Supplementary Appendix

This document contains detailed descriptions of methods and materials (with discussion of noteworthy limitations associated with each parameter estimate), and supplementary tables and figures for Bonander, Holmberg, Gustavsson & Svensson *A model-based economic evaluation of ice cleat distribution programs for the prevention of outdoor falls among adults from a Swedish societal perspective*. It is intended to provide additional insight into the authors' work and the data that supports the economic analysis presented in the paper, including a transparent account of the known limitations of the study. All costs are presented in 2018 Swedish kronor (SEK) throughout the supplement.

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1. Methods

In this section, we provide additional details about the input data and estimation of the parameters of the simulation model described in the main text. We reproduce the equation for the model here for convenience. We estimate the net present value (NPV) of an ice cleat distribution program in municipality *j* over the time period t = 1, 2, ..., T, compared to a business-as-usual scenario, using:

$$NPV_j = \left\{ \sum_{t=1}^T \frac{1}{(1+r)^t} \left[b \left(y_{jt} \left(\frac{\omega_t \theta_j (1/RR - 1)}{1 + \omega_t \theta_j (1/RR - 1)} \right) \right) \right] \right\} - cN_j, \tag{1}$$

where *t* denotes time in years from baseline. The other parameters are introduced in the main text. In the upcoming subsections, we detail the data and estimation used for each.

1.1 Assumed discount rate

We used r = 0.035 to discount future benefits (i.e., 3.5% per year), which is the rate recommended by the Swedish Transport Administration (The Swedish Transport Administration, 2020). We also considered r = 0.05 in our deterministic sensitivity analysis. Costs are not discounted since they all refer to the first year of the intervention, and discounting thus refers to future benefits only.

1.2 Estimation of program costs

We sent an electronic survey to all municipalities in Sweden (n = 290) to collect data on existing ice cleat programs. Of the municipalities that reported having a previous or existing ice cleat distribution program (n = 78), 34 reported data on total program costs and the total number of ice cleats pairs purchased by the municipality. Preferably, all costs associated with the program should be identified and valued, which include the cost of procuring and distributing the ice cleats as well as the time costs for the personnel that lead and work with the ice cleat distribution program.

The obtained cost data varied in quality; some municipalities only reported a total program cost without specifying which cost items were included in their calculations (n = 14). The remaining municipalities reported which cost items they considered. Most of these municipalities reported only the procurement and distribution costs (cost of ice cleats, n = 12), while others provided high-quality data on ice cleat costs, staff costs and (when applicable) the cost of media campaigns related to the program (n = 8).

A histogram of the obtained cost data is presented in Figure S1. Overall, the average reported program cost per purchased pair of ice cleats was 89.9 SEK (SD: 56.8, range: 24.0 to 279.0). We compare the reported costs by groups based on reporting quality in Figure S2. The mean cost estimate was slightly lower in the group that only reported ice cleat costs, but there was no significant differences in means depending reporting quality according to a one-way analysis of variance (ANOVA; p = 0.35), nor in medians according to a Kruskal-Wallis test (p = 0.47). We also found no evidence of a relationship between program cost per ice cleat and program scale (as measured by the number of purchased ice cleats; Spearmans's rho = 0.1, p = 0.56), indicating that the scale of the program is not an important biasing factor in our economic model.

In our model, we make the simplifying assumption that the municipality buys one pair of ice cleats for each population member over the age of 65 years to estimate the total program cost in a specific municipality. This number is based on the total program cost for an average program and should, in addition to the costs of ice cleats, also include administration costs and the cost of media campaigns (as reported by our sample of municipalities with existing programs).

1.2.1 Uncertainty estimation

In the probabilistic sensitivity analysis, we use the mean and standard error of the logarithm of the cost per purchased ice cleat from survey data to simulate costs assuming a log-normal distribution. In the deterministic analysis, we consider a scenario where we replace the mean cost with highest reported cost (279 SEK).

