

STUDY PROTOCOL

# Implementation and Evaluation of a Fall Risk Screening Strategy Among Frail Older Adults for the Primary Care Setting: A Study Protocol

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<sup>1</sup>Tranzo, Tilburg School of Social and Behavioral Sciences, Tilburg University, Tilburg, Noord-Brabant, Netherlands; <sup>2</sup>NIVEL, Utrecht, Netherlands; <sup>3</sup>Huisartsenpraktijk de Ypelaer, Hilvarenbeek, Noord-Brabant, Netherlands; <sup>4</sup>Fysiotherapie Nieuwenhuis, Best, Noord-Brabant, Netherlands **Background:** Falls are an increasing problem among older people. There are several evidence-based interventions available to prevent falls. However, these are not always well implemented in the primary care setting. General practitioners (GPs) are often the first point of contact for health issues, making them the designated professionals for providing falls prevention. Because GPs are often unaware which patients have a high fall risk and patients themselves do not always know they have a high fall risk, this study aims to evaluate the implementation of a targeted fall risk screening strategy among independently living, frail older people in the primary care setting.

Materials and Methods: The targeted fall risk screening strategy used in this study consists of tools for screening high fall risk and for identifying the underlying cause(s) of the high fall risk, an accredited training course in falls prevention for professionals, and service provision by certified physio- and exercise therapists who are able to offer evidence-based falls prevention interventions. This targeted fall risk screening strategy will be implemented in the primary care setting and evaluated at the level of the GP practice and at the level of the patient by using the RE-AIM model of Glasgow et al. In a pre-posttest design, data will be collected of the total number of frail older people who are screened, referred and enrolled for fall-preventive care. Furthermore, barriers and facilitators of the implementation of the fall risk screening strategy will be identified by conducting focus groups and interviews with the care providers and frail older patients. Additionally, the influence of the falls prevention interventions on frail older patients will be evaluated by using a pre-posttest design with a 12-month follow-up period during which data are collected regarding patients' stability, mobility, strength, balance, self-efficacy, health status, and daily activities.

**Study Registration:** This study is approved by the Medical Ethics Committee Brabant, the Netherlands (NL61582.028.17/ P1732) and registered at the Netherlands Trial Register, NL7917.

Keywords: preventive medicine, primary care, geriatric medicine, risk management

#### Introduction

Worldwide, falls are a major public health problem. Approximately 30% of the older people aged 65 and over and 50% of the people aged 80 and over fall at least once a year. The consequences of a fall can vary, for example, from a scratch or bruise to a hip fracture, brain injury, or even death. In the Netherlands, every 5 min, an older person is admitted to the emergency department (ED) due to the consequences of a fall, which resulted in 108,000 treatments at EDs in 2018. These numbers are

Correspondence: WMA Meekes Tranzo, Tilburg School of Social and Behavioral Sciences, Tilburg University, 5000 LE Tilburg, Postbus 90153, Netherlands Tel +31 13 466 4451 Email w.m.a.meekes@tilburguniversity. edu expected to rise due to the increase in the number of older people.<sup>6</sup> Treatment and rehabilitation after a fall can result in considerable medical costs (€960 million direct medical costs). In the Netherlands, the majority of these costs are caused by falls among independently living, frail older people (€810 million direct medical costs).<sup>6</sup>

There is a reasonable level of evidence that several interventions prevent falls and fall-related trauma among independently living older people.<sup>7-9</sup> Falls prevention interventions differ per target group, intensity, type of treatment (group or individual), and approach (eg exercise therapy or addressing risk factors). Multicomponent group or home-based exercises, environmental modifications, medication reviews and addressing cardiovascular problems are examples of evidence-based interventions. 10 For example, Hopewell et al assessed the effects of interventions designed to reduce the incidence of falls among independently living older people and found that multifactorial interventions reduce the rate of falls among older people (Rate Ratio 0.77, 95% CI 0.67 to 0.87; 19 trials; 5853 participants). 11 Furthermore, Sherrington et al identified that exercise can reduce the rate of falls by 23% (Rate Ratio 0.77, 95% CI 0.71 to 0.83; 59 trials, 12,981 participants). 12

