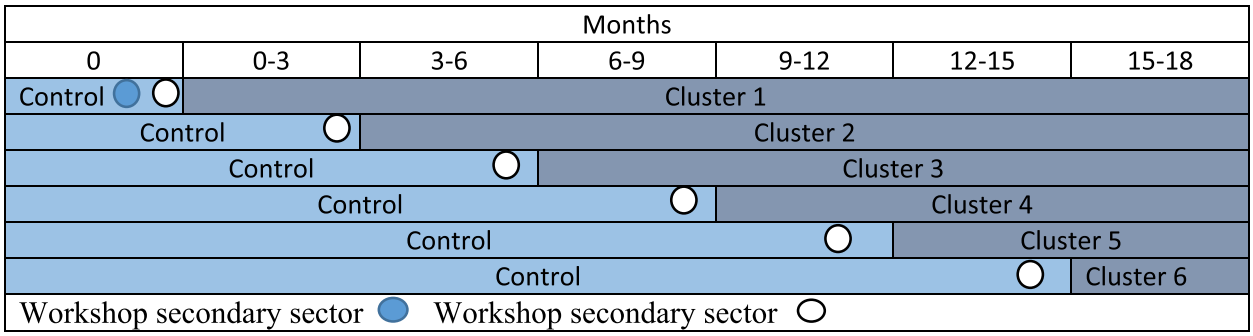

Fig. 1 Overview of the clusters and the crossover from control to intervention

file 1) [10, 11]. A trial registration dataset is reported in Table 1.

Methods

Study setting

The trial will involve a regional hospital in Denmark and all six municipalities in the hospital's catchment area. The municipalities serve a mixed urban and rural population. Two of the municipalities will be divided into two clusters, and four smaller municipalities were combined to two clusters to account for the unequal population size. Services within hospitals and municipalities are free of charge in Denmark, and the responsibility for rehabilitation is shared between sectors [12]. At the time of discharge, older adults with a medically assessed need for rehabilitation are offered a referral for municipal rehabilitation [12]. A list of study sites can be obtained on request from the corresponding author.

Eligibility criteria

The trial will include older adults 65 years of age and older, admitted to the ortho-geriatric ward with a hip fracture and residing in one of the municipalities. Other inclusion criteria are patients able to speak and understand Danish and orientated in time and place. Patients discharged to permanent residence in nursing homes or patients with competing diseases disabling relevant conversation, such as progressed dementia, or receiving palliative care, will be excluded.

Who will take informed consent

Assessment of eligibility and informed consent was obtained up to 72 h post-surgery, by trial data collectors. In cases where cognitive function was medically unresolved, decisions on inclusion were done in discussions with nurses and physiotherapists at the ward and patients' next of kin. Prior to obtaining written consent, patients will receive written and oral information as required by the regional ethics committee. The consent form developed by the national ethics committee in Denmark was used.

Additional consent provisions for collection and use of participant data and biological specimens

Data will be collected in accordance with the Danish Data Protection Agency (20-21854). As required by Danish legislation, written informed consent will be obtained from participants to permit the collection of information from medical records.

Intervention

Usual rehabilitation and care in the primary and secondary sectors

After admission to the emergency department, patients with a hip fracture are transferred to an ortho-geriatric ward. During hospitalisation, the patients are examined by an orthopaedic surgeon and a geriatric specialist. Mobilisation and rehabilitation are initiated within 24 h post-surgery and performed along with vital signs measurement for the early detection of critical illness and complication, throughout the entire hospitalisation period. A physiotherapist is responsible for rehabilitation which comprises walking, exercise, and instruction to a self-training programme. The Cumulated Ambulation Score (CAS) [13] is assessed daily and the need for walking aids is continuously evaluated. The rationale for usual praxis during admission is that early mobilisation and exercise, as well as early detection of critical illness, provide an optimal basis for regaining walking ability and reducing mortality. In the primary sector, usual rehabilitation varies in both content and setting. Content can vary in frequency of rehabilitation sessions and in focus of the session (e.g. gait, walking on stairs, and sit-to-stand at home) [9]. Rehabilitation is typically twice a week, completed in the patients' own home or at

a rehabilitation centre and with a duration of 6–8 weeks [9]. Rehabilitation can be supplemented with restorative care aimed to maintain activities of daily living (ADL). In both rehabilitation and restorative care, the older adults' motivation is obtained by exercising specific ADL tasks. Care in the primary sector follows the plan prescribed by the hospital, and treatment changes have to be prescribed by the general practitioner.

Intervention description

The intervention will be offered to the intervention group in addition to the usual rehabilitation and care. The intervention is comprehensive and includes rehabilitation, empowerment, and care. The duration of the intervention will be 12 weeks (post-surgery). The basis for the intervention is that continuous and progressive rehabilitation, as well as early detection of critical illness and complication during and after hospitalisation, will improve the older adults' physical performance. The older adults are expected to be motivated by an empowerment-orientated praxis [14].

Within the first 2 weeks after discharge, rehabilitation in the primary sector comprises five rehabilitation sessions. This will be followed by supervised rehabilitation twice a week for another 10 weeks. The rehabilitation in both sectors will follow a progressive rehabilitation programme including resistance exercise. Progression of resistance follows the national guideline for hip fractures which suggests resistance is added at 3 sets of 15 unweighted repetitions and progresses to 3 sets of 8 repetitions maximum [7]. For patients with a CAS $\geq$ 4, rehabilitation in a municipal rehabilitation centre will be recommended; alternatively, the resistance exercises will be performed at home with wrist weights. Except for the sit-to-stand exercise, the older adults will be requested to perform the exercises as often as possible, preferably three times a week. The exercise sit-to-stand as many times as possible will be recommended after each of the three main meals a day [15].

In the municipalities, nurses will visit the older adults on the third day after discharge to measure vital signs. Vital signs consist of early detection of illness or complications and pain management, e.g. blood pressure, pulse, respiratory frequency, saturation, consciousness, temperature, and saturation combined with measurement of C-reactive protein and haemoglobin.

An empowerment-orientated practice requires a change in the healthcare professionals' approach towards seeing the older adults as a partner capable of acting and taking responsibility [16]. To implement the empowerment-orientated praxis, two initiatives are used: first, the patients will be given access to knowledge [16]. The older adults will receive a trolley containing the rehabilitation regime, exercise equipment, and a guide, targeted patient and next-of-kin to a digital healthcare app. The app contains videos and informative interviews with doctors and nurses from the ortho-geriatric ward and health professionals from the municipalities [17, 18]. Second, health professionals will participate in a workshop where they will learn about empowerment and how to use it. During the workshop, the health professionals will also be informed on the importance of strength training and measuring vital signs and pain and introduced to the rehabilitation regime. The intervention is described using the Template for Intervention Description and Replication (TIDieR) [19] (Table 2).

Criteria for discontinuing or modifying allocated interventions

Physiotherapists and nurses will be instructed to adapt the exercise to patience individual tolerance. This is to avoid unnecessary harm in terms of exercise-induced pain. Furthermore, patients and health personnel are taught to act and involve hospital doctors or general practitioners if medication needs to be modified.

Strategies to improve adherence to interventions

Adherence to interventions is monitored by the project group by telephone interview with patients every 2 weeks for the first 12 weeks after discharge. All patients will receive an exercise diary, and physiotherapists are required to fill in the progression in resistance weekly. Nurses are required to fill out a nursing diary.

Relevant concomitant care permitted or prohibited during the trial

No restriction on concomitant care was prohibited during the trial.

Provisions for post-trial care

No provisions or compensation will be paid by the trial.

Outcome

Primary outcomes

The primary outcome for the physical function is Timed Up and Go [20] 8 weeks after discharge.

As the study is organised across two sectors, the CAS score measured 30 days after discharge makes a second primary outcome.

TUG is a valid and reliable test that measures the time it takes a person to get up from a chair with an armrest, walk 3 m, return to the chair, and sit [21]. The standard error of measurement (SEM) for patients with hip fractures is 11% [9]. It is hypothesised that patients in the intervention group will achieve a significantly reduced TUG score compared to usual care.

Table 2 Description of intervention and comparator using TIDieR

	Rehabilitation for life	**Usual rehabilitation and care**
Why	Continuous and progressive rehabilitation as well as early detection of critical illness and complication during and after hospitalisation will improve the older adults' physical performance and decrease mortality. Knowledge empowers older adults and facilitates a change in mindset among health professionals.	Activity-based rehabilitation restore and maintain the activities of daily living. Older adults' need to regain functions creates motivation.
What	25 rehabilitation sessions with a physiotherapist over 12 weeks of these 5 within 2 weeks from discharge are planned. A virtual meeting between physiotherapist in the primary and secondary sectors and older adults is conducted in the 2 rehabilitation sessions after discharge. The suitcase contains knowledge and equipment the older adults need to take responsibility and perform daily exercises. Health professionals participate in a workshop. Early detection of critical illness and complications performed day 3 after discharge.	Older adults' general amount of rehabilitation is approximately 1–2 rehabilitation sessions a week for 6–8 weeks. Care has to be prescribed.
Who provide	Physiotherapists, nurses, and social- and health assistants.	Physiotherapists, nurses, and social- and health assistants.
How	Face to face, virtual meetings, and app	Face to face.
Where	Ortho-geriatric ward, the patients' home, and in the rehabilitation centres.	Ortho-geriatric ward, the patients' home, and in the rehabilitation centres.
When and how much	*Weeks 1–2 after discharge:* - Five training sessions with a physiotherapist, duration up to 60 min. -One virtual meeting duration 30 min. -Vial measurements, duration up to 45 min. If necessary, one follow-up meeting with the municipal emergency nurse assessment, duration up to 45 min. Week 3 to week 12 after discharge: 2 weekly rehabilitation session with a duration up to 45 min is planned.	*During admission*: rehabilitation in the ortho-geriatric consist of a daily session with a physiotherapist duration of 30 min. *Week 1 after discharge:* -1 rehabilitation session duration up to 45 min. *Weeks 2–8 after discharge:* -1 or 2 weekly sessions of rehabilitation duration 45 min.
Tailoring	Patients with a CAS score $\geq$ 4 receive rehabilitation at a rehabilitation centre. Progression follows the national guidelines [7].	The patients rehabilitate at home or at a rehabilitation centre, pending on an individual assessment.

The CAS assesses mobility by (a) getting in and out of bed, (b) sit to stand, and (c) gait with a usual walking aid. It is hypothesised that a significantly larger number of patients in the intervention group will have a CAS = 6 at 30 days post-surgery compared to the control [22].

Secondary outcomes

Physical function will also be measured using the New Mobility Score (NMS, 0–9) and the 30-s sit-to-stand test (30s-CST). The NMS assesses the patients' gait inside, outside, and during shopping [23], and the 30s-CST is a valid test that assesses lower body strength [24, 25].

Activities of daily living will be measured using Barthel-20 (0–20), which is a validated tool used to assess the patients' need for help to perform activities of daily living [26].

Other outcomes

Physical function is measured using handgrip strength (HGS) which is a biomarker for ageing [27].

Activities of daily living will be measured using composite physical function (CPF, 0–24). CPF assesses the patients' need for help to basic and instrumental activities of daily living [28].

Pain will be assessed using the 4-point Verbal Rating Scale (VRS, no pain, slight pain, moderate pain, and severe pain) [29].

Readmission will be measured 30 days after discharge.

Mortality will be assessed as an event 30 days after discharge and within the first year.

Quality of life and pain will be measured using the EuroQol Five-Dimension Questionnaire [30]. EQ-5D is a standardised questionnaire, used to assess the patients' health-related quality of life and function [31].

Empowerment will be assessed using the patient activation measure (PAM) [32]. PAM includes thirteen questions addressing prevention and lifestyle changes.

Fatigue will be assessed using the Brief Fatigue Inventory (BFI) [33].

Collaboration between health professionals will be assessed using a questionnaire designed by Joint Action Analytics to measure the relational capacity [34] The questionnaires will be distributed before workshops and 3 months after the workshop.

Costs information will be collected for a cost-utility analysis [35]. Data from registries, municipalities, and hospitals are gathered retrospectively while information on carers' and volunteers' expenses in assisting the older adult in activities of daily living is gathered prospectively.

Costs information and information on the number of supervised training sessions, activity level, pain, place of rehabilitation, and the number of self-training sessions will be collected every 2 weeks for 12 weeks. The patients will be equipped with a diary as a memory aid.

Participant timeline

A timeline and a description of the specific data collected at each time point are presented in Table 3.

Sample size

The annual enrollment of patients with hip fractures from the six municipalities was a mean of 392. With an assumption that 50% of patients fulfilling the inclusion criteria (196 of 392), 48 patients will be available for inclusion every 3 months equal to eight patients per cluster. However, due to frailty, a 20% dropout is expected. Based on these assumptions, we expect approximately six patients per cluster every 3 months for the trial equal to a total of 330 patients.

The power calculation for the TUG is based on a reduction of 25% [36] and an estimated TUG score at discharge of 21.1 s (9.2) [37, 38]. With six patients per cluster every quarter, estimated power is 89%. Interclass coefficient [39] is 0.01, and α is 0.05. Thus, patient recruitment period will be 21 months.

For CAS, the power calculation is based on a 25% increase in the proportion of older adults who, 30 days post-surgery, have a CAS score = 6, power equals 90%.

Recruitment

All older adults admitted to the ortho-geriatric ward will be assessed for inclusion consecutively by data collectors.

Assignment of interventions: allocation

Randomisation will be done in advance using a balanced Internet-based randomisation list [40].

Concealment method

Randomisation will be performed by opening a sequentially numbered opaque envelope every 3 months. A person with no patient contact and unfamiliar with the project will undertake this job.

Implementation

After agreeing to participate, patients are assigned pending on home addresses. Patients' home address will be concealed until informed consent was obtained and pre-fracture baseline data collected. The data collector will inform the patient of the assigned group.

Assignment of interventions: blinding

Who will be blinded

Blinding is not possible as the health professionals need to know the older adults who are citizens in municipality

Table 3 Forms and procedures adapted from the SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials [11]

Time point			Post allocation							
Activity/assessment	**Enrolment** $-t_1$	**Allocation, 0**	**In-hospital,** t_1	**2 weeks,** t_2	**4 weeks,** t_3	**8 weeks,** t_3	**12 weeks,** t_4	**6 months,** t_5	**12 months,** t_6	**Event**
Eligibility screen	X									
Informed consent	X									
Allocation		X								
Demography			X[a]							
TUG			X[a]			X	X	X		
CAS			X		X					
Barthel-20			X			X	X	X	X	
NMS			X			X	X	X	X	
HGS			X[a]			X	X	X	X	
30s-CST			X[a]			X	X	X	X	
EQ 5D			X			X	X	X	X	
CPF			X			X	X	X	X	
VRS			X	X	X	X	X	X	X	
PAM			X[a]			X	X	X	X	
BFI						X	X	X	X	
Care			X	X						
Co-morbidity			X							
Bioimpedance			X				X			
Operation			X							
Re-operation										X
Re-admission										X
Mortality										X

Care covers early detection of illness, complications, and pain management, e.g. blood pressure, pulse, respiratory frequency, saturation, consciences, temperature, and saturation

TUG Timed Up and Go, *CAS* Cumulated Ambulation Score, *Barthel-20* Barthel 20-Item Index, *NMS* New Mobility Score, *30s-CST* 30-s Chair Stand Test, *EQ 5D* EuroQol-5 domain, *CPF* composite physical function, *HGS* handgrip strength, *VRS* Verbal Rating Scale, *BFI* Brief Fatigue Inventory

[a] Marked will be measured at discharge

randomised to intervention. Due to the visibility of intervention, it is not possible to blind the assessor either.

Unblinding

Not applicable.

Data collection and management

Plans for assessment and collection of outcomes

Data collectors collect data in-hospital, and at 8 weeks, 12 weeks, and 6 months through home visits. Inter-rater reliability will be investigated. To promote data quality, assessors are trained and data collections forms and "how to" guides will be developed.

Plans to promote participant retention and complete follow-up

Only health professionals in the primary sector assigned for the workshop will have contact with the older adults assigned for intervention. At the time of the procedure, the project group will ensure that the collection of data at admission and 8 weeks later is not performed by the same project assistant, and the same applies for the following collection of data. In case of dropout, the reason for this will be examined.

Data management

To promote data quality and secure data, data collectors will use iPads and enter the data directly in secured servers. Every 3 months, the project manager perform completeness checks, and the entire project group is instructed to be aware of the data quality.

Confidentiality

The participants will be allocated an individual trial identification number, and the participant's data will be stored on secured servers in accordance with national laws. The data will only be accessible to members of the project group.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use

This trial does not involve collecting biological specimens for storage.

Statistical methods

Statistical methods for primary and secondary outcomes

In the descriptive analyses, intervention, and controls will be described and compared to assess homogeneity. Categorical variables will be compared using the chi-square tests and Student's *t*-test, or log-rank test will be used for continuous variables depending on the distribution (normal or not).

The effect of the intervention for continuous variables will be assessed using a linear mixed model with a random effect for each cluster and a fixed effect for each step of the stepped wedge model.

Categorical and ordinal data will be analysed using either a logistic or an ordinal logistic model. The experiences of the healthcare professional will be examined with a paired Student's *t*-test.

Interim analyses

No interim analysis has been planned because the interventions delivered have been proved feasible and safe for the intended population.

Methods for additional analyses (e.g. subgroup analyses)

As an ancillary analysis, differences in effect pending on clusters will be examined.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

The analyses of outcomes follow the intention-to-treat principle. Missing outcomes will be imputed with multiple imputation [41]. For non-adherence to protocol, non-response analyses will be performed for excluded patients and non-completers. A per-protocol analysis will be conducted as a sensitivity analysis.

Plans to give access to the full protocol, participant-level data, and statistical code

Anonymised data will be made accessible on reasonable request and in compliance with national laws.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee

The trial will be organised with a project group responsible for the day-to-day management, data collection, and deliveries of the trial. The project group plan to meet once a month. A steering committee consisting of stakeholders from hospital and municipalities provide oversight and meets quarterly with the project group. To secure the scientific quality, a research group consisting of a senior researcher will be established. The project group and research group plan meetings by demand but intend to meet at least two times a year. An implementation group consisting of physiotherapists and nurses from hospitals and municipalities will also

be created. The implementation group will be the project group's direct contact to the clinicians and offer a forum to overcome challenges and facilitate communication between sectors and municipalities. The implementation group and project group meet once every 2 months.

Composition of the data monitoring committee, its role, and reporting structure

A data monitoring committee was not deemed relevant as this is an implementation RCT. The interventions are feasible for the patient group and mainly consist of standardised exercise and enabling exercise by reducing the risk of medical complications and pain.

Harms

Given the feasibility of the intervention, no harms are expected.

Frequency and plans for auditing trial conduct

This will be done on a day to day basis and systematically every six month.

Plans for communicating important protocol amendments to relevant parties

Decision on important trial amendments has to be made by the steering committee and will be communicated to all relevant parties. The protocol in the clinical trials registry will be updated.

Dissemination plans

The results will be disseminated through peer-reviewed journals and other media.

Discussion

The project aims to improve physical function in older patients after hip fracture. It is hypothesised that patients in the intervention group will gain a significantly improved physical function compared to patients following usual care.

In the trial, we want to empower patients to self-exercise and to continue exercising after the intervention has ended. We do not expect cognitively impaired patients will be empowered by the stimuli put forward and excluded patients with severe cognitive impairments.

Besides improved physical function, it is important to accentuate that the study operates across sectors and organisational conditions on which the design is based. A clear advantage of the cluster randomised stepped-wedge design is the implementation of the intervention at the end of the trial municipalities and hospitals. By randomising in clusters and introducing incremental roll-out, issues such as impaired organisational commitment should be met [42]. Furthermore, the design has been used in previous trials working in the primary and secondary sectors [42, 43]. At the end of the project, the intervention is implemented offering a manual for how interventions may be implemented in other hospitals and municipalities [44]. A drawback of the design is the risk of unequal exposure to seasonal trends.

The primary time of interest was 8 weeks after discharge, because this is comparable to the average duration of usual rehabilitation in municipalities. Guidelines indicate that 50% of older adults after hip fracture have a need of a 12-week intervention in spite additional effect is unknown [7]. We therefore extended the intervention to 12 weeks to evaluate the additional effect.

The implementation of the intervention might pose some challenges due to the needed organisational changes. Furthermore, procedures to monitor the delivery of the intervention have been set up, in terms of structured telephone interviews every 2 weeks. We expect the content of the trolley in form of exercise diaries, information to apps, and exercise equipment will help empower patients and health professionals.

Data on older patients' activity levels and function enable the evaluation of possible associations between functional improvement and an increase in the level of activity.

Trial status

This is protocol version number 1 date 10 November 2020. Initiation of recruitment commenced on 01 October 2020, and the recruitment completion date will be 30 October 2022.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-022-06321-w.

Additional file 1. Checklist for protocol of a clinical trial.

Acknowledgements

We gratefully acknowledge the municipalities of Kolding, Vejle, Vejen, Billund, Fredericia, and Middelfart and the ortho-geriatric ward at Lillebaelt Hospital for their input and willingness and eagerness to participate in the project.

Authors' contributions

IHB led the coordination and conceptualisation of the trial, supported by BV, BN, and CS. JAI wrote the first draft of the article supported by IHB. IHB, BV, BN, LTP, and CS critically reviewed it and provided comments to improve the manuscript. The authors read and approved the final manuscript. All contributors to the protocol are represented by the authors.

Funding

The project is funded by the National Association of Municipalities, the Region of Southern Denmark, the Novo Nordisk Foundation grant number NNF21OC0068702, the Association of Danish Physiotherapists, and the Research Council of Lillebaelt Hospital - University Hospital of Southern Denmark, Denmark.

Availability of data and materials
Data sharing does not apply to this article as no datasets were generated or analysed during the current study. Exercise regimes, consent forms, further descriptions, etc. can be acquired from the corresponding author.

Declarations

Ethics approval and consent to participate
The study is approved by the Regional Scientific Ethics Committees of Southern Denmark (S-20200070) and the Danish Data Protection Agency (20-21854). As required by the Danish legislation, written informed consent will be obtained from participants to permit the collection of information from medical records. ClinicalTrials.gov Identifier: NCT04424186. Responsibility for the trial conduct is shared between the authors.

Consent for publication
Not applicable.

Competing interests
The contents of the published materials are solely the responsibility of the sponsor, Lillebaelt Hospital, and the individual authors identified and do not reflect the views of the funders. Neither funders nor sponsor will have a role in the study design, data collection, data analysis, data interpretation, or writing of the reports. The trial will be completed indecently by the administering organisation and funders. The authors declare that they have no competing interests.

Author details
[1]Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Odense, Denmark. [2]Department of Regional Health Research, University of Southern Denmark, Odense, Denmark. [3]Department of Health Education, University College South Denmark, Odense, Denmark. [4]Department of Orthopaedic Surgery and Traumatology, Lillebaelt Hospital, University Hospital of Southern Denmark, Odense, Denmark. [5]Department of Public Health, University of Southern Denmark, Odense, Denmark. [6]Department of Geriatric and Palliative Medicine, Bispebjerg and Frederiksberg Hospitals, University of Copenhagen, Copenhagen, Denmark. [7]Department of Medicine, Herlev and Gentofte Hospitals, University of Copenhagen, Copenhagen, Denmark.

Received: 10 November 2020 Accepted: 21 April 2022
Published online: 07 May 2022

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Publisher's Note

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IV

Rehabilitation and care after hip fracture: A cost-utility analysis of stepped-wedge cluster randomized trial

Short title: cost-effectiveness of rehabilitation after Hip fracture

Authors:

Jonas Ammundsen Ipsen[1, 2, 3] MScPT, Jan Abel Olsen[4] PhD, Bjarke Viberg [3,5,6] MD PhD, Lars T. Pedersen[1, 2, 7], MScPH, Inge Hansen Bruun[1, 2] PhD, Eva Draborg[8] PhD.

