

PREFALL - Protocol

Title:

Development of a multivariable prognostic **PRE**diction model for 1-year risk of **FALL**ing in community-dwelling older adults in a non-clinical setting (**PREFALL**).

Registration:

ClinicalTrials.gov Identifier: NCT03608709

Protocol version:

Issue date: 4th of November 2018.

In the event of protocol amendments, this section will describe the date, changes and rationale of each amendment. Changes will not be incorporated into the protocol sections. All authors will be responsible for approving the amendments. Also, GS will be responsible for documentation and implementation of these.

- 4th of November 2018:
 - **Change #1:**
 - An extra recruitment site was added: The local hall of Hjørring. (page 5 and 7)
 - **Rationale:**
 - To optimise recruitment.
 - **Change #2:**
 - End of follow-up was changed from April to August 2021 (page 13)
 - **Rationale:**
 - To optimise recruitment.
- 25th of June 2018:
 - **Change: #1**

- The number of recruiting senior activity centres was reduced from four to three.
- Rationale:
 - A write error in the original protocol.
- **Change: #2**
 - The time frame for the secondary outcome regarding time consumption was changed from “after enrolment of 250 participants” to “after 6 months”.
 - Rationale:
 - Registrational requirement at www.clinicaltrials.gov

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Authors' contributions:

GS is the guarantor and drafted the manuscript for the protocol. GS, SA, MGJ, JR, TM developed selection criteria and chose predictors for the model.
SR will provide hardware for arrhythmia-measurements, expertise on arrhythmias and support to GS in analysing arrhythmia-measurements.

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Introduction:

Falls in community-dwelling older adults are common with an incidence of 30 % in over-65s and 50 % in over-80s.¹ Incidences are expected to increase significantly in the future due to population aging.^{2,3} For instance, as of 2017, the global population older than 65 years is estimated to be 962 million and will increase to 1.4 and 2.1 billion in 2030 and 2050 respectively.² In Denmark, falls are the most common accidents among older adults with around 36,000 fall accidents seen annually by the Danish health services and approximately 680 deaths yearly. This high frequency of fall accidents may also support the fact that falls in Denmark are the fourth most common reason for years lived with disability, thereby giving rise to reduced quality of life.⁴ Furthermore, falls are associated with elevated morbidity, mortality, poorer physical functioning and early admission to long-term care facilities⁵⁻⁷. Thus, this frequent and escalating problem of fall accidents is of major concern.

Fall prevention is therefore highly relevant. It is recognised that fall-preventive strategies should take on a multifaceted approach due the multifactorial aetiology of falls.^{3,8} This is substantiated by more than 400 risk factors of falling that have now been identified.⁹ These spread across different domains including socio-demographics, medical conditions (e.g. atrial fibrillation¹⁰), medication, physical performance (e.g. reduced lower extremity strength^{6,11} or reaction time¹²), psychology (e.g. depression^{13,14} or fear of falling^{12,15}) and cognition (e.g. global cognitive impairment or reduced executive functioning¹⁶⁻²⁰).

In order to aid health care professionals in targeting fall-preventive interventions, individual assessments of fall risk are imperative. In Denmark, municipalities are obliged to perform preventive initiatives to preserve the physical, mental and social health along with the functional capacity and quality of life of their older adults. The aim of these initiatives is to enable the older adults to live an independent and meaningful life for as long as possible. Recently, The Danish Health Authority released an updated manual to support this work.²¹ This emphasised the need for development of a validated prediction model to be used in a municipality environment to identify older adults at risk of falling.

This is due to the abovementioned consequences of falls. To the knowledge of the authors, this is in line with literature being sparse on prognostic prediction models on falls in community-dwelling older adults with data collected outside a clinical environment (i.e. hospitals, GPs and screening or assessment centres).

Objective:

Primary:

To develop and internally validate a multifactorial prognostic prediction model on fall risk in community-dwelling older adults in a non-clinical setting. The intended use of the model is, for municipalities, to refer citizens with high risk of falls to fall-preventive interventions.

Secondary:

1. To estimate time-consumption for the final prediction model.
2. To describe the prevalence of arrhythmias in community-dwelling older adults.

Methods:

Study design and sample size:

A prospective cohort study with 1-year follow-up will be performed in collaboration with the municipality of Hjørring, Denmark. A total sample size of 500 participants is expected. This was chosen due to economical and administrative reasons of the municipality contributing with personnel to include participants and collect data on predictors. Data for the development and internal validation of the model will originate from the same cohort.

