Management of fear of falling after hip fracture

MAAIKE SCHEFFERS-BARNHOORN

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Maaike Nicoline Scheffers-Barnhoorn

Colophon
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Maaike Nicoline Scheffers-Barnhoorn
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Promotor:

Prof. dr. W.P. Achterberg

Co-promotores:

Dr. M. van Eijk

Dr. J.C.M. van Haastregt (Maastricht University)

Leden promotiecommissie:

Prof. A. Gordon (University of Nottingham)

Prof. dr. J. Gussekloo

Prof A.M. Maier (National University of Singapore)

Dr. E.F. van Dam van Isselt

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CONTENTS

Chapter 1

General Introduction

HIP FRACTURE

Proximal femoral fractures, also entitled hip fractures, represent an acute medical event that is common to older adults. In the Netherlands, approximately 17500 patients receive surgical treatment for hip fracture on annual basis [1]. This injury has extensive consequences for the individual patient, affecting health status, daily functioning and participation. It also places a substantial burden on the global health care system as a whole [2-4]. Women have an estimated life-time risk of one in six of sustaining a hip fracture, for men this risk is slightly lower (6%) [5-7]. Worldwide the absolute number of hip fractures is expected to increase substantially far above the 1.6 million reported in 2000 [8]. Estimates suggest the global burden of hip fracture may reach 4.5 million per year in 2050 [9].

Utilization of health care services following hip fracture

For a curative treatment approach, the medical management of a hip fracture requires surgical repair of the fracture. This is accompanied by a hospital admission of several days [10]. Hereafter patients are often referred to post-acute rehabilitation. Rehabilitation services can be provided within an inpatient -, outpatient- or ambulant (home-based) setting [11,12]. An important characteristic of rehabilitation services is that they have a multidisciplinary approach, which implies that various health care professionals are involved in the treatment of patients with hip fracture. A fundamental goal for rehabilitation is to restore the function of the lower extremity, and consequently regain mobility function (including gait), and functioning in basic activities of daily living (ADL), so that patients are able to return home and function independently [11]. However, many patients do not regain their pre-fracture level of functioning (this is described in more detail below). Patients with insufficient recovery often require professional home-care services, or long-term care services. In view of the substantial utilization of health services in (post)acute- and long-term care, it is evident that the care for this population is costly [4,5,13].

Recovery after hip fracture

From a patient's perspective, a hip fracture has significant impact on many health domains. Physical function is limited after hip fracture, and this affects a broad range of activities of daily living. In general, recovery of gait and balance function will require approximately six months. Activities of daily living that involve lower extremity function - such as rising from chair, walking, climbing stairs, putting on socks or shoes – may require a longer recovery period of up to a year after fracture [14]. Despite extensive rehabilitation, less than half of the patients recover to their pre-fracture level of mobility. Recovery of ADL function is also limited, and only 40-70% of the patients regain their prior ADL function [2,3]. Moreover, for 10-20% of the population the excess disability is so significant, that there is a need for admission to a long-term care setting [2].

Hip fracture is also well-known for the high mortality rates, up to 25-30% within the year following fracture [3,15]. An excess mortality risk has been described for this population, which remains beyond the first decade after fracture [16,17]. In patients that survive the first period after fracture, there is an increased risk of a subsequent second hip fracture, generally occurring in the 24 months following initial hip fracture [18,19].

Mental health can also be affected as a consequence of hip fracture [20]. Depression is common in this population, mainly in early stages after fracture, and this has been found to have a negative effect on functional recovery [21]. Likewise, problems in the cognitive domain, such as delirium and cognitive decline, are frequently observed in this population [22,23]. Furthermore, the health-related quality of life (HRQoL) decreases considerably after fracture, and demonstrates poor recovery over time [24].

Improving outcome after hip fracture

The broad range of adverse events and poor outcome following fracture, underpins the need to critically review the opportunities to optimize treatment for patients with hip fracture. Thus, to systematically evaluate and address those risk factors that may be amendable. Over the past decades, the long-term outcomes have merely improved, despite many advances in medical management of hip fractures, and an increased focus on a multidisciplinary treatment approach [25-27]. There is only some evidence to suggest that the one-year mortality rate is slightly decreasing [28]. Fortunately, research in this area is elaborate and ongoing. In the past years, a large number of factors have been identified as predictors for poor functional outcome, including factors related to the health care system or surgery. Important patient-related risk factors include age, pre-fracture functioning and pre-fracture mobility, cognitive function and comorbidity [29-35]. Despite the abundance of identified risk factors, only a few are potentially modifiable, and could be subject to treatment. Within this context, '*fear of falling'* may be of specific interest, as it has been associated with poor functional outcome and mortality after hip fracture [36-39]. The background of fear of falling is discussed in more detail below.

FEAR OF FALLING

Fear of falling can be considered one of the psychological constructs of '*fall-related psychological concerns'.* In the general population of community-dwelling older adults fall-related psychological concerns have been studied quite elaborately in the past decades [40,41]. However, as research in this area advanced, so did the conceptualization of different constructs under this umbrella term [42,43]. In early literature of this topic, *falls efficacy* and *fear of falling* were considered interchangeable. Based on the current theoretical approach to this subject, they should be regarded two distinct constructs. Thus for a correct understanding of fear of falling - the research topic

of this thesis - it is important to differentiate these two constructs. Falls efficacy has been defined as the perceived self-efficacy to perform activities of daily living without falling. Or – in a broader perspective – falls efficacy can be considered the perceived self-efficacy of performing all the necessary actions that are needed in a pre-fall, near-fall, fall-landing or completed fall situation [44]. Fear of falling on the other hand is based on *lasting concerns* about falling, which can lead to an individual avoiding activities that one remains capable of performing [45]. Based on this conceptualization, high levels of fear of falling are believed to lead to reduced falls efficacy, a high (excessive) perceived fall risk, and risk of avoidance behavior [46,47]. In this thesis we focus on the construct fear of falling (FoF): concerns about falling that can lead to avoidance behavior.

Assessment of fear of falling

The 'Falls Efficacy Scale International' (FES-I) is a valid measurement instrument for FoF, which is frequently used in research on this subject [44,48-50]. Additionally, this instrument is recommended in national fall prevention guidelines for evaluation of FoF in daily practice [51]. In contrast to what the name may reflect, this instrument measures *concerns about falling* in relation to seven (short version) or 16 (regular version) social and physical activities inside and outside the home, such as getting (un)dressed, preparing meals, and walking stairs. The level of concerns about falling is measured using a 4-point Likert scale, with response categories '*not at all concerned*', '*somewhat concerned*', '*fairly concerned*' and '*very concerned*'. The FES-I has been validated for patients with hip fracture [52]. In all the studies discussed in this thesis, the FES-I was used to assess and evaluate FoF.

Fear of falling in older adults

In community-dwelling older adults, approximately half of the population has FoF [40,53-55]. This concern about falling is often associated with avoidance or restriction of physical activities. Approximately one-third of the community-dwelling older adults with FoF has fear-related activity restriction. This avoidance behavior can make older adults reluctant to engage in physical activities. Consequently this can result in a diminished balance function, impaired gait, and an increased risk of falling [40]. In community-dwelling older adults FoF has been associated with a (pre)frail status [53]. Depression, anxiety and sarcopenia have been found to be associated with *severe* FoF, or with activity avoidance related to FoF [41,53,54,56,57].

Current state of knowledge on fear of falling following hip fracture

Fear of falling after hip fracture has only been subject to research since two decades, thus the understanding of FoF for this population is still somewhat limited. The etiology and characteristics of FoF following hip fracture may differ from the general population of community-dwelling older adults, as these patients experience a sudden impairment of the physical function as a consequence of an injurious fall. Therefore, findings regarding FoF from the general population of community-dwelling older adults cannot by definition be extrapolated to this population.

Based on literature for patients with hip fracture, various observational studies consistently found that FoF is common [37,38,58]. Prevalence rates of over 60% have been reported for FoF in the early stages of recovery, that is, during the period of inpatient rehabilitation. Additionally, study findings show that FoF is prevalent after discharge home [59,60]. The negative effects of FoF are also evident for this population. Similar to community-dwelling older adults, FoF in this population is associated with reduced physical activity. Moreover, FoF is associated with poor long-term functional recovery after fracture, and patients with FoF have an increased risk of institutionalization [37-39]. Recently FoF has also been identified as a risk factor for hospital readmissions within 90 days after inpatient geriatric rehabilitation [61]. All in all, these findings point toward FoF as an important factor that can hamper the recovery process in patients with recent hip fracture. This emphasizes the need to optimize management of FoF in this population, as also exemplified by the case of Mrs van Dijk.

FEAR OF FALLING IN CLINICAL PRACTICE – MRS VAN DIJK

Five weeks ago Mrs van Dijk sustained a hip fracture as a result of an indoor fall. Currently she is admitted to inpatient geriatric rehabilitation (GR) for the recovery of the fracture. Mrs van Dijk is a 83-year old widower with two children, both living abroad. She lives in a double-story house with bath- and bedroom upstairs. Thus, in order to be able to return home, she has to be able to walk independently indoors, and has to be able to walk up and down the stairs. This is one of the primary goals of her individualized GR program.

In the first three weeks of GR, Mrs van Dijk has an active participation in her rehabilitation therapy. She is somewhat cautious during the physical therapy sessions, but she seems to be able to motivate herself to engage in exercise. There is adequate progress in her recovery process. Although always friendly for the staff, she had an introvert character, and the social interaction with other patients is somewhat limited. Three weeks after admission to GR, the occupational therapist is involved to perform a home visit to evaluate home safety and assess the need for additional aids or adjustments in home. Mrs van Dijk accompanies the occupational therapist during the home visit. Three days after this event she does not show up for the physiotherapy, and in the days hereafter she cancels the therapy sessions. She does not engage in the social activities organized within the GR unit. As the team suspects that Mrs van Dijk may be depressed, the psychologist is involved.

Mrs van Dijk seems discouraged to go home, and is pessimistic about her ability to achieve further recovery. She perceives her current physical disabilities as a natural consequence of aging, and states that she would be better off in a nursing home. The psychologist applies

motivational interviewing techniques, and this leads to the finding that there are some important motives for her to live in her own home. Here-after, she expresses that she is afraid to fall again. Essentially, she is afraid that a next fall may be fatal. The psychologist suspects that it is mainly the FoF that contributes to the current psychological burden. She performs additional diagnostic testing to assess FoF. The FES-I is clearly elevated (score 38 / 64 on the 16-item FES-I), indicative of FoF. Screening for mood and anxiety problems reveals scores just above the cut-off values for these screening instruments (*Hospital Anxiety and Depression Scale*). The GR team questions which treatment is required for Mrs van Dijk's psychological problems, in particular with regard to the fear of falling.

MANAGEMENT OF FEAR OF FALLING

At present there are no clinical guidelines available addressing FoF in patients with hip fracture. However, as illustrated by the case of Mrs van Dijk, there is a need for recommendations for approaches to screening, selection and treatment of FoF in this target group. Important questions regarding the management of FoF include*: 'Which treatment approaches have potential to reduce FoF in patients with a recent hip fracture?*'; '*Which patients benefit from treatment of FoF?*'; and '*What is the natural course of FoF after fracture in the different stages of recovery, and accordingly what is appropriate timing for treatment of FoF?'*

At present there is a considerable knowledge gap regarding FoF after hip fracture. Little is known about the clinical course of FoF after hip fracture, and the available data on this subject is limited by short follow-up. For this population, no standardized treatment programs are available that specifically address the FoF, and studies evaluating FoF interventions lack. Thus it is also unknown which patients may benefit from treatment, and when it is appropriate to provide treatment (timing after fracture).

In contrast, there is a considerable body of evidence on this topic for the general population of community-dwelling older adults [62-71]. In the past two decades various intervention programs have been developed. Group programs are available, as are individual programs (including home-based programs). Interventions vary from programs primarily based on exercise or balance training, specific programs such as tai chi, and programs applying principles based on cognitive behavioral therapy. Programs based on cognitive behavioral approaches in combination with exercise training have shown to been effective to reduce FoF in short- and long term [63,66,72,73]. In the United States, the FoF program '*A Matter of Balance*' proved to be cost-effective to reduce FoF. Based on this program, the Dutch intervention '*Zicht op Evenwicht*' was developed and evaluated, and similarly this program proved to be (cost)effective. This subsequently led to

national implementation of this program, and additionally to development of an individualized home-based program [64,74].

In light of the fact that the Dutch programs are effective and available, we may consider these FoF programs for treatment of FoF in patients with hip fracture. Yet, in order to minimize the negative effect of FoF on the recovery process, it may be appropriate to intervene promptly - in an early stage of rehabilitation. We can question whether these current programs, developed for the general population of community-dwelling older adults, fit the setting of an inpatient rehabilitation setting. Below, we elaborate on this issue. However, for a better understanding of the context of GR, we first describe the custom practice in GR in the Netherlands.

GERIATRIC REHABILITATION SERVICES IN THE NETHERLANDS

In the Netherlands, the average duration of hospital admission after hip fracture is 8.5 days. Hereafter, 55% of patients that are community-dwelling prior to fracture are referred to inpatient geriatric rehabilitation (GR) [75]. Typically, patients that participate in GR programs are characterized by multimorbidity [76]. Compared to patients with a direct discharge home after hip fracture, those referred to GR are older, have poorer pre-fracture ADL function and mobility, and have a higher ASA score at hospital admission (American Society of Anesthesiologists physical status classification), indicative of a poorer physical condition [75].

In the Netherlands GR is typically provided within an inpatient setting in skilled nursing home facilities. Treatment is provided by a multidisciplinary team, led by an elderly care physician, specialized in rehabilitation care for frail older adults. Furthermore, the team consists of nursing staff, a physiotherapist, an occupational therapist and a social worker. Often a dietician, psychologist and on indication a speech therapist are involved too. The general duration of the inpatient GR program after hip fracture is approximately 6 weeks.

Based on the most recent international definition, GR is "*a multidimensional approach of diagnostic and therapeutic interventions, the purpose of which is to optimize functional capacity, promote activity and preserve functional reserve and social participation in older people with disabling impairments*"[12]. In line with this definition, the aim of the Dutch GR program for patients with hip fracture is to improve physical functioning, mobility and self-care in such a manner that the patient will regain independence for basic ADL, and will be self-reliant in the independent living situation (i.e. after discharge home). This implies that the patient is able to walk indoors, and to make a transfer independently, for example standing up from a chair, getting out of bed or using the toilet. During GR the physical therapy is aimed at improving strength of the lower extremity, and

optimizing balance function and gait. Nursing staff assist patients in practicing basic ADL. The elderly care physician attends to issues such as pain management, prevention of complications, fall risk analysis, and management of comorbidity that could potentially influence rehabilitation outcome. Often a comprehensive geriatric assessment (CGA) is performed, which can help identify and timely address factors that have potential to influence or hamper the recovery process, such as social factors (presence of informal care givers), personal factors (motivation), and psychological factors (cognition, mood, anxiety, coping, FoF).

TREATMENT OF FEAR OF FALLING DURING GERIATRIC REHABILITATION

Previous study findings from our research group show that FoF, defined by elevated FES-I levels, is common to patients admitted to GR, specifically those with hip fracture [58,59]. Prompt treatment of FoF may have potential to minimize the risk of avoidance behavior, and consequently help improve physical functioning for this group of patients. However, implementation of the current treatment programs (for community-dwelling older adults) as treatment for FoF during and within GR, raises the following concerns. These programs are not designed to address FoF in patients with a sudden physical impairment as a result of an injurious fall. In line with this, patients in GR participate in an extensive multidisciplinary rehabilitation program. Thus, if such a program is provided as an *additional* treatment in GR, it may not receive appropriate attention. An alternative approach is that a FoF program is integrated in the multidisciplinary GR treatment program. This also offers the opportunity for a multidisciplinary treatment approach to FoF, which could prove to be beneficial [77].

For that reason, we chose to develop and evaluate an intervention for FoF, specifically designed to fit the inpatient GR setting. The afore-mentioned Dutch program '*Zicht op Evenwicht*' [63,64] was adapted into an individualized tailor-made intervention, designed to be integrated in the regular GR treatment program. This led to the development of the *FIT-HIP intervention.*

The effectiveness and the feasibility of the FIT-HIP intervention for clinical practice was subject to further research. This was evaluated in the studies presented in this thesis.

FIT-HIP INTERVENTION

The FIT-HIP intervention is a multi-component cognitive behavioral intervention, aimed at reducing FoF in patients with hip fracture in GR. This individualized treatment program is tailored to the individual needs, preferences and capacities of the participant. The intervention

is essentially conducted by physiotherapists that are part of the multidisciplinary GR team. The intervention consists of various cognitive behavioral elements aimed at reducing FoF, including psycho-education, guided exposure to feared activities, cognitive restructuring, and relapse prevention. Intervention items are integrated in the physical therapy sessions, and combined with the regular exercise training in GR. The guided exposure to mobility-related feared activities is the core element of the intervention. The principles of guided exposure are also applied by the nursing staff, as they are involved in the daily mobilization activities too. Additionally a psychologist - also part of the multidisciplinary GR team - is involved in the intervention and provides additional on-site coaching with regard to the cognitive therapy.

AIM AND OUTLINE OF THIS THESIS

The overall aim of the studies presented in this thesis is to obtain a better understanding of appropriate management for FoF in patients with a recent fracture. For this purpose the following four research questions are addressed:

1] To which extent is the FIT-HIP intervention, a multi-component cognitive behavioral treatment program for FoF, effective in reducing FoF and improving physical function in patients with hip fracture?
2] What is the feasibility of the FIT-HIP intervention provided in inpatient geriatric rehabilitation?
3] Which coping strategies are used by patients with FoF after hip fracture, and how are these associated with pain, mood, anxiety and quality of life?
4] What is the long-term course of FoF after fracture, and what is the effect of pre-fracture FoF on the course after fracture?

The above-mentioned research questions are addressed in various studies, which are presented in this thesis. First, we discuss the FIT-HIP study protocol, which is presented in Chapter 2. This protocol includes an elaborate description of the FIT-HIP intervention, and the study design used to investigate the effectiveness and feasibility of the intervention. In Chapter 3 the effects of the FIT-HIP intervention are evaluated. The effectiveness of the intervention was studied within a cluster randomized controlled trial (cRCT), comparing usual care in GR to the addition of the FIT-HIP intervention to this usual care. FoF was evaluated up to 6 months after discharge from GR. Other outcomes included mobility, ambulation, and self-reported activity restriction. Chapter 4 presents the results of the feasibility study. This observational study was performed alongside the RCT and had a mixed method design, using both quantitative data (questionnaires and logs) and qualitative data (interviews with patients and intervention facilitators). Based on the framework of Saunders et al [78], the following items were addressed to describe the feasibility of the FIT-HIP intervention: 1] recruitment and reach; 2] performance

according to protocol; 3] patients' adherence; and 4] opinions of patients and facilitators on the intervention. In Chapter 5 we explore coping strategies in patients with FoF after hip fracture. This cross-sectional study, using the baseline data of the FIT-HIP trial, described the use of active and passive coping strategies. Additionally, the association was evaluated between the two coping strategies and depression, anxiety, quality of life and pain. Chapter 6 examines the long-term course of FoF after fracture, based on a large inception cohort with follow-up up to 12 months after fracture. We also evaluated the effect of FoF prior to fracture on the course of FoF after fracture. In Chapter 7, the general discussion, the main findings of this thesis, and the implications for clinical practice are discussed in a broader perspective. We also discuss future research perspectives.

REFERENCES

1. Würdemann FS, Voeten SC, Krijnen P, Schipper IB. Variation in treatment of hip fractures and guideline adherence amongst surgeons with different training backgrounds in the Netherlands. Injury 2022;53(3):1122-1130. (In eng). DOI: 10.1016/j.injury.2021.11.006.
2. Dyer SM, Crotty M, Fairhall N, et al. A critical review of the long-term disability outcomes following hip fracture. BMC Geriatr 2016;16(1):158. (In eng). DOI: 10.1186/s12877-016-0332-0.
3. Aarden JJ, van der Esch M, Engelbert RHH, van der Schaaf M, de Rooij SE, Buurman BM. Hip Fractures in Older Patients: Trajectories of Disability after Surgery. J Nutr Health Aging 2017;21(7):837-842. (In eng). DOI: 10.1007/s12603-016-0830-y.
4. Papanicolas I, Figueroa JF, Schoenfeld AJ, et al. Differences in health care spending and utilization among older frail adults in high-income countries: ICCONIC hip fracture persona. Health Serv Res 2021 (In eng). DOI: 10.1111/1475-6773.13739.
5. Veronese N, Maggi S. Epidemiology and social costs of hip fracture. Injury 2018;49(8):1458-1460. (In eng). DOI: 10.1016/j.injury.2018.04.015.
6. Internation Osteoporosis Foundation - Facts and Statistics - Epidemiology of osteoporosis and fragility fractures (https://www.osteoporosis.foundation/facts-statistics/epidemiology-of-osteoporosis-and-fragility-fractures).
7. Kanis JA, Odén A, McCloskey EV, Johansson H, Wahl DA, Cooper C. A systematic review of hip fracture incidence and probability of fracture worldwide. Osteoporos Int 2012;23(9):2239-56. (In eng). DOI: 10.1007/s00198-012-1964-3.
8. Johnell O, Kanis JA. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporos Int 2006;17(12):1726-33. (In eng). DOI: 10.1007/s00198-006-0172-4.
9. Gullberg B, Johnell O, Kanis JA. World-wide projections for hip fracture. Osteoporos Int 1997;7(5):407-13. (In eng). DOI: 10.1007/pl00004148.
10. National Institute for Health and Care Excellence (NICE) Guideline - Hip Fracture: management. (https://www.nice.org.uk/guidance/cg124/chapter/Recommendations#surgical-procedures).
11. Handoll HH, Cameron ID, Mak JC, Panagoda CE, Finnegan TP. Multidisciplinary rehabilitation for older people with hip fractures. Cochrane Database Syst Rev 2021;11:Cd007125. (In eng). DOI: 10.1002/14651858.CD007125.pub3.
12. Grund S, Gordon AL, van Balen R, et al. European consensus on core principles and future priorities for geriatric rehabilitation: consensus statement. Eur Geriatr Med 2020;11(2):233-238. (In eng). DOI: 10.1007/s41999-019-00274-1.
13. Williamson S, Landeiro F, McConnell T, et al. Costs of fragility hip fractures globally: a systematic review and meta-regression analysis. Osteoporos Int 2017;28(10):2791-2800. (In eng). DOI: 10.1007/s00198-017-4153-6.
14. Magaziner J, Hawkes W, Hebel JR, et al. Recovery from hip fracture in eight areas of function. J Gerontol A Biol Sci Med Sci 2000;55(9):M498-507. (In eng). DOI: 10.1093/gerona/55.9.m498.
15. Haleem S, Lutchman L, Mayahi R, Grice JE, Parker MJ. Mortality following hip fracture: trends and geographical variations over the last 40 years. Injury 2008;39(10):1157-63. (In eng). DOI: 10.1016/j.injury.2008.03.022.
16. Katsoulis M, Benetou V, Karapetyan T, et al. Excess mortality after hip fracture in elderly persons from Europe and the USA: the CHANCES project. J Intern Med 2017;281(3):300-310. (In eng). DOI: 10.1111/joim.12586.
17. von Friesendorff M, McGuigan FE, Wizert A, et al. Hip fracture, mortality risk, and cause

of death over two decades. Osteoporos Int 2016;27(10):2945-53. (In eng). DOI: 10.1007/s00198-016-3616-5.

18. Fujita T, Takegami Y, Ando K, et al. Risk factors for second hip fracture in elderly patients: an age, sex, and fracture type matched case-control study. Eur J Orthop Surg Traumatol 2021 (In eng). DOI: 10.1007/s00590-021-02996-0.
19. Sobolev B, Sheehan KJ, Kuramoto L, Guy P. Risk of second hip fracture persists for years after initial trauma. Bone 2015;75:72-6. (In eng). DOI: 10.1016/j.bone.2015.02.003.
20. Kuo LY, Hsu PT, Wu WT, et al. The incidence of mental disorder increases after hip fracture in older people: a nationwide cohort study. BMC Geriatr 2021;21(1):249. (In eng). DOI: 10.1186/s12877-021-02195-w.
21. Jaatinen R, Luukkaala T, Helminen H, Hongisto MT, Viitanen M, Nuotio MS. Prevalence and prognostic significance of depressive symptoms in a geriatric post-hip fracture assessment. Aging Ment Health 2021:1-8. (In eng). DOI: 10.1080/13607863.2021.1998357.
22. Uzoigwe CE, O'Leary L, Nduka J, et al. Factors associated with delirium and cognitive decline following hip fracture surgery. Bone Joint J 2020;102-b(12):1675-1681. (In eng). DOI: 10.1302/0301-620x.102b12.Bjj-2019-1537.R3.
23. Yang Y, Zhao X, Dong T, Yang Z, Zhang Q, Zhang Y. Risk factors for postoperative delirium following hip fracture repair in elderly patients: a systematic review and meta-analysis. Aging Clin Exp Res 2017;29(2):115-126. (In eng). DOI: 10.1007/s40520-016-0541-6.
24. Griffin XL, Parsons N, Achten J, Fernandez M, Costa ML. Recovery of health-related quality of life in a United Kingdom hip fracture population. The Warwick Hip Trauma Evaluation--a prospective cohort study. Bone Joint J 2015;97-b(3):372-82. (In eng). DOI: 10.1302/0301-620x.97b3.35738.
25. Turesson E, Ivarsson K, Thorngren KG, Hommel A. Hip fractures - Treatment and functional outcome. The development over 25 years. Injury 2018;49(12):2209-2215. (In eng). DOI: 10.1016/j.injury.2018.10.010.
26. Abraham DS, Barr E, Ostir GV, et al. Residual Disability, Mortality, and Nursing Home Placement After Hip Fracture Over 2 Decades. Arch Phys Med Rehabil 2019;100(5):874-882. (In eng). DOI: 10.1016/j.apmr.2018.10.008.
27. Flikweert ER, Wendt KW, Diercks RL, et al. A comprehensive multidisciplinary care pathway for hip fractures better outcome than usual care? Injury 2021;52(7):1819-1825. (In eng). DOI: 10.1016/j.injury.2021.04.044.
28. Downey C, Kelly M, Quinlan JF. Changing trends in the mortality rate at 1-year post hip fracture - a systematic review. World J Orthop 2019;10(3):166-175. (In eng). DOI: 10.5312/wjo.v10.i3.166.
29. Xu BY, Yan S, Low LL, Vasanwala FF, Low SG. Predictors of poor functional outcomes and mortality in patients with hip fracture: a systematic review. BMC Musculoskelet Disord 2019;20(1):568. (In eng). DOI: 10.1186/s12891-019-2950-0.
30. van der Sijp MPL, van Eijk M, Niggebrugge AHP, Putter H, Blauw GJ, Achterberg WP. Prognostic Factors for Short-term Recovery of Independence in a Multistate Model for Patients With a Hip Fracture. J Am Med Dir Assoc 2020 (In eng). DOI: 10.1016/j.jamda.2020.08.006.
31. van der Sijp MPL, van Eijk M, Tong WH, et al. Independent factors associated with long-term functional outcomes in patients with a proximal femoral fracture: A systematic review. Exp Gerontol 2020;139:111035. (In eng). DOI: 10.1016/j.exger.2020.111035.
32. Sheehan KJ, Williamson L, Alexander J, et al. Prognostic factors of functional outcome after hip fracture surgery: a systematic review. Age Ageing 2018;47(5):661-670. (In eng). DOI: 10.1093/ageing/afy057.
33. Lim KK, Matchar DB, Chong JL, Yeo W, Howe TS, Koh JSB. Pre-discharge prognostic factors of physical function among older adults with hip fracture surgery: a systematic review.

Osteoporos Int 2019;30(5):929-938. (In eng). DOI: 10.1007/s00198-018-04831-5.

34. Larsson G, Strömberg U, Rogmark C, Nilsdotter A. Cognitive status following a hip fracture and its association with postoperative mortality and activities of daily living: A prospective comparative study of two prehospital emergency care procedures. Int J Orthop Trauma Nurs 2019;35:100705. (In eng). DOI: 10.1016/j.ijotn.2019.07.001.
35. Araiza-Nava B, Méndez-Sánchez L, Clark P, et al. Short- and long-term prognostic factors associated with functional recovery in elderly patients with hip fracture: A systematic review. Osteoporos Int 2022 (In eng). DOI: 10.1007/s00198-022-06346-6.
36. Becker C, Gebhard F, Fleischer S, et al. [Prediction of mortality, mobility and admission to long-term care after hip fractures]. Unfallchirurg 2003;106(1):32-8. (In ger). DOI: 10.1007/s00113-002-0475-7.
37. Visschedijk J, Achterberg W, Van Balen R, Hertogh C. Fear of falling after hip fracture: a systematic review of measurement instruments, prevalence, interventions, and related factors. J Am Geriatr Soc 2010;58(9):1739-48. (In eng). DOI: 10.1111/j.1532-5415.2010.03036.x.
38. Bower ES, Wetherell JL, Petkus AJ, Rawson KS, Lenze EJ. Fear of Falling after Hip Fracture: Prevalence, Course, and Relationship with One-Year Functional Recovery. Am J Geriatr Psychiatry 2016;24(12):1228-1236. (In eng). DOI: 10.1016/j.jagp.2016.08.006.
39. Oude Voshaar RC, Banerjee S, Horan M, et al. Fear of falling more important than pain and depression for functional recovery after surgery for hip fracture in older people. Psychol Med 2006;36(11):1635-45. (In eng). DOI: 10.1017/s0033291706008270.
40. Scheffer AC, Schuurmans MJ, van Dijk N, van der Hooft T, de Rooij SE. Fear of falling: measurement strategy, prevalence, risk factors and consequences among older persons. Age Ageing 2008;37(1):19-24. (In eng). DOI: 10.1093/ageing/afm169.
41. Payette MC, Bélanger C, Léveillé V, Grenier S. Fall-Related Psychological Concerns and Anxiety among Community-Dwelling Older Adults: Systematic Review and Meta-Analysis. PLoS One 2016;11(4):e0152848. (In eng). DOI: 10.1371/journal.pone.0152848.
42. Hughes CC, Kneebone, II, Jones F, Brady B. A theoretical and empirical review of psychological factors associated with falls-related psychological concerns in community-dwelling older people. Int Psychogeriatr 2015;27(7):1071-87. (In eng). DOI: 10.1017/s1041610214002701.
43. Hadjistavropoulos T, Delbaere K, Fitzgerald TD. Reconceptualizing the role of fear of falling and balance confidence in fall risk. J Aging Health 2011;23(1):3-23. (In eng). DOI: 10.1177/0898264310378039.
44. Soh SL, Tan CW, Thomas JI, et al. Falls efficacy: Extending the understanding of self-efficacy in older adults towards managing falls. J Frailty Sarcopenia Falls 2021;6(3):131-138. (In eng). DOI: 10.22540/jfsf-06-131.
45. Tinetti ME, Powell L. Fear of falling and low self-efficacy: a case of dependence in elderly persons. J Gerontol 1993;48 Spec No:35-8. (In eng). DOI: 10.1093/geronj/48.special_issue.35.
46. Adamczewska N, Nyman SR. A New Approach to Fear of Falls From Connections With the Posttraumatic Stress Disorder Literature. Gerontol Geriatr Med 2018;4:2333721418796238. (In eng). DOI: 10.1177/2333721418796238.
47. Lenouvel E, Novak L, Biedermann A, Kressig RW, Klöppel S. Preventive treatment options for fear of falling within the Swiss healthcare system : A position paper. Z Gerontol Geriatr 2021 (In eng). DOI: 10.1007/s00391-021-01957-w.
48. Kempen GI, Yardley L, van Haastregt JC, et al. The Short FES-I: a shortened version of the falls efficacy scale-international to assess fear of falling. Age Ageing 2008;37(1):45-50. (In eng). DOI: 10.1093/ageing/afm157.

49. Hauer K, Yardley L, Beyer N, et al. Validation of the Falls Efficacy Scale and Falls Efficacy Scale International in geriatric patients with and without cognitive impairment: results of self-report and interview-based questionnaires. Gerontology 2010;56(2):190-9. (In eng). DOI: 10.1159/000236027.
50. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age Ageing 2005;34(6):614-9. (In eng). DOI: 10.1093/ageing/afi196.
51. Specialisten RFM. Preventie van valincidenten bij ouderen. (https://richtlijnendatabase.nl/richtlijn/preventie_van_valincidenten_bij_ouderen/startpagina_-_preventie_van_valincidenten.html).
52. Visschedijk JH, Terwee CB, Caljouw MA, Spruit-van Eijk M, van Balen R, Achterberg WP. Reliability and validity of the Falls Efficacy Scale-International after hip fracture in patients aged ≥ 65 years. Disabil Rehabil 2015;37(23):2225-32. (In eng). DOI: 10.3109/09638288.2014.1002573.
53. Merchant RA, Chen MZ, Wong BLL, et al. Relationship Between Fear of Falling, Fear-Related Activity Restriction, Frailty, and Sarcopenia. J Am Geriatr Soc 2020;68(11):2602-2608. (In eng). DOI: 10.1111/jgs.16719.
54. Bahat Öztürk G, Kılıç C, Bozkurt ME, Karan MA. Prevalence and Associates of Fear of Falling among Community-Dwelling Older Adults. J Nutr Health Aging 2021;25(4):433-439. (In eng). DOI: 10.1007/s12603-020-1535-9.
55. Zijlstra GA, van Haastregt JC, van Eijk JT, van Rossum E, Stalenhoef PA, Kempen GI. Prevalence and correlates of fear of falling, and associated avoidance of activity in the general population of community-living older people. Age Ageing 2007;36(3):304-9. (In eng). DOI: 10.1093/ageing/afm021.
56. Esbrí-Víctor M, Huedo-Rodenas I, López-Utiel M, et al. Frailty and Fear of Falling: The FISTAC Study. J Frailty Aging 2017;6(3):136-140. (In eng). DOI: 10.14283/jfa.2017.19.
57. van Haastregt JC, Zijlstra GA, van Rossum E, van Eijk JT, Kempen GI. Feelings of anxiety and symptoms of depression in community-living older persons who avoid activity for fear of falling. Am J Geriatr Psychiatry 2008;16(3):186-93. (In eng). DOI: 10.1097/JGP.0b013e3181591c1e.
58. Visschedijk J, van Balen R, Hertogh C, Achterberg W. Fear of falling in patients with hip fractures: prevalence and related psychological factors. J Am Med Dir Assoc 2013;14(3):218-20. (In eng). DOI: 10.1016/j.jamda.2012.10.013.
59. Visschedijk JH, Caljouw MA, Bakkers E, van Balen R, Achterberg WP. Longitudinal follow-up study on fear of falling during and after rehabilitation in skilled nursing facilities. BMC Geriatr 2015;15:161. (In eng). DOI: 10.1186/s12877-015-0158-1.
60. Benzinger P, Rixt Zijlstra GA, Lindemann U, et al. Depressive symptoms and fear of falling in previously community-dwelling older persons recovering from proximal femoral fracture. Aging Clin Exp Res 2011;23(5-6):450-6. (In eng). DOI: 10.1007/bf03325241.
61. Wan CS, Reijnierse EM, Maier AB. Risk factors of readmissions in geriatric rehabilitation patients: RESORT. Arch Phys Med Rehabil 2021 (In eng). DOI: 10.1016/j.apmr.2021.01.082.
62. Tennstedt S, Howland J, Lachman M, Peterson E, Kasten L, Jette A. A randomized, controlled trial of a group intervention to reduce fear of falling and associated activity restriction in older adults. J Gerontol B Psychol Sci Soc Sci 1998;53(6):P384-92. (In eng). DOI: 10.1093/geronb/53b.6.p384.
63. Zijlstra GA, van Haastregt JC, Ambergen T, et al. Effects of a multicomponent cognitive behavioral group intervention on fear of falling and activity avoidance in community-dwelling older adults: results of a randomized controlled trial. J Am Geriatr Soc 2009;57(11):2020-8. (In eng). DOI: 10.1111/j.1532-5415.2009.02489.x.
64. Dorresteijn TA, Zijlstra GA, Ambergen AW, Delbaere K, Vlaeyen JW, Kempen GI.

Effectiveness of a home-based cognitive behavioral program to manage concerns about falls in community-dwelling, frail older people: results of a randomized controlled trial. BMC Geriatr 2016;16:2. (In eng). DOI: 10.1186/s12877-015-0177-y.

65. Parry SW, Bamford C, Deary V, et al. Cognitive-behavioural therapy-based intervention to reduce fear of falling in older people: therapy development and randomised controlled trial - the Strategies for Increasing Independence, Confidence and Energy (STRIDE) study. Health Technol Assess 2016;20(56):1-206. (In eng). DOI: 10.3310/hta20560.
66. Liu TW, Ng GYF, Chung RCK, Ng SSM. Cognitive behavioural therapy for fear of falling and balance among older people: a systematic review and meta-analysis. Age Ageing 2018;47(4):520-527. (In eng). DOI: 10.1093/ageing/afy010.
67. Kendrick D, Kumar A, Carpenter H, et al. Exercise for reducing fear of falling in older people living in the community. Cochrane Database Syst Rev 2014;2014(11):Cd009848. (In eng). DOI: 10.1002/14651858.CD009848.pub2.
68. Kumar A, Delbaere K, Zijlstra GA, et al. Exercise for reducing fear of falling in older people living in the community: Cochrane systematic review and meta-analysis. Age Ageing 2016;45(3):345-52. (In eng). DOI: 10.1093/ageing/afw036.
69. Kruisbrink M, Crutzen R, Kempen G, et al. Disentangling interventions to reduce fear of falling in community-dwelling older people: a systematic review and meta-analysis of intervention components. Disabil Rehabil 2021:1-11. (In eng). DOI: 10.1080/09638288.2021.1969452.
70. Wetherell JL, Johnson K, Chang D, et al. Activity, balance, learning, and exposure (ABLE): a new intervention for fear of falling. Int J Geriatr Psychiatry 2016;31(7):791-8. (In eng). DOI: 10.1002/gps.4393.
71. Wetherell JL, Bower ES, Johnson K, Chang DG, Ward SR, Petkus AJ. Integrated Exposure Therapy and Exercise Reduces Fear of Falling and Avoidance in Older Adults: A Randomized Pilot Study. Am J Geriatr Psychiatry 2018;26(8):849-859. (In eng). DOI: 10.1016/j.jagp.2018.04.001.
72. Chua CHM, Jiang Y, Lim S, Wu VX, Wang W. Effectiveness of cognitive behaviour therapy-based multicomponent interventions on fear of falling among community-dwelling older adults: A systematic review and meta-analysis. J Adv Nurs 2019;75(12):3299-3315. (In eng). DOI: 10.1111/jan.14150.
73. Huang TT, Chung ML, Chen FR, Chin YF, Wang BH. Evaluation of a combined cognitive-behavioural and exercise intervention to manage fear of falling among elderly residents in nursing homes. Aging Ment Health 2016;20(1):2-12. (In eng). DOI: 10.1080/13607863.2015.1020411.
74. Zijlstra GA, van Haastregt JC, Du Moulin MF, de Jonge MC, van der Poel A, Kempen GI. Effects of the implementation of an evidence-based program to manage concerns about falls in older adults. Gerontologist 2013;53(5):839-49. (In eng). DOI: 10.1093/geront/gns142.
75. van Dartel D, Vermeer M, Folbert EC, Arends AJ, Vollenbroek-Hutten MMR, Hegeman JH. Early Predictors for Discharge to Geriatric Rehabilitation after Hip Fracture Treatment of Older Patients. J Am Med Dir Assoc 2021 (In eng). DOI: 10.1016/j.jamda.2021.03.026.
76. Achterberg WP, Cameron ID, Bauer JM, Schols JM. Geriatric Rehabilitation-State of the Art and Future Priorities. J Am Med Dir Assoc 2019;20(4):396-398. (In eng). DOI: 10.1016/j.jamda.2019.02.014.
77. Robinson JB, Wetherell JL. An Interdisciplinary Intervention for Fear of Falling: Lessons Learned from Two Case Studies. Clin Gerontol 2018;41(4):366-373. (In eng). DOI: 10.1080/07317115.2017.1325423.
78. Saunders RP, Evans MH, Joshi P. Developing a process-evaluation plan for assessing

health promotion program implementation: a how-to guide. Health Promot Pract 2005;6(2):134-47. (In eng). DOI: 10.1177/1524839904273387.

Chapter 2

A multi-component cognitive behavioural intervention for the treatment of fear of falling after hip fracture (FIT-HIP): protocol of a randomised controlled trial.

Scheffers-Barnhoorn MN, van Haastregt JC, Schols JM, Kempen GI, van Balen R, Visschedijk JH, van den Hout WB, Dumas EM, Achterberg WP, van Eijk M.

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ABSTRACT

Background

Hip fracture is a common injury in the geriatric population. Despite surgical repair and subsequent rehabilitation programmes, functional recovery is often limited, particularly in individuals with multi-morbidity. This leads to high care dependency and subsequent use of healthcare services. Fear of falling has a negative influence on recovery after hip fracture, due to avoidance of activity and subsequent restriction in mobility. Although fear of falling is highly prevalent after hip fracture, no structured treatment programme is currently available. This trial will evaluate whether targeted treatment of fear of falling in geriatric rehabilitation after hip fracture using a multi-component cognitive behavioural intervention (FIT-HIP), is feasible and (cost) effective in reducing fear of falling and associated activity restriction and thereby improves physical functioning.

Methods/design

This multicentre cluster randomised controlled trial will be conducted among older patients with hip fracture and fear of falling who are admitted to a multidisciplinary inpatient geriatric rehabilitation programme in eleven post-acute geriatric rehabilitation units. Fifteen participants will be recruited from each site. Recruitment sites will be allocated by computer randomisation to either the control group, receiving usual care, or to the intervention group receiving the FIT-HIP intervention in addition to usual care. The FIT-HIP intervention is conducted by physiotherapists and will be embedded in usual care. It consists of various elements of cognitive behavioural therapy, including guided exposure to feared activities (that are avoided by the participants). Participants and outcome assessors are blinded to group allocation. Follow-up measurements will be performed at three and six months after discharge from geriatric rehabilitation. (Cost)-effectiveness and feasibility of the intervention will be evaluated. Primary outcome measures are fear of falling and mobility.

Discussion

Targeted treatment of fear of falling may improve recovery and physical and social functioning after hip fracture, thereby offering benefits for patients and reducing healthcare costs. Results of this study will provide insight into whether fear of falling is modifiable in the (geriatric) rehabilitation after hip fracture and whether the intervention is feasible.

Trial registration

Netherlands Trial Register: NTR 5695.

Keywords

Fear of falling, Hip fracture, Geriatric Rehabilitation, Randomised controlled trial, Cognitive behavioural therapy

BACKGROUND

Global healthcare is challenged by an ageing population. The number of people aged ≥60 years is expected to increase from 900 million in 2015 up to 2 billion in 2050 worldwide (i.e. 12% and 22%, respectively, of the population). For the oldest old (aged ≥80 years), the calculated trend is an increase from 120 million in 2015 up to 434 million in 2050[1]. Despite the diversity of experienced health in older age, many older adults often face numerous health conditions affecting their physical and mental capacity, independence, autonomy and overall well-being and quality of life. At present there is no evidence that the current generation of older adults is in better health in their older years compared with the previous generation.[2] Due to the relative increase of elderly in the global population, medical and formal care consumption is increasing, placing a burden on healthcare systems and caregivers worldwide. Therefore, healthcare strategies should be aimed at optimising the older adult's functional ability and supporting their independence.

Falls and fall-related injuries, specifically hip fractures, are a major health problem for older adults, threatening physical and functional ability.[3-5] Annually 1.6 million older adults worldwide sustain a hip fracture and this number is expected to reach 4.5 million in 2050.[2] A hip fracture in older adults is associated with poor functional outcome, with a 1-year mortality rate of approximately 30%.[3,4,6,7] Despite surgery and subsequent rehabilitation programmes, many older hip fracture patients experience permanent functional disability as a result of the fracture, with only 40-60% recovering to their pre-fracture level of mobility within 1 year after fracture. Six months after a fracture, about 42-71% have regained their pre-fracture level of functioning in basic activities in daily living (ADL).[3-5,8] Approximately 10-20% are unable to return to their prior residence.[5] The degree of disability may be even greater for frail older adults in need of extensive rehabilitation within an inpatient setting. Therefore, interventions aimed at optimising functional recovery after hip fracture and decreasing future fall risk are important to improve outcome for individual patients, and to reduce the burden on (in)formal care and therefore society.

Social demographic factors (age, gender), pre-fracture physical condition and functioning (walking ability, level of independence in ADL, co-morbidity, hand grip strength), psychological factors (cognitive functioning, depression, fear of falling), pain and anaemia influence functional outcome after hip fracture.[4,9-12] However, only a few of these factors are potentially modifiable and thus eligible to be targeted in an intervention strategy to improve functional outcome. In this context, fear of falling is of specific interest as it has an even greater impact on recovery after hip fracture than does cognitive state, depressive symptoms, or level of perceived pain.[11] In addition, fear of falling is important as it is highly prevalent in both community-dwelling older adults (54%) [13,14] and in patients who have sustained a hip fracture (50-65%).[15,16]

Fear of falling is defined by Tinetti et al. as: '*a lasting concern about falling that leads to an individual avoiding activities that he/she remains capable of performing*'.[17] Consequences of fear of falling (and activity avoidance due to fear of falling) are increased risk of falls, decreased mobility/balance performance, loss of independence, lower social participation, and lower health-related quality of life.[13,18] Therefore, it not only affects physical functioning, but also psychosocial functioning. Specifically, after a hip fracture, fear of falling is associated with a reduction in time spent on exercise during rehabilitation[15] which, in turn, impedes functional performance.

In the Netherlands, about 25-30% of elderly hip fracture patients receive inpatient multidisciplinary rehabilitation care following surgery, due to the acute decrease in their physical functioning and associated dependency in ADL. This vulnerable patient group is discharged from hospital to 'geriatric rehabilitation' (GR), a multidisciplinary inpatient rehabilitation programme within post-acute GR units in nursing homes. The rehabilitation programme, which is led by an elderly care physician, includes physical - and occupational therapy, and treatment of comorbidities. In GR, fear of falling is highly prevalent among patients with hip fracture (63%).[16]

Targeted treatment of fear of falling during rehabilitation after hip fracture could lead to reduction of fear of falling and the associated activity restriction and, therefore, to improved mobilisation, functional recovery and a higher level of independence. To our knowledge, no treatment programmes are currently available for the treatment of fear of falling among this specific patient population.[15,19] However, several programmes are available for the treatment of fear of falling for community-dwelling older adults. For example, the Netherlands has an adapted Dutch version of '*A Matter of Balance*'.[20,21] This multicomponent cognitive behavioural group programme has proven cost-effective in treating fear of falling and has been implemented nationally.[22,23,24] Recently a home-based version of 'A Matter of Balance' was developed and this latter programme also proved (cost)effective in reducing fear of falling and associated activity restriction, disability and indoor falls.[25, 26]

Partially based on the Dutch version of 'A Matter of Balance', and specifically developed for the multidisciplinary GR setting, the multi-component cognitive behavioural FIT-HIP intervention has been developed. It is directed at reducing fear of falling and the associated avoidance of activities and increasing self-efficacy and daily functioning among hip fracture patients admitted to GR. This multicentre cluster randomised controlled trial (RCT) will examine whether the FIT-HIP intervention is feasible and (cost)effective in reducing fear of falling and, therefore, improving functional outcome in hip fracture patients in GR. In addition, it will assess whether the intervention is feasible for patients and healthcare professionals.

Primary objective

In hip fracture patients admitted to multidisciplinary inpatient GR, to compare the effect of the FIT-HIP intervention with usual care in GR, with respect to reducing fear of falling (measured with the Falls Efficacy Scale-International) and improving gait and balance (measured with the Performance-Oriented Mobility Assessment).

Secondary objectives

- To compare the effect of the FIT-HIP intervention with usual care with respect to improving the degree of independence in ADL (Barthel index), ambulation ability (Functional Ambulation Categories) and walking speed.
- To compare the number of fall incidents, mortality, hospital (re)admission and psychosocial functioning (social participation after discharge from GR, measured by the Utrecht Scale for Evaluation of Rehabilitation-subscale Participation; and quality of life, measured by the EuroQol 5D) between the FIT-HIP intervention and usual care.
- To examine the feasibility of the FIT-HIP intervention for participants and therapists conducting the FIT-HIP intervention.
- To perform an economic evaluation, consisting of a cost analysis and cost-utility analysis, comparing the FIT-HIP intervention with usual care. Costs will be measured from a healthcare perspective.

METHODS/DESIGN

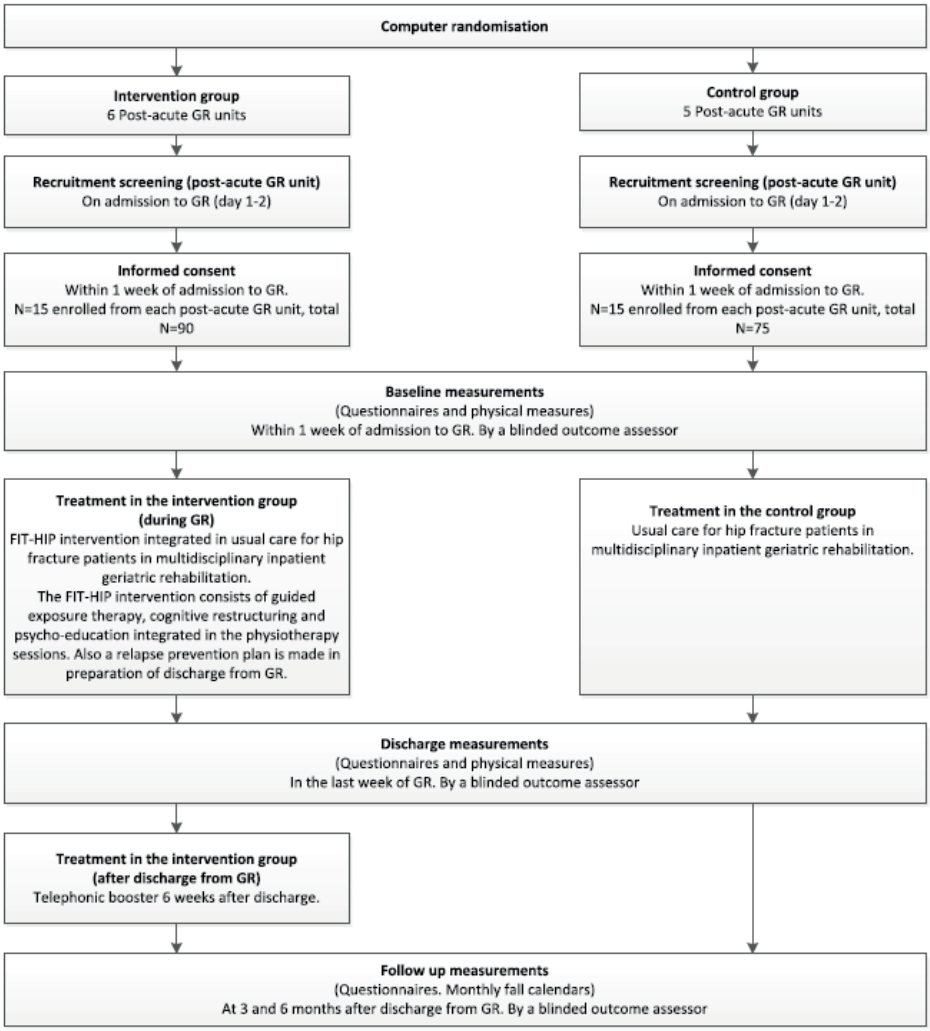
Study design

This multicentre cluster RCT will be conducted among 165 patients with hip fracture and fear of falling, who are admitted to a multidisciplinary inpatient GR programme in post-acute GR units in Dutch nursing homes. For these hip fracture patients in GR, this RCT compares usual care (control group) with an intervention group that includes the addition of the FIT-HIP intervention to the usual care. The FIT-HIP intervention is aimed at reducing fear of falling. Figure 1 presents an overview of the study design. Simultaneously, a process evaluation will be performed to assess the feasibility of the programme.

This study protocol was approved by the Ethics Committee of the Leiden University Medical Center (9 September 2015; P15.212). In addition, the Board of Directors and (if applicable) the research committees of the participating recruitment sites (post-acute GR units of nursing homes) provided consent to participate in the FIT-HIP intervention study.

Prior to baseline assessments and to starting the FIT-HIP treatment (in the intervention group), written consent will be obtained from participants.

Figure 1. Procedures of the FIT-HIP clustered randomised controlled trial.



GR=geriatric rehabilitation (multidisciplinary inpatient rehabilitation programme)

Setting

The department of Public Health and Primary Care (PHEG) of the Leiden University Medical Center will coordinate the FIT-HIP study. Eleven post-acute GR units from nursing homes in the province South Holland are included in this study, most of which work in close collaboration with the PHEG through the University Network for the Care-sector South Holland (UNC-ZH). Annually, the eligible post-acute GR units each have ≥50 patients admitted for GR after orthopaedic events (e.g. trauma, elective surgery or amputation).