Overall, multifactorial programs that address evidencebased interventions are recommended, <sup>10,13</sup> but evidence of the efficacy of the programs that address various causes of fall risk in real-life settings is still limited or not available. <sup>14</sup>

In the Netherlands, general practitioners (GPs) are the gatekeepers for healthcare and thus often the first point of contact for health issues, making them the designated professionals for providing falls prevention to independently living, frail older people. Nonetheless, systematic screening for fall risk does not take place at GP practices, and GPs only know of 20-30% of the falls that occur among their patients. 15 This means that GPs are often unaware which of their patients have an increased risk of falling and are, therefore, unable to offer them adequate fall-preventive care. 16-18 These issues occur not only in the Netherlands but in other countries as well. 16,17 All this leads to the unfavorable situation in which frail older people, for whom falls prevention interventions are potentially effective, do not receive this care. This can result in severe adverse health consequences and lower quality of life for frail older people, including loss of independence.

Currently, there is no strategy for engaging GPs in falls prevention in the Netherlands. According to Paul, falls are preventable, and a systematic approach for identifying risks and addressing them in a concerted manner is key to prevention. <sup>19</sup> Therefore, systematic implementation of falls prevention with a targeted screening strategy at GP practices appears to be essential for making falls prevention more accessible to independently living, frail older people. To improve the implementation and to make long-term engagement in falls prevention possible, it is important to identify and understand the experienced barriers and facilitators of the implementation of the fall risk screening strategy.

Therefore, the aim of this study is to evaluate the implementation of a targeted fall risk screening strategy among independently living, frail older people in the primary care setting. To better understand and improve the implementation of the fall risk screening strategy, experienced barriers and facilitators will be investigated. Evaluation of the implementation of the fall risk screening strategy will primarily be conducted at the level of the GP practice and secondarily at the level of the frail older patient.

In this study, the following research questions will be answered:

- What is the influence of the targeted fall risk screening strategy in the primary care setting on the number of screened, referred, and enrolled frail older people for falls prevention? (GP practice level)
- 2. What are the barriers and facilitators of the implementation of the targeted fall risk screening strategy in the primary care setting? (GP practice level)
- 3. What is the influence of evidence-based falls prevention interventions offered by certified physio-and exercise therapists in a real-life setting on frail older patients' balance, mobility, frequency of falling, fear of falling, self-efficacy, and quality of life? (Patient level)

## **Materials and Methods**

## Design

In this study, a targeted fall risk screening strategy will be implemented at GP practices. The fall risk screening strategy will be evaluated at the level of the GP practice and at the level of the frail older patient by using two pre-posttest designs. The targeted fall risk screening strategy consists of two parts. In the first part, GP practices receive the following tools to screen for fall risk and to offer falls prevention interventions:

1. A validated fall risk screening instrument: this screening instrument is selected after an informal focus group consisting of primary care providers, followed by a systematic literature search (see Appendix I). (The systematic literature is not part of this protocol and will be described elsewhere.)

- 2. A checklist to diagnose the underlying cause(s) of the fall risk: the items on the checklist are based on previous literature regarding risk factors for falls.<sup>20-22</sup> The checklist is completed after a discussion within the research group that includes a GP specialized in geriatric care (see Appendix I).
- 3. An overview of all physio- and exercise therapists certified to offer evidence-based falls prevention interventions in the surrounding area of the GP practices.
- 4. A 4-hour accredited training session about falls prevention for health care professionals: the training session is offered by a trainer from the organization "VeiligheidNL"<sup>23</sup> and is suitable for practice nurses and assistants. The training is not compulsory and is offered free of charge as part of this project.

In the second part, physio- and exercise therapists in the surrounding area are recruited to participate in this study so that each participating GP practice has access to the services of certified physio- or exercise therapists for falls prevention interventions. Physio- and exercise therapists who are not certified to provide an evidence-based falls prevention intervention are offered training.

