Study Protocol and Statistical Analysis Plan

Does the Improved Coordination of Care for Fall- and Fracture Prevention in Oslo Have Effect on the Rate of Hip Fractures, Need of Nursing Homes or Death?

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The study is an evaluation of a new patient follow-up for fall- and fracture prevention in the municipality of Oslo with improvement of coordination of care for elderly (65 years or older, 65+) at risk of fall injuries.

The two major innovations in this initiative are 1) the systematic approach to improving care coordination within the health care system as well as 2) including osteoporosis evaluation in the fall risk assessment in order to reduce risk of fall related fractures.

In this study, the two city boroughs of Nordstrand and Østensjø, who initiated the intervention, are compared with a control group consisting of the other 13 city boroughs of Oslo in a controlled before and after study design.

The care coordination implemented is in line of the framework Øvretveit used in his summary review "Does clinical coordination improve quality and save money?" (2011)ⁱ, and which WHO later adopted in their practice brief "Continuity and coordination of care" (2018)ⁱⁱ. The major steps in the intervention in Oslo are as follows:

- Needs assessment and user involvement. The intervention started with the chief medical officers in the areas of intervention realizing the health burden of hip fractures within their boroughs, as well as the lack of care coordination in the delivery of preventive measures. The steps of the intervention were developed as a cooperative effort with the local health professionals who delivered the services, the chief medical officers in the boroughs and specialists in geriatrics, osteoporosis and injuries at Oslo University Hospital.
- Case finding of individuals with increased risk of a fall injury. In the start of the intervention this was primarily done within the boroughs through physiotherapists and occupational therapists who looked for patients with increased risk of falling in their clinical practices. Education on fall risks and possible follow-up was also given to the General Practitioners (GPs) and at the community centers for case finding. From September 2017 the Injury Clinic at Oslo University Hospital started sending so-called "fall reports" to the boroughs when 65+ patients with fall related injuries had been treated at the clinic, assisting the boroughs in identifying cases and targeting this high-risk population in their preventive initiatives.
- Shared, collaborative single point of entry to care in the boroughs. This is the address to where the fall reports from the Injury Clinic were sent. The same address was conveyed to the GPs and the other health professionals to send messages whenever a need for falls risk assessment and intervention was detected. On the receiving end of this address, is a care coordinator with extensive knowledge about the local health care system and the fall prevention pathway who forwards the messages to launch the right follow-up.
- A cross-sectoral plan for follow-up with role clarification. This was a major part of improving the coordination of care. Who identifies the elderly at risk of fall injuries and how (case finding)? Who performs the fall risk assessments? What measures are taken to reduce risk, who delivers these interventions and how are the at-risk-patients recruited into the follow-up? Both the leadership and those who delivered the services within the boroughs were included in the planning process. The cross-sectoral plans were developed both separately within the two boroughs and some parts in coordination with the Injury

Clinic, specialists at the University Hospital and the Department of Public Health of the Municipality of Oslo.

- <u>Interdisciplinary teams</u> were established in the two boroughs, consisting of those who did fall risk assessments through home visits. The teams consisted mainly of physiotherapists and occupational therapists. Nurses, nutritionists, and clinical pharmacologist were added later. These teams received referrals for risk assessments from the single point of entry, sent from the Injury Clinic as fall reports and as well messages from by other health professionals within the boroughs.
- Tools for multifactorial falls and fracture risk assessment, leading to tailored interventions
 were developed as instruments to ensure the <u>quality of care</u>. The content of these
 assessment tools was based on best-practice and evidence-based, but the format was
 adapted by local health professionals to fit their practices and workflow.
 - The first assessment tool developed, was an interdisciplinary assessment checklist for home visits. The main areas that were assessed was gait and need for physiotherapy and exercise, safety in home environment, need of medical examination, sight, footwear, nutrition status, and support network. This assessment tool has been revised and improved several times in accordance with developing evidence and user preferences.
 - The second tool developed was a <u>checklist for the GPs</u> consisting of a list of medical conditions to consider in patients who had fallen, suggested blood work, guidelines for osteoporosis evaluation, tools for medication review and a description of referral pathways.
 - 3. The third assessment tool developed, was for the <u>doctors at the Injury Clinic</u> to help them to evaluate whom of the fall injury patients to refer for further follow up in the boroughs and/or the geriatric department for falls risk assessment and/or osteoporosis evaluation. A secretary assisted in the logistics of sending the fall reports to the single point of entry in the boroughs.
 - 4. FRAX, an established fracture risk assessment tool, was introduced to all health professionals, but to the GPs in particular.
- <u>Information sharing</u>. Standardized messaging was introduced from the actors responsible for the case finding to those who did falls risk assessment and further to those who performed risk-reducing measures. For instance, the fall reports from the Injury Clinic were a specified type of message with a planned follow-up. Involving the GP in the information loop was key to improve coordination.
- <u>Primary and specialist care referral pathways</u> and processes. The referral pathway to the
 geriatric departments was strengthened with the aim of both increasing the number of
 referrals and for the referrals to be more appropriate, with focus on patients with multi
 morbidity, polypharmacy, and suspected syncopes. Furthermore, access to osteoporosis
 evaluation and intravenous treatment of osteoporosis with zoledronic acid was improved.
- <u>Champions</u> in the two boroughs, at the Injury Clinic and in the Public Health Department of Oslo were chosen, aiming to create enthusiasm and carry the intervention forward within their organizations. The champions in the boroughs worked in close coordination

