Project plan

1. Purpose of the project

This project aims to evaluate an intervention designed to reduce the incidence of fall-related injuries and increase mobility among elderly populations during the winter. In Sweden, 11 250 pedestrians older than 65 years of age annually seek emergency medical attention after fall accidents, 3300 of which are caused by slips due to snow and ice (Schyllander 2014). Many older individuals, especially women, experience a fear of falling which may inhibit their physical activity and mobility in ways that negatively impacts their mental and physical health (Scheffer et al., 2008). This fear increases during the winter months due to the increased slipperiness caused by snow and ice, in which an increased risk of falling poses a limitation to the outdoor, active mobility of elderly populations during colder periods (Pohl et al., 2015). The burden on emergency departments also increases sharply during these months due to the spike in fall-related injuries that follows with colder temperatures and snowy weather (Gyllencreutz, Björnstig, Rolfsman, & Saveman, 2015). In our proposed project, we aim to take a more detailed look at a societal intervention that has begun to spread across Swedish municipalities, in which some municipalities have taken effort to distribute studded footwear to their elderly residents, free of charge. Using a mixed methods-approach (i.e. mixing both quantitative and qualitative analyses), we hope to answer a range of socially relevant research questions that may help policy makers, as well as the public, to make informed decisions regarding such interventions. Specifically, these questions are:

- Q1: How do elderly persons perceive risks as pedestrians? How do they experience the need for, use of, and designing of studded footwear? Does the use of studded footwear allow them to be more active during the winter? Which factors can optimize compliance with municipal studded footwear interventions?

- Q2: What can be learned from the implementation process in municipalities that have implemented free studded footwear programs?

- Q3: What are the population-level effects on pedestrian fall-injuries in municipalities that have distributed studded footwear?

- Q4: Are the efforts cost-effective?

2. Expected results and societal relevance

Our expectation is that the results from this project, whatever they show in the end, will be useful to municipal decision-makers and practitioners working with safety among the community-dwelling elderly. If we find strong evidence that the studded footwear programs are cost-effective, we will be able to make recommendations on large-scale implementation and optimization of such programs. If not, we hope that our qualitative studies will uncover areas for improvement and modification so that they can reach a higher level of effectiveness in preventing fall-related injuries while increasing the winter-time mobility of the elderly population.

3. Communication plan

We will, alongside the scientific publications that the project generates, communicate the results using press releases via the University's communications office. We will also communicate the results directly to relevant elderly organizations (e.g. the Swedish National Pensioners' Organisation, PRO) as well as Sveriges Kommuner och Landsting (SKL) and Trafikverket, which we hope means that our results will reach our two target populations: (1) the community-dwelling elderly and (2) municipal decision-makers and practitioners involved in elderly and/or pedestrian safety. Preliminary results from Gothenburg, based on Holmberg (2017), have already been presented by Holmberg & Bonander at SKL:s Trafik- och gatudagar in Stockholm on the 16th of October, 2017.

4. Collaboration with other universities and actors

This is a joint project that will be conducted primarily at the Center for Public Safety at Karlstad University together with the Health Metrics Unit at the Sahlgrenska Academy, University of Gothenburg. We have been in contact with PRO in order to validate its importance of this project to the elderly community. We will continue to maintain this contact throughout the project in order to make sure that our efforts are in line with societal needs. We will also work closely with practitioners at the municipalities that offer free studded footwear programs to make sure that all organizational aspects are covered and fully understood by our team.

5. Project team

Providing valid answers to the questions posed as a part of this project requires an interdisciplinary team of researchers with experience in epidemiology, nursing and health economics. Our budgetary plan includes funding for one doctoral student (ending with a two-year licentiate degree) with a specialization in elderly health, causal inference and health economics, who will do a majority of the work as part of his/her licentiate thesis. Supervising this student will be a joint effort by researchers at the Centre for Public Safety, Karlstad University (Carl Bonander, Ph.D., specializes in causal inference and epidemiology; Johanna Gustavsson, Ph. Lic., who specializes in elderly safety and nursing care), as well as the Health Metrics unit at the University of Gothenburg (Mikael Svensson, Professor/Ph.D, who specializes in health economics). Both environments offer a promising research setting for the project team.