Participants (and eligibility criteria)

Study participants are patients aged ≥65 years, admitted to one of the 11 participating post-acute GR units for a geriatric rehabilitation programme following surgical repair of a hip fracture, and concerned to fall. Fear of falling is assessed within the first week of admission to GR, using the 1-item fear of falling question ('*Are you concerned to fall?*'). This question has five answer categories (*never – almost never – sometimes – often – very often*). Patients are eligible to participate if they answer this question with *'sometimes, often, or very often'*

An exclusion criterion for this trial is any condition interfering with learnability, e.g. a diagnosis of dementia, major psychiatric disease, or a score of > 1 on the Hetero-anamnesis List Cognition (HAC)[28]. The HAC is derived from the Mini Mental State Examination (MMSE) and is used to explore the presence of premorbid cognitive disabilities. A relative/informal caregiver is asked if there were problems concerning orientation, language, memory, planning and execution of activities, and to which degree the patient needed assistance or professional therapy for these problems. A score of > 1 is suggestive for premorbid cognitive problems. Other exclusion criteria for this trial are a limited life expectancy (< 3 months), the presence of a pathological hip fracture, a pre-fracture Barthel index score of < 15, and insufficient mastery of the Dutch language.

Randomisation (and allocation)

Of the 11 post-acute GR units, six will be randomly allocated by computer-generated randomisation to conduct the FIT-HIP intervention and five are allocated to the control group (usual care). Hip fracture patients will be screened for eligibility for the FIT-HIP study on admission to these post-acute GR units. For this trial, each post-acute GR unit will include a maximum of 15 participants (in order of succession in which patients are admitted to GR, eligible, and willing to participate). Participants will receive treatment (usual care, or the addition of FIT-HIP intervention to usual care) according to the randomisation of the post-acute GR unit to which they are admitted.

Usual care (control group)

Usual care consists of an inpatient multidisciplinary rehabilitation programme (GR) for patients with a hip fracture. This rehabilitation programme is led by an elderly care physician. It comprises physical therapy sessions focussing on balance and gait exercises, and improving muscle strength. The nursing staff and an occupational therapist are also involved in coaching patients in performing ADL, e.g. going to the toilet, and self-care. Each participating post-acute GR unit employs a care-pathway GR, containing formalised agreements on the contents of the multidisciplinary rehabilitation process, such as therapy intensity and assessments during rehabilitation. In general, a patient will receive 5-6 sessions of physiotherapy week.

The FIT-HIP intervention

The FIT-HIP intervention is a multi-component cognitive behavioural intervention aimed at reducing fear of falling in hip fracture patients in GR. It is an individualised treatment programme, tailored to the individual needs, preferences and capacities of the participant. It is coordinated and primarily conducted by physiotherapists. The programme is combined with regular exercise training during the physiotherapy sessions in GR (usual care). The physiotherapists are part of the multidisciplinary GR healthcare team of the participating post-acute GR unit and have experience in the field of (orthopaedic) rehabilitation of frail older adults. Prior to participant recruitment, two physiotherapists per intervention post-acute GR unit will be trained to conduct the FIT-HIP intervention. Also, for each intervention post-acute GR unit, one psychologist (who is part of healthcare team concerned), will be briefed on the intervention and will participate in part of the training.

The psychologists are trained to function as a coach for the physiotherapists, assisting them with cognitive restructuring when they need advice on this subject. If required, they also assist in the additional treatment of participants, e.g. for more complex psychiatric problems such as generalised anxiety disorder or post-traumatic stress disorder (in the event that this only became apparent during admission and could not have been considered an exclusion criterion).

All elements of the FIT-HIP intervention are described in more detail below. The guided exposure to mobility- related activities is the core element of the intervention and is also applied by the nursing staff in the process of mobilisation during GR. The nursing staff was trained in the concepts of guided exposure and instructed how to administer this. The treatment plan for the mobilisation process (guided exposure) is made by the physiotherapists. Based on the existing communication procedures for each post-acute GR unit, communication protocols will be drafted on how the physiotherapists keep the nursing staff updated on the current status of treatment plans for the individual participants.

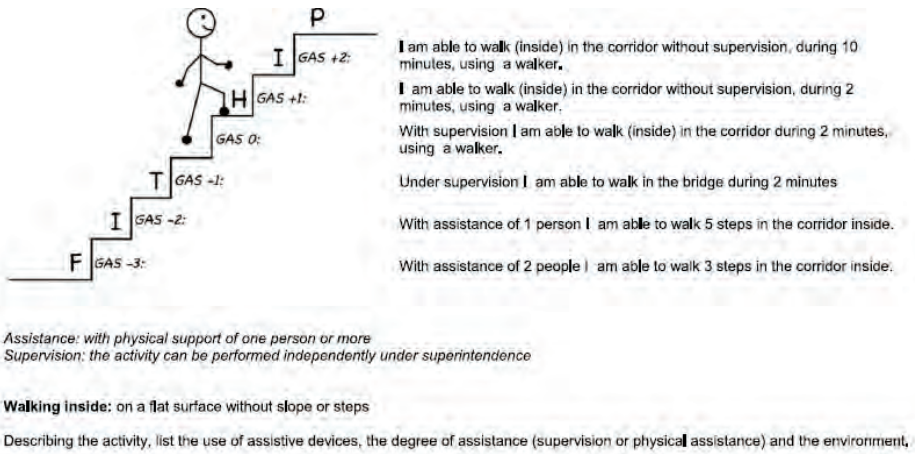
Guided exposure

Guided exposure to the situations that participants fear is the core element of the FIT-HIP intervention. In the case of fear of falling, the feared situation will be a form of activity and therefore the exposure to that situation will be practical training of an activity. These fearful situations are assessed for each patient individually during the intake to GR. In rehabilitation after hip fracture the feared situations may be basic (but fundamental) for the mobilisation process and performing ADL. Examples of assessed situations are: standing, transfer (from bed to chair and vice versa), toilet use, walking inside/outside, and staircase walking. In the intervention, it is also important to focus on participation activities. Therefore, the physiotherapist also assesses which (more complex) activities in daily living the participant considers important or

desirable to able to perform, and which of these may lead to fear of falling, e.g. cycling or using public transport.

For each of these feared situations, guided exposure will be conducted by means of a separate fear hierarchy. In the FIT-HIP intervention the fear hierarchy is represented in a 'fear ladder'. Each 'fear ladder' contains six steps, each step representing a goal. Goals for exposure are ranked according to the intensity of fear of falling it gives rise to, and edited in such a manner that there is an increasing intensity of concern/fear. Goals are formulated in accordance with the Goal Attainment Scaling (GAS) method.[29,30] The GAS is a technique for developing individualised, scaled descriptions of treatment goals. It is a method to evaluate the (rehabilitation) therapy. Goals are formulated in a SMART manner (specific, measurable, acceptable, realistic and defined in time), in collaboration with the patient in order to relate to the personal interests and social environment of the patient. The goals are scaled from -3 to +2, with -3 being deterioration in function, -2 the starting point (current situation when starting the therapy) and 0 being the primary goal. At -1 there is improvement in function but the primary goal in not yet achieved, and at +1 and +2 the function is better than the primary goal. All treatment goals are formulated as functional goals of improvement of mobility. They are not formulated as goals to (primarily) decrease fear. The fear ladders are evaluated with the participant every week and adjusted if necessary. Figure 2 is an example of a FIT-HIP fear ladder.

Figure 2. Example of a FIT-HIP fear ladder (*walking inside*)



The fear ladders are incorporated in the individual FIT-HIP therapy plan. This therapy plan forms a guiding principle for applying the guided exposure in the process of mobilisation. The exposure takes place gradually, with increasing intensity, in a predictable and controllable manner, and under supervision of the physiotherapist. Due to this repeated graded exposure to the

feared situation, the fear is expected to initially increase in the presence of the physiotherapist, but to lessen and gradually fade out during the experience of the activity. Guided exposure will be performed during each physiotherapy session during GR (combined with other physical exercises, such as strength/balance). Participants are also encouraged to practise exposure outside of the therapy sessions (homework). The nursing staff will have a supporting function in this process. The nursing staff is regularly briefed by the physiotherapist to engage in the current principles of the guided exposure for the individual patient.

Cognitive restructuring

This is based on the principles of cognitive behavioural therapy whereby the combination of applied behaviour and effectively recognising and managing negative/unrealistic thoughts and learning to apply realistic thoughts are the key components. Physiotherapists are trained to apply these principles during the therapy sessions. Also, at least once during the rehabilitation, a worksheet is filled in to structure this process (describing the event, thoughts, feeling, behaviour, consequence) and helping the participant to formulate realistic thoughts. The patient learns to examine his/her thoughts and beliefs, and the effect this has on behaviour and feeling (anxiety). This principle is also incorporated in the relapse prevention plan.

Psycho-education

During the initial phase of rehabilitation, shortly after admission to GR, information is given to the participant on anxiety, fear of falling, consequences of fear of falling and self-help possibilities. The rationale and background of guided exposure will be explained. Also, the influence of thoughts/beliefs on emotion and behaviour will be explained (background of the cognitive restructuring).

In the final phase of rehabilitation, when a patient is in preparation of discharge (home), the psycho-education will focus on home safety. This will be processed in the relapse prevention plan.

Relapse prevention plan

In preparation of discharge from GR to the home situation, a relapse prevention plan for fear of falling will be made. The purpose of this plan is to assess situations/circumstances (in the home situation) in which the patient is at risk of a relapse. By means of this plan, the physiotherapist prepares the participant to anticipate these situations and to prevent falling back into old habits in potential fearful situations.

The relapse prevention plan will be worked out and given to the patient as a '*Staying Active Plan*'. It consists of three elements: 1) General home safety and fall prevention. 2) Individual advice for safe ambulation and staying active. Individual advice for use of walking aids/assistance is given,

with precautions if necessary. Also, two individualised physical exercises are described that are recommended for the patient to stay active and in condition in the home situation. Also, if necessary with precautions. The therapist will also discuss that it can be useful to have a buddy to do these exercises with, and who that may be for the patient. 3) (Preventing) a relapse. Information is given about preventing and recognising a relapse, and advice as to what is helpful when a relapse occurs.

Telephonic booster

Six weeks after discharge from GR the physiotherapist conducts a telephonic booster intervention. The purpose of this booster is to evaluate the fear of falling in the first weeks after discharge, discuss difficulties concerning fear of falling and activity restriction, discuss the use of the relapse prevention plan and, if necessary, give new advice for dealing with or preventing fear of falling.

Motivational interviewing

Physiotherapists will also be trained to use motivational interviewing techniques for the guidance of their patients. Motivational interviewing is a client-centred, goal-oriented counselling technique that is used to explore and reinforce the patient's internal motivation for behavioural change. By exploring and resolving ambivalence, it aims at evoking behavioural change.[31] In the FIT-HIP intervention, the motivational interviewing techniques can assist the physiotherapist to explore which (rehabilitation) goals are important for the individual participant, in order to personalise the treatment goals.

Duration of the FIT-HIP intervention

The FIT-HIP intervention, integrated in the usual care, will be conducted during the entire period that the participant is admitted to GR. The duration of the inpatient GR is determined for each participant individually, and is therefore variable. On average, the duration of admission to GR for rehabilitation after hip fracture is 6 weeks. During the trial, the following are registered: i) total duration of GR in days, ii) number of therapy sessions during GR, iii) duration of therapy sessions, and iv) (in the intervention group) performance of the individual components of the FIT-HIP intervention; all these elements can be used as confounding variables in the final outcome analyses.

Blinding

Both the participants and the independent research assistants assessing the outcome measurements are blinded to the group allocation. They are not aware of what usual care is/should be and what the addition of the FIT-HIP intervention is. Healthcare professionals working at the recruitment sites are aware of the allocation status, as the intervention group has been specifically trained to perform the intervention. They are instructed not to inform the participants,

family members and the research assistants assessing outcome measures about the allocation status. The main researcher (MSB) was involved in providing the training for the intervention and therefore cannot be blinded in the initial phase of this trial. For data analysis, the database will be processed to blind data to the initial allocation.

To warrant the blinding of participants in the control group (who receive usual care with possibly no specific treatment for or notice of the fear of falling) a dummy intervention is given in both the control and intervention group. The dummy intervention is an information brochure containing information about fear of falling, its consequences, and possibilities for seeking medical attention or help for this problem. This is regarded as an appropriate dummy intervention, as healthcare strategies directed at reducing risk of falling in older adults that use educational interventions alone, have not proven effective[27]. Therefore, we do not expect this information brochure to have a significant effect on the fear of falling.

Effect evaluation

Primary outcome

1. Mean difference in the Tinetti Performance Oriented Mobility Assessment (POMA) score[32,33] at discharge from GR (or at a maximum of 3 months after admittance to GR), compared between FIT-HIP intervention and usual care. The POMA is a measure of mobility function (gait and balance).

2. Mean difference in the Falls Efficacy Scale International (FES-I) score[34-36] at discharge from GR (or at a maximum of 3 months after admittance to GR), compared between FIT-HIP intervention and usual care. The FES-I is a measure of fear of falling.

Secondary outcomes

Table 1 gives an overview of the secondary outcome measures in the effect evaluation. For these outcome measures, at discharge from GR, mean differences between the intervention and control group will be assessed.

Additional variables

Table 2 gives an overview of the additional variables assessed in this trial.

Process evaluation

To determine the feasibility of the FIT-HIP intervention, a process evaluation will be conducted in accordance with the theory of Saunders et al.[51] Using a mixed-method approach, information about reach, fidelity, exposure, satisfaction and barriers for applying the programme will be assessed. Table 3 gives an overview of the measurement instruments used to collect these data.

Table 1. Secondary outcome measures in the FIT-HIP trial

Domain	Assessment	Description	Time point(s)
Physical functioning and activity	Barthel index[37]	Activities in daily living. Measures (in)dependence in personal care (eating, dressing, bathing, going to the toilet) and mobility.	BA, DA, FU1, FU2
	Functional ambulation categories[38]	Evaluates ambulation ability, describing the degree of human support the person needs when walking.	BA, DA, FU1, FU2
	10-meter walk test[39,40]	Assesses walking function/speed.	BA, DA
	Activity restriction due to fear of falling	Assessed in questionnaire, asking if participant has experienced restriction of activity due to the fear of falling.	BA, DA, FU1, FU2
Falls, complications and health care service usage	Falls (and fall-related injury)	Number of fall incidents and medical attention required as a result of the fall. Assessed using monthly fall calendars.	BA, DA, FU1, FU2
	Complications during GR	Number and type of complication occurring during GR. Assessed by elderly care physician (ECP) in monthly calendars.	Until discharge from GR
	Hospital (re) admission	Number of hospital readmissions and days in hospital. Assessed by ECP in monthly calendars during GR and questionnaire at discharge from GR. Assessed by participants using questionnaire in FU.	DA FU1, FU2
	Mortality		DA, FU1, FU2
	Healthcare consumption after discharge	Number of contacts with health and community services. Assessed by participants using questionnaire in FU.	FU1, FU2
Other outcome characteristics of GR	Duration of admission to GR	Number of days admitted to GR. Assessed by ECP (questionnaire).	DA
	Total amount of therapy in GR	Number of hours of physiotherapy and of contact with ECP. Assessed by physiotherapists in weekly calendars and by ECP in monthly calendars.	Until discharge from GR
	Discharge location	Location of the residence to which participant is discharged after GR. Assessed by ECP (questionnaire).	DA
Health-related quality of life	EuroQol 5D (EQ5D)[41]	The three-level EuroQol 5D (EQ-5D) is a standardised instrument for measuring generic health status. It can be used for calculating quality adjusted life years (QALYs), for the economic evaluation.	BA, DA, FU1, FU2
Participation	The Utrecht Scale for the Evaluation of Rehabilitation-Participation. (USER-P)[42]	Assesses (limitations in) participation in relation to health problems.	BA, FU1, FU2

BA=Baseline assessment (pre-intervention); DA=Discharge assessment (post-intervention); FU1= Follow-up 1 assessments, 3 months after discharge from GR; FU2=Follow-up 2 assessments, 6 months after discharge from GR. ECP=elderly care physician. GR=geriatric rehabilitation (multi-disciplinary inpatient rehabilitation programme). EQ-5D=EuroQol 5D. USER-P=Utrecht Scale for the Evaluation of Rehabilitation - Participation.

Table 2. Additional variables assessed in the FIT-HIP trial

Domain	Assessment	Description	Time point(s)
Socio-demographics	Age, gender, marital status, type of residence prior to hip fracture		BA
General health and physical functioning	Functional comorbidity index (weighed) [43]	Assesses 18 comorbid conditions and their effect on physical functioning.	BA
	Medication use	Number and type of medication used by participants. Assessed by ECP (questionnaire).	BA, DA
	Assistive walking device	Type of assistive walking aid, used for indoor and outdoor usage. Assessed by questionnaire.	BA
	Use of formal care (home care) and informal care (given by relatives/ volunteers)	Assessed by questionnaire.	BA, FU1, FU2
	Previous fall frequency	Number of falls in 6 months prior to hip fracture.	BA
	Handheld grip strength	Evaluated with dynamometer.	BA
	Nutritional status: Body Mass Index	Calculated by dividing bodyweight in kilograms by length in meters squared.	BA, DA
	Numeric Pain Rating Scale (NPRS)[44]	Assesses intensity of pain on an 11-point scale (0-10).	BA, DA, FU1, FU2
Hip fracture (related) characteristics	Type of fracture, operation, weight-bearing capacity	Assessed by ECP (questionnaire).	BA
	Duration of hospital admission due to hip fracture	Number of days in hospital.	BA
	Complications during hospital admission due to hip fracture	Number and type of complications. Assessed by ECP (questionnaire).	BA
Neuropsychological factors	Mini Mental State Examination (MMSE) [45,46]	Screens for cognitive disorders and dementia	BA
	Geriatric Depression Scale, 8-item (GDS-8)[47]	Short adapted version of the GDS-30. Developed to screen depression in nursing home population.	BA
	Hospital anxiety and depression scale – subscale anxiety (HADS-A)[48]	Screens for anxiety.	BA
	Utrecht Coping List; subscales active and passive coping. (UCL)[49]	Assesses coping mechanism. Questionnaire assesses how a person deals with problematic situations in general.	BA
	Pittsburgh Rehabilitation Participation Scale [50]	Participation/ motivation for physiotherapy (PT) during GR.	During every session of PT until discharge

BA=Baseline assessment (pre-intervention); DA=Discharge assessment (post-intervention); FU1=Follow-up 1 assessment, 3 months after discharge from GR; FU2=Follow-up 2 assessment, 6 months after discharge from GR. ECP=elderly care physician. NPRS=Numeric Pain Rating Scale; MMSE=Mini Mental State Examination. GDS-8=Geriatric Depression Scale, 8-item. HADS-A=Hospital anxiety and depression scale – subscale anxiety. UCL=Utrecht's Coping List. PT=physiotherapy.

Table 3. Outcome measures of the FIT-HIP process evaluation

Component and definition	Operationalisation	Measurement instruments									
		SLog	QpD	QpF1	QpF2	Ip	It	Qt	BLog	Sq	D
Reach											
Proportion of the intended target population that participated in the programm	Refusal and dropout rate. Reasons for withdrawal									+	+
Fidelity											
Extent to which the elements of the intervention were implemented as planned	Per therapy session: registration of which intervention components were performed	+									
	Per therapy session: reasons for deviation from individual FIT-HIP therapy plan	+									
	Reasons for deviation from protocol						+				
Dose received - Exposure											
Extent of participants' active engagement in and receptiveness to the programme	Per therapy session: extent of active engagement in therapy	+									
	In general: use of relapse prevention plan (Staying Active Plan)			+	+						
Dose received - Satisfaction											
Satisfaction of participants and therapists with the programme	Overall opinion about the intervention		+	+	+	+	+	+			
	Opinion about the value of the intervention		+	+	+	+	+	+			
	Opinion about the value of the main elements of the intervention		+	+	+	+	+				
	Experienced burden		+			+	+				
Barriers											
The extent to which problems were encountered while applying the programme	Barriers in applying the (individual components of the) intervention.						+				
	Suggestions for improvement		+	+	+	+	+	+			
	Recruitment procedures						+				+
	Maintaining participant engagement						+				+

SLog=Physiotherapist session log; QpD=evaluation questionnaire filled in by participant at discharge from GR; QpF1=evaluation questionnaire filled in by participant at follow-up 1 (3 months after discharge from GR); QpF2=evaluation questionnaire filled in by participant at follow-up 2 (6 months after discharge from GR); Ip=Interview with participant; It=Interview with physiotherapist and psychologist; Qt=evaluation questionnaire filled in by GR team members: elderly care physician, nursing staff and psychologist. BLog=Booster log, registration of telephonic booster; Sq=screening questionnaire filled in at admission to GR. D=data recorded by research assistants during study period.

Therapist data

In the intervention arm of this trial, physiotherapists will register per session which elements of the intervention were conducted, reasons for deviating from the individual FIT-HIP therapy plan and the duration of the therapy sessions, using weekly calendars as session logs. Also, for each therapy session, the Pittsburgh Rehabilitation Participation Scale is filled in as a measure of the extent of active engagement of the participant in the therapy. At the end of the study, the physiotherapists and psychologists conducting the intervention will be invited to take part in qualitative group interviews to discuss in detail their satisfaction with the (components of the) intervention, experienced barriers applying the intervention and suggestions for improvement. Also, matters concerning participant recruitment and maintaining participant engagement will be discussed.

Other members of the GR team (the elderly physician and nursing staff) will be approached to fill in a short evaluation questionnaire about their general opinion of the intervention and to assess to what extent the individual FIT-HIP therapy plans were routinely discussed in the GR team.

Participant data

All participants in the intervention arm of this trial will receive evaluation questionnaires at discharge from GR and at follow-up (3 and 6 months after discharge from GR). In these questionnaires, information on experienced benefits and burden of the intervention, and suggestions for improvement of the intervention, will be assessed. In addition, qualitative interviews will be held with a (random) subgroup of the participants, to gain more insight into these matters.

Economic evaluation

The economic evaluation consists of a cost analysis and a cost-utility analysis, both with a 6-month time horizon after discharge from GR. Costs will be measured from a healthcare perspective. In the cost-utility analysis, the difference in healthcare costs between the strategies will be compared to the difference in Quality-Adjusted Life Years (QALYs, calculated using the 3-level Dutch EQ-5D tariff [52] and the visual analogue scale for health). Estimated healthcare costs will include the costs of the FIT-HIP intervention (estimated from the study registration) and other healthcare utilisation (estimated using quarterly questionnaires filled in by the patients). Other healthcare utilisation will include care provided by general practitioners, consultations of medical specialists and paramedics, home care, informal care, hospitalisation, and residential care. A cost-price analysis will be performed for the FIT-HIP intervention; other healthcare items will be valued using standard prices.

Sample size

This study tests the null hypothesis that there is no difference in POMA score between the intervention and control group at discharge from GR. The criterion for significance (alpha) was set at 0.050. The test is 2-tailed, which means that an effect in either direction will be interpreted. With a sample size of 40 in both groups, the study will have power of 80% to yield a statistically significant result. Based on our previous research, the minimal clinical relevant difference (mean difference of the POMA at discharge measurement) was set at -3.8, with the common within-group standard deviation at 6.0. The corresponding means are 17.0 vs. 20.8. This effect was selected as the smallest effect that would be important to detect, in the sense that any smaller effect would not be of clinical or substantive significance. It is also assumed that this effect size is reasonable, in the sense that an effect of this magnitude could be anticipated in this field of research.

Compensation for design effect and possible loss to follow-up was taken into account in the choice of sample size. For the design effect (cluster randomisation), the intraclass correlation coefficient (ICC) for the outcome measure POMA is expected to be 0.05 because of clustering of data and because there may be inequality of the numbers within clusters. For the possible loss to follow-up, specifically death in the 3-month rehabilitation phase is not expected be ≥10%. Instead of the 40 patients calculated with the power analysis, we will include 75 patients per group.

As 11 post-acute GR units were interested in participating, we decided to include one additional intervention post-acute GR unit, in case of unsuspected drop-out of one intervention location. Thus, we aim to include a total of 165 participants.

Data analyses

Differences between the intervention and control group in characteristics of participants at baseline will be tested with chi-square tests for categorical variables, Mann-Whitney U-test for continuous variables with skewed distributions, and one-way ANOVA for normally distributed continuous variables. Given the hierarchical data structure, multilevel analyses will be used for continuous outcomes, and logistic Generalized Estimated Equation (GEE) analyses for dichotomous outcomes. Logistic GEE is preferred to logistic multilevel analyses because of the instability of the latter. Analyses will be based on an intention-to-treat principle and the level of significance will be set at $p<0.05$. Missing data will be handled as missing (no imputation). Multilevel analyses will be performed with MLwiN. All other analyses will be performed with IBM SPSS statistics.

With regard to the qualitative data (assessed for the process evaluation), these will be analysed by means of coding techniques based on transcriptions of the qualitative interviews. In the

economic evaluation, group averages will be compared using unequal-variance t-tests, according to the intention-to-treat principle. Costs will be compared to QALYs using net-benefit analysis. Multiple imputation will be used to account for missing values. Sensitivity analysis will be performed on the time horizon (base case 6 months vs. 12 months) and the utility measure (base case Dutch EQ-5D tariff vs. visual analogue scale for health).

DISCUSSION

At present, the functional recovery after a hip fracture in frail older adults is limited, resulting in a considerable amount of long-term disability. Therefore, a hip fracture has major consequences for individual patients, as well as for society, due to the costs of healthcare and the burden on caregivers. Based on the current literature, only a few factors influencing functional recovery after hip fracture could prove to be modifiable. As fear of falling is highly prevalent in hip fracture patients and leads to avoidance of activity, it is probably a significant factor contributing to limited recovery after hip fracture. To our knowledge this is the first RCT to evaluate the effect of treatment of fear of falling in this population. This multicentre cluster RCT will provide insight into whether targeted treatment of fear of falling during geriatric rehabilitation after hip fracture, using the FIT-HIP intervention, is effective in reducing fear of falling and associated avoidance of activities and, therefore, improving functional outcome after hip fracture.

The key component in this trial, guided exposure, is based on the principles of cognitive behavioural therapy. It encourages the systematic confrontation of feared stimuli (situations), in a graded approach. It is the preferred treatment in various types of anxiety disorders, including phobias. In the FIT-HIP programme, the guided exposure is used in conjunction with psychoeducation and cognitive restructuring. The programme has been developed together with experts that developed a treatment programme on fear of falling in community-dwelling older adults, which was shown to effectively reduce the fear of falling.[21-26]

Because the FIT-HIP programme is integrated in usual care, the additional costs are expected to be limited. In an earlier phase we conducted a small pilot study, aimed at testing the FIT-HIP training and the feasibility of the intervention for healthcare professionals and participants. The additional time spent on therapy for the purpose of this intervention appeared to be limited in the pilot, but will become clear after the evaluation of the intervention. Also, guided exposure was easily integrated in the usual care. Although the principles of guided exposure are often practiced in usual care, they are not generally as structured and intentional as in this intervention.

A strength of this study is that the feasibility for healthcare professionals and patients will be evaluated through a process evaluation. Cost effectiveness will also be assessed. If this intervention proves to be (cost)effective in improving functional outcome after hip fracture and is feasible, it could offer major benefits for individual patients, their (family) caregivers and for society.

This study also has some challenges. Cluster randomisation was chosen as the study design, as the risk of contamination of the FIT-HIP intervention on usual care would be too substantial in view of the complex nature of the intervention. All participating recruitment sites (post-acute GR units) employ a standardised care pathway for patients with hip fracture. This care pathway contains formalised agreements on the content of the multidisciplinary rehabilitation process.[53] As the post-acute GR units are all part of different Dutch care organisations, there could be subtle differences in the usual care for hip fracture patients. These differences (quantity and quality of the received therapy) will be assessed in the process evaluation.

A second challenge in this study, is the blinding. As the FIT-HIP intervention is compared to 'care as usual', blinding is only partially possible. Generally, participants should not be aware of what usual care is and what the addition of the FIT-HIP intervention could be. If, however, the usual care does not take note of the fear of falling, the participant could suspect being allocated to the control group. To limit this effect, all participants receive an information brochure on fear of falling and self-help possibilities. Educational interventions alone, aimed at increasing knowledge about fall prevention, have not proven to be effective in fall prevention and we therefore do not expect that this will contaminate the effect of the intervention.[27] The health-care professionals (physiotherapists, psychologist and nursing staff) receive specific training for conducting the FIT-HIP treatment and are therefore aware of allocation; however, they are instructed not to inform the participants, family or research assistants. Outcome assessors (research assistants) are blinded to allocation.

In conclusion, this study will provide insight into whether fear of falling is modifiable in the rehabilitation process after hip fracture. The results of this trial will be disseminated in peer-reviewed journals and via professional and scientific conferences.

DECLARATIONS

Abbreviations

ADL=activities of daily living; ECP=elderly care physician; EQ-5D=EuroQol 5D; FES-I=Falls Efficacy Scale-International; FIT-HIP trial=Fear of falling InTervention in HIP fracture geriatric rehabilitation; GAS=Goal Attainment Scaling; GDS=Geriatric Depression Scale; GR=geriatric

rehabilitation (multidisciplinary inpatient rehabilitation programme); HAC= Hetero-anamnesis list cognition; HADS-A= Hospital anxiety and depression scale – subscale anxiety. LUMC=Leiden University Medical Center; NPRS=Numeric Pain Rating Scale; MMSE=Mini Mental State Examination; QALY=Quality-Adjusted Life Years; PHEG=Department of Public Health and Primary Care; POMA=The Tinetti Performance Oriented Mobility Assessment; PT=physiotherapy; RCT= randomised controlled trial; UCL=Utrecht's Coping List; UNC-ZH=University Network for the Care-sector South Holland; USER-P=Utrecht Scale for the Evaluation of Rehabilitation-Participation.

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Availability of data and materials

Not applicable

Authors' contributions

WPA, MvE, JCMvH, GIJMK, JMGAS, RvB, JHMV and EMD designed the primary study and first version of the intervention. WvdH is involved for the economic evaluation in this trial. WPA and MvE led the grant application. MSB was involved in the further development of the intervention, together with WPA, MvE, JCMvH, GIJMK, JMGAS and Bart Beck (nursing home psychologist, and teacher at LUMC). MSB was involved in the recruitment of post-acute GR units and provided training of the intervention post-acute GR units, together with Bart Beck. The manuscript was drafted by MSB, in collaboration with all other authors. All authors read and approved the final manuscript.

Competing interests

All authors declare they have no competing interests.

Consent for publication

Not applicable

Ethics approval and consent to participate

This study protocol was reviewed and approved by the Ethics Committee of the Leiden University Medical Center (The Netherlands) (reference number: P15.212). Written consent will be obtained from all participants prior to participation in this trial.

REFERENCES

1. World Health Organization: Factsheet Ageing and Health (N°404). September 2015. http://www.who.int/mediacentre/factsheets/fs404/en/
2. World Health Organization: World Report on Ageing and Health (2015). http://apps.who.int/iris/bitstream/10665/186463/1/9789240694811_eng.pdf?ua=1
3. Keene GS, Parker MJ, Pryor GA. Mortality and morbidity after hip fractures. BMJ 1993; 307 (6914): 1248-50.
4. Koval KJ, Zuckerman JD. Functional recovery after fracture of the hip. J Bone Joint Surg Am 1994; 76(5):751-8.
5. Dyer SM, Crotty M, Fairhall N, Magaziner J, Beaupre LA, Cameron ID, Sherrington C; Fragility Fracture Network (FFN) Rehabilitation Research Special Interest Group. A critical review of the long-term disability outcomes following hip fracture. BMC Geriatr 2016;16:158.
6. Abrahamsen B, van Staat, Ariely R, Olson M, Cooper C. Excess mortality following hip fracture: a systematic epidemiological review. Osteoporos Int 2009; 20(10):1633-50
7. Roche JJ, Wenn RT, Sahota O, Moran CG. Effect of comorbidities and postoperative complications on mortality after hip fracture in elderly people: prospective observational cohort study. BMJ 2005; 331(7529):1374
8. van Balen R, Steyerberg EW, Polder JJ, Ribbers TL, Habbema JD, Cools HJ. Hip fracture in elderly patients: Outcomes for function, quality of life, and type of residence. Clin Orthop Relat Res 2001; 390:232-43.
9. Mossey JM, Mutran E, Knott K, Craik R. Determinants of recovery 12 months after hip fracture: The importance of psychosocial factors. Am J Public Health 1989; 79(3):279-86.
10. Magaziner J, Simonsick EM, Kashner TM, Hebel JR, Kenzora JE. Predictors of functional recovery one year following hospital discharge for hip fracture: a prospective study. J Gerontol 1990;45 (3): M101-107.
11. Oude Voshaar RC, Banerjee S, Horan M, Baldwin R, Pendleton N, Proctor R, et al. Fear of falling more important than pain and depression for functional recovery after surgery for hip fracture in older people. Psychol Med. 2006;36(11):1635-45.
12. Kristensen MT. Factors affecting functional prognosis of patients with hip fracture. Eur J Phys Rehabil Med 2011; 47(2): 257-64.
13. Scheffer A C, Schuurmans MJ, van Dijk N, van der Hooft T, de Rooij SE. Fear of falling: Measurement strategy, prevalence, risk factors and consequences among older persons. Age Ageing 2008; 37(1):19-24.
14. Zijlstra GA, van Haastregt JC, van Eijk JT, van Rossum E, Stalenhoef PA, Kempen GI. Prevalence and correlates of fear of falling, and associated avoidance of activity in the general population of community-living older people. Age Ageing. 2007;36(3):304-9.
15. Visschedijk J, Achterberg W, Van Balen R, Hertogh C. Fear of falling after hip fracture: a systematic review of measurement instruments, prevalence, interventions, and related factors. J Am Geriatr Soc 2010; 58 (9): 1739-48.
16. Visschedijk J, van Balen R, Hertogh C, Achterberg W. Fear of falling in patients with hip fractures: Prevalence and related psychological factors. J Am Med Dir Assoc 2013; 14(3): 218-20.
17. Tinetti ME, Powell L. Fear of falling and low self-efficacy: A case of dependence in elderly persons. J Gerontol 1993; 48 Spec No:35-8.
18. Van der Meulen E, Zijlstra GA, Ambergen T, Kempen GI. Effect of fall-related concerns on physical, mental, and social function in community-dwelling older adults: a prospec-

tive cohort study. J Am Geriatr Soc 2014; 62(12):2333-8

19. Crotty M, Unroe K, Cameron ID, Miller M, Ramirez G, Couzner L. Rehabilitation interventions for improving physical and psychosocial functioning after hip fracture in older people. Cochrane Database Syst Rev 2010 (1):CD007624.
20. Tennstedt S, Howland J, Lachman M, Peterson E, Kasten L, Jette A. A randomized, controlled trial of a group intervention to reduce fear of falling and associated activity restriction in older adults. J Gerontol B Psychol Sci Soc Sci 1998 ; 53(6):384-92.
21. Zijlstra GA, Tennstedt SL, van Haastregt JC, van Eijk JT, Kempen GI. Reducing fear of falling and avoidance of activity in elderly persons: The development of a Dutch version of an American intervention. Patient Educ Couns 2006; 62(2):220-7.
22. Zijlstra GA, van Haastregt JC, Ambergen T, van Rossum E, van Eijk JTM, Tennstedt SL et al. Effects of a multicomponent cognitive behavioral group intervention on fear of falling and activity avoidance in community-dwelling older adults: Results of a randomized controlled trial. J Am Geriatr Soc 2009; 57(11):2020-8.
23. van Haastregt JC, Zijlstra GA, Hendriks MR, Goossens ME, van Eijk JT, Kempen GI. Cost-effectiveness of an intervention to reduce fear of falling. Int J Technol Assess Health Care 2013; 29(3):219-26.
24. Zijlstra GA, van Haastregt JC, Du Moulin MF, de Jonge MC, van der Poel A, Kempen GI. Effects of the implementation of an evidence-based program to manage concerns about falls in older adults. Gerontologist. 2013;53(5):839-49.
25. Dorresteijn TA, Zijlstra GA, Ambergen AW, Delbaere K, Vlaeyen JW, Kempen GI. Effectiveness of a home-based cognitive behavioral program to manage concerns about falls in community-dwelling, frail older people: results of a randomized controlled trial. BMC Geriatr 2016; 16:2.
26. Tanja Dorresteijn. A home-based program to manage concerns about falls. Feasibility, effects and costs of a cognitive behavioural approach in community-dwelling, frail older people. PhD dissertation. Maastricht 2016.
27. Lesley D Gillespie, M Clare Robertson, William J Gillespie, Catherine Sherrington, Simon Gates , Lindy M Clemson et al. Interventions for preventing falls in older people living in the community. Cochrane Database Syst Rev. 2012;(9):CD007146.
28. Meijer R, van Limbeek J, de Haan R: Development of the Stroke-unit Discharge Guideline: choice of assessment instruments for prediction in the subacute phase post-stroke. Int J Rehabil Res. 2006, 29 (1): 1-8.
29. Stolee P, Rockwood K, Fox RA, Streiner DL. The use of goal attainment scaling in a geriatric care setting. J Am Geriatr Soc. 1992;40(6):574-8.
30. Stolee P, Stadnyk K, Myers AM, Rockwood K. An individualized approach to outcome measurement in geriatric rehabilitation. J Gerontol A Biol Sci Med Sci. 1999;54(12):M641-7.
31. Miller WR, Rollnick S. Motiverende gespreksvoering. Een methode om mensen voor te bereiden op verandering [Dutch] *Motivational Interviewing. Preparing people for change.* 10th ed. Ekklesia, 2013
32. Tinetti ME. Performance-oriented assessment of mobility problems in elderly patients. J Am Geriatr Soc 1986;34(2):119-126.
33. Faber MJ, Bosscher RJ, van Wieringen PC. Clinimetric properties of the performance-oriented mobility assessment. Phys Ther. 2006;86(7):944-954.
34. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age Ageing. 2005;34(6):614–9.
35. Kempen GI, Todd CJ, Van Haastregt JC, Zijlstra GA, Beyer N, Freiberger E et al. Cross-cultural validation of the falls efficacy scale international (fes-i) in older people: Results from Germany, the Netherlands and the

UK were satisfactory. Disabil Rehabil. 2007; 29(2):155-62.

36. Visschedijk JH, Terwee CB3, Caljouw MA, Spruit-van Eijk M, van Balen R, Achterberg WP. Reliability and validity of the Falls Efficacy Scale-International after hip fracture in patients aged ≥ 65 years. Disabil Rehabil 2015;37(23):2225-32
37. Collin C, Wade DT, Davies S, Horne V. The Barthel ADL Index: a reliability study. Int Disabil Stud. 1988, 10(2): 61-3
38. Holden MK, Gill KM, Magliozzi MR, Nathan J, Piehl-Baker L. Clinical gait assessment in the neurologically impaired. Reliability and meaningfulness. Phys Ther. 1984,64 (1): 35-40.
39. Collen FM, Wade DT, Bradshaw CM. Mobility after stroke: reliability of measures of impairment and disability. Int Disabil Stud. 1990;12(1):6-9
40. Tyson S, Connell L. The psychometric properties and clinical utility of measures of walking and mobility in neurological conditions: a systematic review. Clin Rehabil. 2009;23(11):1018-33.
41. EuroQol Research Foundation. 2016. http://www.euroqol.org/.
42. Post MW, van der Zee CH, Hennink J, Schafrat CG, Visser-Meily JM, van Berlekom SB. Validity of the Utrecht Scale for evaluation of rehabilitation-participation. Disabil Rehabil 2012; 34(6):478-85
43. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. J Clin Epidemiol. 2005;58(6):595-602.
44. Hjermstad MJ, Fayers PM, Haugen DF, Caraceni A, Hanks GW, Loge JH et al. Studies Comparing Numerical Rating Scales, Verbal Rating Scales, and Visual Analogue Scales for Assessment of Pain Intensity in Adults: A Systematic Literature Review. J Pain Symptom Manage. 2011;41(6):1073-93
45. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patient for the clinician. J Psychiatr Res 1975;12:189–98.
46. Tombaugh TN, McIntyre NJ. The mini-mental state examination: a comprehensive review. J Am Geriatr Soc. 1992;40:922–35.
47. Jongenelis K, Gerritsen DL, Pot AM, Beekman AT, Eisses AM, Kluiter H, et al. Construction and validation of a patient- and user-friendly nursing home version of the Geriatric Depression Scale. Int J Geriatr Psychiatry 2007;22:837–42.
48. Spinhoven P, Ormel J, Sloekers PPA, Kempen GIJM, Speckens AEM, Van Memert AM et al. A validation study of the Hospital Anxiety and Depression Scale (HADS) in different groups of Dutch subjects. Psychol Med 1997; 27(2):363-70.
49. Schreurs PJG, Van de Willige G, Brosschot JF, Tellegen B, Graus GMH.. The Utrecht Coping List (UCL Manual). 1993. Lisse: Swets & Zeitlinger.
50. Lenze, EJ, Munin, MC, Quear T, Dew MA, Rogers JC, Begley AE, Reynolds CF. The Pittsburgh Rehabilitation Participation Scale: reliability and validity of a clinician-rated measure of participation in acute rehabilitation. Arch Phys Med Rehabil. 2004; 85(3): 380-384.
51. Saunders RP, Evans MW, Joshi P. Developing a process-evaluation plan for assessing health promotion program implementation: A how-to guide. Health Promot Pract 2005;6:134-47
52. Lamers LM, McDonnell J, Stalmeier PF, Krabbe PF, Busschbach JJ. The Dutch tariff: results and arguments for an effective design for national EQ-5D valuation studies. Health Econ. 2006; 15:1121-32.
53. Richtlijn Proximale femurfracturen (2016) [Dutch]: *Guideline proximal femoral fracture*. https://richtlijnendatabase.nl/?query=proximale+femurfractuur&specialism=&sort=0

Chapter 3

Effects of the FIT-HIP Intervention for Fear of Falling After Hip Fracture: A Cluster-Randomized Controlled Trial in Geriatric Rehabilitation

Scheffers-Barhoorn MN, van Eijk M, van Haastregt JCM, Schols JMGA, van Balen R, van Geloven N, Kempen GIJM, Achterberg WP.

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ABSTRACT

Objectives

Fear of falling (FoF) is common after hip fracture and can impede functional recovery due to activity restriction. The FIT-HIP intervention was designed to target FoF and consequently to improve mobility. The aim of this study was to evaluate the effect of the FIT-HIP intervention in patients with FoF in geriatric rehabilitation (GR) after hip fracture.

Design, setting and participants

This cluster randomized controlled trial was performed in 11 post-acute GR units in the Netherlands (2016-2017). Six clusters were assigned to the intervention group, five to the usual care group. We included 78 patients with hip fracture and FoF (aged ≥ 65 years; 39 per group).

Intervention(s)

The FIT-HIP intervention is a multi-component cognitive behavioral intervention conducted by physiotherapists, embedded in usual care in GR. The FIT-HIP intervention was compared to usual care in GR.

Measurements

FoF was assessed with the Falls Efficacy Scale International (FES-I); mobility with the Performance Oriented Mobility Assessment (POMA). Data were collected at baseline, discharge and 3 and 6 months post-discharge from GR. Primary endpoints were change scores at discharge. Linear mixed models were used to evaluate treatment effect.

Results

No significant between groups differences were observed for primary outcome measures. With the usual care group as reference, the FES-I estimated difference between mean change scores was 3.3 (95% CI -1.0; 7.5, p=0.13) at discharge from GR; -4.1 (95% CI -11.8; 3.6, p=0.29) after 3 months and -2.8 (95% CI -10.0; 4.4, p=0.44) after 6 months. POMA estimated difference was -0.3 (95% CI -6.5; 5.8, p=0.90).

Conclusion and implications

The FIT-HIP intervention was not effective in reducing FoF. Possibly FoF (shortly) after hip fracture can to some extent be appropriate. Consequently, this implies the study was not able to accurately identify and accordingly treat FoF that is maladaptive (reflective of disproportionate anxiety).

BACKGROUND

Despite advances made in both the acute care for hip fracture patients and post-acute rehabilitation services provided,[1-6] long-term functional recovery after hip fracture still remains limited.[7,8] Although many factors can impede recovery after hip fracture, only a few are potentially modifiable.[9-12] In this regard fear of falling (FoF), defined as *'a lasting concern about falling that leads to an individual avoiding activities that he/she remains capable of performing',* may be an important risk factor.[13] More than 50% of patients who have sustained a hip fracture express FoF.[14-16] Fear of falling can hamper progress in functional performance as a result of avoidance of activities.[14] Moreover, it is associated with an increased risk of falling, decreased mobility, loss of independence, institutionalization, and lower quality of life and social participation.[14,17,18] Therefore, treatment of FoF after hip fracture may be a key element in approaches to improve functional recovery after fracture.

In the past decades several interventions for community-dwelling older adults with FoF have been developed and evaluated.[19,20] These programs often use a cognitive behavioral approach, including cognitive restructuring, personal action plans to encourage engagement and physical activity, exposure in vivo (e.g. practicing activities in fear-related real-life situations), information on fall prevention, and motivational interviewing. One of these programs is the widely used intervention program '*A Matter of Balance*', which has proven to be (cost)effective to reduce FoF in community-dwelling older adults in the US and the Netherlands.[21-26] However, none of the programs available focus on patients with hip fracture.

In the Netherlands, specialized inpatient multidisciplinary rehabilitation services for frail older patients are organized as 'geriatric rehabilitation' (GR) within post-acute GR units.[27] The rehabilitation program includes physical and occupational therapy, and treatment of comorbidities. Approximately half of all older adults with hip fracture in the Netherlands are referred to GR following surgical repair of the fracture. In order to adequately address FoF in this specific population, it is essential that intervention strategies are designed to fit the rehabilitation setting. For this purpose, the cognitive behavioral approach used in the Dutch version of '*A Matter of Balance*' was adapted to an individualized tailor-made intervention: the Fear of falling InTervention in HIP fracture geriatric rehabilitation (i.e. the FIT-HIP intervention).[28] The FIT-HIP intervention is incorporated in the multidisciplinary GR treatment program.

This study aims to evaluate whether the FIT-HIP intervention is effective in reducing FoF and, consequently, improving mobility when compared to care as usual in GR.

METHODS

This cluster randomized controlled trial (RCT) compared usual care in inpatient multidisciplinary GR in the Netherlands to usual care *combined* with the FIT-HIP intervention.[28] Eleven GR units (clusters) were recruited to participate. The Ethics Committee of the Leiden University Medical Center (LUMC) approved the study protocol (P15.212; 09-09-2015), which is registered in the Netherlands Trial Register (No. NTR 5695).

Recruitment of participants

All patients admitted to the participating GR units due to recent hip fracture were screened for eligibility in the first week of admission. Inclusion criteria were age ≥ 65 years and at least sometimes being concerned to fall, based on a 1-item question, i.e. *'Are you concerned to fall?'* (answer options: *never – almost never – sometimes – often – very often*).

Exclusion criteria were: 1) the presence of a condition interfering with learnability (formal diagnosis of dementia; major psychiatric disease or a score > 1 on the Hetero-anamnesis List Cognition (HAC)[29] which is suggestive for premorbid cognitive disabilities); 2) pre-fracture Barthel index score < 15; 3) pathological hip fracture; 4) life expectancy < 3 months; and 5) insufficient mastery of the Dutch language.

All participants provided written informed consent to participate prior to baseline assessment.

Randomization and blinding

Following recruitment of all participating GR units, five were randomly assigned to the usual care group and six to the intervention group. Computer-generated randomization was performed by an independent researcher of the LUMC using the random generator of SPSS (version 23.0).

Outcome measures were assessed by independent research assistants blinded to group allocation. Healthcare professionals were instructed not to inform the participants about allocation status. In a further attempt to conceal treatment allocation for participants, at enrollment, all participants received a four-page information brochure on FoF.[28] As healthcare strategies directed at reducing risk of falling in older adults based on educational interventions alone have not proven effective,[30] we expected this to serve as a suitable dummy intervention.

Interventions

FIT-HIP intervention

Details of the intervention have been published previously;[28] a summary is presented in Table 1. The FIT-HIP intervention consists of various cognitive behavioral elements aimed at reducing the FoF, including psycho-education, guided exposure to feared activities, cognitive restructur-

ing, and relapse prevention. The intervention is integrated in the physical therapy sessions and combined with the regular exercise training in GR.

From each GR unit allocated to the intervention group, two physiotherapists were trained to conduct the intervention. All intervention units additionally provided a psychologist to counsel the physiotherapists as needed, specifically with regard to the 'cognitive restructuring'. During monthly meetings organized by each GR team individually, the physiotherapists and psychologists discussed the participants' progress and the challenges in the treatment. Physiotherapists were also encouraged to directly consult their 'buddy' psychologist if they encountered difficulties during treatment. Furthermore, the nursing staff was briefed on the background and rationale of guided exposure, to help them incorporate these principles in their work, and to adhere to the '*FIT-HIP fear ladders*' (Table 1).

Table 1. Overview of the FIT-HIP intervention

Element	Description
Guided exposure – *rationale*	Guided exposure is the graded and repeated exposure to situations that give rise to fear (of falling). As recurrent exposure to the feared situation or activity is performed under supervision and in a manner that is predictable and controllable, this leads to the positive experience that the fear gradually fades out as the activity is practiced more often. After the fear for this specific situation has subsided, the exposure can be extended to the 'next level', practicing the activity in a manner that leads to a greater level of fear (fear hierarchy for graded exposure). For fear of falling (FoF), the feared activities will be situations concerning physical activity. In the rehabilitation after hip fracture, this will predominantly be basic activities in daily living, such as transferring, standing and walking.
Implementation in the FIT-HIP intervention	In the FIT-HIP intervention the physiotherapist helps the participant assess situations that give rise to FoF (within the first week of admission to geriatric rehabilitation (GR)). For each 'feared' activity the physiotherapist and participant draft a fear hierarchy, designed as a 'fear ladder' (template example published in protocol).[28] The FIT-HIP fear ladder consists of six 'steps', each step representing a functional goal. The functional goal describes in which manner the activity is practiced/performed. The goals are ranked with an increasing level of FoF as the activity gets more complex (or has to be performed with less assistance). The FIT-HIP fear ladders are the guiding principle for the multidisciplinary approach to apply guided exposure for all aspects of mobilization. The physiotherapist evaluates the fear ladders with the participant weekly and the fear ladders are revised on the basis of progress (reduction of FoF).
*Intervention provider(s)**	Physiotherapists during physical therapy sessions. As applicable, by nursing staff when assisting patients in basic activities of daily living that give rise to FoF. Nursing staff assisting participants in practicing 'fearful' activities as 'homework assignments' after physical therapy.
Schedule	Incorporated in all physical therapy sessions (and nursing care activities) for the duration of inpatient multidisciplinary GR as long as FoF persists.
Cognitive restructuring - *rationale*	Thoughts (and associated beliefs) influence how a person feels and accordingly how a person appraises and responds to a situation. Excessive concern to fall (fear of falling) can be based on unrealistic thoughts and beliefs with regard to (risk of) falling. This excessive FoF may lead to avoidance of (physical) activity and consequently fortify the FoF. Cognitive restructuring is a technique used to explore thoughts and beliefs and therefore to identify, challenge and modify unrealistic thoughts. In the FIT-HIP intervention participants are coached to explore their thoughts concerning physical activity and fall risk. In doing so they are encouraged to identify maladaptive and unrealistic thoughts and in turn formulate and apply more realistic thoughts. The principle of (un)realistic thoughts is also incorporated into the relapse prevention plan (see below).

Table 1. Overview of the FIT-HIP intervention	
Implementation in the FIT-HIP intervention	Physiotherapists are trained to guide the participant in exploring their thoughts concerning physical activity and (risk of) falling. A worksheet is used to structure the process of cognitive restructuring and to provide the participant insight in this process (analyzing the situation and the associated thoughts, feelings, behavior and consequences and subsequently formulating more realistic thoughts).
*Intervention provider(s)**	Physiotherapists. A psychologist is trained as a 'buddy' to coach the physiotherapists in these principles as when additional help is needed.
Schedule	During at least one physical therapy session the cognitive restructuring is applied and practiced with the participant. Subsequently, the participant is encouraged to fill in the worksheet as a 'homework assignment'. This is reviewed and discussed during the next therapy session. These 'key' thoughts can briefly be recapitulated in situations when the FoF is noticeable in the physical therapy sessions. The process of cognitive restructuring can be repeated as needed (when the FoF persists).
Psycho-education - *rationale and implementation in the FIT-HIP intervention*	The psycho-education is used to reinforce the various elements of the FIT-HIP intervention. In the initial phase of GR the participant receives information on anxiety, (consequences and treatment of) FoF and the rationale and background of guided exposure and cognitive restructuring. In the final phase of GR, when discharge home is being planned, the psycho-education focusses on home safety. The information on home safety is also processed in the relapse prevention plan (see below).
*Intervention provider(s)**	Physiotherapists discuss the information with the participant.
Schedule	During at least two physical therapy sessions (one in the initial phase of rehabilitation; the other preceding the discharge home). As applicable, the psycho-education can additionally be incorporated in the therapy sessions, related to situations occurring during therapy (for example fall prevention).
Relapse prevention - *rationale*	The relapse prevention is aimed at helping the participant to anticipate and cope with relapse to FoF.
Implementation in the FIT-HIP intervention	In the FIT-HIP intervention the relapse prevention is designed to optimize the transition to predominantly independent living circumstances after discharge home. For this purpose, a 'relapse prevention plan' is composed together with the participant. This '*Staying Active Plan*' aims at preparing the participant for challenging situations in which there is a risk for relapse to FoF and activity restriction. The '*Staying Active Plan*' consists of (information on) 1. General home safety and fall prevention; 2. Individualized advice for safe ambulation and how to stay active; 3. Preventing, recognizing and dealing with a relapse (including notice of (mal)adaptive) thoughts). The information is discussed together with the participant and presented in writing as a reference book. In addition, a telephonic booster is conducted six weeks after discharge from GR. The telephonic booster is aimed at evaluating the FoF (and activity restriction). If necessary advice is given how to deal with FoF, in addition to the prior advice formulated in the '*Staying Active Plan*'.
*Intervention provider(s)**	Both the '*Staying Active Plan*' and telephonic booster are conducted by physiotherapists.
Schedule	During at least one physical therapy session during GR ('*Staying Active Plan*') and one telephonic booster session after discharge home.
Motivational interviewing	Physiotherapists are trained* in motivational interviewing techniques to assist the participant in the process of behavior change. These techniques help the physiotherapist gain insight into the participant's extrinsic and intrinsic motivation and explore which rehabilitation goals are important for the participant, in order to personalize treatment goals in the FIT-HIP intervention.