Affiliations:

1. Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding
2. Department of Regional Health Research, University of Southern Denmark, Odense
3. Department of Orthopaedic Surgery and Traumatology. Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding
4. UiT The Arctic University of Norway, Department of Community Medicine, Tromsø
5. Department of Orthopaedic Surgery and Traumatology. Odense University Hospital, Odense
6. Department of Clinical Research, University of Southern Denmark, Odense
7. Department of Health Education, University College South Denmark, Esbjerg
8. Danish Centre for Health Economics, Department of Public Health, University of Southern Denmark, Odense

Corresponding author: Jonas Ammundsen Ipsen, Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding, Sygehusvej 24, 6000 (45) Kolding, Denmark, Email: Jonas.Ammundsen.Ipsen@rsyd.dk

Submission summary
Abstract: 200 words
Lay abstract: 150 words
Manuscript: 3685 words

Number of tables: 3
Number of figures: 3
Number of references: 36
Number of supplementary: 3

Abstract

Objective: To estimate the effectiveness and costs of RFL compared to usual rehabilitation and care after hip fracture to determine which course offered the most value for money.

Design: Cost-utility analysis

Patient: Community-dwelling patients 65+ after hip fracture

Method: 123 intervention and 122 control patients. Data was collected at five points from discharge to one-year follow-up. Cost analysis included expenses to hospital, general practice, specialist services, medications, rehabilitation, home and informal care, transport, and waiting times. The primary endpoint was the incremental cost per quality-adjusted life year (QALY).

Results: The intervention group experienced a statistically significant mean QALY gain of 0.02 compared to the control group. The intervention was more costly by 4224 € resulting in an incremental cost of 159,990 € per QALY gained. Two municipalities had several patients in respite care yielding an imbalance. A subanalysis excluding these patients demonstrated QALY gain to 0.03 and the cost difference of 2586 € was not statistically significant.

Conclusion: The intervention demonstrated a slight improvement in effectiveness over the control but was costly. For patients not requiring respite care, the intervention effect was slightly higher, and the cost differences statistically insignificant. Hence offering the intervention to these patients is most viable.

Lay abstract

Hip fractures are common, devastating, and costly to rehabilitate. The effectiveness of rehabilitation varies due to demand for comprehensive care from hospitals, municipalities, and family members. In this study, we evaluated two rehabilitation programs to see which one offered the best value for money. We monitored 123 patients in the intervention group and 122 in the control group over one year, assessing their quality of life at five different points. We calculated the one-year difference in quality of life and included costs related to healthcare services, rehabilitation, home care, transportation, and support from relatives. While the intervention did slightly improve quality of life, it came with a high price tag. However, for more specific patient subgroups the intervention was better and less costly. Hence focusing on subgroups might be an economically viable next step. Additionally, the burden on relatives was high, demonstrating the extensive reliance on family for ongoing support.

Introduction

Hip fractures are common, costly, and detrimental to older patients' daily living and quality of life (QOL) (1, 2). Substantial resources are assigned to treatment, rehabilitation, and care to facilitate recovery (1-3). Nevertheless, only 40-60% of patients return to their pre-fracture mobility even one or two years after discharge (4). Rehabilitation and care are key interventions to facilitate recovery and resumption of independence. However, the effectiveness and cost of rehabilitation services and care varies on how much, when, and how it is delivered.

Globally, hip fracture cost estimates vary significantly, and to our knowledge, none include all relevant costs from a societal perspective. For instance, is informal caregiving prevalent after hip fractures and valued at 2-4% of the gross domestic product (GPD) in Sweden and the Netherlands (5-9). Transportation to and from rehabilitation is free for patients who cannot transport themselves in Scandinavia (10-12). Additionally, Rehabilitation services can be delivered individually or team-based. In team-based sessions, one physiotherapist supervises more patients simultaneously which needs to be accounted for in the valuation. Hence the cost estimates associated with rehabilitation after hip fracture are likely imprecise.

Given the expected demographic developments in the population, the total costs of hip fractures will only increase in the future (13). At the same time, the influx of new and expensive treatments also puts pressure on the limited resources. Hence, prioritisation is inevitable. However, information on costs and effects is imperative to prioritise resources efficiently.

In 2020, a cluster-randomized stepped-wedge clinical trial, Rehabilitation for Life (RFL), was initiated. RFL assessed the effect of early resistance exercises and detection of critical illness and complications in an empowerment-orientated praxis. Compared to usual rehabilitation and care, RFL entailed more rehabilitation sessions, supervised team-based resistance exercises, and systematic follow-up of potential medical complications after discharge from municipal nurses (14). However, whether RFL offers better, worse, or similar patient outcomes is unknown, and that also applies to the associated costs, including, among others, informal care and transportation costs. This cost-utility analysis aimed to estimate the effectiveness and costs of RFL compared to usual rehabilitation and care after hip fracture to determine which course offered the most value for money.

Method

Health economic analysis plan

This study was a trial-based, cost-utility analysis. Reporting followed the updated Consolidated Health Economic Evaluation Reporting Standards statement (CHEERS) (15). A Health Economic Statistical Analysis Plan (SAP) was developed and uploaded to PURE University of Southern Denmark on 15-04-2024 before the measurement of costs was completed (16).

Population

Inclusion criteria were community-dwelling, cognitively non-impaired patients aged 65 years or older who sustained hip fractures and consented to participate in the cost-utility analysis. Exclusion criteria were inability to speak or understand Danish, discharge from hospital to permanent residence in nursing homes, communication impairments, such as progressed dementia and aphasia, other disabling diseases making them unable to participate in rehabilitation, or a short life expectancy.

Setting and location

The Danish healthcare system is divided into two self-governing sectors. Regions cover hospitals, general practice, specialists, and prescription drugs, while municipalities cover rehabilitation and care outside hospitals, including home nursing services. Hospitals and municipalities are divided into catchment areas, each with one hospital and several municipalities. The healthcare system is a universal single-payer system, and rehabilitation and care are free of charge (17). One hospital and the six municipalities within the catchment area participated in this study. The catchment area serves a mixed urban and rural population. The responsibility of providing rehabilitation and care depends on the patient's location (in-hospital or at home) (17, 18).

Comparator and intervention

Usual rehabilitation and care

All hip fracture patients receive surgery, mobilisation, and care during their hospital stay. After discharge, a municipal rehabilitation program is initiated. It usually consists of supervised exercise in the patient’s private homes or at a rehabilitation center, encompassing one or two weekly sessions of 30 to 60 minutes each for six to eight weeks (28). Municipal nursing is offered according to the patient's needs.

Intervention

The RFL intervention was delivered in addition to usual rehabilitation and care and entailed continuous rehabilitation and care delivered in an empowerment-orientated praxis. The patients received five supervised resistance exercise sessions by municipal-employed physiotherapists during the first two weeks after discharge. The third of these sessions entailed a virtual meeting between the patient, one hospital physiotherapist, and one municipality physiotherapist. From week three to week twelve, the patients received 20 resistance exercise sessions supervised by a physiotherapist from the municipality. Municipality-employed nurses conducted a home visit on day three after discharge. They assessed the patient's health, including infection testing, and if needed, they could confer with medical doctors at the hospital. The empowerment-orientated praxis was intended to enable patients to gain control over their rehabilitation and care. It consisted of three initiatives: i) medical information and knowledge were provided to the patients using a digital application (MitSygehus); ii) the health professionals participated in a workshop where they were instructed on how to facilitate the empowerment of the patients; iii) the patients received physical reminders through a trolley, a mug, weight cuffs, a printed exercise diary and exercise programs. A study protocol has been published for additional information on RFL and comparator (14).

Perspective

The national retirement age is 67, and this study only included patients 65+, so a limited societal perspective, excluding production gains or losses, was used.

Time horizon

The follow-up period was one year. Incremental costs and utility were assumed to be well-established after six months, as most improvements after hip fracture occur within the first six months after discharge (4).
Due to the duration of the follow-up of one year, discounting was not applied.

Selection of outcomes

Primary outcome

The primary outcome was the incremental cost per quality-adjusted life year (QALY). QALYs combine time lived and Health-Related Quality of Life (HRQoL), including items covering physical function and mental function, into a single index number where "1" corresponds to perfect health and "0" corresponds to being dead. HRQoL was measured using the EuroQol five-dimension five-

level questionnaire (EQ-5D-5L) (19) as a standardised questionnaire used to assess HRQoL. It comprised five dimensions: mobility, self-care, usual activities, pain, and anxiety/depression, each described using five severity levels (19). The patient's HRQoL was assigned utility weights from the Danish EQ-5D-5L reference set (i.e. health states are assigned values on a scale between -0.759 and 1.000) (20). The outcome was reported as the total difference in QALYs, from which the incremental cost per QALY gain was estimated.

Secondary outcomes

Demographic characteristics were age, sex, body mass index (BMI), living arrangement (i.e., living alone or cohabiting), and health status using the American Society of Anesthesiologists classification system (ASA) (31). The ASA score ranged from 1 to 6 and was dichotomised into a low-risk group (ASA 1-2) and a high-risk group (ASA ≥3) (21).

Mobility was measured using the clinician-applied 0-9 New Mobility Score (NMS) to assess the patient's gait function indoor, outdoor, and during shopping. This score was measured at discharge, at eight weeks, twelve weeks, six months, and one year after discharge (22).

Activities of daily living (ADL) were measured using Barthel-20 to assess a patient's need for assistance (23). Barthel-20 measures the patient's self-perceived ability to perform basic ADLs on a scale from 0 to 20 at discharge and eight, twelve weeks, six months, and one year after discharge.

Costs

Hospital costs included all in-hospital and out-patient contacts and services from admission to six-month follow-up, along with the reimbursements the hospital receives from the region for delivering the services per the Diagnosis-related group (DRG), and were collected from the hospital's administrative systems (24).

Municipal costs were the extent of rehabilitation, nursing services, and homecare delivered by the municipalities, from discharge to six-month follow-up collected from the municipal administrative systems. The amount was measured in minutes and converted to hours. Valuation of hours was the gross salary plus 40% to account for administration costs, as recommended by the Danish Health Technology Council (25). Nursing 54 € per hour (gross salary 36.8 € x 40%), homecare 47.0 € per hour (33.6 € x 40%). Rehabilitation was delivered individually or team-based (approximately four patients to one physiotherapist). We could not obtain information on whether the municipalities delivered one-to-one or team-based rehabilitation. Hence, every two weeks during the first three months after discharge, the patients were contacted and asked how many rehabilitation sessions they had participated in and whether these sessions were one-to-one or team-based. The percentage

of the total amount of rehabilitation sessions delivered as one-to-one was calculated for each group (one-to-one session: control 68.0%, intervention 34.0%). The cost of one-to-one rehabilitation was estimated at 46.2 € and team-based rehabilitation at 11.5 €.

Respite stay costs constituted temporary admissions to a municipal rehabilitation unit or nursing home. These were offered if the patients were too frail to be discharged directly to their homes. The number of days in a respite stay was collected from the municipality's administrative systems and valued as the cost per day, including overhead costs. The cost per day of a respite stay was estimated to be 327.7 €. It covered all costs (rehabilitation, care, and nursing), including overhead charges to operate the unit and rehabilitate the patient.

Transportation costs were estimated as one of two modes of transportation, either if rehabilitation was delivered in the patient's home (physiotherapist traveled to the patient's home) or in a municipal rehabilitation center (patients traveled to the rehabilitation center). We could not obtain transportation costs to and from rehabilitation from municipality registers. Thus, every second week during the first twelve weeks after discharge, the patients were contacted and asked how many rehabilitation sessions they had participated in at home or in a rehabilitation center. The municipality estimated the mean transport cost to be 37 € per round trip.

General practice cost the number of contacts with general practitioners and other private health professionals was collected from the National Health Service Register (26). The valuation was based on the service fee.

Prescription drugs costs the use of prescription medication was collected from the National Register of Pharmaceutical Sales (26). The valuation was the market price for the medication.

Informal care (IC) costs patients recorded the number of hours of informal care received from relatives in diaries. These were collected bi-weekly for the first twelve weeks after discharge. The valuation was the standardised hourly earnings (37,1 € per hour) recommended by the Danish Health Technology Council (25). The patients were instructed to record only the need for IC generated by the hip fracture and how long they received IC. Patients who did not fill in the diary were asked to estimate the hours of IC the previous week and to include both weeks; the estimate was multiplied by two.

Waiting time costs Transportation to and from rehabilitation sessions was delivered free of charge to the patients by the municipalities (by taxi). The same taxi picked up several patients, and to allow

for flexibility in the planning, the patients had to be ready to leave up to one hour before the scheduled time of arrival of the taxi. Patients were contacted every second week, the first twelve weeks after discharge, to measure waiting time. They were asked how many rehabilitation sessions they received, where they were delivered (at home or in a rehabilitation center), how they got to the rehabilitation center (by taxi or traveling by themselves), and how much time they spent waiting and spending in transportation to the rehabilitation center. Waiting time was valued based on the standardised hourly earnings of 37,1 € (25).

Data collection

A physiotherapist from the RFL trial contacted the patients five times during the one-year follow-up period: at discharge, at eight weeks after surgery, twelve weeks after surgery, six months after surgery, and one year after discharge. Measurement at discharge was carried out at the hospital, and the remaining four follow-ups were carried out during in-home visits and phone calls one year after discharge.

After a hip fracture, patients are in a crisis, which affects their memory (35, 36). This, combined with the time between follow-ups, made it unlikely patients could recall detailed information. Hence, the cost of transportation, informal care, and waiting time were collected during the same bi-weekly phone interviews. Non-responders were contacted twice on two separate days before a missing data point was accepted (i.e., four telephone calls were performed) to mitigate missing data due to non-response to the phone call.

Currency, price date, and conversion

Costs were collected in Danish Kroner (DKK), converted, and reported in euro (€) using the average 2023 conversion rate of 1 € to 7.46 DKK (27).

Statistical analysis plan

We assessed the baseline characteristics of the population. For continuous variables, differences were assessed using Wilcoxon's rank sum test as variables did not follow a normal distribution. Reporting was in the median and interquartile range (IQR). Categorical variables were assessed using Pearson's Chi2 test, and reporting was in numbers and percentages. The cost was estimated as total costs between groups from surgery to six-month follow-up and presented as aggregated and disaggregated in duration (e.g. hours or days) and monetary value. As we had several measurements on the same patients, an adjusted linear mixed regression model was used to estimate the change in

utility between groups. The fixed effect parameter included time and group allocation (time#group), the random effect parameter included each individual as a cluster, and an interaction between time and group allocation was specified in the model.

$$Yij = \beta 0 + \beta 1 \times Timeij + \beta 2 \times Groupij + \beta 3 \times (Time \times Group)ij + \beta 4 \ldots + ui + \in ij$$

Y_{ij} was the utility score of the EQ-5D-5L for the *i*th individual and the *j*th timepoint. Hence, Yij was the sum or fixed effect of time (β1) multiplied by the fixed effect of group (β2) plus the fixed effect of the interaction between time and group (β3) plus the fixed effect of each covariate ($\beta 4$ ...) plus time at the *j*th timepoint (Time*ij*) + the group membership for the *i*th patient at the *j*th timepoint (Group*ij)*. Multiplied with the interaction between time and group $(Time \times Group)ij$ and a random effect for the *i*th patient (ui) and the random error ($\in ij$). Model fit was tested using the Akaikes Information Criterion (AIC). We adjusted the model for the covariates that differentiate from zero at a significance level of .05 in a Wald chi-squared test (age, ASA, Cohabiting, surgery, mobility, and length of stay in hospital). There were no interactions between groups, and the model assumption was fulfilled. The health state of each individual at each time point was predicted. Using the predicted health states and time spent in these the individual patients' QALY gain was calculated. The mean difference in QALY gain and cost was used to estimate the Incremental Cost-Effectiveness Ratio (ICER). Uncertainty of the ICER was estimated using bootstrapping where each observation was reproduced by 1000 bootstraps (28). Results were visualised in a cost-effectiveness plane and compared to the commonly used willingness-to-pay threshold of (20 000 €) per QALY (29, 30). As a sensitivity analysis, the analysis was run using a healthcare sector perspective. Three patients died during follow-up. They were imputed with a utility score of zero. An analysis was run with them excluded. Of the 25 patients in respite care, 19 were from two early-intervention municipalities, causing group imbalances. A subanalysis excluding these patients was therefore conducted. The impact of each dimension of the EQ-5D-5L was explored by estimating a change in mean level scores between groups over time. The significance level for all statistical analyses was set to 95%. Statistical analyses were performed with StataCorp. 2019 (Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC).

Results

Patients were recruited from September 2020 to February 2023. 1114 were screened, and 476 were eligible. Of those recruited, 67 withdrew their consent, and eight were lost to follow-up. Thus, 122

were randomised to the control group and 123 to the intervention group. Their median age was 79 (IQR 74-84), and 164 were female. See Figure 1. At baseline, the intervention and control groups were comparable. See Table I.

ICER Estimate

There was a small, but statistically significant, difference in QALY gain of 0.02 (95% CI 0.00; 0.05) in favor of the intervention. The cost difference was 4224 € (95% CI 722 €; 7727 €) favoring the control. The incremental cost per QALY gained was 159,990 €. Of the bootstrapped observations, 96 % were in the northeast corner of the ICER plane, figure 1, indicating that patients receiving the intervention had better outcomes at a higher cost, figure 2. The probability of the intervention being cost-effective was seven percent, figure III. There was no significant variation in secondary outcomes or between the intervention and control on the mean level scores of the dimensions of the EQ-5D.

The Major cost drivers differentiating the control and intervention groups were respite stay (difference 4751 €), rehabilitation (difference 505 €), general practitioner (difference 336 €), waiting time (difference 992 €), and informal care (-482 €), table III.

Utilizing a healthcare perspective (i.e., informal caregiving and waiting time excluded) reduced the cost difference but did not change the ICER. Excluding the patient's discharge to a respite stay increased the QALY gain to 0.03 (95% CI 0.01; 0.06) and decreased the incremental costs to 2586 € (95% CI -674 €, 5847 €) and the incremental cost per QALY was 67531 € and statistically insignificant, Supplementary 2 and 3.

Ninety-one percent of the population received informal care from relatives, which accounted for seven percent of the total median cost and exceeded the cost associated with formal care

Discussion

Summary of findings

The 'Rehabilitation for Life' (RFL) study demonstrated a minor, yet statistically significant, improvement in Quality Adjusted Life Years (QALY) albeit with significantly higher costs. Removing indirect costs reduced the overall expense, but RFL remained costlier. Excluding patients in respite care slightly increased QALY gains, drastically lowered incremental costs to a statistically insignificant level, and for seven percent the intervention was better and less costly. Hence the

intervention should not be offered to the entire sub-population indiscriminately, but for some subgroups for instance patients discharged to their own homes, the intervention is potentially viable.

A notable finding was the substantial role of informal care provided by relatives, reflecting a broader trend where responsibilities have increasingly shifted from hospitals to municipalities, leading to faster patient discharges compared to a decade ago. This shift has seemingly extended to informal caregivers as well, who now bear more responsibilities (9, 31). This hypothesis is supported by findings by Statistics Denmark who report that elders with partners receive formal care later and when they receive it they receive more than patients without partners (32).

Interpretation

Previous cost-utility analyses of rehabilitation interventions following hip fracture include the study by Milte et al. (33), which compared exercise and nutritional intervention to usual care. Their findings showed a statistically insignificant QALY gain of 0.02 and a mean cost difference of 567 AUD (33). In contrast, the QALY gain identified in our study was similar but reached statistical significance. This discrepancy could stem from differences in how QALY gain was calculated: In our study, QOL was assessed five times from discharge over the course of a year, and we utilized a linear mixed model (LMM) (31). The LLM approach allowed us to include both fixed and random effects, capturing variations within patients over time and thus reducing uncertainty around our estimated QALY gain (32). Another relevant study by Taraldsen et al. (34) examined a late-phase exercise intervention compared to usual care and found no difference in QALY or costs. When compared with the analyses by Milte et al. (33) and Taraldsen et al. (34), our 'Rehabilitation For Life' intervention appears costlier. Our measurement of costs was more comprehensive, encompassing both direct and indirect costs and RFL intervention included video conferences and hotlines linking physiotherapists and nurses across hospitals and municipalities. It also extended services to patients discharged to respite care, who require more intensive observation and rehabilitation due to their frailty. Hence this cost-difference was somewhat expected. Extending the intervention for patients in respite stay did markedly increase the intervention cost, as these patients were not evenly distributed between intervention and control. This was due to organizational differences between municipalities where municipalities in clusters one, two, and three had very different policies in access to and duration of stay in respite stay.

Strength and limitations

Our study utilized the five-level EQ-5D-5L, which is more responsive to changes than the three-level version (34-36), and we repeatedly measured QOL during the one-year follow-up. We conducted an extensive measurement of costs, collecting all municipal costs directly from municipal administrative systems, an approach confirmed by data managers to include some homecare services not recorded in national registries. Transportation and informal care costs are undeniably relevant as they affect nearly all patients in this study. Our thorough and broad measurement of costs is a clear strength of this study. As the trial was conducted over three years and we had several measurements on each patient, the mixed regression analysis reduced the uncertainty of patients' utility gain.

A significant limitation is that transportation, waiting time, and informal care costs were measured for only three months, while other costs were measured for six months, potentially leading to an underestimation of incremental costs. Moreover, we assumed costs to be incremental six months post-hip fracture based on findings by Dyer et al. 2016 (4), which suggested that major functional improvements occur within the first six months post-surgery. Both the control and intervention groups showed diminishing utility scores from the six-month to the one-year follow-up, which might indicate rising home care costs, thus possibly underestimating incremental costs. Despite this, the larger decline in quality of life in the intervention group suggests that extending the follow-up to one year would unlikely alter the study's conclusions. The impact of excluding patients who died before the 26-week follow-up was likely distributed equally between intervention and control as the mortality rates were equal between groups. However, it reduced the generalisability of findings to a sub-group of patients with lower mortality risk.

Conclusion

This study reveals that while the 'Rehabilitation for Life' (RFL) intervention marginally enhances QALY, it also incurs significantly higher costs than usual rehabilitation and care. The RFL intervention showed slightly improved outcomes for patients discharged to their homes, potentially without additional costs. The findings are limited to a healthier subgroup, and this should be reflected in the interpretation. Moreover, the study indicates that a significant majority (91%) of patients received familial support, with the economic contribution of this informal care exceeding

that provided by municipal services. This shift suggests a crucial point for consideration by both policymakers and researchers: the ongoing reallocation of caregiving responsibilities from hospitals to families, prompted by changes in the roles between hospitals and municipalities.

Acknowledgements

Conflict of interest declaration

The authors have no conflicts of interest to declare

Funding/ financial support

The authors gratefully acknowledge funding provided by the research council at Lillebaelt Hospital, the Association of Danish Physiotherapists, and the Novo Nordic Foundation (grant number NNF21OC0068702). The contents of the published materials are solely the responsibility of the Administering Institution of Lillebaelt Hospital and the individual authors identified and do not reflect the views of the research council or the Novo Nordic Foundation. The study's funders had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The systematic review was completed independently of the administering organization and donors.