The Centre for Public Safety (CPS, www.kau.se/cps) at Karlstad University is a research center that aims to facilitate interdisciplinary research within the fields of injury epidemiology and societal safety. Current and past research projects and dissertations produced by the team at CPS, which includes researchers from both the health and social sciences, involve many topics and methodological approaches relevant to the current project. For instance, we have produced two theses that focus specifically on elderly health and falls (Nilson, 2014; Gustavsson, 2015), and one thesis that focuses on causal inference in policy evaluation of injury-related interventions (Bonander, 2016). We have a close relationship with Trafikverket, who is currently funding a research program at CPS (The Vision Zero Academy), including a postdoctoral fellow that focuses specifically on implementation science in the context of the Swedish Vision Zero policy for road traffic injuries and its sister policies in other sectors. We also collaborate with Professor Per Nilsen, the director at the Lifestyle Intervention Implementation Research Group at Linköping University, in several projects. Hence, we are well equipped to provide a good research environment for a doctoral student with a focus on elderly health and policy evaluation. We will also be able to share insights and consult with many of these contacts during the course of the project.

The Health Metrics unit at the University of Gothenburg (www.healthmetrics.gu.se) consists of a multidisciplinary team of statisticians, health economists and epidemiologists that work on a wide range of methodological issues related to health statistics and economic evaluation of health interventions. Professor Svensson has supervised several doctoral students with a focus on health economic evaluation methods and applied cost-effectiveness studies and has published the research in leading health economics and evaluation journals. The Health Metrics unit also has a strong applied statistics research program, and several of the senior researchers from that program will be part of this project in an extended network and as potential mentors.

6. Originality of the project

Some small-scale studies exist on the effects of studded footwear on friction and safety (Berggård & Johansson, 2010; Gard & Berggård, 2006; McKiernan, 2005), but none have investigated the implementation and impact of free studded footwear programs. One master thesis conducted by Robin Holmberg under the supervision of Carl Bonander (principal investigator for this project) studied the impact of a free studded footwear program for the elderly population in Gothenburg (Holmberg, 2017). Using a quasi-experimental method and injury data from emergency departments, Holmberg was able to demonstrate a significant reduction in fall-related injuries due to slipping on snow and ice after the implementation of the program in 2013. This study sparked our interest for continued research into these programs, and it still remains to be answered whether or not these results can be replicated in other municipalities that have implemented these programs. We also, as the research questions stated above indicate, aim to delve deeper into the qualitative aspects of the intervention by performing interview studies with elderly people in similar municipalities, as well as conducting cost-effectiveness analyses. Hence, we believe that our study is original and of added value to decision-makers in light of the current state of the evidence.

7. Project implementation and research methods

We aim to conduct a comprehensive, mixed-methods evaluation of existing studded footwear programs in Swedish municipalities. A comprehensive program evaluation involves, according to Rossi, Lispey & Freeman (2003), the following steps:

1. Assessing the need for the program.
2. Uncovering and analyzing the program theory.
3. Studying the implementation through process evaluation.
4. Evaluating the impact of the program (i.e. outcome evaluation).
5. Performing an economic evaluation of the program.

With these steps in mind, we have designed a research plan that covers all steps, from needs assessment of the target population (community-dwelling elderly), to understanding and scrutinizing the underlying theories behind the program (2), collecting and analyzing data on the implementation process (3) via interviews with municipal personnel involved in the actual implementation, and impact (4) and economic evaluation (5) considering the costs of the programs against the benefits in terms of reductions in fall-related injuries. Table 1 gives a brief overview as to how we aim to answer these questions. See the sections below for a more detailed description.