*Physiotherapists received two training sessions (four hours each); psychologists one 4-h session (together with physiotherapists).

Usual care

In the Netherlands, inpatient geriatric rehabilitation is multidisciplinary care led by an elderly care physician.[31] General aspects of physiotherapy treatment include training of mobility, balance and gait, and exercise to improve muscle strength. Nursing staff and an occupational therapist are involved to help improve self-care, by coaching patients to perform basic activities of daily living (ADL), such as transferring and bathing.[15,27] In general, a patient receives 5-6 physiotherapy sessions per week, although therapy intensity may vary due to variations in patients' physical endurance and the formalized agreements on therapy intensity employed by the GR units.

Outcome measures

Baseline (T0) and discharge (T1) assessments were performed in the first and last week of the GR trajectory, by means of structured face-to-face interviews and task-oriented physical tests. Follow-up assessments at 3 and 6 months after discharge (T2/T3) were performed by postal questionnaires. Missing data at follow-up and the Functional Ambulation Categories (see below) were acquired by telephonic interviews.

The purpose of the FIT-HIP intervention is to reduce FoF in order to improve physical functioning. Therefore, the FIT-HIP trial had two primary outcome measures: i) the post-intervention change in FoF measured with the Falls Efficacy Scale International (FES-I),[32] and ii) change in mobility function assessed with the Performance Oriented Mobility Assessment (POMA).[33]

The FES-I is a 16-item instrument, scored on a 4-point Likert scale, assessing FoF (defined as concerns about falling) related to basic and more demanding physical and social activities. The total score on the FES-I ranges from 16-64, with higher scores indicating a higher level of FoF. The FES-I has good reliability and validity, and its use has been validated in Dutch patients with hip fracture in GR.[32]

The POMA is a reliable and valid clinical examination tool that assesses gait and balance ability, as a measure for mobility in older adults.[33] It consists of a 9-item balance scale and a 7-item gait scale. The total score ranges from 0-28, with lower scores indicating a greater risk of falling. In the event the participant was unable to perform the test due to physical impairment, we set the score to 0. The POMA was assessed at baseline and at discharge, whereas the FES-I was assessed at all four measurement points.

Secondary outcome measures were self-reported activity restriction due to FoF and (in)dependence in walking ability measured by the Functional Ambulation Categories (FAC). Activity restriction due to FoF was assessed with a 1-item question *'Do you avoid activities due to fear of falling'*. Response categories were *never (0) – almost never (1) – sometimes (2) – often (3) – very often (4)*. The FAC evaluates ambulation ability on a 6-point ordinal scale, describing the degree

of support needed when walking; this scale ranges from non-functional walking (score 0) to independent walking on all surfaces (score 5).

Additional variables

At baseline, we collected sociodemographic data and information on various aspects of physical and mental health for descriptive purposes (Table 2). To compare the therapy intensity in both groups, we collected data at participant level on frequency and duration of all therapy provided in GR (information obtained from routine data registration used for reimbursement purposes). Adverse events such as fall incidents, hospital readmissions and death were registered by attending elderly care physicians during GR. During follow-up, this information was assessed with the questionnaires sent to participants.

Sample size

As the ultimate goal to treat FoF is to improve functional recovery after hip fracture, we chose to use POMA to calculate sample size. To have 80% power to detect a statistically significant and minimal clinically relevant difference of 3.8 in the POMA score between groups at discharge from GR, we needed 40 participants per group (corresponding means 17.0 and 20.8, respectively; standard deviation per group 6.0); this was based on an alpha of 5% (two-sided). The intraclass correlation was set to 0.05 to account for the effect of cluster randomization. To additionally account for a minimum of 10% loss to follow-up at discharge, we planned to recruit 15 participants per cluster.

Statistical analysis

All analyses were performed on an intention-to-treat basis using IBM SPSS Statistics for Windows version 23.0. Statistical significance was set at $P < 0.05$ (two sided). The mean change score in outcome measure from baseline (score Tx – score T0) was used for all effectiveness analyses. These 'within-group differences' were compared between the treatment groups using a linear mixed model to account for the clustering of participants within the GR units. In this model we also corrected for the imbalance found between treatment groups with regard to the baseline FAC score and Functional Comorbidity Index (FCI). Both delayed postoperative ambulation and comorbidity are established risk factors for negative outcomes after hip fracture.[9,10,34] The treatment effect is presented as an estimated difference between the mean change score per group [with corresponding 95% confidence interval (CI)], with the usual care group as reference.

In addition to this primary, most extensive linear mixed model, we evaluated treatment effects solely adjusted for i) baseline value of outcome measure; ii) baseline value of outcome measure + baseline FAC score; and iii) baseline value of outcome measure and baseline FCI score. Detailed information on the linear mixed models, is presented in Appendix 1.

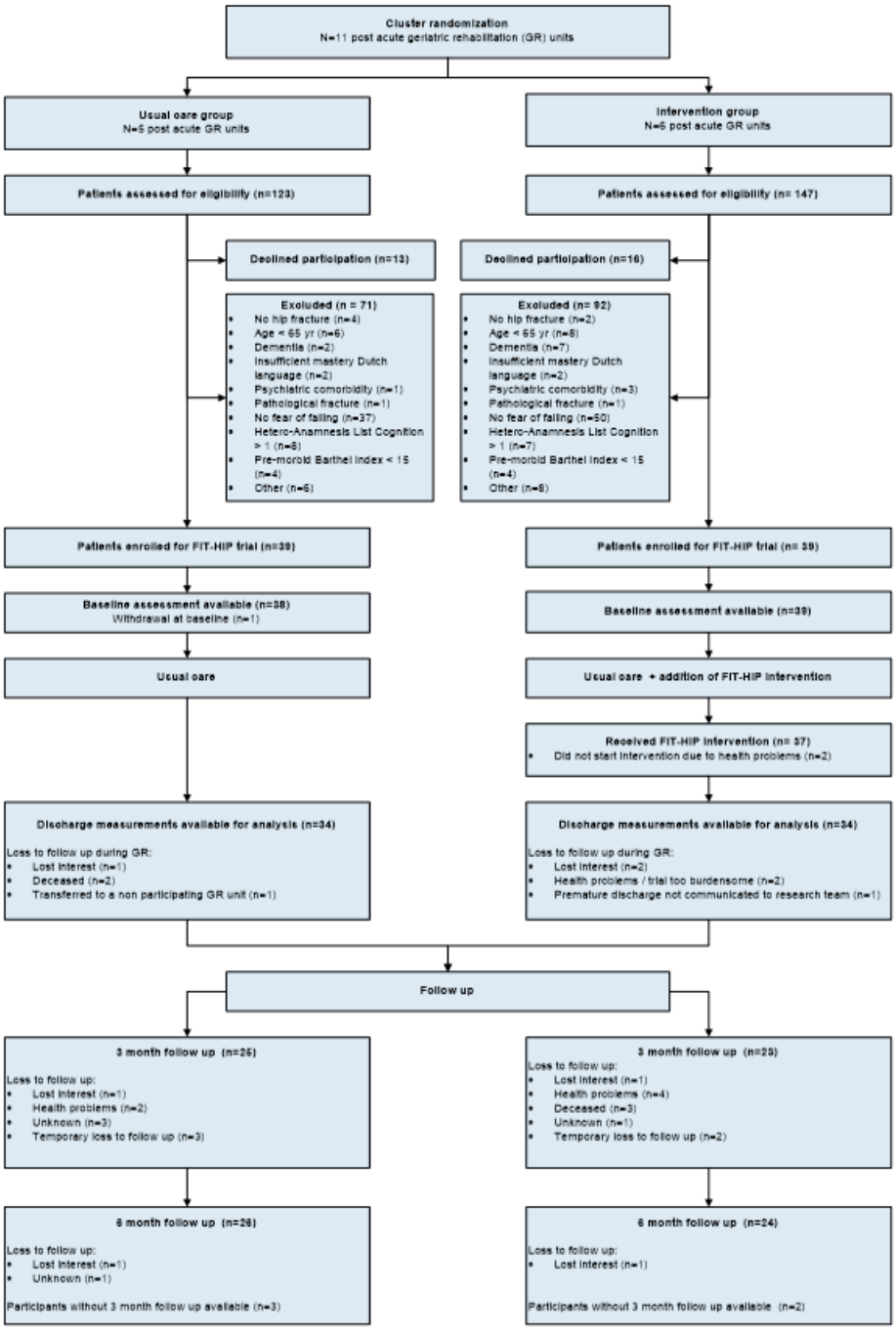
Table 2. Baseline characteristics of the FIT-HIP participants and characteristics of Geriatric Rehabilitation outcomes

	All participants (n=77)		Usual care group (n=38)		Intervention group (n=39)		*P*-value*
Demographic data							
Age (years); mean (SD)	82.5	(7.6)	81.3	(7.9)	83.7	(7.3)	0.18
Female gender; n (%)	61	(79.2)	27	(71.1)	34	(87.2)	0.98
Living alone; n (%)	51	(66.2)	24	(63.2)	27	(69.2)	0.64
Comorbidity, functional status and physical functioning							
Functional comorbidity index (0-18) ‡; median (IQR) §	3.0	(1.0-5.0)	2.5	(1.0-4.0)	3.5	(1.8-6.0)	0.05
10MWT in m/s; median (IQR) §	0.0	(0.0-0.3)	0.0	(0.0-0.5)	0.0	(0.0-0.3)	0.27
Pre-fracture activity restriction due to fear of falling; n (%)							0.72
- Never / almost never / sometimes	70	(90.9)	36	(94.7)	34	(87.2)	
- Often/ very often	7	(9.1)	2	(5.3)	5	(12.8)	
(Neuro)psychological factors; median (IQR) §							
GDS-8 total score (0-8) ‡	0.0	(0.0-2.0)	0.0	(0.0-2.0)	1.0	(0.0-2.0)	0.93
HADS-A total score (0-21) ‡	3.0	(1.0-6.8)	3.0	(1.0-5.3)	4.0	(1.0-8.3)	0.36
MMSE (0-30) †	27.0	(25.0-29.0)	27.0	(25.0-29.0)	27.0	(24.0-29.0)	0.74
Primary outcomes							
Falls Efficacy Scale International (FES-I) (0-64) ‡; mean (SD) §							
FES-I baseline / T0	34.2	(10.6)	34.4	(11.4)	33.9	(9.9)	0.84
FES-I discharge / T1	29.9	(10.0)	27.0	(8.2)	32.8	(11.0)	
FES-I 3-month follow-up / T2	35.9	(13.0)	36.6	(12.4)	35.1	(13.9)	
FES-I 6-month follow-up / T3	36.5	(11.9)	36.5	(11.9)	36.5	(12.1)	
Performance Oriented Mobility Assessment (0-28) †; median (IQR)							
POMA baseline/ T0	0.0	(0.0-8.0)	0.0	(0.0-10.5)	0.0	(0.0-4.0)	0.13
POMA discharge/ T1 §	17.0	(13.0-20.0)	18.0	(13.8-21.0)	17.0	(12.5-20.0)	
Secondary outcomes							
Activity restriction due to fear of falling (0-4) ‡; median (IQR)							
Baseline/ T0	0.0	(0.0-2.0)	0.0	(0.0-1.3)	0.0	(0.0-2.0)	0.43
Discharge/ T1	0.0	(0.0-1.0)	0.0	(0.0-0.3)	0.0	(0.0-1.0)	
3-month follow-up / T2	2.0	(1.0-3.0)	2.0	(1.0-2.5)	2.0	(1.0-3.0)	
6-month follow-up / T3	2.0	(1.0-2.3)	2.0	(1.0-3.0)	2.0	(0.3-2.0)	
Functional Ambulation Categories (FAC)(0-5) †; median (IQR)							
FAC baseline/ T0	2.0	(1.0-3.0)	3.0	(2.0-4.0)	2.0	(0.0-3.0)	0.002
FAC discharge/ T1	4.0	(4.0-5.0)	4.0	(4.0-5.0)	4.0	(4.0-4.3)	
FAC 3-month follow-up / T2	5.0	(4.0-5.0)	5.0	(4.0-5.0)	4.5	(4.0-5.0)	
FAC 6-month follow-up / T3	5.0	(4.0-5.0)	5.0	(4.0-5.0)	5.0	(4.0-5.0)	
Geriatric Rehabilitation outcome characteristics							
Discharge home after GR; n (%) §	63	(94.0)	32	(97.0)	31	(91.2)	0.61
Duration of admission to GR (days); median (IQR) §	38.0	(29.0-64.0)	37.0	(21.0-63.0)	42.5	(33.8-64.5)	0.15

10MWT=10-meter walk test; GDS-8=8-item Geriatric Depression Scale; HADS-A=Hospital Anxiety and Depression Scale-subscale Anxiety; MMSE=Mini Mental State Examination; Self-reported activity restriction due to fear of falling, scores indicate never (0), almost never (1), sometimes (2), often (3) and very often (4)

* Continuous variables tested with one-way analysis of variance (normal distribution) and Mann-Whitney u-test (skewed distribution); Dichotomous variables tested with χ^2 test. † Higher scores indicate better status. ‡ Lower scores indicate better status. § Numbers do not add up to final numbers due to missing data. SD=standard deviation; IQR=interquartile range

Figure 1. Flow diagram of the FIT-HIP study



RESULTS

Figure 1 presents the participant flow chart of the FIT-HIP trial. Participants were recruited between March 2016 and January 2017. Due to a limited inclusion rate (despite extending the recruitment period by two months), only 78 participants were included (39 in each group). Both groups had a similar drop-out rate during the study; frequently related to health problems. No GR units withdrew participation during the trial.

Table 2 presents the baseline characteristics of the study population; mean age was 83 (SD=7.6) years, the majority was female (79%), and lived alone prior to fracture (66%). The treatment groups differed in baseline ambulation function and comorbidity count (median FAC score usual care group: 3; respectively 2 in the intervention group (p=0.002); median FCI score usual care group: 2.5; respectively 3.5 in the intervention group (p=0.05)). Both groups had a similar length of stay in GR and similar rates of discharge home. No significant differences were identified with regard to therapy intensity (total amount of treatment in GR; physiotherapy and treatment by psychologist; data not shown).

Table 3 presents the results of the primary models, adjusted for baseline score of outcome measure, baseline FAC and FCI. Data from the less extensive models is presented in Appendix 2, and only differed from the primary model with regard to the FES-I score at T1.

Primary outcome measures: fear of falling and mobility

At discharge from GR, the usual care group showed a decrease in FoF compared to the intervention group. However, this difference was not significant (estimated difference between the mean change scores for FES-I score of 3.3 (95% CI -4.1; 3.6) (p=0.13)), and did not persist after discharge. In the usual care group, the FES-I score increased to a greater extent, leading to comparable levels of FoF in both groups during follow-up (Table 3; Figure 2). At discharge, no differences between groups were found for the POMA change score (estimated difference between mean change scores -0.3; 95% CI -6.5; 5.8) (p=0.90).

Secondary outcomes

Both groups had a slight decrease in activity restriction due to FoF at discharge, and a subsequent increase during follow-up. The outcome scores were comparable. The two groups did not differ with regard to ambulation function (Table 3).

Harms /adverse events

Comparable rates of mortality and hospital readmissions were found in both groups (Appendix 3). However, more fall events and participants encountering > 1 fall event were identified in the usual care group.

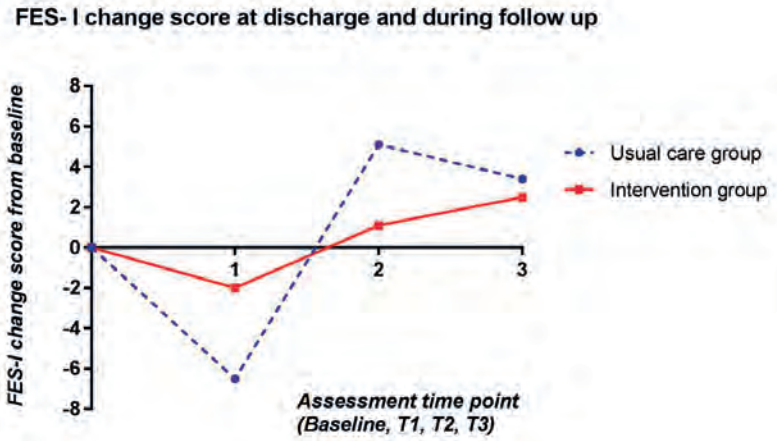
Table 3. Effects of the FIT-HIP intervention on primary and secondary outcomes: within and between-group differences between baseline and discharge, and at 3 and 6-month follow-up

	Baseline value		Within-group differences						Between-group differences: adjusted mean difference (95% CI) using primary linear mixed model. Intervention vs usual care group*					
	T0		ΔT1-0		ΔT2-T0		ΔT3-T0		T1		T2		T3	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	Adj mean diff	*P*	Adj mean diff	*P*	Adj mean diff	*P*
Primary outcomes														
FES-I (16-64)														
Usual care	37	34.4 (11.4)	33	-6.5 (8.9)	23	5.1 (16.5)	24	3.4 (18.4)						
Intervention	37	33.9 (9.9)	33	-2.0 (10.2)	23	1.1 (13.0)	23	2.5 (10.9)	3.3 (-1.0; 7.5)	0.13	-4.1(-11.8;3.6)	0.29	-2.8(-10.0;4.4)	0.44
POMA (0-28)														
Usual care	38	5.3 (7.0)	34	10.8 (8.2)		†		†						
Intervention	39	3.5 (6.8)	33	11.5 (7.9)		†		†	-0.3 (-6.5;5.8)	0.90	†		†	
Secondary outcomes														
Activity restriction due to fear of falling (0-4)														
Usual care	38	0.7 (1.0)	34	-0.3 (1.2)	25	1.3 (1.1)	26	1.2 (1.6)						
Intervention	39	0.9 (1.1)	34	-0.2 (1.1)	23	1.2 (1.4)	24	0.7 (1.4)	0.1 (-0.5;0.7)	0.77	-0.1 (0.8;0.7)	0.82	-0.5 (-1.2;0.3)	0.23
FAC (0-5)														
Usual care	38	2.7 (1.4)	34	1.4 (1.4)	21	1.7 (1.4)	25	1.8 (1.4)						
Intervention	39	1.7 (1.4)	34	2.2 (1.3)	22	2.4 (1.3)	21	2.6 (1.4)	0.1 (-0.3;0.5)	0.62	0.0 (-0.5;0.6)	0.90	0.1 (-0.6;0.8)	0.75

Adj mean diff = adjusted mean difference. FES-I= Falls Efficacy scale International (higher score indicating a higher level of fear of falling); POMA= Performance Oriented Mobility Assessment (higher score indicates better balance and gait function). Self-reported activity restriction due to fear of falling, scores indicate never (0), almost never (1), sometimes (2), often (3) and very often (4); FAC = Functional Ambulation Categories (higher score indicates a higher level of dependence in ambulation).

Δ = change score reflecting difference between the score at time point (Tx) and baseline score (T0) *Primary linear mixed model analysis adjusting for cluster randomization (random intercept at cluster level) ; with baseline value of outcome measure, baseline value of FAC and baseline value of Functional Comorbidity Index (FCI) as fixed effects. Between-group difference describes adjusted difference in Δ between the usual care and intervention group, with usual care group as reference category. † Not applicable, POMA was only assessed at discharge (T1), not at follow-up.

Figure 2. FES-I change score at discharge and during follow-up.



FES-I= Falls Efficacy Scale International. Range 16-64; higher score indicating a higher level of fear of falling. Baseline assessment score as reference for change score.

DISCUSSION

This cluster RCT among patients with hip fracture found no positive effects of the FIT-HIP intervention on the primary outcome measures for mobility (POMA) and fear of falling (FES-I), when compared to usual care. At discharge from GR, the usual care group had a greater reduction in FES-I score compared with the intervention group. However, this difference did not persist over time and, due to a trend toward a greater increase of FoF in the usual care group, this resulted in comparable levels for both groups at 3 and 6 months after discharge. Additionally, no differences were observed between the groups with regard to ambulation (FAC) and self-reported activity restriction due to FoF.

Inappropriate timing of screening and treatment of FoF is perhaps the most important explanation for the finding that the FIT-HIP intervention did not prove to be beneficial in reducing FoF. Although the negative effect of FoF on physical and functional outcome after hip fracture is well established,[14,35-37] a recent study provided insight into the course of FoF after hip fracture in relation to long-term physical functioning.[16] These latter results confirm findings from Oude Voshaar and colleagues and illustrate that FoF that presents shortly after the fracture (2-4 weeks) is not predictive for poorer long-term physical performance (6-12 months), in contrast to FoF that is present 6-12 weeks after the fracture.[13,16] This suggests a 'time-mediated effect' for FoF after fracture. Accordingly, this may indicate that FoF that occurs in the initial course of rehabilitation after hip fracture can be transient and may even represent an adaptive and normal response to the sudden impairment in physical condition (including reduced balance

function), as opposed to FoF that persists or arises at a later stage. In the present trial, we assessed FoF in the first week of GR. Generally, this represents the second week after fracture (due to an average hospital admission of one week). Treatment started directly after enrollment and was administered only during inpatient GR (with the exception of the telephonic booster post-discharge).[28] An inpatient GR program for hip fracture patients usually lasts 6-7 weeks,[15,27] as was also the case in our study. This implies that the FIT-HIP intervention mainly targets the initial phase of recovery after fracture in which FoF does not seem to be associated with negative long-term effects on functional outcome.

If we then postulate that FoF does not by definition solely have negative effects, and may under certain circumstances be an adaptive response, it may be of interest to (re)consider the role of anxiety in the context of fall related concerns. Anxiety has been associated with (higher levels of) FoF, both in community dwelling older adults,[38] and in patients with hip fracture.[15] In recent literature, FoF has been approached and reconceptualized from perspectives from post-traumatic stress disorder (PTSD).[39,40] In this context, Adamczewska and collegue argue that the presence of anxiety is the key to whether FoF becomes maladaptive. In our study population, low scores were reported for symptoms of anxiety (median HADS-A score at baseline 3.0 in the usual care group respectively 4.0 in the intervention group; score > 7 indicating possible anxiety disorder). If anxiety has a critical role in the development of maladaptive or excessive forms FoF, this would suggest an inappropriate selection of the target group in our study, and may present a second reason for the absence of effect of the FIT-HIP intervention.

A possible explanation for the unexpected post-intervention effect at discharge (i.e. the reduction in FES-I score in the usual care group in contrast to relatively consistent levels in the intervention group), is that treatment of FoF leads to increased awareness of fall risk and fall-related concerns. This was also found by Faes and colleagues in the evaluation of a multifactorial falls prevention program aimed at reducing FoF of falling in frail community-dwelling older adults.[41] However, an important outcome in our study is that the differences in level of FoF were not accompanied by differences in reported activity restriction due to FoF and physical performance (POMA/FAC). Furthermore, the effect identified in the usual care group was not sustained.

Considering that a different (i.e. more advanced) timing may be more appropriate to target FoF, we can subsequently question whether the FIT-HIP intervention has the potential to effectively reduce FoF. To our knowledge there are no comparable studies reporting on treatment of FoF in patients with hip fracture (although a protocol has been published),[42] or in other target groups in (geriatric) rehabilitation that are known to frequently report FoF.[43] The cognitive behavioral approach used in the FIT-HIP intervention is based on intervention programs proven effective in reducing FoF in community-dwelling older adults.[21-26] Various reviews have

evaluated interventions for FoF in community-dwelling older people and found that efficacious interventions were typically multi-component programs, combining exercise and cognitive behavioral therapy.[19,20,44,45] Similarly, this was effective in reducing FoF in nursing home residents.[46] In particular cognitive restructuring, personal goal setting, promotion of physical activities, graded tasks and behavioral practice are mentioned as core elements to reduce concerns about falls.[44,47] The key element of the FIT-HIP intervention is guided exposure to the feared activities and this is embedded in physical therapy sessions, therefore representing the combination of a cognitive behavioral approach and exercise. Promotion of physical exercise is also an important part of our relapse prevention. Furthermore, cognitive restructuring is represented in the FIT-HIP intervention, although the intensity and duration may differ from other programs. Therefore, based on current knowledge and practice, the FIT-HIP intervention has (in theory) effective components to reduce FoF. The planned process evaluation of this trial will assess to what extent the intervention was performed according to the protocol.

The results of this study demonstrate that management of FoF after recent hip fracture remains a challenge. In our opinion, several aspects of FoF after hip fracture need to be unraveled before proceeding to evaluate an intervention in a later phase of the rehabilitation process. We recommend that further research first focuses on exploring the 'time-mediated effect' of FoF after hip fracture, thereby gaining insight into how the direct physical consequences of hip fracture (e.g. diminished muscle strength and balance, and dependence in ADL), influence and relate to FoF. Subsequently, it is important to evaluate how to distinguish the normal adaptive form of FoF from the dysfunctional and perhaps disproportionate form that requires treatment. A better understanding of the concept of FoF after fracture (including the possible mediating role of anxiety), can help in adequately assessing when, and to what extent, treatment for FoF is required.

To our knowledge, the FIT-HIP study is the first to evaluate and report on treatment for FoF after hip fracture. A major strength of the study is the cluster RCT design with a 6-month follow-up period. We could therefore limit contamination with regard to the complex intervention.[48] As the transition to the home setting is probably a significant trigger for FoF,[43] it is important to evaluate long-term effects following discharge home, as we have done. A limitation of cluster randomization compared to individual randomization is the increased risk of imbalance in (observed and also unknown) baseline characteristics, as was seen in our data (FAC and FCI). However, sophisticated statistical techniques such as linear mixed models are able to take into account the clustering effects and adjust for the imbalance. Correcting for comorbidity did lead to a different outcome compared to less extensive models, which underpins the need to adjust for this established factor influencing outcome after hip fracture. [9,10,34] As the study was performed within inpatient multidisciplinary GR, the participants represent a particularly vulnerable group, and the results are not generalizable to all hip fracture patients. However, a

general feature of the GR population (reflecting eligibility criteria for GR), is that, based on the functional prognosis, there is reasonable probability that the patient will recover sufficiently to return home. This generally implies a reasonable pre-fracture functional ability and sufficient learning ability (no major cognitive deficits). This is in line with our inclusion criteria. However, there may be a underrepresentation of psychiatric symptoms in our study population (hence a relatively better functional prognosis). This may contribute to the ceiling effect seen for the FAC.

CONCLUSION / RELEVANCE

This cluster RCT demonstrates that the FIT-HIP intervention was not effective in reducing FoF and improving mobility in geriatric rehabilitation after recent hip fracture. In order to adequately identify whether treatment of FoF is required, further research should explore the concept of FoF after fracture and differentiate between: i) FoF that can be considered a normal and adaptive response and ii) conditions when it is dysfunctional and disproportional.

For current clinical practice, we suggest to primarily focus on the FoF that hampers progress in functional recovery. We recommend routine screening of FoF at onset and evaluation of the rehabilitation treatment, in order to observe the course of FoF and timely identify when FoF becomes maladaptive. Screening for co-morbid anxiety may also be useful in this context. The existing treatment programs (e.g. *'A Matter of Balance'* [22-26]) can be considered for treatment of maladaptive FoF in later stages of rehabilitation. When excessive or dysfunctional FoF is present in the initial phase of rehabilitation, we expect that a cognitive behavioral approach (such as guided exposure and cognitive restructuring) can be effective.

For an overview of the main insights and recommendations - see Appendix 4.

DECLARATIONS

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Conflicts of interest

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REFERENCES

1. Wilson H. Orthogeriatrics in Hip Fracture. Open Orthop J. 2017;11:1181-1189
2. Giannoulis D, Calori GM, Giannoudis PV. Thirty-day mortality after hip fractures: has anything changed? Eur J Orthop Surg Traumatol. 2016;26(4):365-70
3. Asplin G, Carlsson G, Zidén L, et al. Early coordinated rehabilitation in acute phase after hip fracture - a model for increased patient participation. BMC Geriatr. 2017;17(1):240
4. Handoll HH, Cameron ID, Mak JC, et al. Multidisciplinary rehabilitation for older people with hip fractures. Cochrane Database Syst Rev. 2009;(4):CD007125
5. Crotty M, Unroe K, Cameron ID, et al. Rehabilitation interventions for improving physical and psychosocial functioning after hip fracture in older people. Cochrane Database Syst Rev. 2010(1):CD007624
6. Nordström P, Thorngren KG, Hommel A, et al. Effects of Geriatric Team Rehabilitation After Hip Fracture: Meta-Analysis of Randomized Controlled Trials. J Am Med Dir Assoc. 2018;19(10):840-845
7. Dyer SM, Crotty M, Fairhall N, et al. Fragility Fracture Network (FFN) Rehabilitation Research Special Interest Group. A critical review of the long-term disability outcomes following hip fracture. BMC Geriatr 2016;16:158
8. Aarden JJ, van der Esch M, Engelbert RHH, van der Schaaf M, et al. Hip Fractures in Older Patients: Trajectories of Disability after Surgery. J Nutr Health Aging. 2017;21(7):837-842
9. Dyer SM, Crotty M, Fairhall N, et al. Fragility Fracture Network (FFN) Rehabilitation Research Special Interest Group. A critical review of the long-term disability outcomes following hip fracture. BMC Geriatr 2016;16:158
10. Dyer SM, Crotty M, Fairhall N, et al. Fragility Fracture Network (FFN) Rehabilitation Research Special Interest Group. A critical review of the long-term disability outcomes following hip fracture. BMC Geriatr 2016;16:158
11. Aarden JJ, van der Esch M, Engelbert RHH, van der Schaaf M, et al. Hip Fractures in Older Patients: Trajectories of Disability after Surgery. J Nutr Health Aging. 2017;21(7):837-842
12. Kristensen MT. Factors affecting functional prognosis of patients with hip fracture. Eur J Phys Rehabil Med. 2011;47(2):257-64
13. Morri M, Chiari P, Forni C, et al. What Factors Are Associated With the Recovery of Autonomy After a Hip Fracture? A Prospective, Multicentric Cohort Study. Arch Phys Med Rehabil. 2018;99(5):893-899
14. Magaziner J, Simonsick EM, Kashner TM, et al. Predictors of functional recovery one year following hospital discharge for hip fracture: a prospective study. J Gerontol 1990;45(3):M101-107
15. Mossey JM, Mutran E, Knott K, et al. Determinants of recovery 12 months after hip fracture: The importance of psychosocial factors. Am J Public Health 1989; 79(3):279-86
16. Oude Voshaar RC, Banerjee S, Horan M, et al. Fear of falling more important than pain and depression for functional recovery after surgery for hip fracture in older people. Psychol Med. 2006;36(11):1635-45
17. Visschedijk J, Achterberg W, Van Balen R, et al. Fear of falling after hip fracture: a systematic review of measurement instruments, prevalence, interventions, and related factors. J Am Geriatr Soc. 2010;58(9):1739-48
18. Visschedijk J, van Balen R, Hertogh C, et al. Fear of falling in patients with hip fractures: Prevalence and related psychological factors. J Am Med Dir Assoc 2013;14(3):218-20
19. Bower ES, Wetherell JL, Petkus AJ, et al. Fear of Falling after Hip Fracture: Prevalence,

Course, and Relationship with One-Year Functional Recovery. Am J Geriatr Psychiatry. 2016;24(12):1228-1236

20. Scheffer A C, Schuurmans MJ, van Dijk N, et al. Fear of falling: Measurement strategy, prevalence, risk factors and consequences among older persons. Age Ageing 2008; 37(1):19-24
21. Van der Meulen E, Zijlstra GA, Ambergen T, et al. Effect of fall-related concerns on physical, mental, and social function in community-dwelling older adults: a prospective cohort study. J Am Geriatr Soc 2014;62(12):2333-8
22. Zijlstra GA, van Haastregt JC, van Rossum E, et al. Interventions to reduce fear of falling in community-living older people: a systematic review. J Am Geriatr Soc. 2007;55(4):603-15
23. Whipple MO, Hamel AV, Talley KMC. Fear of falling among community-dwelling older adults: A scoping review to identify effective evidence-based interventions. Geriatr Nurs. 2018;39(2):170-177
24. Tennstedt S, Howland J, Lachman M, et al. A randomized, controlled trial of a group intervention to reduce fear of falling and associated activity restriction in older adults. J Gerontol B Psychol Sci Soc Sci. 1998;53(6):384-92.
25. Zijlstra GA, Tennstedt SL, van Haastregt JC, et al. Reducing fear of falling and avoidance of activity in elderly persons: The development of a Dutch version of an American intervention. Patient Educ Couns 2006;62(2):220-7
26. Zijlstra GA, van Haastregt JC, Ambergen T, et al. Effects of a multicomponent cognitive behavioral group intervention on fear of falling and activity avoidance in community-dwelling older adults: Results of a randomized controlled trial. J Am Geriatr Soc 2009;57(11):2020-8
27. van Haastregt JC, Zijlstra GA, Hendriks MR, et al. Cost-effectiveness of an intervention to reduce fear of falling. Int J Technol Assess Health Care 2013;29(3):219-26
28. Zijlstra GA, van Haastregt JC, Du Moulin MF, et al. Effects of the implementation of an evidence-based program to manage concerns about falls in older adults. Gerontologist. 2013;53(5):839-49
29. Dorresteijn TA, Zijlstra GA, Ambergen AW, et al. Effectiveness of a home-based cognitive behavioral program to manage concerns about falls in community-dwelling, frail older people: results of a randomized controlled trial. BMC Geriatr 2016;16:2
30. Holstege MS, Caljouw MAA, Zekveld IG, et al. Successful Geriatric Rehabilitation: Effects on Patients' Outcome of a National Program to Improve Quality of Care, the SINGER Study. J Am Med Dir Assoc. 2017;18(5):383-387
31. Scheffers-Barnhoorn MN, van Haastregt JC, Schols JM, et al. A multi-component cognitive behavioural intervention for the treatment of fear of falling after hip fracture (FIT-HIP): protocol of a randomised controlled trial. BMC Geriatr 2017;17:71.
32. Meijer R, van Limbeek J, de Haan R: Development of the Stroke-unit Discharge Guideline: choice of assessment instruments for prediction in the subacute phase post-stroke. Int J Rehabil Res. 2006;29(1):1-8.
33. Gillespie LD, Clare Robertson M, Gillespie WJ, et al. Interventions for preventing falls in older people living in the community. Cochrane Database Syst Rev. 2012;9:CD007146
34. Verenso. Elderly care physicians in the Netherlands: Professional profile and competencies (2015). https://www.verenso.nl/_asset/_public/Vereniging/VER0026_Professionalprofile_broch_DEF.pdf
35. Visschedijk JH, Terwee CB, Caljouw MA, et al. Reliability and validity of the Falls Efficacy Scale-International after hip fracture in patients aged ≥ 65 years. Disabil Rehabil 2015;37(23):2225-32
36. Faber MJ, Bosscher RJ, van Wieringen PC. Clinimetric properties of the performance-oriented mobility assessment. Phys Ther. 2006;86(7):944-954
37. Lim KK, Yeo W, Koh JSB, et al. The Role of Prefracture Health Status in Physical and Mental Function After Hip Fracture Surgery. J Am Med Dir Assoc. 2018;19(11):989-994.

38. McKee KJ, Orbell S, Austin CA, et al. Fear of falling, falls efficacy, and health outcomes in older people following hip fracture. Disabil Rehabil. 2002;24(6):327-33
39. Portegijs E, Edgren J, Salpakoski A, et al. Balance confidence was associated with mobility and balance performance in older people with fall-related hip fracture: a cross-sectional study. Arch Phys Med Rehabil. 2012;93(12):2340-6
40. Jellesmark A, Herling SF, Egerod I, et al. Fear of falling and changed functional ability following hip fracture among community-dwelling elderly people: an explanatory sequential mixed method study. Disabil Rehabil. 2012;34(25):2124-31
41. Payette MC, Bélanger C, Léveillé V et al. Fall-Related Psychological Concerns and Anxiety among Community-Dwelling Older Adults: Systematic Review and Meta-Analysis. PLoS One. 2016; 11(4): e0152848
42. Bloch F. A New Accurate Clinical Assessment Tool for Fear of Falling Is Needed for Older Patients. J Am Med Dir Assoc. 2019 Feb;20(2):220-221.
43. Adamczewska N, Nyman SR. A New Approach to Fear of Falls From Connections With the Posttraumatic Stress Disorder Literature. Gerontol Geriatr Med. 2018;4:1-7
44. Faes MC, Reelick MF, Melis RJ, et al. Multifactorial fall prevention for pairs of frail community-dwelling older fallers and their informal caregivers: a dead end for complex interventions in the frailest fallers. J Am Med Dir Assoc. 2011;12(6):451-8
45. Kampe K, Kohler M, Albrecht D, et al. Hip and pelvic fracture patients with fear of falling: development and description of the "Step by Step" treatment protocol. Clin Rehabil. 2017;31(5):571-581
46. Visschedijk JH, Caljouw MA, Bakkers E, et al. Longitudinal follow-up study on fear of falling during and after rehabilitation in skilled nursing facilities. BMC Geriatr. 2015;15:161
47. Liu TW, Ng GYF, Chung RCK, et al. Cognitive behavioural therapy for fear of falling and balance among older people: a systematic review and meta-analysis. Age Ageing. 2018;47(4):520-527
48. Kendrick D, Kumar A, Carpenter H, et al. Exercise for reducing fear of falling in older people living in the community. Cochrane Database Syst Rev. 2014;28(11):CD009848.
49. Huang TT, Chung ML, Chen FR, et al. Evaluation of a combined cognitive-behavioural and exercise intervention to manage fear of falling among elderly residents in nursing homes. Aging Ment Health. 2016;20(1):2-12
50. Vestjens L, Kempen GI, Crutzen R, et al. Promising behavior change techniques in a multicomponent intervention to reduce concerns about falls in old age: a Delphi study. Health Educ Res. 2015;30(2):309-22
51. Flicker L. Intervention research in nursing homes: the rise and rise of the cluster randomized trial. J Am Med Dir Assoc. 2008;9(4):213-4

APPENDIX

Table A1. Linear mixed model structure used in the FIT-HIP study

Primary model	
Fixed effects (all outcome measures)	Treatment group* Baseline value outcome measure Baseline value FAC Baseline value FCI
Additional fixed effects (for outcome measures with assessments at T2 and T3) †	Time (T1-T3) Interaction term 'treatment group x time'
Random effects	Intercept ‡
Covariance structure §	Factor analytic first order

Primary model: linear mixed model analysis adjusting for cluster randomization, baseline value of outcome measure, and, to take into account the imbalance found (in possible confounders) between groups at baseline, the baseline value of Functional Ambulation Categories (FAC) and Functional Comorbidity Index (FCI). Based on change score in outcome measure from baseline (score Tx – score T0). T1=discharge from Geriatric Rehabilitation (GR); T2= 3 month follow up after discharge from GR. T3= 6 month follow up after discharge from GR.

Other models: compared to the primary model, the three less extensive linear mixed model analyses contain following fixed effects (in addition to treatment group): i) baseline value outcome measure; ii) baseline value outcome measure + FAC score iii) baseline value outcome measure + baseline FCI score.

*Treatment group: [usual care group] respectively [intervention group]. † Outcome measures with assessments at T2 and T3: FES-I= Falls Efficacy scale International; FAC = Functional Ambulation Categories; and self-reported activity restriction due to fear of falling. ‡ Random intercept accounting for dependence within a cluster. § Based on Akaike's information criterion. Factor analytic first order is a covariance structure that allows temporal correlation (i.e. accounts for dependence between multiple measurements of the same patient).

Table A2. Treatment effects of FIT-HIP intervention - All linear mixed models

	Between-group differences: Intervention vs usual care group*					
	T1		T2		T3	
	Adj mean diff (95% CI)	P-value	Adj mean diff (95% CI)	P-value	Adj mean diff (95% CI)	P-value
FES-I (16-64)						
Adjusted for: baseline FES-I	4.9 (1.1; 8.7)	0.013	-2.6 (-10.1; 4.9)	0.50	-0.7 (-7.6; 6.3)	0.85
Adjusted for: baseline FES-I + FAC	4.4 (0.4; 8.5)	0.033	-3.0 (-10.5; 4.5)	0.43	-1.1 (-8.1; 5.9)	0.75
Adjusted for: baseline FES-I + FCI	3.5 (-0.5; 7.5)	0.09	-3.9 (-11.6; 3.7)	0.31	-2.6 (-9.7; 4.5)	0.47
Adjusted for: baseline FES-I + FAC + FCI	3.3 (-1.0; 7.5)	0.13	-4.1 (-11.8; 3.6)	0.29	-2.8 (-10.0; 4.4)	0.44
POMA (0-28)						
Adjusted for: baseline POMA	-0.7 (-3.8; 2.4)	0.64	†		†	
Adjusted for: baseline POMA + FAC	-0.2 (-3.5; 3.2)	0.92	†		†	
Adjusted for: baseline POMA + FCI	-0.3 (-6.4; 5.7)	0.89	†		†	
Adjusted for: baseline POMA + FAC + FCI	-0.3 (-6.5; 5.8)	0.90	†		†	
Activity restriction due to fear of falling (AR) (0-4)						
Adjusted for: baseline AR	0.2 (-0.3; 0.8)	0.41	0.0 (-0.7; 0.7)	0.96	-0.4 (-1.1; 0.4)	0.33
Adjusted for: baseline AR + FAC	0.2 (-0.4; 0.7)	0.50	0.0 (-0.7; 0.7)	0.90	-0.4 (-1.1; 0.4)	0.30
Adjusted for: baseline AR + FCI	0.1 (-0.5; 0.7)	0.68	-0.1 (-0.8; 0.7)	0.87	-0.4 (-1.2; 0.3)	0.24
Adjusted for: baseline AR + FAC + FCI	0.1 (-0.5; 0.7)	0.77	-0.1 (-0.8; 0.7)	0.82	-0.5 (-1.2; 0.3)	0.23
FAC (0-5)						
Adjusted for: baseline FAC	0.0 (-0.4; 0.4)	0.92	-0.1 (-0.6; 0.5)	0.85	0.0 (-0.6; 0.6)	1.00
Adjusted for: baseline FAC + FCI	0.1 (-0.3; 0.5)	0.62	0.0 (-0.5; 0.6)	0.90	0.1 (-0.6; 0.8)	0.75

Adj mean diff = adjusted mean difference. T1=discharge from Geriatric Rehabilitation (GR); T2= 3 month follow up after discharge from GR. T3= 6 month follow up after discharge from GR. FES-I= Falls Efficacy scale International (higher score indicating a higher level of fear of falling); POMA= Performance Oriented Mobility Assessment (higher score indicates better balance and gait function). Self-reported activity restriction due to fear of falling, scores indicate never (0), almost never (1), sometimes (2), often (3) and very often (4); FAC = Functional Ambulation Categories (higher score indicates a higher level of dependence in ambulation). † Not applicable, POMA was only assessed at discharge (T1), not at follow-up.

*Linear mixed model analysis adjusting for cluster randomization (random intercept at cluster level) and one or more of the following fixed effects: baseline value of outcome measure; baseline value of FAC; baseline value of Functional Comorbidity Index (FCI). Between-group difference describes adjusted difference in Δ (=change score Tx -T0), between the usual care and intervention group, with usual care group as reference category.

Table A3. Adverse events reported during the FIT-HIP study

	Usual care group		Intervention group	
	During GR	Follow-up	During GR	Follow-up
Death (n)	2	0	0	3
Hospital readmissions (n)				
Total amount of readmissions	3	5	3	2
Participants with readmission(s)	3	4	2	2
Fall events (n)				
Total amount of fall events	12	19	4	5
Participants with fall event(s)	4	10	4	4
Fracture(s) due to fall event*	0	1	0	2

GR = inpatient multidisciplinary Geriatric Rehabilitation. Follow up = assessments at 3 and 6 months after discharge from Geriatric Rehabilitation.

*Usual care group: fracture of the thumb; intervention group: ankle fracture and second hip fracture.

Table A4. Main Insights From the FIT-HIP Study

What is already known on this topic

- Fear of falling (FoF) is highly prevalent (in rehabilitation) after hip fracture. For hip fracture patients, there is currently no treatment program available.
- FoF can lead to avoidance of activities which consequently can hamper progress in rehabilitation. In hip fracture patients, FoF is associated with diminished long term functional outcome. Recent literature however suggests that this effect does not apply directly after hip fracture, but from 6 weeks post-fracture.
- This may imply that FoF can under certain conditions be adaptive. Recent approaches to FoF propose that anxiety determines whether FoF develops to a maladaptive form.

Key findings and insights from the FIT-HIP trial

- The FIT-HIP intervention, a multi-component cognitive behavioral approach integrated in usual care in geriatric rehabilitation after hip fracture, was not effective in reducing FoF or improving functional outcome in early rehabilitation after hip fracture.
- Timing of treatment of FoF after hip fracture may largely contribute to the absence of effect, as treatment was administered shortly after fracture.
- In view of the assumption that FoF is not by definition always dysfunctional and maladaptive, appropriate screening to identify maladaptive forms of FoF (that require treatment) remains a challenge. Anxiety may have a crucial role in this context.

Implications for clinical practice

- Not all patients with FoF after hip fracture require treatment in the initial stage of rehabilitation. However, it is important to identify patients with maladaptive or disproportionate FoF that impedes physical activity and progress in functional recovery.
- We recommend screening for FoF at onset of the rehabilitation and routinely when the rehabilitation treatment is evaluated, in order to observe the course of FoF and timely identify when FoF becomes maladaptive. Additionally, screening for anxiety may be supportive to identify individuals at risk for dysfunctional FoF.
- When dysfunctional FoF is present in later stages of rehabilitation (with independent ambulation), it can be addressed by existing treatment programs for community dwelling older adults, such as programs based on 'A Matter of Balance'. Cognitive behavioral approaches such as guided exposure can be considered for treatment in initial stages of rehabilitation.

Recommendations for further research

- Further research should focus on appropriately identifying maladaptive forms of FoF. In this regard, both the aspect of timing after hip fracture and the (possible) mediating role of anxiety on FoF is of interest.

Chapter 4

Feasibility of a multicomponent cognitive behavioral intervention for fear of falling after hip fracture: process evaluation of the FIT-HIP intervention.

Scheffers-Barnhoorn MN, van Eijk M, Schols JMGA, van Balen R, Kempen GIJM, Achterberg WP, van Haastregt JCM. BMC Geriatr. 2021 Apr 1;21(1):224. doi: 10.1186/s12877-021-02170-5. PMID: 33794804; PMCID: PMC80177

ABSTRACT

Background

This study describes the process evaluation of an intervention developed to reduce fear of falling (FoF) after hip fracture, within an inpatient geriatric rehabilitation setting. This 'FIT-HIP intervention' is a multicomponent cognitive behavioral intervention, conducted by physiotherapists and embedded in usual care in geriatric rehabilitation in the Netherlands. A previous study (cluster randomized controlled trial) showed no beneficial effects of this intervention when compared to usual care. The aim of this study was to gain insight into factors related to the intervention process that may have influenced the effectiveness of the intervention.

Methods

This process evaluation was conducted using an observational prospective study design. Based on quantitative and qualitative data derived from session logs, evaluation questionnaires and interviews, we addressed: 1] recruitment and reach; 2] performance according to protocol; 3] patients' adherence; and 4] opinions of patients and facilitators on the intervention. Participants in this study were: a) patients from 6 geriatric rehabilitation units, who were invited to participate in the intervention (39 adults aged ≥65 years with hip fracture and FoF) and; b) intervention facilitators (14 physiotherapists and 8 psychologists who provide coaching to the physiotherapists).

Results

Thirty-six patients completed the intervention during inpatient geriatric rehabilitation. Apart from cognitive restructuring and telephonic booster (which was not provided to all patients), the intervention was performed to a fair degree in accordance with protocol. Patients' adherence to the intervention was very good, and patients rated the intervention positively (average 8.1 on a scale 0-10). Although most facilitators considered the intervention feasible, a limited level of FoF (possibly related to timing of intervention), and physiotherapists' limited experience with cognitive restructuring were identified as important barriers to performing the intervention according to protocol.

Conclusions

The FIT-HIP intervention was only partly feasible, which may explain the lack of effectiveness in reducing FoF. To improve the intervention's feasibility, we recommend selecting patients with maladaptive FoF (i.e. leading to activity restriction), being more flexible in the timing of the intervention, and providing more support to the physiotherapists in conducting cognitive restructuring.

Trial registration

Netherlands Trial Register: NTR5695 (7 March 2016)

Key words

Process evaluation, Feasibility, Fear of falling, Hip fracture, Cognitive behavioral intervention, Geriatric rehabilitation

BACKGROUND

Many older adults who have sustained a hip fracture will go through an extensive and generally challenging process of rehabilitation.[1,2] During this recovery process, a substantial number of patients will experience concerns about falling (once) again.[3,4] This fear of falling (FoF), is defined as '*a lasting concern about falling that leads to an individual avoiding activities that he/she remains capable of performing*'.[5] Prevalence rates of up to 63% have been reported for FoF in inpatient geriatric rehabilitation after hip fracture.[4] As a consequence of the activity restriction associated with FoF, deterioration in physical functioning and a decline in social participation and quality of life can occur.[3,6] FoF may even have more effect on functional recovery after fracture than pain and depression.[7] Hence, FoF appears to be an important risk factor for impaired recovery,[3,8,9] which could possibly be addressed by treatment.

Patients with a recent hip fracture differ from the general population of community-dwelling older adults in that they experience a sudden impairment of their gait function and consequently become dependent in (basic) activities of daily living.[2] In the Netherlands, approximately half of all older patients with a hip fracture follow an inpatient multidisciplinary rehabilitation program after surgical repair of the fracture. These '*geriatric rehabilitation*' services are specialized in the medical care for frail older adults.[10] Therapy is aimed at optimizing the patient's physical condition and restoring (gait) function.[11] Physical therapy focuses on training balance and muscle strength, and practicing activities of daily living.[12] At present there are no treatment programs aimed specifically at reducing FoF after a recent hip fracture. However, for community-dwelling older adults, various evidence-based interventions have been developed to reduce FoF.[13-18] Particularly the treatment programs that combine exercise with cognitive behavioral approaches have been found to be effective in reducing FoF.[16-18] In the Netherlands, two of these evidence-based programs using cognitive behavioral approaches have been nationally implemented (based on *'A Matter of Balance'*[19]).[15,20] However, in their current format (community- or home-based), these established programs are not suitable for the therapeutic setting of inpatient geriatric rehabilitation. The cognitive behavioral approaches used in these programs were therefore adjusted to an individualized treatment program that fits the (physio) therapeutic setting within rehabilitation services. This *Fear of falling InTervention in HIP fracture geriatric rehabilitation* (FIT-HIP intervention) was designed to reduce FoF and consequently to improve functional outcome in inpatient geriatric rehabilitation after hip fracture.[21] However, a recent cluster randomized controlled trial evaluating the effects of the FIT-HIP intervention showed the program was not effective in reducing FoF or improving functional outcome after hip fracture.[12]

The aim of this process evaluation therefore is to gain insight into factors that may have influenced the effectiveness of the intervention. Subsequently, findings from this study can provide

insight into opportunities to improve both the intervention itself and its implementation in clinical practice. In this study we assessed the feasibility of the FIT-HIP intervention in clinical practice based on the following aspects of the intervention process: 1] recruitment and reach; 2] performance according to protocol (*dose delivered and fidelity*); 3] adherence (*dose received exposure*); and 4] opinion on the intervention provided by patients and facilitators (*dose received satisfaction and context*). These items are based on the framework of Saunders and colleagues.[22,23] This model for process evaluation is frequently used within health care innovations and is based on the widely acknowledged principles of Steckler et al (2002).[24]

METHODS

Study design

This process evaluation has an observational prospective design, combining qualitative and quantitative research methods. It was conducted in conjunction with the cluster randomized controlled trial that evaluated effectiveness of the FIT-HIP intervention.[12] Ethical approval was provided by the Ethics Committee of the Leiden University Medical Center (LUMC) and the study was registered in the Netherlands Trial Register (NTR5695). Patients were recruited between March 2016 and January 2017 from 11 post-acute geriatric rehabilitation units in the Netherlands. For the present study we focused on the patients and intervention facilitators from the six units that were allocated to the FIT-HIP intervention.