1.2.2 Strengths and limitations

Strengths:

- We use data from 34 existing programs in Sweden to estimate costs.
- There is no evidence of scaling effects on costs depending on program size.

Limitations:

• We lack insight into the exact calculations (i.e., data per cost item) used by many municipalities. However, the cost data is consistent across groups of municipality based on reporting quality.

1.3 Estimated effect of ice cleat use on injury risks

We rely on data from a randomized controlled trial (RCT) conducted on 109 older adults (age range: 65-96 years) in Wisconsin, USA (McKiernan, 2005). To our knowledge, this is the only study that provides a credible estimate of the causal effect of ice cleats on falls and fall-related injuries. The study is relatively small and the estimates, which are based on only a few events, are thus imprecise. The estimated *RR* for falls is 0.45 (95% CI: 0.23-0.85). For injurious falls, the estimated *RR* is 0.1 (95% CI: 0.02-0.53).

There are reasons to suspect that these estimates may be overly optimistic. For instance, the trial sample only includes individuals who had fallen at least once during the previous year. While it is not directly obvious that the *RR* would differ from a general population sample, one could suspect that the efficacy might be smaller in healthier groups.

In addition, the estimate for injurious falls is only based on 11 events (10 in the control group, 1 in the treatment group), and can therefore be characterized as an extreme estimate based on very little data. The *RR* for falls is based on 62 events (43 in the control group, 19 in the treatment group). While we are more interested in the effect on injurious falls, we believe that the more conservative estimate for falls may be more appropriate given the sample size it is based on. Further, ice cleats are designed to

reduce the risk of injury via a reduction in fall frequency. Unless ice cleats also have an effect on injury severity, a reduced fall risk could serve as a reasonable proxy for reduced injury risk. We therefore rely on the *RR* for falls in our base case estimation, which is more conservative than relying on the estimate for injurious falls.

1.3.1 Uncertainty estimation

We assume a log-normal distribution for the *RR*, with standard errors derived from the reported confidence intervals, in our probabilistic analyses. In our deterministic sensitivity analyses, we decreased the assumed effect by half (RR = 0.73) and by three-quarters (RR = 0.875), given our concern that the effect size may be overstated for a general population of older adults.

1.3.2 Strengths and limitations

Strengths:

• We rely on estimates from an RCT, which is the gold standard for estimating the causal effects of treatments.

Limitations:

- The effect estimate comes from a single study with a small sample.
- The estimate is based on a sample of older adults from the US who had a history of falls, and may not be directly generalizable to our target population.

1.4 Estimation of the monetary benefit per injury averted

We used the most recent estimates of the monetary value of an averted pedestrian fall injury (*b* in Equation (1)) used for economic evaluations by the Swedish Transport Administration (3 380 826 SEK) (The Swedish Transport Administration, 2020), as we believe that this is the most relevant estimate for the context of our study. An English summary of their guidelines can be found <u>here</u> [accessed 2021-02-18]. Generally speaking, the monetary benefit per injury averted (from a societal

perspective) is a combination of the reduced material costs in terms healthcare utilization, production loss (e.g., due to sick leave or death), administration costs, material damage to property, and informal care (e.g., by family or friends), in addition to the willingness to pay for an averted injury in the population (The Swedish Transport Administration, 2020). The willingness to pay is intended to reflect the utility loss from physical and psychological suffering in monetary terms.

Given that our target population is above the standard retirement age in Sweden, we subtracted costs related to production loss (34.7% of the total material costs according to (Olofsson, Gralén, et al., 2016)), which is 56 075 SEK * (1-0.347) = 36 612 SEK. This gives an adjusted monetary benefit of 3 361 363 SEK, which we used in our main analyses. This adjustment does not affect the end result to a meaningful extent, as the majority of the estimated benefits per averted injury (3 324 751 SEK, 98.3\%) are related to the estimated willingness to pay for an averted pedestrian fall injury. Fatal falls are not included in this figure due to a very low fatality risk related to pedestrian falls¹.