Contributors

Data management was provided and REDCap was hosted by OPEN, OPEN, Open Patient Data Explorative Network, Odense University Hospital, Region of Southern Denmark

All authors met the criteria for authorship stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals:

Study concept and design: Jonas Ammundsen Ipsen and Eve Draborg

Acquisition of Data: Jonas Ammundsen Ipsen, Eva Draborg Lars T. Pedersen, Bjarke Viberg, Inge Hansen Bruun

Analysis and Interpretation: Jonas Ammundsen Ipsen, Eva Draborg, Jan Abel Olsen

Drafting of the manuscript: Jonas Ammundsen Ipsen

Critical revision of the manuscript for important intellectual content: Jonas Ammundsen Ipsen, Jan Abel Olsen, Eva Draborg Lars T. Pedersen, Bjarke Viberg, Inge Hansen Bruun

Ethical Clearance

Assessment of eligibility and informed consent was obtained during the first 72 hours post-surgery. In cases where cognitive function was medically unresolved, decisions on inclusion or exclusion were made in dialogue with nurses and physiotherapists at the hospital and with the patient's next of kin. Before obtaining written consent, patients received written and oral information as required by The Regional Ethics Committee of Southern Denmark S-20200070. Data was collected by the Danish Data Protection Agency (20-21854).

Tables and figures

Figure 1. Flow chart of the inclusion process

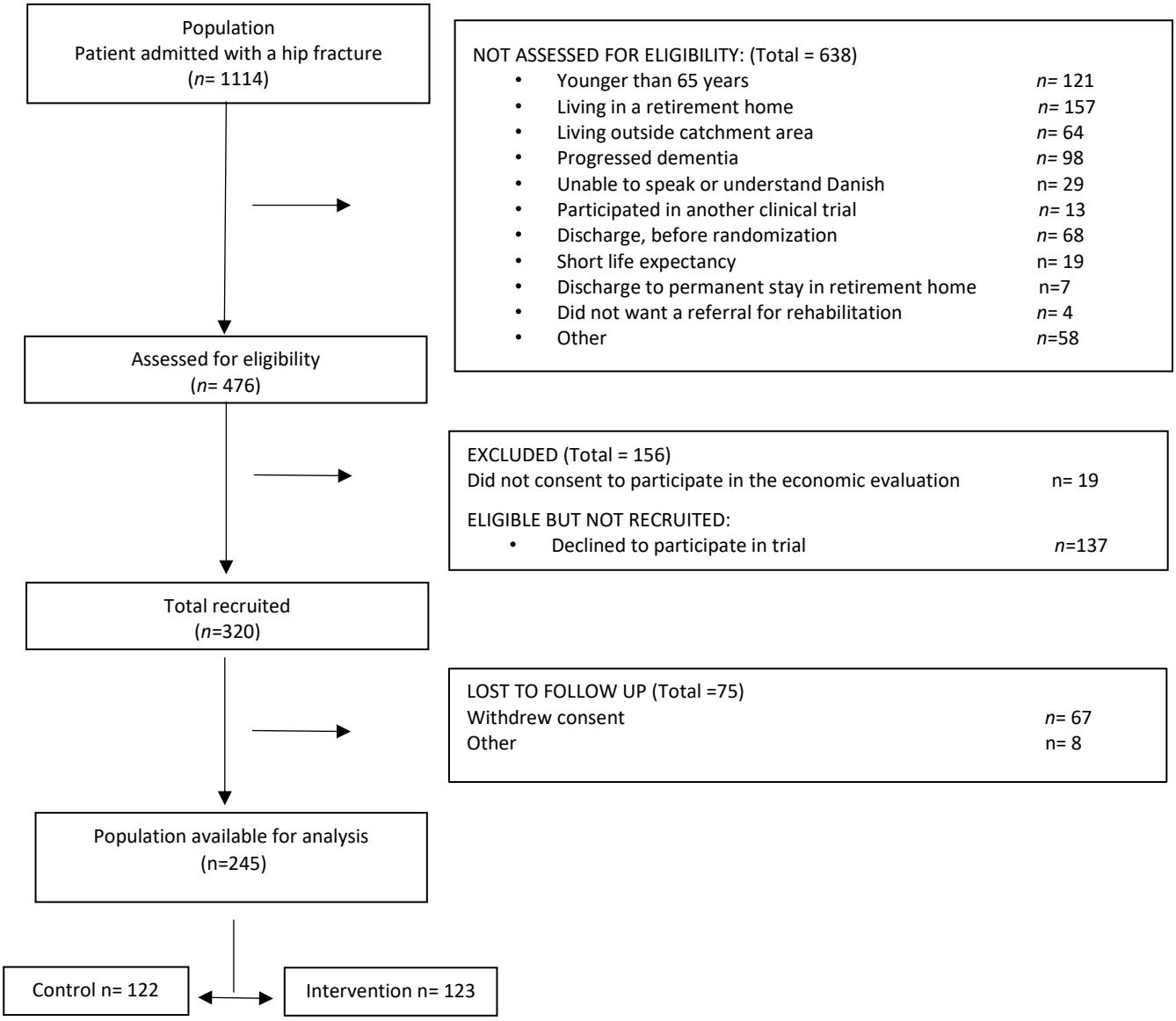


Table I. Patient characteristics			
	Intervention: Rehabilitation For Life	Control: Usual rehabilitation and care	Population
n (%)	123 (50.2)	122 (49.8)	245 (100.0)
sex, n (%)			
Female	81 (65.9)	83 (68.0)	164 (66.9)
Male	42 (34.1)	39 (32.0)	81 (33.1)
Age, n (%)			
65-74 years	29 (23.6)	41 (33.6)	70 (28.6)
75-84 years	68 (55.3)	62 (50.8)	130 (53.1)
85+ years	26 (21.1)	19 (15.6)	45 (18.4)
ASA, n (%)			
Low	71 (57.7)	64 (52.5)	135 (55.1)
High	52 (42.3)	58 (47.5)	110 (44.9)
BMI, n (%)			
18.5-24.9	64 (52.0)	55 (45.1)	119 (48.6)
< 18.4	4 (3.3)	7 (5.7)	11 (4.5)
25-29.9	39 (31.7)	42 (34.4)	81 (33.1)
30+	16 (13.0)	18 (14.8)	34 (13.9)
Cohabiting, n (%)			
Living with a partner	65 (52.8)	58 (47.5)	123 (50.2)
Living alone	58 (47.2)	64 (52.5)	122 (49.8)
surgery, n (%)			
arthroplasty	41 (33.3)	42 (34.4)	83 (33.9)
sliding hip screw	28 (22.8)	32 (26.2)	60 (24.5)
intramedullary nail	54 (43.9)	48 (39.3)	102 (41.6)
Mobility			
Independent	96 (78.0)	86 (70.5)	182 (74.3)
Dependent on others	27(22.0)	36(29.5)	63 (25.7)
American Society of Anesthesiologists classification system – ASA Mobility – New Mobility Score – NMS			

Figure 2. ICER plane visualising the 1000 bootstrapped reproduced observations to the societal perspective.

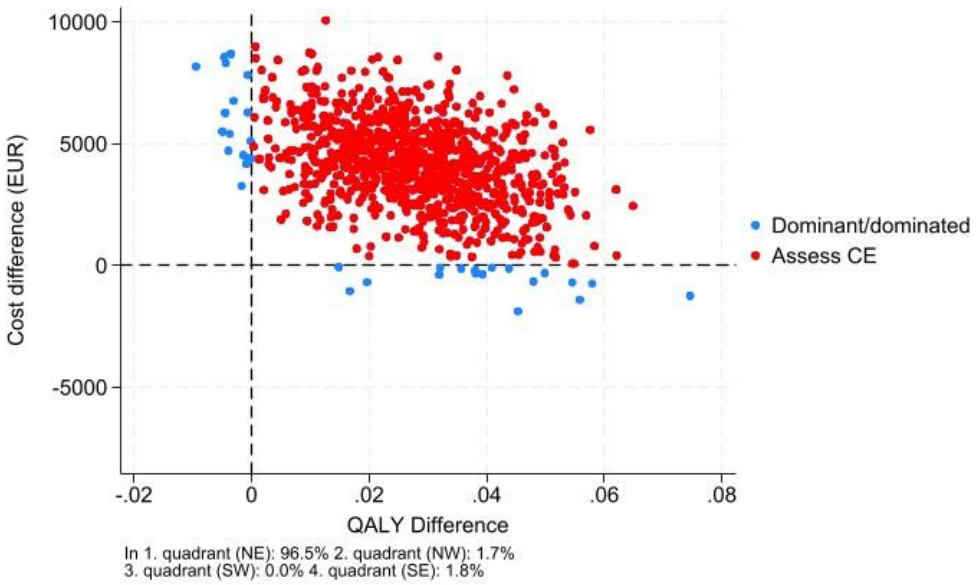


Figure 3. CEAC curve. Visualising the probability of the intervention being cost-effective to the societal perspective.

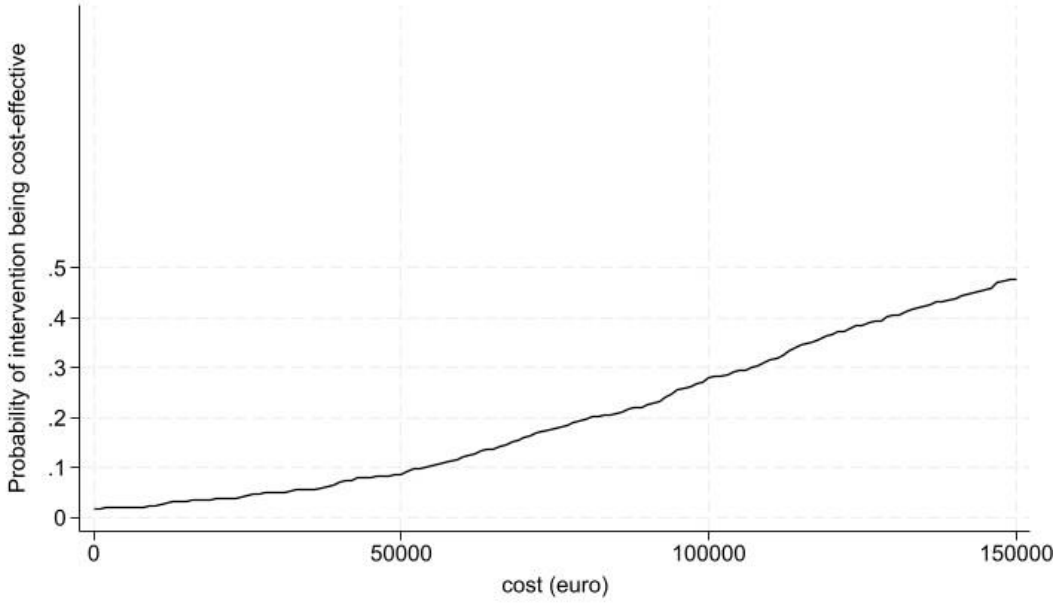


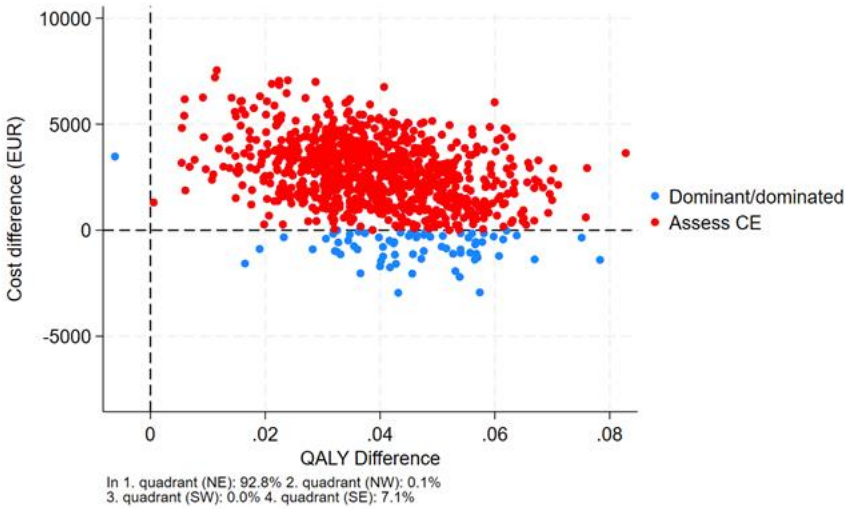
Table II. Clinical outcomes					
	Intervention: 'Rehabilitation for Life'		Control: Usual rehabilitation and care		P
	Median	IQR	Median	IQR	
Dischrage					
EQ-5D value	0.51	0.26 0.68	0.54	0.24 0.67	**0.02**
EQ VAS score	55	50 75	60	50 75	0.45
Mobility	2	1 3	2	1 4	**0.04**
ADL	14	10 17	15	12 17	0.06
Eight weeks					
EQ-5D value	0.65	0.48 0.75	0.64	0.40 0.76	0.48
EQ VAS score	70	50 80	75	50 80	0.86
Mobility	6	4-7	6	4 7	0.17
ADL	19	18 20	19	17 20	0.29
Twelve weeks					
EQ-5D value	0.74	0.63 0.80	0.71	0.56 0.80	0.38
EQ VAS score	75	50 84	75	50 85	0.73
Mobility	6	5 9	6	4 8	**0.03**
ADL	19	18 20	19	17 20	0.35
Six months					
EQ-5D value	0.76	0.69 0.83	0.75	0.58 0.81	**0.03**
EQ VAS score	75	50 85	75	50 84	0.20
Mobility	7	6 9	7	5 9	0.09
ADL	20	19 20	19	18 20	**0.02**
One year					
EQ-5D value	0.72	0.55 0.81	0.73	0.63 0.81	0.76
EQ VAS score	75	60 84	75	50 90	0.23
Mobility	7	6 9	7	6 9	0.18
ADL	20	18 20	19	18 20	0.27
QALY					
QALY crude				0.00 (-0.01; 0.00)	
QALY adjusted				0.02 (0.00; 0.05)	
QALY adjusted patients dying excluded				0.01 (-0.00; 0.04)	
QALY adjusted patients in respite stay excluded				0.03 (0.01; 0.06	
EQ-5D value; the EuroQol five-item five-level questionnaire (EQ-5D-5L), with values based on the Danish value set EQ VAS; the EuroQol Visual Analogue Scale VAS (0-100) Quality adjusted life year – QALY Adjustments: age, ASA, Cohabiting, surgery, mobility and length of stay in hospital					

Table III. Cost			
	Intervention: Rehabilitation For Life	Control: Usual rehabilitation and care	Differences in costs
Median (IQR)	123 (50)	122 (50)	245 (100)
Inhospital cost	9253 € (8177 €; 13535€)	8983 € (8497 €; 10541 €)	270 €
Outpatient cost	442.5 (154 €; 1724 €)	214.8 € (84 €; 829 €)	227 €
Rehabilitation cost	1193 € (900 €; 1697 €)	688 € (323 €; 1164 €)	505 €
Homecare cost	1163 € (188 €; 5123 €)	1165 € (60 €; 5755 €)	-2 €
Community nursing cost	364.8 € (155.7 €; 978.3 €)	594 € (119 €; 1382 €)	-229 €
Respite stay cost	13271 € (8520 €; 20727 €)	8520 € (4423 €; 14746 €)	4751 €
Transport cost	384 € (192 €; 552 €)	48 € (24 €,144 €	133 €
General practitioner cost	476 € (186 €; 760 €)	343 € (148 €; 693 €)	336 €
Other health practitioners	145€ (29; 340)	150 € (0; 288)	-5 €
Prescription drugs cost	55 € (25 €; 110 €)	54 € (29 €; 98 €)	0 €
Informal care cost	1075 € (519 €; 2476 €)	1558 € (630 €; 2893 €)	-482 €
Waiting time cost	1137 € (612 €; 2285 €)	145 € (49 €; 728 €)	992 €
Total cost limited societal perspective	21938 € (15477 €; 33957 €)	16357 € (12345 €; 29259 €)	5581 €
Total cost healthcare sector perspective	17994 € (12037 €; 29164 €)	13699 € (10962 €; 25461 €)	4294 €

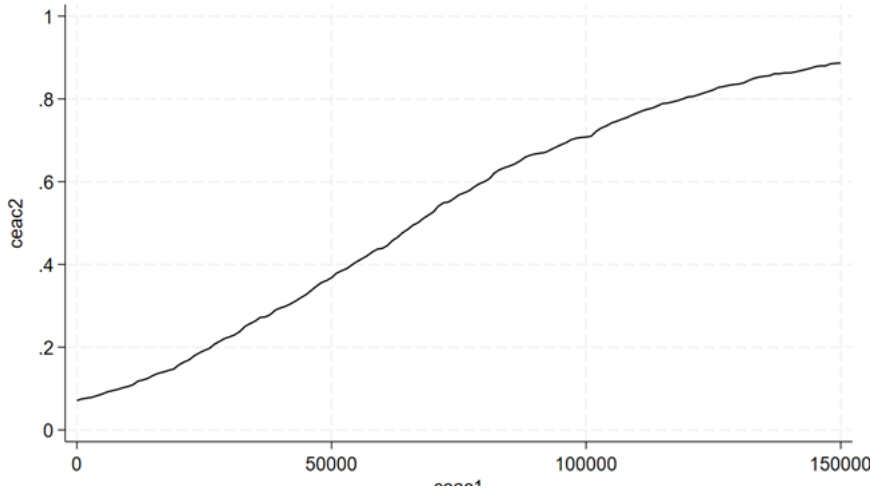
Supplementary

Supplementary I. rehabilitation and care services received and on which valuation based			
	Rehabilitation For Life	Usual rehabilitation andd care	Difference
Median (IQR)	123 (50.2)	122 (49.8)	245 (100.0)
Inhospital (days)	6.8 (5.6; 11.1)	5.7 (4.9; 7.9)	1
Outpatient (hours)	9.9 (6.6; 14.4)	7.5 (4.6; 13.0)	2
Rehabilitation (hours)	25.8 (19.5; 36.8)	14.9 (7.0; 25.2)	11
Homecare (hours)	24.8 (4.0; 109.0)	24.8 (1.3; 122.5)	0
Community nursing (hours)	6.4 (2.7; 17.2)	10.4 (2.1; 24.3)	-4
Respite stay (days)	40.5 (26.0; 63.3)	26.0 (13.5; 45.0)	14
Transport (trips)	32.0 (16.0; 46.0)	4.0 (2.0; 12.0)	28
General practitioner (contacts)	20.0 (12.2; 33.5)	17.0 (10.0; 32.5)	3
Other practitioners (contacts)	6.0 (4.0; 10.0)	7.0 (4.0; 14.5)	-1
Prescription (packages)	6.0 (3.0; 11.0)	7.0 (4.0; 11.0)	-1
Informalcare (hours)	29.0 (14.0; 66.7)	42.0 (17.0; 78.0)	-13
Waitingtime (hours)	30.7 (16.5; 61.6)	3.9 (1.3; 19.6)	26

Supplementary 2. ICER for Patients discharge to own home



Supplementary 3 CEAC for patients discharged to their own home



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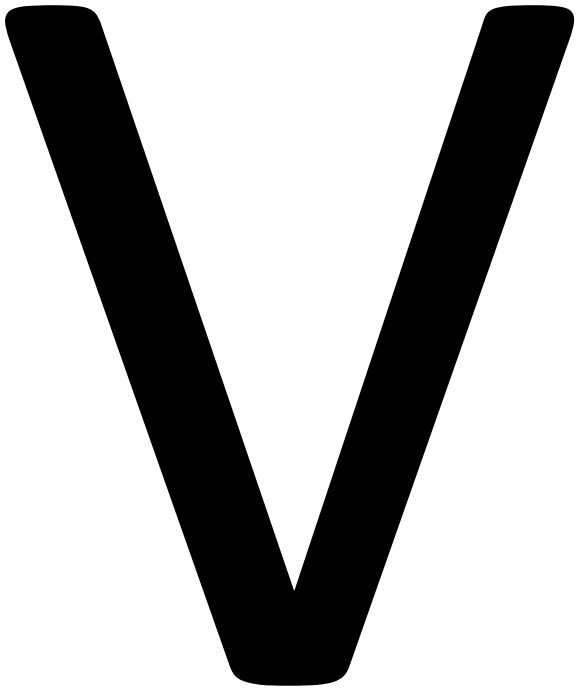

Appendix Study I

The format and content has not been edited by Journal of Rehabilitation Medicine.

Appendix S1: Search string

Search string: Ovid MEDLINE(R) ALL <1946 to May 14, 2021>
Hip fracture. mp. OR exp Hip Fractures/ OR (fracture.mp. AND femur neck.mp. OR exp Femur Neck/) OR Femoral Neck Fractures.mp. OR exp Femoral Neck Fractures/ OR (Intertrochanteric.mp. AND fracture.mp) OR (Subtrochanteric.mp. AND fracture.mp) OR (pertrochanteric.mp. AND fracture.mp) OR ((exp Osteoporosis/ or Osteoporosis.mp. OR exp Osteoporotic Fractures/ OR Osteoporotic.mp.) AND fracture.mp) AND exp Rehabilitation/ or rehabilitation.mp. OR exp Exercise/ OR Exercise.mp. OR Recovery of Function.mp. OR exp "Recovery of Function"/ OR Multifactorial intervention.mp. OR activities of daily living.mp. OR exp "Activities of Daily Living"/ OR convalescence.mp. OR exp Convalescence/ AND quality adjusted life years.mp. OR exp Quality-Adjusted Life Years/ OR QALY.mp. OR exp Cost-Benefit Analysis/ or cost-utility.mp. OR cost.mp. or exp "Costs and Cost Analysis"/ OR cost-effectiveness.mp.