Intervention

The FIT-HIP intervention is an individualized, multicomponent intervention based on cognitive behavioral approaches. It aims to reduce FoF in inpatient geriatric rehabilitation after hip fracture. The intervention is conducted by physiotherapists from the participating units and is integrated in usual care in geriatric rehabilitation (i.e. physical therapy sessions). The following cognitive behavioral elements are embedded in the intervention: 1] guided exposure to feared activities; 2] cognitive restructuring; 3] psychoeducation; 4] relapse prevention (*Staying Active Plan* and telephonic booster); and 5] motivational interviewing. These elements are combined with regular exercise training in rehabilitation. The physiotherapists are counseled by psychologists (from participating units) during daily practice. This coaching is organized as (on-site) monthly meetings and interim consultation at the request of the physiotherapists.

The study protocol published previously[21] and Table 1 provide detailed information on the rationale and schedule of the various items within intervention. The intervention, which is integrated in the regular geriatric rehabilitation treatment, starts directly after admission and lasts for the duration of the inpatient rehabilitation (in general six to seven weeks).[10] First, patients have an intake interview with the physiotherapist, to assess which circumstances cause

concerns of falling, and to determine treatment goals. Next, based on this information, the physiotherapist puts together a tailor-made treatment plan for the application of the guided exposure (i.e. the *FIT-HIP fear ladders*). Guided exposure is considered the core element of the FIT-HIP intervention and is applied within the regular physical therapy sessions as long as the FoF persists. Guided exposure may not be necessary in all sessions (in the event the FoF has subsided). Cognitive restructuring is also tailored to the patient's needs. The frequency will depend on whether the patient has unrealistic thoughts and on the patient's receptiveness to such an approach. Cognitive restructuring is practiced at least twice during the inpatient rehabilitation treatment (including a homework assignment) and can be repeated as needed. Psychoeducation is provided in the initial stage of rehabilitation (first three weeks) and in the final stage when discharge is being planned. In both stages the information is provided during at least one session. The psychoeducation in the final stage is integrated in the relapse prevention plan (i.e. *Staying Active Plan*), a reference book given to the patient at discharge. A topic list of the psychoeducation is provided in Additional file 1. The telephonic booster six weeks after discharge (one session) is the final element of the intervention. Motivational interviewing does not have a fixed schedule in the intervention, as it is applied by the physiotherapists during the entire FIT-HIP program, in order to assess and relate to the patient's intrinsic and extrinsic motivation for rehabilitation.

Participants

Patients were older adults (≥ 65 years) with fear of falling, admitted to inpatient geriatric rehabilitation following hip fracture. FoF was assessed using the following one-item question with a 5-point Likert scale, '*Are you concerned to fall?*' (answer options: *never - almost never - sometimes - often - very often*). Eligible for participation were patients who reported concerns about falling at least 'sometimes'. Exclusion criteria included conditions interfering with learnability [dementia; a score >1 on the Hetero-anamnesis List Cognition (HAC)[25] (suggestive for premorbid cognitive disabilities); or major psychiatric disease]; furthermore, a pre-fracture Barthel index score <15; pathologic hip fracture; life expectancy <3 months; and insufficient mastery of the Dutch language. All patients provided written informed consent for participation in the study. Thirty-nine patients were included in the present study.

The intervention providers, from here forward entitled *facilitators*, were physiotherapists working in the participating intervention units (two per unit), and psychologists. The physiotherapists were actively engaged in the multidisciplinary geriatric rehabilitation team and had experience in the field of (orthopedic) rehabilitation for frail older adults. One psychologist from each unit was involved for the on-site coaching of physiotherapists. Most participating units were specialized in orthopedic rehabilitation and the patient volume of these units varied from [19-34]. Initially facilitators from six units were trained, but due to a limited inclusion rate after four months, we included an additional unit (affiliated to one of the participating units).

Table 1. Overview of the FIT-HIP intervention

Element	Description
Guided exposure – *rationale*	Guided exposure is the graded and repeated exposure to situations that give rise to fear (of falling). As recurrent exposure to the feared situation or activity is performed under supervision and in a manner that is predictable and controllable, this leads to the positive experience that the fear gradually fades out as the activity is practiced more often. After the fear for this specific situation has subsided, the exposure can be extended to the 'next level', practicing the activity in a manner that leads to a greater level of fear (fear hierarchy for graded exposure). For fear of falling (FoF), the feared activities will be situations concerning physical activity. In the rehabilitation after hip fracture, this will predominantly be basic activities in daily living, such as transferring, standing and walking.
Implementation in the FIT-HIP intervention	In the FIT-HIP intervention the physiotherapist helps the participant assess situations that give rise to FoF (within the first week of admission to geriatric rehabilitation (GR)). For each 'feared' activity the physiotherapist and participant draft a fear hierarchy, designed as a 'fear ladder' (template example published in protocol).[28] The FIT-HIP fear ladder consists of six 'steps', each step representing a functional goal. The functional goal describes in which manner the activity is practiced/performed. The goals are ranked with an increasing level of FoF as the activity gets more complex (or has to be performed with less assistance). The FIT-HIP fear ladders are the guiding principle for the multidisciplinary approach to apply guided exposure for all aspects of mobilization. The physiotherapist evaluates the fear ladders with the participant weekly and the fear ladders are revised on the basis of progress (reduction of FoF).
*Intervention provider(s)**	Physiotherapists during physical therapy sessions. As applicable, by nursing staff when assisting patients in basic activities of daily living that give rise to FoF. Nursing staff assisting participants in practicing 'fearful' activities as 'homework assignments' after physical therapy.
Schedule	Incorporated in all physical therapy sessions (and nursing care activities) for the duration of inpatient multidisciplinary GR as long as FoF persists.
Cognitive restructuring - *rationale*	Thoughts (and associated beliefs) influence how a person feels and accordingly how a person appraises and responds to a situation. Excessive concern to fall (fear of falling) can be based on unrealistic thoughts and beliefs with regard to (risk of) falling. This excessive FoF may lead to avoidance of (physical) activity and consequently fortify the FoF. Cognitive restructuring is a technique used to explore thoughts and beliefs and therefore to identify, challenge and modify unrealistic thoughts. In the FIT-HIP intervention participants are coached to explore their thoughts concerning physical activity and fall risk. In doing so they are encouraged to identify maladaptive and unrealistic thoughts and in turn formulate and apply more realistic thoughts. The principle of (un)realistic thoughts is also incorporated into the relapse prevention plan (see below).
Implementation in the FIT-HIP intervention	Physiotherapists are trained to guide the participant in exploring their thoughts concerning physical activity and (risk of) falling. A worksheet is used to structure the process of cognitive restructuring and to provide the participant insight in this process (analyzing the situation and the associated thoughts, feelings, behavior and consequences and subsequently formulating more realistic thoughts).
*Intervention provider(s)**	Physiotherapists. A psychologist is trained as a 'buddy' to coach the physiotherapists in these principles as when additional help is needed.
Schedule	During at least one physical therapy session the cognitive restructuring is applied and practiced with the participant. Subsequently, the participant is encouraged to fill in the worksheet as a 'homework assignment'. This is reviewed and discussed during the next therapy session. These 'key' thoughts can briefly be recapitulated in situations when the FoF is noticeable in the physical therapy sessions. The process of cognitive restructuring can be repeated as needed (when the FoF persists).

Table 1. Overview of the FIT-HIP intervention	
Psychoeducation - *rationale and implementation in the FIT-HIP intervention*	The psycho-education is used to reinforce the various elements of the FIT-HIP intervention. In the initial phase of GR the participant receives information on anxiety, (consequences and treatment of) FoF and the rationale and background of guided exposure and cognitive restructuring. In the final phase of GR, when discharge home is being planned, the psycho-education focusses on home safety. The information on home safety is also processed in the relapse prevention plan (see below). For detailed information of the psychoeducation, see the topic list presented in Additional file 1
*Intervention provider(s)**	Physiotherapists discuss the information with the participant.
Schedule	During at least two physical therapy sessions (one in the initial phase of rehabilitation; the other preceding the discharge home). As applicable, the psycho-education can additionally be incorporated in the therapy sessions, related to situations occurring during therapy (for example fall prevention).
Relapse prevention - *rationale*	The relapse prevention is aimed at helping the participant to anticipate and cope with relapse to FoF.
Implementation in the FIT-HIP intervention	In the FIT-HIP intervention the relapse prevention is designed to optimize the transition to predominantly independent living circumstances after discharge home. For this purpose, a 'relapse prevention plan' is composed together with the participant. This '*Staying Active Plan*' aims at preparing the participant for challenging situations in which there is a risk for relapse to FoF and activity restriction. The '*Staying Active Plan*' consists of (information on) 1. General home safety and fall prevention; 2. Individualized advice for safe ambulation and how to stay active; 3. Preventing, recognizing and dealing with a relapse (including notice of (mal)adaptive) thoughts). The information is discussed together with the participant and presented in writing as a reference book. In addition, a telephonic booster is conducted six weeks after discharge from GR. The telephonic booster is aimed at evaluating the FoF (and activity restriction). If necessary advice is given how to deal with FoF, in addition to the prior advice formulated in the '*Staying Active Plan*'.
*Intervention provider(s)**	Both the '*Staying Active Plan*' and telephonic booster are conducted by physiotherapists.
Schedule	During at least one physical therapy session during GR ('*Staying Active Plan*') and one telephonic booster session after discharge home.
Motivational interviewing	Physiotherapists are trained* in motivational interviewing techniques to assist the participant in the process of behavior change. These techniques help the physiotherapist gain insight into the participant's extrinsic and intrinsic motivation and explore which rehabilitation goals are important for the participant, in order to personalize treatment goals in the FIT-HIP intervention.

Notes: This table was published in *Journal of the American Medical Directors Association.* 2019;20(7):857-865.e852. Scheffers-Barnhoorn MN, van Eijk M, van Haastregt JCM, et al. Effects of the FIT-HIP Intervention for Fear of Falling After Hip Fracture: A Cluster-Randomized Controlled Trial in Geriatric Rehabilitation. Copyright of Elsevier (2019)

*Physiotherapists received two training sessions (four hours each); psychologists one 4-h session (together with physiotherapists). Nursing staff was briefed on the background and rationale of guided exposure, in order to help them incorporate these principles in their work and to adhere to the '*FIT-HIP fear ladders*' (45-60 min). Training was provided by the researcher (MSB) together with a cognitive behavioral therapist (BB; furthermore a health care psychologist and teacher). After training and start of the trial, the researcher (MSB) had regular telephonic sessions with the facilitators to discuss recruitment procedures and questions regarding the treatment protocol.

In total, 14 physiotherapists (12 female) and eight psychologists (all female) were involved in the FIT-HIP program, and all were trained to perform the FIT-HIP intervention. For training details: see Table 1.

Data collection

Table 2 presents an overview of the measurement instruments used to assess information for this process evaluation. Patients received a self-administered evaluation questionnaire at discharge from geriatric rehabilitation; and again at three and six months after discharge. We applied purposive sampling for the qualitative interviews with patients,[26] and aimed to conduct interviews with a selection of patients from all participating units and representing both sexes, until data saturation occurred. Patients were approached by telephone for the interviews. Physiotherapists were asked to fill in session logs for all therapy sessions, providing information on attendance, therapy content (which FIT-HIP elements were performed), reasons to deviate from protocol and the duration of therapy. Adherence was assessed using the *Pittsburg Rehabilitation Participation Scale* (PPRS) to score participants' active engagement during therapy. The PPRS is a 6-point Likert scale ranging from '*none*' (patient refused therapy) to '*excellent*'. The physiotherapists were approached for a semi-structured site-specific group interview, and psychologists for a telephone interview. They also received an evaluation questionnaire. As physicians and nursing staff are also involved in the general rehabilitation process, they were approached to fill in a short evaluation questionnaire (five questions), to assess the extent to which they had been informed of or involved in the patients' FIT-HIP treatment.

Interviews were conducted after the six-month follow-up. They were performed by the author MSB and recorded on audiotape (with the exception of the telephone interviews).

Data analysis

Quantitative data from the questionnaires and the session logs was analyzed by means of descriptive statistics using IBM SPSS Statistics version 23. The qualitative data from open-end questions in the questionnaires, session logs and the interviews, were transcribed and categorized based on content by author MSB. Telephone interviews were summarized and categorized.

Table 2. Outcome measures and associated measurement instruments used for the FIT-HIP process evaluation

	Registration forms		Evaluation questionnaires			Interviews		Other
	Physiotherapy session log	Telephonic booster log	Patient (T1,2,3) *	Facilitator †	GR team ‡	Patient	Facilitator †	Log researcher §
Recruitment								
Barriers to recruitment							X	X
Maintaining patient engagement							X	X
Performance according to protocol								
Intervention items conducted	X	X						
Reasons to deviate from protocol	X						X	
Patient adherence								
Active participation during physical therapy	X							
Reasons for not attending physical therapy	X							
Adherence to homework			X					
Use of *'Staying Active Plan'*			X					
Opinion on the intervention								
Overall opinion on the intervention			X			X	X	
Opinion of the value of the intervention (benefit)			X	X	X	X	X	
Perceived burden of the intervention			X			X		
Feasibility to perform the intervention				X			X	
Barriers to performing or implementing the intervention				X			X	X
Suggestion for improvement of the intervention			X	X	X	X	X	X

Notes: GR= inpatient Geriatric Rehabilitation. *T1 = at discharge from GR, T2 = 3 months after discharge from GR, T3 = 6 months after discharge from GR; † Facilitator = physiotherapist and psychologist; ‡ GR team = elderly care physician and nursing staff. § Log researcher = log of additional data recorded by research (assistants), including reasons for dropout and information from informal evaluations with facilitators during study.

Interviews performed by author MSB (clinician - trainee elderly care physician + PhD student, not involved in clinical care for the participants of the study). Setting: patient interviews in participant's home. Facilitator interviews in clinic. Duration interviews: one hour.

RESULTS

Recruitment, reach and response

Enrollment of patients per unit varied from 1-11 (Additional file 2). Thirty-nine patients were assigned to the FIT-HIP intervention, 34 of whom were female (87.2%). Age varied from 65-98 years (mean: 83.7 ± 7.3) and the majority lived alone prior to the fracture (n=27; 69.2%). At baseline one-third of the patients experienced concerns to fall (very) often, and the mean FES-I score (*Falls Efficacy Scale-International*) was 33.9 (SD:9.9); see also Additional file 3. The flow chart presented in Figure 1 shows recruitment, reach and response for both patients and facilitators. The timing of enrollment for the study (first week of rehabilitation) was regularly experienced as inconvenient by patients, as it was difficult for them to anticipate and oversee both the rehabilitation (treatment program) and participation in the study. The main challenge for maintaining patient engagement in the study was poor health. Thirty-six of the 39 patients completed the intervention during inpatient rehabilitation. Two patients did not receive the intervention and one withdrew from treatment in the final stage of rehabilitation due to health problems.

Based on patients that were actively enrolled in the study at the various assessments, the response rate for the patients' evaluation questionnaires was 58.8% (n=20) at discharge; and 92% (n=23) and 95.8% (n=23) at three and six months follow-up. We conducted interviews with nine patients; three patients declined to be interviewed. All units were represented within the interviews, with the exception of unit 4 (n=1 patient enrolled; Additional file 2). We excluded one session log from data analysis, as data were largely missing.

Two physiotherapists and one psychologist discontinued participation (Figure 1). One of these physiotherapists had treated one patient according to the FIT-HIP intervention, the other had no FIT-HIP patients. Ten of the 14 physiotherapists and six of the seven psychologists participated in the interviews. Response rates for health care professionals' evaluation questionnaires were: N=6 for physiotherapists (42.9%; representing four units); N=4 for psychologists (50.0%; representing three units); N=4 for physicians (44.4%; representing three units) and N=4 for nursing staff (representing two units).

Performance according to protocol

The FIT-HIP intervention was conducted during inpatient geriatric rehabilitation and in our study the length of stay varied from 21-98 days (median: 42). From study inclusion until discharge, patients on average received 30.7 physiotherapy sessions (range: 8-105), accounting for 15.7 hours of physiotherapy (range: 3.9-52.5).

Figure 1. Flow diagram of the FIT-HIP process-evaluation

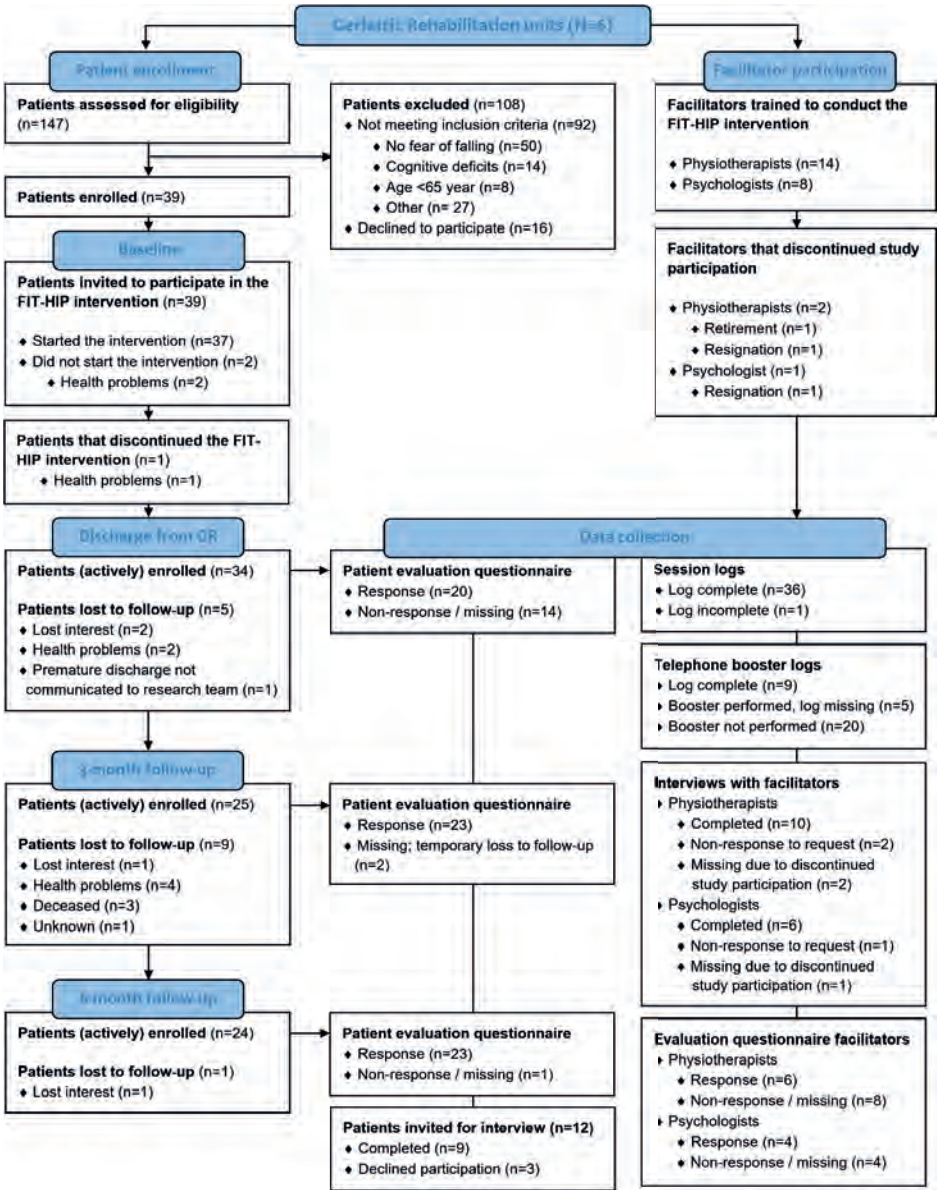

Table 3 provides an overview of the dose delivered per FIT-HIP intervention element. The FIT-HIP intake was carried out for all patients. Guided exposure, the key element of the intervention, was delivered to 97.2% of the patients (n=35). Lack of FoF after enrollment was the reason for not using guided exposure (n=1). On average, guided exposure was incorporated in 56.6% of all physiotherapy sessions (ranging from 5-100%; tailored to patient's needs and response

Table 3. Performance according to protocol

	Patients from all units (n=36)*		
	n	%	Min-max
FIT-HIP intake			
Number of patients who received the FIT-HIP intake	36	100	†
Guided exposure			
Number of patients with ≥ 1 session(s) of guided exposure	35	97.2	†
Mean number of sessions with guided exposure per patient‡; mean (SD)	18.9 (18.3)	†	1-95
Percentage of therapy sessions with guided exposure‡; mean (SD)	†	56.6 (28.3)	5-100
Psychoeducation			
Number of patients with ≥ 1 session(s) of psychoeducation within the first 3 weeks of study participation	34	94.4	†
Mean number of sessions with psychoeducation within the first 3 weeks of study participation per patient‡; mean (SD)	1.9 (1.3)	†	1-7
Cognitive restructuring (homework)			
Number of patients with ≥ 1 session(s) with cognitive restructuring	26	72.2	†
Mean number of sessions with cognitive restructuring per patient‡; mean (SD)	3.5 (1.9)	†	1-8
Number of patients who received ≥ 1 homework assignment for cognitive restructuring	18	50.0	†
Mean number of sessions registered for cognitive restructuring homework per patient‡; mean (SD)	1.8 (1.2)	†	1-6
Staying Active Plan			
Number of patients who received a *Staying Active Plan*	34	94.4	†
Mean number of sessions registered for the *Staying Active Plan* per patient ‡; mean (SD)	2.0 (1.0)	†	1-4
Telephonic booster			
Number of patients who received the telephonic booster after discharge	14	38.9	†

Notes: * All patients who (in part) received the FIT-HIP intervention (n=37); data missing from n=1 patient. † Not applicable. ‡ Based on patients who have received that element of the FIT-HIP intervention.

to treatment). Cognitive restructuring was performed according to protocol less frequently; 26 patients (72.2%) had this element within their treatment program. On average cognitive restructuring was incorporated in 3.5 ± 1.9 sessions. Eighteen patients (50.0%) received homework assignment(s) for cognitive restructuring. With regard to reasons for deviating from protocol for cognitive restructuring, lack of FoF was mentioned for three patients, and for the remaining seven patients the reason was unknown. The telephonic booster was carried out for 38.9% of the patients (n=14; of which n=9 were registered in booster log), resulting in this being the intervention element that was most frequently not performed according to protocol. Facilitators from unit 3 forgot to perform the booster (n=11 patients), one patient was repeatedly not available, and for the remaining patients who did not receive the booster, the reason was unknown.

Regarding the coaching of physiotherapists provided by psychologists, interviews revealed that the frequency of meetings decreased over time. At the start of the study, meetings were initiated and the intervention protocol was reviewed again within the team. However, during the course of the study there were few consultation requests from the physiotherapists and consequently the meetings did not take place each month.

Adherence

Based on the PRPS, active participation during the intervention sessions was very good to excellent for the majority of patients (56%; n=20). One patient's participation was rated as 'fair', the remaining 15 (41.2%) as 'good'. Patients reported their adherence to homework (including physical exercises) as follows: during rehabilitation they performed their homework *'sometimes'* (11.1%; n=2), *'most of the time'* (55.6%; n=10) or *'always'* (33.3%; n=6). Time spent on homework varied from 30-420 minutes per week. Three months post-discharge eight patients (42.1%) had *'never'* used the *Staying Active Plan;* three patients (15.8%) *'seldom or sometimes'* and eight patients *'most of the time'*. The reported adherence for the *Staying Active Plan* at six months was comparable.

Opinion on the intervention

Patient opinions

In general, patients had a positive opinion about the treatment provided by physiotherapists and rated this with a mean of 8.1 (scale 0-10 with higher scores indicating a more favorable opinion) (range 6-10; n=19). Ninety percent of the patients (n=18) evaluated quality of the facilitators as being (very) good. A large majority of the patients would recommend this treatment for fear of falling to other patients (88.2%; n=15). In general, the perceived burden of the physical effort during physiotherapy was rated as being *'just right'* (65.0%; n=13), yet 25.0% experienced it as *'too much'*. Using a 5-point Likert scale we assessed the perceived benefit of the intervention. At discharge from rehabilitation, half of the patients reported that the intervention was (very) helpful to reduce fear of falling and none reported having experienced no benefit from the intervention. The reported benefit after discharge decreased to 39.1% (n=9) at three months, and 33.4% (n=6) at six months. Patients reported most benefit from the *Staying Active Plan* (75.1%), guided exposure (62.5%) and psychoeducation (55.6%) (Table 4). After discharge, the reported benefit of the *Staying Active Plan* decreased to 35.7% and 36.4% after three and six months. The telephonic booster was considered least beneficial.

Interviews showed the patients were positive about the physiotherapists. The patient-therapist relationship was mentioned as an important facilitator for recovery. Patients specified the following key factors within this patient-therapist relationship: 1] trust in the competence of the therapist; 2] calm and supportive personality of the therapist; 3] personal attention for the patient during therapy; and 4] the continuity in treatment - provided by that specific therapist.

The fact that therapy was provided on a daily basis - sometimes multiple sessions - was helpful to (re)gain self-confidence. Additionally, patients experienced that having other patients as a reference during group sessions was supportive for recovery.

Table 4. Patients' perceived benefit of the FIT-HIP intervention

	Assessment		
	Discharge	3 months follow-up	6 months follow-up
This intervention item was (very) helpful to reduce the fear of falling*	n (%)	n (%)	n (%)
Psychoeducation (n=18)	10 (55.6)	†	†
Guided exposure (n=16)	10 (62.5)	†	†
Cognitive restructuring (n=16)	7 (43.8)	†	†
Cognitive restructuring homework (n=15)	6 (40.0)	†	†
Staying Active Plan (in general) (n= 16 / n=14 / n=11)	12 (75.1)	5 (35.7)	4 (36.4)
Telephonic booster (n=11)	†	1 (9.1)	†

Notes: * Based on a 5-point Likert scale with answer categories: *not at all; barely; a little; a lot; very much*. The last two answer categories (a lot; very much) describe that the intervention was (very) helpful to reduce fear of falling. † Not applicable

Care professionals' opinions

The majority of the physiotherapists (70%, n=7, representing four units) had a favorable opinion of the intervention and stated it was a good intervention for the treatment of FoF. These seven physiotherapists mentioned that intervention items such as psychoeducation, guided exposure and to some extent cognitive restructuring are already part of their (physiotherapy) treatment, but receive more attention and are offered in a more structured manner because of the intervention. Preferences for type of cognitive behavioral approach did, however, differ among these physiotherapists (guided exposure n=4; cognitive restructuring n=1; use of guided exposure or cognitive restructuring tailored to patient's response to these approaches n=2). Both physiotherapists and psychologists mentioned that this cognitive restructuring can be challenging for physiotherapists, depending on prior experience with psychosocial interventions. All facilitators questioned to what extent patients would use the *Staying Active Plan* after discharge.

For the physiotherapists with a less favorable opinion of the intervention, time constraints were an important barrier to performing the intervention according to protocol. They felt that treatment of fear (of falling) was more appropriate for psychologists and doubted the added value of the guided exposure principles over current usual care. Physiotherapists with positive attitudes toward the intervention (n=7), on the other hand, did not perceive time as a barrier to implementing the intervention (for future purposes). Although (mild) cognitive impairment was regularly observed in the study population, this was usually not perceived to be a barrier to applying treatment principles. Additional file 4 presents an overview of all challenges, barriers

and suggestions for improvement that were mentioned in this process evaluation; the main suggestions are highlighted below.

Suggestions for improvement

First, physiotherapists observed that after enrollment, the level of FoF among patients appeared to be limited, which consequently hindered the execution of the intervention according to protocol. To improve the efficiency and feasibility of the intervention on that account, it may be helpful to reconsider the selection of the target group (i.e. screening), and initiate treatment at a later stage of geriatric rehabilitation (i.e. if the FoF persists). Second, physiotherapists indicated that having more flexibility to tailor the treatment protocol to the individual patient would be helpful. In their experience, some patients were more receptive to guided exposure and others to cognitive restructuring. Hence, it would be useful to choose the most appropriate element for each individual patient, for example based on their treatment response and anxiety trait(s).

The third suggestion was to intensify the collaboration (and coaching function) between psychologists and physiotherapists, specifically with regard to cognitive restructuring. Although most physiotherapists felt they were capable of (partly) performing cognitive restructuring (as appropriate, with additional training and experience), they suggested it would be helpful if the psychologist routinely observed a physiotherapy session (for example once every week or two weeks). This would provide the opportunity to give additional advice to the physiotherapist, but also to monitor whether additional (psychological) treatment is required. To promote an interdisciplinary approach to addressing FoF, it was also recommended to train nursing staff in early recognition of FoF.

DISCUSSION

This study assessed the feasibility of a multicomponent cognitive behavioral intervention for FoF after hip fracture, integrated in usual care in inpatient rehabilitation. To a fair degree the intervention was performed according to protocol, but cognitive restructuring and the telephonic booster were not provided to all patients. Patients rated the intervention positively and half of them reported that the intervention was (very) helpful in reducing FoF. Most facilitators were positive about the intervention and considered it feasible. However, this study also identified barriers that may have affected this feasibility, and these should be addressed to improve the intervention. Two important barriers were the limited level of FoF after enrollment (possibly related to timing of the intervention), and the fact that physiotherapists, having limited experience with such approaches, perceived cognitive restructuring as challenging.

A considerable body of evidence demonstrates that programs based on cognitive behavioral approaches (preferably combined with physical exercise) are effective to reduce FoF in older adults with fall risk.[16-18,27] However, despite the benefit perceived by patients, the FIT-HIP intervention was not effective in reducing FoF when compared to usual care.[12] It is therefore crucial to reflect on the intervention process, in particular cognitive restructuring as this was not administered to all patients and was considered the most challenging element for facilitators. First, the dose of cognitive restructuring within the intervention does not differ significantly from other programs,[14,28,29] and this does not explain the absence of effect. However, in our study fewer patients received cognitive restructuring according to protocol (72.2% in the FIT-HIP study versus 83.4% in the home-based program for FoF in community-dwelling older adults).[30] This may have contributed to the lack of effectiveness.

The fact that cognitive restructuring is perceived as challenging does not by definition imply it is not feasible in practice or not suitable for frail older adults. Literature on nurse-led programs for FoF in community-dwelling older adults confirms the finding that cognitive restructuring can be challenging for facilitators and participants, yet these programs - despite the perceived difficulties - proved to be effective.[14,15,20] Regarding the appropriateness of cognitive restructuring for frail older adults, facilitators in our study acknowledged that even in cases of mild cognitive impairment, this approach still had potential short-term effects (during the therapy session), enhancing the rehabilitation process.

In a broader perspective, we could question whether it is appropriate for physiotherapists to apply cognitive restructuring. In the past years, interest in incorporating a biopsychosocial approach to physiotherapy practice to enhance the rehabilitation process has increased.[31] Research illustrates that overall, physiotherapists have positive attitudes and beliefs regarding psychosocial interventions.[31] Common barriers to implementation of psychosocial interventions in clinical practice include lack of knowledge, time constraints (including the perceived need to prioritize physical care) and the scope of practice (role clarity and public perceptions of traditional physiotherapist role).[31,32] These factors were also identified in our study, but rather than the lack of knowledge, the facilitators mentioned a desire for more experience. The current literature concerning psychosocial interventions with physiotherapists as facilitators recommends that, in order to ensure treatment fidelity, psychologists should provide comprehensive training and mentoring to the physiotherapists, including performance feedback.[32,33] Effectiveness of such an approach is supported by a recent study that showed positive effects of a physiotherapist-led in-home intervention to reduce FoF and activity avoidance, including cognitive restructuring and exposure therapy, in community-dwelling older adults.[18] The physiotherapists received weekly supervision by a psychologist, based on video tapes of the therapy sessions. Likewise, the *'Step by Step intervention'* aimed at reducing FoF after hip- or pelvic fracture, performed by physiotherapists who received weekly supervision by clinical

psychologists, also had favorable effects on reducing FoF.[27] In our intervention protocol the supervision by psychologists was limited to monthly team meetings and individual coaching on request. In practice this supervision occurred less frequently. This is therefore an area of attention for the future.

Reflecting on the *therapy intensity* in our intervention, thus comparing the individual intervention items to various effective multi-component interventions for FoF, is not straightforward, as this is not always described in detail in the available literature. Also, tailoring of the intervention to the specific needs of the patients can complicate insight in the therapy intensity. The core element of the FIT-HIP intervention is guided exposure to feared activities, which is integrated in most of the therapy sessions. In other intervention programs this element was generally limited to one or two therapy sessions.[28,33] Only the ABLE intervention, an in-home intervention for community dwelling older adults with excessive FoF, incorporated the exposure as a more elementary part of the program.[29] To the best of our knowledge, based on the intervention protocols, all programs had comparable frequency of delivery for psychoeducation on home safety and relapse prevention. Comparable to our program, the ABLE program included psychoeducation on the background on anxiety consequences and rationale for treatment.[28,29,33] The only other treatment program for FoF in this specific target group, the *'Step by Step intervention'* includes problem-solving and relaxation techniques as additional items as compared to the FIT-HIP intervention.[33] The intended therapy intensity of cognitive therapy in this program was similar to our intervention. Hence, the therapy intensity of the individual FIT-HIP intervention items, in the form of *therapy frequency*, does in itself not clearly explain the lack of effectivity of the FIT-HIP intervention.

Regarding the feasibility of the telephonic booster (six weeks after discharge): this element proved to be easily forgotten, as the physiotherapist was no longer involved in the patient's treatment after discharge. We incorporated the booster in the intervention based on lessons learned from the programs based on a *'Matter of Balance '*[30,34], and the insight that (increase in) FoF is common after discharge from geriatric rehabilitation.[35] We can, however, question whether a telephonic booster is useful for our target group, as patients who received the booster reported no benefit from this intervention element. Perhaps it would be more appropriate to extend the treatment for FoF to an ambulatory rehabilitation setting (in-home).[27,36]

An important barrier to acknowledge is the limited level of the FoF reported after enrollment in the study (i.e. selection of the target population). Facilitators pointed out that during screening (first week of rehabilitation), patients were mainly sedentary. Once patients started the process of mobilization (i.e. walking during therapy), in clinical practice the FoF appeared to decrease. The timing of the intervention in relation to the timeline after fracture may be a relevant factor to consider in the selection of the target group. Current literature illustrates

that FoF present 2-4 weeks after fracture is not associated with negative effects on long-term functional outcomes, contrary to FoF present 6-12 weeks post-fracture.[7,8] Provided that the fear is not *disproportionate* and does not lead to significant avoidance behavior (activity restriction), this could imply that FoF shortly after fracture can in some cases be a normal or adaptive process which does not require treatment. Unfortunately, for this specific group of patients, it is currently unknown what a *disproportionate level* of FoF is as measured with established instruments such as the FES-I. We can question whether the standard cut-off values are appropriate for this target group, especially because the FES-I appears to be more closely related to functional performance than to psychological concepts such as anxiety.[37] Patients with hip fracture experience a sudden impairment of the lower body function, and a certain level of 'caution' in relation to an increased fall risk in the early stage of recovery after fracture, may be an appropriate response. For clinical practice it seems relevant to monitor the course of FoF. Findings from a cohort study of hip fracture patients show three distinct patterns of FoF evolving from 4-12 weeks after fracture; i] patients with consistently low levels of FoF; ii] patients with high levels of FoF at 4 weeks that continue to increase; iii] patients with high levels of FoF at 4 weeks which decrease at 12 weeks post-fracture.[38] It is currently unknown how these distinct trajectories relate to avoidance behavior. However, it is plausible that especially those patients that have increasing levels of FoF are more susceptible to develop activity restriction as a consequence of FoF. Accordingly this may be an important group to address by means of intervention.

Another factor to consider when screening for FoF, is the (mediating) role of anxiety (traits) in the development of maladaptive or dysfunctional fear of falling.[18,39,40] Findings from Bower et al. show that patients with higher scores for neuroticism were more likely to have high levels of FoF.[38] Also, the previously mentioned in-home cognitive behavioral program for FoF that was conducted by physiotherapists and showed positive effects on reducing FoF and activity restriction, was aimed at patients with *disproportionate* FoF; as defined as high fear and low to moderate objective fall risk and functional impairment because of FoF.[29] The majority of participants had a psychiatric disorder, most frequently a pre-existing anxiety disorder.[18] In contrast, the FIT-HIP study population reported low scores for anxiety, had a lower level of FoF at baseline (Falls Efficacy Scale-International); and we excluded patients with generalized anxiety.[12,21] It may therefore be useful to incorporate screening for more generalized anxiety symptoms and also specifically include patients with anxiety for treatment.

Limitations

This process evaluation has several limitations. First, we cannot rule out the possibility of socially desirable answers given by patients and facilitators. To reduce the risk of such bias, we informed patients that data would be handled confidentially by the research team (not involved in treatment). For facilitators, we emphasized that their input was essential to improve the

intervention for future purposes. Second, the timing of the interviews may have led to recall bias among facilitators and patients. However, facilitators had no trouble recalling the intervention and were able to identify barriers and suggest improvements. Additionally, we collected information on barriers from the regular informal contact with physiotherapists (researcher log) during the course of the study. We therefore have extensive information concerning the intervention's feasibility, especially from the facilitator's perspective. A third limitation is the relatively low response for the evaluation questionnaires from patients at discharge from rehabilitation. Physiotherapists coordinated this assessment, as the date of discharge could occasionally be brought forward. They sometimes forgot to hand out the questionnaires. Despite additional postal 'follow-up' in these cases, the response rate remained limited. Finally, data on performance according to protocol (including fidelity), was limited to self-report measures (session logs and interviews), which can lead to more favorable responses in comparison to more objective measures. However, video recording of the physiotherapy sessions was considered to be too intrusive for the patients. The strength of this process evaluation is that the results are based on extensive quantitative and qualitative information obtained from patients and facilitators (both physiotherapists and psychologists). This was analyzed within a well-established framework for process evaluations (Saunders)[22] and provided a good insight into the feasibility of the FIT-HIP intervention, possible barriers to implementation and suggestions for improving the intervention.

Recommendations for improvement

First, in order to select an appropriate target population that can benefit from treatment, it is crucial to select patients with maladaptive FoF. Currently we do not know how to accurately quantify *disproportionate* levels of fear of falling for this specific target group. However, factors such as anxiety and avoidance behavior may contribute to the development of maladaptive FoF, and may aid the process of determining which patients require treatment. We therefore recommend screening patients for FoF, related activity restriction and comorbid anxiety at the start of the rehabilitation, and every time the rehabilitation treatment is evaluated. To assess activity restriction related to FoF, an instrument such as SAFE (Survey of Activities and Fear of Falling in the Elderly) could prove to be useful.[41] Treatment of FoF does not by definition have to be initiated directly at the start of rehabilitation, but treatment is advised when avoidance behavior for physical activities is observed. We also recommend treatment for FoF in the event the FoF is progressive or persists, which implies treatment in later stages of rehabilitation.

Second, to improve the feasibility of the FIT-HIP intervention we recommend the following adjustments regarding the content and organization of the intervention. 1] Intensify collaboration between physiotherapists and psychologists to (a form of) collective treatment, in order to support performance feedback for the physiotherapists and to enable timely identification when treatment is required from psychologist. We advise that psychologists observe the patient

during a physiotherapy session once a week. Furthermore, within each individual team, there should be clear agreements regarding the extent to which cognitive restructuring is provided by the physiotherapist (based on prior experience and the preferences of the physiotherapist), and which indications require referral to the psychologist. 2] We support the idea of a more tailored approach to applying guided exposure and cognitive restructuring. Based in part on the presence of anxiety traits, facilitators observed that some patients were more receptive to guided exposure and others to cognitive restructuring. We propose that physiotherapists continue to initiate treatment with both approaches and that the (most) appropriate treatment is determined during the joint treatment with psychologists. 3] More attention to cognitive restructuring in the training of facilitators may also be beneficial, as this element was perceived as most challenging. 4] Last, the telephonic booster can be eliminated from the intervention, due to lack of both feasibility for the facilitators and perceived benefit of the patients.

CONCLUSION

This process evaluation shows that the FIT-HIP intervention was only partly feasible, which may have contributed to the lack of effectiveness of the intervention. To improve feasibility and effectiveness, we recommend a number of adjustments to the intervention. These include selecting patients with *maladaptive* FoF (specifically in the context of avoidance behavior for physical activities), being more flexible with regard to the timing of the intervention (initiating treatment at a later stage of rehabilitation), and providing more support to the physiotherapists with regard to the cognitive restructuring. Although the FIT-HIP intervention in its current form was not effective, and only partly feasible, there is sufficient evidence that cognitive behavioral therapy is a feasible and effective approach to reduce FoF in older adults. We therefore expect that, with the proposed improvements, the FIT-HIP intervention has the potential to effectively reduce FoF. However, further research is needed to prove whether the suggested adjustments result in improved feasibility and effectiveness of the intervention.

DECLARATIONS

List of abbreviations

FES-I= Falls Efficacy Scale-International
FoF = Fear of Falling
FIT-HIP = Fear of falling InTervention in HIP fracture geriatric rehabilitation
LUMC = Leiden University Medical Center

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Authors' contributions

All authors were involved in the design of the study. MS was responsible for the data acquisition. MS and JvH performed the data analysis. All authors were involved in the interpretations of the findings. MS drafted the manuscript; all authors contributed to the manuscript and provided approval for the final submitted version of the manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval was provided by the Ethics Committee of the Leiden University Medical Center (LUMC); reference number P15.212 (09-09-2015). All participants provided written informed consent to participate in the FIT-HIP study.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

REFERENCES

1. Handoll HH, Cameron ID, Mak JC, Finnegan TP. Multidisciplinary rehabilitation for older people with hip fractures. *The Cochrane database of systematic reviews.* 2009(4):Cd007125.
2. Magaziner J, Chiles N, Orwig D. Recovery after Hip Fracture: Interventions and Their Timing to Address Deficits and Desired Outcomes--Evidence from the Baltimore Hip Studies. *Nestle Nutrition Institute workshop series.* 2015;83:71-81.
3. Visschedijk J, Achterberg W, Van Balen R, Hertogh C. Fear of falling after hip fracture: a systematic review of measurement instruments, prevalence, interventions, and related factors. *Journal of the American Geriatrics Society.* 2010;58(9):1739-1748.
4. Visschedijk J, van Balen R, Hertogh C, Achterberg W. Fear of falling in patients with hip fractures: prevalence and related psychological factors. *Journal of the American Medical Directors Association.* 2013;14(3):218-220.
5. Tinetti ME, Powell L. Fear of falling and low self-efficacy: a case of dependence in elderly persons. *Journal of gerontology.* 1993;48 Spec No:35-38.
6. Scheffer AC, Schuurmans MJ, van Dijk N, van der Hooft T, de Rooij SE. Fear of falling: measurement strategy, prevalence, risk factors and consequences among older persons. *Age and ageing.* 2008;37(1):19-24.
7. Oude Voshaar RC, Banerjee S, Horan M, et al. Fear of falling more important than pain and depression for functional recovery after surgery for hip fracture in older people. *Psychological medicine.* 2006;36(11):1635-1645.
8. Bower ES, Wetherell JL, Petkus AJ, Rawson KS, Lenze EJ. Fear of Falling after Hip Fracture: Prevalence, Course, and Relationship with One-Year Functional Recovery. *The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry.* 2016;24(12):1228-1236.
9. Ko Y, Lee J, Kim SY, Baek SH. Identification of Factors Related to Functional Decline of Korean Older Adults After Hip Fracture Surgery: A Cross-Sectional Study. *Research in gerontological nursing.* 2019:1-9.
10. Holstege MS, Caljouw MAA, Zekveld IG, et al. Successful Geriatric Rehabilitation: Effects on Patients' Outcome of a National Program to Improve Quality of Care, the SINGER Study. *Journal of the American Medical Directors Association.* 2017;18(5):383-387.
11. Achterberg WP, Cameron ID, Bauer JM, Schols JM. Geriatric Rehabilitation-State of the Art and Future Priorities. *Journal of the American Medical Directors Association.* 2019;20(4):396-398.
12. Scheffers-Barnhoorn MN, van Eijk M, van Haastregt JCM, et al. Effects of the FIT-HIP Intervention for Fear of Falling After Hip Fracture: A Cluster-Randomized Controlled Trial in Geriatric Rehabilitation. *Journal of the American Medical Directors Association.* 2019;20(7):857-865.e852.
13. Zijlstra GA, Tennstedt SL, van Haastregt JC, van Eijk JT, Kempen GI. Reducing fear of falling and avoidance of activity in elderly persons: the development of a Dutch version of an American intervention. *Patient education and counseling.* 2006;62(2):220-227.
14. Zijlstra GA, van Haastregt JC, Ambergen T, et al. Effects of a multicomponent cognitive behavioral group intervention on fear of falling and activity avoidance in community-dwelling older adults: results of a randomized controlled trial. *Journal of the American Geriatrics Society.* 2009;57(11):2020-2028.
15. Dorresteijn TA, Zijlstra GA, Ambergen AW, Delbaere K, Vlaeyen JW, Kempen GI. Effectiveness of a home-based cognitive behavioral program to manage concerns about falls in community-dwelling, frail older people: results of a randomized controlled trial. *BMC geriatrics.* 2016;16:2.

16. Liu TW, Ng GYF, Chung RCK, Ng SSM. Cognitive behavioural therapy for fear of falling and balance among older people: a systematic review and meta-analysis. *Age and ageing.* 2018;47(4):520-527.
17. Chua CHM, Jiang Y, Lim S, Wu VX, Wang W. Effectiveness of cognitive behaviour therapy-based multicomponent interventions on fear of falling among community-dwelling older adults: A systematic review and meta-analysis. *Journal of advanced nursing.* 2019.
18. Wetherell JL, Bower ES, Johnson K, Chang DG, Ward SR, Petkus AJ. Integrated Exposure Therapy and Exercise Reduces Fear of Falling and Avoidance in Older Adults: A Randomized Pilot Study. *The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry.* 2018;26(8):849-859.
19. Tennstedt S, Howland J, Lachman M, Peterson E, Kasten L, Jette A. A randomized, controlled trial of a group intervention to reduce fear of falling and associated activity restriction in older adults. *The journals of gerontology Series B, Psychological sciences and social sciences.* 1998;53(6):P384-392.
20. Zijlstra GA, van Haastregt JC, Du Moulin MF, de Jonge MC, van der Poel A, Kempen GI. Effects of the implementation of an evidence-based program to manage concerns about falls in older adults. *The Gerontologist.* 2013;53(5):839-849.
21. Scheffers-Barnhoorn MN, van Haastregt JC, Schols JM, et al. A multi-component cognitive behavioural intervention for the treatment of fear of falling after hip fracture (FIT-HIP): protocol of a randomised controlled trial. *BMC geriatrics.* 2017;17(1):71.
22. Saunders RP, Evans MH, Joshi P. Developing a process-evaluation plan for assessing health promotion program implementation: a how-to guide. *Health promotion practice.* 2005;6(2):134-147.
23. Wilson DK, Griffin S, Saunders RP, Kitzman-Ulrich H, Meyers DC, Mansard L. Using process evaluation for program improvement in dose, fidelity and reach: the ACT trial experience. *Int J Behav Nutr Phys Act.* 2009;6:79.
24. Steckler AL, L & Israel, B. Process Evaluation for Public Health Interventions and Research. *Wiley.* 2002.
25. Meijer R, van Limbeek J, de Haan R. Development of the Stroke-unit Discharge Guideline: choice of assessment instruments for prediction in the subacute phase post-stroke. *International journal of rehabilitation research Internationale Zeitschrift fur Rehabilitationsforschung Revue internationale de recherches de readaptation.* 2006;29(1):1-8.
26. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. *Administration and policy in mental health.* 2015;42(5):533-544.
27. Pfeiffer K, Kampe K, Klenk J, et al. Effects of an intervention to reduce fear of falling and increase physical activity during hip and pelvic fracture rehabilitation. *Age and ageing.* 2020;49(5):771-778.
28. Dorresteijn TA, Zijlstra GA, Delbaere K, van Rossum E, Vlaeyen JW, Kempen GI. Evaluating an in-home multicomponent cognitive behavioural programme to manage concerns about falls and associated activity avoidance in frail community-dwelling older people: Design of a randomised control trial [NCT01358032]. *BMC health services research.* 2011;11:228.
29. Wetherell JL, Johnson K, Chang D, et al. Activity, balance, learning, and exposure (ABLE): a new intervention for fear of falling. *International journal of geriatric psychiatry.* 2016;31(7):791-798.
30. Dorresteijn TA, Rixt Zijlstra GA, Van Haastregt JC, Vlaeyen JW, Kempen GI. Feasibility of a nurse-led in-home cognitive behavioral program to manage concerns about falls in frail older people: a process evaluation. *Research in nursing & health.* 2013;36(3):257-270.
31. Driver C, Kean B, Oprescu F, Lovell GP. Knowledge, behaviors, attitudes and beliefs

of physiotherapists towards the use of psychological interventions in physiotherapy practice: a systematic review. *Disability and rehabilitation.* 2017;39(22):2237-2249.

32. Nielsen M, Keefe FJ, Bennell K, Jull GA. Physical therapist-delivered cognitive-behavioral therapy: a qualitative study of physical therapists' perceptions and experiences. *Physical therapy.* 2014;94(2):197-209.
33. Kampe K, Kohler M, Albrecht D, et al. Hip and pelvic fracture patients with fear of falling: development and description of the "Step by Step" treatment protocol. *Clinical rehabilitation.* 2017;31(5):571-581.
34. van Haastregt JC, Zijlstra GA, van Rossum E, van Eijk JT, de Witte LP, Kempen GI. Feasibility of a cognitive behavioural group intervention to reduce fear of falling and associated avoidance of activity in community-living older people: a process evaluation. *BMC health services research.* 2007;7:156.
35. Visschedijk JH, Caljouw MA, Bakkers E, van Balen R, Achterberg WP. Longitudinal follow-up study on fear of falling during and after rehabilitation in skilled nursing facilities. *BMC geriatrics.* 2015;15:161.
36. van Balen R, Gordon AL, Schols JMGA, Drewes YM, Achterberg WP. What is geriatric rehabilitation and how should it be organized? A Delphi study aimed at reaching European consensus. *European Geriatric Medicine.* 2019.
37. Visschedijk JH, Terwee CB, Caljouw MA, Spruit-van Eijk M, van Balen R, Achterberg WP. Reliability and validity of the Falls Efficacy Scale-International after hip fracture in patients aged >/= 65 years. *Disability and rehabilitation.* 2015;37(23):2225-2232.
38. Bower ES, Wetherell JL, Petkus AJ, Lenze EJ. Neuroticism predicts fear of falling after hip fracture. *International journal of geriatric psychiatry.* 2020.
39. Adamczewska N, Nyman SR. A New Approach to Fear of Falls From Connections With the Posttraumatic Stress Disorder Literature. *Gerontology & geriatric medicine.* 2018;4:2333721418796238.
40. Young WR, Mark Williams A. How fear of falling can increase fall-risk in older adults: applying psychological theory to practical observations. *Gait & posture.* 2015;41(1):7-12.
41. Allison LK, Painter JA, Emory A, Whitehurst P, Raby A. Participation restriction, not fear of falling, predicts actual balance and mobility abilities in rural community-dwelling older adults. *J Geriatr Phys Ther.* 2013;36(1):13-23.

APPENDIX

Additional file 1. Topic list for psychoeducation within the FIT-HIP intervention

Part	Main topic(s)	Subtopics
1	Fear in general	Background on the function of fear. Dysfunctional forms of fear. Consequences of fear (on behavior); short term - relief of feelings of anxiety; long term - tendency to keep avoiding the situation. Leading to reduced self-efficacy.
	Fear of falling	Background on fear of falling - definition, symptoms, prevalence. Behavioral consequences: activity restriction; avoidance of physical activities with consequences for muscle strength, condition, balance. Increased risk of falling. Impact on social participation. Reduced quality of life.
	Perspective	Treatment possibilities – a guided approach to help stay active. Practicing physical activity under supervision in a controllable manner.
2	Guided exposure	Background on behavioral therapy. Interaction between behavior, cognition (thoughts) and emotion (feelings). Behavior influences emotional state. Behavioral therapy addresses behavior; evaluating how to alter the behavior to more functional forms. Background on guided exposure. Gradual, graded exposure to fearful situations: repeated mild anxiety response in controlled setting, eventually leading to reduction or extinction of fear. FIT-HIP fear ladders, illustrating the 'stepped' approach to the graded exposure to feared situations.
3	Cognitive therapy	Background on cognitive therapy. Interaction between cognitions (thoughts), emotion (feelings) and behavior. Thoughts and/or cognitions can be affect how we feel. And this can in turn influence our behavior. Automatic thoughts. Background on cognitive behavioral therapy: analyzing cognitions. Are they helpful? And if not, how can we address this to formulate more helpful cognitions.
4	General-prevention: *physical activity*	Stay active to keep muscles strong and supple. This will help reduce fall risk and in the event of accidental fall, aid in getting up easier. Thirty minutes of activity a day is helpful; for example walking, cycling, or house-hold chores.
	General fall-prevention: *home-safety*	Awareness for: sufficient lighting, potential hazards in home (cables, rugs, doorsteps), sufficient passageway for walking with walking aids. Alert systems. Occupational therapy: home-safety evaluation
	Fall-prevention: *other*	Awareness for: footwear, vision, medication
5	Personalized fall-prevention	Personalized advice regarding walking aids. Personalized advice regarding physical activity; with suggestions for exercises to perform. How to integrate exercise in the day schedule. Physical activity 'buddy'. Personalized advice regarding home safety.
6	Relapse prevention	Involve significant others (friends, family) to help stay active (physical activity buddy). Personal advice on how to recognize a relapse (which behavior, which feelings, which non-helpful thoughts). Advice how to address the non-helpful thoughts Ask help, discuss FoF with others (for example GP)

Additional file 2. Enrollment of and data on patients and facilitators per Geriatric Rehabilitation unit

	All units	GR unit 1	GR unit 2	GR unit 3	GR unit 4	GR unit 5*	GR unit 6
Patients (n)							
Included in the study	39	5	5	11	1	9	8
Who received the intervention	37	5	5	11	1	7	8
With completed evaluation questionnaire at discharge	20	3	3	5	0	3	6
With completed evaluation questionnaire at 3-month follow up	23	3	4	7	0	3	6
With completed evaluation questionnaire at 6-month follow up	23	4	4	6	0	4	5
Participating in patient interviews	9	2	1	3	0	1	2
Physiotherapists (n)							
Trained to conduct the FIT-HIP intervention	14	2	2	2	2	4	2
Completing study	12	2	1	2	2	3	2
Participating in evaluation interview	10	2	1	2	0	3	2
Psychologists (n)							
Involved in the FIT-HIP intervention	8	1	1	1	1	3	1
Completing study	7	1	1	0	1	3	1
Participating in evaluation interview	6	1	1	0	1	2	1

Note: * Geriatric Rehabilitation unit with a co-location included and trained 4 months after start of the trial.

