Fall prevention implemented in primary healthcare

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48555

Source
ToetsingOnline

Brief title
Fall prevention in primary healthcare

Condition

- Other condition

Synonym
fall risk, Falls

Health condition

gevolgen van vallen (zeer divers; bv. gebroken heup, hersenletsel, kan ook gevolgen hebben op sociaal leven)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Fall prevention, fall risk, implementation in healthcare

Outcome measures

Primary outcome

The objective of this study is to evaluate if the implementation of a systematic and targeted screening of fall risk among independently living frail older people in primary care will result in more referrals to existing evidence-based fall preventive care. This will be evaluated with help of the RE-AIM model of Glasgow et al (1999): Reach, Effectiveness, Adoption, Implementation and Maintenance. Evaluation will take place at the level of the primary care provider (implementation index) in Part 1 and the level of the patient (patient-related outcome measures) in Part 2 of this study;

In Part 1 of this research, the reach of the implementation strategy at the level of the primary care provider will be evaluated with the following outcome measures:

1. The percentage of vulnerable elderly screened for fall prevention care;

2. The percentage of screened vulnerable elderly eligible for a fall prevention program;

3. The percentage of eligible elderly for a fall prevention program that agreed with a referral to a fall prevention program

4. The percentage of vulnerable elderly that actually start the program

5. The percentage of vulnerable elderly that complete the program

In Part 2 of this research, the effectiveness of the fall prevention implementation strategy on patient level will be assessed. In this part, based on the patient*s risk profile, patients are offered fall preventive treatment by their GP, practice nurse or home care provider like referral to an exercise program, treatment of urine incontinence, or perhaps an adjustment of medication. The group of patients who receive an exercise program are called group 1. The group of patients who are treated by their GP in example for urine incontinence or adjustment of medication, are called group 2. Patients from both groups can receive several fall preventive treatments, yet group 1 patients always receive an exercise program and group 2 patients do not. (see Figure 1. Overview procedures fall prevention implementation study, in the Protocol.) Patients from group 1 will be followed more intensively than patients from group 2.

The outcome measures of patients from group 1 are assessed at baseline (T0), at the end of the intervention (T1) and after 12 months (T2) (See Figure 2. Timeline assessments group 1, in the Protocol). The following four physical tests, six short questionnaires and a falls-calendar will be conducted/provided by the GP, practice nurse, home care provider and the physio- or exercise therapist:

1. The Functional Reach Test (FRT): The patient is instructed to stand next to

a wall, but not to touch it. The arm is positioned at 90 degrees of shoulder flexion with a closed fist. The started position is recorded at the third metacarpal head on the yardstick. The patient is asked to reach forward as far as possible, without taking a step. The difference between the start and the end position of the third metacarpal is used as score. Three trials are done and the average of the last two is noted (Weiner, 1992)

2. The Timed-Get-Up-and-Go-Test (TUG): This test will be used to assess patients* mobility. The patient is asked to rise from a chair, walk three meters, turn around, walk back to the chair and sit down. The physio- or exercise therapist will measure the time required for this test with a stopwatch. Three trials are done and the average of the last two is noted (Podsiadlo, 1991)

3. Timed Chair Stand test (TCS): This test is used to assess the patient*s muscle strength. The patient is asked to sit and stand as quick as possible five times in a row from a chair without using their arms. The physio- or exercise therapist will measure the time required for this test with a stopwatch.

4. Tandem Stance test (TS): This test is used to assess the patient*s balance. The patients is asked to stand in three positions (that increase in difficulty) for 10 seconds. The physio- or exercise therapist will note the time and positions the patients was able to complete.

5. Valgeschiedenis Vragenlijst: This questionnaire consists of five questions regarding the patient*s fall history, fall-related injuries and health.

6. Short Falls Efficacy Scale-International (Short FES-I): A questionnaire of 7

items to measure fear of falling and self-efficacy to manage daily situations (Kempen, 2007).

7. EQ-5D-5L: A standardised measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal. The assessment consists of 5 multiple choice questions regarding mobility, self-care, usual activities, pain/discomfort and anxiety/depression. In addition it has a scale regarding once health on that day (Van Reenen & Janssen, 2015)

8. Impact Intervention Questionnaire: This questionnaire consists of 5 questions corresponding to the EQ-5D-5L standardised measure. These questions are about the patient feeling worse, the same or better regarding mobility, self-care, usual activity, pain/discomfort and anxiety/depression compared to before the intervention.

9. Activiteiten Vragenlijst: This questionnaire consists of 5 questions regarding living environment, mobility, free time and social contact.