#### Theoretical Framework

The targeted fall risk screening strategy will be evaluated by using the RE-AIM model of Glasgow et al.<sup>24</sup> This model helps to focus on essential program elements for improving the sustainable adoption and implementation of effective, generalizable, and evidence-based interventions.<sup>25</sup> The model uses the concepts Reach, Effectiveness, Adoption, Implementation, and Maintenance to translate research into action. Reach refers to the proportion of people who are willing to participate in an intervention, and in this study, it concerns the proportion of frail older patients with a high fall risk willing to participate in falls prevention interventions. Effectiveness refers to the impact of the intervention and will be assessed by the patient-related outcome measures such as fall incidents, balance, fear of falling, and quality of life (see Outcome measures). Adoption relates to the development of organizational support to deliver the intervention. This concept will be investigated by describing the proportion of GP practices of the GP care group that were willing to participate in this study. Implementation refers to how to ensure the intervention is delivered properly, and Maintenance relates to the long-term incorporation of the intervention. These last two concepts will be explored by identifying the experiences, barriers, and facilitators of the care providers when implementing and providing falls prevention. Table 1 provides an overview of the concepts of the RE-AIM model with the corresponding definitions, data sources, and the data to be collected.

## Ethics and Dissemination

This study is approved by the Medical Ethics Committee Brabant, the Netherlands (NL61582.028.17/ P1732). The results from this study will be disseminated through peerreviewed publications, through conference presentations, and by informing policymakers and consumers to maximize health impact.

## Setting

In 2011, a home care organization and a GP care group (owned by 155 GPs) developed a strategy to improve healthcare for frail older people, which led to the Care Program for Frail Older People for the area Midden-Brabant, the Netherlands. 26 Since 2014, other primary care providers (pharmacists, dieticians, occupational therapists) and secondary care providers (geriatricians) have also joined in the Care Program for Frail Older People. To date, 74 of the 155 GPs and their practice and district nurses have been participating in the program aimed at the coordination of healthcare for frail older people.<sup>27</sup> As part of the program, frailty in older people is systematically diagnosed and registered. For the assessment of frailty, the TRAnsmuraal Zorg Assessment Geriatrie (TRAZAG) instrument or the Tilburg Frailty Indicator is used. TRAZAG makes use of several instruments to assess Activities Daily Living (ADL), instrumental ADLs, nutrition, mobility, fall risk, incontinence, medication, vision and hearing impairment, cognition and depressive symptoms. 28,29 The Tilburg Frailty Indicator assesses demographics, physical, psychological, and social components of frailty. 30,31 Each frail older person is assigned a care coordinator, and a care plan is drafted, which is evaluated during bimonthly multidisciplinary consultations. Although falls prevention is one of the priorities of the Care Program for Frail Older People, not every GP in the GP care group provides falls prevention in a systematic

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Table I Definitions, Data Sources and Operationalization of the Concepts of the RE-AIM Model of Glasgow et al<sup>24</sup>

Concept	Definition	Data Source	Operationalization	
Reach	The proportion of participants who are willing to participate in an intervention	Data from care providers	<ul> <li>The percentage of frail older people screened for fall risk</li> <li>The percentage of screened frail older people eligible for a falls prevention intervention</li> <li>The percentage of eligible older people for a falls prevention intervention that agreed with a referral to a fall preventive exercise program from a physio- or exercise therapist</li> </ul>	
Effectiveness	The effectiveness of the intervention	Questionnaire surveys, physical tests, falls-calendars, logs from researchers	<ul> <li>Drop-out rates</li> <li>Patient's pre-post changes in stability, mobility, muscle strength, balance, fear of falling, self-efficacy, quality of life, health status and daily activities</li> <li>Patient's number of falls in previous year and during 12-month follow-up</li> <li>Number of adverse events</li> </ul>	
Adoption	The development of organizational support to deliver the intervention	Questionnaire surveys, logs from researchers	The proportion of GP practices of the GP care group that were willing to implement the fall risk screening strategy  Data on barriers and facilitators of care providers to participate in this study	
Implementation	The extent to which the intervention is delivered properly	Questionnaire surveys, logs from researchers, online focus group, informal interviewing, data from care providers	<ul> <li>Pre-post changes of proportion of patients diagnosed with high fall risk and treated for high fall risk at GP practices</li> <li>Qualitative data on care providers' experienced barriers and facilitators for the implementation of the fall risk screening strategy</li> <li>The percentage of frail older people that actually start the fall prevention exercise program</li> <li>The percentage of frail older people that complete the fall prevention exercise program</li> </ul>	
Maintenance	The incorporation of the intervention so it is delivered over the long term	Logs from researchers, online focus group, informal interviewing	Qualitative data on care providers' experienced barriers and facilitators regarding the implementation of the fall risk screening strategy and intention to keep on going     The proportion of participating GP practices that used the fall risk screening strategy at the end of the implementation period	