Additional file 3. Fear of falling and associated activity restriction				
	Baseline (n=39)	Discharge (n=34)	3 month FU (n=24)	6 month FU (n=25)
Falls-Efficacy Scale International (FES-I) total score* Range 0-64; mean (SD)	33.9 (9.9)	32.8 (11.0)	35.1 (13.9)	36.5 (12.1)
Level of fear of falling measured with the VAS-score†* Range 0-100; mean (SD)	54.0 (17.4)	46.3 (24.2)	52.1 (28.8)	48.6 (28.1)
Fear of falling measured with the 1-item question‡ *'Are you concerned to fall?'*				
Number of participants with this response (%)			**	**
Never	0	3 (8.8)	0	1 (4.2)
Almost never	3 (7.7)	6 (17.6)	3 (13.0)	3 (12.5)
Sometimes	24 (61.5)	17 (50.0)	10 (43.5)	12 (50.0)
Often	10 (25.6)	6 (17.6)	6 (26.1)	5 (20.8)
Very often	2 (5.1)	2 (5.9)	4 (17.4)	3 (12.5)
Activity restriction measured with the 1-item question‡; *'Do you avoid activities due to fear of falling?'*				
Number of participants with this response (%)			**	**
Never	§	21 (61.8)	3 (13.0)	6 (25.0)
Almost never	§	7 (20.6)	6 (26.1)	5 (20.8)
Sometimes	§	5 (14.7)	7 (30.4)	9 (37.5)
Often	§	1 (2.9)	4 (17.4)	3 (12.5)
Very often	§	0	3 (13.0)	1 (4.2)

Notes: FU= follow up. *Lower scores indicate less fear of falling. †VAS = Visual analogue scale. VAS-FoF: '*On a scale of 0-100, with 0 being no concerns and 100 exceptionally high levels of concerns about falling,* how would you rate your concern about falling?' ‡ Based on a 5-point Likert scale with answer categories: *never; almost never; sometimes; often; very often*. § Not applicable **Numbers do not add up to final numbers due to missing data.

Additional file 4. Feedback and suggestions for improvement of the intervention provided by facilitators

Intervention element	Feedback	Suggestions for improvement
FIT-HIP intervention (as a whole)	1] Limited level of fear of falling (FoF) was perceived as a barrier to performing the intervention.	1 a] Improve the assessment of FoF, to determine those forms that require treatment (maladaptive FoF). 1 b] Consider starting treatment at a later stage of the inpatient rehabilitation.
FIT-HIP intake	1] Patients brought up few goals regarding (social) participation.	1] -
	2] In the current format, insight into the coping strategies used by patients is lacking	2] Consider adding the concept of illness beliefs to the intake. This provides insight into coping strategies.
Guided exposure	1] Patients may experience difficulty in formulating goals for fear ladders, due to cognitive impairment or lack of practical insight and understanding of the recovery process and rehabilitation goals.	1] Facilitators may need to provide (more) assistance in formulating goals for the fear ladders.
	2] Limited level of FoF can be a barrier to employing guided exposure.	2] Use fear ladders/guided exposure on indication. (tailoring intervention)
	3] The use of fear ladders for patients with more generalized forms of anxiety may enhance their fear and therefore be less appropriate.	3] Use fear ladders/guided exposure on indication. (tailoring intervention)
	4] It can be challenging to involve the entire health care team to support the guided exposure.	4] Involve the nursing staff and physician in drawing up the treatment plans for guided exposure.
Psychoeducation	1] Time and (re)sources to embed psychoeducation in care as usual are limited and can be perceived as a barrier to conducting it.	1 a] Consider embedding the psychoeducation into group sessions (with other target groups than hip fracture patients). 1 b] Consider a handout with information instead of psychoeducation provided by physiotherapist.
	2] Patients and other health care professionals may have different expectations regarding the content of physical therapy sessions (i.e. more physical exercises, less cognitive therapy).	2] The facilitators who perceive patients' expectation of the physiotherapist's role to be a barrier, suggest that psychoeducation be provided by a psychologist.

Additional file 4. Feedback and suggestions for improvement of the intervention provided by facilitators		
Cognitive restructuring including homework	1] Limited level of FoF can be a barrier to conducting the cognitive restructuring.	1] Use cognitive restructuring on indication (tailoring intervention).
	2] Cognitive restructuring can be time-consuming due to limited experience of the physiotherapist.	2] Perform cognitive restructuring together with psychologist (mentoring), to gain more experience.
	3] Cognitive restructuring can be difficult to perform. Not a role for physiotherapists.	3] The physiotherapists who state that cognitive restructuring is not part of a physiotherapist's role/ work, suggest that cognitive restructuring is performed by psychologists.
	4] Patients and other health care professionals may have different expectations regarding the content of physical therapy sessions (i.e. more physical exercises, less cognitive therapy).	4] Those facilitators who perceive patients' expectation of the physiotherapist's role to be a barrier, suggest the cognitive restructuring be conducted by a psychologist.
	5] One physiotherapist mentioned that the template for cognitive restructuring is difficult to use in this target group.	5] Simplify the template for cognitive restructuring.
	6] Cognitive impairment can make cognitive restructuring more challenging to perform.	6] Short-term effects (during the therapy session) can still be achieved. Application of cognitive restructuring can therefore still be appropriate.
Staying Active Plan	1] All physiotherapists questioned the long-term benefit of the Staying Active Plan.	1] -
	2] There is a limited input/ contribution from the patient (regarding personalized goals).	2] Facilitators may need to provide (more) assistance in formulating personalized goals.
	3] It is difficult to involve informal care givers (often children who work).	3] -
Telephonic booster	1] If problems occur after discharge, they will be present soon after discharge.	1] Perform the booster shortly after discharge.
	2] Reimbursement for inpatient geriatric rehabilitation stops after discharge. Therefore, there is no financing for the booster.	2] -
Motivational interviewing	1] Some facilitators had limited prior experience with motivational interviewing.	1] Provide additional training to facilitators with limited experience in motivational interviewing.

ADDITIONAL FILE 5. EVALUATION QUESTIONNAIRES (ENGLISH)

Seven different evaluation questionnaires were used to assess feasibility of the FIT-HIP intervention for patients, facilitators (physiotherapists and psychologists) and other health-care professionals in geriatric rehabilitation (nursing staff, elderly care physician). The questionnaires have been translated from the original language (Dutch) to English. The questionnaires are summarized below.

ADDITIONAL FILE 5 - QUESTIONNAIRE 1

Patient evaluation questionnaire – T1. Discharge from inpatient geriatric rehabilitation

Background

In the past few weeks you have participated in the FIT-HIP trial, a study aimed at evaluating the treatment of fear of falling after hip fracture. The inpatient rehabilitation treatment program you were following has recently ended (or will soon finish). We are interested in your experience with the treatment for fear of falling provided within the rehabilitation program. We therefore kindly ask you to answer the following questions. In this questionnaire we focus on treatment provided by physiotherapists and, if applicable, psychologists.

The data will be handled confidentially, only the research team has insight into this information (the therapists do not have insight into your answers).

Physiotherapy

1. On a scale of 1-10, how satisfied are you with the treatment provided to you during the physiotherapy sessions?
   - o I would rate the physiotherapy sessions: … [0-10]

2. What is your general opinion about the (quality of) the physiotherapist(s)?
   - o Very poor
   - o Poor
   - o Sufficient / average
   - o Good
   - o Very good

3. Was the physiotherapy treatment helpful to reduce the level of fear of falling?
   - o No, not at all
   - o No, barely
   - o Yes, a little
   - o Yes, a lot
   - o Yes, very much

4. What do you think of the physical effort expected of you during physical therapy?
   - o Far too much
   - o Too much

- o Just right
- o Not (quite) enough
- o Not nearly enough

5. Was the following content of physiotherapy treatment helpful to reduce the level of fear of falling?

a. Information about fear of falling and fall-risk
- o No, not at all
- o No, barely
- o Yes, a little
- o Yes, a lot
- o Yes, very much
- o Not applicable

b. Guided exposure to physical activity, based on your FIT-HIP treatment plan
- o No, not at all
- o No, barely
- o Yes, a little
- o Yes, a lot
- o Yes, very much
- o Not applicable

c. Challenging your thoughts about falling
- o No, not at all
- o No, barely
- o Yes, a little
- o Yes, a lot
- o Yes, very much
- o Not applicable

d. Home work: physical exercise
- o No, not at all
- o No, barely
- o Yes, a little
- o Yes, a lot
- o Yes, very much
- o Not applicable

e. Home work: challenging thoughts about falling
- o No, not at all
- o No, barely
- o Yes, a little
- o Yes, a lot

- o Yes, very much
- o Not applicable

f. Composing the 'Staying Active Plan' with your therapist
- o No, not at all
- o No, barely
- o Yes, a little
- o Yes, a lot
- o Yes, very much
- o Not applicable

6. Did you do the homework (physical exercises) provided to you?

o Never
o Seldom
o Sometimes
o Usually
o Always

7. On average, per week, how much time did you spend on the homework (physical exercises) [….minutes] / week

8. Did you use the worksheet '*Challenging Thoughts*' for homework assignment(s)?
- o No
- o Yes, I used this worksheet [….] time(s)

Treatment provided by a psychologist

9. Did you receive treatment from a psychologist, specifically for the fear of falling?
- o No à you may continue with question 13
- o Yes à you may continue with question 10

10. On a scale of 1-10, how satisfied are you with the treatment provided to you by the psychologist?
- o I would rate the treatment provided by the psychologist: … [0-10]

11. What is your general opinion about the (quality of) the psychologist?
- o Very poor
- o Poor
- o Sufficient / average
- o Good
- o Very good

12. Was the treatment provided by the psychologist helpful to reduce the level of fear of falling?
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

Inpatient rehabilitation treatment program

12. Would you recommend this treatment program for fear of falling, provided within the inpatient rehabilitation, to friends or family?
    - o No
    - o Yes

13. Do you have any additional remarks regarding the treatment program?

ADDITIONAL FILE 5 - QUESTIONNAIRE 2

Patient evaluation questionnaire – T2. Three months after discharge from geriatric rehabilitation

Background

In the past few months you have participated in the FIT-HIP trial, a study aimed at evaluating the treatment of fear of falling after hip fracture. Three months ago you were discharged from inpatient geriatric rehabilitation. We are interested in the perceived benefit of the treatment program to reduce fear of falling, specifically after discharge home. We therefore kindly ask you to answer the following questions.

Rehabilitation treatment program

1. Was the inpatient geriatric rehabilitation treatment program helpful to reduce the level of fear of falling in the past three months?
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

2. As a result of the inpatient geriatric rehabilitation treatment program, in the past three months,:

a. I am less concerned to fall
    - o Disagree
    - o Agree

b. I have avoided less activities
    - o Disagree
    - o Agree

Telephonic consultation with physiotherapist

3. Was the telephonic consultation with the physiotherapist, a few weeks after discharge from inpatient geriatric rehabilitation, helpful to reduce the level of fear of falling?
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much
    - o I did not receive a telephonic consultation with the physiotherapist

Staying Active Plan

4. Has your '*Staying Active Plan*' been helpful to reduce the level of fear of falling in the past three months?
   - o No, not at all
   - o No, barely
   - o Yes, a little
   - o Yes, a lot
   - o Yes, very much
   - o I do not have a '*Staying Active Plan*'

5. Your '*Staying Active Plan*' contains suggestions for physical exercises. Have you practiced these suggested exercises in the past three months?
   - o Never
   - o Seldom
   - o Sometimes
   - o Usually
   - o Always

6. Your '*Staying Active Plan*' discusses situations which can trigger fear of falling, and gives suggestions what can be helpful to do in such circumstances. Have the suggestions been helpful to reduce the level of fear of falling in the past three months?
   - o No, not at all
   - o No, barely
   - o Yes, a little
   - o Yes, a lot
   - o Yes, very much
   - o I do not have a '*Staying Active Plan*'

7. Do you have any additional remarks?

ADDITIONAL FILE 5 - QUESTIONNAIRE 3

Patient evaluation questionnaire – T3. Six months after discharge from geriatric rehabilitation

Background

In the past few months you have participated in the FIT-HIP trial, a study aimed at evaluating the treatment of fear of falling after hip fracture. Six months ago you were discharged from inpatient geriatric rehabilitation. We are interested in the perceived benefit of the treatment program to reduce fear of falling, specifically after discharge home. We therefore kindly ask you to answer the following questions.

Rehabilitation treatment program

1. Was the inpatient geriatric rehabilitation treatment program helpful to reduce the level of fear of falling in the past three months?
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

2. As a result of the inpatient geriatric rehabilitation treatment program, in the past three months:

a. I am less concerned to fall
    - o Disagree
    - o Agree

b. I have avoided less activities
    - o Disagree
    - o Agree

Staying Active Plan

3. Has your '*Staying Active Plan*' been helpful to reduce the level of fear of falling in the past three months?
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

- o I do not have a '*Staying Active Plan*'

4. Your '*Staying Active Plan*' contains suggestions for physical exercises. Have you practiced these suggested exercises in the past three months?
   - o Never
   - o Seldom
   - o Sometimes
   - o Usually
   - o Always

5. Your '*Staying Active Plan*' discusses situations which can trigger fear of falling, and gives suggestions what can be helpful to do in such circumstances. Have the suggestions been helpful to reduce the level of fear of falling in the past three months?
   - o No, not at all
   - o No, barely
   - o Yes, a little
   - o Yes, a lot
   - o Yes, very much
   - o I do not have a '*Staying Active Plan*'

6. Do you have any additional remarks?

ADDITIONAL FILE 5 - QUESTIONNAIRE 4

Evaluation questionnaire FIT-HIP intervention – physiotherapist(s)

Background

The FIT-HIP trial, aimed at evaluating the treatment of fear of falling after hip fracture, has been performed within your health care organization. In the past few months, you have conducted the FIT-HIP intervention. We are interested in your experience with the intervention, and would like to gain insight into the feasibility of the intervention. We therefore kindly ask you to answer the following questions.

General opinion of the FIT-HIP intervention

1. On a scale of 1-10, what is your general opinion of the FIT-HIP intervention?
    - o I would rate the FIT-HIP intervention: … [0-10]

Feasibility of the FIT-HIP intervention

2. To what extent were you able to adequately apply the following elements of the FIT-HIP intervention?

a. Provide psycho-education (concerning fear of falling and fall-risk)
    - o Insufficiently
    - o Barely
    - o Reasonably
    - o Well
    - o Very well

b. Perform the FIT-HIP intake interview
    - o Insufficiently
    - o Barely
    - o Reasonably
    - o Well
    - o Very well

c. Compose the individual FIT-HIP treatment plan (FIT-HIP fear ladders)
    - o Insufficiently
    - o Barely
    - o Reasonably
    - o Well
    - o Very well

d. Guided exposure (using the individual FIT-HIP treatment plan)
    - o Insufficiently
    - o Barely

- o Reasonably
- o Well
- o Very well

e. Assess fear of falling with VAS-scale
- o Insufficiently
- o Barely
- o Reasonably
- o Well
- o Very well

f. Cognitive restructuring (challenging thoughts)
- o Insufficiently
- o Barely
- o Reasonably
- o Well
- o Very well

g. Motivational interviewing techniques
- o Insufficiently
- o Barely
- o Reasonably
- o Well
- o Very well

h. Compose the 'Staying Active Plan'
- o Insufficiently
- o Barely
- o Reasonably
- o Well
- o Very well

i. Conduct the telephonic consultation (booster after discharge)
- o Insufficiently
- o Barely
- o Reasonably
- o Well
- o Very well

3. Is time-constraint a barrier to any future application of the FIT-HIP intervention ?
- o No
- o Yes

Perceived benefit of the FIT-HIP intervention

4. In your opinion, have patients had benefit of the FIT-HIP intervention?
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

5. In your opinion, have patients had benefit of the following elements of FIT-HIP intervention?

a. Psycho-education (concerning fear of falling and fall-risk)
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

b. Guided exposure
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

c. Cognitive restructuring (challenging thoughts) regarding (fear of) falling
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

d. Motivational interviewing techniques
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

e. The 'Staying Active Plan'
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot

- o Yes, very much

f. Telephonic consultation (booster after discharge)

- o No, not at all
- o No, barely
- o Yes, a little
- o Yes, a lot
- o Yes, very much

Specific instruments and methods

6. Was the use of the Goal Attainment Scale helpful?
   - o No, not at all
   - o Yes, a little
   - o Yes, very

7. Was the use of the VAS-scale for assessing fear of falling during the guided exposure helpful?
   - o No, not at all
   - o Yes, a little
   - o Yes, very

8. Was the use of the worksheet *'Challenging Thoughts'* helpful for the patients?
   - o No, not at all
   - o Yes, a little
   - o Yes, very

9. Was the monthly coaching with psychologists helpful?
   - o No, not at all
   - o Yes, a little
   - o Yes, very

10. Did you have sufficient material to perform the FIT-HIP intervention. If not, please could you explain.
    - o Yes,
    - o No, namely…[….]

Suggestions for improvement

11. Do you have suggestions for improvement for the following elements of the FIT-HIP intervention:

a. Psycho-education (concerning fear of falling and fall-risk)

b. FIT-HIP intake interview

c. The individual FIT-HIP treatment plan (*FIT-HIP fear ladders*)
d. Guided exposure (using the *individual FIT-HIP treatment plan*)
e. Assessment of level of fear of falling with VAS-scale
f. Cognitive restructuring (*challenging thoughts*)
g. Motivational interviewing techniques
h. The '*Staying Active Plan*'
i. The telephonic consultation (booster after discharge)

12. Do you have additional remarks, or ideas to improve the intervention?

ADDITIONAL FILE 5 - QUESTIONNAIRE 5

Evaluation questionnaire FIT-HIP intervention – psychologist

Background

The FIT-HIP trial, aimed at evaluating the treatment of fear of falling after hip fracture, has been performed within your health care organization. In the past few months you have been involved in the FIT-HIP intervention. We are interested in your experience with the intervention, and would like to gain insight into the feasibility of the intervention. Therefore we kindly request you to answer the following questions.

The role of psychologist within the FIT-HIP intervention

1. Have you, in the context of the FIT-HIP trial:

a. Coached physiotherapist(s)
   - o No
   - o Yes

b. Treated FIT-HIP patients for fear of falling
   - o No
   - o Yes

2. If you did provide treatment for fear of falling to FIT-HIP patients, what was the content of the therapy:

a. Psycho-education
b. Cognitive restructuring
c. Guided exposure
d. Other, namely …[….]

3. In your opinion, was the monthly coaching session helpful for the physiotherapists
   - o No, not at all
   - o Yes, a little
   - o Yes, very

Feasibility of the FIT-HIP intervention

4. In your opinion, are there certain elements of the FIT-HIP intervention that are challenging for a physiotherapist to perform. What are possible reasons for this?
    - o No
    - o Yes, namely:
    - o Psycho-education …[….]
    - o Guided exposure …[….]
    - o Other, namely …[….]

5. In your experience, do patients with fear of falling have specific characteristics, which would indicate treatment by a psychologist (in addition to or instead of a physiotherapist)
    - o No,
    - o Yes, namely …[….]

General opinion of the FIT-HIP intervention

6. On a scale of 1-10, what is your general opinion of the FIT-HIP intervention?
    - o I would rate the FIT-HIP intervention: … [0-10]

Perceived benefit of the FIT-HIP intervention

7. In your opinion, have patients had benefit of the following elements of FIT-HIP intervention, provided by physiotherapists?

a. Psycho-education (concerning fear of falling and fall-risk)
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much
    - o I don't know

b. Guided exposure
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much
    - o I don't know

c. Cognitive restructuring (challenging thoughts) regarding (fear of) falling
   - o No, not at all
   - o No, barely
   - o Yes, a little
   - o Yes, a lot
   - o Yes, very much
   - o I don't know

d. Motivational interviewing techniques
   - o No, not at all
   - o No, barely
   - o Yes, a little
   - o Yes, a lot
   - o Yes, very much
   - o I don't know

e. The 'Staying Active Plan'
   - o No, not at all
   - o No, barely
   - o Yes, a little
   - o Yes, a lot
   - o Yes, very much
   - o I don't know

f. Telephonic consultation (booster after discharge)
   - o No, not at all
   - o No, barely
   - o Yes, a little
   - o Yes, a lot
   - o Yes, very much
   - o I don't know

Suggestions for improvement

8. Do you have suggestions for improvement for the following elements of the FIT-HIP intervention:

a. Guided exposure (using the individual FIT-HIP treatment plan)
b. Cognitive restructuring (challenging thoughts)
c. Motivational interviewing techniques

9. Do you have additional remarks, or ideas to improve the intervention?

ADDITIONAL FILE 5 - QUESTIONNAIRE 6

Evaluation questionnaire FIT-HIP intervention – Elderly Care Physician

Background

The FIT-HIP trial, aimed at evaluating the treatment of fear of falling after hip fracture, has been performed within your health care organization. In the past few months your patients (with hip fracture and fear of falling) have received the FIT-HIP intervention.

We would like to gain further insight into the feasibility of the intervention, for patients and health-care professionals. Therefore we kindly request you to answer the following questions.

Individual FIT-HIP treatment plan

1. Were you informed about the content of the individual FIT-HIP treatment plans?
    - o For all the FIT-HIP patients
    - o For the majority of the FIT-HIP patients
    - o For about half of the FIT-HIP patients
    - o For the minority of the FIT-HIP patients
    - o For none of the FIT-HIP participants patients

2. In your opinion, did the whole team of rehabilitation professionals adhere to/ follow the individual FIT-HIP treatment plan?
    - o Always
    - o Usually
    - o Sometimes
    - o Barely
    - o Never

Perceived benefit of the FIT-HIP intervention

3. In your opinion, have patients had benefit of the FIT-HIP intervention?
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

General opinion of the FIT-HIP intervention

4. On a scale of 1-10, what is your general opinion of the FIT-HIP intervention?
   - o I would rate the FIT-HIP intervention: … [0-10]

Suggestions for improvement

5. Do you have additional remarks, or ideas to improve the intervention?

ADDITIONAL FILE 5 - QUESTIONNAIRE 7

Evaluation questionnaire FIT-HIP intervention – Nursing Staff

Background

The FIT-HIP trial, aimed at evaluating the treatment of fear of falling after hip fracture, has been performed within your health care organization. In the past few months your patients (with hip fracture and fear of falling) have received the FIT-HIP intervention.

We would like to gain further insight into the feasibility of the intervention, for patients and health-care professionals. Therefore we kindly request you to answer the following questions.

Individual FIT-HIP treatment plan

1. Were you informed about the content of the individual FIT-HIP treatment plans?
    - o For all the FIT-HIP participants
    - o For the majority of the FIT-HIP participants
    - o For about the half of the FIT-HIP participants
    - o For the minority of the FIT-HIP participants
    - o For none of the FIT-HIP participants

2. How often were changes to the individual FIT-HIP treatment plans or progress discussed with the nursing staff (by the physiotherapist)?
    - o Every day
    - o Several times a week
    - o Once a week
    - o Once every two weeks
    - o Once a month
    - o Never

3. Did the nursing staff adhere to/ follow the individual treatment plans?
    - o Always
    - o Usually
    - o Sometimes
    - o Barely
    - o Never

Perceived benefit of the FIT-HIP intervention

4. In your opinion, have patients had benefit of the FIT-HIP intervention?
    - o No, not at all
    - o No, barely
    - o Yes, a little
    - o Yes, a lot
    - o Yes, very much

General opinion of the FIT-HIP intervention

5. On a scale of 1-10, what is your general opinion of the FIT-HIP intervention?
    - o I would rate the FIT-HIP intervention: … [0-10]

Suggestions for improvement

6. Do you have additional remarks, or ideas to improve the intervention?

Chapter 5

Coping strategies of older adults with a recent hip fracture within inpatient geriatric rehabilitation.

Scheffers-Barnhoorn MN, Sharma-Virk M, van Balen R, van Eijk M, Achterberg WP.

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ABSTRACT

Objectives

Coping strategies may play an important role as facilitator or barrier for functional recovery after hip fracture. This study explored 1] active and passive coping strategies in hip fracture patients within inpatient geriatric rehabilitation (GR) 2] the association of these coping strategies with depression, anxiety, pain and health-related quality of life (HRQoL)

Method

Secondary data analysis (FIT-HIP trial). Participants were patients with hip fracture, aged 65+ years, admitted to post-acute GR units. Coping was assessed using the 'Active Tackling' and 'Passive Reacting' subscale of Utrecht Coping List (UCL). Depression, anxiety, pain and HRQoL was assessed using GDS-8, HADS-A, NPRS and EQ5D-VAS. Based on UCL norm tables - for both subscales - we dichotomized the group into (extremely) high use of this coping strategy i.e. 'predominantly active coping' (PAC), and 'predominantly passive coping' (PPC); versus their corresponding 'residual groups', i.e. the remaining participants.

Results

72 participants were included. Participants mostly used active coping (PAC: 33.3%), however those engaging in passive coping (23.6%) had significantly more depression and anxiety symptoms (GDS-8 ≥ 3: 31.1% respectively 9.1%, p=0.040; HADS-A ≥ 7: 58.8% vs 10.9%; p=0.00).

Conclusion

Active tackling and passive reacting coping strategies are used by up to one-third of patients with recent hip fracture. Passive coping was associated with more symptoms of depression and anxiety, which in turn may influence rehabilitation negatively. Screening of (passive) coping strategies could contribute to prompt identification of hip fracture patients at risk for negative health outcomes.

Trial registration

Netherlands Trial Register: NTR5695 (March 7, 2016)

Keywords

Coping (strategies), hip fracture, geriatric rehabilitation

INTRODUCTION

Hip fracture presents a major health challenge for older adults, with often far-reaching consequences for both physical health and psychosocial well-being [1,2]. The short- and long-term functional impairment and loss of independence associated with hip fracture is illustrated by the fact that only 30-40% of the patients regain their prior level of mobility, and 10-20% are unable to return home [3]. From a psychological perspective, symptoms of depression, anxiety and fear of falling (FoF) are frequently seen in patients with hip fracture [4-7]. Alongside the fact that such symptoms are burdensome for the individual patient, these potentially modifiable psychological factors are also known to have a negative effect on the rehabilitation process after hip fracture [7-9]. Coping may be an important factor to consider within this context. Exposure to health problems can be considered a major stressor. The manner in which a patient deals with this distress, i.e. the coping strategy, may influence active participation in and receptiveness for treatment. Certain types of coping (passive or avoidant), have been associated with negative health outcomes, such as more physical impairment, higher levels of pain, and depression [10-13]. Coping has also been associated to quality of life, specifically in relation to the long term consequences of health problems such as stroke [14].

Coping has been defined by Lazarus & Folkman as "thoughts and behaviours that people use to manage the internal and external demands of situations that are appraised as stressful" [15]. Although many types of coping strategies have been defined in the past years, in general two main categories of coping strategies are utilized, namely the '*problem-focused coping*' and '*emotion- focused coping*' [16,17]. Problem-focused coping is aimed at modifying or managing the source of distress, for example by making a plan of action to solve a problem; and emotion-focused coping is aimed at regulating the negative emotions associated with the problem. In general active coping approaches will be more oriented towards problem-focused coping, while passive coping is characterized by avoidance and is more emotion-focused. Different types of coping strategies can be used for the same stressor, as individuals will have to deal with the demands of the stressor itself, and manage their emotions. The choice for type of strategy may depend on whether or not the problem is perceived as modifiable. When evaluating coping strategies, it is also important to keep in mind that the efficacy of the different approaches is situational, and may change within the course of time (duration of stressor). [18]

Only one study has previously evaluated specific coping strategies within patients that have sustained a hip fracture [19]. The study population consisted solely of female patients, and found that older women used a variety of coping strategies, with '*seeking social support*' being the strategy most frequently used. Several emotion-focused coping strategies were associated with poorer functional recovery after hip fracture. This study however is more than 25 years old, was not performed within a rehabilitation setting and took place long after hip fracture

(on average 8 months). In a broader perspective, a recent systematic mixed methods review provided additional insight into how older adults deal with the consequences of hip fracture in daily life [20]. Important topics identified within this *health promoting perspective* were the battle for independence, active participation, and willingness to engage in their recovery. Within this regard, a patient's ability to identify and use resources to manage with the challenges and their motivation to influence decisions seem to be important to support the recovery process.

As coping may have a substantial role within the recovery process of a major health-related stressor such as hip fracture [1], it is important to gain a better understanding of coping in the early stage of rehabilitation. The objectives of this study are therefore to i] explore the active and passive coping strategies used by older patients with a recent hip fracture participating in a multidisciplinary inpatient geriatric rehabilitation programme, and ii] evaluate the association between the above-mentioned coping strategies and the presence of symptoms of depression and anxiety, pain and patient's health-related quality of life (HRQoL).

METHODS

Study design

This explorative cross-sectional study is a secondary data analysis of the FIT-HIP trial, a cluster randomized controlled trial evaluating treatment of fear of falling (FoF) in older adults with hip fracture, within inpatient geriatric rehabilitation (GR) (the Netherlands). A full description of the study protocol has been published previously [21]. In short, usual care for patients with hip fracture in GR is compared to the addition of the intervention aimed to reduce FoF, embedded in usual care. The FIT-HIP intervention is conducted by physiotherapists in GR and is based on various cognitive behavioural approaches.

Ethical approval for the trial was provided by the Ethics Committee of the Leiden University Medical Centre (LUMC), and the study was registered in the Netherlands Trial Register (NTR5695). All participants provided written informed consent prior to study procedures.

Participants and data collection

Recruitment and enrolment for the FIT-HIP trial took place from March 2016 - January 2017. Participants were older adults aged 65 years and above, with a recent hip fracture and FoF, admitted to one of the 11 participating GR units. FoF was assessed using a single question - 'Are you concerned to fall?' - with five answer categories (never - almost – never - sometimes - often - very often). Patients that reported being at least sometimes concerned to fall were eligible to participate. Key exclusion criteria included: 1) conditions interfering with learnability (cognitive impairment, major psychiatric disease, insufficient mastery of the Dutch language)

and 2) factors prognostic for limited functional recovery (pre-fracture Barthel index score < 15, presence of pathological hip fracture, life expectancy of < 3 months).

For the current analysis, we included all participants with complete 'active tackling' and 'passive reacting' subscales of the Utrecht Coping List (UCL) questionnaire (N=72 of the 78 participants in the FIT-HIP trial).

Outcome measures

All outcome measures were assessed at baseline; the first week of inpatient geriatric rehabilitation programme. Coping strategies were assessed using the Utrecht Coping List (UCL) [22,23]. This measurement instrument is validated for persons aged 14 years and older. The UCL consists of 47 questions categorized in the following seven subscales: '*active tackling*', '*passive reacting'*, '*palliative reacting*', '*seeking social support*', '*avoidance'*, '*expressing of emotions*' and '*reassuring thoughts*'. For this study we assessed the '*active tackling'* and '*passive reacting'* subscales of UCL, both comprising of 7 items. An overview of the items of the *active tackling* and *passive reacting* subscales is presented in Appendix 1. Each item can be answered on a four-point Likert scale, measuring how often an individual uses that particular strategy (1: never; 2: sometimes; 3: often and 4: very often). For both subscales, summed scores range from 7 to 28, with higher scores indicating a greater use of that strategy. Each UCL subscale has individual gender-specific norm tables.

To assess symptoms of depression, the 8-item Geriatric Depression Score (GDS-8) was used, a short version of GDS-30. GDS-8 has been validated for purposes of screening for depression in vulnerable older adults [24]. A higher score suggests more depressive symptoms (maximum score 8), and a score of three or more is indicative of relevant depressive symptoms. The Hospital Anxiety and Depression Scale - Anxiety subscale (HADS-A) was used to measure symptoms of anxiety in older adults [25]. HADS-A subscale consists of seven items, rated on a four-point Likert scale (maximum score: 21, higher score indicating more symptoms of anxiety). A cut-off value of seven is employed as a score that is suggestive of anxiety, which may require additional medical attention. In our study pain was assessed with the Numeric Pain Rating Scale (NPRS), a self-report measure used to assess the intensity of pain on a 11-point scale (0 representing no pain, up to 10 representing severe disabling pain) [26,27]. In general a cut-off value of ≥ four is handled as moderate pain. HRQoL was assessed with the EQ5D-VAS (scale 0-100, with a higher score indicating better perceived quality of life) [28].

Other variables

Sociodemographic data were collected at baseline. Comorbidity was measured using Functional Comorbidity Index (FCI) [29]. Additionally we collected information regarding medication use (drug prescriptions at admission to GR).

Statistical analysis

Descriptive statistics were used to present the general characteristics of the study population. Subsequently, we made a distinction between the study population as a whole, and the subgroups of participants with tendency to use active tackling and/ or passive reacting coping strategies. For both subscales separately, we used the existing norm tables to dichotomize the group of participants into a group that: i] predominantly uses active tackling and/ or passive reacting coping strategies, versus ii] the remaining part of the group that does not regularly engage in these coping strategies (i.e. the '*residual group*'). The norm tables comprise of five categories based on the summed score (range 7-28), namely: 'extremely low'-, 'low'-, 'average'-, 'high'- and 'extremely high' use of this coping strategy [23]. Participants that scored high or extremely high on the active tackling and/or passive reacting subscale were defined as the group with '*predominantly active coping* (PAC)' respectively '*predominantly passive coping* (PPC)'. The remaining part of the group, with participants that scored extremely low, low or average, was characterized as the '*residual group*'. For the active tackling subscale, a cut-off score of 21 was employed (both sexes). For the passive reacting subscale the cut-off value was 12 for female and 13 for male gender.

To categorize GDS-8, HADS-A and NPRS based on the presence of relevant symptom burden, we dichotomized the scores based the previously mentioned cut-off values. The Fisher exact test was performed to analyse the associations between coping strategies and depression, anxiety, pain (comparing proportions); the Mann Whitney test for the association with HLQoL as the distribution of this data was skewed. All analyses were conducted using SPSS for Windows (version 23.0). The significance threshold was set at 0.05 for all analyses.

RESULTS

A total of 72 patients were included in this study. Table 1 presents the baseline characteristics for all participants, the PAC and PPC group. Within the whole study population, the majority was female (77.8%) and lived alone prior to the hip fracture (63.8%). One third of the participants were categorized into the PAC group (N=19 with high active coping and N=5 very high active coping). Seventeen participants (23.6%) predominantly used passive reacting coping strategies (Table 2).

Participants in the PPC group were slightly younger when compared to the total population (78.4 versus 82.3 years) and were predominantly female (88.2%). When comparing the PPC to the PAC group, participants with tendency for passive reacting coping reported a lower level of HLQoL but lower levels of pain. Use of pain medication, paracetamol in particular, was high in all participants.

Table 1. Characteristics of the study population; additionally specified for participants with predominantly active and / or passive coping

	All participants (n=72)		Predominantly Active Coping (PAC) group (n=24) †		Predominantly Passive Coping (PPC) group (n=17) ‡	
Socio-demographics						
Age in years; mean (SD)	82.3	(7.7)	83.1	(7.3)	78.4	(8.4)
Female gender; n (%)	56	(77.8)	17	(70.8)	15	(88.2)
Living alone prior to fracture; n (%)	46	(63.9)	14	(58.3)	12	(70.6)
General health aspects						
Functional Comorbidity Index (total score; 0-18); median (IQR)	3.00	(1.0-5.0)	4.00	(2.0-6.0)	3.00	(2.0-4.75)
Health related quality of life (EQ5D-VAS; 0-100); median (IQR)	60.0	(50.0-70.0)	70.0	(52.5-78.8)	60.0	(45.0-70.0)
Average pain in past week (NPRS; 0-10); median (IQR)	6.0	(4.0-8.0)	6.0	(5.0-7.0)	5.0	(4.5-7.0)
(Neuro)psychological factors						
MMSE score (0-30); median (IQR)	27.0	(25.0-29.0)	27.0	(24.0-29.0)	27.0	(24.5-29.5)
Participants with GDS-8 score ≥ 3; n (%)*	10	(14.1)	2	(8.3)	5	(31.3)
Participants with HADS-A score ≥ 7; n (%)	16	(22.2)	3	(12.5)	10	(58.8)
Participants with prescription for pain medication*						
Paracetamol; n (%)	58	(86.6)	21	(91.3)	14	(82.4)
NSAID's; n (%)	7	(10.4)	1	(4.3)	2	(11.8)
Morphine; n (%)	26	(38.8)	8	(34.8)	8	(47.1)
Patients with prescription for psychotropic medication*						
Antidepressants; n (%)	6	(9.0)	3	(13.0)	1	(5.9)
Benzodiazepine; n (%)	4	(6.0)	1	(4.3)	-	-
Antipsychotics; n (%)	4	(6.0)	1	(4.3)	1	(5.9)

Notes: *numbers do not add up to final numbers due to missing data, valid % is shown. † Predominantly active coping (PAC) group: comprising of individuals with high (n=19) or extremely high active (n=5) coping based on the Active Tackling subscale of the Utrecht Coping List (UCL). ‡ Predominantly passive coping (PPC) group: comprising of individuals with high passive coping (n=17) based on the Passive Reacting subscale of the UCL (no participants had extremely high passive coping).
SD = standard deviation; IQR = interquartile range; EQ5D-VAS = instrument of Euro-QoL group defining patient's self- rated health on vertical visual analogue scale; NPRS = Numeric Pain Rating Scale; MMSE = Mini Mental State Examination; GDS-8 = 8-item Geriatric Depression Scale; HADS-A = Hospital Anxiety and Depression Scale; NSAID's = Non-Steroidal Anti-inflammatory Drugs.

To determine if high levels of active tackling and passive reacting coping can coincide within individual patients, we drafted a scatterplot presented in Figure 1. Three participants (4.2%) scored high on both subscales.

With regard to the specific coping strategies (items per coping subscale), '*thinking of different possibilities to solve problems*' and '*staying calm in a difficult situation*' were the active tackling strategies that were reported most often (49% respectively 48% of all participants reported

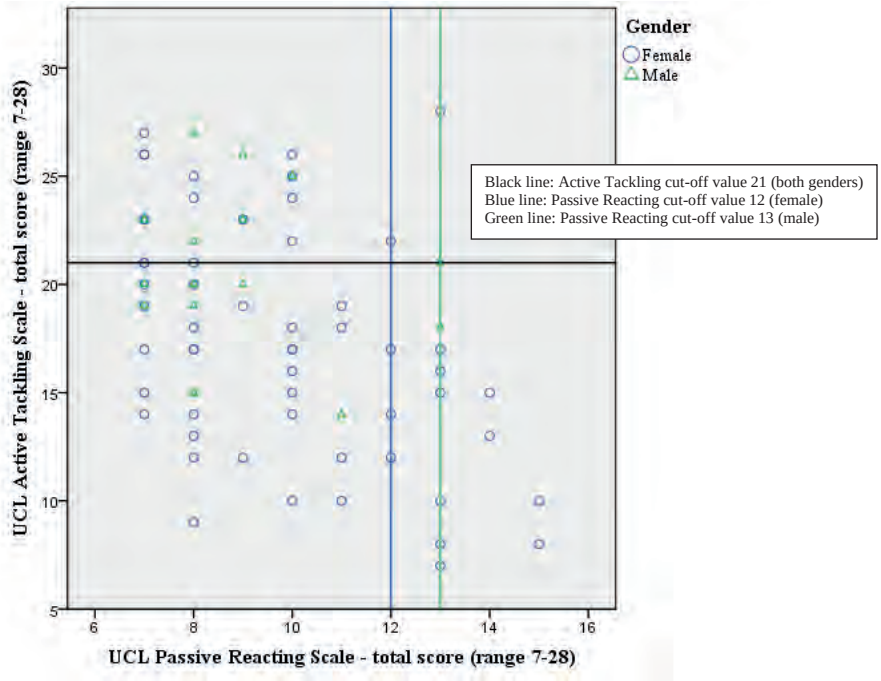
Table 2. Active Tackling and Passive Reacting coping at onset of inpatient geriatric rehabilitation		
UCL - Active Tackling Scale		
Total score all participants (7-28); median (IQR)	18.0	(14.0-22.0)
Classification based on norm tables; participants n (%)	72	(100)
Extremely low active coping	12	(16.7)
Low active coping	7	(9.7)
Average active coping	29	(40.3)
High active coping	19	(26.4)
Extremely high active coping	5	(6.9)
UCL - Passive Reacting Scale		
Total score all participants (7-28); median (IQR)	9.0	(8.0-11.0)
Classification based on norm tables; participants n (%)	72	(100)
Extremely low passive coping	15	(20.8)
Low passive coping	17	(23.6)
Average passive coping	23	(31.9)
High passive coping	17	(23.6)
Extremely high passive coping	0	(0.0)

Notes: UCL = Utrecht Coping List. Total score for both subscales (Active Tackling and Passive Reacting) range 7-28, with a higher score representing a greater extent of use of this coping strategy. Classification into five categories (extremely low, low, average, high, extremely high use of the coping strategy), is based on norm-tables for UCL (age and gender specific). IQR = interquartile range

using this (very) often). For the passive reacting strategies, '*being totally preoccupied with a problem'* was reported most often (12% of all participants), followed by '*being worried about their past'* (11%). No participants reported substance abuse as a form of passive coping strategy when experiencing problems.

Table 3 shows the associations between active tackling respectively passive reacting coping, and symptoms of depression and anxiety, pain and perceived quality of health. The PAC- and PPC groups were compared to their corresponding residual group; i.e. the remaining participants, that scored (very) low to average on the specific subscales. Significantly more participants in the PPC group had a GDS score ≥ 3 or HADS-A score of ≥ 7 when compared to the residual group (GDS-8 score ≥ 3: 31.1% respectively 9.1%, p=0.040; and HADS-A score ≥ 7: 58.8% vs 10.9%; p=0.00). No significant associations were found for the PAC group. Coping strategies were not associated with pain (NPRS ≥ 4) and HLQoL.

Figure 1. Active Tackling versus Passive Reacting coping within individual participants



UCL= Utrecht Coping List. Upper left quadrant (n=21) represents: high score only for Active Tackling. Lower left quadrant (n=34) represents: low score for both Active Tackling and Passive Reacting coping strategies (patients in residual group for both subscales). Upper right quadrant (n=3) represents: high score for both Active Tackling and Passive Reacting coping strategies (Active Tackling ≥ 21; Passive Reacting ≥ 12 for women / ≥ 13 for men). Lower right quadrant: high score only for Passive Reacting (n=14).

Table 3. Association between active and passive coping with symptoms of depression, anxiety, pain and health related quality of life

	UCL - Active Tackling Scale			UCL - Passive Reacting Scale		
	Predominantly Active Coping † (n=24)	Residual group ‡ (n=48)	P value	Predominantly Passive Coping § (n=17)	Residual group ‡ (n=55)	P value
Participants with GDS-8 ≥ 3; (%)	8.3	17.0	0.477	31.3	9.1	0.040
Participants with HADS-A ≥ 7; (%)	12.5	27.1	0.232	58.8	10.9	< 0.001
Participants with NPRS ≥ 4; (%)	87.5	75.0	0.356	88.2	76.4	0.495
EQ5D-VAS score (range 0-100); median(IQR)*	70.0 (52.5-78.8)	60.0 (50.0-70.0)	0.091	60.0 (45.0-70.0)	65.0 (50.0-75.0)	0.125

Notes: * P values are based on Fisher Exact test, except for the EQ5D-VAS, where Mann-Whitney test was used. † Predominantly active coping group: comprising of individuals with *high* (n=19) or *extremely high* active (n=5) coping based on the Active Tackling subscale of the Utrecht Coping List (UCL). ‡ Residual group: the remaining part of the group, with participants that scored (extremely) low or average on the specific UCL subscale (either Active Tackling Scale or Passive Reacting Scale). §Predominantly passive coping group: comprising of individuals with *high* passive coping (n=17) based on the Passive Reacting subscale of the UCL (no participants had *extremely high* passive coping). GDS-8 = 8-item Geriatric Depression Scale; HADS-A = Hospital Anxiety and Depression Scale; NPRS = Numeric Pain Rating Scale; EQ5D-VAS = instrument of Euro-QoL group defining patient's self- rated health on vertical visual analogue scale; IQR = interquartile range.

DISCUSSION

The findings of this study show that a reasonable proportion (one-third) of the older adults that have recently sustained a hip fracture and are at onset of an inpatient geriatric rehabilitation programme, use an active tackling coping approach. However, almost a quarter of the participants engage in passive reacting coping, and this group has significantly more symptoms of depression and anxiety. No associations were found for coping with pain or HRQoL.

To our knowledge detailed information regarding the use of specific coping strategies within the population of patients with hip fracture have only been reported in one previous study [19]. The study population differed from our study in that sense that all participants were women. A second noteworthy difference is the timing of the assessment of coping in relation to the stressor, on average eight months after hip fracture in contrast to 1-2 weeks post-fracture in our study. More specifically, the difference in timing represents a different phase of functional recovery after hip fracture; and accordingly distinct health challenges related to the hip fracture [30]. Although the coping data of the two studies does somewhat differ, in part due to the fact that the current study did not include all UCL subscales in order to reduce the burden for participants, some comparisons can be made. In Roberto's study, coping was assessed with the *Ways of Coping Questionnaire,* and based on this evaluation the strategy '*seeking social support*' was used most frequently, followed by '*accepting responsibility*' and '*self-controlling*' (both emotion-focused), and '*planful problem-solving*' (problem-focused). In contrast to reasonable levels of active tackling in our study, '*active confronting*' was used least in Roberto's study. Although participants in both studies report regular use of some form of problem-focused coping, the discrepancies in the preference for type of coping strategy could largely be explained by the time-frame (i.e. timing of assessment of coping in relation to the stressor). For a better understanding of how a temporal factor contributes to differences in the choice of coping strategy, findings should be interpreted within the general principles of coping in older age.

Literature on coping in older adults describe the following principles. 1] Older adults are confronted by different stressors than younger individuals. With increasing age, adults will more frequently be confronted with health problems, disability and grief. [31,32]. The type of stressor(s) may also model or determine the choice of coping strategies; depending on whether the problem can be modified, or if it is more suitable to deal with the emotional consequences. 2] In general, older adults remain able to use the different types of coping strategies effectively. However, it has also been observed that they use less strategies, less frequently use active confrontive strategies, and often employ emotion-focused coping. Seeking social support is frequently reported in this population. [16,31,33,34]. 3] However, in light of dealing with health-problems and aging limitations, both problem-focused coping and emotion-focused approaches are commonly used [16,35].

Thus, when faced with a health-related stressor, what determines an individual's response and preference for a more problem-focused or emotion-focused approach? Folkman & Lazarus state that an individual's appraisal of the event, either as negative and stressful, or as challenges to be handled, influence their choice of coping strategies [36]. We could argue that the time-frame of confrontation with the stressor affects patients' appraisal of the stressor, through experience with and hence expectations regarding the impact of this problem. In other words is it realistic to expect improvement or functional recovery; or should this health condition be considered chronic, with permanent disabilities? Hip fracture is an acute event with sudden physical impairment. If older adults have the expectation to recover, following the surgical repair, it is likely that at the beginning of a rehabilitation programme patients have a greater focus on their recovery process. This in turn could influence their motivation for active engagement in therapy. As the time proceeds and patients come to appraise the consequences of the hip fracture as an enduring health problem, the focus may shift to more emotion-focused strategies, as also seen in the study performed by Roberto. This is also illustrated in a longitudinal study on rehabilitation after brain injury, which showed that patients used less active problem-focused and more passive emotion-focused coping within the course of the rehabilitation [37]. Likewise, this may also explain why patients with a chronic condition such as COPD (chronic obstructive pulmonary disease) have lower levels of active tackling coping when admitted to inpatient rehabilitation (16.5% versus 33.3% in our study; both assessed with the UCL) [12].

The second finding in the current study, that passive reacting coping was associated with more symptoms of depression and anxiety, confirm Roberto's findings. There is a considerable amount of evidence in support of this association, both for the general geriatric population [38-40], and also specifically for patients within a rehabilitation setting (stroke, COPD) [12,13]. Although the causal relationship between coping and mood/anxiety has not yet been defined for patients with hip fracture, findings from this study show that a quarter of the patients use passive reacting strategies, which in turn may add to the risk of depression and anxiety. Prevalence rates for anxiety and depression are high among older adults with hip fracture (35.0% respectively 44.5%) [7 41 42], and these conditions are associated with greater risk of poor outcomes of rehabilitation [1,8,43]. Moreover, there is evidence to suggest that 10% of patients with hip fracture develop depressive symptoms after fracture, with a persistent high level of symptoms up to a year after fracture [44]. Prompt identification of depressive symptoms and associated risk-factors for new-onset mood disorders are therefore important to facilitate recovery after fracture.

Depression in this population may however prove to be a challenge. At present, there is limited evidence for effective interventions to prevent or address depression in patients with hip fracture. [4,45]. Moreover, current literature on late-life depression demonstrates that depression in older age has a more chronic course, and an increased risk to be treatment resistant [46]. From a biological perspective, certain factors related to the (neuro)biological aging process such as

physical frailty and cognitive decline, may contribute to the development and expression of neuropsychiatric symptoms, and in part explain the impaired prognosis of late-life depression. [47]. How all these mechanisms relate to each other, is still unknown, and is at present subject to further research [48].

From a clinical perspective however, it is important to focus on modifiable factors that have potential to aid the recovery process. Within this regard, it may be beneficial to assess coping within the rehabilitation after hip fracture. Passive coping strategies, through their tendency for avoidance behaviour, could possibly complicate adherence and commitment to treatment [49]. However, programmes based on cognitive behavioural approaches, such as problem-solving therapy (PST), may have potential to enhance adaptive problem-solving coping skills. Such approaches have proven to be effective in rehabilitation after stroke [50]. More specifically, PST has proven to be effective to reduce depressive symptoms in older adults with passive coping [49]. At present however, hip fracture rehabilitation programmes do not include assessment of coping or treatment programmes to enhance coping skills. This therefore remains an area of attention for further research and clinical practice.

Limitations of the present study

There are several limitations of the present study. First, it is important to acknowledge that we only assessed active and passive coping strategies. We limited the number of subscales, in order to limit the burden for participants. The choice for these two subscales was based on the fact that we expect these strategies to be most relevant for the inpatient rehabilitation setting; i.e. facilitating or hampering the early phase of recovery. This does however lead to a lack of insight into other potentially important coping strategies for the geriatric population, such as seeking social support. Secondly, due to the cross-sectional design it is not possible to demonstrate cause and effect in the association between coping strategies and symptoms of depression and anxiety. Accordingly, the direct effect of coping strategies on rehabilitation outcome remains uncertain. Third, data from this study was derived from FIT-HIP trial, which was not primarily designed to address the coping strategies. All participants had FoF, which may have biased the findings regarding symptoms of anxiety and depression. On the other hand, FoF has been reported in as much as 60% of the older patients with hip fracture [6], and the level of anxiety reported in the study population was low [51]. Also, FoF is not limited to patients with hip fracture; prevalence rates in the general geriatric population and in other geriatric rehabilitation patients are high too [52,53]. Hence, the study population should be reasonably representative for hip patients in general. Fourth, the UCL norm tables are based on data of older adults with a maximum age limit of 65 years, and we can therefore question whether these are applicable for the oldest-old. However, at present there is no other alternative validated coping instrument specifically for older adults. Previous studies with older adults within a rehabilitation setting have used the UCL too [54]. Last, the sample size was limited, which may affect the strength and

certainty of associations. However, we may consider the study as an explorative study and hence the insights as an orientation on coping in this specific target population.

CONCLUSION AND FUTURE IMPLICATIONS

The findings of this study show that a reasonable proportion of patients with hip fracture engage in active tackling coping strategies at onset of inpatient rehabilitation. However, also roughly a quarter of the patients predominantly use passive coping strategies. Passive coping was associated more symptoms of depression and anxiety, which in turn may add to the risk of poorer functional recovery after hip fracture. To timely identify patients at risk for negative outcome(s) of rehabilitation, more specifically for psychological problems that may intervene with recovery, we advocate screening for (passive) coping strategies at onset of the rehabilitation. Future research is needed to gain insight into the relationship between coping and mood/anxiety for patients with hip fracture. Additionally, research should focus on intervention possibilities to enhance skills for more efficient coping.