Table 1. Overview of the study design for the project

Evaluation step	**Design 1**	**Design 2**
(1) Needs assessment	Descriptive statistical analysis following a target population (postal) survey using a random sample of the target population in Gothenburg as a case study (see **Section 7.1** for details).	Qualitative analysis following focus group interviews with elderly persons living in municipalities with studded footwear programs and municipalities that do not have studded footwear programs (see **Section 7.2** for details).
(2) Uncovering and analyzing the program theory.	We will follow the methods for theoretical evaluation proposed by Weiss (1995), further detailed in Rossi et al. (2003). The theoretical work involved in this step will be conducted in conjunction with the empirical studies	
(3) Process evaluation	Descriptive statistical analyses from an online survey that will be sent to representatives from all 291 municipalities that collects data relevant for the effect study in Step 4, most importantly to find out which municipalities have implemented these programs. We will also ask questions regarding the implementation activities in this study. (See **Section 7.4** and Step 4 below for details)	We will select and interview a random sample of municipalities. If the number of municipalities that have implemented a studded footwear program is small, we might choose to interview the entire sample. We will ask questions regarding the implementation process and analyze the data qualitatively, following the framework detailed by Saunders et al. (2005) (see **Section 7.3** for details).
(4) Outcome evaluation	We will conduct an online survey that will be sent to relevant personnel in all 291 municipalities in Sweden (i.e. a total population survey). The purpose of this survey, in the context of the outcome evaluation, will be to (1) identify which municipalities have implemented studded footwear programs, (2) for whom (i.e. who is eligible to collect), and (3) when the intervention started. This information will help us identify the effect using statistical methods for causal inference. Additional information will also be collected that can be relevant to understanding e.g. differences in effect and implementation (delivery methods, pricing (if any), percentage of the population who has claimed their pair, etc). Data on program costs will also be collected using this survey (for step 5).	Using the information collected from the online survey (see Step 3), we will conduct a quasi-experimental outcome evaluation using outcome data from administrative registers (emergency department data from the Swedish Traffic Accident Data Acquisition). We aim to use a difference-in-differences design, but we will also consider using a regression discontinuity design (see **Section 7.4** for details). We will consider both average effects of the programs, as well as the moderation effects induced by e.g. differences in program delivery methods, target population and implementation.
(5) Economic evaluation	Cost data will be collected in conjunction with the online municipal survey (see Step 4).	Cost-benefit and cost-effectiveness analyses will be conducted using the results from Step 4 (see **Section 7.5** for details). We will consider parameter uncertainty in all steps using simulation methods.

In the following text, which provides a more detailed description of each study contained in this project, we have split the presentation of the study design into the four research questions posed above:

Q1: How do elderly persons perceive risks as pedestrians? How do they experience the need for, use of, and designing of studded footwear? Does the use of studded footwear allow them to be more active during the winter? Which factors can optimize compliance with municipal studded footwear interventions?

To answer the first set of research questions, we aim to conduct a two-step study including a survey and an interview study. As mentioned above, several municipalities have programs for distribution of studded footwear. We are planning to survey the Gothenburg region were people older than 65 years of age have been offered a free pair of studded footwear since 2013 as a pilot case before conducting our effect studies, due to the relatively large size of the region (Gothenburg is the second largest city in Sweden) and length of experience with the program. In the first year of the program, 60 000 elderly citizens collected their studded footwear and after that 2000-3000 pairs have been collected annually. This means that approximately 62% of the target population has collected their pair. In later parts of the study (the process, outcome and cost-effectiveness evaluations), we will turn to a larger sample of municipalities.

7.1 Target population survey

We plan to draw a statistically representative sample from the population entitled to studded footwear in the Gothenburg region that will be sent a (postal) questionnaire. The questions will cover information such as if they have collected the footwear or not (and why), levels, situation(s), perceptions and motivation for use, willingness to pay, perceived need for the studded footwear intervention and other relevant questions identified in the inductive interview study (Section 7.2).

We believe that this study will provide valuable information in regards to understanding and interpreting the results from the effect and economic evaluation studies. The data on the number of collected pairs tells us that many individuals from the eligible population intend to use studded footwear, but in the survey we also aim to confirm the level of actual usage, which is an important parameter for the outcome evaluation (Section 7.4). We will hire a statistical consulting agency (e.g. Statistics Sweden or Statisticon) to aid with survey constructions and data collection for this part of the work.

7.2 Interview study

In this part we are planning to conduct focus group interviews with elderly citizens in municipalities that have a distribution program and with elderly persons in municipalities that do not. In both types of focus groups, two for each municipality, we will ask them to discuss their perceptions of risk as older pedestrians, preventative measures in general, and especially studded footwear. We also plan to inspire them to talk about what can encourage them to keep an active lifestyle. By conducting focus groups we get a deeper knowledge of how the elderly perceive risk and what they are willing to do to prevent falls. The focus group method is designed to collect a joint experience of a phenomenon. We plan to gather the groups at least two times each as this has shown to be a successful way to build confidence in the group and get solid results. By gathering elderly people and inspire them to focus on this subject we hope that they can share their views and form an

understanding of how they wish to target the risk of falls as pedestrians. Gustavsson will lead this part of the study due to her prior experience with focus group interviews and interviews with elderly persons (Gustavsson, Rahm, Jernbro & Nilson (2017); Gustavsson, Jernbro & Nilson (manuscript in preparation)).

Q2: What can be learned from the implementation process in municipalities that have implemented free studded footwear programs?

7.3 Process evaluation

Many evaluation studies examine only the outcomes associated with an intervention or program. Such evaluations are often criticized for skipping an important step in fully understanding the causal pathways from implementation to impact (Rossi et al. 2003), making it impossible to distinguish between impact failure due to theoretical problems with the intervention itself, or failures due to factors related to poor or incomplete implementation. Conducting a process evaluation alongside any outcome evaluation of community-based interventions (such as the programs we focus on here) is therefore recommend by e.g. the UK Medical Research Council (Moore et al. 2015). Hence, we aim to conduct a qualitative process evaluation in a sample of municipalities (the exact number will be determined during the collection phase).