manner and if falls prevention is provided, the quality varies between practices. According to unpublished data obtained from an informal focus group with GPs, practice nurses and district nurses from the GP care group, some GPs immediately take action when they know a patient has fallen once while other GPs might take action after they know a patient has fallen several times. Therefore, the care group wants to promote the implementation of a targeted fall risk screening strategy among all their GPs. More

information about the Dutch primary health care setting, in general, can be found in the report of Schäfer et al.<sup>32</sup>

### Patient and Public Involvement

Although we tried to set up a patient advisory group consisting of frail older people, we did not succeed, mainly due to transportation and health issues. Therefore, before starting the implementation of the targeted fall risk screening strategy, we interviewed five frail older people and an informal focus

group was conducted with GPs and practice and district nurses to investigate their needs and wishes regarding falls prevention. In addition, an advisory board consisting of two frail older people and important stakeholders (ie, physiotherapists; representatives of the municipality, a home care organization, and the GP care group; and researchers of other falls prevention studies in the Netherlands) will meet annually to discuss the set-up, execution, and results of the study.

## **Participants**

#### **GP** Practices

All GP practices from the GP care group are invited to participate in this study through emails, letters, presentations, and face-to-face visits. Furthermore, the consultant of the GP care group and a GP specialized in geriatric care involved in this study will approach GPs and practice nurses in person or by phone for participation.

### Physio- and Exercise Therapists

Physio- and exercise therapists are recruited through emails sent via the Royal Dutch Association for Physiotherapy (Dutch: "Koninklijk Nederlands Genootschap voor Fysiotherapie, KNGF") or by phone by the research team. Therapists are eligible to participate in this study if they are certified to offer an evidence-based falls prevention intervention or if they are willing to participate in an evidence-based falls prevention training program.

#### **Patients**

Patients are eligible to participate if they meet all of the following inclusion criteria:

- 1. speak Dutch or English;
- 2. are aged 70 years or older;
- 3. have the cognitive capacity to give informed consent according to their GPs' professional expertise;
- 4. are classified as frail by their GPs based on the Tilburg Frailty Indicator (TFI),<sup>30</sup> the TRAZAG Start Document,<sup>28</sup> another frailty screening strategy, or the GPs' professional expertise;
- 5. have a high fall risk according to the validated fall risk screening instrument (see <u>Appendix I</u>) or according to the professional expertise of their GPs;
- have a Care Intensity Package (CIP; Dutch: "Zorg Zwaarte Pakket") between one and five. The CIP indicates the type and intensity of the required care.

For CIP 5 and above, patients do not live independently anymore.

Patients are not eligible to participate in this study if they meet one of the following exclusion criteria:

- are currently participating in a physio- or exercise therapist's falls prevention intervention;
- have moderate to severe communication restrictions or impairments according to the professional expertise of their GPs;
- are not healthy enough to participate in this study according to the professional expertise of their GPs (for example, life expectancy <2 year).</li>

# Interventions from Physio- or Exercise Therapists

When frail older patients with a high fall risk are referred to physio- or exercise therapists, the therapists will offer the patients one of the falls prevention interventions presented in Table 2. 33–40 These interventions are described as qualified evidence-based falls prevention exercise programs by the Dutch Center for Healthy Living. 41,42 This Center maintains a database containing preventive interventions available in the Netherlands ranked by level of evidence. 42 The physio- or exercise therapists offer evidence-based falls prevention interventions tailored to the needs and wishes of the patient. If several exercise programs are available within the region, the patient will be referred to the intervention that best suits the patient's individual needs.