DECLARATIONS

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REFERENCES

1. Proctor R, Wade R, Woodward Y, et al. The impact of psychological factors in recovery following surgery for hip fracture. Disability and rehabilitation 2008;30(9):716-22. (In eng). DOI: 10.1080/09638280701403536.
2. Ziden L, Wenestam CG, Hansson-Scherman M. A life-breaking event: early experiences of the consequences of a hip fracture for elderly people. Clinical rehabilitation 2008;22(9):801-11. (In eng). DOI: 10.1177/0269215508090204.
3. Dyer SM, Crotty M, Fairhall N, et al. A critical review of the long-term disability outcomes following hip fracture. BMC geriatrics 2016;16:158. (In eng). DOI: 10.1186/s12877-016-0332-0.
4. Burns A, Banerjee S, Morris J, et al. Treatment and prevention of depression after surgery for hip fracture in older people: randomized, controlled trials. Journal of the American Geriatrics Society 2007;55(1):75-80. (In eng). DOI: 10.1111/j.1532-5415.2007.01016.x.
5. Visschedijk J, Achterberg W, Van Balen R, Hertogh C. Fear of falling after hip fracture: a systematic review of measurement instruments, prevalence, interventions, and related factors. Journal of the American Geriatrics Society 2010;58(9):1739-48. (In eng). DOI: 10.1111/j.1532-5415.2010.03036.x.
6. Visschedijk J, van Balen R, Hertogh C, Achterberg W. Fear of falling in patients with hip fractures: prevalence and related psychological factors. Journal of the American Medical Directors Association 2013;14(3):218-20. (In eng). DOI: 10.1016/j.jamda.2012.10.013.
7. Gialanella B, Prometti P, Monguzzi V, Ferlucci C. Neuropsychiatric symptoms and rehabilitation outcomes in patients with hip fracture. American journal of physical medicine & rehabilitation 2014;93(7):562-9. (In eng). DOI: 10.1097/phm.0000000000000062.
8. Lenze EJ, Munin MC, Dew MA, et al. Adverse effects of depression and cognitive impairment on rehabilitation participation and recovery from hip fracture. International journal of geriatric psychiatry 2004;19(5):472-8. (In eng). DOI: 10.1002/gps.1116.
9. Oude Voshaar RC, Banerjee S, Horan M, et al. Fear of falling more important than pain and depression for functional recovery after surgery for hip fracture in older people. Psychological medicine 2006;36(11):1635-45. (In eng). DOI: 10.1017/s0033291706008270.
10. Eisenberg SA, Shen BJ, Schwarz ER, Mallon S. Avoidant coping moderates the association between anxiety and patient-rated physical functioning in heart failure patients. J Behav Med 2012;35(3):253-61. (In eng). DOI: 10.1007/s10865-011-9358-0.
11. Ramírez-Maestre C, Esteve R, López AE. Cognitive appraisal and coping in chronic pain patients. Eur J Pain 2008;12(6):749-56. (In eng). DOI: 10.1016/j.ejpain.2007.11.004.
12. Stoilkova A, Wouters EF, Spruit MA, Franssen FM, Janssen DJ. The relationship between coping styles and clinical outcomes in patients with COPD entering pulmonary rehabilitation. Copd 2013;10(3):316-23. (In eng). DOI: 10.3109/15412555.2012.744389.
13. Visser MM, Heijenbrok-Kal MH, Spijker AV, Oostra KM, Busschbach JJ, Ribbers GM. Coping, problem solving, depression, and health-related quality of life in patients receiving outpatient stroke rehabilitation. Arch Phys Med Rehabil 2015;96(8):1492-8. (In eng). DOI: 10.1016/j.apmr.2015.04.007.
14. Darlington AS, Dippel DW, Ribbers GM, van Balen R, Passchier J, Busschbach JJ. Coping strategies as determinants of quality of life in stroke patients: a longitudinal study. Cerebrovasc Dis 2007;23(5-6):401-7. (In eng). DOI: 10.1159/000101463.
15. Lazarus RSF, S. Stress, appraisal, and coping. New York: Springer 1984:141.

16. Levasseur M, Couture M. Coping strategies associated with participation and quality of life in older adults. Canadian journal of occupational therapy Revue canadienne d'ergotherapie 2015;82(1):44-53. (In eng). DOI: 10.1177/0008417414552188.
17. Folkman S, & Lazarus, R.S. Manual for the Ways of Coping Questionnaire. 1988.
18. Blum SB, M.; Silver R.C. Coping. Encyclopedia of Human Behavior 2012:596-601. DOI: https://doi.org/10.1016/B978-0-12-375000-6.00110-5.
19. Roberto KA. Coping strategies of older women with hip fractures: resources and outcomes. Journal of gerontology 1992;47(1):P21-6. (In eng).
20. Lind J, Mahler M.A systematic mixed methods review: Recovering from a hip fracture in a health promoting perspective. Nursing open 2019;6(2):313-329. (In eng). DOI: 10.1002/nop2.214.
21. Scheffers-Barnhoorn MN, van Haastregt JC, Schols JM, et al. A multi-component cognitive behavioural intervention for the treatment of fear of falling after hip fracture (FIT-HIP): protocol of a randomised controlled trial. BMC geriatrics 2017;17(1):71. (In eng). DOI: 10.1186/s12877-017-0465-9.
22. Turner H, Bryant-Waugh R, Peveler R, Bucks RS. A psychometric evaluation of an English version of the Utrecht Coping List. Eur Eat Disord Rev 2012;20(4):339-42. (In eng). DOI: 10.1002/erv.2173.
23. Schreurs P.J.G vdWG, Brosschot J.F, Tellegen B., Graus G.M.H. . De Utrechtse Coping Lijst, UCL omgaang met problemen en gebeurtenissen [The Utrecht Coping List]. 1993(Swets en Zeitlinger, Lisse, the Netherlands).
24. Jongenelis K, Gerritsen DL, Pot AM, et al. Construction and validation of a patient- and user-friendly nursing home version of the Geriatric Depression Scale. International journal of geriatric psychiatry 2007;22(9):837-42. (In eng). DOI: 10.1002/gps.1748.
25. Spinhoven P, Ormel J, Sloekers PP, Kempen GI, Speckens AE, Van Hemert AM. A validation study of the Hospital Anxiety and Depression Scale (HADS) in different groups of Dutch subjects. Psychological medicine 1997;27(2):363-70. (In eng). DOI: 10.1017/s0033291796004382.
26. Hjermstad MJ, Fayers PM, Haugen DF, et al. Studies comparing Numerical Rating Scales, Verbal Rating Scales, and Visual Analogue Scales for assessment of pain intensity in adults: a systematic literature review. J Pain Symptom Manage 2011;41(6):1073-93. (In eng). DOI: 10.1016/j.jpainsymman.2010.08.016.
27. Herr KA, Spratt K, Mobily PR, Richardson G. Pain intensity assessment in older adults: use of experimental pain to compare psychometric properties and usability of selected pain scales with younger adults. Clin J Pain 2004;20(4):207-19. (In eng). DOI: 10.1097/00002508-200407000-00002.
28. EuroQol Research Foundation. 2020 (https://euroqol.org/).
29. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. J Clin Epidemiol 2005;58(6):595-602. (In eng). DOI: 10.1016/j.jclinepi.2004.10.018.
30. Magaziner J, Chiles N, Orwig D. Recovery after Hip Fracture: Interventions and Their Timing to Address Deficits and Desired Outcomes--Evidence from the Baltimore Hip Studies. Nestle Nutrition Institute workshop series 2015;83:71-81. (In eng). DOI: 10.1159/000382064.
31. Chen Y, Peng Y, Xu H, O'Brien WH. Age Differences in Stress and Coping: Problem-Focused Strategies Mediate the Relationship Between Age and Positive Affect. Int J Aging Hum Dev 2018;86(4):347-363. (In eng). DOI: 10.1177/0091415017720890.
32. Nieto M, Romero D, Ros L, et al. Differences in Coping Strategies Between Young and Older Adults: The Role of Executive Func-

tions. Int J Aging Hum Dev 2020;90(1):28-49. (In eng). DOI: 10.1177/0091415018822040.

33. Lau BWK. Stress, coping and ageing. JHKC Psychiatry 1994;4:39-44.
34. Folkman S, Lazarus RS, Pimley S, Novacek J. Age differences in stress and coping processes. Psychol Aging 1987;2(2):171-84. (In eng). DOI: 10.1037//0882-7974.2.2.171.
35. Löffler C, Kaduszkiewicz H, Stolzenbach CO, et al. Coping with multimorbidity in old age--a qualitative study. BMC Fam Pract 2012;13:45. (In eng). DOI: 10.1186/1471-2296-13-45.
36. Folkman S, Lazarus RS. An analysis of coping in a middle-aged community sample. J Health Soc Behav 1980;21(3):219-39. (In eng).
37. Wolters G, Stapert S, Brands I, Van Heugten C. Coping styles in relation to cognitive rehabilitation and quality of life after brain injury. Neuropsychol Rehabil 2010;20(4):587-600. (In eng). DOI: 10.1080/09602011003683836.
38. Bjørkløf GH, Engedal K, Selbæk G, Kouwenhoven SE, Helvik AS. Coping and depression in old age: a literature review. Dement Geriatr Cogn Disord 2013;35(3-4):121-54. (In eng). DOI: 10.1159/000346633.
39. Bjørkløf GH, Engedal K, Selbæk G, Maia DB, Coutinho ES, Helvik AS. Locus of control and coping strategies in older persons with and without depression. Aging Ment Health 2016;20(8):831-9. (In eng). DOI: 10.1080/13607863.2015.1040722.
40. Murayama Y, Yamazaki S, Yamaguchi J, Hasebe M, Fujiwara Y. Chronic stressors, stress coping and depressive tendencies among older adults. Geriatr Gerontol Int 2020;20(4):297-303. (In eng). DOI: 10.1111/ggi.13870.
41. Charles-Lozoya S, Cobos-Aguilar H, Barba-Gutiérrez E, et al. Depression and geriatric assessment in older people admitted for hip fracture. Rev Med Chil 2019;147(8):1005-1012. (In eng). DOI: 10.4067/s0034-98872019000801005.
42. Feng L, Scherer SC, Tan BY, Chan G, Fong NP, Ng TP. Comorbid cognitive impairment and depression is a significant predictor of poor outcomes in hip fracture rehabilitation. Int Psychogeriatr 2010;22(2):246-53. (In eng). DOI: 10.1017/s1041610209991487.
43. Gialanella B, Ferlucci C, Monguzzi V, Prometti P. Determinants of functional outcome in hip fracture patients: the role of specific neuropsychiatric symptoms. Disability and rehabilitation 2015;37(6):517-22. (In eng). DOI: 10.3109/09638288.2014.932446.
44. Cristancho P, Lenze EJ, Avidan MS, Rawson KS. Trajectories of depressive symptoms after hip fracture. Psychological medicine 2016;46(7):1413-25. (In eng). DOI: 10.1017/s0033291715002974.
45. Romeo R, Knapp M, Banerjee S, et al. Treatment and prevention of depression after surgery for hip fracture in older people: cost-effectiveness analysis. Journal of affective disorders 2011;128(3):211-9. (In eng). DOI: 10.1016/j.jad.2010.07.026.
46. Schaakxs R, Comijs HC, Lamers F, Kok RM, Beekman ATF, Penninx B. Associations between age and the course of major depressive disorder: a 2-year longitudinal cohort study. Lancet Psychiatry 2018;5(7):581-590. (In eng). DOI: 10.1016/s2215-0366(18)30166-4.
47. Lugtenburg A, Zuidersma M, Wardenaar KJ, et al. Subtypes of Late-Life Depression: A Data-Driven Approach on Cognitive Domains and Physical Frailty. J Gerontol A Biol Sci Med Sci 2021;76(1):141-150. (In eng). DOI: 10.1093/gerona/glaa110.
48. Reynolds CF, 3rd, Lenze E, Mulsant BH. Assessment and treatment of major depression in older adults. Handb Clin Neurol 2019;167:429-435. (In eng). DOI: 10.1016/b978-0-12-804766-8.00023-6.
49. Choi NG, Hegel MT, Sirrianni L, Marinucci ML, Bruce ML. Passive coping response to depressive symptoms among low-income homebound older adults: does it affect depression severity and treatment outcome? Behav Res Ther 2012;50(11):668-74. (In eng). DOI: 10.1016/j.brat.2012.07.003.
50. Visser MM, Heijenbrok-Kal MH, Van't Spijker A, Lannoo E, Busschbach JJ, Ribbers GM. Problem-Solving Therapy During Outpatient

Stroke Rehabilitation Improves Coping and Health-Related Quality of Life: Randomized Controlled Trial. Stroke 2016;47(1):135-42. (In eng). DOI: 10.1161/strokeaha.115.010961.

51. Scheffers-Barnhoorn MN, van Eijk M, van Haastregt JCM, et al. Effects of the FIT-HIP Intervention for Fear of Falling After Hip Fracture: A Cluster-Randomized Controlled Trial in Geriatric Rehabilitation. Journal of the American Medical Directors Association 2019;20(7):857-865.e2. (In eng). DOI: 10.1016/j.jamda.2019.03.009.
52. Scheffer AC, Schuurmans MJ, van Dijk N, van der Hooft T, de Rooij SE. Fear of falling: measurement strategy, prevalence, risk factors and consequences among older persons. Age and ageing 2008;37(1):19-24. (In eng). DOI: 10.1093/ageing/afm169.
53. Visschedijk JH, Caljouw MA, Bakkers E, van Balen R, Achterberg WP. Longitudinal follow-up study on fear of falling during and after rehabilitation in skilled nursing facilities. BMC geriatrics 2015;15:161. (In eng). DOI: 10.1186/s12877-015-0158-1.
54. Stoilkova A, Janssen DJ, Franssen FM, Spruit MA, Wouters EF. Coping styles in patients with COPD before and after pulmonary rehabilitation. Respir Med 2013;107(6):825-33. (In eng). DOI: 10.1016/j.rmed.2013.03.001.

APPENDIX

Appendix 1. Topic list of the UCL Active Tackling and Passive Reacting Subscales
UCL - Active Tackling Scale
Undertake immediate action in response to problems
Perceive problems as a challenge
A broad approach to problems
Stay calm in difficult situations
Consider different solutions for problems
Goal-oriented approach to problems
Structured evaluation of problems
UCL - Passive Reacting Scale
Self-isolation / social withdrawal
Pessimistic approach
Worry about the past
Substance (ab)use to reduce tension
Fantasy as escape strategy
Being pre-occupied by problems
Feeling unable to act

Chapter 6

Course of fear of falling after hip fracture: findings from a 12-month inception cohort.

Submitted as: Scheffers-Barnhoorn MN, Haaksma ML,
Achterberg WP, Niggebrugge AHP, van der Sijp MPL, van Haastregt JCM, van Eijk M.

ABSTRACT

Objectives

To examine the course of fear of falling (FoF) up to one year after hip fracture, including the effect of pre-fracture FoF on the course.

Design

Observational cohort study with 12-month follow-up.

Setting

Haaglanden Medical Centre, the Netherlands.

Participants

444 community-dwelling adults aged 70 years and older, admitted to hospital with a hip fracture.

Main outcome measure

Short Falls Efficacy Scale International (FES-I), with a cut-off score ≥ 11 to define elevated FoF levels.

Results

Six weeks after hip fracture the study population-based mean FES-I was located around the cut-off value of 11, and levels decreased only marginally over time. One year after fracture almost one-third of the population had FoF (FES-I ≥ 11). Although the group with pre-fracture FoF (42.6%) had slightly elevated FES-I levels during the entire follow-up, the effect was not statistically significant. Patients with persistent FoF at 6 and 12 weeks after fracture (26.8%) had the highest FES-I levels, with a mean well above the cut-off value during the entire follow-up. For the majority of patients in this group FoF is still present one year after fracture (84.9%).

Conclusions

FoF as defined by a FES-I score ≥ 11 is common within the first year after hip fracture. Patients with persistent FoF at 12 weeks have the highest FES-I levels in the first year after fracture, and for most of these patients the FoF remains. For timely identification of patients who may benefit from intervention, we recommend structural assessment of FoF, which includes screening for (pre-fracture) FoF immediately after fracture, and subsequently at onset of rehabilitation, and 12 weeks after fracture.

Key words

Fear of falling, hip fracture, clinical course, prospective cohort study

INTRODUCTION

Hip fracture, being one of the most serious fall-related injuries and representing the second most common fragility fracture in older adults, has a significant impact on the health care system [1,2]. Despite extensive rehabilitation, a considerable number of patients experience permanent morbidity and disability, resulting in substantial costs in both (post-)acute settings and long-term care [3-6]. Moreover, the expected rise in absolute numbers – up to 4 million in 2025, and over 6 million in 2050 – will further contribute to the high economic burden and societal impact [7,8]. To date, many prognostic factors have been identified [9-11]. This includes fear of falling (FoF), defined as '*a lasting concern about falling that leads to an individual avoiding activities that he/she remains capable of performing*' [12-15]. Considering that FoF is common following hip fracture and has been found to impede functional recovery after fracture, this may be a meaningful factor to address in order to improve the recovery process [13,14,16,17].

Although various effective treatment programmes are available for community-dwelling older adults, studies evaluating treatment of FoF for patients with hip fracture are scarce, and their findings inconclusive [18-21]. One possible explanation for the inconsistent findings is the timing of the intervention. To date, the interventions have been conducted mainly during inpatient rehabilitation, representing the early stage of recovery. However, associations between FoF and impaired functional recovery were found primarily for the period six weeks after fracture and beyond, not for the early stages after hip fracture (2-4 weeks) [13,14]. This may imply that FoF in the early stages of recovery is not a barrier to functional recovery under all circumstances. Insight into the course of FoF after hip fracture can provide a better understanding of the characteristics of FoF in this population, and help differentiate between patients with limited FoF, and those at risk for *maladaptive* FoF, i.e., those forms of FoF that lead to impairment of physical activities and daily functioning. In turn, this may help identify patients who may benefit from intervention. However, at present little is known about the clinical course of FoF after hip fracture, and the available data on this subject is limited by short follow-up [22].

In light of the above-mentioned knowledge gap, the objective of this study is to examine the course of FoF up to one year after fracture. This includes analysis of FoF trajectories for specific subgroups that could be relevant for clinical practice, such as patients who have experienced FoF prior to the hip fracture. No previous studies have evaluated how pre-fracture FoF relates to FoF after fracture. However, the a*bsence* of pre-fracture FoF has been associated with *successful* short-term functional recovery, which points towards an important role for pre-fracture FoF in the recovery process [12]. Although the mechanism for this effect remains to be determined, we expect that pre-fracture FoF has the potential to affect the course of FoF after fracture, and could therefore affect functional outcome. For this purpose we will explore FoF trajectories based on the presence / absence of FoF prior to fracture. Furthermore, we

will explore whether persistent FoF in the first 12 weeks (short-term) is related to an increased risk for FoF one year after fracture.

METHODS

Study design, setting and patients

This is a longitudinal observational inception cohort study. The study population consists of patients with a hip fracture admitted to the *Haaglanden Medical Center* hospital, the Netherlands, in the period 1 January 2018 to 1 March 2020. All data was assessed as part of routine data collection for this target group [23]. We included all patients aged 70 years or older, who were community-dwelling prior to fracture (i.e., not permanently residing in a nursing home or other residential care setting before admission), and for whom complete data was available for the covariates required for the analyses (see below).

The Medical Research Ethics Committee of the Haaglanden Medical Center, and the hospital's board of directors approved the study protocol of the inception cohort (METC Southwest Holland; protocol number 16-059) [23]. Because of its observational design, informed consent was not required according to the Dutch regulations. This current study has been performed in accordance with the STROBE guidelines [24].

Assessments

Data was collected at four fixed time points. Baseline data was collected during hospital admission. Follow-up assessments were conducted during the out-patient follow-up visits at 6, 12 and 52 weeks after fracture.

Primary outcome measure

Fear of falling was measured with the Short Falls Efficacy Scale International (FES-I), administered during all three follow-up visits. The Short FES-I is a 7-item instrument, scored on a 4-point Likert scale, assessing FoF related to basic physical and social activities. The total score on the Short FES-I ranges from 7 to 28, with higher scores indicating a higher level of FoF. The Short FES-I has proved to be a valid measure to assess FoF in frail older adults, including those with cognitive impairment [25]. The standard FES-I cut-off score of ≥ 11 was used as reference to define elevated levels of FoF [26].

FoF trajectories for specific patient groups

The course of FoF was modelled for specific subgroups, based on factors expected to distinguish between high or low FoF levels. This led to FoF trajectories for specific subgroups.

First, we compared the course of FoF for patients with pre-fracture FoF to those without it. Pre-fracture FoF was assessed in retrospect, related to the period directly before fracture, using a one-item fear of falling question ('*Are you afraid of falling?*') [27]. Pre-fracture FoF was operationalized as follows: 1] no pre-fracture FoF (patients reporting '*not at all*'); and 2] pre-fracture FoF present (patients reporting either '*a little*', '*quite a bit*' or '*very much*').

Secondly, we explored FoF trajectories for groups based on FoF status at 6 *and* 12 weeks. Using the FES-I cut-off score of 11, this led to the following *FoF trend groups*: 1] No FoF (= FES-I < 11 at 6- and 12-week follow-up); 2] Transient FoF (= FES-I ≥ 11 at 6 weeks and FES-I < 11 at 12 weeks); 3] Late-onset FoF (= FES-I < 11 at 6 weeks and ≥ 11 at 12 weeks); 4] Persistent FoF (= FES-I ≥ 11 at 6 and 12 weeks).

Independent variables

Pre-fracture mobility and comorbidity have been associated with FoF after hip fracture and were therefore included as covariates in the statistical models [22,28]. The *Parker Mobility Score* (PMS) was used as a (retrospective) measure of mobility [29], related to the period directly before fracture. This measurement instrument assesses indoor- and outdoor mobility, and the ability to do shopping. Each item is scored as: no difficulty; with walking aid; with assistance; or not at all able. The total score ranges from 0-9, with higher scores indicating better mobility. For the analyses, pre-fracture PMS was dichotomized into PMS < 9 (assistance needed in mobility) and PMS 9 (independent mobility). The *American Society of Anesthesiologists classification* (ASA) [30] was used to measure general health status (indirectly a measure of medical comorbidity; no other data on comorbidity available in current data set). For the analyses, this variable was dichotomized (category I-II, and > II). Age, which has been associated with FoF in older adults, was also included as a covariate [31].

Additional variables

For a background description of the study population several characteristics were determined, including age and sex. Independence in activities in daily living (ADL) was measured using the *Katz Index of Independence in Activities of Daily Living* (Katz-ADL). It was assessed in retrospect, related to the period directly before fracture, to describe pre-fracture level of functioning [32]. Cognitive impairment is common in this population and was determined based on an existing formal diagnosis of dementia, and with the *6-Item Cognitive Impairment Test* (6-CIT) [33,34]. Nutritional problems are frequently reported for this population, and these were measured with the *Mini Nutritional Assessment–Short Form* (MNA-SF) [35].

To provide insight into the extent of functional recovery after fracture, we used a combined outcome measure, which represents the recovery of independence of ADL [6,12]. The combined outcome measure is based on the following variables: 1] mortality; 2] (in)dependent living

situation; and 3] recovery of ADL function to pre-fracture level, measured with KATZ-ADL. *Successful* recovery was operationalized as: no mortality (all causes) + living independently in a private residence (including a residential home setting, and as needed with home care) + recovery to pre-fracture ADL function (current KATZ ADL ≤ pre-fracture ADL). Recovery was considered *unsuccessful* when not all criteria were met. Rates of successful recovery are presented for the 6-, 12-, and 52-week follow-up for the four *FoF trend groups*.

Statistical analysis

Descriptive analyses were used to summarize characteristics of the study population. To examine the course of FoF up to one year after fracture, we used linear mixed models (LMM). The unconditional growth model - illustrating the course of FoF for the study population as a whole – modelled FES-I as linear function of time; with *age, pre-fracture PMS* and *ASA classification* as covariates (all centred to the mean); in addition to a random intercept. Time was operationalized as weeks since hip fracture.

We examined the effect of pre-fracture FoF on the course of FoF after fracture, in linear mixed model 1 (LMM1). LMM1 was an extension of our unconditional growth model, which additionally included pre-fracture FoF as a predictor of the intercept and the slope. In the second linear mixed model (LMM2) we explored the course for the four FoF trend groups. LMM2 included the same covariates as LMM1, with in addition the FoF trend group variable as a predictor of the intercept and the slope. In contrast to the unconditional model and LMM1, the FES-I in LMM2 was modelled from 12 weeks post hip fracture onward, as this model included the independent variable 'FoF trend groups', which was based on the observed FES-I at 6 and 12 weeks.

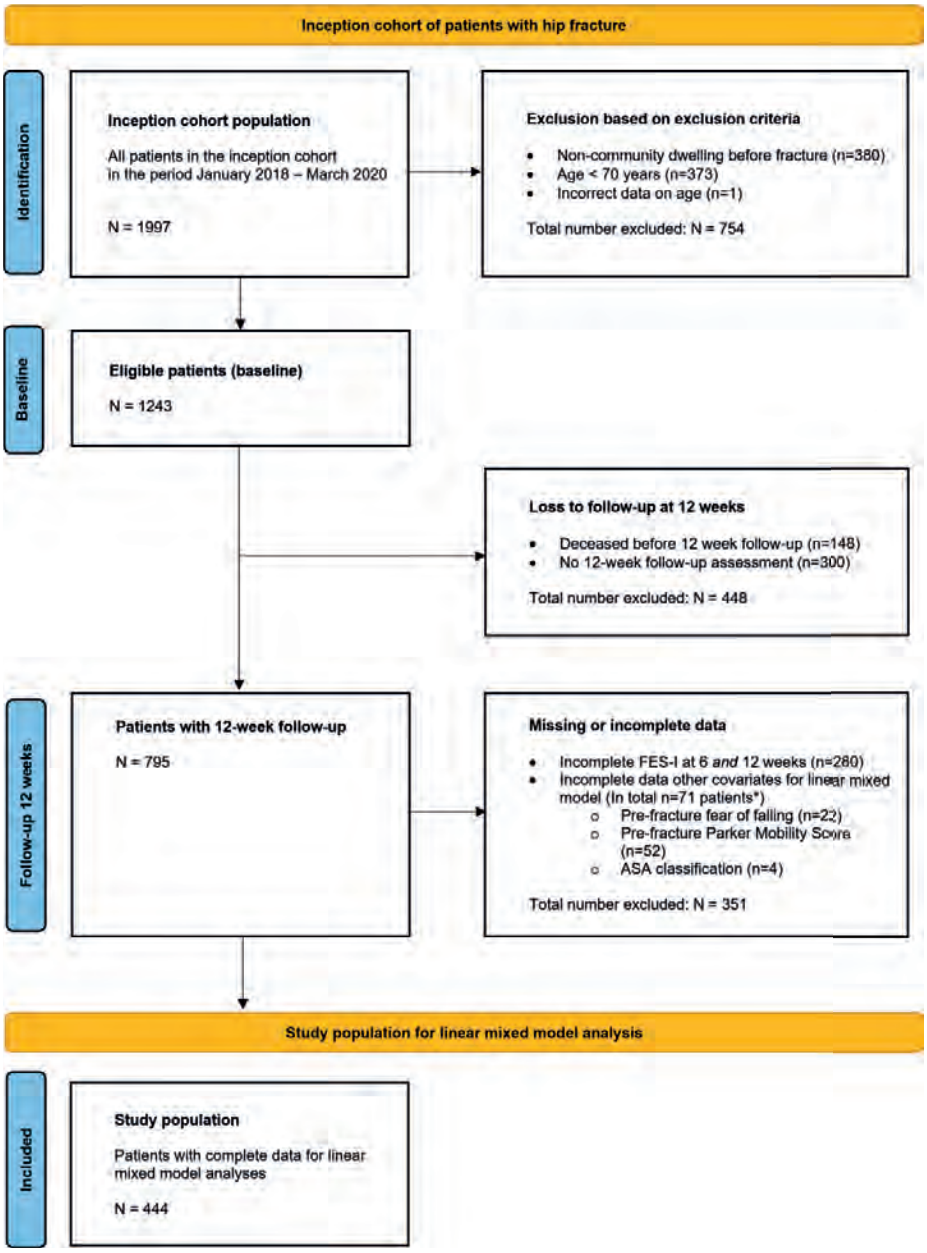
Outcomes are presented as parameter estimates of the linear mixed models. In addition, we present estimated mean FES-I scores at 6, 12, and 52 weeks after fracture for subgroups of our sample. The course of FoF is illustrated in graphs for a patient with sample average values of all covariates. All statistical analyses were performed using IBM SPSS version 25.0 (Windows), graphs were constructed in R version 4.1.0.

RESULTS

The study population consisted of all 444 patients with complete data for all variables required for the analyses (Figure 1). Most patients were female (n=305; 68.7%) and the average age was 81.9 years (SD: 7.1) (Table 1). Prior to the fracture, a considerable proportion of the population had experienced FoF (n= 189; 42.6%). Classification by FoF trend groups shows that absence of FoF is common (no FoF trend group n=190; 42.8%), as is persistent FoF (n=119; 26.8%). Transient FoF accounts for 16.9% (n=75), and late-onset FoF for 13.5% of the population (n=60).

Our final study population (n=444) was younger (Δ= -2.5 years [95% CI: -3.4- -1.7]; p <0.001), had a higher pre-fracture score for the PMS (Δ= 1.6 [95% CI: 1.4-1.9]; p <0.001), and a slightly lower ASA score (Δ= -0.2 [95% CI: -0.2 - -0.1]; p <0.001), as compared to patients that were excluded due to missing data for relevant variables (n=799) (Figure 1).

Figure 1. Flow chart of the study



* Note: multiple missing measurements per patient possible

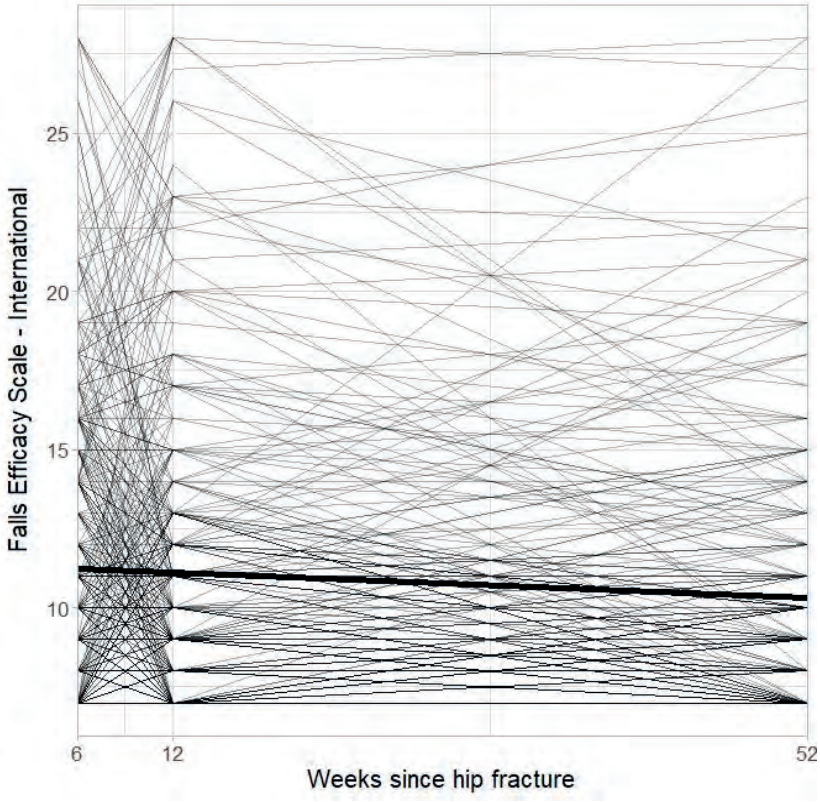
Table 1. Baseline characteristics of the study population (n=444)	
Socio-demographic characteristics	
Age at time of fracture (years); mean (SD)	81.9 (7.1)
Female gender; n (%)	305 (68.7)
Pre-fracture health status (baseline assessments); n (%)	
Patients with ASA Physical Status Classification > II *	234 (52.7)
Nutritional status - based on Mini Nutritional Assessment (MNA)†	
Patients with MNA score 0-7 (malnutrition)	9 (2.2)
Patients with MNA score 8-11 (risk of malnutrition)	93 (22.6)
Cognitive functioning †	
Patients with pre-fracture diagnosis dementia	6 (1.4)
Patients with pre-operative 6-CIT score > 10 *	35 (8.1)
Patients with pre-fracture fear of falling ‡	189 (42.6)
Pre-fracture physical functioning (baseline assessments)	
KATZ-ADL (0-6); median (IQR) *	0.0 (0.0-1.0)
Parker Mobility Scale (0-9); median (IQR) §	9.0 (6.0-9.0)

Notes: ASA classification=American Society of Anesthesiologists classification; 6-CIT=6-Item Cognitive Impairment Test; KATZ-ADL=Katz Index of Independence in Activities of Daily Living; SD=standard deviation; IQR=interquartile range. * Lower scores indicate better status. † Numbers do not add up to final numbers due to missing data, valid % are shown. ‡ Pre-fracture fear of falling was assessed using a one-item fear of falling question ('*Are you afraid of falling?*'), related to the period directly before fracture. Answer categories: '*Not at all*', '*A little*', '*Quite a bit*' and '*Very much*'; of which the 3 latter answers were categorized as 'pre-fracture fear of falling'. § Higher scores indicate better status.

The unconditional growth model demonstrates that the course of FoF up to a year after hip fracture is characterized by a study population-based mean FES-I level that starts just above the cut-off value of 11 at 6 weeks after fracture, and shows a marginal decline over time (Figure 2). Estimates are presented in Appendix 1. One year after fracture, almost one-third of the patients have elevated FES-I levels (n=132; 29.7%). In view of the individual observed trajectories, we see a considerable degree of heterogeneity.

Analyses of FoF trajectories for patients with pre-fracture FoF (n=189) compared to those without it (n=255), show a decrease in FES-I levels for both groups (Figure 3). However, the mean FES-I for the group with pre-fracture FoF is above the cut-off value of 11 during the entire follow-up, as opposed to the group without pre-fracture FoF (values presented in Appendix 2). Although patients with FoF prior to fracture had higher FES-I levels, the effect of pre-fracture FoF on the course of post-fracture FoF was not significant (estimate 0.78; p=0.067).

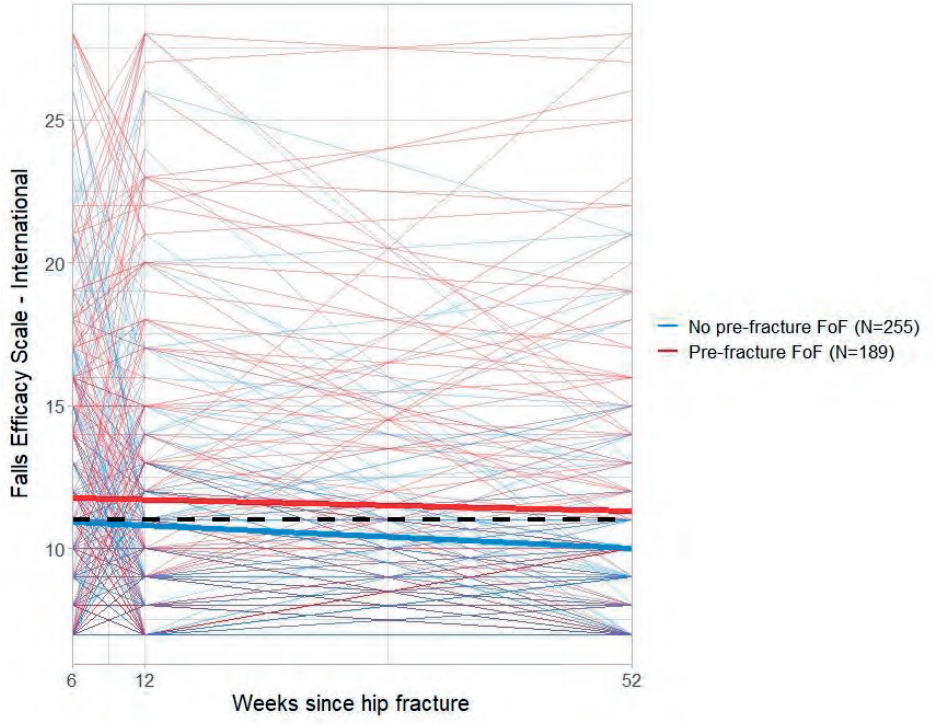
Figure 2. Course of fear of falling up to one year after hip fracture



Notes: Falls Efficacy Scale International (7-item) with range 7-28; lower scores indicating less fear of falling. Accentuated line represents the estimated mean FES-I score for the whole population (n=444). Based on the unconditional linear mixed-model with mean-centred values for covariates. Thin lines represent observed FES-I trajectories of the individual patients.

Figure 4 illustrates the FoF trajectories for each of the four FoF trend groups and shows that each group has a distinct evolution of FoF over time, with different rates of change. The *persistent FoF* trend group has the highest FES-I levels, and although this decreases to some extent over time, levels remain above the cut-off value of 11 during the entire follow-up (estimated mean FES-I: 16.6 at 12 weeks and 14.1 at 52 weeks after fracture). Similarly, the course for the *late-onset* trend group is characterized by an elevated estimated mean FES-I score, yet levels are lower than in the *persistent FoF* group and approach the cut-off value of 11 around 52 weeks after fracture. Both the *no FoF* trend group and *transient FoF* group have FES-I levels well below the cut-off in the period 12-52 weeks. The heterogeneity in the individual observed trajectories is most profound for the *persistent FoF* and *transient FoF* groups (Appendix 3).

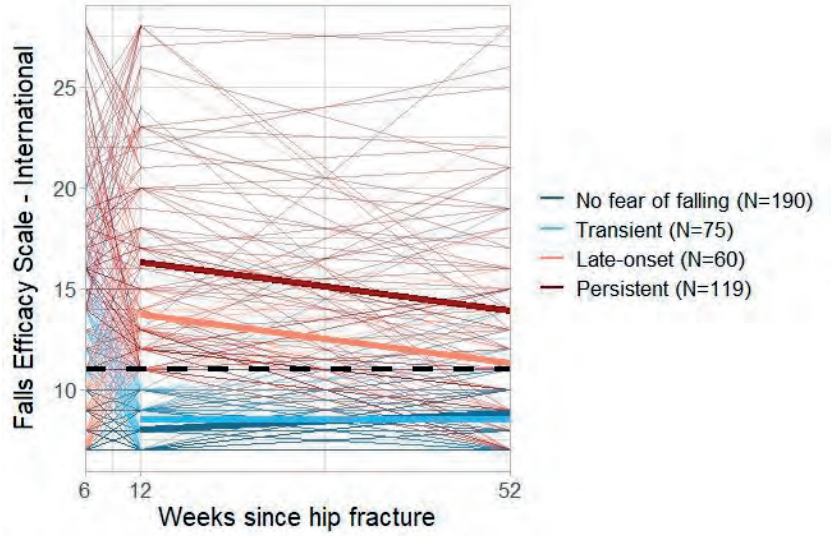
Figure 3. Course of fear of falling up to one year after hip fracture, for patients with or without pre-fracture fear of falling.



Notes: FoF=fear of falling. Falls Efficacy Scale International (7-item) with range 7-28; lower scores indicating less fear of falling. Accentuated solid lines (blue and red) represent the estimated mean FES-I score for the two groups; based on LMM1. The mean FES-I presented in this graph is based on mean-centred values for covariates. It thus represents the course of FoF of a patient with versus *without* pre-fracture FoF, and sample mean values for all other covariates (e.g. age 81.9 years). The dotted black line represents the FES-I cut-off value of 11. The thin coloured lines represent observed FES-I trajectories of individual patients.

In Appendix 4, characteristics of each of the FoF trend groups are presented, including baseline characteristics, and data on outcome after fracture. Prior to fracture, both the *persistent FoF* and *late-onset FoF* group had more health problems, and reduced mobility function. Twelve weeks after fracture, one third of patients in the *persistent FoF* group had a successful recovery regarding independence in ADL function, compared to half of the patients in the *transient FoF* and *late-onset FoF* groups, and almost 80 percent in the *no FoF* group. Insight into the long-term recovery rate is somewhat limited as a result of missing data for a quarter of the population at one year after fracture (Appendix 5). However, the results do point toward better recovery rates for the *No FoF* group as compared to the other three groups that had FoF at 6 and/or 12 weeks after fracture. We evaluated the proportion of patients with FoF (elevated FES-I levels) one year after fracture, based on the estimated FES-I derived from LMM2. FoF was most mostly present in the *late-onset* FoF (n=26; 43.3%) and the *persistent FoF* groups (n=101; 84.9%).

Figure 4. Fear of falling trajectories for pre-defined 'fear of falling trend groups'



Notes: FoF = fear of falling. Falls Efficacy Scale International (7-item) with range 7-28; lower scores indicating less FoF. Accentuated coloured solid lines represent the estimated mean FES-I score for the different FoF trend groups, based on LMM2. The mean FES-I presented in this graph is based on mean-centred values for covariates. It thus represents the course of FoF of a patient within each of the four FoF trend groups, with sample mean values for all other covariates (e.g. age 81.9 years). The dotted black line represents the FES-I cut-off value of 11. The thin coloured lines represent observed FES-I trajectories of individual patients.

The four FoF trend groups were defined based on the presence/absence of fear of falling at 6 *and* 12 weeks. No FoF = FES-I < 11 at 6- and 12-week follow-up; Transient FoF = FES-I ≥ 11 at 6 weeks and FES-I < 11 at 12-week follow-up; Late-onset FoF = FES-I < 11 at 6 weeks and ≥ 11 at 12-week follow-up; Persistent FoF = FES-I ≥ 11 at 6- and 12-week follow-up.

DISCUSSION

Main findings

This is the first study to evaluate FoF up to 12 months after hip fracture. The findings illustrate that the population-based mean FES-I is located around the current established cut-off value of 11, and that levels decrease only slightly over time. However, individual patient trajectories are heterogeneous and amidst this diversity, certain subgroups are noteworthy in view of the elevated FES-I levels. Patients with FoF prior to the hip fracture on average had higher FES-I levels during the entire follow-up period, yet this association between pre-fracture and post-fracture FoF was just above the significance threshold. FoF trend groups analyses show that both the *persistent FoF* group (FES-I elevated at 6 and 12 weeks after fracture) and the *late-onset FoF* group (FES-I elevated at 12 weeks after fracture), have a long-term course characterized by elevated FES-I levels. The *persistent FoF* group – accounting for a quarter of the population – has the most profound levels, with mean FES-I remaining well above the cut-off value of 11 up to one year after fracture.

Strengths and limitations of the study

An important strength of this study is that, owing to the longitudinal design with one-year follow-up, it provides novel insight into the long-term course of FoF after hip fracture. The findings contribute to filling an important knowledge gap in hip fracture research. FoF can be considered a potentially modifiable risk factor, that, when addressed adequately, has the potential to improve functional outcome for this vulnerable population. Findings from this study can assist in identifying an appropriate target population for intervention. An additional strength is that the study design is based on a large inception cohort (without in- or exclusion criteria), increasing the generalizability of the results to a broad population of patients with hip fracture.

However, some limitations of this current study should be considered. First, the analyses were based on a subpopulation – patients with complete cases of FES-I scores at 6 and 12 weeks. This reflects a population that survived the first three months after fracture, was able to visit the out-patient clinic, and did not have severe cognitive deficits that could interfere with the assessment of the FES-I. Patients with advanced cognitive problems or serious physical and functional impairment (i.e., residing in nursing home) may be underrepresented in this population. Indeed we found significant differences between the selected and excluded population regarding the covariates in our model – age, ASA classification, Parker Mobility Score. However, for age and ASA the differences may be considered modest, and we can question the clinical relevance. Second, pre-fracture FoF was assessed in retrospect, which in theory could lead to recall bias. This was also assessed using a one-item fear of falling question, which complicated the comparison between pre-fracture and post-fracture FoF. Future studies should preferably use FES-I for all assessments, in order to enable comparison of the *extent* of FoF before and after fracture, and hence improve insight into the course of FoF, with the fracture as an intermediate event. Finally, we did not assess mood and anxiety in the present study. In community-dwelling older adults depression has been associated with FoF (and activity restriction) [36]. In recent FoF literature it has also been suggested that anxiety determines whether FoF becomes maladaptive [37]. Neuroticism has also been identified as a risk factor for high FoF after fracture [22]. We recommend that future studies evaluate these psychological factors in relation to the course of FoF.

Comparison with current literature on fear of falling

We can question whether FoF, in patients with hip fracture, may to some extent be a normal or adaptive response to the recent fall-related medical event and current physical impairment. Oshima et al. found that for community-dwelling older adults, mobility problems (standing balance and gait) were associated with the development of FoF [38]. This concept may also be applicable for the early stage after fracture, which is characterized by sudden impairment of gait function. This could partly explain our finding that, shortly after hip fracture, the mean FES-I is located around the cut-off value. Another important finding in literature is that the negative

effects of FoF on functional recovery are not found for FoF in the very early phase after hip fracture, but only from 6 weeks after fracture and beyond [13,14]. How this finding relates to the natural course of FoF after fracture is still unknown, owing to a research gap on this subject. Longitudinal data on FoF after hip fracture is scarce and current literature focuses mainly on the cross-sectional presence of FoF. Only two longitudinal studies provide some insight into FES-I levels over time. Similar to our findings, the population-based mean FES-I levels in these studies were ≥ 11 in the early stage after hip fracture. Furthermore, in these studies FoF levels were found around the FES-I cut-off score, at 12 weeks after fracture [22], and 6 months after rehabilitation respectively [39]. This supports the overall course of FoF observed in our study.

However, as our findings demonstrate a considerable degree of heterogeneity in the individual trajectories, it seems helpful to explore specific subgroups, in order to identify patients with 1] excessive FoF, or 2] persistent FoF. Both features could be indicative of *maladaptive* FoF in this population, i.e., FoF that impedes physical activity and daily functioning. To examine whether FoF at 12 weeks is related to an increased risk of FoF in the long term (one year after fracture), we explored FoF trajectories from 12 weeks onward, for the four different trend groups, based on observed FoF at 6 and 12 weeks. Only one previous study evaluated specific FoF trajectories, but within an earlier timeframe, i.e., in the period 4-12 weeks after fracture [22]. Using latent class analysis to model the course, the study found three distinct FoF trajectories, namely *minimal FoF* (72%), *decreasing FoF* (17%) and *increasing FoF* (11%). Despite differences in timeframe and methodology, some parallels can be drawn between study findings. First, a considerable part of the population either has low FES-I levels, or moderate FoF levels around the FES-I cut-off of 11. Second, there is a small group with elevated FES-I levels in the early stage after fracture (4-6 weeks) who demonstrate a trend of recovery in the subsequent period (*decreasing FoF* group respectively *transient FoF* trend group in our study). Third, patients with a trajectory characterized by repeated elevated FES-I levels up to 12 weeks, have substantial levels at onset (4-6 weeks after fracture), with a mean FES-I around 16. A novel finding of our study is that patients in this group with *persistent FoF* have the poorest recovery of independence in ADL function, with only a third of the patients showing successful recovery at 12 weeks after fracture. However, it is noteworthy that recovery for the other groups with FoF, i.e., the transient FoF group with FoF at 6 weeks and late-onset FoF group with FoF at 12 weeks after fracture, is somewhat limited too.

This study also examined pre-fracture FoF in relation to the FoF after fracture, as it is undetermined whether pre-fracture and post-fracture FoF can be considered a continuum. At present, there is no comparative literature on this topic, although one previous study provides evidence that pre-fracture FoF affects short-term functional recovery [12]. Our findings illustrate that, contrary to those without pre-fracture FoF, patients with pre-fracture FoF have sustained elevated FES-I levels over time. Although the association was not statistically significant, the

observed difference between groups with and without pre-fracture FoF indicates that pre-fracture FoF may to some extent influence FoF after fracture, and that it may be relevant to assess this in clinical practice.

Implication for clinical practice

When FoF is evident and impairs daily functioning, existing treatment approaches for community-dwelling older adults are recommended [18,19]. Functional recovery of lower extremity function after hip fracture can continue to almost a year after fracture [40], and we therefore expect that treatment for FoF in advanced stages after hip fracture has potential to optimize functional ability. Considering the high FES-I levels, the chronic nature of the FoF, and the poor recovery of independence in ADL function in the *persistent FoF* trend group, we believe that it is mainly this group - roughly a quarter of the population - that is at risk for *maladaptive* FoF and could consequently benefit from intervention. Timely identification of these patients requires a structural approach to assessing FoF up to at least 12 weeks after fracture. This may call for efforts from various health care professionals in the different care settings that the patient passes through in the rehabilitation process. Essentially, we recommend screening for pre-fracture FoF immediately after fracture to limit risk of recall bias, to assess the FoF levels in the acute phase, at onset of rehabilitation, and at 12 weeks after fracture.

CONCLUSION

Although FES-I levels decrease to some extent in the year following hip fracture, FoF as defined by a FES-I score ≥ 11 remains present over time for a considerable part of the population. Patients with persistent FoF at 12 weeks have the highest FES-I levels during the entire follow-up, a high rate of FoF one year after fracture, and limited recovery of independence in ADL function. These patients may benefit from an intervention to address the FoF. To identify patients at risk for high or persistent FoF in a timely manner, we therefore recommend structural assessment of FoF, including screening for (pre-fracture) FoF directly after fracture, at onset of rehabilitation, and 12 weeks after fracture.

What is already known on this topic

- Fear of falling (FoF) is common after hip fracture, and when it is present in the period 6 weeks after fracture and beyond, it can hamper functional recovery
- In contrast to positive effects seen for treatment of community-dwelling older adults, the evidence in support of treatment of FoF shortly after hip fracture is inconclusive
- The long-term course of FoF after hip fracture is unknown

What this study adds

- In the first year after hip fracture, the FoF levels decrease somewhat overall, yet elevated FES-I levels remain common
- Highest FES-I levels are observed for patients with persistent FoF at 6 *and* 12 weeks post-fracture, with levels well above the cut-off value during the year following fracture. Recovery of ADL independence is poor for patients with persistent FoF.

DECLARATIONS

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Contributor and guarantor information

MvdS and AN designed the current data collection structure for this inception cohort and monitored the data collection. AN and MvE are regularly involved in the data-collection of this ongoing inception cohort. MSB performed the data-analysis, together with MH and MvE. MSB, MH, WA, JvH and MvE were involved in the interpretation of the results. MSB drafted the manuscript. All authors contributed to the manuscript, provided feedback, and have read and approved the final version. MSB is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Data sharing

The dataset used for the purpose of this study are available from the corresponding author on reasonable request.

Ethical approval

The Medical Research Ethics Committee of the Haaglanden Medical Center, and the hospital's board of directors approved the study protocol of the inception cohort (METC Southwest Holland; protocol number 16-059). Because of its observational design, informed consent was not required according to the Dutch regulations.

Transparency statement

The lead author (MSB) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Competing interests declaration

All authors declare they have no conflicts of interest.

Patient and Public Involvement

There was no patient and public involvement in any stage of this study.