with the two Chief medical officers of the boroughs. The intervention received yearly grants ("Samhandlingsmidler") from a joint committee from the Specialist and Primary health care in Oslo for improving coordination of care from August 2016, which made it possible to allocate time for working on this project. The yearly grants amounted to 0,3 – 1 yearly salary mainly distributed between the champions, so most of the intervention used resources within the normal budget and activity. The champions mobilized colleagues and experts, developed the assessment tools, educated of health professionals and were a driving force in expanding the intervention.

- Tailored interventions to reduce risk of falls and fractures. The two intervention boroughs already offered, as all other boroughs in Oslo, strength and balance exercise groups and had occupational therapists who did home safety assessments on referral before study start. The new care coordination led to a mapping of the existing variety of exercise groups, and some increase both in the number and variety of the exercise options. Other interventions like safety measures at home, different aids, nutrition, osteoporosis treatment, medication assessment and geriatric evaluation was also better described and made available. The extensive mapping of the local intervention possibilities was useful and was utilized as a menu to choose from when tailoring interventions for the individual after a multi factorial risk assessment.
- <u>Collaborative training and education</u> were offered for all health care professionals involved in the fall prevention pathways; all those involved in case finding, coordination, risk assessments and preventative interventions. The champions were responsible for organizing the education. This was offered in a smaller scale within local health centers and clinics, gatherings for all the GPs within the two boroughs, and from august 2018 through bigger events arranged annually by the Public Health Department in Oslo. The education focused on what may increase the risk of falling, osteoporosis, effect of different interventions, and sharing of practices and experiences.
- The main <u>technology enabler</u> in this intervention, was the digitalization in 2018 of the home visit assessment tool in the Electronic Patient Records (EPR) for the boroughs. In addition, a way of registering falls in the same EPR as well as a clear routine for how to document the multifactorial assessment and the follow up within this system, was a great support for those who did the home assessments and follow-up interventions. Digitalization of the fall reports in 2018 from the Injury Clinic, also was an improvement.

Timeline

Improving care coordination is a process. The investigators have, however, chosen to define these dates as the start of intervention, as this was the time when the systematic needs assessment together with the interdisciplinary and cross-sectoral approach to the fall-risk-prevention-problem, started.

These were the milestones which were chosen as start dates of the intervention:

1. Start of intervention in Nordstrand borough is set to January 1, 2015.

The Chief Medical Officer in Nordstrand mobilized the health professionals in a systematic needs assessment. They improved case finding, developed a checklist for multifactorial falls risk assessment through home visits, recruited more elderly at risk into exercise programs, and started education of health professionals including the GPs in coordination with the geriatricians at the University Hospital and local nursing homes. They also improved primary prevention with winter road safety measures and education of the general elderly population on fall risks and safety measures.

After Østensjø and the Injury Clinic at Oslo University Hospital joined the intervention in September 2016, the intervention in Nordstrand was done in collaboration and coordinated with these partners.