Because not all physio- and exercise therapists in the area are certified to provide these falls prevention interventions, they are offered the falls prevention intervention training A Matter of Balance-NL (Dutch: "Zicht op Evenwicht").

## Study Procedure

The five steps below describe the evaluation process of the targeted fall risk screening strategy at the level of both the GP practice and the patient. In addition, Appendix II provides flowcharts describing the steps for 1) the set-up of the implementation of the targeted fall risk screening strategy, 2) the data collection at the GP practices, 3) the data collection from physio-and exercise therapists and 4) the data collection among the frail older patients.

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# STEP I: Identification of Important Factors for the Fall Risk Screening Strategy

Before starting the implementation of the targeted fall risk screening strategy, an informal focus group with six to eight GPs and practice and district nurses will be organized. During this focus group, the primary care providers' needs and wishes regarding falls prevention and a fall risk screening instrument will be explored. Subsequently, a systematic literature study will be conducted to identify a validated fall risk screening instrument that best meets their needs and wishes.

Furthermore, about five informal interviews will be conducted with frail older people who had a fall. During these interviews, patients' perspectives, experiences, needs, wishes, barriers, and facilitators regarding falls prevention will be identified. These interviews will provide insight into how to approach and treat frail older patients with an increased risk of falling (See Appendix II, Flow Figure 1)

#### STEP 2: Assessment of Current Care

To assess current care, the participating GP practices will receive a short questionnaire regarding the number of frail older patients screened for fall risk, referred to falls prevention interventions, and enrolled in a falls prevention exercise program during the previous 12 months. In addition, the care providers will describe the barriers and facilitators they encountered in the provision of falls prevention. This self-reported data act as baseline data for the evaluation of the targeted fall risk screening strategy at GP practice level (See Appendix II, Flow Figure 2)

# STEP 3: Provision of Tools to Implement the Fall Risk Screening Strategy

The GP care group's GPs and practice nurses will be invited for a training program on the targeted fall risk screening strategy. Besides the screening for fall risk instruction, attention will be paid to the psychosocial barriers of older people to participate in falls prevention. For example, as indicated in the literature, patients' pride and concerns with public appearance are important reasons to decline participation in a falls prevention program. Additionally, the GPs and practice nurses will receive both a checklist to diagnose the underlying cause of the fall risk (see Appendix I) and an overview of certified physio- and exercise therapists who are able to offer evidence-based falls prevention interventions in the surrounding area (see Table 2). They will also be offered the possibility to follow a four-hour training session

concerning falls prevention for health care professionals (See Appendix II, Flow Figure 1)

# STEP 4: Implementation of the Fall Risk Screening Strategy

The majority of the GP practices already systematically assess patients for frailty based on the Tilburg Frailty Indicator (TFI), <sup>30</sup> the TRAZAG Start Document, or their own professional expertise. <sup>28,29</sup> The screening for fall risk will be added to this systematic frailty screening. The integration of falls prevention within existing protocols and guidelines of GP care groups is expected to positively influence implementation. Patients who are eligible and interested in participating in this study will receive a flyer, a patient information letter, and an informed consent form. In addition, the practice nurse will contact the patients by phone in case they need any further information about the study.

Based on the patients' risk profiles, the GPs (or the practice nurses) will offer the patients an intervention to reduce their high fall risk, such as a referral to an exercise program offered by a certified physio- or exercise therapist in the neighborhood, treatment of urine incontinence, and/ or adjustment of medication. (See <u>Appendix II</u>, and <u>Flow Figure 4</u>)

# STEP 5: Evaluation of the Implementation of the Fall Risk Screening Strategy

To evaluate the implementation of the targeted fall risk screening strategy at the level of the GP practice, data regarding the GP practice's number of screened, referred, and enrolled frail older patients for falls prevention as a percentage of the total number of frail older patients will be collected. Furthermore, an online focus group and informal interviews will be conducted with participating GPs and practices nurses, and an online focus group will be conducted with participating physio- and exercise therapists. Data from the online focus groups and informal interviews will be used to identify barriers and facilitators regarding the implementation of the fall risk screening strategy and to identify the care providers' intention to continue using the fall risk screening strategy. Additionally, logs will be kept by the researchers to keep track of the proportion of GPs that wanted to participate in this study and the proportion of GPs that used the fall risk screening strategy at the end of the study (see Table 1) (See Appendix II, Flow Figure 2).

