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Management of fear of falling after hip fracture

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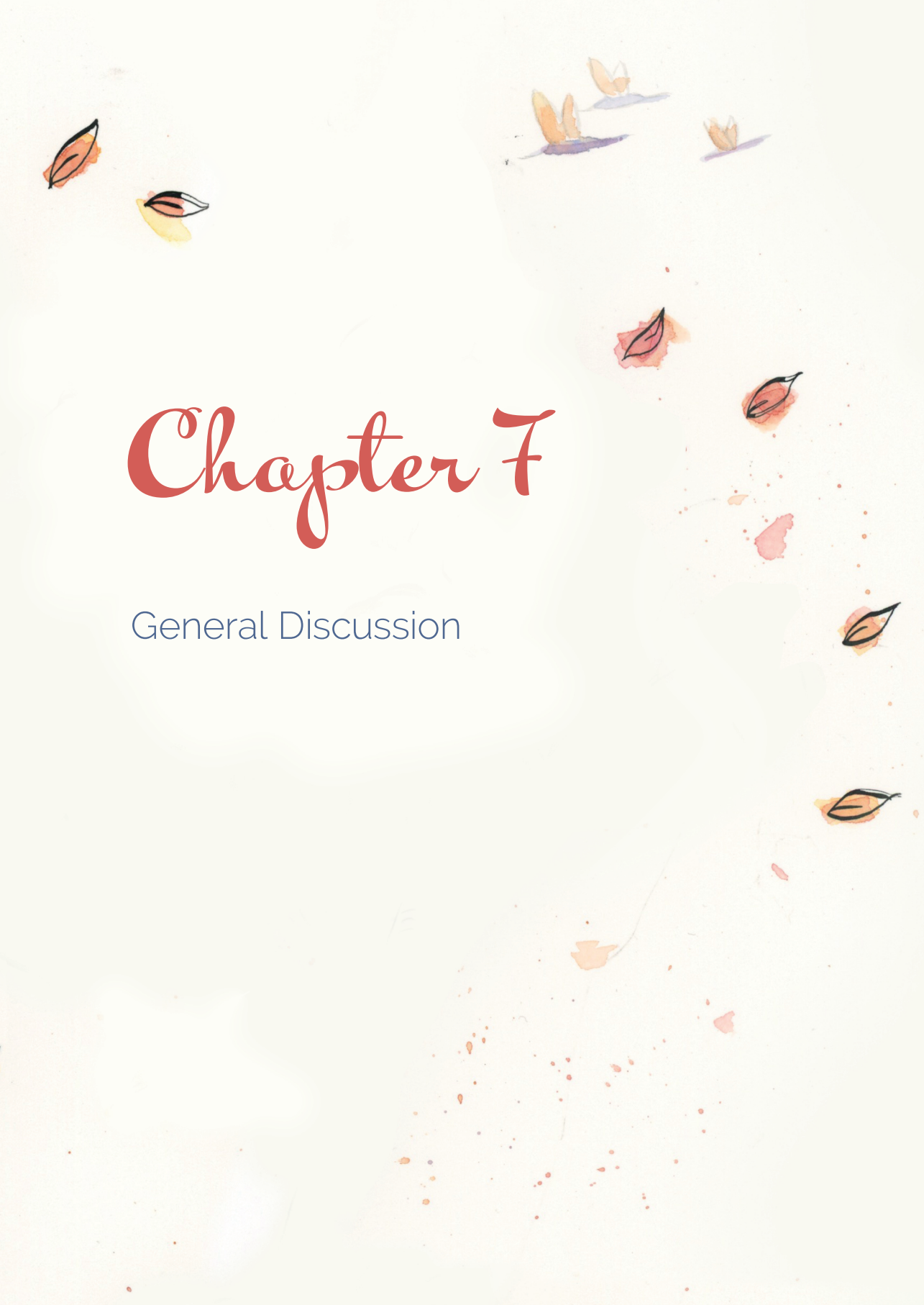
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Chapter 7

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 population¹⁻⁴. 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 FoF⁶⁻⁸. 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 as 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 ($\geq 11/28$) 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 2000⁹⁻¹¹. 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 FoF¹²⁻¹⁴. 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 FoF¹²⁻²⁰, 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 population²¹. 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 discharge²². 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 FoF²⁵. 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 facilitators²⁴. 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 therapy²⁶. This may support the suggestion that it could be useful to 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 definition²⁹⁻³¹, 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 in 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 fracture³⁷. 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 activities³⁶. 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 month⁴⁰. 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 FoF⁵³. The FES-I has been validated for patients with hip fracture in inpatient geriatric rehabilitation⁵⁴. Studies evaluating FoF in patients with hip fracture, including the trial evaluating the *Step by Step* intervention, have used this measurement instrument. As such it 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.