2. Start of intervention in Østensjø borough is set to September 1, 2016.

Østensjø started a collaboration with Nordstrand borough and the Injury Clinic in September 2016 after a grant proposal ("Samhandlingsmidler") was awarded funding. This led to a development of a formal multifactorial falls and fracture risk assessment tool for GPs, a revision of the interdisciplinary falls risk assessment tool from Nordstrand for home visits, establishing referral pathways within primary care and with specialist care established. In addition, education programs for both GPs and other health professionals in primary care was strengthened. Local champions were chosen and interdisciplinary working groups were established.

3. The Injury Clinic supported case finding from September 2017

All municipalities started receiving **fall reports** regarding consenting patients with fall injuries treated at the Injury Clinic at the University Hospital in Oslo from September 2017. This improved the case finding in both Nordstrand and Østensjø, who already had a coordinated care plan in place, which were presumed to be the crucial part of the intervention. The 13 other municipalities did not have the same coordinated care. Their patients received care as usual, which varied between the boroughs.

4. The end of the study period is set to December 31. 2019

The intervention in Oslo expanded to include most of the city boroughs after 2019. From January 2020 five more boroughs started care coordination, another five during 2021 and further one in 2022. The end of the study period with comparison between the two boroughs who started this intervention and the others, is therefore set to the end of 2019, before the 13 others began their systematic coordination of care.

Statistical Analysis Plan

The investigators will use a controlled before and after study design to evaluate this intervention.

The cohort

All elderly 65 age or older in Oslo are included in Oslo Fall Cohort with registry data from Statistics Norway, the National Population Registry, Norwegian Patient Registry (NPR), and the Electronic Patient Records for the health services in the local municipalities. Data is available on all participants from 2010 and the investigators will start following them from January 2012 until December 2019 with the intervention starting as specified in the timeline (see above). The study will follow each cohort participants prospectively and analyze the data by Cox proportional hazards regression or similar.

Fall injury will be included as a time-varying exposure variable. The individuals in the cohort are all registered as non-fallers until they are registered with a new fall injury in the NPR database, when they shift status to fallers.

Exposure categories

• Fallers in the intervention boroughs

Fallers 65+ years from the borough of Nordstrand from January 1. 2015 Fallers 65+ years from the borough of Østensjø from September 1. 2016

• Fallers in the control boroughs

Fallers 65+ years from all the 13 other boroughs of Oslo.

Non-fallers

All non-fallers from the complete Oslo population 65+ years.

Main analysis: In the main analysis (2015-2019), fallers from the two intervention boroughs, Nordstrand (from January 2015) and Østensjø (from September 2016), will be compared with fallers from the control boroughs during the intervention. In addition, the two categories of fallers will also be compared with the non-fallers. A similar analysis will be performed before the intervention started using data from 2012-2013. Any differences between the intervention and control boroughs before the intervention started will be taken into account.

In a <u>secondary analysis</u>, the total incidence (not restricted to fallers) of hip fracture in the intervention boroughs will be compared with the incidence of hip fracture in the control boroughs, and a similar comparison will be made before the intervention started. Adjustment for possible time trends will be considered.

Primary outcome variables

- Hip fracture
- Admittance to nursing home, long term
- Death (all-cause mortality)

Secondary outcome variables

Other fall injuries

In each analysis, participants with a hip fracture or living in a nursing home at baseline will be excluded.

Statistical power

According to statistics from NPR before the intervention started, around 22% of the home dwelling elderly treated for a fall injury came from the intervention boroughs of Nordstrand and Østensjø.

If 22% of the patients with falls are exposed to the fall prevention intervention and 607 of all fallers suffer a hip fracture during a follow-up of five years (2015-2019), it will enable us to detect a relative risk reduction of 24% (RR= 0.76) at the 0.05 significance level with a power of 80%.

Data management and analysis

The Cohort Data is stored at Services for Sensitive Data (TSD) at the University of Oslo.

The analysis in the evaluation is based on registry data and no analysis relating the intervention to the outcomes has been done before registration in clinicaltrials.gov. The outcome variables are the same as indicated in the study protocol in the grant application to the Norwegian Research Council (NRC) in 2018.

¹ https://www.health.org.uk/publications/does-clinical-coordination-improve-quality-and-save-money

[&]quot; http://apps.who.int/iris/bitstream/handle/10665/274628/9789241514033-eng.pdf?ua=1