To evaluate the influence of the falls prevention interventions at patient level, frail older patients will be divided

Table 2 Evidence-Based Falls Prevention Interventions

Intervention	Purpose (Next to Preventing Falls)	Population	Duration	Level of Evidence*
A Matter of Balance-NL (Dutch: "Zicht op Evenwicht") <sup>33,34</sup>	Reduce fear of falling and related misleading thoughts; Improve daily activity.	Older people who are worried about falling and/or who avoid activities as a result of their fear for falling	16 group- sessions with I follow up session 8 weeks 2 hours	IV Strong evidence for effectiveness
In Balance (Dutch: "In Balans") <sup>35</sup>	Increase awareness of high fall risk situations;Influence activity behavior; Improve condition, mobility, confidence and relaxation.	Independently living people aged ≥65 and older people living in residential care centers who feel insecure and/or anxious about falling	24 group- sessions 14 weeks I-2 hours	l Well substantiated
Nijmegen Falls Prevention Program (Dutch: "Vallen Verleden Tijd") <sup>36</sup>	Increase awareness of high fall risk situations; Decrease fear of falling; Improve activity level, mobility and balance.	Community dwelling older people who should be able to walk 15 minutes without aid and with a high risk of falling based on mobility problems, fall history and fear of falling	10 group- sessions 5 weeks 1.5 hours	IV Strong evidence for effectiveness
OTAGO <sup>37–40</sup>	Improve static and dynamic balance, leg muscle strength, walking ability, general endurance, activities of daily living function, confidence;  Decrease fear of falling.	Community dwelling people aged ≥65 with a high risk of falls and frail older people	6 home visits and 11 monitoring moments by phone	l Well substantiated

Note: \* Level of evidence defined by the Dutch Centre for Healthy Living which varies from O (well described) to IV (strong evidence for effectiveness).

into the following four groups after they have been diagnosed with high fall risk:

Group 1: Patients who want to participate in the study are referred to a falls prevention intervention from a physioor exercise therapist, and may or may not receive treatment from the GP, for example, for urine incontinence, vision problems, or medication adjustment.

Group 2: Patients who want to participate in the study and are not referred to a physio- or exercise therapist but are treated by the GP, for example, for urine incontinence, vision problems, or medication adjustment.

Group 3: Patients who want to participate in the study but do not want to be treated for high fall risk.

Group 4: Patients who do not want to participate in this study and, therefore, cannot be followed up.

Patients from group 1 will receive a more intensive followed-up to investigate the influence of the exercise program offered by certified physio- and exercise therapists. During a 12-month follow-up, all participating frail older patients will be assessed using the outcome measures described below, see paragraph Outcome measures.

In addition, a few randomly selected patients from groups 1 and 2 will be interviewed to explore their

experiences with the fall preventive care received (See Appendix II, Flow Figure 3 and Flow Figure 4)

### Outcome Measures

The targeted fall risk screening strategy will be evaluated at the level of the GP practice by using the following outcome measures:

- the percentage of frail older patients screened for fall risk.
- 2. the percentage of screened frail older patients eligible for a falls prevention intervention;
- the percentage of older patients eligible for a falls prevention intervention who agreed to participate in a falls prevention exercise program;
- 4. the percentage of frail older patients that start the falls prevention exercise program;
- 5. the percentage of frail older patients that complete the falls prevention exercise program.