REFERENCES

1. Ravindrarajah R, Hazra NC, Charlton J, Jackson SHD, Dregan A, Gulliford MC. Incidence and mortality of fractures by frailty level over 80 years of age: cohort study using UK electronic health records. BMJ Open 2018;8(1):e018836. (In eng). DOI: 10.1136/bmjopen-2017-018836.
2. International Osteoporosis Foundation. (https://www.osteoporosis.foundation/facts-statistics/epidemiology-of-osteoporosis-and-fragility-fractures).
3. Dyer SM, Crotty M, Fairhall N, et al. A critical review of the long-term disability outcomes following hip fracture. BMC Geriatr 2016;16(1):158. (In eng). DOI: 10.1186/s12877-016-0332-0.
4. Aarden JJ, van der Esch M, Engelbert RHH, van der Schaaf M, de Rooij SE, Buurman BM. Hip fractures in older patients: Trajectories of disability after surgery. The journal of nutrition, health & aging 2017;21(7):837-842. DOI: 10.1007/s12603-016-0830-y.
5. Papanicolas I, Figueroa JF, Schoenfeld AJ, et al. Differences in health care spending and utilization among older frail adults in high-income countries: ICCONIC hip fracture persona. Health Serv Res 2021 (In eng). DOI: 10.1111/1475-6773.13739.
6. Handoll HH, Cameron ID, Mak JC, Panagoda CE, Finnegan TP. Multidisciplinary rehabilitation for older people with hip fractures. Cochrane Database Syst Rev 2021;11(11):Cd007125. (In eng). DOI: 10.1002/14651858.CD007125.pub3.
7. Cooper C, Campion G, Melton LJ, 3rd. Hip fractures in the elderly: a world-wide projection. Osteoporos Int 1992;2(6):285-9. (In eng). DOI: 10.1007/bf01623184.
8. Veronese N, Maggi S. Epidemiology and social costs of hip fracture. Injury 2018;49(8):1458-1460. (In eng). DOI: 10.1016/j.injury.2018.04.015.
9. van der Sijp MPL, van Eijk M, Tong WH, et al. Independent factors associated with long-term functional outcomes in patients with a proximal femoral fracture: A systematic review. Exp Gerontol 2020;139:111035. (In eng). DOI: 10.1016/j.exger.2020.111035.
10. Xu BY, Yan S, Low LL, Vasanwala FF, Low SG. Predictors of poor functional outcomes and mortality in patients with hip fracture: a systematic review. BMC Musculoskelet Disord 2019;20(1):568. (In eng). DOI: 10.1186/s12891-019-2950-0.
11. Sheehan KJ, Williamson L, Alexander J, et al. Prognostic factors of functional outcome after hip fracture surgery: a systematic review. Age Ageing 2018;47(5):661-670. (In eng). DOI: 10.1093/ageing/afy057.
12. van der Sijp MPL, van Eijk M, Niggebrugge AHP, Putter H, Blauw GJ, Achterberg WP. Prognostic Factors for Short-term Recovery of Independence in a Multistate Model for Patients With a Hip Fracture. J Am Med Dir Assoc 2020 (In eng). DOI: 10.1016/j.jamda.2020.08.006.
13. Oude Voshaar RC, Banerjee S, Horan M, et al. Fear of falling more important than pain and depression for functional recovery after surgery for hip fracture in older people. Psychol Med 2006;36(11):1635-45. (In eng). DOI: 10.1017/s0033291706008270.
14. Bower ES, Wetherell JL, Petkus AJ, Rawson KS, Lenze EJ. Fear of Falling after Hip Fracture: Prevalence, Course, and Relationship with One-Year Functional Recovery. Am J Geriatr Psychiatry 2016;24(12):1228-1236. (In eng). DOI: 10.1016/j.jagp.2016.08.006.
15. Tinetti ME, Powell L. Fear of falling and low self-efficacy: a case of dependence in elderly persons. J Gerontol 1993;48 Spec No:35-8. (In eng). DOI: 10.1093/geronj/48.special_issue.35.
16. Visschedijk J, Achterberg W, Van Balen R, Hertogh C. Fear of falling after hip fracture: a systematic review of measurement instruments,

prevalence, interventions, and related factors. J Am Geriatr Soc 2010;58(9):1739-48. (In eng). DOI: 10.1111/j.1532-5415.2010.03036.x.

17. Visschedijk J, van Balen R, Hertogh C, Achterberg W. Fear of falling in patients with hip fractures: prevalence and related psychological factors. J Am Med Dir Assoc 2013;14(3):218-20. (In eng). DOI: 10.1016/j.jamda.2012.10.013.
18. Dorresteijn TA, Zijlstra GA, Ambergen AW, Delbaere K, Vlaeyen JW, Kempen GI. Effectiveness of a home-based cognitive behavioral program to manage concerns about falls in community-dwelling, frail older people: results of a randomized controlled trial. BMC Geriatr 2016;16:2. (In eng). DOI: 10.1186/s12877-015-0177-y.
19. Zijlstra GA, van Haastregt JC, Ambergen T, et al. Effects of a multicomponent cognitive behavioral group intervention on fear of falling and activity avoidance in community-dwelling older adults: results of a randomized controlled trial. J Am Geriatr Soc 2009;57(11):2020-8. (In eng). DOI: 10.1111/j.1532-5415.2009.02489.x.
20. Pfeiffer K, Kampe K, Klenk J, et al. Effects of an intervention to reduce fear of falling and increase physical activity during hip and pelvic fracture rehabilitation. Age Ageing 2020;49(5):771-778. (In eng). DOI: 10.1093/ageing/afaa050.
21. Scheffers-Barnhoorn MN, van Eijk M, van Haastregt JCM, et al. Effects of the FIT-HIP Intervention for Fear of Falling After Hip Fracture: A Cluster-Randomized Controlled Trial in Geriatric Rehabilitation. J Am Med Dir Assoc 2019;20(7):857-865.e2. (In eng). DOI: 10.1016/j.jamda.2019.03.009.
22. Bower ES, Wetherell JL, Petkus AJ, Lenze EJ. Neuroticism predicts fear of falling after hip fracture. Int J Geriatr Psychiatry 2020;35(5):498-506. (In eng). DOI: 10.1002/gps.5261.
23. van der Sijp MPL, Schipper IB, Keizer SB, Krijnen P, Niggebrugge AHP. Prospective comparison of the anterior and lateral approach in hemiarthroplasty for hip fractures: a study protocol. BMC Musculoskelet Disord 2017;18(1):361. (In eng). DOI: 10.1186/s12891-017-1724-9.
24. STROBE - STrengthening the Reporting of OBservational studies in Epidemiology. (https://www.strobe-statement.org/).
25. Hauer KA, Kempen GI, Schwenk M, et al. Validity and sensitivity to change of the falls efficacy scales international to assess fear of falling in older adults with and without cognitive impairment. Gerontology 2011;57(5):462-72. (In eng). DOI: 10.1159/000320054.
26. Delbaere K, Close JC, Mikolaizak AS, Sachdev PS, Brodaty H, Lord SR. The Falls Efficacy Scale International (FES-I). A comprehensive longitudinal validation study. Age Ageing 2010;39(2):210-6. (In eng). DOI: 10.1093/ageing/afp225.
27. Jørstad EC, Hauer K, Becker C, Lamb SE. Measuring the psychological outcomes of falling: a systematic review. J Am Geriatr Soc 2005;53(3):501-10. (In eng). DOI: 10.1111/j.1532-5415.2005.53172.x.
28. Visschedijk JH, Caljouw MA, van Balen R, Hertogh CM, Achterberg WP. Fear of falling after hip fracture in vulnerable older persons rehabilitating in a skilled nursing facility. J Rehabil Med 2014;46(3):258-63. (In eng). DOI: 10.2340/16501977-1264.
29. Voeten SC, Nijmeijer WS, Vermeer M, Schipper IB, Hegeman JH. Validation of the Fracture Mobility Score against the Parker Mobility Score in hip fracture patients. Injury 2020;51(2):395-399. (In eng). DOI: 10.1016/j.injury.2019.10.035.
30. Hackett NJ, De Oliveira GS, Jain UK, Kim JY. ASA class is a reliable independent predictor of medical complications and mortality following surgery. Int J Surg 2015;18:184-90. (In eng). DOI: 10.1016/j.ijsu.2015.04.079.
31. Scheffer AC, Schuurmans MJ, van Dijk N, van der Hooft T, de Rooij SE. Fear of falling: measurement strategy, prevalence, risk factors and consequences among older persons.

Age Ageing 2008;37(1):19-24. (In eng). DOI: 10.1093/ageing/afm169.

32. Katz S, Downs TD, Cash HR, Grotz RC. Progress in development of the index of ADL. Gerontologist 1970;10(1):20-30. (In eng). DOI: 10.1093/geront/10.1_part_1.20.
33. O'Sullivan D, O'Regan NA, Timmons S. Validity and Reliability of the 6-Item Cognitive Impairment Test for Screening Cognitive Impairment: A Review. Dement Geriatr Cogn Disord 2016;42(1-2):42-9. (In eng). DOI: 10.1159/000448241.
34. Upadhyaya AK, Rajagopal M, Gale TM. The Six Item Cognitive Impairment Test (6-CIT) as a screening test for dementia: comparison with Mini-Mental State Examination (MMSE). Curr Aging Sci 2010;3(2):138-42. (In eng). DOI: 10.2174/1874609811003020138.
35. Kaiser MJ, Bauer JM, Ramsch C, et al. Validation of the Mini Nutritional Assessment short-form (MNA-SF): a practical tool for identification of nutritional status. J Nutr Health Aging 2009;13(9):782-8. (In eng). DOI: 10.1007/s12603-009-0214-7.
36. Yao Q, Jin W, Li Y. Associations between fear of falling and activity restriction and late life depression in the elderly population: Findings from the Irish longitudinal study on ageing (TILDA). J Psychosom Res 2021;146:110506. (In eng). DOI: 10.1016/j.jpsychores.2021.110506.
37. Adamczewska N, Nyman SR. A New Approach to Fear of Falls From Connections With the Posttraumatic Stress Disorder Literature. Gerontol Geriatr Med 2018;4:2333721418796238. (In eng). DOI: 10.1177/2333721418796238.
38. Oshima K, Asai T, Fukumoto Y, Yonezawa Y, Nishijima A. Development and persistence of fear of falling relate to a different mobility functions in community-dwelling older adults: one-year longitudinal predictive validity study. Aging Clin Exp Res 2021 (In eng). DOI: 10.1007/s40520-020-01756-0.
39. Tu CY, Shields N, Gill SD, Tacey M, Lindner C, Hill KD. Longitudinal changes in physical activity levels and fear of falling after hip fracture. Physiother Res Int 2021;26(1):e1884. (In eng). DOI: 10.1002/pri.1884.
40. Magaziner J, Hawkes W, Hebel JR, et al. Recovery from hip fracture in eight areas of function. J Gerontol A Biol Sci Med Sci 2000;55(9):M498-507. (In eng). DOI: 10.1093/gerona/55.9.m498.

APPENDIX

Appendix 1. Results of linear mixed-model analyses to describe the course of fear of falling after hip fracture (n=444)

Parameter	Unconditional model			Model 1: pre-fracture fear of falling			Model 2: fear of falling trend groups		
	Estimate	95% CI	P-value	Estimate	95% CI	P-value	Estimate	95% CI	P-value
Fixed effects *									
Intercept	11.37	[10.98; 11.77]	0.000	11.04	[10.51; 11.57]	0.000	7.81	[7.29; 8.32]	0.000
Linear rate of change/week (slope)	- 0.02	[-0.03; -0.01]	0.000	- 0.02	[-0.04; 0.01]	0.000	0.02	[0.00; 0.03]	0.015
Pre-fracture fear of falling									
Absent				Reference category			Reference category		
Present				0.78	[-0.06; 1.62]	0.067	0.26	[-0.45; 0.97]	0.479
Interaction with time				0.01	[-0.01; 0.03]	0.183	0.02	[0.00; 0.04]	0.024
Fear of falling trend groups									
No fear of falling							Reference category		
Transient fear of falling							0.74	[-0.24; 1.72]	0.141
Interaction with time							-0.02	[-0.05; 0.01]	0.254
Late-onset fear of falling							6.66	[5.60; 7.73]	0.000
Interaction with time							-0.08	[-0.11; -0.05]	0.000
Persistent fear of falling							9.24	[8.38; 10.10]	0.000
Interaction with time							-0.08	[-0.11; -0.06]	0.000
Random effects									
Intercept (initial FES-I value)	10.13	[8.41; 12.21]	0.000	9.91	[8.22; 11.96]	0.000	4.21	[3.10; 5.72]	0.000
Residual covariance †									
6 weeks	11.12	[9.30; 13.30]	0.000	11.15	[9.33; 13.33]	0.000	‡	‡	‡
12 weeks	8.95	[7.32; 10.93]	0.000	9.03	[7.40; 11.02]	0.000	4.41	[3.28; 5.92]	0.000
52 weeks	7.02	[5.45; 9.04]	0.000	6.86	[5.32; 8.85]	0.000	7.75	[6.22; 9.65]	0.000

In all models, time is operationalized as weeks since hip fracture. * All 3 models are adjusted for (mean-centred) age, ASA classification and pre-fracture Parker Mobility Score. † Diagonal covariance structure for repeated measures. ‡ Not applicable, the course for model 2 is modelled from 12 weeks onward, as this model included the independent variable 'FoF trend groups', which was based on the observed FES-I at 6 and 12 weeks.

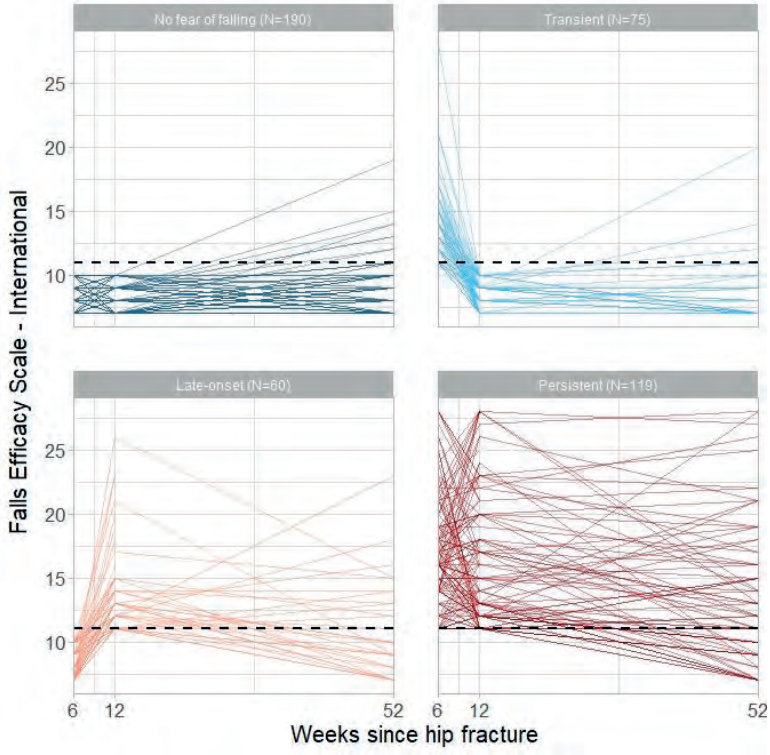
Appendix 2. Course of fear of falling after hip fracture – estimated mean FES-I* in the period up to 52 weeks after hip fracture

LMM1 – Pre-fracture fear of falling †			
	Estimated mean FES-I †		
Pre-fracture FoF (total n=444)	6 weeks after hip fracture	12 weeks after hip fracture	52 weeks after hip fracture
No pre-fracture FoF (n=255)	10.5 (2.6)	10.3 (2.6)	9.4 (2.6)
Pre-fracture FoF present (n=189)	12.3 (3.6)	12.3 (3.6)	11.9 (3.6)

LMM2 – Fear of falling trend group †			
	Estimated mean FES-I †		
FoF trend group (total n=444) §	6 weeks after hip fracture	12 weeks after hip fracture	52 weeks after hip fracture
No FoF (n=190)	‡	7.8 (0.7)	8.4 (1.0)
Transient FoF (n=75)	‡	8.5 (0.7)	8.5 (1.0)
Late-onset FoF (n=60)	‡	13.8 (1.7)	11.3 (1.9)
Persistent FoF (n=119)	‡	16.6 (2.8)	14.1 (3.0)

Notes: LMM=linear mixed model; FoF=fear of falling. * FES-I=Falls Efficacy Scale International (7-item); range 7-28; lower scores indicating less fear of falling. † Analysis based on linear mixed model. Models include fixed intercept and a random intercept, in addition to the covariates age, ASA classification and pre-fracture Parker Mobility Score (all mean-centred). LMM 1 includes pre-fracture FoF as a predictor for the intercept and the slope. LMM 2 includes both pre-fracture FoF and FoF trend group as intercept and slope predictors. § FoF trend groups based on the observed FES-I scores at 6 and 12 weeks follow-up. *No FoF* = FES-I < 11 at 6- and 12-week follow-up. *Transient FoF* = FES-I ≥ 11 at 6 weeks and FES-I < 11 at 12-week follow-up. *Late-onset FoF*= FES-I < 11 at 6 weeks and ≥ 11 at 12-week follow-up. *Persistent FoF* = FES-I ≥ 11 at 6- and 12-week follow-up. ‡ Not applicable, LMM 2 is based on FES-I data from 12 weeks to 52 weeks after fracture.

Appendix 3. Fear of falling after hip fracture – observed FES-I values for the four 'FoF trend groups'



Notes: FoF=fear of falling. Falls Efficacy Scale International (7-item) with range 7-28; lower scores indicating less FoF. The dotted black line represents the FES-I cut-off value of 11. The thin coloured lines represent observed FES-I trajectories of individual patients.

The four FoF trend groups were defined based on the presence /absence of fear of falling at 6 and 12 weeks. No FoF = FES-I < 11 at 6- and 12-week follow-up; Transient FoF = FES-I ≥ 11 at 6 weeks and FES-I < 11 at 12-week follow-up; Late-onset FoF = FES-I < 11 at 6 weeks and ≥ 11 at 12-week follow-up; Persistent FoF = FES-I ≥ 11 at 6- and 12-week follow-up.

Appendix 4. Characteristics of the four distinct fear of falling (FoF) trend groups (total n=444)†

	No FoF n=190 (42.8%)	Transient FoF n=75 (16.9%)	Late-onset FoF n=60 (13.5%)	Persistent FoF n=119 (26.8%)
Baseline characteristics				
Age at time of fracture (years); mean (SD)	80.6 (6.7)	82.2 (7.3)	83.3 (8.2)	83.3 (6.8)
Female gender; n (%)	128 (67.4)	45 (60.0)	43 (71.7)	89 (74.8)
Pre-fracture health status (baseline assessments); n (%)				
Patients with ASA Physical Status Classification > II ‡	82 (43.2)	44 (58.7)	33 (55.0)	75 (63.0)
Nutritional status - based on Mini Nutritional Assessment (MNA) *				
Patients with MNA score 0-7 (malnutrition)	1 (0.6)	1 (1.4)	1 (1.9)	6 (5.5)
Patients with MNA score 8-11 (risk of malnutrition)	33 (18.5)	13 (18.1)	16 (30.2)	31 (28.4)
Cognitive functioning				
Patients with pre-fracture diagnosis dementia *	3 (1.6)	0 (0.0)	1 (1.7)	2 (1.7)
Patients with pre-operative 6-CIT score > 10 ‡	11 (5.9)	8 (10.8)	6 (10.3)	10 (8.8)
Patients with pre-fracture fear of falling **	65 (34.2)	34 (45.3)	23 (38.3)	67 (56.3)
Pre-fracture physical functioning (baseline assessments)				
ADL function - KATZ-ADL score (0-6); median (IQR) ‡	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-2.0)	0.0 (0.0-2.0)
Mobility - Parker Mobility Scale (0-9); median (IQR) §	9.0 (7.0-9.0)	9.0 (7.0-9.0)	7.0 (6.0-9.0)	6.0 (6.0-9.0)
Outcomes after hip fracture				
Recovery of independence in ADL ††; n(%) *				
Patients with successful recovery - 6 weeks after fracture	99 (52.9)	23 (31.5)	12 (21.1)	29 (24.8)
Patients with successful recovery - 12 weeks after fracture	148 (79.1)	41 (54.7)	30 (50.8)	43 (36.4)
Patients with successful recovery - 52 weeks after fracture	115 (78.2)	26 (59.1)	22 (48.9)	44 (47.8)
Fear of falling; n (%)				
Patients with elevated estimated FES-I (≥11) ‡‡ - 52 weeks after fracture	1 (0.5)	1 (1.3)	26 (43.3)	101 (84.9)

Appendix 4. Characteristics of the four distinct fear of falling (FoF) trend groups (total n=444)†
Notes: FoF=fear of falling; ASA classification=American Society of Anesthesiologists classification; 6-CIT=6-Item Cognitive Impairment Test; KATZ-ADL=Katz Index of Independence in Activities of Daily Living; ADL=Activities of Daily Living; FES-I=Falls Efficacy Scale International; SD=standard deviation; IQR=interquartile range.
† FoF trend groups based on the observed FES-I scores at 6 and 12 weeks: 1] No FoF = FES-I < 11 at 6- and 12-week follow-up; 2] Transient FoF = FES-I ≥ 11 at 6 weeks and FES-I < 11 at 12-week follow-up; 3] Late-onset FoF = FES-I < 11 at 6 weeks and ≥ 11 at 12-week follow-up; and 4] Persistent FoF = FES-I ≥ 11 at 6- and 12-week follow-up. * Numbers do not add up to final numbers due to missing data, valid % is shown. ‡ Lower scores indicate better status. § Higher scores indicate better status. ** Pre-fracture fear of falling was assessed using the one-item fear of falling question ("*Are you afraid of falling?*"), related to the period directly before fracture. Answer categories: "*Not at all*", "*A little*", "*Quite a bit*" and "*Very much*"; of which the 3 latter answers were categorized as 'pre-fracture fear of falling'. †† Recovery of independence in ADL = combined outcome measure based on the following variables: 1] mortality; 2] (in)dependent living situation; and 3] recovery of ADL function to pre-fracture level, measured with KATZ-ADL. Successful recovery was operationalized as: no mortality (all causes) + living independently in a private residence (including a residential home setting, and as needed with home care) + recovery to pre-fracture ADL function (current KATZ ADL ≤ pre-fracture ADL). ‡‡ Estimated FES-I based on the LMM2.

Appendix 5. Missing data in final study population (n=444)

Assessments missing - N	Baseline*	6 weeks after hip fracture	12 weeks after hip fracture	52 weeks after hip fracture
KATZ-ADL	0	0	2	122 ‡
Information regarding current residence	0	10	3	110 ‡
Recovery of independence in ADL §	†	10	5	116
FES-I	†	0	0	170 ‡

Chapter 7

General Discussion

This thesis aims to provide insight into appropriate management of fear of falling (FoF) for patients with a recent hip fracture.

FoF, often specified as a concern about falling, is common after hip fracture. Prevalence rates of over 60% have been described for this population [1-4]. Moreover, FoF has been established as a risk factor for poor recovery after hip fracture [2,4,5]. FoF is regularly accompanied by fear-related avoidance behavior such as limited participation in (physical) activities, and this avoidance behavior may be key to the negative consequences of FoF [6-8]. It is therefore relevant to consider treatment of FoF for patients with (recent) hip fracture. If a decrease in the level of FoF is accompanied by a reduction of avoidance behavior, treatment of FoF can have potential to improve functional outcome for this population.

To date clinical guidelines offering tools for the management of FoF in older patients with a recent hip fracture are absent, and in current literature there is a critical knowledge gap on this subject. For this purpose the studies presented in this thesis address issues that are related to management of FoF after hip fracture. Extending on previous work of the research team regarding FoF in patients with hip fracture, a first step was set toward evaluating treatment of FoF in this population. A treatment program for FoF was developed for the inpatient geriatric rehabilitation setting (the FIT-HIP intervention), and the effects of treatment were studied. Additionally the feasibility of the intervention was evaluated. To support the identification of patients with FoF that may benefit from treatment, observational studies were used to gain more insight into the course of FoF after hip fracture over time. The observational studies also explored whether coping and pre-fracture FoF are relevant factors to consider within the context of management of FoF.

To summarize, the studies discussed in this thesis addressed the following research questions:

1] To which extent is the FIT-HIP intervention, a multi-component cognitive behavioral treatment program for FoF, effective in reducing FoF and improving physical function in patients with hip fracture?
2] What is the feasibility of the FIT-HIP intervention provided in inpatient geriatric rehabilitation?
3] Which coping strategies are used by patients with FoF after hip fracture, and how are these associated with mood, anxiety, pain and quality of life?
4] What is the long-term course of FoF after fracture, and what is the effect of pre-fracture FoF on the course of FoF after fracture?

In this final chapter of the thesis, the main research findings are presented and critically discussed in the context of important methodological considerations. Hereafter implications and recommendations for clinical practice and future research are presented.

MAIN RESEARCH FINDINGS

Effectiveness of the FIT-HIP intervention

The FIT-HIP intervention is a multi-component cognitive behavioral treatment program for FoF, designed to fit the setting of inpatient geriatric rehabilitation (GR). The intervention is integrated into the multidisciplinary GR treatment program for patients with hip fracture. The key component of the FIT-HIP intervention is guided exposure to feared situations or activities, such as making a transfer, walking, or performing certain activities of daily living (ADL). Furthermore, the intervention includes psycho-education, cognitive restructuring, relapse prevention and a telephonic booster after discharge from GR. Motivational interviewing techniques are included to support the process of behavior change. The intervention is conducted by physiotherapists, and intervention elements are integrated in the usual physical therapy sessions in GR. A psychologist is involved to provide additional on-site coaching to the physiotherapists with regard to the cognitive therapy.

The effectiveness of the intervention was evaluated using a cluster randomized controlled trial design. The FIT-HIP intervention - integrated in usual care in GR - was compared to care as usual for patients with hip fracture admitted to GR. FoF was measured with the Falls Efficacy Scale-International (FES-I). Study findings showed that the FIT-HIP intervention was not effective in reducing FoF levels, both directly after discharge from GR, and during the follow-up period up to six months after discharge from GR. Furthermore, the treatment groups did not differ with regard to improvement in mobility function during the GR period, measured with the Performance Oriented Mobility Assessment (POMA). Likewise, no differences between the intervention and usual care group were found for ambulation function and self-reported activity restriction for all assessments up to 6 months after GR.

Feasibility of the FIT-HIP intervention

The process evaluation of the FIT-HIP trial aimed to evaluate the feasibility of the intervention, and accordingly provide insight into factors that may have influenced the effectivity of the intervention. Within the FIT-HIP trial most intervention elements were performed according to protocol. Yet this was not applicable to cognitive restructuring and the telephonic booster, as these intervention elements were not provided to all participants. In general, the care professionals who conducted the intervention considered the FIT-HIP intervention to be feasible for clinical practice. However two important barriers were identified that affected the feasibility of the intervention. First, a low level of FoF was regularly observed among the included patients, and this hampered the administration of the intervention according to protocol. In the experience of the intervention facilitators, the FoF subsided soon after admission to GR. For this reason they suggested to initiate treatment in a later stage of GR, when the FoF persists over the course of time in GR. The limited level of FoF that was observed in clinical practice also

indicates that the screening and selection procedure for (treatment of) FoF requires improvement.

The second barrier that was found to influence the feasibility of the intervention, is that cognitive restructuring can be challenging for physiotherapists to perform, when they do not have prior experience with these techniques. The physiotherapists proposed that a more interdisciplinary treatment approach to FoF, with intensified collaboration between physiotherapists and the psychologist, could be beneficial to improve the feasibility and quality of the cognitive behavior therapy approaches (CBT). Furthermore, more extensive training of the physiotherapists regarding the element of cognitive restructuring is recommended.

Coping strategies of patients with fear of falling

Medical conditions such a hip fracture affect general health status, daily functioning and quality of life, and can therefore be considered a major stressor for an individual. Coping refers to cognitive and behavioral strategies that people use to deal with stressful situations. Coping strategies may influence participation in and receptiveness to treatment. Little is known about the concept of coping after hip fracture, therefore an explorative study based on baseline data of the FIT-HIP study was conducted to gain insight into coping in this population. One-third of the study population engaged in active tackling coping. However, passive reacting coping was common too, and almost a quarter predominantly used passive coping strategies. Use of passive reactive coping strategies was associated with more symptoms of depression and anxiety.

Long-term course of fear of falling after hip fracture

Although in general the level of FoF did in time decrease to some extent, FoF defined by an elevated FES-I score (≥ 11/28) was common in the first year following fracture. A reasonable group of patients did not experience FoF up to 12 weeks after fracture (42.6%). Yet the study findings also illustrate that a considerable amount of patients had FoF that endured within the year following fracture. The FoF was most prominent for patients with elevated FES-I levels at 6 and 12 weeks (*the persistent FoF group*; accounting for a quarter of patients with hip fracture), as this group had FES-I levels well above the cut-off value of 11 during the entire year following hip fracture. Patients with persistent FoF also had the lowest rate of functional recovery. However, it is noteworthy that the *late-onset FoF group* (FES-I < 11 at 6 weeks and FES-I ≥ 11 at 12 weeks) also had a course characterized by elevated FES-I levels up to one year after fracture. Findings of this study further showed that patients with pre-fracture FoF had higher levels of FoF compared to those patients without FoF prior to fracture, but this effect was not statistically significant.

THEORETICAL CONSIDERATIONS

The intervention

The finding that the FIT-HIP intervention was not effective in reducing FoF levels in our target population calls for a critical review of the intervention itself, and the study methodology and procedures of the FIT-HIP trial.

The field of research regarding FoF in patients with (recent) hip fracture is relatively young, and the first publications on this subject originate from around 2000 [9-11]. The studies presented in this thesis are the first that report on a treatment program primarily aimed at reducing FoF in patients with a (recent) hip fracture. The principles of the FIT-HIP intervention were therefore primarily derived from research on treatment programs for community-dwelling older adults. The FIT-HIP intervention was developed based on *'A Matter of Balance',* and the Dutch versions that were based on the principles of this treatment program for FoF [12-14]. Multiple studies have evaluated the effects of this treatment program, both in the United States, and in the health-care settings in the Netherlands, for treatment in group setting as well as for the home-based setting (aimed at the more frail population) [15-18]. All in all, there is a considerable amount of evidence illustrating the positive effects of this program to reduce FoF [12-20], thus the lack of effectiveness of the FIT-HIP treatment program is somewhat surprising. There are however some differences with regard to the intervention characteristics (content and delivery) between the two programs, and these are discussed below.

Cognitive behavioral therapy

Both *'A Matter of Balance'* and the FIT-HIP intervention are founded on the principles of cognitive behavioral treatment (CBT). From a broad perspective, when reflecting on CBT as a therapeutic approach to FoF, CBT approaches have been found effective to reduce FoF, both in general population of community-dwelling older adults, and in nursing home patients [19,20]. Recently another interventional study evaluated a treatment program for FoF in patients with hip fracture (Germany). This study, in which the *Step by Step* intervention was evaluated, provides some evidence in support of the fact that CBT may have potential to reduce FoF in this target population [21]. The *Step by Step* intervention is a multi-component treatment program for patients with hip- or pelvic fractures, provided within a transitional care setting, i.e. during inpatient GR, and additionally in the home-based setting after discharge [22]. This program includes various aspects of cognitive behavioral therapy. In contrast to the FIT-HIP intervention, this intervention showed some favorable effects on reducing FoF, albeit after the period of home-based treatment (not during inpatient geriatric rehabilitation) [21].

It is important to acknowledge that CBT is a broad concept, and we can therefore question which elements of CBT have the greatest potential to reduce FoF. At present, there is no

evidence to suggest that certain CBT approaches may be superior in their treatment effect on FoF [23,24]. Many of the treatment programs for FoF are multi-component interventions, and this makes it difficult to identify which intervention items are most effective in reducing FoF. When comparing the FIT-HIP intervention to other treatment programs, including *'A Matter of Balance'*, there are no apparent differences regarding the *frequency* of sessions with psycho-education, cognitive restructuring and relapse prevention which could explain the differences in treatment effect [13,14,22,25]. However, the FIT-HIP intervention differs from *'A Matter of Balance* ', and other treatment programs, in that sense that there is a prominent role for the guided exposure in the FIT-HIP treatment program. One other intervention, the home-based *ABLE* intervention for older adults with *excessive* FoF, also incorporated exposure as an elementary part of the treatment (United States). The study evaluating this program showed favorable effects for reducing FoF [25]. Thus there is some evidence in support of the effectivity of guided exposure to reduce (excessive) FoF, albeit for the general population of community-dwelling older adults. To which extent guided exposure as a treatment approach for FoF is also appropriate for the geriatric rehabilitation setting remains uncertain, as the FIT-HIP study is the first to evaluate this approach in the inpatient GR setting.

Delivery of the intervention

In view of the literature showing positive effects of CBT as a treatment approach for FoF, it is plausible that - based on the *content* the FIT-HIP intervention - the program has potential to reduce FoF. Thus it is important to reflect on other intervention characteristics which may explain differences in treatment effects, for example the delivery of the intervention. A noteworthy difference in the design of the FIT-HIP intervention compared to other programs, is that it is incorporated into *'usual care'*, i.e. the physical therapy sessions during GR. In that sense it is not a separate or exclusive treatment program. In the development of the intervention it was thought to be beneficial to integrate the intervention into usual care, as it may increase awareness for FoF throughout the whole multidisciplinary GR program. However, we can also question whether the intervention items receive the full attention when integrated in the general physical therapy sessions. This remains area of attention for future research. For clinical practice it may be relevant to consider to provide treatment within *separate* and *additional* therapy sessions, that are specifically marked as treatment for FoF and fully dedicated to address the FoF as topic. Such an approach was also used in the *Step by Step* intervention during the inpatient GR, and may prove to be beneficial to increase the effectivity of treatment.

Feasibility of the intervention for physiotherapists

In the different treatment programs for FoF that have been evaluated over the years, various health care professionals have been involved as intervention facilitators [24]. There is no evidence to suggest that physiotherapists are not suited to provide CBT. The *Step by Step* and the *ABLE* intervention were performed by physiotherapists and had positive effects [21,25]. However it

is important to check whether the intervention facilitators feel competent to provide (certain items of) the CBT. Findings from the feasibility study show that cognitive therapy can be perceived as challenging without prior experience with these techniques. In this regard, more attention for supervision and mentoring by psychologists seems appropriate. Both the *Step by Step* and *ABLE* intervention incorporated weekly supervision of the physiotherapists, including performance feedback, in the intervention. This can help build up the (perceived) competence of physiotherapist and improve fidelity of the intervention. It can also enhance the collaboration toward a more interdisciplinary approach to FoF. Furthermore, specifically for the situation in which intervention items are integrated into usual care, it is important to be aware that physiotherapists may struggle with role clarity and the perceived need to prioritize physical therapy [26]. This may support the suggestion that it could useful be separate the usual physical therapy sessions from therapy sessions with specific focus on addressing FoF.

Timing of treatment

Another factor that may contribute to the lack of effect of the FIT-HIP intervention, is the timing of treatment provided. Although little is known about the natural course of FoF after fracture, and how this relates to the negative effect on functional recovery, the two studies evaluating both FoF and functional recovery over time, show that FoF at 2 and 4 weeks is not associated with worse functional recovery, in contrast to FoF present at 6 and 12 weeks after fracture [4,5]. This suggests that FoF that is present in the very early stage after hip fracture, does not by definition lead to significant problems in daily functioning. In the FIT-HIP study, participants were recruited in the first week of admission to GR (generally representing the second week after fracture). Treatment started directly after inclusion, for the duration of the inpatient GR (on average approximately 6 weeks). If indeed for most patients the FoF in early stages of recovery does not hamper recovery, the timing of the FIT-HIP intervention may not have been appropriate for effective treatment of FoF.

The timing may also explain the contradictory findings in relation to the *Step by Step* intervention. The *Step by Step* intervention was provided during 3-5 weeks of inpatient rehabilitation, followed by additional treatment in the period up to 2 months after discharge from inpatient rehabilitation. No effect was found directly after the inpatient rehabilitation, the positive effect on reduction in FoF was only found one month after the intervention. This may point toward the fact that a more advanced timing of treatment may be more appropriate and effective.

Setting in which treatment is provided

The results of study evaluating the *Step by Step* intervention may also demonstrate beneficial effects of treatment mainly for the ambulant home-based setting. Observational studies have found that there is an increase in the level of FoF after discharge home from GR [27,28]. This may in part be explained by the fact that the GR setting has a lot of support and supervision, which can

contribute to a secure feeling for patients. In contrast, in the home-based setting patients are principally self-reliant, and it is plausible that the transition home can trigger FoF. The results of the longitudinal study presented in this thesis additionally confirm that FoF is common in later stages of recovery (6 weeks post-fracture onwards). This could imply that treatment for FoF may especially be relevant for the ambulant setting. It also underpins the need to monitor FoF levels after discharge home, and intervene promptly when FoF persists in the ambulant setting and hampers further recovery.

METHODOLOGICAL CONSIDERATIONS

Regarding the studies presented in this thesis, there are several methodological issues that require attention, including the selection of patients, measurement of FoF, the generalizability of the results (external validity) and the design of the trial.

One of the most critical methodological issues of the studies presented in this thesis, is the selection of patients with fear of falling. The FIT-HIP intervention was not effective in reducing FoF, and the selection of the population may in part explain this lack of effectiveness. In retrospect we may argue that the selection of the target population should be aimed at identifying those patients in whom the FoF interferes in daily functioning, for example as a result of avoidance of activities, as it is the expectation that especially these patients may experience positive effects of treatment for FoF. It is however questionable whether the patients of the FIT-HIP study population had FoF that led to problems in daily functioning. Based on the feasibility study there is evidence to suggest that FoF subsided soon. Unfortunately the FIT-HIP trial contains little data to verify whether the limited level of FoF that was observed in clinical practice, was indeed accompanied by minimal impact on daily functioning. However, in theory, several factors in the selection procedure of the FIT-HIP trial may have contributed to selection of a study population with limited FoF. These include the broad inclusion criteria and insufficient attention for the aspect of avoidance behavior. These methodological issues are discussed in more detail below, after a brief description of the recent conceptual approaches to the construct of FoF. These insights into the construct of FoF are presented to provide context for the methodological limitations regarding both the selection of patients with FoF, and the measurement of FoF.

The construct of fear of falling: considering the maladaptive character of fear of falling

At present a standardized definition and classification of FoF a definition is absent, and this complicates an adequate selection procedure of the target population. In current literature there is inconsistency with regard to the definition [29-31], and FoF is often used as an umbrella term for both the 'cognitive-based' constructs such as falls efficacy and balance confidence,

as well as the more 'emotion-based' constructs such as concerns about falling [23,24,32]. The research presented in this thesis has been conducted based on the conceptualization that FoF is an emotion-based construct (a concern about falling), that will often have behavioral consequences (avoidance of activities). This is also in line with the definition of fear of falling as originally presented by Tinetti, i.e. *'a lasting concern about falling that leads to an individual avoiding activities that he/she remains capable of performing'* [33]. More specifically, the FIT-HIP trial was developed and conducted based on the expectation that FoF after hip fracture will lead to problems in daily functioning. However, based on current literature, and the latest theoretical approaches to the construct of FoF, we can question whether FoF after hip fracture is by definition (always) problematic.

In the past few years there has been increased awareness for the fact that not all fall-related psychological concerns per se have negative effects [34,35]. In some circumstances, for example when there is an elevated fall risk, it may be appropriate to have a certain level of caution and not engage in activities that have a serious risk of falling. In particular this may also be applicable to patients with hip fracture in early stages of rehabilitation, as they experience a sudden impairment of (lower extremity) function, resulting an altered gait and increased fall risk. In recent literature terminology such as '*maladaptive*' or '*disproportionate*' has been used in relation to FoF, in an effort to outline when FoF does present as a problem for the individual. Such an approach may help to distinguish merely 'elevated' levels of concerns about falling, from FoF that clearly has negative consequences for daily functioning, for example as a result of *excessive* avoidance of activities. However, the concept of 'maladaptive FoF 'has also not sufficiently been defined yet [25,36].

There is however growing attention for factors that can contribute to problematic or *maladaptive* FoF, and that may characterize maladaptive FoF. Anxiety has regularly been associated with (higher levels of) FoF, and with avoidance behavior [1,3,37-39]. Specifically for patients with hip fracture, neuroticism was identified as a predictor for high and persistent FoF after hip fracture [37]. Thus anxiety (traits) may influence the extent of FoF and moderate the consequences of FoF towards a *maladaptive* response. The role of anxiety within the construct of FoF is also supported by various new conceptual theoretical frameworks for FoF, which are often based on posttraumatic stress disorder (PTSD) theory. In these conceptualizations of FoF, anxiety and the behavioral consequences of anxiety (avoidance behavior) are considered important characteristics within the construct of FoF [30,34,36,40,41]. Adamczewska and Nyman argue that anxiety determines whether FoF becomes maladaptive, as anxiety leads to *excessive* avoidance behavior, restricting participation in daily activities [36]. Another framework for FoF based on the PTSD theory also describes significant distress as a criterium for FoF, and mentions that symptoms have to be present for at least one month [40]. This temporal (time-related) factor may also be relevant to the FoF in patients with hip fracture, as there is evidence to suggest that in

early stages of rehabilitation, not all FoF is problematic, but that especially the FoF that persists over time can hamper the recovery process. All in all, it may be important to be mindful of *maladaptive* features when evaluating FoF in research or practice.

Selection of patients with FoF in the FIT-HIP study

Based on the latest insights into the construct of FoF, it may be relevant to consider *maladaptive* FoF, when selecting a target population for (evaluating) the treatment of FoF. Reflecting on the screening procedure of the FIT-HIP trial, it is important to acknowledge that the handled inclusion criteria were not directly aimed at maladaptive FoF. Based on a one-item fear of falling question, patients were eligible when they were *sometimes*, *often or very often* concerned about falling (broad inclusion criteria). The selection did not include the behavioral aspect of FoF (fear-related avoidance behavior). At baseline 88.2% of the study population reported they (almost) never avoided activities as a result of FoF, reflecting a very limited extent of avoidance behavior. Furthermore, certain procedures may have contributed to underrepresentation of psychological factors that contribute to maladaptive FoF. Patients with pre-fracture major depression or anxiety disorder were excluded as this was expected to affect learnability. Based on current knowledge, it is likely that this group of patients may experience more problems as a result of the FoF [42-44]. Additionally, the timing of recruitment may have also introduced a selection bias toward a group with less psychological problems. Inclusion of participants had to take place in the first week of GR, to facilitate the onset of treatment within the first week of admission to GR. A consequence of this recruitment procedure was that patients had little time to decide whether they wanted to participate. Factors that may contribute to patients being more reluctant to participate, such as anxiety and depression, may possibly be underrepresented. In conclusion, the selection procedure used within the FIT-HIP trial may be insufficient to discriminate between FoF that can be considered a normal or adaptive response, in contrast to FoF that impedes daily functioning and can be considered maladaptive. This may have led to selection of patients with a limited extent of FoF, which in turn may in part explain the lack of treatment effect.

For future purposes, a screening approach with more attention for characteristics of maladaptive FoF may prove to be beneficial. This is supported by the fact that recent intervention studies that have incorporated anxiety-related characteristics in the screening procedure, have shown favorable effects of treatment to reduce FoF *(ABLE intervention, Step by Step intervention)* [21,25].

Measuring FoF

In the studies presented in this thesis, FoF was evaluated with the Falls Efficacy Scale-International (FES-I) [45-47]. In the past years several other measurement instruments for FoF have been developed, including *The Survey of Activities and in the Elderly* (SAFFE) [48-50], *Fear of Falling*

Questionnaire Revised (FFQ-R) [51,52], and the *Fear of Falling Assessment Score* (FoFAS) [40], but these are not yet commonly used. The FES-I is frequently used both in research and clinical practice, and is also recommended in fall prevention guidelines for the assessment of FoF [53]. The FES-I has been validated for patients with hip fracture in inpatient geriatric rehabilitation [54]. Studies evaluating FoF in patients with hip fracture, including the trial evaluating the *Step by Step* intervention, have used this measurement instrument. As such is could currently be considered the gold standard to assess FoF [1-4,21,27].

However, reflecting on the concept of *maladaptive FoF*, a few issues should be taken into account when interpreting results of FoF research based on the FES-I. Foremost, it is important to be mindful of the fact that FES-I only reflects the emotional aspect of FoF, namely the concerns about falling. Insight into the (behavioral) consequences of the concerns about fear of falling lack, and this should be assessed separately in order to gain more insight into the aspect of maladaptive FoF. In the FIT-HIP study avoidance behavior was assessed with a one-item question, but we can question whether this has sufficient discriminative properties to accurately identify patients with 'problematic' avoidance behavior. As the study findings in this thesis only present information on (elevated) levels of concerns about falling, this complicates interpretation in terms of whether these elevated FES-I levels also reflect maladaptive FoF.

Another methodological issue regarding the use of FES-I as measurement instrument for FoF, is that there are no specific cut-off values for patients with hip fracture. In the studies in this thesis, the norm values for the general population of community-dwelling older adults are used. At present it remains uncertain to which degree these reference values are appropriate for FoF shortly after hip fracture. Likewise, it is not known which FES-I levels can be indicative for maladaptive FoF. The uncertainty regarding appropriate reference values for this target population, complicates the clinical interpretation of the measurement. In absence of specific reference- or cut-off values for the FES-I for patients with hip fracture, and reliable information on activity restriction, the course of FoF over time may additionally provide valuable information in identifying patients at risk for maladaptive FoF. As also seen in the longitudinal study presented in this thesis, patients with persistent 'high' levels of FoF may be at risk for impaired functional recovery. As such persistent elevated FES-I levels may also be indicative for maladaptive FoF.

As a final methodological reflection regarding the use of the FES-I, it is important to be aware of the fact that FES-I with its' activity-related item structure, is more related to (appraisal of) physical performance than to psychological constructs such as anxiety [54,55]. Thus the aspect of anxiety, which may be important for maladaptive FoF, may be underrepresented in the FES-I scores. Baseline assessment of anxiety in the FIT-HIP trial showed limited levels of anxiety in the study population. Thus elevated FES-I levels (as seen in the FIT-HIP trial), may not always

reflect anxiety characteristics. It may therefore be appropriate to additionally evaluate anxiety in conjunction with the FES-I.

To conclude, for future (research) purposes it may be useful to explore avoidance behavior and anxiety, in addition to assessment of the FES-I, in order to gain insight into the maladaptive character of FoF. Recently a revised FES-I has been developed and evaluated, to gain insight to avoidance behavior due to FoF: the FES-I Avoidance Behavior (FES-IAB) [56]. Each item of the FES-I which has been answered with at least some concerns about falling, is followed by an additional question '*Do you avoid performing this activity due to concerns about falling?*'. The instrument showed good psychometric properties when evaluated in community-dwelling older adults, and may also be a valuable instrument to evaluate the behavioral consequences of FoF in patients with hip fracture.

Generalizability of the study results

Both study populations used to answer the research questions in this thesis represent older adults that were community-dwelling prior to fracture. This implies that the findings will not be generalizable to patients with *advanced* cognitive problems, or severe physical impairment, who require 24-hour care provision in a long-term care setting. As discussed earlier in the discussion, there is some relevant selection bias in the FIT-HIP population, and the study population may represent a group with limited psychological comorbidity and limited level of FoF. Thus the finding that the FIT-HIP intervention is not effective is essentially applicable to a relatively 'healthy' group in terms of psychological burden. Furthermore when considering the generalizability of the findings, it is important to take into account the effect of cognitive functioning, as cognitive impairment has been associated with FoF [57]. Cognitive impairment has also been related to the persistence of FoF [58], and this may therefore be a risk factor for maladaptive FoF. There is evidence to suggest that FoF is mainly present in patients with mild cognitive impairment, and to a lesser degree in patients with global cognitive impairment (dementia) [59,60]. As the longitudinal study is based on an inception cohort of community-dwelling older adults, this will also include patients with mild cognitive impairment living in the community, and thus the findings provide a reliable insight into the course of FoF for the general population of community-dwelling older adults who have sustained a hip fracture. In contrast the FIT-HIP study excluded patients with pre-fracture cognitive deficits, and this can lead to underrepresentation of mild cognitive impairment, which in turn could contribute to limited FoF levels.

Final methodological considerations regarding the randomized controlled trial

A cRCT design was chosen to limit the risk of contamination of the complex multicomponent behavioral intervention. An important disadvantage of a cRCT is that, compared to randomization at individual level, there is a risk of imbalance of baseline characteristics. This was also seen

in the FIT-HIP trial, for clinically relevant factors. Sophisticated statistical techniques such as the mixed model analyses used in the analyses of the effect study, can account for clustering effects, and adjust for important observed differences between groups. However, it is important to be aware of unobserved between-group differences that are not accounted for in the analyses, but that have potential to influence the treatment effect (residual confounding). For future purposes, a stepped-wedge design could be considered as an alternative for the cRCT, reducing the risk of between-group imbalances.

IMPLICATIONS AND RECOMMENDATIONS

Implication for practice

Management of FoF after hip fracture should be aimed at identifying patients with maladaptive FoF, and consequently providing treatment to this group of patients. The process of identifying patients with FoF that can be considered maladaptive, requires a screening approach that gains insight into whether, and to which extent, the FoF interferes in daily functioning. When reflecting on the different risk factors that possibly contribute to maladaptive FoF, it is plausible that they have different patterns in how, and when they affect daily functioning. For example, patients with neuroticism and anxiety traits may be prone to prompt development of avoidance behavior (during GR). In contrast, patients with cognitive impairment may benefit from an environment with supervision and assistance, and the FoF in this group may mainly be triggered after discharge home. Thus structural and regular monitoring of FoF, and its interference with daily functioning, is recommended throughout the various care settings in order to facilitate prompt identification and treatment of patients with maladaptive FoF. Screening for FoF in the hospital setting is recommended as a baseline assessment, to aid the monitoring of FoF over time.

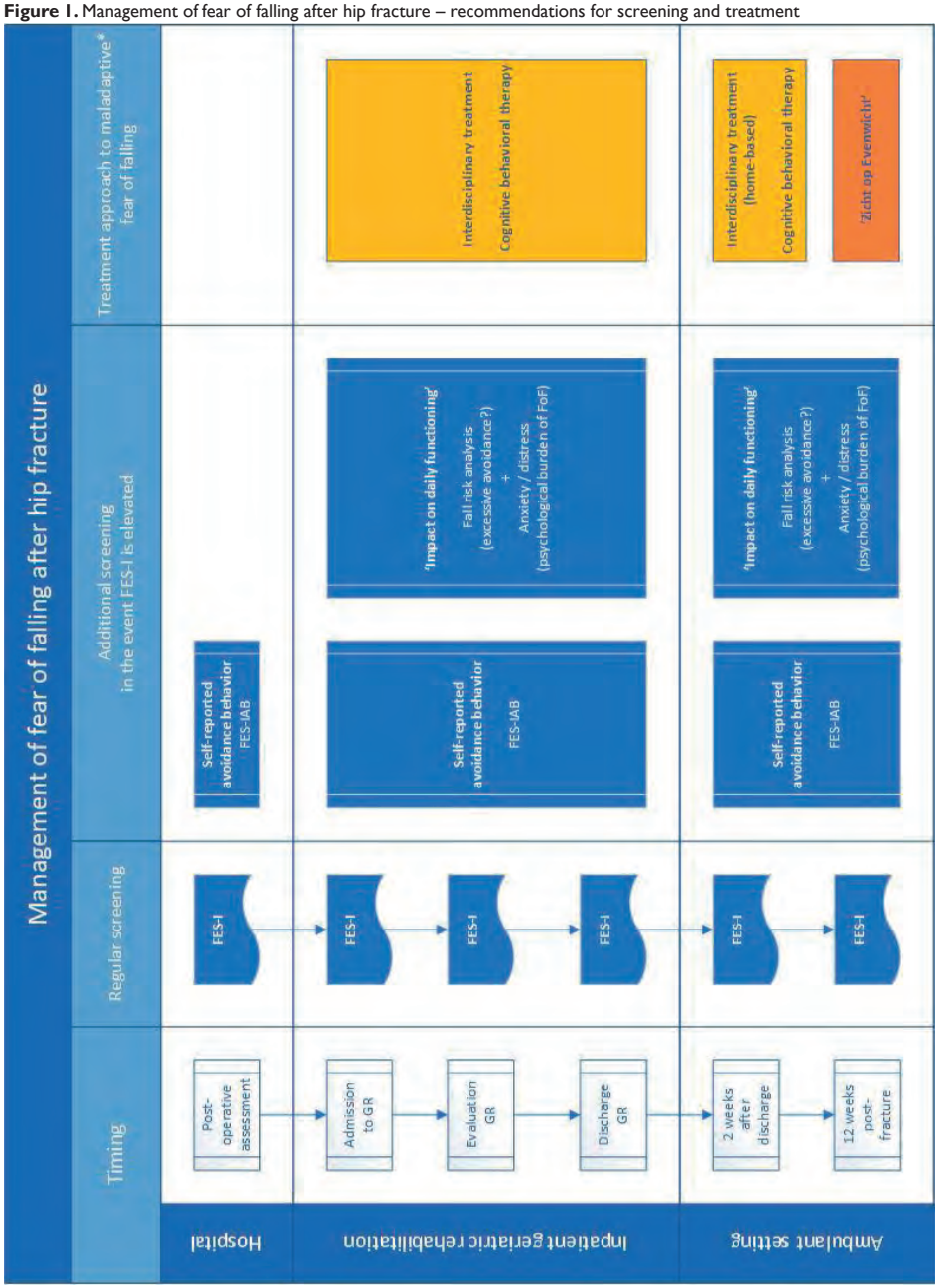
Figure 1 presents an overview of the recommendations for the management of FoF in clinical practice. This includes both the screening procedure and the recommendations regarding treatment.

Recommendations for the screening procedure

In absence of a standardized definition and classification of maladaptive FoF, for current clinical practice the following three criteria may be useful to assist the selection of patients with FoF that can be considered maladaptive.

1. Concerns about falling (the emotion-based characteristic of FoF)
2. Avoidance behavior (the behavioral response to FoF)
3. Significant impact on daily functioning (consequences of FoF)

Figure 1. Management of fear of falling after hip fracture – recommendations for screening and treatment



These characteristics of FoF are based on the predominate criteria of the recent conceptual theoretical frameworks for FoF, and screening for maladaptive FoF is aimed at evaluating these three concepts.

Concerns about falling

As the Falls Efficacy Scale-International (FES-I) is the most common measurement instrument used to assess concerns about falling, and has proven to be feasible in clinical practice, this is recommended to assess the level of concerns about falling. Screening with FES-I is recommended as the first step of screening. When the FES-I score is elevated, additional screening is advised to evaluate avoidance behavior (criterium 2) and the impact FoF has on daily functioning (criterium 3).

Avoidance behavior

The FES-IAB can be used to provide insight into the (self-reported) subjective avoidance behavior.