The purpose of the process evaluation is to identify, and communicate, issues that can arise in the implementation phase of studded footwear programs and how they relate to the outcomes of the program (Saunders, Evans & Joshi, 2005). We will conduct interviews with municipal workers who administrated the implementation, using snowball sampling to identify other parties who can share insights into the issues involved if necessary (e.g. distributors, retail stores). Part of the process evaluation can also be integrated into the municipal survey (detailed below in the section related to the impact study), as well as the target population survey (the e.g. questions regarding dose and reach in the list below). We will focus on understanding how the key elements detailed by Saunders et al. (2005) can affect the intervention. These are:

- Fidelity (quality of the implementation),
- Dose and reach (proportion of the elderly population reached by information about the intervention, to which extent they use the studded footwear etc),
- Recruitment (strategies used to deliver information to the target population and recruit e.g. studded footwear retailers)
- Context (aspects of the natural, social or organizational environment that can affect the program outcomes).

The interview data will then be analyzed qualitatively using the framework described in Sauders et al. (2005) to identify common flaws (or successes) in implementation practice and the program logic/theory behind the studded footwear interventions. We expect that the insights gained from this will be especially useful for municipal decision-makers who plan to implement similar programs in their community, and for optimization of new and existing studded footwear interventions.

Q3: What are the population-level effects on pedestrian fall-injuries in municipalities that have distributed studded footwear?

7.4 Outcome evaluation

Before we can conduct the intervention effect study, we will need to collect some background data, including a survey of which municipalities that provide studded footwear to their elderly population, and the methods by which they do so, including when they began. This survey will also aim to gather data on costs for the economic evaluation study (see Section 7.5), and include questions relevant to understand certain aspects of the implementation process (see Section 7.3). This will be an online survey sent to representatives from all 291 municipalities in Sweden. The project group has prior experience with this type of survey to municipalities (Jönsson & Gustavsson , 2017; Olsson, Gustavsson & Andersson, 2012; Skröder & Gustavsson (manuscript in preparation)).

We are already aware of some municipalities that have adopted this approach, and when they began and which age groups are eligible. For instance, Stockholm began distributing studded footwear to residents older than 75 years in 2015. Borås municipality began during the same year, but distribute to residents aged 65+, and Uddevalla municipality has, since December 2016, distributed free safety studs to their residents aged 70+ years. Based on this snapshot of municipalities, we can conclude that there are variations in several features that can be exploited to identify intention-to-treat effects using routinely collected emergency department data on pedestrian falls. Primarily, we intend to use data from the Swedish Traffic Accident Data Acquisition (STRADA) register, which covers all emergency departments in Sweden and includes relevant variables such as municipality, date of accident, road conditions (e.g. covered by snow/ice), sex and age. If deemed necessary, we might also considering using the Swedish National Inpatient Register as a secondary data source, which provides less detailed information, but also covers accidents that occur outside the road traffic system. All data required for the suggested quasi-experiments below are available in these registers, or in other administrative registers (e.g. external demographic data from Statistics Sweden), which brings down the data collection costs for the effect study. Further, we will only require data at the aggregate level, which means that the data extraction costs will be minimal.

Our preferred design exploits the time-varying implementation of the interventions using younger age groups as internal controls for local weather effects and other, local unobservable changes, in a difference-in-difference-in-differences analysis. The method is an extension of the classic econometric difference-in-differences method, which compares changes over time between (at least) one treated and one untreated group. If the groups follow common trends on the outcome variable over time, unobservable confounding is controlled and the resulting estimates are unbiased (Angrist & Pischke, 2008). In most applications, different geographical units are compared. To further control for unobservable confounding variables, which is important in this case due to the impact of local weather on the outcome, internal controls can also be added to further adjust for unobservable changes within municipalities (see e.g. Long, Yemane & Stockley, 2010, for an application to an age-specific health reform in the United States). The results from a master's thesis supervised by Bonander (Holmberg, 2017), which focuses specifically on Gothenburg municipality, shows that this approach appears feasible, as we can observe that younger age groups are affected similarly by common weather shocks and follow common trends on the outcome in the pre-intervention period, which are two highly important identifying assumptions in this particular case. Using a difference-in-differences design, the student has provided evidence of an effect in Gothenburg

corresponding to a 36 percent reduction in emergency treated pedestrian fall injuries due to slipping on snow/ice after 62 percent of the target population had collected their studded footwear. In this extension of this study, we aim to test if this holds true for other treated municipalities as well.