Search string ALL Embase Classic+Embase <1947 to 2021 May 14>
hip fracture.mp. OR exp hip fracture/ OR femoral neck fracture.mp. OR (exp femoral neck fracture/ OR fracture.mp. AND exp fracture/ OR femur neck.mp. OR exp femoral neck/) OR (interthrochanteric.mp. OR exp femur intertrochanteric fracture/ AND exp fracture/ OR femur neck.mp) OR (exp femur subtrochanteric fracture/ OR subtrochanteric.mp. AND exp fracture/ OR femur neck.mp) OR (exp femur pertrochanteric fracture/ OR pertrochanteric.mp. AND exp fracture/ OR femur neck.mp) OR (exp osteoporosis/ or osteoporosis.mp. OR osteoporotic.mp. OR exp fragility fracture/ AND exp fracture/ OR femur neck.mp) AND rehabilitation.mp. OR exp rehabilitation/ OR exercise.mp. OR exp exercise/ OR Recovery of Function.mp. OR exp convalescence/ OR functional recovery.mp. OR Multifactorial intervention.mp. OR activities of daily living.mp. OR exp daily life activity/ AND quality adjusted life years.mp. OR exp quality adjusted life year/ OR QALY.mp. OR cost-utility.mp. OR exp "cost utility analysis"/ OR cost-effectiveness.mp. OR exp "cost effectiveness analysis"/

Scopus
TITLE-ABS-KEY ("intertrochanteric fracture*") OR TITLE-ABS-KEY ("Hip fractur*") OR TITLE-ABS-KEY ("pertrochanteric fracture*") OR TITLE-ABS-KEY ("femoral neck fractur*") OR TITLE-ABS-KEY ("Osteoporotic fracture*" AND hip) OR TITLE-ABS-KEY ("osteoporosis fractur*" AND hip) AND TITLE-ABS-KEY (rehabilitation) OR TITLE-ABS-KEY (exercise) OR TITLE-ABS-KEY (recovery) OR TITLE-ABS-KEY (convalescence) OR TITLE-ABS-KEY ("Multifactorial intervention") OR TITLE-ABS-KEY ("Activities of daily living") OR TITLE-ABS-KEY (adl) AND TITLE-ABS-KEY (cost-benefit) OR TITLE-ABS-KEY (cost-utility) OR TITLE-ABS-KEY (cost-effectiveness) OR TITLE-ABS-KEY (qaly) OR TITLE-ABS-KEY ("quality adjusted life years")

HTA – Center for review and dissemination
(("Hip Fractures"[mh]) OR (Hip fracture) OR (femoral neck fractur*) OR (osteoporotic fractur* AND hip) OR (osteoporos* fractur* AND hip)) AND ((ADL) OR ("Activities of Daily Living"[mh]) OR (Multifactorial intervention) OR (Convalescence) OR (Recovery) OR ("Recovery of Function"[mh]) OR (Exercise) OR ("Exercise"[mh]) OR (Rehabilitation) OR ("Rehabilitation"[mh]))

International HTA database
(("Hip Fractures"[mh]) OR (Hip fracture) OR (femoral neck fractur*) OR (osteoporotic fractur* AND hip) OR (osteoporos* fractur* AND hip)) AND ((ADL) OR ("Activities of Daily Living"[mh]) OR (Multifactorial intervention) OR (Convalescence) OR (Recovery) OR ("Recovery of Function"[mh]) OR (Exercise) OR ("Exercise"[mh]) OR (Rehabilitation) OR ("Rehabilitation"[mh]))

Econlit via Proquest
Hip fracture OR "osteoporo* fracture*"

Academic search premier: Ebsco
DE "HIP joint fractures" OR “Hip Fractures” OR "femoral neck fracture" OR "pertrochanteric OR "subtrochanteric fracture" OR "intertrochanteric fracture" OR ("osteoporotic fracture" AND Hip) OR ("osteoporosis fracture"AND HIP) AND DE "REHABILITATION" OR Rehabilitation OR DE "EXERCISE" OR exercise OR recovery OR convalescence OR DE "CONVALESCENCE" Exploted OR "Multifactorial intervention" OR “activities of daily living” OR DE "ACTIVITIES of daily living" exploted AND cost utility OR DE "QUALITY-adjusted life years" OR "quality adjusted life year" OR "cost-effectiveness" OR DE "COST effectiveness"

Cochrane library: CDSR and Central
Hip fractures [Mesh] OR Hip fracture OR Femoral Neck Fractures [Mesh] OR Femoral neck fractures OR femur neck fracture* OR intertrochanteric fracture* OR pertrochanteric fracture* OR subtrochanteric fracture* OR Osteoporotic fractures [Mesh] OR Osteoporotic fracture* OR "osteoporosis fracture" AND Rehabilitation [Mesh] OR Rehabilitation OR Exercise [Mesh] OR Exercise OR Exercise OR Recovery of Function [Mesh] OR "recovery of function" OR "functional recovery" OR Convalescence OR "Multifactorial intervention" OR "activities of daily living" OR ADL AND quality adjusted life years [Mesh] OR "quality adjusted life year*" OR QALY OR Cost-utility OR Cost-benefit analysis [Mesh] OR Cost-effectiveness

Cinahl via Ebsco
(MH "Hip Fractures+") OR ""hip fracture"" OR "femoral neck fracture" OR "femur neck fracture" OR "intertrochanteric fracture" OR "pertrochanteric fracture" OR "subtrochanteric fracture" OR (MH "Osteoporotic Fractures") OR "osteoporotic fractures" AND (MH "Rehabilitation+") OR "Rehabilitation" OR (MH "Exercise+") OR "exercise" OR (MH "Recovery+") OR "functional recovery" OR "convalescence" OR "Multifactorial intervention" OR (MH "Activities of Daily Living+") OR "activities of daily living" AND (MH "Quality-Adjusted Life Years") OR "quality adjusted life year" OR QALY OR (MH "Costs and Cost Analysis") OR "cost effectiveness"

Appendix S2 –Dataextraction

Data extraction Milte, R.	
Study	Cost-effectiveness of individualized nutrition and exercise therapy for rehabilitation following hip fracture
General study characteristics	
First author and year of publication	Milte, R. 2016
Trial completion year	2010
Source of funding	National Health and Medical Research Council (426758). Australian Postgraduate Award and Flinders University Research Scholarship.
Competing interests	Not stated
Publication type	Journal paper
Setting	Three acute care settings and one rehabilitation setting in Australia
person characteristics	Home-dwelling persons' aged 70 years or above, absence of severe cognitive impairments and body mass index between 18 and 35 kg/m^2. No pathological fracture and not admitted from a residential aged care facility and able to ambulate, communicate with staff in English and medically stable within 14 days post-surgery.
Intervention type	A coordinated and individualized care plan for each participant, focusing on strength and balance exercises and nutritional therapy. The exercises were based on the Otago exercise programme, combining strength, balance, and walking training undertaken 3 times per week. Participants were visited by the trial physical therapist every 14 days to progress exercises. Dietary strategies included dietary counselling focusing on timing, size, and frequency of meals, recommendations of nutrient-rich foods and recipes, referral to community meal programmes, and provision of commercial oral nutritional supplements or commercial protein powders as deemed appropriate. Participants were visited by the trial dietitian every 14 days (alternately to physical therapist visits) to review dietary intake and modify strategies. For 10 weeks
usual physical rehabilitation and care	Usual rehabilitation programmes recommended during hospitalization, social visits weekly from trial staff and generic nutrition, exercise and falls prevention information.
Eligibility criteria	Same as trial population
Study perspective	healthcare sector perspective including use of community services such as residential care
Type of EE	Cost-utility analysis
Analytic method	Trial based
Study methods and outcome	
Time frame of EE	6 months
Discount rate costs	Not described due to timeframe
Discount rate effects	Not described due to timeframe
Inflation rate	Not described
Type and category of costs	Hospital and municipal resource use

Data source of resource use	Person reported and registries
Methods for identifying resource use	Healthcare utilization was collected with questionnaires provided to the person at weekly visits by trial staff for the duration of the 6-month intervention. Utilization of medical and pharmaceutical benefits items were requested from the Medical Benefits Scheme and the Pharmaceutical Benefits Scheme, which included claims for eligible pharmaceuticals, medical and other health worker consultations, laboratory and radiological procedures, and other medical procedures
Assumptions for measurement of resources	None stated
Methods used to calculate unit costs	Costs were adjusted to 2010 prices using a consumer price index and was valued by applying accepted unit costs to utilization of health care services recorded at individual level from National Hospital Cost Data Collection and Department of Veteran Affairs.
Costs reported or converted currency	Health resource cost 45.331 AUD (intervention) 44.764 AUD (control) diff=567 AUD (-6.166, 7.300)
Data source of effects	Effect was measured at baseline to give a retrospective analysis of HRQoL in the 6 months prior to fracture, and in the past week at 6-month follow-up. This was to determine the rate of return to pre-fracture HRQoL
Methods of measurement of effects	Health gain was assessed using the AQoL-4D questionnaire.
Methods of valuation of effects	Valuation was based on the preference weights of 350 members of the Australian general population.
Effects	QALY gain 0.155 (intervention) 0.139 (control) diff=0.02 (-0.027, 0.059)
Incremental cost–effectiveness ratios	The incremental cost-effectiveness ratio was $AUD 28,350 per quality-adjusted life year gained.
Analyses of uncertainty (e.g. sensitivity analyses)	Probabilistic sensitivity analysis was used to assess uncertainty of ICER estimate, by re-sampling the original data to replicate the result of the ICER 1000 times. Giving an empirical estimate of the sampling distribution.
Outcome(s) of analyses of sensitivity analyses	ICER = 28.350 AUD intervention dominates to 51.768 AUD. The level of uncertainty indicates the true mean lies between less costs and higher health gain and just above the willingness-to-pay threshold on 50.000 AUD.
Authors' conclusions	A comprehensive 6-month programme of physical rehabilitation from dietitians and physical therapists could be provided at a relatively low additional cost in this group of home-dwelling persons after hip fracture. The incremental cost-effectiveness ratio indicates likely cost-effectiveness, although there was a very high level of uncertainty in the findings.

Data extraction Taraldsen, R.	
Study	Short and long-term clinical effectiveness and cost-effectiveness of a late-phase community based balance and gait exercise program following hip fracture. The EVA-hip randomized controlled trial

General study characteristics	
First author and year of publication	Taraldsen, R. 2019
Trial completion year	2014
Source of funding	Norwegian Women's Health Association and the Norwegian Extra Foundation for Health and Rehabilitation through the EXTRA funds, the Norwegian Fund for Postgraduate Training in Physiotherapy, and the Liaison Committee between the Central Norway Regional Health Authority (RHA), Trondheim Municipality, and the Norwegian University of Science and Technology (NTNU)
Competing interests	Authors declared no competing interests
Publication type	Journal paper
Setting	persons was recruited during admission at Trondheim Hospital and received the intervention in own home by physiotherapist from the Municipality of Trondheim
person characteristics	Evaluation of eligibility was performed in two steps, first during hospitalization and at baseline registrations at 4 months. During hospitalization: eligible persons were home dwelling prior to the fracture, lived in the municipality of Trondheim, were 70 years or older, diagnosed and underwent surgery for intra-capsular or extra-capsular hip fractures (femur neck, pertrochanteric and suntrochanteric fractures (ICD-10 S72.0-S72.2)). persons were excluded if the fracture was pathological, life expectancies were less than 3 months, they were unable to walk 10 m (with or without walking aids) prior to the fracture or were participating in conflicting research projects. At baseline after 4 months: participants were excluded after a medical examination if they had contraindications for training (unstable medical conditions) or were bedridden.
Intervention	In addition to usual rehabilitation and health care intervention persons received a home-based programme starting 4 months post-surgery. Sessions was supervised by a physiotherapist twice weekly for 10 weeks, each session lasting approximately 45 minutes. The programme consisted of the following five weight-bearing exercises, all entailing change in base of support: 1) walking; 2) stepping in a grid pattern; 3) stepping up on a box; 4) sit-to-stand; and 5) lunge. Each exercise was described at five difficulty levels to allow for the standardized registration of individualization and progression. Progression was obtained by introducing variations in the task to challenge weight transfer, increasing movement speed, adding weight by using weight-vests, introducing more complex combinations of movements, and by adding secondary tasks (dual task condition). Exercises were meant to be performed without compensating strategies such as hand support or asymmetric weight bearing. Ten physiotherapists with varying background and experience were responsible for administering the exercise programme, as part of their ordinary work in the municipality.

Usual physical rehabilitation and care	The control group received treatment as usual, which included a variety of different approaches, from no follow-up at all to quite extensive interdisciplinary rehabilitation in their homes or in an institution. persons in the intervention group were given a choice whether to continue the treatment they already received in addition to the exercise programme they were randomized to, or to postpone this too after completing the exercise intervention.
Eligibility criteria	Same as trial population
Study perspective	Broad healthcare sector perspective
Type of EE	Cost-utility analysis
Analytic method	Trial based
Study methods and outcome	
Time frame of EE	8 months measured from 4 month baseline to 12 month follow-up.
Discount rate costs	Not described
Discount rate effects	Not described
Inflation rate	Not described
Type and category of costs	Utility of healthcare sector services including physiotherapy, home-based services, nursing-home stays, general practitioner visits and hospital services
Data source of resource use	Resource use was collected from national and local registries including medical records from hospital and municipality.
Methods for identifying resource use	Hospital services (inpatient, day patient or outpatient services) and medications was collected from the patient hospital medical records. Data on use of health services delivered by the municipality units was collected from the patient municipality records, e.g., home-based services and short-term nursing home stay. The use of services from general practitioners and private physiotherapists was collected from the Norwegian Directorate of Health.
Assumptions for measurement of resources	None stated
Methods used to calculate unit costs	persons utilization of primary care and hospitalization was combined with unit costs to calculate cost per person. Valuation of cost was calculated from the fee-for-service information from Helfo and measured in 2012 euros.
Costs reported or converted currency	Mean total cost intervention 26219 euro (SD 25468) control 25976 (SD 2863 total costs difference 242.9 (-8.8, 8.6)
Data source of effects	Effect was measured as health-related quality of life by the EuroQol-5 dimension-3L (EQ-5D-3L).
Methods of measurement of effects	Health gain was assessed using the EQ-5D- 3L questionnaire at 4 month baseline and 12 month follow-up at an outpatient clinic and at the movement laboratory at the hospital. persons unable or reluctant to participate was offered home visits.
Methods of valuation of effects	The different health states generated from the EQ-5D-3L were assigned values from the UK time-trade-off tariff.
Effects	Intervention 0.73 (0.23) control 0.73 (0.33) no difference in effect
Incremental cost–effectiveness ratios	ICER can’t when effects is 0

Analyses of uncertainty (e.g. sensitivity analyses)	The uncertainty of the ICER was assessed by bootstrapping, using 1000 bootstrap samples from the original data set (including the missing values) and performing MI for each bootstrap sample
Outcome(s) of analyses of sensitivity analyses	Of the 1000 replicates, 63% gave a negative QALY difference (points to the left of the vertical line, a gain in favor of control), and 51% of the replicates gave higher costs for the intervention group (points above the horizontal line). The probability that the intervention was cost-effective was below 39% for any ICER ceiling ratio below 150 000 EUR per QALY gained
Authors' conclusions	A relatively short home-based, supervised exercise program targeting balance and gait had an immediate and lasting small effect on gait speed and an effect on lower limb function without an increase in total health care costs. However, a tendency to include the fitter participants, a relatively high number of participants who were unable to complete the intervention and no apparent effect on daily life activities or self-reported health outcomes suggest that more comprehensive approaches are required to maximise recovery following hip-fracture

Data extraction Prestmo, A.	
Study	Comprehensive geriatric care for persons with hip fractures: a prospective, randomised, controlled trial
General study characteristics	
First author and year of publication	Prestmo, A. 2015
Trial completion year	2010
Source of funding	This study was funded by the Norwegian Research Council, the Central Norway Health Authority, the St Olav Hospital Trust, Department of Neuroscience at the Norwegian University of Science and Technology, the Foundation for Scientific and Industrial Research at the Norwegian Institute of Technology (SINTEF) and St Olav Hospital Fund for Research and Innovation, and the Municipality of Trondheim. Co-author SEL received support from the Oxford NIHR Musculoskeletal Biomedical Research Unit, Nuffi eld Orthopaedic Centre, University of Oxford and from the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health
Competing interests	Authors declared no competing interests
Publication type	Journal paper
Setting	persons were recruited in the emergency ward and was allocated to an orthopaedic ward for orthopaedic care or a geriatric ward for comprehensive geriatric care.
Person characteristics	Home-dwelling people aged 70 years or older who had been able to walk 10 m before the fracture were eligible. (persons living in their homes or sheltered housing, or who were staying temporarily in any kind of institution were defined as home-dwelling.) We excluded persons with pathological fractures, multiple traumas, or a short life expectancy, or who were living permanently in nursing homes or already participating in the investigation.

Intervention	The clinical pathway for comprehensive geriatric care was organised both before and after the operation as a systematic and interdisciplinary process, with an emphasis on comprehensive medical assessment and treatment, initiation of rehabilitation through mobilisation, and planning of discharge started early. Individualised rehabilitation plans were developed for persons who were discharged directly home. The number of staff members per bed was higher in the comprehensive geriatric care unit than in the orthopaedic care unit (nurses 1·67 vs 1·48, doctors 0·13 vs 0·11, physiotherapist 0·13 vs 0·09, and occupational therapist 0·13 vs 0·00). The orthopaedic ward was relocated to a new hospital building on 1 Sept, 2009.
usual physical rehabilitation and care	Preoperative and postoperative care was undertaken in the two wards by separate teams. persons in both groups of the trial received care and physiotherapy in accordance with national and international guidelines. Geriatricians or other doctors with skills in the management of older people did not routinely visit the orthopaedic ward, and orthopaedic specialists did not routinely visit the geriatric ward. By request, for only a few persons, geriatricians briefly assessed persons receiving orthopaedic care; vice versa, the orthopaedic surgeon assessed a few persons receiving comprehensive geriatric care.
Eligibility criteria	Same as trial population
Study perspective	Broad healthcare sector perspective
Type of EE	Cost-utility analysis
Analytic method	Trial based
Study methods and outcome	
Time frame of EE	12 months from baseline to 12 month follow-up.
Discount rate costs	Not described
Discount rate effects	Not described
Inflation rate	Not described
Type and category of costs	use healthcare sector resources.
Data source of resource use	Utility of health services was collected in administrative systems, municipal persons records and registries.
Methods for identifying resource use	All information concerning the index stay was collected from St Olav Hospital's patient administrative system. Post discharge hospital service utilisation data was collected from St Olav Hospital's patient administrative system and institutional rehabilitation data from the Norwegian Patient Register, with supplementary information from the municipal patient records. Nursing home utilisation data and information on resource consumption of primary health and social care services were collected from municipal patient records, with two exceptions: visits to general practitioners (GPs) and visits to physiotherapist were collected from the Norwegian Health Economics Administration
Assumptions for measurement of resources	There was no missing data on the use of resources except for one person who withdrew consent for further collection of data during hospital treatment.
Methods used to calculate unit costs	Published unit costs were used if available; otherwise information from local experts and municipal web-sites was used to establish unit cost. All cost values are presented in 2010 Euro (EUR). The average exchange rate in 2010 was eight Norwegian kroner (NOK) to one EUR.

	The unit cost of the index stay was calculated as the sum of surgical treatment cost and length of stay (LOS) multiplied by per diem cost. Surgical treatment cost was assumed equal across groups and calculated based on published data. The cost per diem of care in the orthogeriatric and the orthopaedic ward was calculated separately on the basis of staff level differences3 and wage cost information from the hospital accounting system multiplied by an over-head. The staff category specific wage costs per full time equivalent were equal across Comprehensive Geriatric Care (CGC) and Orthopaedic Care (OC), with staff category levels as the only difference. Staff level per person in CGC and OC groups respectively were: nurses 1·67/1·48, medical doctors 0·13/0·11, physiotherapists 0·13/0·09 and occupational therapists 0·13/0·00. The unit cost for institutional rehabilitation was gathered from the municipality and private care providers. The costs of nursing home services are calculated by using average per diem costs for these services, as they are reported to Statistics Norway. Other primary health and social care services include home nursing care, hour based rehabilitation, home care services, safety alarm, meals-on-wheels, visits to day centre and GP services, for which published unit costs were applied, except for safety alarm and meals-on-wheels.
Costs reported or converted currency	Total cost of intervention was 54 332 euro (SD 38 048) total cost of control was 59.486 (SD 44301) Difference was -5154 euro (-13.311, 3007)
Data source of effects	Effect was measured as health-related quality of life by the EuroQol-5 dimension-3L (EQ-5D-3L).
Methods of measurement of effects	At baseline all persons were given an equal EQ-5D-3L baseline score based on a systematic review of osteoporosis-related utility values to 12 month follow-up. The twelve month follow-up was done at the hospital. For very sick persons the data collection was done wherever they resided.
Methods of valuation of effects	The different health states generated from the EQ-5D-3L were assigned values from the UK time-trade-off tariff.
Effects	QALY gain intervention 0.52 (SE 0.22) control 0.45 (SE 0.23) difference 0.09 (0.02, 0.16)
Incremental cost–effectiveness ratios	The ICER was calculated to €–71 751 per QALY gained favoring the intervention.
Analyses of uncertainty (e.g. sensitivity analyses)	Uncertainty about the incremental cost-effectiveness ratio (ICER) was estimated by bootstrapping the costs and effects 1000 times.
Outcome(s) of analyses of sensitivity analyses	Bootstrap results suggest that comprehensive geriatric care has a 99% probability of being cost effective compared with orthopaedic care, with the assumption of a threshold of €62 500 per QALY gained.
Authors' conclusions	This is the first trial to show benefit and cost effectiveness when persons aged 70 years or older with hip fractures are admitted directly to a geriatric ward for comprehensive geriatric care. Existing guidelines suggest that treatment of older persons with fragility fractures should be organised as orthogeriatric care. The present study supports these recommendations for older persons with hip fractures, and shows that preoperative and postoperative orthogeriatric management of these persons improves outcomes for 4 months, and for at least 1 year after surgery, compared with treatment in traditional orthopaedic trauma wards.

Appendix S3. Quality criteria.

Quality criteria. Checklist used for Risk of Bias assessment, using Drummonds Checklist (2)	
Question	Criteria for Yes
Research question well defined?	Was it clear what the authors was trying to do?
Comprehensive description of alternatives?	Was the physical rehabilitation and care internvention and its comparator explicitly described?
Effectiveness of program established?	Was the results based on a randomized trial and did it reflect what would happened in regular practice?
Important & relevant costs & consequences for each alternative identified?	Were all important cost and outcomes to the applied perspective identified
Costs & consequences measured accurately & appropriately?	Was the cost reported in appropriate units: the hours working time, number of visits, lost workdays, 'gained life years', and presented in a disaggretated form?
Costs & consequences valued credibly?	Were cost and outcomes valued correctly
Costs & consequences adjusted for differential timing?	Was outcome and cost reported in present value? Did the authors appropriately discound value from trial conduct year to year of publication?
Incremental analysis of costs & consequences performed?	Were the incremental costs analyzed in relation to the additional benefit it delivers, and was it appropriate?
Allowance made for uncertainty in estimates?	Were the main areas of uncertainty considered and described in uncertainty analysis?
Presentation & discussion of study results include all issues of concern to users?	Was the weaknesses of the analysis and how results was reached discussed? Helping readers interpret their results.

Appendix S4 costs included

Included cost to health care perspective.			
Secondary sector			
Cost included +/-	Milte et al	Taraldsen et al	Prestmo et al
Somatic hospital stay	+	+	+
Psychiatric hospital stay	-	+	-
Outpatient visit somatic	+	+	+
Outpatient visit psychiatric	-	+	-
Surgery	-	-	+
Hospital stay post discharge	-	-	+
Ambulatory rehabilitation	+	-	-
Primary sector			
Rehabilitation stay	+	+	+
Nursing home stay	+	+	+
Home care	+	+	+
Physical therapists	+	+	+
Private physical therapists	-	+	-
Occupational therapists	-	+	-
Other allied health visits	+	-	-
Home care services	+	+	+
Safety alarms	-	+	+
Meal on wheels	-	+	+
Daycenter visits	-	+	+
General practitioner	+	-	+
Dietetics visits	+	-	-
Protein supplements	+	-	-
Medication	+	-	-
Medical test claimed	+	-	-
Procedures claimed	+	-	-
Other claims	+	-	-

Appendix S5 – Transferability assessment

Transferability between Milte. R 2016 and Denmark		
General knockout criteria		
Countries	Australia	Denmark
The evaluated technology is not comparable to the one that shall be used in the decision country		Passed
The comparator is not comparable to the that is relevant to the decision country		Passed
The study does not poses an acceptable quality		Passed
	Correspondence between study (Australia) and decision country (3)	ICER of decision country based on ICER of study country is:
Methodological characteristics		
Perspective	Health care sector perspective including community costs	Medium to high
Discount rate	Not described due to timeframe	Unbiased (short)
Medical cost approach	High	unbiased
Productivity cost approach	Not relevant	
Medical system characteristics		
Absolute and relative prices in health care	High	High
Practice variation	Low (description of setting limited)	High
Technology assess	High	Unbiased
Population characteristics		
Disease incidence/prevalence	High	Unbiased
Case-mix	High	Unbiased
Life expectancy	High	Unbiased
Health status preferences	High	Unbiased
Acceptance, compliance and incentives to persons	High	Unbiased
Productivity and work-loss time	Not relevant	
Disease spread	High	Unbiased

Transferability between Taraldsen, R. 2019 and Denmark		
General knockout criteria		
Countries	Norway	Denmark
The evaluated technology is not comparable to the one that shall be used in the decision country		Passed
The comparator is not comparable to the that is relevant to the decision country		Passed
The study does not poses an acceptable quality		Passed
	Correspondence between study (Australia) and decision country (3)	ICER of decision country based on ICER of study country is:
Methodological characteristics		
Perspective	Broad health care sector perspective	High
Discount rate	Not described	Unbiased (short)
Medical cost approach	High	unbiased
Productivity cost approach	Not relevant	
Medical system characteristics		
Absolute and relative prices in health care	High	Unbiased
Practice variation	High	Unbiased
Technology assess	High	Unbiased
Population characteristics		
Disease incidence/prevalence	High	Unbiased
Case-mix	High	Unbiased
Life expectancy	High	Unbiased
Health status preferences	High	Unbiased

Acceptance, compliance and incentives to persons	High	Unbiased
Productivity and work-loss time	Not relevant	
Disease spread	High	Unbiased

Transferability between Prestmo, A. 2015 and Denmark		
General knockout criteria		
Countries	Norway	Denmark
The evaluated technology is not comparable to the one that shall be used in the decision country		Passed
The comparator is not comparable to the that is relevant to the decision country		Passed
The study does not poses an acceptable quality		Passed
	Correspondence between study (Australia) and decision country (3)	ICER of decision country based on ICER of study country is:
Methodological characteristics		
Perspective	Broad health care sector perspective	High
Discount rate	Not described	Unbiased (short)
Medical cost approach	High	unbiased
Productivity cost approach	Not relevant	
Medical system characteristics		
Absolute and relative prices in health care	High	Unbiased
Practice variation	High	Unbiased
Technology assess	High	Unbiased
Population characteristics		
Disease incidence/prevalence	High	Unbiased
Case-mix	High	Unbiased
Life expectancy	High	Unbiased
Health status preferences	High	Unbiased
Acceptance, compliance and incentives to persons	High	Unbiased
Productivity and work-loss time	Not relevant	
Disease spread	High	Unbiased

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Appendix Study II

Statistical analyses plan

Publication date:

Document version: Submitted manuscript

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Statistical analyses plan for the prospective cohort study:

Prevalence of older patients' use of informal care after hip fracture: a prospective cohort study

Author Group

Jonas Ammundsen Ipsen[1, 2] MScPT (Primary investigator, Corresponding author)

Inge Hansen Bruun[1, 2] PhD

Eva Draborg[3] PhD, Associated professor

Bjarke Viberg [4,5,6], MD, PhD, Professor

1. Department of Physical Therapy and Occupational Therapy, Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding
2. Department of Regional Health Research, University of Southern Denmark, Odense
3. Danish Centre for Health Economics, Department of Public Health, University of Southern Denmark, Odense
4. Department of Orthopaedic Surgery and Traumatology. Lillebaelt Hospital, University Hospital of Southern Denmark, Kolding
5. Department of Orthopaedic Surgery and Traumatology. Odense University Hospital, Odense
6. Department of Clinical Research, University of Southern Denmark, Odense

Background

Care has changed over the last decades with shorter hospital admissions and more persons are cared for at home (1, 2). The ageing population and expected increase in health care expenditures due to long term care may provide incentive to transfer tasks to the informal caregivers (3). Access to modern aids, such as lifts, also means that more patients can be cared for in their own home (4).