Study setting, participants, data collectors, process of recruitment and data collection:

According to Danish legislation on health and social services, Danish municipalities are responsible for developing and initiating prophylactic and health-promoting initiatives for their senior citizens. This is done through different authorities in the municipality (e.g. preventive-home-visits, senior activity centres). Also, the municipality of Hjørring administers a local hall for citizens together with general- and patient associations.

Therefore, data collection will be performed in participants' own homes through preventive-home-visits, at senior activity centres and at the local hall in the municipality of Hjørring, Denmark.

Preventive home visits (PHV):

The primary aims of PHVs are to empower the citizens to help themselves, support them in utilising own resources and preserve their functional capacity. The target group of PHVs is community-dwelling older adults primarily +75 years old. When turning 75 years old, a letter is sent to the citizen inviting him/her to an information meeting on senior life and the option to receive a PHV in their own homes. If they accept, a PHV will be scheduled. When turning 80 years old, the citizen will receive an annual letter offering a prescheduled PHV. In this case, the citizen has to actively decline the offer in order to not receive the PHV. Also, certain predefined groups at risk are included in the target group. PHVs are not offered to citizens already receiving local authority home help except for those receiving help with cleaning. As of 2017, the target group of PHVs in the municipality of Hjørring consisted of approximately 4,800 community-dwelling older adults of which 2,053 received a PHV. We expect to include 400 participants from PHVs. However, in case of economical, administrative or timing problems, this may alter. This will be noted in the amendments section to this protocol. PHVs are performed by trained nurses. These will collect data on participants in this setting. Each citizen in the target group will consecutively have a visit scheduled approximately 1-2 months beforehand. In connection with this scheduling, the participant information for this study will be mailed to the citizen. At the visit, citizens will be given oral information on the study in order to give consent for participation and will be assessed by data collectors according to in- and exclusion criteria. Afterwards, baseline tests will be performed. Within approximately 7 working days, participants will receive a phone call from the municipality. Here they will be assisted in completing the questionnaire and have the Orientation-Memory-Concentration test performed over the phone.

Senior activity centres (SAC):

The primary aim of SACs is to enhance quality of life of its attending citizens. This is done through empowerment of the citizen to preserve own resources and physical,

psychological and social abilities through different activities. The target group of SACs is primarily retirees (+65 years old), but also early retirees (+60 years old) with reduced physical, psychological or social functional capacity. In order to attend the activities, a small user charge (2 €) is required. Transportation to the SACs is either done through community transport schemes or on one's own. As of 2018, 318 citizens of the target group attend SACs in the municipality of Hjørring weekly. We expect to include 100 participants from SACs. However, in case of economical, administrative or timing problems, this may alter. This will be noted in the amendments section to this protocol. The activity centres are staffed with health care workers. These will collect data on participants in this setting. There are five SACs in the municipality of Hjørring of which three will be recruited from. These are located in the city of Hjørring, Hirtshals and Sindal. This was chosen due to economical and administrative reasons. Participants will be recruited at occasions where citizens are gathered at the SACs. At these occasions, a video of GS giving oral information on the study will be presented. If interested in participating, citizens will be given written information in order to give consent for participation and assessed by data collectors according to in- and exclusion criteria. This recruitment method for the SACs was chosen due to practical reasons since attendance at the SACs is varying. Afterwards, baseline tests will be performed. Within approximately 7 working days, participants will receive a phone call from the municipality. Here they will be assisted in completing the questionnaire and have the Orientation-Memory-Concentration test performed over the phone.

The Local Hall of Hjørring:

The local hall of Hjørring constitutes a meeting point for 84 general- and patient associations within the municipality²². Furthermore, citizens from the municipality attend the hall for social events. Participants will be recruited at occasions where citizens are gathered at the local hall. An employee of the municipality, or GS, will frequently visit the local hall to recruit these. At these occasions, a video of GS giving oral information on the study will be presented or the study will be presented in-person by GS. If interested in participating, citizens will be given written information in order to give consent for participation and assessed by data collectors according to in- and exclusion criteria. This

recruitment method was chosen due to practical reasons since attendance is varying. Also, the video of GS will frequently be broadcasted at the local information-channel on TV informing about the project taking place in the local hall.