Significant impact on daily functioning

Reference values for the levels of concerns about falling (FES-I), and levels of avoidance behavior (FES-IAB) that can be considered (in)appropriate are absent. Thus this third criterium, appraisal of the impact of FoF on daily functioning, is key to determine whether FoF can be considered maladaptive. The burden of FoF, the impact on daily functioning, can be related to the behavioral response to FoF (excessive avoidance behavior), but also to the emotion-based aspect of FoF (for example distress). To evaluate the impact of avoidance behavior, an objective fall risk analysis is advised in conjunction to the self-reported avoidance (FES-IAB). This will help to evaluate to which extent the self-reported avoidance behavior is appropriate in relation to the actual fall risk ('safe behavior'), or whether the avoidance of activities can be considered *excessive* (unnecessary impairment of activities). In rehabilitation setting the Short Physical Performance Battery (SPPB) is commonly used to measure mobility function and fall risk, and this is a measure that could be considered for this purpose [61]. To gain insight into the psychological burden related to FoF, assessment of anxiety is recommended. The Hospital Depression and Anxiety Scale (HADS-A) is commonly used in clinical practice, and recommended in clinical fall prevention guidelines, and can be considered for this purpose [53].

Recommendations for treatment

Treatment of FoF is recommended when elevated FES-I and FES-IAB levels are accompanied by observable negative consequences of the FoF on daily functioning, such as excessive avoidance behavior or significant distress. Cognitive behavioral therapy has repeatedly proved to be effective for treatment of anxiety disorders, and for addressing FoF in community-dwelling older adults, and can therefore be used to address maladaptive FoF in our target population

[13,14,25]. In the event that treatment is required within the inpatient GR setting, an interdisciplinary treatment approach with combined treatment by psychologists and physiotherapist is recommended. Such an approach can easily be facilitated in the GR setting, and may prove beneficial for treatment of FoF [62]. However, in contrast to the primary design of the FIT-HIP intervention in which the intervention items were integrated in usual care, we recommend that treatment for FoF is organized as additional and separate therapy sessions with a specific focus for addressing FoF. Furthermore it is important to be aware than an interdisciplinary approach requires specific agreements with regard to which discipline is responsible for which treatment approach. Cognitive restructuring can be provided by both disciplines, but in the event that this is provided by physiotherapists, regular coaching by psychologists is recommended. Video recordings of the therapy sessions can be used to facilitate performance feedback.

For treatment of FoF after discharge home, the Dutch version of *'A Matter of Balance'* is advised. This program, *'Zicht op Evenwicht'*, is available in a group version and an individual home-based version. Both have proven to be effective to reduce FoF in the general population of community-dwelling older adults, and thus seem appropriate for the ambulant setting [13,14,18]. Alternatively, for those patients that have (had) FoF during GR and have a high risk of persistent FoF after discharge home, we may also consider home-based rehabilitation, as an extension of the inpatient GR services. Treatment provided in the context of home-based rehabilitation can also be organized as an interdisciplinary approach, with treatment provided by both a physiotherapist and psychologist. However, at present an important barrier for such an approach is reimbursement, and this is an area of attention for policy makers [63,64].

Future research

The primary focus of future research should be to optimize the identification of patients with maladaptive FoF. The aim is to provide a screening procedure that can determine and quantify the consequences of FoF, i.e. its impact on daily functioning. A first step in this process is an observational longitudinal study, evaluating the course of concerns about falling (FES-I levels) in relation to subjective avoidance behavior (FES-IAB), and to objective measures of physical functioning. This may help identify risk factors for persistent FoF which is accompanied by avoidance behavior. It may also be useful to evaluate the screening procedure presented in the recommendation section of this thesis (Figure 1), in order to assess whether this is an appropriate screening approach to identify patients with maladaptive FoF, and to which extent it is feasible in the transitional care setting. Furthermore, instead of focusing on the specific *type* of activities that are avoided, it may be useful to evaluate the *amount* of physical activity as a measure for avoidance behavior. In this regard, sensor monitoring may be able to assist in gaining insight into the consequences of FoF by providing information on (patterns of) physical activity in general, sedentary behavior, or even signs that can be indicative for distress (heartrate, sleep patterns).

A second step in further research on this topic, would be to evaluate treatment approaches to FoF, both within the GR setting, and in ambulatory setting. After a period in medical literature in which the RCT was the golden standard to evaluate effectiveness of treatment (at group level), in the past few years there is increasing interest for N-of-1 trials [65-67]. In this study design, which can be considered a cross-over RCT in a single patient, the goal is to determine the optimal treatment approach. An important advantage of such an approach is that it can determine treatment effect at individual level, which better fits the perspective of personalized medicine. It also contributes to understanding individual treatment responses. For complex multi-component interventions this may also provide more opportunities to evaluate which intervention items are effective under which conditions. This could help improve or tailor the intervention. Therefore this may be an interesting research method to help gain insight into treatment responses to different types of cognitive behavioral approaches for FoF. In addition to this research, further research is needed to establish the treatment effect of '*Zicht op Evenwicht'* in it's current form for patients with a recent hip fracture in the ambulant setting.

Another topic for further research is the complex interplay of the psychological factors associated with FoF, such as anxiety, depression, cognition and neuroticism. Additional information on how these factors relate to each other, can help to optimize the screening process for, and identification of patients with maladaptive FoF. Furthermore is may be relevant to explore to which extent coping strategies are modifiable in older adults, and whether problem-solving coping skills can effectively be used in this population.

OVERALL CONCLUSION

Fear of falling (FoF) specified as a concern about falling, is common after hip fracture, and has previously been associated with impaired functional recovery. This thesis provides evidence that a multi-component cognitive behavioral treatment approach to FoF in the early stages of recovery after hip fracture, during inpatient rehabilitation, is not effective to reduce FoF and improve physical functioning. Although the intervention itself may be improved by enhancing the collaboration between physiotherapists and psychologists to a more interdisciplinary approach, the lack of treatment effect is perhaps mostly explained by inappropriate selection of the target group, and the timing of the intervention. The selection of patients with FoF after recent hip fracture is subject to critical revision.

This thesis provides recommendations for the management of FoF after hip fracture. The challenge for current clinical practice, and for future research, is to identify patients with maladaptive FoF – i.e. FoF that has significant impact on daily functioning, for example as a result of excessive avoidance behavior or distress. A quarter of the population has persistent high levels

of FoF at 6 and 12 weeks after hip fracture, and may be prone to the negative effects of FoF. Therefore we recommend regular screening for FoF throughout the transitional care settings in order to monitor FoF levels. When FoF levels are elevated, additional screening is advised to gain insight into avoidance behavior and the impact of FoF on daily functioning. Considerations for treatment approaches are provided in this thesis.

EPILOGUE: THE FOLLOW-UP OF MRS VAN DIJK

In the general introduction of this thesis, the case of Mrs van Dijk was presented to illustrate how FoF may present in clinical practice, and which questions are raised regarding the management of FoF. This epilogue discusses the follow-up of Mrs van Dijk, and can be considered an illustration of the proposed management of FoF after hip fracture.

Five weeks post-fracture, Mrs van Dijk has an elevated FES-I score. The GR team questions whether treatment is required. Unfortunately there are no previous FES-I assessments available to evaluate the course of FoF after fracture, and to establish whether there is a persistent FoF, or an increase in her levels of FoF. However, in retrospect Mrs van Dijk already had some concern about falling before she sustained the current hip fracture. The elevated HADS scores (anxiety and depression) point toward for a risk factor for high FoF and avoidance behavior. As the psychologist suspects that there is excessive avoidance behavior, she administers a FES-IAR which also has an elevated score.

The physiotherapy is asked to evaluated the gait and balance function, and actual fall risk. The Short Physical Performance Battery shows a good balance and gait function (total score 10/12; actual fall risk not elevated), which does not support the elevated level of FoF and activity restriction reported by Mrs van Dijk. We can conclude that there is an excessive avoidance behavior, which indefinitely leads to significant impact on daily functioning (social isolation, prolongation of inpatient rehabilitation). This is the reason to initiate treatment for FoF. The psychologist provides treatment with cognitive behavioral approaches, such as cognitive restructuring, to address the anxiety and fear responses. Additionally the psychologist coaches the physiotherapists to apply the principles of guided exposure within the mobilization process.

REFERENCES

1. Visschedijk J, van Balen R, Hertogh C, Achterberg W. Fear of falling in patients with hip fractures: prevalence and related psychological factors. J Am Med Dir Assoc 2013;14(3):218-20. (In eng). DOI: 10.1016/j.jamda.2012.10.013.
2. Visschedijk J, Achterberg W, Van Balen R, Hertogh C. Fear of falling after hip fracture: a systematic review of measurement instruments, prevalence, interventions, and related factors. J Am Geriatr Soc 2010;58(9):1739-48. (In eng). DOI: 10.1111/j.1532-5415.2010.03036.x.
3. Visschedijk JH, Caljouw MA, van Balen R, Hertogh CM, Achterberg WP. Fear of falling after hip fracture in vulnerable older persons rehabilitating in a skilled nursing facility. J Rehabil Med 2014;46(3):258-63. (In eng). DOI: 10.2340/16501977-1264.
4. Bower ES, Wetherell JL, Petkus AJ, Rawson KS, Lenze EJ. Fear of Falling after Hip Fracture: Prevalence, Course, and Relationship with One-Year Functional Recovery. Am J Geriatr Psychiatry 2016;24(12):1228-1236. (In eng). DOI: 10.1016/j.jagp.2016.08.006.
5. Oude Voshaar RC, Banerjee S, Horan M, et al. Fear of falling more important than pain and depression for functional recovery after surgery for hip fracture in older people. Psychol Med 2006;36(11):1635-45. (In eng). DOI: 10.1017/s0033291706008270.
6. Scheffer AC, Schuurmans MJ, van Dijk N, van der Hooft T, de Rooij SE. Fear of falling: measurement strategy, prevalence, risk factors and consequences among older persons. Age Ageing 2008;37(1):19-24. (In eng). DOI: 10.1093/ageing/afm169.
7. Ahn S, Song R. Exploring Fear of Falling Related Activity Avoidance among Postmenopausal Women. Int J Environ Res Public Health 2021;18(8) (In eng). DOI: 10.3390/ijerph18084042.
8. Zijlstra GA, van Haastregt JC, van Eijk JT, van Rossum E, Stalenhoef PA, Kempen GI. Prevalence and correlates of fear of falling, and associated avoidance of activity in the general population of community-living older people. Age Ageing 2007;36(3):304-9. (In eng). DOI: 10.1093/ageing/afm021.
9. Anders RL, Ornellas EM. Acute management of patients with hip fracture. A research literature review. Orthop Nurs 1997;16(2):31-46. (In eng).
10. McKee KJ, Orbell S, Austin CA, et al. Fear of falling, falls efficacy, and health outcomes in older people following hip fracture. Disabil Rehabil 2002;24(6):327-33. (In eng). DOI: 10.1080/09638280110093686.
11. Petrella RJ, Payne M, Myers A, Overend T, Chesworth B. Physical function and fear of falling after hip fracture rehabilitation in the elderly. Am J Phys Med Rehabil 2000;79(2):154-60. (In eng). DOI: 10.1097/00002060-200003000-00008.
12. Tennstedt S, Howland J, Lachman M, Peterson E, Kasten L, Jette A. A randomized, controlled trial of a group intervention to reduce fear of falling and associated activity restriction in older adults. J Gerontol B Psychol Sci Soc Sci 1998;53(6):P384-92. (In eng). DOI: 10.1093/geronb/53b.6.p384.
13. Zijlstra GA, van Haastregt JC, Ambergen T, et al. Effects of a multicomponent cognitive behavioral group intervention on fear of falling and activity avoidance in community-dwelling older adults: results of a randomized controlled trial. J Am Geriatr Soc 2009;57(11):2020-8. (In eng). DOI: 10.1111/j.1532-5415.2009.02489.x.
14. Dorresteijn TA, Zijlstra GA, Ambergen AW, Delbaere K, Vlaeyen JW, Kempen GI. Effectiveness of a home-based cognitive behavioral program to manage concerns about falls in community-dwelling, frail older people: results of a randomized controlled

trial. BMC Geriatr 2016;16:2. (In eng). DOI: 10.1186/s12877-015-0177-y.

15. Sartor-Glittenberg C, Bordenave E, Bay C, Bordenave L, Alexander JL. Effect of a Matter of Balance programme on avoidance behaviour due to fear of falling in older adults. Psychogeriatrics 2018;18(3):224-230. (In eng). DOI: 10.1111/psyg.12310.
16. Valatka R, Krizo J, Mallat A. A Survey-Based Assessment of "Matter of Balance" Participant Fall-Related Experience. J Trauma Nurs 2021;28(5):304-309. (In eng). DOI: 10.1097/jtn.0000000000000602.
17. Yoshikawa A, Ramirez G, Smith ML, Lee S, Ory MG. Systematic review and meta-analysis of fear of falling and fall-related efficacy in a widely disseminated community-based fall prevention program. Arch Gerontol Geriatr 2020;91:104235. (In eng). DOI: 10.1016/j.archger.2020.104235.
18. Zijlstra GA, van Haastregt JC, Du Moulin MF, de Jonge MC, van der Poel A, Kempen GI. Effects of the implementation of an evidence-based program to manage concerns about falls in older adults. Gerontologist 2013;53(5):839-49. (In eng). DOI: 10.1093/geront/gns142.
19. Whipple MO, Hamel AV, Talley KMC. Fear of falling among community-dwelling older adults: A scoping review to identify effective evidence-based interventions. Geriatr Nurs 2018;39(2):170-177. (In eng). DOI: 10.1016/j.gerinurse.2017.08.005.
20. Liu TW, Ng GYF, Chung RCK, Ng SSM. Cognitive behavioural therapy for fear of falling and balance among older people: a systematic review and meta-analysis. Age Ageing 2018;47(4):520-527. (In eng). DOI: 10.1093/ageing/afy010.
21. Pfeiffer K, Kampe K, Klenk J, et al. Effects of an intervention to reduce fear of falling and increase physical activity during hip and pelvic fracture rehabilitation. Age Ageing 2020;49(5):771-778. (In eng). DOI: 10.1093/ageing/afaa050.
22. Kampe K, Kohler M, Albrecht D, et al. Hip and pelvic fracture patients with fear of falling: development and description of the "Step by Step" treatment protocol. Clin Rehabil 2017;31(5):571-581. (In eng). DOI: 10.1177/0269215517691584.
23. Kruisbrink M, Crutzen R, Kempen G, et al. Disentangling interventions to reduce fear of falling in community-dwelling older people: a systematic review and meta-analysis of intervention components. Disabil Rehabil 2021:1-11. (In eng). DOI: 10.1080/09638288.2021.1969452.
24. Kruisbrink M, Delbaere K, Kempen G, et al. Intervention Characteristics Associated With a Reduction in Fear of Falling Among Community-Dwelling Older People: A Systematic Review and Meta-analysis of Randomized Controlled Trials. Gerontologist 2021;61(6):e269-e282. (In eng). DOI: 10.1093/geront/gnaa021.
25. Wetherell JL, Bower ES, Johnson K, Chang DG, Ward SR, Petkus AJ. Integrated Exposure Therapy and Exercise Reduces Fear of Falling and Avoidance in Older Adults: A Randomized Pilot Study. Am J Geriatr Psychiatry 2018;26(8):849-859. (In eng). DOI: 10.1016/j.jagp.2018.04.001.
26. Driver C, Kean B, Oprescu F, Lovell GP. Knowledge, behaviors, attitudes and beliefs of physiotherapists towards the use of psychological interventions in physiotherapy practice: a systematic review. Disabil Rehabil 2017;39(22):2237-2249. (In eng). DOI: 10.1080/09638288.2016.1223176.
27. Visschedijk JH, Caljouw MA, Bakkers E, van Balen R, Achterberg WP. Longitudinal follow-up study on fear of falling during and after rehabilitation in skilled nursing facilities. BMC Geriatr 2015;15:161. (In eng). DOI: 10.1186/s12877-015-0158-1.
28. Abel B, Eckert T, Pomiersky R, et al. Transition from inpatient rehabilitation to the home environment in cognitively impaired older persons after hip fracture. J Rehabil

Med 2020;52(11):jrm00130. (In eng). DOI: 10.2340/16501977-2757.

29. Hughes CC, Kneebone, II, Jones F, Brady B. A theoretical and empirical review of psychological factors associated with falls-related psychological concerns in community-dwelling older people. Int Psychogeriatr 2015;27(7):1071-87. (In eng). DOI: 10.1017/s1041610214002701.
30. Adamczewska N, Nyman SR. Falls-efficacy as a multiple dimension construct: the role of post-traumatic symptoms. Aging Ment Health 2021:1-8. (In eng). DOI: 10.1080/13607863.2021.1913474.
31. Hadjistavropoulos T, Delbaere K, Fitzgerald TD. Reconceptualizing the role of fear of falling and balance confidence in fall risk. J Aging Health 2011;23(1):3-23. (In eng). DOI: 10.1177/0898264310378039.
32. Kumar A, Delbaere K, Zijlstra GA, et al. Exercise for reducing fear of falling in older people living in the community: Cochrane systematic review and meta-analysis. Age Ageing 2016;45(3):345-52. (In eng). DOI: 10.1093/ageing/afw036.
33. Tinetti ME, Powell L. Fear of falling and low self-efficacy: a case of dependence in elderly persons. J Gerontol 1993;48 Spec No:35-8. (In eng). DOI: 10.1093/geronj/48.special_issue.35.
34. Landers MR, Nilsson MH. A theoretical framework for addressing fear of falling avoidance behavior in Parkinson's disease. Physiother Theory Pract 2022:1-17. (In eng). DOI: 10.1080/09593985.2022.2029655.
35. Thiamwong L, Ng BP, Kwan RYC, Suwanno J. Maladaptive Fall Risk Appraisal and Falling in Community-Dwelling Adults Aged 60 and Older: Implications for Screening. Clin Gerontol 2021;44(5):552-561. (In eng). DOI: 10.1080/07317115.2021.1950254.
36. Adamczewska N, Nyman SR. A New Approach to Fear of Falls From Connections With the Posttraumatic Stress Disorder Literature. Gerontol Geriatr Med 2018;4:2333721418796238. (In eng). DOI: 10.1177/2333721418796238.
37. Bower ES, Wetherell JL, Petkus AJ, Lenze EJ. Neuroticism predicts fear of falling after hip fracture. Int J Geriatr Psychiatry 2020;35(5):498-506. (In eng). DOI: 10.1002/gps.5261.
38. Payette MC, Bélanger C, Léveillé V, Grenier S. Fall-Related Psychological Concerns and Anxiety among Community-Dwelling Older Adults: Systematic Review and Meta-Analysis. PLoS One 2016;11(4):e0152848. (In eng). DOI: 10.1371/journal.pone.0152848.
39. van Haastregt JC, Zijlstra GA, van Rossum E, van Eijk JT, Kempen GI. Feelings of anxiety and symptoms of depression in community-living older persons who avoid activity for fear of falling. Am J Geriatr Psychiatry 2008;16(3):186-93. (In eng). DOI: 10.1097/JGP.0b013e3181591c1e.
40. Bloch F. A New Accurate Clinical Assessment Tool for Fear of Falling Is Needed for Older Patients. J Am Med Dir Assoc 2019;20(2):220-221. (In eng). DOI: 10.1016/j.jamda.2018.10.005.
41. Peeters G, Bennett M, Donoghue OA, Kennelly S, Kenny RA. Understanding the aetiology of fear of falling from the perspective of a fear-avoidance model - A narrative review. Clin Psychol Rev 2020;79:101862. (In eng). DOI: 10.1016/j.cpr.2020.101862.
42. Lee TH, Kim W. Is fear of falling and the associated restrictions in daily activity related to depressive symptoms in older adults? Psychogeriatrics 2021 (In eng). DOI: 10.1111/psyg.12664.
43. Scarlett L, Baikie E, Chan SWY. Fear of falling and emotional regulation in older adults. Aging Ment Health 2019;23(12):1684-1690. (In eng). DOI: 10.1080/13607863.2018.1506749.
44. Yao Q, Jin W, Li Y. Associations between fear of falling and activity restriction and late life depression in the elderly population: Findings from the Irish longitudinal study on ageing (TILDA). J Psychosom Res

2021;146:110506. (In eng). DOI: 10.1016/j.jpsychores.2021.110506.

45. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age Ageing 2005;34(6):614-9. (In eng). DOI: 10.1093/ageing/afi196.
46. Kempen GI, Yardley L, van Haastregt JC, et al. The Short FES-I: a shortened version of the falls efficacy scale-international to assess fear of falling. Age Ageing 2008;37(1):45-50. (In eng). DOI: 10.1093/ageing/afm157.
47. Hauer KA, Kempen GI, Schwenk M, et al. Validity and sensitivity to change of the falls efficacy scales international to assess fear of falling in older adults with and without cognitive impairment. Gerontology 2011;57(5):462-72. (In eng). DOI: 10.1159/000320054.
48. Liu TW, Ng SSM. The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly for assessing fear and activity avoidance among stroke survivors. PLoS One 2019;14(4):e0214796. (In eng). DOI: 10.1371/journal.pone.0214796.
49. Ersoz Huseyinsinoglu B, Tufekcioglu Z, Birinci T, Demirdag F. The Reliability and Validity of the Turkish Version of the Survey of Activities and Fear of Falling in the Elderly. J Geriatr Phys Ther 2021;44(2):E132-e137. (In eng). DOI: 10.1519/jpt.0000000000000260.
50. Brodowski H, Strutz N, Mueller-Werdan U, Kiselev J. Categorizing fear of falling using the survey of activities and fear of falling in the elderly questionnaire in a cohort of hospitalized older adults: A cross-sectional design. Int J Nurs Stud 2022;126:104152. (In eng). DOI: 10.1016/j.ijnurstu.2021.104152.
51. Dautel A, Gross M, Abel B, et al. Psychometric properties of the German version of the Fear of Falling Questionnaire-revised (FFQ-R) in a sample of older adults after hip or pelvic fracture. Aging Clin Exp Res 2021;33(2):329-337. (In eng). DOI: 10.1007/s40520-020-01657-2.
52. Bower ES, Wetherell JL, Merz CC, Petkus AJ, Malcarne VL, Lenze EJ. A new measure of fear of falling: psychometric properties of the fear of falling questionnaire revised (FFQ-R). Int Psychogeriatr 2015;27(7):1121-33. (In eng). DOI: 10.1017/s1041610214001434.
53. Specialisten RFM. Preventie van valincidenten bij ouderen. (https://richtlijnendatabase.nl/richtlijn/preventie_van_valincidenten_bij_ouderen/startpagina_-_preventie_van_valincidenten.html).
54. Visschedijk JH, Terwee CB, Caljouw MA, Spruit-van Eijk M, van Balen R, Achterberg WP. Reliability and validity of the Falls Efficacy Scale-International after hip fracture in patients aged ≥ 65 years. Disabil Rehabil 2015;37(23):2225-32. (In eng). DOI: 10.3109/09638288.2014.1002573.
55. Eckert T, Kampe K, Kohler M, et al. Correlates of fear of falling and falls efficacy in geriatric patients recovering from hip/pelvic fracture. Clin Rehabil 2020;34(3):416-425. (In eng). DOI: 10.1177/0269215519891233.
56. Kruisbrink M, Crutzen R, Kempen G, Zijlstra GAR. Assessing avoidance behavior due to concerns about falling: Psychometric properties of the FES-IAB in a sample of older adults of an online panel. Arch Gerontol Geriatr 2021;97:104469. (In eng). DOI: 10.1016/j.archger.2021.104469.
57. Noh HM, Roh YK, Song HJ, Park YS. Severe Fear of Falling Is Associated With Cognitive Decline in Older Adults: A 3-Year Prospective Study. J Am Med Dir Assoc 2019;20(12):1540-1547. (In eng). DOI: 10.1016/j.jamda.2019.06.008.
58. Drummond FMM, Lourenço RA, Lopes CS. Incidence, persistence and risk factors of fear of falling in older adults: cohort study (2008-2013) in Rio de Janeiro, Brazil. Rev Saude Publica 2020;54:56. (In eng). DOI: 10.11606/s1518-8787.2020054001939.
59. Borges Sde M, Radanovic M, Forlenza OV. Fear of falling and falls in older adults with mild cognitive impairment and Alzheimer's disease. Neuropsychol Dev Cogn B Aging Neuropsychol Cogn 2015;22(3):312-21. (In eng). DOI: 10.1080/13825585.2014.933770.

60. Uemura K, Shimada H, Makizako H, et al. Effects of mild and global cognitive impairment on the prevalence of fear of falling in community-dwelling older adults. Maturitas 2014;78(1):62-6. (In eng). DOI: 10.1016/j.maturitas.2014.02.018.
61. Lauretani F, Ticinesi A, Gionti L, et al. Short-Physical Performance Battery (SPPB) score is associated with falls in older outpatients. Aging Clin Exp Res 2019;31(10):1435-1442. (In eng). DOI: 10.1007/s40520-018-1082-y.
62. Robinson JB, Wetherell JL. An Interdisciplinary Intervention for Fear of Falling: Lessons Learned from Two Case Studies. Clin Gerontol 2018;41(4):366-373. (In eng). DOI: 10.1080/07317115.2017.1325423.
63. Vreeburg E dGA, Achterberg WP. Regeltjes staan beste revalidatiezorg in de weg. Maak ambulant revalideren voor kwetsbare ouderen beter toegankelijk. Medisch Contact (https://www.medischcontact.nl/nieuws/laatste-nieuws/artikel/regeltjes-staan-beste-revalidatiezorg-in-de-weg.htm).
64. Bouwstra H, Wattel LM, de Groot AJ, Smalbrugge M, Hertogh CM. The Influence of Activity-Based Funding on Treatment Intensity and Length of Stay of Geriatric Rehabilitation Patients. J Am Med Dir Assoc 2017;18(6):549.e15-549.e22. (In eng). DOI: 10.1016/j.jamda.2017.02.003.
65. McDonald S, Nikles J. N-of-1 Trials in Healthcare. Healthcare (Basel) 2021;9(3) (In eng). DOI: 10.3390/healthcare9030330.
66. He W, Cui Z, Chen Y, Wang F, Li F. Status of N-of-1 Trials in Chronic Pain Management: A Narrative Review. Pain Ther 2021;10(2):1013-1028. (In eng). DOI: 10.1007/s40122-021-00314-4.
67. Kwasnicka D, Inauen J, Nieuwenboom W, et al. Challenges and solutions for N-of-1 design studies in health psychology. Health Psychol Rev 2019;13(2):163-178. (In eng). DOI: 10.1080/17437199.2018.1564627.

Chapter 8

Summary

SUMMARY

Fall incidents are common in older adults. Annually approximately one in three adults of 65 years and older will experience a fall event, and for the population of 75+ years roughly half will have at least one fall within a year. These fall events often lead to physical injuries, such as head injuries and fractures. A hip fracture is one of the serious injuries that can be sustained as a result of a fall. In the Netherlands, each year approximately 17.500 older adults are admitted to hospital for treatment of a hip fracture. The recovery process after a hip fracture is time-consuming. After surgical repair of the fracture, a period of rehabilitation follows. Approximately half of the older adults with a hip fracture are referred to inpatient geriatric rehabilitation (GR). Many health care professionals are involved in the multidisciplinary geriatric rehabilitation program, including nursing staff, a physical therapist, an occupational therapist, a dietician, and if appropriate a psychologist, social worker or speech therapist. The rehabilitation program is led by an Elderly Care Physician (ECP).

Despite many advances in medical management of hip fractures, both regarding surgical approaches and the rehabilitation for this group of patients, physical recovery after hip fracture is still limited. Many patients do not recover to their pre-fracture level of functioning (ability to perform activities of daily living independently), and often mobility function is limited too. Therefore it is important to be aware of factors that can contribute to or present as a risk factor for impaired recovery after hip fracture. In this context, fear of falling may be of interest.

After an injurious fall such as a hip fracture, older adults are often concerned to fall. This concern about falling is also referred to as fear of falling (FoF). FoF can lead to patients being reluctant to engage in physical activity, and hence can lead to avoidance of activities. This avoidance behavior can consequently hamper physical recovery. Previous literature illustrates that FoF in patients with hip fracture is a risk factor for impaired recovery. To date no treatment programs are available for FoF in this target group. However, in the Netherlands a FoF intervention is available for community-dwelling older adults, and this treatment program has proved to be effective to reduce the FoF. If treatment of FoF in patients with hip fracture leads to reduction of FoF, and consequently to less avoidance of physical activities, this has potential to improve functional outcome for this group of patients.

The research presented in this thesis focusses on FoF in patients with hip fracture and aims to obtain a better understanding of appropriate management of FoF in patients with a recent hip fracture. For this purpose, the FIT-HIP study was developed and performed. The FIT-HIP study aimed to evaluate the effects, feasibility and costs of a treatment program for fear of falling after hip fracture. The main research findings of the FIT-HIP study are briefly discussed below,

together with the results of the other studies presented in this thesis. The economic evaluation of the FIT-HIP study is not included in this thesis.

Main research findings of this thesis

The aim of the FIT-HIP study was to develop and evaluate a treatment program for FoF for patients with a recent hip fracture. Chapter 2 of this thesis presents the study protocol of the FIT-HIP study, including the protocol of the *FIT-HIP intervention*. The FIT-HIP intervention is a multi-component cognitive behavioral treatment program, designed for the inpatient geriatric rehabilitation setting (GR). The intervention is essentially conducted by physiotherapists that are part of the multidisciplinary GR team. The intervention consists of various cognitive behavioral elements aimed at reducing FoF, including guided exposure to feared activities, cognitive restructuring, psycho-education, and relapse prevention. Intervention items are integrated in the physical therapy sessions, and combined with the regular exercise training in GR. Additionally a psychologist - also part of the multidisciplinary GR team - is involved in the intervention and provides additional on-site coaching with regard to the cognitive therapy. The FIT-HIP intervention is provided during the period of inpatient GR.

Chapter 3 describes the results of the study evaluating the effects of the FIT-HIP treatment program. The effects were studied using a cluster randomized controlled trial. The FIT-HIP intervention - integrated in usual care in GR - was compared to care as usual for patients with hip fracture admitted to GR. In total 78 participants were included (from 11 GR units). Study findings showed that the FIT-HIP intervention was not effective in reducing FoF, both directly after discharge from GR, and during the follow-up period up to six months after discharge from GR. Furthermore, the two treatment groups did not differ with regard to improvement in mobility function (balance and gait) during the GR period. Moreover, no differences between the intervention and usual care group were found for ambulation function and self-reported activity restriction up to 6 months after GR.

Chapter 4 of this thesis presents the study findings of the feasibility study, which was performed alongside the effect study. Questionnaires and interviews with intervention facilitators (physiotherapists and psychologists) and study participants were used to evaluate to which extent the FIT-HIP intervention was feasible to perform within the GR setting. The study results show that in general the FIT-HIP intervention was feasible, and that most items were performed according to protocol. However, two important barriers were identified that have potential to hamper performing the intervention according to protocol. The first barrier was a limited level of FoF. An important finding was that after study inclusion, when treatment started, the extent of FoF seemed to be limited for many participants. The physiotherapists therefore advised to start treatment in a later stage of rehabilitation, when the FoF persists over time. The second barrier was that the cognitive restructuring can to be challenging for physiotherapists

to perform. For future purposes a more elaborate training regarding this specific intervention element is required. Additionally, it may be beneficial to intensify the collaboration between physiotherapists and psychologists to a form of collective (interdisciplinary) treatment.

In Chapter 5 the coping strategies of patients with fear of falling after hip fracture were explored. Coping refers to cognitive and behavioral strategies that people use to deal with stressful situations. Medical conditions such a hip fracture affect general health status, daily functioning and quality of life, and can therefore be considered a major stressor for an individual. Coping strategies may influence active participation in and receptiveness to treatment. At present, little is known about the concept of coping after hip fracture, therefore an explorative study based on baseline data of the FIT-HIP study was conducted to gain insight into coping in this population. One of the baseline assessments of the FIT-HIP study was the Utrecht Coping List (UCL), which assesses various coping strategies. In the FIT-HIP study 'active tackling' and 'passive reacting' coping was assessed. In total 72 participants had data available for the UCL. Study results show that one-third of the study population predominantly engaged in active tackling coping. However, passive reacting coping was common too, and almost a quarter predominantly used passive coping strategies. Use of passive reactive coping strategies was associated with more symptoms of depression and anxiety.

The final study presented in this thesis (Chapter 6) focusses on the long-term course of FoF after hip fracture. A possible explanation for lack of efficacy of the FIT-HIP intervention is that study participants had a low extent of fear of falling. Additionally, the timing of the intervention may also contribute to lack of effect. The treatment started directly after admission to GR, which generally represents the second week after fracture. Based on current literature there is evidence that the negative effect of FoF on functional recovery is only applicable for FoF that is present 6 weeks after fracture (or later), and not in very early stages after hip fracture (2 respectively 4 weeks after fracture). This may suggest that FoF that is present very early after fracture could under certain circumstances be a normal, adaptive response. This may also imply that in early stages of rehabilitation not all patients with FoF require treatment for FoF. In view of these findings, we can question how to identify those patients with FoF that may benefit from intervention (i.e. the selection of the target group). We can also question whether treatment in a later stage of recovery may be more appropriate. Insight into the course of FoF after hip fracture may be helpful in this regard. As the long-term course of fear of falling after hip fracture was unknown, we evaluated the course of fear of falling up to one year after fracture. Data from a large inception cohort was used for this purpose. Chapter 6 of this thesis presents the findings of the study evaluating the long-term course of fear of falling after hip fracture. The database used for this study was based on routine data of patients with hip fracture. Patients with hip fracture admitted to the Haaglanden Medical Centre all receive an outpatient follow-up assessment at 6 and 12 weeks after fracture, and one year after hip fracture. Fear of

falling, measured with the Falls Efficacy Scale International (FES-I, 7-item), was assessed as part of the routine data. The FES-I was used to evaluate the long-term course of fear of falling, up to one year after fracture. In our study, we focused on patients that were community-dwelling prior to the fracture.

Study results show that the population based mean FES-I is located around the current established cut-off value of 11, and that levels decrease only slightly over time. There is however a great deal of heterogeneity within the individual trajectories (for individual patients). Therefore specific subgroups were analyzed. The long-term course of FoF was modelled for subgroups based on the short-term FoF trajectories (trend between 6 and 12 weeks). Groups were analyzed based on the following categories: *no FoF* (FES-I below the cut-off value of 11 at 6 and 12 weeks), *transient FoF* (FES-I ≥ 11 at 6 weeks, FES-I < 11 at 12 weeks), *late-onset FoF* (FES-I < 11 at 6 weeks, FES-I ≥ 11 at 12 weeks), and *persistent FoF* (FES-I ≥ 11 at 6 and 12 weeks). Of the 444 patients included, roughly a quarter had persistent FoF at 12 weeks. Compared to patients without FoF (no FoF group; approximately 40%), those with transient FoF (17%), and patients with late-onset FoF (13.5%), the group with persistent FoF had the most profound levels of FoF. Most of these patients still had FoF one year after fracture, and the functional recovery was impaired for this group compared to the other groups. We also evaluated the effect of FoF that was present before fracture (pre-fracture FoF) on the course after fracture. Patients with pre-fracture FoF had higher levels of FoF after fracture, when compared to patients without pre-fracture FoF, but this difference was not significant.

CONCLUSION

Findings from the studies presented in this thesis provide new insights that contribute to management of FoF after recent hip fracture. The FIT-HIP intervention is the first treatment program for FoF in this target group that has been evaluated. Results show that the intervention is not effective in reducing FoF and improving functional recovery in early stages of rehabilitation. Both the selection of the target population and the timing of the intervention may have contributed to lack of treatment effect. There is evidence to suggest that FoF that is present shortly after fracture (< 6 weeks post-fracture) does not by definition have a negative effect on the recovery process. Appropriate selection of the target group, i.e. identifying those patients that may benefit from treatment, remains an important area of attention for both clinical practice and for further research purposes. Timely identification and treatment of patients with persistent FoF is essential. We therefore we recommend regular screening for FoF throughout the transitional care settings during the first 12 weeks after fracture. In addition to monitoring of the levels of FoF (extent of FoF), it also seems important to gain insight into the effects (or consequences) of FoF on daily functioning. For example the extent of (excessive) avoidance of

activities and distress as a result of the FoF. This can help distinguish solely elevated FoF levels, from maladaptive FoF that has an evident negative effect on daily functioning, and thus on the recovery process. Treatment should be aimed at maladaptive FoF.

Chapter 9

Samenvatting (summary in Dutch)
Dankwoord
Curriculum Vitae

NEDERLANDSE SAMENVATTING

Vallen is een veelvoorkomend problemen onder ouderen. Naar schatting komt 1 op de 3 volwassenen van 65 jaar en ouderen jaarlijks ten val, en voor 75-plussers zal ongeveer de helft een valpartij doormaken op jaarbasis. Vallen gaat vaak gepaard met lichamelijk letsel, waaronder hersenletsel of botbreuken. Een heupbreuk (ofwel heupfractuur) is een van de ernstige letsels die kan optreden als gevolg van een val. In Nederland worden jaarlijks ongeveer 17.500 ouderen hiervoor in het ziekenhuis opgenomen. Het herstel van een heupfractuur is een langdurig proces. Na een operatie volgt een periode van revalidatie, vaak in een instelling. Ongeveer de helft van de ouderen die in Nederland een heupfractuur heeft opgelopen, wordt na ontslag uit het ziekenhuis opgenomen in de 'geriatrische revalidatie zorg'(GRZ) voor multidisciplinaire revalidatie. De GRZ wordt gekenmerkt door revalidatiebehandeling die wordt verzorgd door een team zorgprofessionals met onder andere verpleegkundigen, een fysiotherapeut, ergotherapeut, diëtist, en waar nodig een psycholoog, maatschappelijk werker of logopedist. De revalidatie behandeling wordt gecoördineerd door een specialist ouderengeneeskunde.

Ondanks vele ontwikkelingen in de behandeling voor patiënten met een heupfractuur, onder andere op het gebied van chirurgische technieken en revalidatie voor deze doelgroep, blijft het herstel na een heupfractuur beperkt. Een groot deel van de patiënten herstelt niet volledig tot het oude niveau van dagelijks functioneren, en heeft een slechtere loopfunctie, in vergelijking met voor de heupfractuur. Om deze reden is het belangrijk om oog te blijven houden voor factoren die kunnen bijdragen aan een gecompliceerd herstel na een heupfractuur. Een van de risicofactoren die het herstel negatief kan beïnvloeden is valangst.

Veel mensen die recent een heup hebben gebroken zijn bezorgd om te vallen. Dit wordt ook wel 'valangst' genoemd. Deze valangst kan ertoe leiden dat men activiteiten gaat vermijden en minder gaat bewegen. Dit kan weer nadelige gevolgen hebben voor het revalidatie proces. Uit eerder onderzoek blijkt dan ook dat valangst na een heupfractuur kan leiden tot een verminderd fysiek herstel. Tot op heden ontbreekt een behandeling voor valangst voor deze doelgroep. Echter zijn er in Nederland wel behandelprogramma's voor thuiswonende ouderen die erop gericht zijn om valangst te verminderen. Uit eerder onderzoek blijkt dat deze behandeling helpt om de valangst te verminderen. Indien behandeling van valangst ook bij ouderen met een heupfractuur effectief zou zijn om de valangst te verminderen, er minder activiteiten worden vermeden en men meer gaat bewegen, zou behandeling mogelijk kunnen bijdragen aan een beter fysiek herstel.

Het onderzoek in dit proefschrift richt zich daarom op valangst bij patiënten die een heupfractuur hebben doorgemaakt en heeft als doel te onderzoeken wat een passend (behandel)beleid is voor valangst na een heupfractuur. Dit werd onder andere onderzocht door middel van het

FIT-HIP onderzoek. Het FIT-HIP onderzoek richtte zich op de vraag of: 1) behandeling van valangst in de revalidatie na een heupfractuur effectief is om valangst te verminderen en het fysiek herstel te bevorderen; 2) of deze behandeling goed uitvoerbaar is; en 3) wat de kosten van deze behandeling zijn. De onderzoekresultaten van de FIT-HIP studie, en de bevindingen van de andere studies die in het kader van dit proefschrift zijn uitgevoerd, worden hieronder kort beschreven. De kosten evaluatie valt buiten het bestek van dit proefschrift.

Belangrijkste bevindingen van het proefschrift

Het FIT-HIP onderzoek richtte op het ontwikkelen en onderzoeken van een behandelprogramma voor het verminderen van valangst bij mensen die recent een heup hebben gebroken. Hoofdstuk 2 van dit proefschrift beschrijft de opzet van het FIT-HIP onderzoek en presenteert het protocol van de *FIT-HIP behandeling*. Deze FIT-HIP behandeling is gebaseerd op cognitieve gedragstherapie en wordt gegeven binnen de GRZ. Fysiotherapeuten werkzaam in de GRZ werden getraind om de behandeling te geven. De cognitieve gedragstherapie bestond onder andere uit *guided exposure* (stapsgewijze en gedoseerde blootstelling aan activiteiten die aanleiding geven tot valangst), *cognitieve therapie* (gedachten uitdagen, het toetsen in hoeverre de gedachten die aanleiding geven tot angst of bezorgdheid reëel zijn) en *voorlichting*. Ook was er aandacht voor preventie van een terugval na ontslag naar huis. De FIT-HIP behandeling werd verwerkt in de reguliere fysiotherapie sessies. Fysiotherapeuten werden ondersteund door psychologen ('buddy's), om hen waar nodig te begeleiden in de uitvoering van bepaalde onderdelen van de cognitieve gedragstherapie (coaching functie). De FIT-HIP behandeling vond plaats gedurende de opname in de GRZ.

Hoofdstuk 3 bespreekt de onderzoeksresultaten van de effectstudie, die het behandeleffect van de FIT-HIP behandeling heeft getoetst. Door middel van een 'cluster gerandomiseerde gecontroleerde studie' werd het effect van de FIT-HIP behandeling vergeleken met de reguliere zorg in de GRZ. In totaal werden hiervoor 78 deelnemers vanuit 11 verschillende GRZ instellingen geïncludeerd voor de FIT-HIP studie. De helft van de deelnemers ontving de FIT-HIP behandeling verwerkt in de reguliere zorg in de GRZ, de andere helft alleen de reguliere zorg in de GRZ. De onderzoeksresultaten lieten zien dat de FIT-HIP behandeling geen effect had op valangst, zowel direct na de GRZ behandeling, alsook gedurende follow up tot 6 maanden na ontslag naar huis. Er werd ook geen verschil gevonden tussen de twee groepen wat betreft verbetering van de mobiliteit (balans en loopfunctie) direct na de GRZ behandeling. Tevens werden er geen verschillen gevonden tussen de groepen wat betreft de zelf-gerapporteerde vermijding van activiteiten als gevolg van de valangst, en de mate van zelfstandigheid van het lopen, tot 6 maanden na ontslag uit de GRZ.

In aansluiting op de effectstudie werd ook onderzocht in welke mate de FIT-HIP behandeling goed uit te voeren is in de GRZ praktijk (Hoofdstuk 4). Door middel van vragenlijsten en inter-

views met deelnemers en zorgverleners, werd de uitvoerbaarheid van dit behandelprogramma nader onderzocht. De resultaten van deze studie laten zien dat de FIT-HIP behandeling over het algemeen goed uit te voeren was, en grotendeels volgens protocol werd uitgevoerd. Echter kwamen twee belangrijke barrières naar voren die de uitvoering van de FIT-HIP behandeling kunnen bemoeilijken. De eerste is een beperkte mate van valangst. Een belangrijk gegeven wat uit dit onderzoek naar voren komt is dat veel deelnemers na de start van het onderzoek (dus bij aanvang van de behandeling), weinig valangst leken te hebben. Om deze reden werd door de fysiotherapeuten voorgesteld om de behandeling in een later stadium van de revalidatie te starten, bij revalidanten waarbij de valangst duidelijk blijft aanhouden. Ten tweede bleek een bepaald onderdeel van de behandeling – de cognitieve therapie – in sommige gevallen wat lastiger uit te voeren voor de fysiotherapeuten. Hierin zou voor de toekomst een grotere mate van samenwerking met de psycholoog (in een interdisciplinair samenwerkingsverband), en meer training voor de fysiotherapeuten gewenst zijn.

In hoofdstuk 5 werd de coping stijl van patiënten met valangst na een heupfractuur onderzocht. Coping refereert aan de manier waarop een persoon omgaat met stressvolle situaties of tegenslagen. Gezondheidsproblemen zoals een heupfractuur kunnen als een grote stressor worden beschouwd. De coping stijl die iemand hanteert kan van invloed zijn op actieve participatie in en ontvankelijkheid voor de geboden behandeling. Tot op heden is weinig bekend over coping in deze doelgroep, en om deze reden werd hier nader onderzoek naar gedaan. Hiervoor werd gebruik gemaakt van de FIT-HIP gegevens. Deelnemers hadden bij opname in de GRZ een gevalideerde vragenlijst ingevuld die zowel de actieve coping alsook de passieve coping meet. Op basis van de 72 deelnemers met beschikbare data, bleek dat een derde hoofdzakelijk gebruik maakt van een actieve coping stijl. Echter gebruikt ook ruim een kwart van de populatie overwegend een passieve coping stijl, en het gebruik van passieve coping was geassocieerd met meer symptomen van depressie of angst. Er werd geen verband gevonden tussen coping en pijn of kwaliteit van leven.

Het laatste onderzoek dat in dit proefschrift wordt gepresenteerd (Hoofdstuk 6), richtte zich op het natuurlijk beloop van valangst. Een mogelijke verklaring voor het ontbreken van een behandeleffect van de FIT-HIP behandeling is dat de deelnemers in de FIT-HIP studie een beperkte mate van valangst hadden. Ook de timing van de behandeling speelt hierbij wellicht een rol. De behandeling werd nu direct aan het begin van de revalidatie opgestart – meestal de tweede week na de heupfractuur. Op basis van eerder onderzoek blijkt dat valangst pas vanaf 6 weken na de heupfractuur in verband wordt gebracht met de nadelige effecten op het herstel. Dit zou erop kunnen wijzen dat in sommige gevallen valangst in de zeer vroege fase na de heupbreuk een normale reactie kan zijn. Mogelijk dat niet alle mensen met valangst meteen hoeven te worden behandeld. Bovengenoemde bevindingen gaven aanleiding tot de vraag hoe we op een goede manier die mensen met valangst kunnen identificeren, die wél

baat zouden kunnen hebben bij behandeling (de selectie van de doelgroep). En of behandeling in een later stadium wellicht passend zou zijn. Inzicht in het natuurlijk beloop van valangst zou ondersteunend kunnen zijn voor bovengenoemde vragen. Om meer zicht te krijgen op het natuurlijk beloop van valangst na heupfractuur, werd een aanvullende studie gedaan, buiten het bestek van de FIT-HIP studie (gepresenteerd in Hoofdstuk 6).

Hoofdstuk 6 van het proefschrift beschrijft de onderzoeksbevindingen van de beloop studie. Wij gebruikte voor dit onderzoek gegevens van een groot inceptie cohort. Dit betreft een database van het Haaglanden Medisch Centrum waarbij als onderdeel van de reguliere zorg alle patiënten die in verband met een heupfractuur werden geopereerd, poliklinisch werden vervolgd op vaste tijdstippen (6 weken, 12 weken en 12 maanden na de heupfractuur). Valangst werd standaard meegenomen bij de poliklinische controles en werd gemeten met de Falls Efficacy Scale International (FES-I, 7-item). Ons onderzoek naar het beloop van valangst richtte zich op patiënten die voor de heupfractuur thuis woonden (niet in een instelling).

De resultaten van de beloop studie laten zien dat op groepsniveau de valangst slechts minimaal afneemt in de loop van de tijd. De gemiddelde FES-I bevindt zich rondom de afkapwaarde die wijst op valangst (FES-I score van 11). Er is echter sprake van een grote variatie wat betreft het beloop van de individuele patiënten. Daarom onderzochten we ook het beloop voor specifieke groepen. We bekeken het lange termijn beloop voor vier 'trendgroepen', gebaseerd op hoe de valangst zich ontwikkeld had tussen 6 en 12 weken. De 'trendgroepen' werden als volgt gecategoriseerd: 1] *geen valangst* groep (FES-I onder de afkapwaarde van 11 bij 6 en 12 weken), *kortdurende valangst* groep (FES-I ≥ 11 bij 6 weken, FES-I < 11 bij 12 weken), *late valangst* groep (FES-I < 11 bij 6 weken, FES-I ≥ 11 bij 12 weken), en *aanhoudende valangst* groep (FES-I ≥ 11 bij 6 en 12 weken). Van de 444 patiënten bleek ongeveer een kwart van hen aanhoudende valangst te hebben bij 12 weken. In vergelijking met de groep die geen valangst had (ongeveer 40%), of kortdurend valangst had (17%), of late valangst (13.5%), had de groep met aanhoudende valangst de hoogste mate van valangst gedurende het jaar na de fractuur. De meerderheid van deze patiënten met aanhoudende valangst blijft valangst behouden in het eerste jaar na de heupfractuur. De patiënten in deze groep hadden ook een slechter fysiek herstel. Verder onderzochten we het effect van valangst die voor de heupfractuur aanwezig was, op het beloop van valangst na de heupfractuur. Hoewel het hebben van valangst voor de heupfractuur wel leidt tot een hogere mate van valangst na de fractuur, bleek dit effect niet statistisch significant.

CONCLUSIE

De resultaten van dit proefschrift leveren nieuwe inzichten die bijdragen aan het medisch (behandel)beleid van valangst voor patiënten met een recente heupfractuur. De FIT-HIP

behandeling is het eerste behandelprogramma voor valangst die is onderzocht voor deze doelgroep. De onderzoeksbevindingen laten zien dat het behandelprogramma niet effectief is om valangst te verminderen en het fysiek herstel te verbeteren, wanneer behandeling wordt gegeven in de vroege fase van revalidatie. Zowel de selectie van de doelgroep en de timing van de behandeling hebben mogelijk bijgedragen aan het ontbreken van effectiviteit van de behandeling. Mogelijk dat valangst in een zeer vroege fase na een heupfractuur (< 6 weken) niet voor alle patiënten belemmerend is voor het herstel. De selectie van patiënten blijft dan ook een belangrijk aandachtspunt voor zowel de klinische praktijk alsook voor verder onderzoek. Het tijdig identificeren en behandelen van de groep patiënten met persisterende valangst is van belang. We adviseren daarom structurele en regelmatige screening voor valangst gedurende de eerste 12 weken na fractuur. Het lijkt ook van belang om naast inzicht in de mate van valangst, ook inzicht te krijgen in de gevolgen van valangst voor het dagelijks functioneren. Dat wil zeggen: in kaart brengen of er sprake is van (overmatige) vermijdingsgedrag en/of veel stress of angst als gevolg van de valangst. Deze informatie kan helpen om onderscheid te maken tussen patiënten die alleen maar enige bezorgdheid hebben om te vallen, en die groep patiënten waarvan de valangst daadwerkelijk consequenties heeft voor het dagelijks functioneren, en het herstel dus ook duidelijk zou kunnen belemmeren ('de niet-functionele valangst'). Behandeling dient gericht te zijn op deze laatstgenoemde groep, met niet-functionele valangst.

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CURRICULIM VITAE

Maaike Barnhoorn werd op 11 juni 1986 geboren in Sandton, Zuid Afrika. De basisschool werd gevolgd in Zuid Afrika; de middelbare school in Nederland op het Visser 't Hoofd Lyceum te Leiden. In 2005 behaalde zij haar VWO diploma. Hierna volgde zij de opleiding Geneeskunde aan de Vrije Universiteit in Amsterdam. Tijdens de opleiding Geneeskunde werden al mooie ervaringen opgedaan binnen het vakgebied ouderengeneeskunde; aanvankelijk door de zorgstage in het eerste jaar, en daarnaast gedurende de semi-arts stage binnen de Osira Zorggroep. De klinische ervaringen van de semi-arts stage gaven bij Maaike aanleiding tot een aantal wetenschappelijke vragen. Onder begeleiding van specialisten ouderengeneeskunde verbonden aan het Gerion konden deze vragen uitgewerkt tot een onderzoek die verricht werd in het kader van de wetenschapsstage. Tijdens deze wetenschapsstage werd ervaring opgedaan met kwantitatieve en kwalitatieve onderzoeksmethoden, en dit werd door Maaike als heel inspirerend ervaren. Hier werd dan ook het spreekwoordelijke zaadje geplant voor de interesse in de wetenschap.

Na het afronden van de Master Geneeskunde (2012) heeft Maaike ruim een jaar gewerkt als ANIOS ouderengeneeskunde bij Marente, alwaar ervaring werd opgedaan met psycho-geriatrie, somatiek en geriatrische revalidatie. In september 2013 startte zij met de opleiding tot specialist ouderengeneeskunde. Vanaf maart 2015 werd de opleiding gecombineerd met een promotie onderzoek (AIOTO-SO). Het promotieonderzoek van Maaike richtte zich op de FIT-HIP trial, die gefinancierd werd vanuit een ZonMW (HGOG). De opleiding tot specialist ouderengeneeskunde werd in 2021 afgerond. Momenteel werkt Maaike als specialist ouderengeneeskunde bij Activite. Daarnaast is ze als docent en coördinator van de Lijn Wetenschappelijke Vorming verbonden aan de opleiding tot specialist ouderengeneeskunde in Leiden (SOOL).

Maaike is in 2009 getrouwd met Paul Scheffers. Samen met Benjamin (2016) en Hannah (2019) genieten zij van de andere niet-werk gerelateerde avonturen van het leven.