After hip fracture, patients physical state deteriorates and their need for help increases (5, 6). The increased need for help are met by formal or informal caregivers or a mix depending on the persons personal preferences and public health services (7). Others factors that may affects the patients use informal care are their ability to; mobilise (8), activities of daily living (9) overall health (8), access to informal caregivers, type of surgery (10). Further different municipalities may have different policies on use of informal caregivers.

Being an informal caregiver of patients after hip fracture are time consuming and associated with increased relational, physical and mental health problems as results of providing informal care (11). A large proportion of informal caregivers perceived the burden of providing care as high (12). Informal care are typical not measured or included in health economic evaluations and decision-making (13, 14). The aim of this study was to assess the prevalence of informal care received by older persons after hip fracture.

We hypothesized following:

1. Older persons receive a considerable amount of help from informal caregiver after hip fracture

2. Older persons' need for help from informal caregivers decline within the first three months after hip fracture
3. Persons which are well mobilised at discharge from hospital employs less help from informal caregivers
4. Patient with low need of help with basic activity of daily living receive less help from informal caregivers
5. Patients with higher perceived health may have less need for informal care
6. Patients living alone receive less help from informal caregivers
7. Type of surgery may affect peoples' need for help from informal caregivers
8. Help from informal caregivers may diverge between municipality of residence

Methods

Study design

This study was a prospective cohort study utilising physical measurements and patient reported outcome (PRO) data. Reporting follows the guidelines for strengthening the reporting of observational studies in Epidemiology (STROBE). Data was collected in the 'Rehabilitation for Life' a stepped-wedge cluster-randomised controlled trial (15).

Setting

The cohort encompass a regional hospital in Denmark and all six municipalities in the hospital's catchment area. The municipalities serve a mixed urban and rural population. Services within hospitals and municipalities are free of charge in Denmark (16). At the time of discharge, the municipality takes over the responsibility of providing care (16).

Participants

The study included persons of 65 years of age and older admitted to the ortho-geriatric ward with a hip fracture and residing in one of the six municipalities. Other inclusion criteria were ablity to

speak and understand Danish language and well orientated in time and place. Persons discharged to permanent residence in nursing homes or persons with competing diseases disabling relevant conversation, such as progressed dementia, or receiving palliative care, was excluded.

Informed Consent

Assessment of eligibility and informed consent was obtained up to 72-hour post-surgery. In cases where cognitive function was medically unresolved decision on in- or exclusion were made in discussions with nurses and physiotherapist at the ward and the persons next-of-kin. Prior to obtaining written consent persons received written and oral information as required by regional ethics committee. The consent form developed by the national ethics committee in Denmark was used.

Consent provisions for collection

Data was collected in accordance with the Danish Data Protection Agency (20-21854). As required by Danish legislation, written informed consent was obtained from participants to permit the collection of information from medical records

Primary outcome

The primary outcome was the amount of help patients received the first three months after hip fracture. The outcome was divided in two groups. Group 1 had received help from informal caregiver the first three months after discharge (T_1-T_3). The second group had not.

Secondary outcome

Secondarily this study assessed:

- The development in help from informal caregivers from T_1-T_3
- The proportion of variance explained between patients receiving informal care after or not pending on mobility, ADL levels, overall health, cohabient or not and surgery type

- If informal care varied across municipalities

Variables

Demographic: age, gender, body mass index (BMI), living arrangement, and American society of anaesthesiologist of physical status (ASA) (17).

Cognitive function: Hindsøe score

Mobility: Timed up and Go Test (18) and New Mobility Score (NMS) (19)

Activities of daily living: Barthel-20 (0-20) (20)

Pain: four-point Verbal Rating Scale

Overall health: was measured using the EuroQol five-dimension vas score (21)

Table 1. variable description

Outcome	type	Description
Sex	Dichotomy	Male or female
Age	Continuous	65 years or above
Body Mass Index	Continuous	The anthropometric variables height and weight were used to calculate body mass index (kg/m2)
Living arrangement	Categorical	Alone, cohabiting or other
ASA	Categorical	1 normal healthy person, 2 mild systemic disease, 3 severe systemic disease, 4 severe systemic disease that is a constant threat to life, 5 moribound not expected to survive without surgery and 6 declared brain dead (17).
Hindsoe score	Categorical	1 score 9-7 unaffected cognitive function 2 score 6-5 impaired cognitive function 3 score 0-4 severe dementia
Operation type	Categorical	1 total hip alloplastic, 2 hemialloplastic 3 DHS 4 Gamma nail 5 girdle stone
NMS	Categorical	Instrumental mobility by a) walking indoor b) walking outdoor c) going shopping 0-9 (19)
Barthel-20	Continous	Assess persons' need for help to perform basic activities of daily living 0-26 (22)

EQ5D-5L vas	Numeric	EQ-5D is a standardised questionnaire, used to assess the patients' health-related quality of life and function (23)
Pain VRS	Categorical	Pain in the operated leg was meausered using the four point verbal rating scale (VRS) 1 no pain, 2 slight pain, 3 moderate pain, and 4 severe pain (24)

Data collection and source

Data on use of informal care was collected in telephone interviews with patients every two weeks after discharge (t_1) to 12-week follow-up (t_3). As a memory aid all persons received a diary in which they were asked to report the number of hours delivered by informal care givers on a weekly basis. The data collection procedure was pilot tested in advance. In the telephone interview the data collector asked:

"After your hip fracture, have you had any new need for help or care from friends or relatives that you did not have before, e.g. help to take a shower, getting dressed or contacting the municipality or hospital?"

If *"yes"* the patients were asked report from the diary. If the diary was not filled persons was asked:

"Try to recall the last week. For how long have you approximately received help for relatives and friends?"

To cover both weeks the amount of help reported was multiplied by two.

Secondary outcomes were collected in-hospital at discharge (T_1). Barthel-20, VRS, EQ5D vas and NMS. Demographic variables (sex, age, BMI, living cohabient), ASA, operation type and Hindsøe score was collected form medical journals. All data was collected by trained data collectors.

Timeline and description of data collected at each time point are presented in Table 2.

Table 2 Time point Activity/assessment	Eligibility screen t_0	Discharge t_1	8 weeks t_2	12 weeks t_3
Eligibility screen	X			
Informed consent	X			
Demography		X		
ASA		X		
Hindsøe		X		
Operation type		X		
VRS pain operated leg		X	X	X
NMS score		X	X	X
TUG score		X	X	X
Barthel-20 score		X	X	X
EQ5D vas		X	X	X
Informal Care*				

CAS, Cumulated Ambulation Score. Barthel-20, Barthel 20 item index. NMS, New Mobility Score, EQ5D, EuroQol-5 domain. Verbal Rating Scale.
*Informal care was collected every two week until t_3

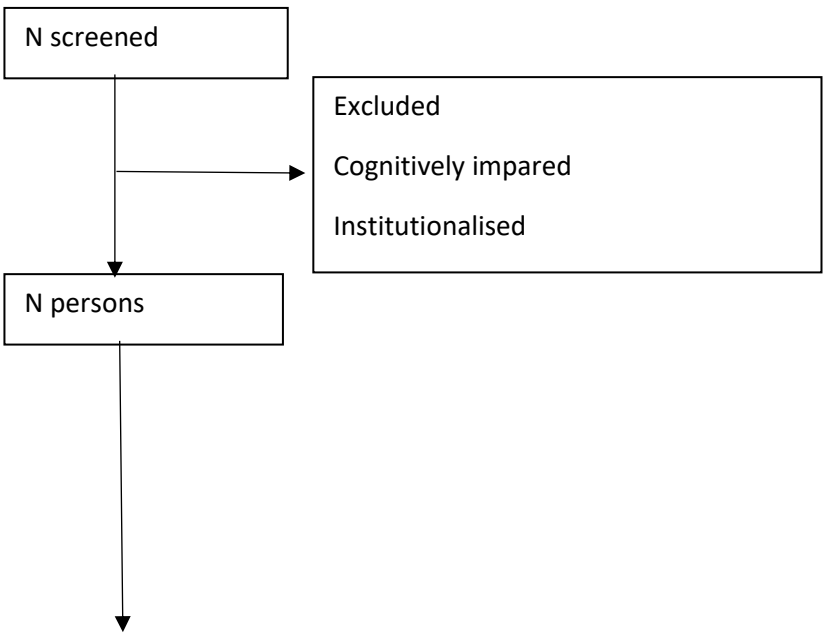
Study size

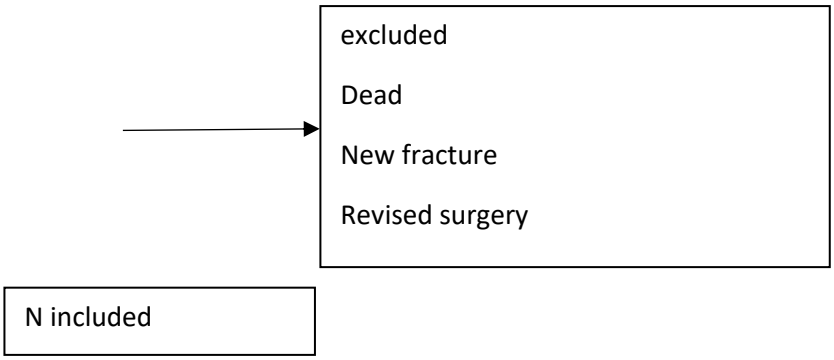
All persons admitted to the hospital, and resident in the catchments area, with a hip fracture from September 2020 - XXXX was screened for eligibility.

Results

Figur 1.

Flowchart of inclusion





Tabel 3 patient demographics table

Outcome T1	Recipient (n=xxx)	Missing	Non-recipient (n=xxx)	Missing
Sex				
Age				
BMI				
Cohabient				
ASA score				
Hindsoe score				
Operation type Total hip alloplastic Hemi alloplastic DHS Gamma Girdle stone				
Pain NRS operated leg				
NMS score				
TUG score				
Barthel-20				
Overall Health				

Table 4 primary outcome table

Primary outcome		
	Mean	SD
Hours of informal help T1-T3		
	N	%

Proportion of patients recieving informal help T1-T3						
	week 2 (n/%)	week 4 (n/%)	week 6 (n/%)	week 8 (n/%)	eek 10 (n/%)	week 12 (n/%)
Proportion for patients receiving informal care						
	week 2 (mean/SD)	week 4 (mean/SD	week 6 (mean/SD	week 8 (mean/SD	week 10 (mean/SD	Week 12 (mean/SD
Hours of informal help						
Sensitivity analysis						
	Odds ratio		Confidence interval		Proportion of variance	
Mean hours of help adjusted for TUG score						
Mean hours of help adjusted for Barthel-20 score						
Mean hours of help adjusted for operation type						
Mean hours of help adjusted for cohabiting status						

Table 5 mean amount of help by municiplaities

Municipality	Mean hours	SD

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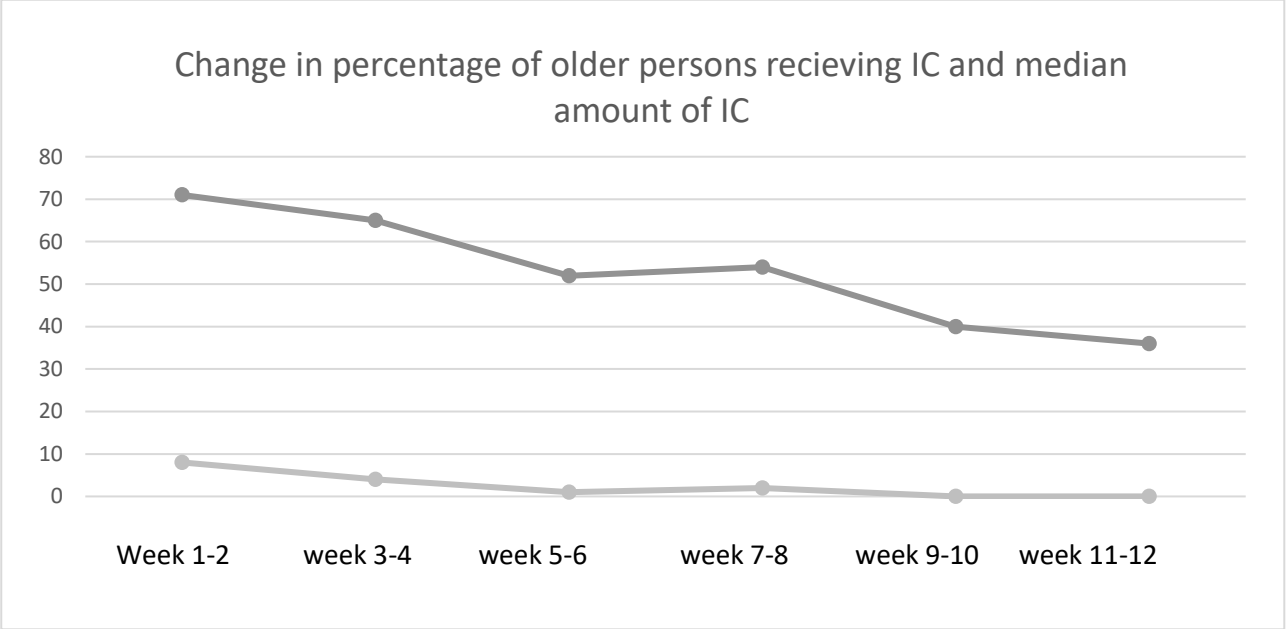
Supplementary 1. Translated cost diary used as a memory guide for the older persons

Tabel 1. Relatives		
Uge	What type of assistance did you recieve	Time spent
Week 1		Hours: Minutes:
Week 2		Hours: Minutes:
Week 3		Hours: Minutes:
Week 4		Hours: Minutes:
Week 5		Hours: Minutes:
Week 6		Hours: Minutes:
Week 7		Hours: Minutes:
Week 8		Hours: Minutes:
Week 9		Hours: Minutes:
Week 10		Hours: Minutes:
Week 11		Hours: Minutes:
Week 12		Hours: Minutes:

Supplementary 2. The change in percentage of older persons receiving IC and the median amount of hours.



Supplementary 3. Supplementary 3. The proportion of variance explained by variables differentiating recipients from non-recipients and high dependent persons from low dependent persons at a statistically significant level.

	Variable	Odds ratio	95% CI-interval	R^2
Recipient of IC	Type of surgery	1.12	0.701, 1.818	0.010
High dependence	Type of surgery*	2.35	1.295, 4.236	0.040
	Living with a partner*	2.94	1.742, 4.959	0.050
	CAS score	0.83	0.688, 1.009	0.010
	Barthel-20 score	0.93	0.875, 1.000	0.011
	Combined	-	-	0.104
Cumulated Ambulation Score - CAS associations significant at a 95% confidence level are marked by *				

Appendix Study III

Sygepleje

Træning for Livet

Dette dag til dag program tilhører: _____

Region Syddanmark

”Træning for livet – sygepleje”

- Målgruppen er patienter med hoftenære brud, som udskrives til eget hjem i Middelfart, Vejen, Kolding, Billund, Vejle og Fredericia Kommune
- Formålet er tidlig opsporing af sygdom, forebygge komplikationer og genindlæggelser.
- Formålet er at forebygge lungebetændelse, urinvejsinfektioner, fald, forstoppelse, underernæring og dehydrering.

Sygeplejersken kommer på besøg i hjemmet ca. 3 dage efter udskrivelse eller førstkommende hverdag herefter. Ortogeriatrisk afsnit adviserer kommunen således:

- Middelfart Kommune via forløbsplan og telefonisk på telefon
- Vejen Kommune adviseres via forløbsplan og telefonisk på telefon
- Kolding Kommune adviseres via forløbsplan og telefonisk på telefon
- Billund Kommune adviseres via forløbsplan og telefonisk på telefon
- Vejle Kommune adviseres via forløbsplan
- Fredericia Kommune adviseres via forløbsplan

Udfyldelse af programmet

- Programmet udfyldes med kuglepen
- Programmet sendes retur til Fysio- og Ergoterapien, Kolding Sygehus, når det er udfyldt. (Adressen findes s. 10)
- Det tilstræbes, at alle punkter udfyldes

Kontaktpersoner

Ortogeriatrisk afsnit Kolding Sygehus	Ortogeriatrisk afsnit Bedste kontakttid er 7-15 men telefonen besvares hele døgnet.	76 36 23 40

Udskrivelse fra Ortogeriatrisk afsnit Kolding Sygehus

DATO_____

Operationsdato			
Udskrivelsesdato			
Plan for sårpleje		Skiftes med tør forbinding efter behov	
		Andet:	
		Agraffer/suturer fjernes 12. dagen svarende til d.	
Plan for smertebehandling		Fast smertestillende:	
		Smertestillende efter behov:	
Plan for blodfortyndende medicin		Inj Fragmin sc gives til og med d.	
		Andet:	
Basale værdier ved udskrivelsen		Blodtryk	
		Puls	
		Respirationsfrekvens	
		SAT	
		Bevidsthed	
		Temperatur	
		Samlet score	
Accepterede afvigelser for basale værdier			

Middelfart Meldes til akutfunktionen teamet pr. telefon 20 27 32 84		**Vejen** Meldes til akutfunktionen teamet pr. telefon 30 92 33 00		**Kolding** Meldes til akutfunktion teamet pr. telefon 30 57 71 28
Billund Meldes til akutfunktion teamet pr. telefon 25 55 77 16		**Vejle** Meldes til akutfunktionen via forløbsplaner		**Fredericia** Meldes til akutfunktionen via forløbsplaner

Udskrivelse fra Ortogeriatrisk afsnit Kolding Sygehus

DATO_____

Plan for mobilisering		Fuld støtte (sæt kryds)
		Andet (beskriv):
Gangredskab ved udskrivelse		
Antal timer ude af sengen seneste døgn		

Smertevurdering hvile		Ingen smerter
		Lette smerter
		Moderate smerter
		Svære smerter

Smertevurdering mobilitet		Ingen smerter
		Lette smerter
		Moderate smerter
		Svære smerter

Hgb udskrivelse	
CRP udskrivelse	
Afføring	
Andet:	

DAG 3 efter udskrivelse

DATO_____

Basale værdier		Blodtryk	
		Puls	
		Respirationsfrekvens	
		SAT	
		Bevidsthed	
Kontakt Ortogeriatrisk afsnit ved TOBS 2 eller mere.		Temperatur	
		Samlet score	

TOBS	VITALVÆRDIER	SCORE
Puls	>130	3
	110 - 129	2
	90 - 109	1
	50 - 89	0
	40 - 49	1
	< 39	2
Bevidsthed	Agiteret	1
	Habituel	0
	Reagerer kun på tiltale	1
	Reagerer kun på smerte	2
	Ingen reaktion	3
Temperatur	>40	3
	39 – 39.9	2
	38 – 38.9	1
	36 – 37.9	0
	34 – 35.9	2
	< 33.9	3
Respiration	>25	3
	21 - 24	2
	12 - 20	0
	9 - 11	1
	< 8	3
Systolisk blodtryk	>200	2
	100 - 199	0
	80 - 99	1
	70 - 79	2
	< 69	3
Saturation	< 85	3
	85 – 89	2
	90 – 92	1
	>93	0

DAG 3 efter udskrivelse

DATO_____

Måling af Hgb		Kontakt til Ortogeriatrisk afsnit ved Hgb < 5,5
Måling af CRP		Kontakt til Ortogeriatrisk afsnit ved CRP > 50 Ved CRP på 20 – 49, skal CRP gentages efter 2 døgn.

Smertevurdering hvile		Ingen smerter
		Lette smerter
Kontakt til Ortogeriatrisk afsnit ved moderate til svære smerter som ikke afhjælpes med pn smertestillende		Moderate smerter
		Svære smerter

Smertevurdering mobilitet		Ingen smerter
		Lette smerter
Kontakt til Ortogeriatrisk afsnit ved moderate til svære smerter som ikke afhjælpes med pn smertestillende		Moderate smerter
		Svære smerter

Gangredskab		
Antal timer ude af sengen i døgnet		Opfordre borgeren til at være ude af sengen så meget som muligt for at forebygge sygdom og sengelejekomplikationer
CAS score		(vejledning næste side)
Har borgeren de rigtige og nødvendige hjælpemidler		Hvis nej: Kontakt til Ortogeriatrisk afsnit
Har borgeren den fornødne hjemmehjælp i hjemmet		Hvis nej: Kontakt visitationen
Har borgeren den fornødne hjemmesygepleje i hjemmet?		Hvis nej: Kontakt visitationen

DAG 3 efter udskrivelse DATO_____

Cumulated Ambulation Score (CAS) er en score, der anvendes ved vurdering af basismobilitet

0 = kan ikke 1 = kan med personstøtte 2 = kan selvstændigt	Basismobilitet indeholder følgende 3 elementer 1. Ud af og op i seng (0-2) 2. Rejse sig og sætte sig i stol (0-2) 3. Gang med aktuelt gangredskab (0-2) eller gang uden hjælpemidler	➔ Giver en score fra 0 til 6

Ud af og op i seng

Patienter kommer fra liggende til stående eller over i stol og tilbage til liggende i seng.