Eligibility criteria:

The following in- and exclusion criteria were chosen by an expert panel consisting of GS, SA, MGJ, JR, and TM. Reasons are stated in the underlying bullets of the criteria.

Inclusion criteria:

1. Community-dwelling older adults, i.e. not living in nursing homes.
 - This was decided due to this being the target group of prophylactic initiatives in the municipality of Hjørring.
2. 75 years old or above.
 - This was decided due to the PHVs are primarily targeted towards citizens at this age category.

Exclusion criteria:

1. Presence of acute illness defined by the presence of a participant-reported experience of illness arisen within 7 days prior to inclusion impairing their everyday functioning in such a way that they opt out of social activities outside their homes while this state is present.
 - a. This was decided in order to assume the measurements of the predictors being based on the potentially best performance of each participant.
2. Unable to understand Danish evaluated by the data collectors.
 - a. This was decided in order to ensure compliance with instructions for predictor measurements.
3. Diagnosed with dementia.
 - a. This was decided for ethical reasons in terms of achieving informed consent for participation.
4. Unable to stand up for 60 seconds without support. Support is defined by any assistive devices or help from another person.

- a. This was decided since it is a requirement in order to perform the physical tests using the Nintendo Wii Balance Board.

Outcome:

Primary outcome:

The primary outcome is number of falls. These will be monitored using monthly prepaid fall calendars and validated by a phone call if a fall is registered.²³ Also, circumstances of the fall will be ascertained in the phone call.

Blinding:

Assessors of the outcome will be blinded towards the predictors due to test results not being available before end of follow-up. Also, assessors of the outcome will be blinded to the questionnaire results by not having access to these in REDCap.

Secondary outcome:

Time consumption for final prediction model:

After 6 months, GS will perform a field trip to the SACs and PHVs to observe and record time-consumption in each setting.

Arrhythmias:

Prevalence of arrhythmias will be calculated as the proportion of participants having arrhythmias in the study population at the time of the baseline measurements. Due to practical reasons, recordings will be analysed for occurrence of arrhythmias after follow-up has been completed. Both brady- and tachyarrhythmias will be considered.

Predictors:

Data collection of predictors will be performed at baseline. In order to collect data on predictors in a time-efficient way. It was decided to collect these both by tests performed by data collectors on the inclusion date and questionnaires filled out by study participants in cooperation with a health care worker at the municipality over the telephone. All results from tests and questionnaires will be typed into REDCap (Research Electronic Data Capture, Vanderbilt University, Nashville, USA) electronic data capture tool hosted at Region Nordjylland, Denmark. The following predictors were chosen by an expert panel consisting of GS, SA, MGJ, JR, and TM. Reasons are stated in the underlying bullets of the criteria. First, a brief summary on the process of how predictors were selected will be given followed by a short description of each predictor.

Predictor selection process: A feasibility study.

This model is intended for health care professionals in a non-clinical setting, in this case the municipality of Hjørring with a setting consisting of homes and activity centres. Therefore, it needs to be time-efficient, low-cost and practicable. In order to ease implementation if the model is successful in accuracy, the predictors for data collection was chosen by an expert panel on the basis of scientific value and experiences from a feasibility study performed as a precursor for this study.

The feasibility study investigated the feasibility of measuring a set of predictors, selected by the expert panel, with regards to time-consumption and user experiences both from participants and data collectors in order to ensure participant and public involvement. These predictors constituted the basis from which final selection for the prospective cohort study was performed.

Tests:

Arrhythmias

Our study will be the first to investigate the prevalence of arrhythmias in a Danish population of older adults (+75 years old) by performing data collection in participants' own environments (i.e. own homes and activity centres). All participants will receive 4.5-5 days of 2-lead continuous heart rhythm monitoring (E-patch system, BioTelemetry Inc, Denmark).²⁴

Lower limb reaction time:

This was chosen since a slow reaction time was found in earlier studies to increase the risk of falling.¹² Measurements will be performed using a Nintendo Wii Balance Board with appropriate software Fysiometer (Brønderslev, Denmark).²⁵

Unilateral lower extremity strength:

This was chosen since a poor lower strength in lower extremities was found in earlier studies to increase the risk of falling.^{6,11} Measurements will be performed using a Nintendo Wii Balance Board with appropriate software Fysiometer (Brønderslev, Denmark).²⁶

Grip strength:

This was chosen since a poor grip strength was found in earlier studies to increase the risk of frailty,²⁷ which is associated to increased fall risk.²⁸ Measurements will be performed using a Nintendo Wii Balance Board with appropriate software Fysiometer (Brønderslev, Denmark).²⁹

Balance with dual-tasking:

This was chosen since a poor dual-tasking ability was found in earlier studies to an increased fall risk.^{17,30–32} Measurements will be performed using a Nintendo Wii Balance Board with appropriate software Fysiometer (Brønderslev, Denmark).³³ Simultaneously, participants will be instructed mention as many things one can buy in a supermarket, while attempting to stand still on the board.