The willingness to pay estimate is based on a stated preference survey using the so-called chained approach, which combines willingness to pay and standard gamble questions, conducted by Olofsson, Persson *et al* (2016) (n = 880). The survey was conducted on the behalf of the Swedish Transport Administration to estimate the value of QALYs lost due to fatal and non-fatal traffic-related accidents in Sweden. These estimates were then related to the average QALY loss per pedestrian fall injury, which is based on EQ-5D follow-up surveys collected from a sample of individuals injured and treated (emergency and/or inpatient care) for pedestrian falls in Sweden (n = 256, mean age: 64 years, average estimated QALY loss: 1.387) (Olofsson, Gralén, et al., 2016). The surveys were collected up to a year after the event, and extrapolated to the remaining expected life years per respondent with a

¹ According to public use data from the Swedish National Patient and Cause of Death registers (accessed 2021-02-16 via the National Board of Health and Welfare's website; <u>www.socialstyrelsen.se</u>), 30 people above the age of 65 years died due to a snow or ice-related fall (ICD-10 code: W00) in Sweden between 2008-2017. Meanwhile, 53 791 patients over 65 years were treated at inpatient and/or outpatient facilities due to non-fatal snow or ice-related falls, which implies a very low case-fatality rate.

discount rate of 3.5% per year as recommended by the Swedish Transport Administration (The Swedish Transport Administration, 2020).

1.4.1 Uncertainty estimation

In the main text, we present a deterministic sensitivity analysis based on an alternative (lower) willingness to pay estimate given its central role in the estimated monetary benefit per injury averted. Our choice of alternative is based on the observation that the implied willingness to pay per QALY assumed by the Swedish Transport Administration is approximately 2 400 000 SEK, which is about five times the number recommended for reimbursement decisions within the healthcare sector in Sweden (500 000 SEK) (Socialstyrelsen, 2011). Assuming this willingness to pay per QALY instead, the estimated monetary benefit per injury averted is reduced to $(1.387*500\ 000) + (36\ 612) = 730\ 112$ SEK. We used this figure in our sensitivity analysis.

1.4.2 Strengths and limitations

Strengths:

• Estimates of monetary benefits per averted injury are directly relevant to the decision-making context in this study; they are used by the Swedish Transport Agency and based on data from a Swedish samples.

Limitations:

• The QALY estimates are based on a sample that is, on average, younger than our target population. All else being equal, the extrapolation to remaining life years is therefore likely to overestimate the QALYs lost for an average person aged 65+ years. However, older people are more fragile and likely to suffer from severe injury after a fall, which speaks for a potential bias in the opposite direction as well. We also note that the age distribution of older people (65+ years) treated at inpatient and outpatient facilities for ice and snow-related fall injuries has the highest density at 65 years (Figure S3), indicating that a sample with a mean

age of 64 years (as was used to estimate lost QALYs) may be reasonably accurate for our target population.

 Willingness-to-pay studies to identify the monetary value of the health risks are known to have potential biases, such as hypothetical bias (overstating WTP because no real transaction is made) and scope bias (difficult for respondents to assess how WTP relates to small changes in baseline risks).

1.5 Estimation of annual injury rates per municipality

The National Board of Health and Welfare supplied us with aggregate, municipality-level data on the number of patients aged 65 years or above treated for snow and ice-related injuries (International Classification of Diseases [ICD-10] external cause code: W00) as reported to the Swedish National Patient Register. For each municipality (n = 290), we received an aggregate sum of patients treated at outpatient and/or inpatient facilities over the period 2008-2017.

We obtained data on age- and period-specific population size for each municipality from Statistics Sweden (based on data from the total population register), which we used to determine the number of person-years of observation in each municipality.

