

Fall prevention implemented in primary healthcare

No registrations found.

| | |
|------------------------------|---------------------|
| Ethical review | Positive opinion |
| Status | Recruitment stopped |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON26230

Source

Nationaal Trial Register

Brief title

TBA

Health condition

Frail independently living older people, diseases not specified

Sponsors and support

Primary sponsor: Tilburg University

Source(s) of monetary or material Support: ZonMw

Intervention

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 prevention interventions. 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 prevention interventions 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 prevention interventions, 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). 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. Fall history questionnaire: 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. Activity Questionnaire: 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.
11. Questionnaire Treatment Fall-risk: This questionnaire consists of three questions about which interventions 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).

The following 2 questionnaires and falls-calendar will be conducted/provided by the GP, practice nurse or home care provider:

1. Fall history questionnaire: 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.
3. Questionnaire Treatment Fall-risk: This questionnaire consists of three questions about which interventions the participant received regarding to their fall risk.

Secondary outcome

n.a.

Study description

Background summary

Background

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 interventions 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 interventions are also available in the Dutch context. But a general systematic implementation of these kind of interventions is missing. Population based risk assessment does not take place. Furthermore there is no complete coverage of service provision of fall prevention interventions 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 prevention interventions are potentially effective do not receive these interventions.

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 prevention interventions.

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 pre- posttest design to evaluate the implementation strategy at the level of the patient.

Study population

We plan to include approximately 200 frail patients aged 75 years and older from GPs, practice nurses and home care providers.

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 prevention interventions 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 prevention 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 prevention interventions, 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).

Nature and extent of the 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 interventions which are offered

to patients in this research are also offered and used in usual care, they are only not well implemented in daily practice. 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.

Study objective

H0: Implementation of a systematic and targeted screening of fall risk among independently living frail older people in primary care will not influence on the number of referrals to existing evidence-based fall prevention interventions.

H1: Implementation of a systematic and targeted screening of fall risk among independently living frail older people in primary care will influence on the number of referrals to existing evidence-based fall prevention interventions.

Study design

T0 (baseline)

T1 (directly after intervention finished)

T2 (12 months after baseline)

Intervention

A systematic and targeted fall risk screening approach will be implemented at GP practices. The systematic fall risk screening approach used in this study 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 with primary care providers followed by a systematic literature search.
2. A checklist to diagnose the underlying cause of the fall risk: This checklist is created by using previous literature regarding risk factors for falls (VeiligheidNL et al., 2015; WHO, 2008; Nederlandse Vereniging voor Klinische Geriatrie, 2017) and completed after a discussion within the research group that includes a GP specialized in elderly care.
3. An overview of all physio- and exercise therapists who are certified to offer falls prevention interventions in the area of the GP practices.
4. A four-hour accredited training concerning fall prevention for health care professionals: The training is provided by a trainer from the organisation 'VeiligheidNL' (VeiligheidNL, 2019) and suitable for nurses and assistants. The training is not compulsory and offered for free within this project.

In the second part, physio- and exercise therapists in the area are recruited to participate in this study until complete coverage of service provision of falls prevention interventions offered by certified physio- or exercise therapists is reached. Physio- and exercise therapists who are not certified to provide an evidence-based falls prevention intervention are offered training.

Furthermore, physio- or exercise therapists will offer patients evidence-based fall prevention interventions. These interventions are described as qualified evidence-based fall preventive exercise programs by the Dutch Centre for Healthy Living (Loketgezondleven, 2019; MOVISIE et al., 2013). The physio- or exercise therapists will offer the evidence-based falls prevention interventions tailored to the needs and wishes of the patients.

Contacts

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Eligibility criteria

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 $2 < \text{year}$), or

5. Having a ZorgZwaartePakket (Care Intensity Package) of 5 or higher, indicating not living independent.

Study design

Design

| | |
|---------------------|---------------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

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

IPD sharing statement

Plan to share IPD: No

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 30-07-2019 |
| Application type: | First submission |

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

NTR-new NL7917

Other METC Brabant, Netherlands : P1732 Valpreventie in de eerstelijns zorg

Study results