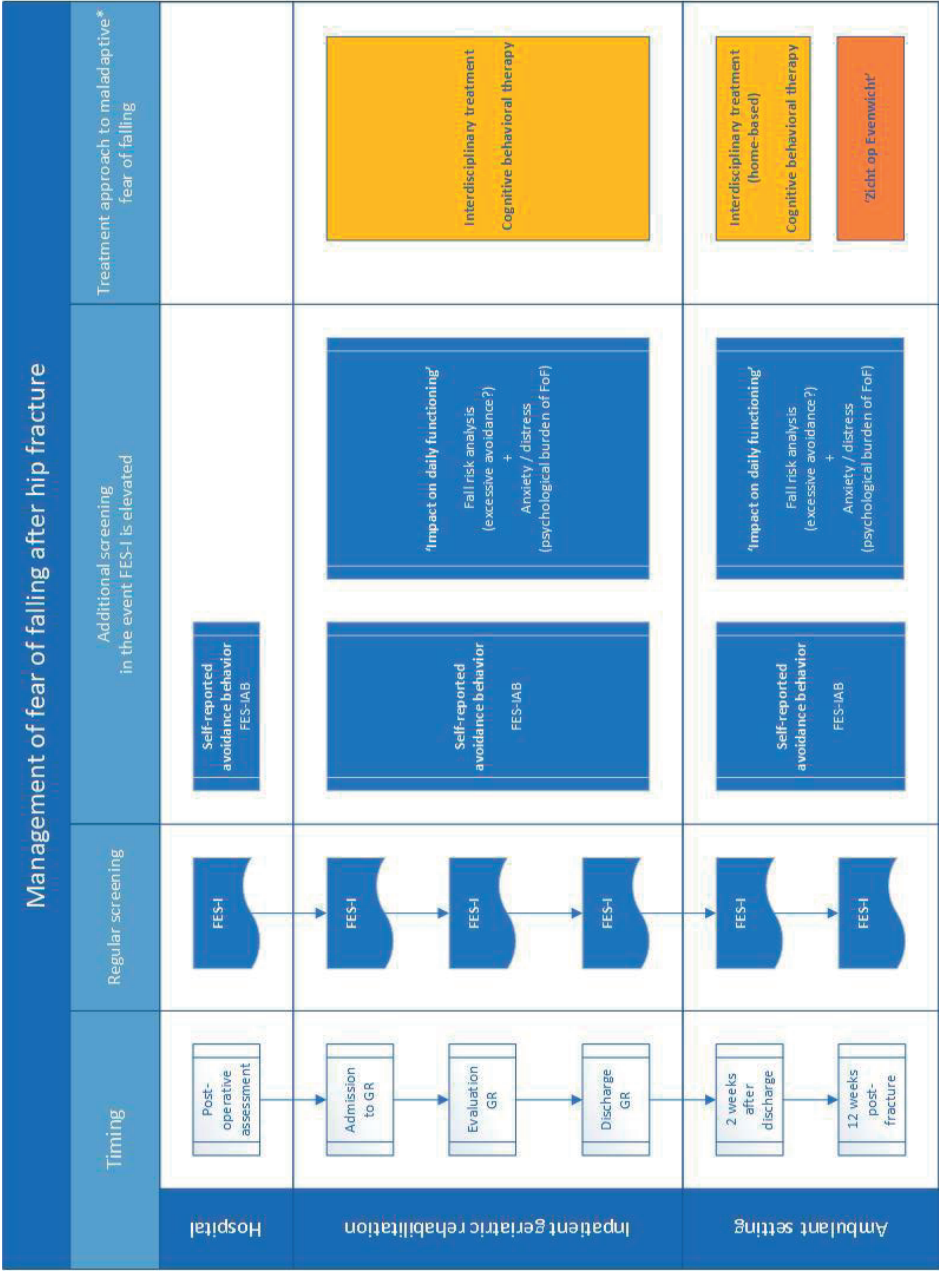
Figure 1 presents an overview of the recommendations for the management of FoF in clinical practice. This includes both the screening procedure and the recommendations regarding treatment.

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 (criterion 2) and the impact FoF has on daily functioning (criterion 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 criterion, 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 purpose⁶¹. 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 purpose⁵³.

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 that 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 trials⁶⁵⁻⁶⁷. 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 it 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 evaluate 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.

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