A secondary design option is to use a regression-discontinuity design, exploiting the fact that different municipalities have chosen varying treatment eligibility cut-offs in terms of age to test for differences-in-discontinuities in fall-related injuries at these ages, similar to the design used by Bonander, Gustavsson & Nilson (2016). The approach is an extension of the quasi-experimental regression discontinuity (RD) design, which rivals the randomized controlled experiment in terms of internal validity under the assumption that certain conditions are met, the most important one being that confounders are randomly distributed around the treatment age cut-off. Specifically, regular RD designs handle unobserved confounders by only comparing individuals just below the sharp treatment age cut-off to individuals just above the cut-off, which generates a pseudo-randomization into treatment and control groups under the assumption that nothing else happens at that exact age that also affects the outcome variable (Hahn, Todd, & Van der Klaauw, 2001). Using a difference-in-discontinuity design, we are also able to control for common, unrelated changes at that the treatment cut-off age by comparing municipalities with different treatment age cut-offs, or no intervention. Hence, if we find a sharp jump in fall-related injuries at 65 in municipalities using this treatment age cut-off, but find similar effects in municipalities that use other age groups or do not distribute free studded footwear, we might assume the results are biased. Conversely, we might assume the effect is causal if the jump is unique, or significantly larger, in intervention municipalities.

Q4: Are the efforts cost-effective?

7.5 Economic evaluation

Providing free studded footwear is not a particularly costly intervention, but it does nonetheless consume public funds, and should therefore be subject to scrutiny from an economic perspective as well. Using the quasi-experimental effect estimates from study two and cost data from the surveys, we aim to conduct a cost-effectiveness study to determine whether the interventions are, on average, beneficial from a social welfare perspective, in order to determine whether a more widespread adoption should be recommended.

The first step of the economic evaluation will be to estimate the incremental cost of the intervention, which is the total cost with the intervention compared to the total cost with no intervention (i.e. not providing studded footwear). The costs of the intervention (i.e. providing the studded footwear, administrative costs etc.) will be compared with the potential cost reductions (e.g. reduced health care costs and social service costs due to fewer fall injuries). Depending on the effectiveness of the intervention the incremental cost may be positive (e.g. if the reduction of fall injuries is low and therefore provides no substantial health care cost reduction) or negative (e.g. if the reduction in fall injuries is large and therefore provides a substantial health care cost reduction). If the incremental cost is negative, i.e. the intervention reduces societal cost due to fewer fall injuries, we can directly conclude that the intervention is cost-effective.

If, however, the incremental cost is positive (the intervention increases societal costs), we move on to the second step and compare the incremental cost with the health benefits in order to assess if the increased costs is motivated by adequate health benefits (compared to health benefits that could be reached by spending the same amount of resources on other interventions). We will, among other measures, estimate health benefits in the form of Quality Adjusted Life Years (QALY), which combines the effects on reduced mortality and increased health-related quality of life from a beneficial health intervention. By relating the costs of the intervention to the health benefits measured in QALYs we can compare the cost-effectiveness of this intervention with a vast number of other public health interventions in order to determine its relative cost-effectiveness.

8. Project period and time plan

The project will take place over course of three years, from September 1st 2018 to September 1st 2021.

Year 1

- The doctoral student will take courses in causal inference and health economics.
- Ethical approval for the target group survey and interview studies will be applied for by Bonander and Gustavsson.
- The online municipal survey and the target population survey (in Gothenburg) will be conducted by Bonander and Gustavsson, who have conducted similar surveys before.
- The doctoral student will, together with Bonander and Gustavsson, initiate the process evaluation study.

Year 2

- The doctoral student will collect and analyze data for the quasi-experimental effect study, and author paper one for their licentiate thesis (quasi-experimental study) together with Bonander.
- Gustavsson will conduct the focus group interview study together with the doctoral student or a research assistant.
- The process evaluation study will be finalized.
- The doctoral student will continue to take courses until the required 30 ECTS credits are met.

Year 3

- The doctoral student will conduct the economic evaluation study and draft paper two for their licentiate thesis under Svensson supervision.
- The licentiate thesis, which includes two papers (at least one published), should be finalized and defended.
- The results from the comprehensive evaluation study will be documented in a report (written in Swedish), primarily authored by Bonander & Gustavsson.
- The results will be communicated (see Section 3 for details).

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