- *Der scores 2, når funktionen klares selvstændigt.* Ved selvstændigt forstås at det ikke er nødvendigt med hverken verbal instruktion eller personstøtte, heller ikke af sikkerhedsmæssige hensyn. Alle gangredskaber kan anvendes.

- *Der scores 1 ved behov for personstøtte.* Personstøtte kan være alt fra verbal støtte til massiv hjælp fra en eller flere personer, inklusiv hjælpemidler.

- *Der scores 0 for patienter, der ikke er i stand til at forlade sengen.* Herved forstås patienter, der på trods af massiv hjælp fra en eller flere personer, inklusiv hjælpemidler, ikke kan komme op at stå eller komme op at sidde i en stol.

Rejse/sætte sig i en stol

Patienten kommer fra siddende til stående til siddende i stol med armlæn.

- *Der scores 2, når funktionen klares selvstændigt.* Ved selvstændigt forstås at det ikke er nødvendigt med hverken verbal instruktion eller personstøtte, heller ikke af sikkerhedsmæssige hensyn.

- *Der scores 1 ved behov for personstøtte.* Personstøtte kan være alt fra verbal støtte til massiv hjælp fra en eller flere personer, inklusiv hjælpemidler.

- *Der scores 0 for patienter, der ikke er i stand til at komme op og sidde i en stol.* Herved forstås patienter, der på trods af massiv hjælp fra en eller flere personer, inklusiv hjælpemidler, ikke er i stand til at komme op at sidde i en stol.

Gang inden døre

- *Der scores 2, når selvstændig gang med et gangredskab er opnået.* Ved selvstændig gang forstås at det ikke er nødvendigt med hverken verbal instruktion eller personstøtte, heller ikke af sikkerhedsmæssige hensyn. Alle gangredskaber kan anvendes.

- *Der scores 1 ved behov for personstøtte.* Personstøtte kan være alt fra verbal støtte til massiv hjælp fra en eller flere personer, inklusiv gangredskab.

- *Der scores 0 for patienter, der ikke er i stand til at gå.* Herved forstås patienter, der på trods af massiv hjælp fra en eller flere personer, inklusiv gangredskab, ikke er i stand til at gå.

DAG 3 efter udskrivelse DATO_____

Opfølgning på:		
Den smertestillende behandling - Passende behandling - Bør øges? - Kan reduceres?		
Medicin generelt - Indtager borgeren sin medicin korrekt?		
Væske indtag - Har borgeren et sufficient væskeindtag		
Ernæringsindtag - Har borgeren et sufficient ernæringsindtag		
Søvn - Får borgeren dækket sit søvnbehov?		
Tarmfunktion - Har borgeren gang i maven?		
Fald - Er borgeren faldtruet? - Har borgeren haft fald efter udskrivelse?		

Mistanke om begyndende sygdom?
Konklusion og plan

- **Iværksatte handlinger**

Træning for Livet

Dette hæfte skal retur til

Fysio- og Ergoterapi, Kolding Sygehus

Kan sendes til: **Att. Forsknings- og udviklingsterapeut Inge Hansen Bruun, Kolding Sygehus, Sygehusvej 24, 6000 Kolding**

Kan scannes og mailes som sikker mail til: fysio.og.ergoterapi.kolding@rsyd.dk

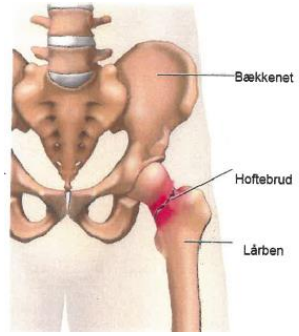
Dit Træningsprogram

Det første skridt

'Træning for Livet'

Træningsprogrammet tilhører _____

Dette træningsprogram har vi udviklet til dig, som har brækket dit lårben.
For at komme tilbage til din "gamle" hverdag igen, er det vigtigt, at du er aktiv, bevæger dig og træner – både under og efter din indlæggelse.
Aktivitet, bevægelse og træning betyder mindre tab af din muskelstyrke – og det gør, at du lettere og hurtigere kan klare hverdagens gøremål og at du kan leve det liv du gerne vil.



Fakta:
Aktivitet, bevægelse og træning vil også
betyde hurtigere heling af bruddet,
mindske din træthedsfølelsen og
forebygge forstoppelse.

Smerter
Husk at tage din smertestillende medicin. Hvis den ikke hjælper på dine smerter, er det vigtigt, at du informerer plejepersonalet, så de kan hjælpe dig.
Det er vigtigt, at du er smertedækket, så du kan træne.
Til at vurdere dine smerter skal du anvende følgende skala:
Ingen smerter
Lette smerter
Moderate smerter
Svære smerter

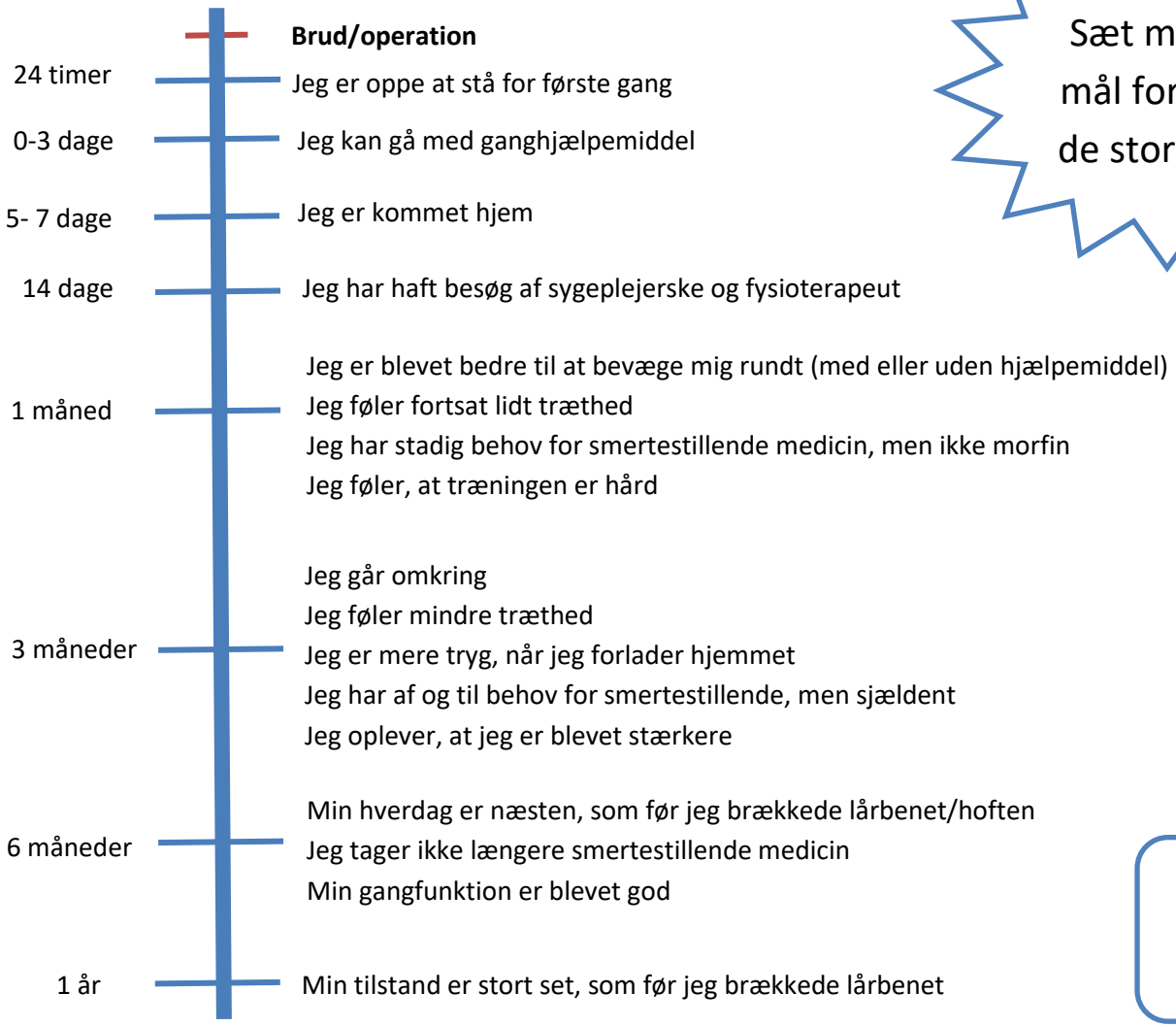
Mit Sygehus
Her har du mulighed for at finde mere information omkring smerter og andre emner som du måske mangler svar på i forbindelse med dit hoftebrud. Det er også muligt for dig og dine pårørende at se alle dine fremtidige aftaler på sygehuset. I Mit Sygehus finder du ligeledes video instruktioner af alle øvelser.

Genoptræning
Under indlæggelsen instruerer fysioterapeuten dig i øvelser, som du **selv** kan udføre.
Umiddelbart efter udskrivelsen vil du få besøg af en fysioterapeut og sammen vil I planlægge dit videre træningsforløb. I Træningsprogrammet "Det første skridt" træner du uden modstand, men det er vigtigt for dit helbred, at du øger sværhedsgraden og træner med vægte når det er muligt.

Vi anbefaler ligeledes, at du træner i det kommunale træningscenter, når du er så mobil, at du

- selv kan komme ud og ind af sengen og
- rejse og sætte dig fra en stol eller
- gå rundt med et ganghjælpemiddel.

Min vej til en normal gang/hverdag



Sæt mindre mål for at nå de store mål.

Smertestillende medicin, kost og træning er afgørende for, at du kan nå dit mål.

HUSK
Tiderne er vejledende, da ikke alle forløb er ens.

Dit Træningsprogram

Det første skridt

Formålet med programmet er, at

- aktivere blodomløbet
- aktivere musklerne
- bevæge det opererede ben

Når du træner, må du gerne opleve, at det strammer og spænder i benet.

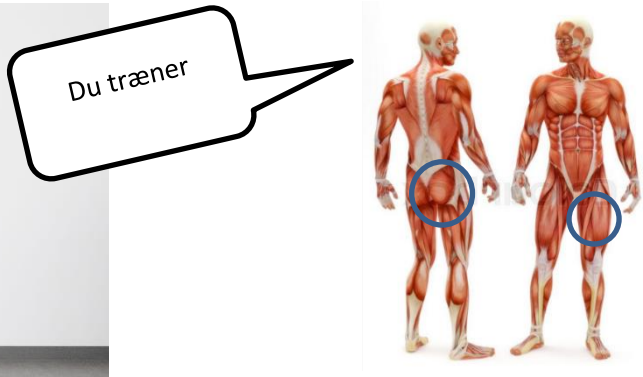
Siddende og gående

Det er vigtigt, at du allerede lige efter operationen er siddende og gående så meget som muligt. Det er med til at forebygge lungebetændelse, blodpropper mv.

Kom op at sidde på en stol til måltiderne og gå til toilettet.

Øvelse: Måltidsøvelsen

Bør ALTID udføres efter dagens tre hovedmåltider (morgen, frokost og aften)
Muskelarbejde kræver proteiner, og derfor har musklerne særdeles gode træningsvilkår efter et måltid.
Øvelse: Rejs og sæt dig så mange gange som muligt, du må gerne bruge armlænet. Du kan evt. udføre øvelsen ved et bord.



Øvelser

Alle øvelserne skal udføres både med det opererede ben og det ikke-opererede ben.

Liggende øvelser

Øvelse: Aktivere blodomløbet

Du skal ligge på ryggen med strakte ben og vippe i fodleddene

- gentag øvelsen hyppigt

Øvelse: Øge bevægeligheden omkring hofte og knæ

Du skal ligge på ryggen med strakte ben.

Bøj benet ved at lade hælen glide

på underlaget. Stræk derefter benet igen

- gentag øvelsen hyppigt

Øvelse: Bevægeøvelse for hoften

Du skal ligge på ryggen med strakte ben.

Med strakt knæ føres foden udad, glidende over underlaget væk, fra modsatte ben, og ind igen

- gentag øvelsen hyppigt

Øvelse: Aktivere lårmusklen

Du skal ligge på ryggen med strakte ben og en pude under det ene knæ.

Pres knæet ned i puden, så foden løftes. Sænk foden igen

- gentag øvelsen hyppigt

Siddende øvelser

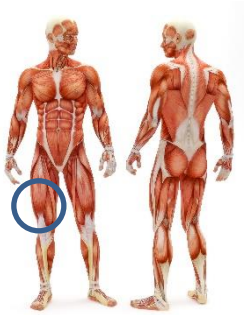
Øvelse: Aktivere hoftebøjeren - siddende

Du skal sidde på en stol.

Løft låret fri fra stolesædet, sænk låret

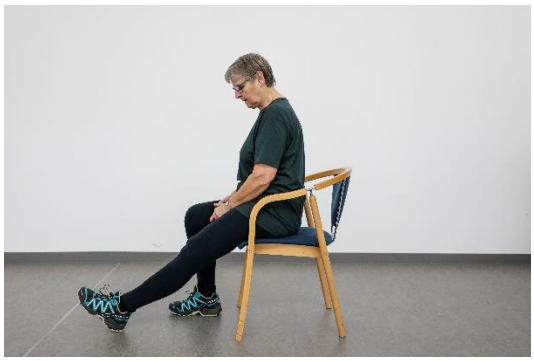
- gentag øvelsen hyppigt

Øvelse: Strække knæet



Du skal sidde på en stol. Lad foden glide frem og tilbage på gulvet ved at strække og bøje knæet

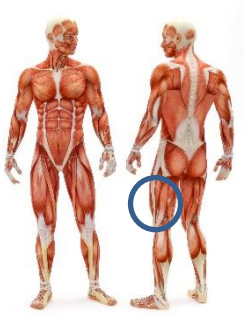
- gentag øvelsen hyppigt



Skriv antallet af gentagelser i den udleverede Træningsdagbog

Når du kan gentage øvelsen 3 x 15 gange skal du videre til Dit Træningsprogram ”Næste skridt

Stående øvelser



Øvelse: Bøje knæet – stående

Du skal stå ved eksempelvis sengegavlen, en stol eller et køkkenbord.

Bøj knæet, ved at løfte foden bagud og op mod bagdelen.

Stræk knæet

- gentag øvelsen hyppigt

Skriv antallet af gentagelser i den udleverede Træningsdagbog

Du kan finde video af alle øvelserne i Mit Sygehus.

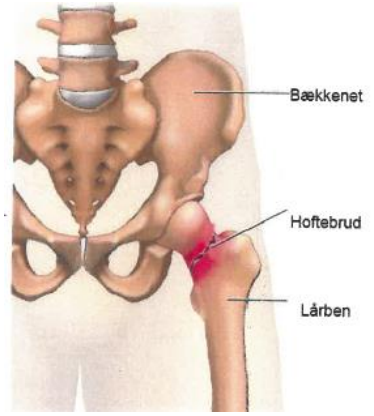
Dit Træningsprogram

Det næste skridt

'Træning for Livet'

Træningsprogrammet tilhører _____

Du har fået udleveret træningsprogrammet "Det næste skridt. det betyder, at antallet af træningsgentagelser er øget og at du er et skridt tættere på at leve det liv, der giver mening for dig. Det er vigtigt, at du foruden træningsøvelserne også er aktiv og bevæger dig.



Fakta:
Aktivitet, bevægelse og træning vil
betyde mindre tab af muskelstyrke
betyde hurtigere heling af bruddet,
mindske træthedsfølelsen og
forebygge forstoppelse

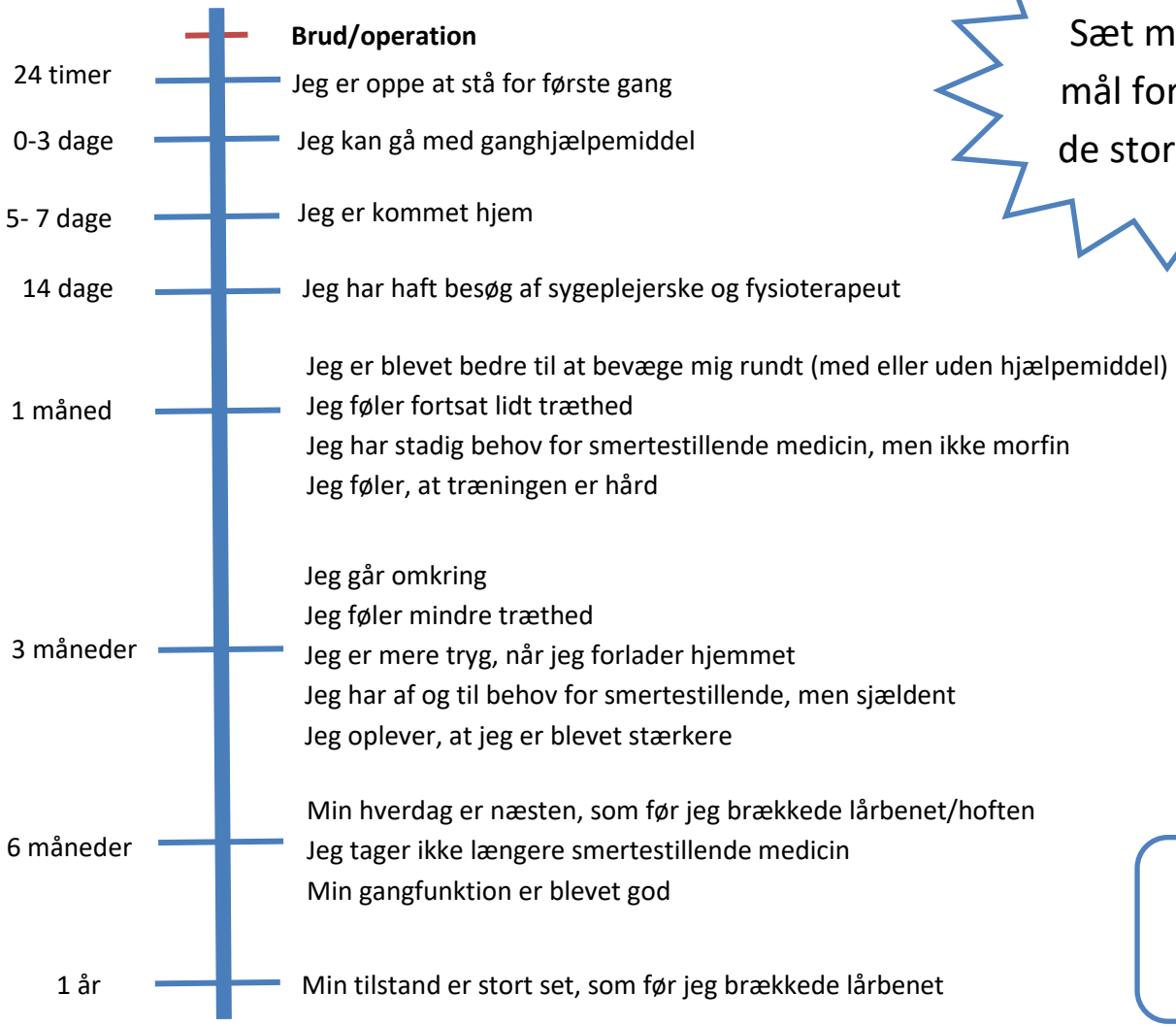
Smerter
Husk at tage din smertestillende medicin. Hvis den ikke hjælper på dine smerter, er det vigtigt, at du informerer plejepersonalet, så de kan hjælpe dig.
Det er vigtigt, at du er smertedækket, så du kan træne.
Til at vurdere dine smerter skal du anvende følgende skala:
Ingen smerter
Lette smerter
Moderate smerter
Svære smerter

Mit Sygehus
Her har du mulighed for at finde mere information omkring smerter og andre emner, som du måske mangler svar på i forbindelse med dit hoftebrud. Det er også muligt for dig og dine pårørende at se alle dine fremtidige aftaler på sygehuset. I Mit Sygehus finder du ligeledes video instruktioner af alle øvelser.

Genoptræning
Du planlægger sammen med din fysioterapeut dit træningsforløb, men det er vigtigt for dit helbred, at du øger sværhedsgraden og træner med vægte når det er muligt.
Vi anbefaler ligeledes, at du træner i det kommunale træningscenter, når du er så mobil, at du

- selv kan komme ud og ind af sengen og
- rejse og sætte dig fra en stol eller
- gå rundt med et ganghjælpemiddel.

Min vej til en normal gang/hverdag



Sæt mindre mål for at nå de store mål.

Smertestillende medicin, kost og træning er afgørende for, at du kan nå dit mål.

HUSK
Tiderne er vejledende, da ikke alle forløb er ens.

Dit Træningsprogram

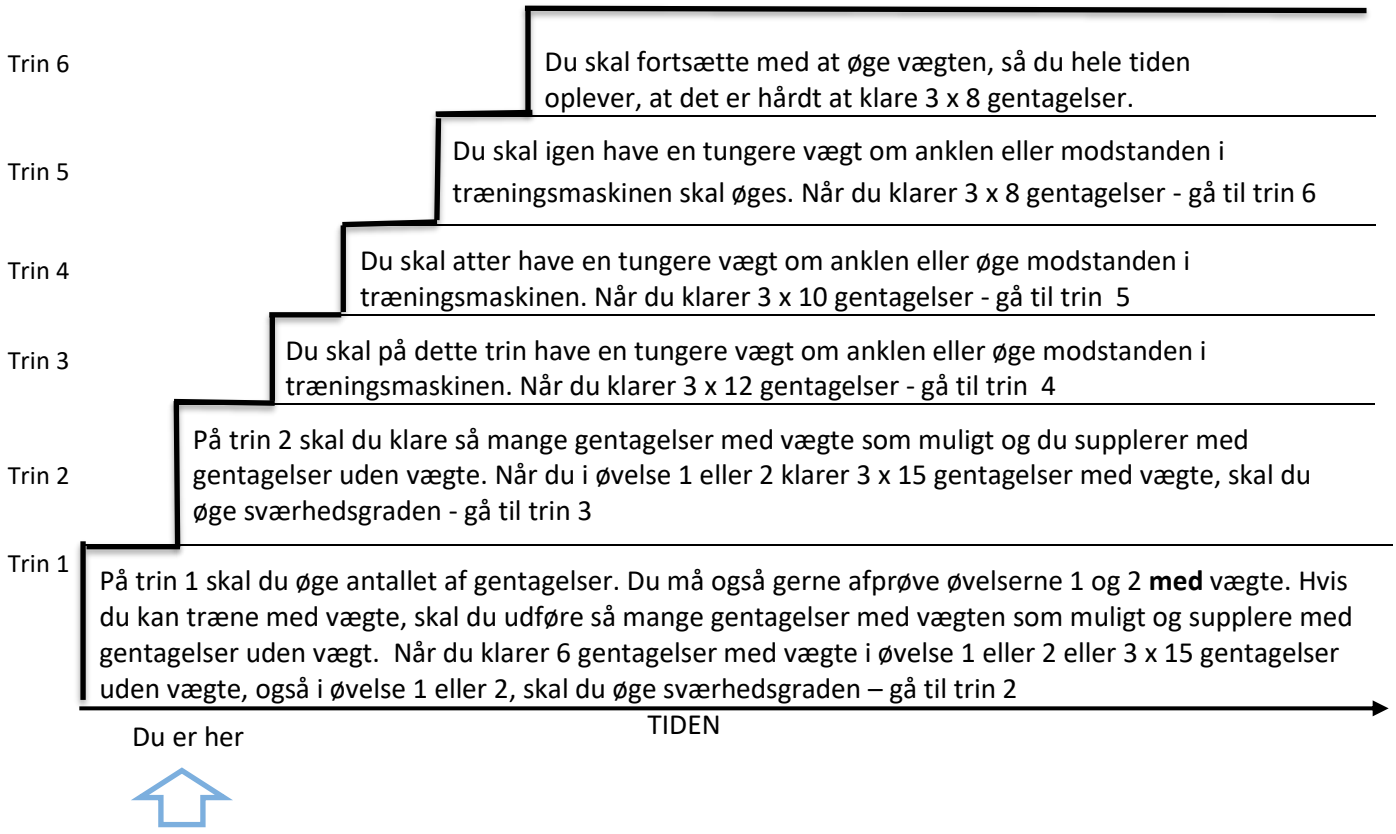
Det næste Skridt

Formålet er, at

- Styrke muskulaturen
- Forbedre balancen

Når du træner, må du gerne opleve, at det strammer og spænder i benet.