Walking speed:

This was chosen since a poor gait speed was found in earlier studies to an increased fall risk.³⁴ Participants will be instructed to do a 4-meter walk at regular speed. Time spent will be noted using a stop watch. The fastest of the two measurements will be selected for further analysis.

Physical activity:

This will be measured using an accelerometer incorporated in the hearth rhythm monitoring device.

Questionnaire:

The following list specifies predictors of falls and participant characteristics that will be included in the questionnaire.

- Age.⁶
- Gender.³⁵
- Comorbidities.³⁶
- Medication.³⁵
- Educational level.¹⁵
- Status of living.³⁵
- Prior falls.^{12,14,15,35,37}
- Walking aids.¹⁴
- Alcohol consumption.¹⁵
- Using multifocal lenses.³⁸
- Having dogs or cats in the household.¹⁵
- Health-related quality of life using EQ-5D-3L by the EuroQol group.³⁹
- Nutrition status.⁴⁰
- Symptoms of urinary incontinence³⁷, pain when walking¹⁴ and dizziness.^{12,14,15}

- Patient self-assessment as a measure of self-awareness of fall risk: Do you think that you could fall during the next year?⁴¹
- Fear of falling using Short FES-I 7-item.^{12,15}
- Depression using Geriatric Depression Scale 4 item.^{13,14}
- Frailty using the Tilburg Frailty Indicator^{28,42}
- Activities of Daily Living using the Vulnerable Elders Survey⁴³.
- Orientation-Memory-Concentration test performed over the telephone.^{44–46}

Blinding:

Due to nature of the study design, all assessments of predictors for the outcome to be predicted, future falls, will be blinded.

Statistical methods:

A description of the flow of participants through the study will be given including number of participants with and without the outcome. Baseline characteristics of non-fallers, single fallers and recurrent fallers (>2 falls) together with follow-up time will be summarised using descriptive statistics. A summary on the number of participants with missing data for predictors and the outcome will be given. Missing data will afterwards be handled using multiple imputation methods. The relevant predictors for falls will be selected using shrinkage methods and cross-validation⁴⁷ on a multivariable Cox regression including relevant predictors. The full prediction model will be presented to allow for prediction of individuals together with an explanation on how to apply it. In continuation hereof, participants will be classified as “at high, medium, or low-risk of falling”. This categorisation should improve the likelihood of implementing the model in clinical practice. Furthermore reporting of results will follow the Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies: The CHARMS Checklist.⁴⁸ Also, further mathematical modelling will be performed. Statistical analyses will be performed using statistical software. Also, an analysis will be made to adjust for fall-preventive initiatives prompted by the municipality.

Ethics:

Written informed consent will be obtained from all patients by the data collectors. Consent will also be asked for regarding future/ancillary studies on the cohort. The study was approved by The Danish Data Protection Agency (number 2018-82). The Ethics Committee in the Region of North Jutland, Denmark, stated that no approval was necessary as the study included testing and a questionnaire, but no intervention. When data has been analysed, participants will be contacted in case of abnormal findings on their heart rhythm analysis.

Time schedule:

Baseline data collection is expected to start in June 2018 and proceed until 500 participants have been recruited. Follow-up will end in August 2020 at the latest.

Access to data:

All authors will have access to the final dataset. However, if data are to be used outside the institution of Region Nordjylland, a processor agreement has to be made according to the Danish Data Protection Agency.

Declaration of interests:

The authors declare having no conflicts of interest. However, MGJ developed and holds a patent on the software used for grip strength, unilateral lower extremity strength, grip strength and balance measures in the study. Due to this, MGJ was left out of the final decision on predictors for the study.

Dissemination and reporting:

We plan to publish studies in peer-reviewed journals in English. The reporting of the study will follow guidelines for Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD). Also, reporting of outcome measures on the prediction model will comply with according to the Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies (CHARMS) check list.

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