10. Falls-calendar: All participants receive a falls-calendar on which they can write down on a day to day basis if they have had a fall or not. On this calendar they write down a *N* for not fallen and an *F* for fallen. After each month they can detach the page for that month and send it back to the research team. No patient details will be on the calendar. No stamp is necessary.
In case the patient has fallen, the researcher will call the patient and ask him/her a few questions about the cause of the fall, related injuries and hospital admission. (See questionnaire Questions Falls-Calendar)

11. Vragenlijst Behandeling Valrisico: This questionnaire consists of three

questions about which interventions/treatment the participant received regarding to their fall risk.

The patients from group 2 will conduct one questionnaire at baseline and a questionnaire after 12 months. Furthermore they will be asked to keep track of their fall-incidence during these 12 months (T0-T2). (See Figure 3. Timeline assessment group 2, in the Protocol.) The following 2 questionnaires and falls-calendar will be conducted/provided by the GP, practice nurse or home care provider:

1. Valgeschiedenis Vragenlijst: This questionnaire consists of five questions regarding the patient*s fall history, fall-related injuries and health.
2. Falls-calendar: All participants receive a Falls-calendar on which they can write down on a day to day basis if they have had a fall or not. On this calendar they write down a *N* for not fallen and an *F* for fallen. After each month they can detach the page for that month and send it back to the research team. No patient details will be on the calendar. No stamp is necessary.
In case the patient has fallen, the researcher will call the patient and ask him/her a few questions about the cause of the fall, related injuries and hospital admission. (See questionnaire Questions Falls-Calendar)
3. Vragenlijst Behandeling Valrisico: This questionnaire consists of three questions about which interventions/treatment the participant received regarding to their fall risk.

Secondary outcome

n.a.

Study description

Background summary

Falls are an important and increasing problem among increasing numbers of frail older people. A further increase lies ahead because of the rising numbers of independently living elderly (VeiligheidNL, 2015). There are treatments available to prevent falls with a reasonable level of evidence. Exercise therapy and addressing risk factors in the home environment seem the most promising. These treatments are also available in the Dutch context. But a general systematic implementation of these kind of treatments is missing. Population based risk assessment does not take place. Furthermore there is no complete coverage of service provision of fall treatment offered by qualified physio- or exercise therapists in the region, whereas close to home availability of these services is especially important for the target population of vulnerable elderly. So, in general, there is a gap between evidence and the day to day practice in primary and home care to date leading to the unfavorable situation that elderly for which fall risk treatment is potentially effective do not receive this treatment.

Study objective

The objective of this study is to evaluate if the implementation of a systematic and targeted screening of fall risk among independently living frail older people in primary care will result in more referrals to existing evidence-based fall preventive care.

Study design

This prospective cohort study consists of 2 parts with 2 research designs. In Part 1, we use a quasi-experimental design to evaluate the implementation strategy at the level of the primary care provider. In Part 2, we use a pretest-posttest design to evaluate the implementation strategy at the level of the patient.

Intervention

A suitable and validated fall risk screening tool will be offered to GPs, practice nurses and home care providers. They will identify frail older people

at risk of falling. Based on the patient*s risk profile, patients are offered fall preventive treatment like referral to an exercise program, treatment of urine incontinence, or perhaps an adjustment of medication. If the patient is referred to an exercise program, the physio- or exercise therapist will offer a qualified fall preventive intervention (Sight on Balance, Falls in the Past, Wait you Fall, In Balance, OTAGO) tailored to the needs and wishes of the patient. In this study, the group of patients who receive an exercise program are called group 1. The group of patients who are treated by their GP in example for urine incontinence or adjustment of medication, are called group 2. Patients from both groups can receive several fall preventive treatments, yet group 1 patients always receive an exercise program and group 2 patients do not. (See Figure 1. Overview procedures fall prevention implementation study, of the Protocol).

Study burden and risks

Since this project is in line with usual care, we do not anticipate any disadvantages or risks for the elderly patients in being involved in this project. The treatments which are offered to patients in this research are also offered and used in usual care, they are only not well implemented in daily practise. The older participants in this study will be supervised by their own GP, practice nurse, home care provider and physio- or exercise therapist as in usual care. We only strive for this usual care to be applied more often. The only differences compared to usual care are the assessments for this research. These assessments consist of four physical test, six short questionnaires and a falls-calendar. The four physical tests have been conducted in previous research and for as far the research team knows, there are no disadvantages of conducting these assessments (except of the time required to complete the assessments). Therefore the risks for taking part in this research does not exceed that of usual care, and for this reason we have not undertaken any measures to reduce the risk of participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients from GPs, practice nurses or home care providers who are frail and have an increased fall risk.

Exclusion criteria

1. Not classified as frail according to the TFI, TRAZAG Startdocument, own expertise or another frailty screening instrument,
2. Currently undertaking fall prevention interventions from a physio- or exercise therapist,
3. Moderate to severe communication restrictions or impairments,
4. According to their GP not healthy enough to participate in this study (e.g. life expectancy 2< year), or
5. Having a ZorgZwaartePakket (Care Intensity Package) of 5 or higher.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-09-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-06-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL61582.028.17