Trappen, sådan styrker du musklerne.



Træningen skal passe til dig

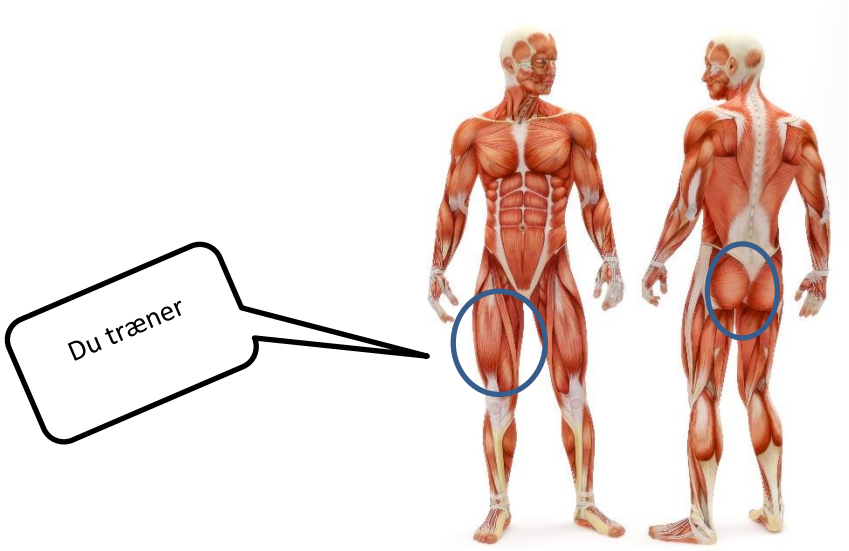
Når du træner med vægte har musklerne krav på aflastning/restitution, og derfor er 3 ugentlige træningssessioner med vægte optimalt. De øvrige dage må du gerne træne, hvis du kan, - alternativt gå ture og udføre måltidsøvelsen.

Øvelse: Måltidsøvelsen

Bør ALTID udføres efter dagens tre hovedmåltider (morgen, frokost og aften)

Muskelarbejde kræver proteiner, og derfor har musklerne særdeles gode træningsvilkår efter et måltid.

Øvelse: Rejs og sæt dig så mange gange som muligt. Det er bedst, hvis du, rejser dig uden at bruge armlænet.



Daglige gøremål

Gang til postkasse, trappegang, gå og vande blomster, stå og lave mad er OGSÅ vigtige aktiviteter.

Opvarmning

Under indlæggelsen og hjemme hos dig selv kan opvarmningen være en kort gå tur eller at rejse sig fra og sætte sig i en stol.

OBLIGATORISKE ØVELSER

Øvelser

Alle øvelserne nedenfor skal udføres både med det opererede ben og det ikke-opererede ben.

Liggende øvelser

Øvelse: Bækkenløft

Du skal ligge på ryggen med bøjede knæ og fødderne i underlaget. Løft bagdelen fra underlaget. Sænk bagdelen

- gentag øvelsen hyppigt

Siddende øvelser

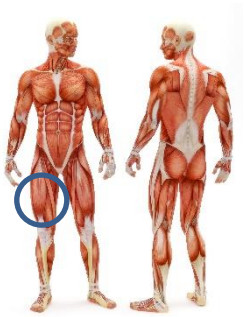
Øvelse 1: Strække knæet

Du skal sidde i en stol.

Stræk knæet helt ud ved at løfte foden fra underlaget.

Bøj knæet

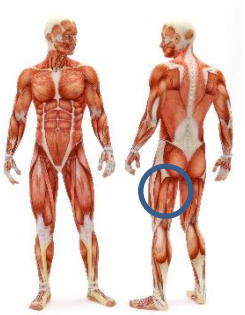
- gentag øvelsen hyppigt



Skriv antallet af gentagelser i den udleverede Træningsdagbog

Når du kan gentage øvelsen 3 x 15 gange skal du videre til
trin 2 i Trappen (side 4) og følge Dit Træningsprogram -Nu med vægte

Stående øvelser



Øvelse 2: Bøje knæet

Du skal stå ved eksempelvis sengegavlen, en stol eller et køkkenbord.

Bøj knæet, ved at løfte foden bagud og op mod bagdelen.

Stræk knæet

- gentag øvelsen hyppigt

Skriv antallet af gentagelser i den udleverede Træningsdagbog

Når du kan gentage øvelsen 3 x 15 gange skal du videre til
trin 2 i Trappen (side 4) og følge Dit Træningsprogram -Nu med vægte

Øvelse: Stående hoftestræk

Stående fører du det ene ben bagud og tilbage igen

- gentag øvelsen hyppigt

Øvelse: Føre benet ud til siden

Stående fører du benet lige ud til siden og tilbage igen

- gentag øvelsen hyppigt

Du kan finde video af ovenstående øvelser i Mit Sygehus.

EKSTRA ØVELSER

Ekstra øvelserne er øvelser, som du med fordel kan lave, snak med din fysioterapeut inden du begynder.

Øvelser: Knæbøjninger

Du skal stå bag ved en stol, hvis du ønsker støtte

Gå ned i knæene, og stræk derefter knæene igen

- gentag øvelsen

Øvelser: Høje knæløft

Du skal lave et så højt et knæløft som du kan, gerne til vandret.

Sænk knæet og løfte det modsatte knæ

– gentag øvelsen

Træning af balancen

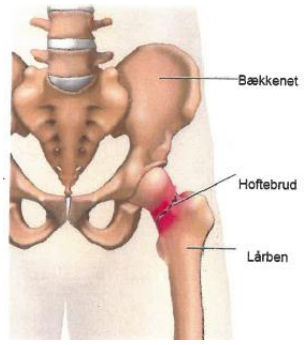
Gå fx frem og tilbage, gå sidelæns uden at holde fast /uden brug af hjælpemidler

Saml noget op fra gulvet uden at støtte dig til noget.

Dit Træningsprogram
- Nu med vægte

Træningsprogrammet tilhører _____

Godt gået! Du er nu i gang med at træne med vægte hjemme og i dit kommunale genoptræningscenter! Du vil også opleve, at du kommer tættere og tættere på at få din "gamle" hverdag tilbage. For at komme helt i mål er det imidlertid vigtig, at du fortsat er aktiv, bevæger dig og træner.



Fakta:
Træning med vægte vil
øge din muskelstyrke og
mindske træthedsfølelsen

Smerter
Husk at tage din smertestillende medicin. Hvis den ikke hjælper på dine smerter, er det vigtigt, at du informerer plejepersonalet, så de kan hjælpe dig.
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Til at vurdere dine smerter skal du anvende følgende skala:
Ingen smerter
Lette smerter
Moderate smerter
Svære smerter

Mit Sygehus
Her har du mulighed for at finde mere information omkring smerter og andre emner som du måske mangler svar på i forbindelse med dit hoftebrud. Det er også muligt for dig og dine pårørende at se alle dine fremtidige aftaler på sygehuset. I Mit Sygehus finder du ligeledes video instruktioner af alle øvelser.

Genoptræning
Du planlægger sammen med din fysioterapeut dit træningsforløb, men det er vigtigt for dit helbred, at du øger sværhedsgraden og træner med vægte når det er muligt.

Vi anbefaler ligeledes, at du træner i det kommunale træningscenter, når du er så mobil at du

- selv kan komme ud og ind af sengen og
- rejse og sætte dig fra en stol eller
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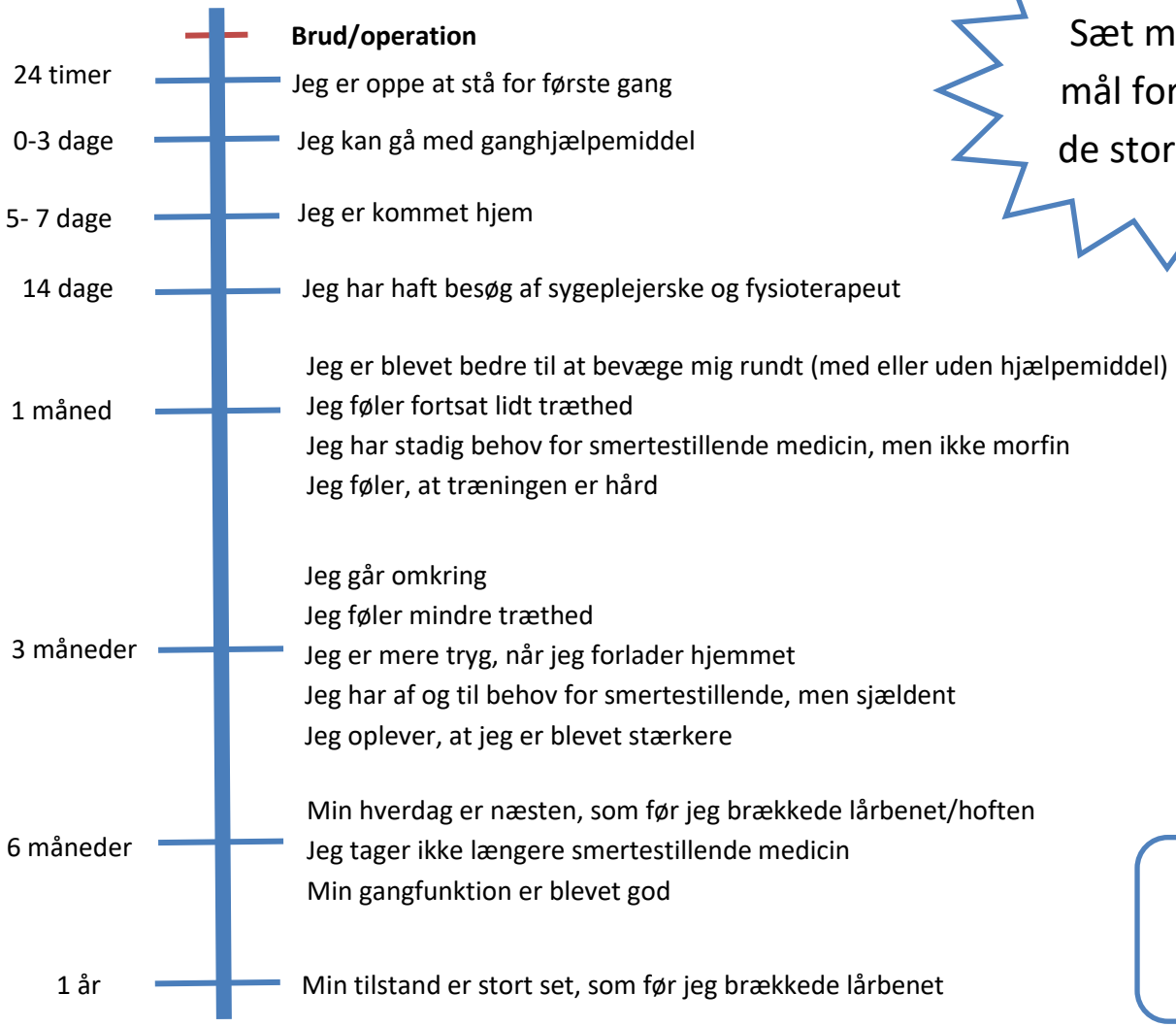
Min vej til en normal gang/hverdag



Sæt mindre mål for at nå de store mål.

Smertestillende medicin, kost og træning er afgørende for, at du kan nå dit mål.

HUSK
Tiderne er vejledende, da ikke alle forløb er ens.

Dit Træningsprogram

- nu med vægte

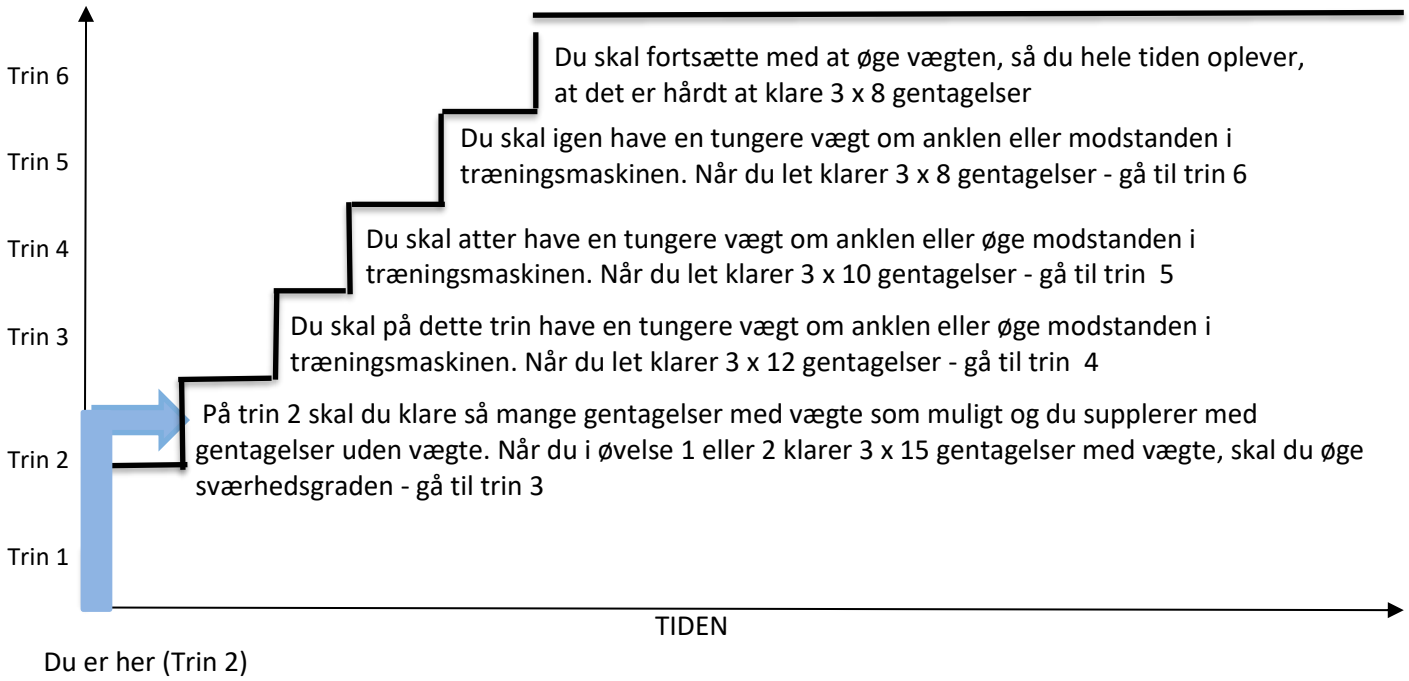
Formålet er, at

- Styrke muskulaturen
- Forbedre balancen

Når du træner, må du gerne opleve, at det strammer og spænder i benet.

Trappen, sådan styrker du musklerne.

- Du planlægger sammen med fysioterapeuten, hvilken vægt du skal starte med i trin 2.



Træningen skal passe til dig

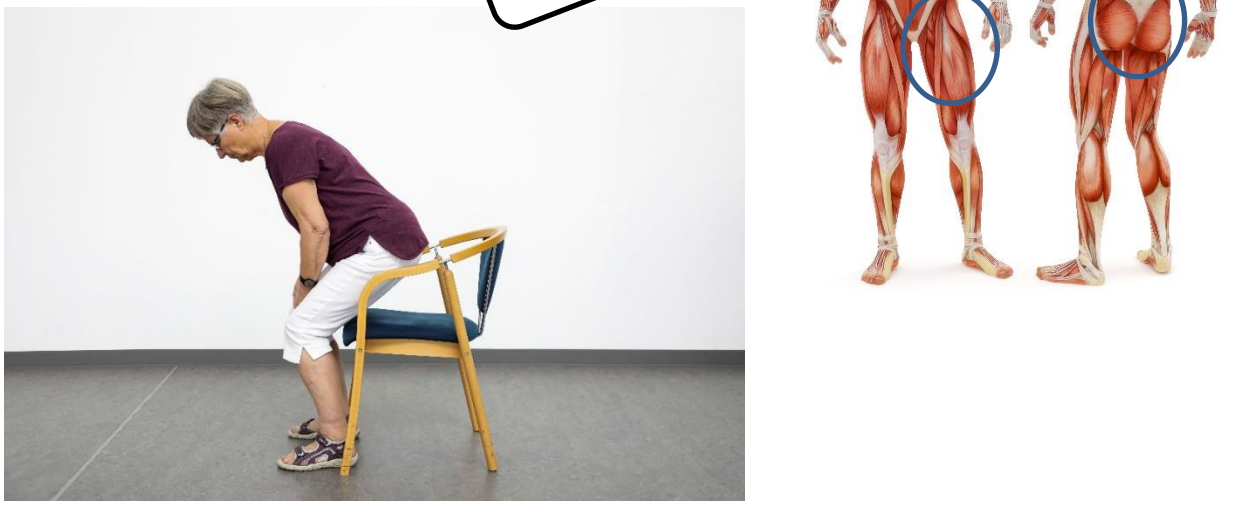
Når du træner med vægte har musklerne krav på aflastning/restitution, og derfor er 3 ugentlige træningssessioner med vægte optimalt. De øvrige dage må du gerne træne, hvis du kan, - alternativt gå ture og udføre måltidsøvelsen.

Øvelse: Måltidsøvelsen

Bør ALTID udføres efter dagens tre hovedmåltider (morgen, frokost og aften)

Muskelarbejde kræver proteiner, og derfor har musklerne gode træningsvilkår efter et måltid.

Øvelse: Rejs og sæt dig så mange gange som muligt, uden at du bruger armlænet.



Daglige gøremål

Gåture udenfor, trappegang, havearbejde er fysiske aktiviteter, der supplerer styrketræning godt, Men de kan ikke erstatte styrketræningen.

Opvarmning (10 min)

Hjemme kan opvarmningen være en kort gåtur, øvelser uden brug af vægte eks. at rejse sig fra og sætte sig i en stol eller en rask gåtur.

I træningscentret er det eksempelvis cykling på kondicykel, gang på gangbånd, Nustep.

Styrketræning (30 min)

Alle øvelserne skal udføres både med det opererede ben og det ikke-opererede ben.

Dit Træningsprogram

- Nu med vægte

Program til hjemmebrug

Obligatoriske øvelser

Øvelse 1: Knæstræk

Når du kan klare 3 x 15 gentagelser skal du anvende en vægtmanchet i din træning.

Du placerer vægtmanchetten rundt om anklen, som vist på billedet.
Du skal sidde på stolen med bøjet knæ. Stræk knæet helt ud ved,
at løfte foden fra gulvet.
Bøj knæet

- gentag øvelsen svarende til dit trin på Trappen (se side 4)

Skriv antallet af gentagelser og kg. i den udleverede Træningsdagbog.

Øvelse 2: Bøje knæet

Når du kan klare 3 x 15 gentagelser skal du anvende en vægtmanchet i din træning.

Du placerer vægtmanchetten rundt om anklen, som vist på billedet.
Du skal stå ved eksempelvis en stol, en sengegavl eller et køkkenbord.
Bøj knæet, ved at løfte foden bagud og op mod bagdelen.
Stræk knæet

- gentag øvelsen svarende til dit trin på Trappen (se side 4)

Skriv antallet af gentagelser og kg. i den udleverede Træningsdagbog

Øvelse: Hoftestræk

Når du kan klare 3 x 15 gentagelser skal du til at anvende en vægtmanchet i din træning.

Du placerer vægtmanchetten omkring den ene ankel.

Du fører det ene ben bagud og frem igen

- gentag øvelsen svarende til dit trin på Trappen (se side 4)

Øvelse: Føre benet ud til siden

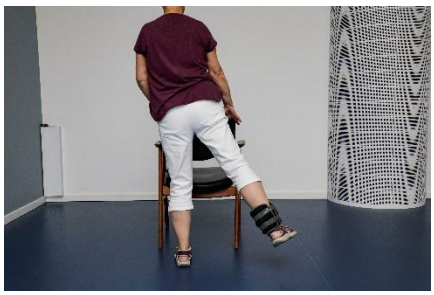
Når du kan klare 3 x 15 gentagelser skal du til at anvende vægtmanchet i din træning.

Du placerer vægtmanchetten omkring den ene ankel.

Før benet med vægtmanchetten lige ud til siden og

tilbage igen

- gentag øvelsen svarende til dit trin på Trappen (se side 4)



Du kan finde video af ovenstående øvelser i Mit Sygehus.

Dit Træningsprogram

- i din kommunes træningscenter

Udførelsen af øvelser afhænger af hvilke maskiner, der er til rådighed i din kommune
Din fysioterapeut vil vise dig, hvordan du kan udføre øvelsen.

Obligatoriske øvelser

Øvelse 1: Knæstræk

- gentag øvelsen svarende til dit trin på Trappen (se side 4)



Skriv antallet af gentagelser og kg. i den udleverede Træningsdagbog.

Øvelse 2: Bøje knæet

- gentag øvelsen svarende til dit trin på Trappen (se side 4)



Skriv antallet af gentagelser og kg. i den udleverede Træningsdagbog

Øvelse: Hoftestræk

- gentag øvelsen svarende til dit trin på Trappen (se side 4)

Øvelse: Føre benet ud til siden

- gentag øvelsen svarende til dit trin på Trappen (se side 4)

Øvelse: Føre benet ind mod midten

- gentag øvelsen svarende til dit trin på Trappen (se side 4)

EKSTRA ØVELSER – Træningscenter

Øvelse: Benpres

- gentag øvelsen svarende til dit trin på Trappen (se side 4)

Balancetræning (10 min)

I træningscenter brug eksempelvis balancepude, vippebræt

22. Yuan, S., et al., *The Influence of Marriage and Cohabitation on Physical Activity Among Middle-Aged and Older People.* J Appl Gerontol, 2023: p. 7334648231203124.
23. Barnett, I., C. Guell, and D. Ogilvie, *How do couples influence each other's physical activity behaviours in retirement? An exploratory qualitative study.* BMC Public Health, 2013. **13**(1): p. 1197.

ClinicalTrials.gov

NIH National Library of Medicine
National Center for Biotechnology Information

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer (https://clinicaltrials.gov/about-site/disclaimer) for details.

COMPLETED

'Rehabilitation for Life'

ClinicalTrials.gov ID NCT04424186

Sponsor Kolding Sygehus

Information provided by Kolding Sygehus (Responsible Party)

Last Update Posted 2024-04-16

Study Details Tab

Study Overview

Brief Summary

Despite implementing hospital quality programs after hip fracture surgery older adults often experience a decline in the level of physical function, reduced quality of life; and the mortality and readmission rates are high.

Early mobilization is important in order to prevent loss of muscle mass; however to prevent morbidity an early start of strength training is also necessary. Furthermore, the risk of complications, morbidity, and mortality are associated with insufficient management of pain.

The project aims to examine the effect of measuring vital signs and consistent rehabilitation in the primary and secondary sectors in older adults after hip fracture surgery.

Method/ design:

The study is a cluster-randomized stepped wedge study. Participants will be recruited among patients admitted to an orthogeriatric ward who are 65 years of age or older and citizens in one of three municipalities. Participants are also the health professionals in the orthogeriatric ward and the three municipalities.

The three municipalities form five clusters, which are randomized, and every three-month one cluster cross from control to intervention.