The influence of the falls prevention interventions at patient level will be assessed by using the following outcome measures:

- 1. Functional Reach Test to assess stability 45-47
- 2. Timed-Get-Up-and-Go Test to assess mobility; 48-51
- 3. Timed Chair Stand Test to assess muscle strength; 52–54
- 4. Tandem Stance Test to assess balance; 55,56
- 5. Short Falls Efficacy Scale-International to assess fear of falling and self-efficacy;<sup>57,58</sup>
- 6. EQ-5D-5L to measure health status; 59,60
- 7. a 5-item questionnaire to assess fall history:
- 8. a 5-item questionnaire to assess patients own perspectives on their health status;
- 9. a 5-item questionnaire on daily activities;
- 10. a 3-item questionnaire to assess which intervention-(s) the patient received to prevent falls.

As described above, frail older patients are divided into four groups after they have been diagnosed with high fall risk. Figure 1A and B show which assessments are conducted in

each group of patients. Additionally, all participants keep track of their falls during the 12-month follow-up with the help of daily falls calendars. The calendars will be sent to the researchers on a monthly basis. If a fall occurs, the researcher will phone the patient to ask a few questions about the cause of the fall, any related injuries, and hospital admission. If a patient fails to send the calendars, the researcher will call the patient and ask about the occurrence of any falls in the previous month.

## **Analysis**

Data regarding the evaluation of the implementation of the fall risk screening strategy at GP practice level will be analyzed by using descriptive analysis in SPSS.61 Data from the standardized performance tests and questionnaires will be used to investigate the influence of the falls prevention interventions at patient level. The data

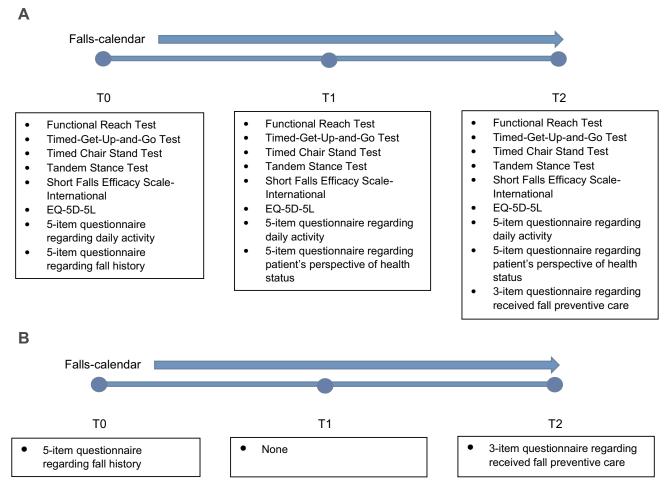


Figure I (A) Timeline assessments of group I patients who receive an intervention from a physio- or exercise therapist before intervention starts (T0), directly after the intervention (T1) and 12 months after starting the intervention (T2). (B) Timeline assessments of group 2 and group 3 patients who do not receive an intervention from a physio- or exercise therapist before intervention starts (T0), directly after the intervention (T1) and 12 months after starting the intervention (T2).

will be analyzed by conducting a multilevel analysis for longitudinal data, adjusted for potential confounders.

Interviews with participating patients will be conducted until data saturation, when no new themes emerge in the analysis, is reached. The interviews will be transcribed. The interviews and online focus groups will be open coded by two researchers. The codes will be discussed and a coding scheme will be developed from the different themes that emerge. The interviews and online focus groups will be selective coded and compared by two researchers. After consensus has been reached, the coding will be thematic analyzed using the ATLAS.ti 8 coding program for qualitative data analysis.<sup>62</sup>

## Sample Size Calculation

A sample size calculation was conducted based on the study of Schoon who stated that GPs in the Netherlands know of 20–30% of the falls among their older patients. <sup>15</sup> Furthermore, according to a report by Seymour, 11% of the people with moderate or severe frailty are registered to have experienced a fall. <sup>63</sup> Considering that of the overall population of frail older people in the Netherlands about 20% are diagnosed with high fall risk and 30% in the intervention population, 137 frail older people will be required to achieve 80% power (type II error of 0.20) with a type I error of 5%. The complete sample size calculation can be found in Appendix III.

#### Discussion

The primary objective of this study is to evaluate the implementation of a targeted fall risk screening strategy among independently living, frail older people in the primary care setting. In the Netherlands, as well as in many other countries. GPs are often the first point of contact for health issues.<sup>64</sup> They have insight into the patient's medical history, home setting, and social network. Therefore, they appear to be the designated professional for recognizing and offering falls prevention. An expected result of this study is that the targeted fall risk screening strategy will support GPs and practice nurses in their daily practice routines when it comes to recognizing high fall risk and offering falls prevention. The care providers might also become more aware of the importance of falls prevention. Therefore, compared to the usual care, the targeted fall risk screening strategy is expected to lead to more referrals to falls prevention interventions.

We expect that the targeted fall risk screening strategy will make falls prevention interventions more accessible to frail older people and, consequently, reduce falls. This expectation can be supported by Rubenstein, who concluded in his study that detection and amelioration of fall risk factors can reduce falls.<sup>65</sup> Older people are often not aware of having a high fall risk, and they are often unfamiliar with the available fall preventive services. When primary care providers help older patients to gain access to fall preventive services, this could result in better health outcomes for these patients. Falls and patients' fear of falling can be reduced and patients' balance, strength, confidence, quality of life, and independence might be maintained or improved. These health outcomes can result in a reduction in hospital admissions, revalidation treatments, and other related treatments, which in turn could lead to a reduction in health care costs. 66 Overall, this would be a more efficient provision of health care. Moreover, we expect that the results of this study will add valuable information to the knowledge of the systematic implementation of falls prevention for those who need a tailored treatment geared to their personal situations. Previous research often investigated the effect of falls prevention interventions in a controlled setting. This means that, at the moment, only scarce evidence is available about the effectiveness of multifactorial programs preventing falls among older people in a real-life setting. 14,67

Furthermore, this study will provide important insights into the experienced barriers and facilitators when implementing falls prevention at GP practices. Child et al concluded in their literature review that "factors underpinning the successful implementation of fall-prevention programmes are complex" and that "no single factor can be identified as key facilitator". <sup>44</sup> One of the factors pointed out by Child et al is the importance of access to falls prevention interventions. Interventions to prevent falls are offered on a limited scale in the primary care setting, both internationally <sup>68</sup> and in the Netherlands. <sup>69</sup> This is obviated in the current study by recruiting certified physioand exercise who are able to offer evidence-based falls prevention interventions.

## **Protocol Adaptations**

Originally, this prospective cohort study consisted of two parts with two different research designs to evaluate the targeted fall risk screening strategy (see The Netherlands National Trial Register: NL7917). First, we wanted to use a quasi-experimental design to evaluate the screening strategy at the level of the GP practice. The intervention group, consisting of GPs participating in the Care Program for Frail

Older People of the GP care group, would have been compared to a non-randomized comparison group of GPs who provide care as usual for a period of 12 months. However, during the study, the quasi-experimental design was changed into a pre-posttest design. Recruitment of GPs for the intervention group turned out to be more difficult than expected, and it took 1 year longer than anticipated. Some GP practices started with the implementation in January 2018 and others in January 2019. As a result, the time available for the implementation and evaluation of the targeted fall risk screening strategy differed among GP practices of the intervention group (follow-up between 4 and 16 months). The control group, on the other hand, received follow-up for a period of 12 months. This made an adequate comparison between the two groups impossible. Therefore, we decided to change the quasi-experimental design to a pre-posttest design. In the second part of the study, we intended to use a pre- posttest design to evaluate the influence of falls prevention interventions on patients. This pre-posttest did not change. We did not have a control group in this part of the study because it would be unethical to prevent patients at risk of falling from participating in a falls prevention program. Health care providers should offer all eligible patients adequate care.

### **Abbreviations**

GP, general practitioner; ED, emergency department; TRAZAG, Transmuraal Zorg Assessment Geriatrie; TFI, Tilburg Frailty Indicator.

# Ethics Approval and Informed Consent

This study is approved by the Medical Ethics Committee Brabant, the Netherlands (NL61582.028.17/ P1732).

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## **Author Contributions**

All authors made substantial contributions to the conception and design of the study and acquisition, analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content;

gave final approval of the version to be published; and agreed to be accountable for all aspects of the work.

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