Feedback

The study compares usual practice (control) to an intervention named 'Rehabilitation of Life'. An intervention best described as an empowerment-oriented cross-sectorial program including vital sign measurement and systematic progressive rehabilitation and combined with convenient access for collaboration among professionals.

Primary outcome: Timed Up and Go (TUG) measured 2 months after the time of operation.

The investigators hypothesize that 'Rehabilitation of Life' for older adults with a hip fracture will result in a significant reduced TUG-score in comparison to a practice not offering 'Rehabilitation of Life'

Official Title

Effect of Measuring Vital Signs and Coherent Rehabilitation in Primary and Secondary Sectors in Older Adults After Hip Fracture Surgery

Conditions

Hip Fractures

Intervention / Treatment

- Other: 'Rehabilitation for Life'
- Other: Usual care and rehabilitation

Other Study ID Numbers

- SLB-Phys-06-2020

Study Start (Actual)

2020-09-22

Primary Completion (Actual)

2023-04-09

Study Completion (Actual)

2024-02-09

Enrollment (Actual)

339

Study Type

Interventional

Phase

Not Applicable

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Fractures (https://medlineplus.gov/fractures.html) Hip Injuries and Disorders (https://medlineplus.gov/hipinjuriesanddisorders.html) Rehabilitation (https://medlineplus.gov/rehabilitation.html) Vital Signs (https://medlineplus.gov/vitalsigns.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Oculocerebral Syndrome With Hypopigmentation (https://rarediseases.info.nih.gov/diseases/105/oculocerebral-syndrome-with-hypopigmentation)

FDA Drug and Device Resources (https://clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

This study has 1 location

Denmark

Southern Denmark Locations

Kolding, Southern Denmark, Denmark, 6000
Inge Bruun

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Patients with a hip fracture
- Patients of 65 years of age or older
- Patients admitted to an orthogeriatric ward
- Patient who are citizens in one og three municipalities

Exclusion Criteria:

- Patients discharged for permanent residence in nursing homes
- Patients who cannot participate in a conversation
- Terminal registered patients.

Ages Eligible for Study

65 Years and older (Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Health Services Research
Allocation : Randomized
Interventional Model : Crossover Assignment
Interventional Model Description: A cluster-randomized stepped wedge study. A design that is initiated with a period without interventions followed by a form of cross-over, in which each cluster systematic cross from control to intervention.
Masking : Double (Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: 'Rehabilitation for Life' Vital sign measurement and rehabilitation	Other: 'Rehabilitation for Life' • An empowerment-oriented cross-sectorial program including vital sign measurement and systematic progressive rehabilitation combined with convenient access for collaboration among professionals.
Active Comparator: Usual care and rehabilitation Usual care and rehabilitation provided in primary and secondary sectors	Other: Usual care and rehabilitation • The care and rehabilitation usual provided to patients after hip fracture surgery

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Timed up and go	Measures functional mobility, as the time in seconds it takes a person to rise from a chair with arms, walk 3 m and return to the chair. A higher scores mean a worse outcome	Two months after the time of operation

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Cumulated Ambulation Score (CAS)	Measures basic mobility. The score 0-6. Higher scores mean a better outcome	One months after the time of operation

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Kolding Sygehus

Investigators

- Study Chair: Inge Bruun, post doc, The Region of Southern Denmark and University of Southern Denmark

Publications

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- Ipsen JA, Pedersen LT, Viberg B, Norgaard B, Suetta C, Bruun IH. Rehabilitation for life: the effect on physical function of rehabilitation and care in older adults (https://pubmed.ncbi.nl

after hip fracture-study protocol for a cluster-randomised stepped-wedge trial. Trials. 2022 May 7;23(1):375. doi: 10.1186/s13063-022-06321-w. m.nih.gov/35526010)

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2020-06-05

First Submitted that Met QC Criteria

2020-06-08

First Posted

2020-06-09

Study Record Updates

Last Update Submitted that met QC Criteria

2024-04-15

Last Update Posted

2024-04-16

Last Verified

2022-03

More Information

Terms related to this study

Keywords Provided by Kolding Sygehus

Rehabilitation
cross-sectorial cooperation
older

Additional Relevant MeSH Terms

Fractures, Bone
Wounds and Injuries
Femoral Fractures
Hip Injuries
Leg Injuries
Hip Fractures

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

No

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: June 26, 2020

ClinicalTrials.gov ID: NCT04424186

Study Identification

Unique Protocol ID: SLB-Phys-06-2020
Brief Title: 'Rehabilitation for Life'
Official Title: Effect of Measuring Vital Signs and Coherent Rehabilitation in Primary and Secondary Sectors in Older Adults After Hip Fracture Surgery
Secondary IDs:

Study Status

Record Verification: June 2020
Overall Status: Not yet recruiting
Study Start: August 1, 2020 [Anticipated]
Primary Completion: April 30, 2022 [Anticipated]
Study Completion: April 30, 2023 [Anticipated]

Sponsor/Collaborators

Sponsor: Kolding Sygehus
Responsible Party: Sponsor
Collaborators:

Oversight

U.S. FDA-regulated Drug: No
U.S. FDA-regulated Device: No
U.S. FDA IND/IDE: No
Human Subjects Review: Board Status: Pending
Board Name: The Regional Committees on Health Research Ethics for Southern Denmark
Board Affiliation: Region af Southern Denmark
Phone: 0045 76 63 10 00
Email: komite@rsyd.dk
Address:

Damhaven 12, 7100 Vejle, Denmark

Data Monitoring: No
FDA Regulated Intervention: No

Study Description

Brief Summary: Despite implementing hospital quality programs after hip fracture surgery older adults often experience a decline in the level of physical function, reduced quality of life; and the mortality and readmission rates are high.

Early mobilization is important in order to prevent loss of muscle mass; however to prevent morbidity an early start of strength training is also necessary. Furthermore, the risk of complications, morbidity, and mortality are associated with insufficient management of pain.

The project aims to examine the effect of measuring vital signs and consistent rehabilitation in the primary and secondary sectors in older adults after hip fracture surgery.

Method/ design:

The study is a cluster-randomized stepped wedge study. Participants will be recruited among patients admitted to an orthogeriatric ward who are 65 years of age or older and citizens in one of three municipalities. Participants are also the health professionals in the orthogeriatric ward and the three municipalities.

The three municipalities form five clusters, which are randomized, and every three-month one cluster cross from control to intervention.

The study compares usual practice (control) to an intervention named 'Rehabilitation of Life'. An intervention best described as an empowerment-oriented cross-sectorial program including vital sign measurement and systematic progressive rehabilitation and combined with convenient access for collaboration among professionals.

Primary outcome: Timed Up and Go (TUG) measured 2 months after the time of operation.

The investigators hypothesize that 'Rehabilitation of Life' for older adults with a hip fracture will result in a significant reduced TUG-score in comparison to a practice not offering 'Rehabilitation of Life'

Detailed Description:

Conditions

Conditions: Hip Fractures

Keywords: Rehabilitation
cross-sectorial cooperation
older

Study Design

Study Type: Interventional

Primary Purpose: Health Services Research

Study Phase: N/A

Interventional Study Model: Crossover Assignment
A cluster-randomized stepped wedge study. A design that is initiated with a period without interventions followed by a form of cross-over, in which each cluster systematic cross from control to intervention.

Number of Arms: 2

Masking: Double (Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 330 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 'Rehabilitation for Life' Vital sign measurement and rehabilitation	'Rehabilitation for Life' An empowerment-oriented cross-sectorial program including vital sign measurement and systematic progressive rehabilitation combined with convenient access for collaboration among professionals.
Active Comparator: Usual care and rehabilitation Usual care and rehabilitation provided in primary and secondary sectors	Usual care and rehabilitation The care and rehabilitation usual provided to patients after hip fracture surgery

Outcome Measures

Primary Outcome Measure:

1. Timed up and go
   Measures functional mobility, as the time in seconds it takes a person to rise from a chair with arms, walk 3 m and return to the chair. A higher scores mean a worse outcome

   [Time Frame: Two months after the time of operation]

Secondary Outcome Measure:

2. Cumulated Ambulation Score (CAS)
   Measures basic mobility. The score 0-6. Higher scores mean a better outcome

   [Time Frame: One months after the time of operation]

Eligibility

Minimum Age: 65 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with a hip fracture
- Patients of 65 years of age or older
- Patients admitted to an orthogeriatric ward
- Patient who are citizens in one og three municipalities

Exclusion Criteria:

- Patients discharged for permanent residence in nursing homes
- Patients who cannot participate in a conversation
- Terminal registered patients.

Contacts/Locations

Central Contact Person: Inge Bruun, post doc
Telephone: +45 7636 2886
Email: Inge.Hansen.Bruun@rsyd.dk

Central Contact Backup:

Study Officials: Inge Bruun, post doc
Study Chair
The Region of Southern Denmark and University of Southern Denmark

Locations:

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information:

Appendix Study IV

Health economic evaluation-analysis plan

This plan describes the statistical analysis plan for an economic evaluation of Rehabilitation for Life (RFL) compared to usual rehabilitation and care.

Aim

This economic evaluation aims to assess utility gains and cost for RFL compared to usual rehabilitation and care one year after hip fracture.

Method

Health economic analysis plan

This cost-utility analysis will be trial-based, and reporting will follow the updated Consolidated Health Economic Evaluation Reporting Standards Statement (CHEERS) [1].

Target population and subgroups

Inclusion criteria will be community-dwelling, cognitively non-impaired persons aged 65 years or older who sustained a hip fracture and who consent to participate. Exclusion criteria will be inability to speak or understand Danish, discharge from hospital to permanent residence in nursing homes, communication impairments, such as progressive dementia and aphasia or other disabling diseases, or short life expectancy.

Setting

This study will be completed under usual conditions in Denmark and include one catchment area comprising one hospital and six municipalities serving a mixed rural and urban population. The health care system is a universal single-payer system divided into primary (municipalities) and secondary (hospital) sectors. The responsibility of providing rehabilitation and care depends on the location of the older person (in-hospital or at home) [2, 3]. Hospital and municipal rehabilitation and care services are offered free of charge. In addition to services delivered by formal caregivers, informal caregivers assist older persons after hip fractures to varying extents [4].

Comparator and intervention

RFL and usual rehabilitation and care after hip fracture involve mobilisation and care during the hospital stay. After discharge, the municipal rehabilitation program is initiated. It will usually consist of supervised exercise in the older persons' private homes or at a rehabilitation centre, encompassing one or two weekly sessions for six to eight weeks [5]. Municipal home nursing care after hip fracture is only offered by request and according to need. Motivation to participate in usual rehabilitation and care is expected to arise from the older persons' desires to regain the pre-fracture level of function.

The RFL intervention will be delivered in addition to usual rehabilitation and care and entail continuous and progressive rehabilitation and care delivered in an empowerment-orientated praxis. The older persons will receive five supervised resistance exercise sessions during the first 14 days after discharge. The third of these sessions entails a virtual meeting between the older person and the physiotherapist from the hospital and the municipality. From week three to week twelve, the older persons receive 20 resistance exercise sessions supervised by a physiotherapist from the municipality. Nurses in the municipality will conduct a home visit on day three after discharge and assess the person's health, including measuring vital signs and testing for infections. A hotline between the hospital and the municipality is established to enable the nurses in the municipality to confer with nurses and medical doctors at the orthogeriatric department at the hospital and, if needed, treat the older person at home. The empowerment-orientated praxis will enable older persons to gain control over their rehabilitation and care. It consists of the three following initiatives. First, providing medical information and knowledge to the participants (i.e. how to manage pain and how to eat to support muscle growth) by introducing them to a digital app containing video interviews with medical doctors and nurses from the hospital and physiotherapists and nurses from the municipalities. Second, The health professionals participate in a workshop

where they will be introduced to how to facilitate the empowerment of the older person. Third, the older persons will receive physical reminders through a trolley and a mug with inscriptions: "I rehabilitate for Life" and "Remember to do sit-to-stand exercises after each meal". Each older person will receive weight cuffs, a printed exercise diary and exercise programs.

A study protocol has been published for additional information on RFL and comparator [6].

Perspective

As the national retirement age is 67 years and this study only includes persons 65+ years, a societal perspective, excluding production loss, will be applied.

Time horizon

The trial follow-up period will be one year. Incremental costs and utility are assumed to be stable after six months, as most improvements after hip fracture occur within the first six months after discharge [7].

Discount rate

Due to the duration of the follow-up of one year, discounting was not applied.

Selection of outcomes

Primary outcome

The primary outcome will be the incrementel cost per quality-adjusted life year (QALY). QALYs combine time lived and Quality of life (QoL), including items covering physical function (gait, self-care and usual activities) and mental function (pain, anxiety and depression) into a single index number where "1" corresponds to one year of complete health and "0" corresponds to being dead. QoL will be measured using the EuroQol five-dimension five-level questionnaire (EQ-5D-5L) [8]. EQ-5D-5L is a standardised questionnaire used to assess health-related Quality of life. It comprises the following five dimensions: mobility, self-care, usual activities, pain and anxiety/depression, and it has five levels of response (from no problems to severe problems or inability to perform) [8]. The individual older person's health states will be assigned utility weights from the Danish EQ-5D-5L

reference set (i.e. each health state will be assigned a value between -0.759 and 1.000) [9]. The outcome will be reported as the total difference in cost per QALY.

Demographic characteristics: age, sex, body mass index (BMI), living arrangement (i.e., alone or cohabiting), length of stay in hospital, and health status using the American Society of Anaesthesiologists classifications system (ASA). The ASA score is clinician–applied and provides an overall health status assessment before surgery [10]. The ASA score ranges from 1-6 and is dichotomised into a low-risk group (ASA 1-2) and a high-risk group (ASA ≥3), as done by Viberg et al. 2023 [11].

Mobility New Mobility Score (NMS) measures the older person's gait function inside, outside and during shopping and is a clinician-applied 0-9 score measured at discharge, eight weeks, twelve weeks and six months after discharge [12].

Activities of daily living (ADL) are measured using Barthel-20 to assess a patient's need for assistance [13]. Barthel-20 measures the older person's self-perceived ability to perform basic activities of daily living. It is measured on a scale from 0-20 at discharge and eight, 12 weeks, and six months after discharge.

Measurements of outcomes

Trained data collectors will contact the older persons five times during the one-year follow-up period. The first follow-up will be approximately five days after surgery on the day of discharge. The second follow-up will be approximately eight weeks after discharge. The third follow-up will be approximately twelve weeks after discharge; the fourth follow-up will be approximately six months after discharge, and the fifth follow-up will be approximately one year after discharge. The discharge measurements will be collected in the hospital, and the remaining four follow-ups will be completed in-home visits or phone calls. The timeline for the measurement of outcomes is presented in Table 1.

Measurement and valuation of resources and costs

Hospital cost: all contacts with the hospital from admission to six-month follow-up will be retrieved from the hospital's administrative systems and valued using the regional Diagnosis-related group (DRG) for hip fractures [14]. The DRG tariffs express the national average operating costs for treating patients within each DRG group.

Municipal cost: all contacts with the municipal will be collected from municipal administrative systems, and valuation will be based on the recommendations from the Danish Health Technology Council [15].

Respite stays constitute temporary admissions in a municipal rehabilitation unit or nursing home offered to older persons unable to be discharged directly to their homes. The number of days in a respite stay will be collected from municipal administrative systems and valued as the cost per day, including overhead. As we do not have information on the respite stay cost per day, we use the annual total expenditure, including overhead, to calculate the mean cost per day.

$$cost\ per\ day\ in\ respite\ stay = \frac{annual\ cost\ per\ stay\ including\ overhead}{365}$$

Cost of use of GP and other health professionals. Contacts to general practitioners and private health professionals will be collected from the National Health Service Register [16]. Valuation will be based on the service fee.

Medication. The use of prescription medication will be collected from the National Register of Pharmaceutical Sales [16]. Valuation will be the market price for the medication.

Informal care*:* the older persons will record hours of informal care received from family or friends in diaries, and this information will be collected bi-weekly from T1-T3. Valuation will be the standardised hourly earnings recommended by the Danish Health Technology Council [15].

Transportation: every two weeks, the patients are contacted and asked if they receive rehabilitation in a rehabilitation centre or at home and, if in a rehabilitation centre, how they got to the centre (i.e. drive themselves, drive with an informal caregiver or if the municipality arranges the transportation) during the period from T1 to T3. Patients who drive themselves are asked how long it takes (minutes) to commute to and from the rehabilitation centre. The transporttime is valued using the stardardised hourly earnings. Patientes driven by an informal caregiver are asked how long it takes (minute) to commute to and from the rehabilitation center the valuation of the informal caregivers time are valued using the standardised hourly earnings. Transport to the rehabilitation centre by the municipal taxa service will be valued using the municipal pay-for-service. For patients receiving home based rehabilitation it is assumed the physiotherapist will have a twenty minute commune each way. This is equivalent to the helath technology and research recommendation of assuming 20 km for patients and from hospital. The valuation of the therapist transport time to patients home will be based on the recommendations for a physiotherapist average hourly salary [15]

Patient time in transport: the older persons are asked how long they are spend in transportation to and from rehabilitation centres, waiting time included. Transportation time is valued using the standardised hourly earnings recommended by the Danish Health Technology Council [15]

Table 1. Timeline for collection of outcomes from randomisation to one-year follow-up						
Activity/Assessment	Randomisation T0	Discharge T1	Eight weeks T2	Twelve weeks T3	Six months T4	One year T5
Demography	X					
EQ-5D-5L		X	X	X	X	X
New Mobility Score		X	X	X	X	
Barthel-20 score		X	X	X	X	
Hospital costs		X	X	X	X	
Municipal costs		X	X	X	X	
Respite stay		X	X	X	X	
GP and other private health practitioners		X	X	X	X	
Medication		X	X	X	X	
Informal Care			X	X		
Transportation			X	X		

Currency, price date, and conversion

The cost will be collected in Danish Kroner (DKR) and converted and reported in euro (€) using the average 2023 conversion rate of 1 DKR to 0.134 € [17].

Study size

The participants for the economic evaluation will be identified in the original RFL trial, and the number of participants who consent to participate will, therefore, determine the number of participants in this economic evaluation.

Informed Consent

Assessment of eligibility and informed consent will be obtained during the first 72 hours post-surgery. In cases where cognitive function is medically unresolved, decisions on inclusion or exclusion will be made in dialogue with nurses and physiotherapists at the hospital and with the

patient's next of kin. Before obtaining written consent, patients will receive written and oral information as required by The Regional Ethics Committee of Southern Denmark S-20200070. Data will be collected by the Danish Data Protection Agency (20-21854).

Analysis plan

The statistical analysis plan will be presented in the following steps.

Step 1. Comparability between groups

In step one, we will assess differences between groups at randomisation. We will also test bi-nominal distribution using the Wilcoxon rank sum or Pearson's chi-squared test. If there are differences between groups, we will examine whether these are systematic.

Step 2. Utility and cost

We will assess the total cost and effect difference six months after the hip fracture. Six months was chosen as Dyer et al. 2016 [7] identified that for most older persons after hip fracture, the improvements in the level of function stagnate after six months.

Costs

The cost will be the difference in total cost between groups from T1 to T4

$$Total\ cost = \ (cost\ T0 - T1) + (costT1 - T2) + (cost\ T2 - T3) + (costT3 - T4)$$

Utility

As we have several measurements on the same person's utility at times T1 to T4, we will use the predicted utility from an adjusted linear mixed regression model where the change in utility will be estimated with a fixed effect parameter of time and group allocation (time#group), a random effect parameter including each individual as cluster and an interaction between time and group allocation.

$$Yij = \ \beta 0 + \beta 1 \times Timeij + \beta 2 \times Groupij + \beta 3 \times (Time \times Group)ij + \beta 4 \ldots + \ ui + \in ij$$

Y_{ij} will be the utility score of the EQ-5D-5L for the *i*th individual and the *j*th timepoint. Hence, Yij will be the sum or fixed effect of time (β1) multiplied by the fixed effect of group (β2) plus the

fixed effect of the interaction between time and group (β3) plus the fixed effect of each covariate ($\beta 4$ ...) plus time at the *j*th timepoint (Time*ij*) + the group membership for the *i*th individual at the *j*th timepoint (Group*ij)*. Multiplied with the interaction between time and group $(Time \times Group)ij$ and a random effect for the *i*th individual (ui) and the random error ($\in ij$).

Adjustments will include age, sex, cohabiting status, type of surgical procedure, seasonal variation, municipality, length of stay at the hospital and amount of received informal care. Model fit will be tested using Akaikes information criterion (AIC), where a lower value indicates a better fit of the model. To avoid overfitting the model, the final adjusted model will only include an adjustment for the covariates that differentiate from zero at a significance level of .05 in a Wald chi-squared test, indicating that the covariate improves the model. We will test for interactions between groups by each included covariate.

Model assumptions will be assessed:

For patients deceased between T4-T5 a utility score for period are imputed.

Linearity will be assessed by visually inspecting scatterplots of observed and predicted values.

Normality will be assessed by visual inspection histograms, Q-Q plots of the residuals, and scatter plots of residuals and predicted values.

Homoscedasticity will be assessed by plotting residuals against predicted values.

As a sensitivity analysis, we evaluate the capacity of older persons to sustain their functional improvements by examining their utility progress over six months to one year. This was done by extending the adjusted linear mixed model to include the T5.

Step 3. Cost per QALY

We will use the previously described adjusted linear mixed model to estimate the total difference in one-year utility gain between groups from T1- T5.

Incremental Cost-Effectiveness ratio (ICER) will be calculated as the difference in intervention costs divided by the difference in Quality-adjusted life year gain between groups.

$$\text{ICER} = \frac{\text{cost difference}}{\text{QALY difference}}$$

As Denmark does not have an official willingness-to-pay threshold, we will compare the cost per QALY to a predefined willingness-to-pay threshold of a cost-effective treatment defined by the National Institute for Health and Care Excellence at 22 804€ (20 000£) per QALY [18, 19].

Results will be visualised in a cost-effectiveness plane, and the intervention risk of being below the willingness-pay threshold will be visualised using a cost-utility acceptability curve.

We will explore the impact of each element of the EQ-5D-5L-items by estimating the mean level score for each item over time by plotting the margins of each item over time.

As a sensitivity analysis, we will redo the analysis as crude, with the inclusion of a person dying within T0-T4 and with the inclusion of extreme outliers.

Step 4 Sub-analysis

The older person's ability to maintain utility gains may vary depending on their characteristics and type of surgical technique. Hence, we will perform three sub-group analyses.

1. A high BMI has been associated with a lower level of physical activity [20, 21]; we hypothesise that non-obese older persons will maintain a higher utility score from T4 to T5 compared to obese older persons. To test this hypothesis, we divide the intervention and control group into subgroups of non-obese (BMI ≤ 27.5) and obese (BMI > 27.5).

2. Cohabiting and social support have been associated with higher levels of physical activity [22, 23]. Hence, we hypothesise that patients living with a partner will maintain higher utility scores from T4 to T5. To test this hypothesis, we divide the intervention and control groups into subgroups of living with a partner or alone.
3. In this study, patients received one of three types of surgical techniques (arthroplasty, intramedullary nail or sliding hip screw). An arthroplasty is cemented to the Column Femora. The intramedullary nail and sliding hip screw are used to stabilise the fracture during healing. Hence, we hypothesise that older persons with a fracture treated with an intramedullary nail or sliding hip screw will have a slower increase in utility from T1 to T4 and that they will have more difficulties maintaining their utility gain from T4 toT5 compared to patients who are treated using an arthroplasty, as these may experience less pain. To test this hypothesis, we divide the intervention and control group into two surgical groups: arthroplasty or intramedullary nail and sliding hip screw.

The significance level for all statistical analyses will be set to $p<.05$. Statistical analyses will be performed with StataCorp. 2019 (Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC).

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