Finally, the Swedish Meteorological and Hydrological Institute (SMHI) supplied us with estimates of the yearly number of days with snow cover per municipality. The values were interpolated from 338 measurement stations located around the country (collecting data on snow depth) and correspond to estimates for the regional center in each municipality (averaged over the period 2003 to 2018).

Statistical model

We modelled the total number of patients across the entire 10-year period (O_j) as a function of annual number of snow days (S_j) and person-years of observation (P_j) . We used the *mgcv* package for *R* to fit a negative binomial generalized additive model with automatic knot selection for the spline terms. The model can be expressed as:

$$\ln O_j = \alpha + f(S_j) + f(\ln P_j) + \epsilon_j$$

where α is the intercept, $f(S_j)$ and $f(\ln P_j)$ are flexible spline terms and ϵ_j is the error term. The model output and estimated splines are presented in Table S2 and Figure S4, respectively. To estimate y_j for our simulation model (Equation (1)), we computed an annualized number of patients using $\hat{y}_j = \exp(\widehat{\ln O_j})/10$.

1.5.1 Uncertainty estimation

We used the point estimate $\ln O_j$ and its associated standard error (on the log scale, obtained using the *predict* function in R) to simulate the conditional mean injury rate in a given municipality depending on its age-matched population size and climate. We assumed a log-normal distribution for the conditional mean.

The number of ice and snow-related injuries can also vary heavily from year to year within the same municipality. As we do not have access to annual data for each municipality, we used the relative year-to-year variability around an average year at the national level to characterize yearly fluctuations around the municipality-specific conditional means. We restricted this analysis to inpatient data in order to gain access to a longer time series (2001-2019; publicly available data from the National Board of Health and Welfare; <u>www.socialstyrelsen.se</u> [accessed 2021-02-16]). The time series is presented in Figure S5. In each draw of the simulation, we drew a random number from a log-normal distribution with the same mean and standard deviation as the data in the figure. The resulting number is used as a multiplicative factor x_t to model the yearly variation around the estimated conditional mean. The estimated injury rate at time *t* and municipality *j* is then given by $\hat{y}_{jt} = x_t \hat{y}_t$.

1.5.2 Strengths and limitations

Strengths:

- Swedish population registries contain virtually complete data on population size (Ludvigsson et al., 2016).
- The Swedish National Patient Register has complete national coverage of outpatient and inpatient facilities, and the data is considered to be of high quality (Ludvigsson et al., 2011).
- We can model local annual injury rates as a function of climate and population size.

Limitations:

- Potential coding errors (e.g., missing external cause codes) in the hospital data may lead to underestimation of the true injury rate per municipality. This could, in turn, lead to an underestimation of the absolute intervention effect in our simulations.
- Seventy-eight municipalities have already implemented ice cleat programs (74 of them after 2012), and the effects from these may be present in some municipality-years during the period. This would artificially lower the baseline rate and, because we use relative effect measures to model effects on injury rates, this could bias the overall result towards the null (i.e., underestimate the actual effect of the existing ice cleat programs). Our data do not allow us to separate the already treated municipality-years. However, we believe that the effect on the overall result is likely to be small. The most substantial part of the effect is likely limited to the first intervention year (Bonander & Holmberg, 2019), and because our data represents an aggregate over the period 2008-2017, the influence of the interventions on the period-average rate should be relatively small.

1.6 Estimation of the share of potential compliers – initial change

Conceptually, we consider the population to consist of three different groups, only one of which will be susceptible to change. First, we have the always-takers. This group would own and (always or almost always) use ice cleats during icy road conditions even without a program, and will therefore not contribute to the effect of the program. The same is true for the never-takers, who will not change their behavior even when presented with the option to obtain a free pair of ice cleats. Finally, we have our group of interest; the potential compliers. These individuals do not currently use ice cleats, but will change their behavior because of the program.

Estimating the proportion of compliers presents some challenges, as it requires data on current usage rates in addition to some way to discern potential compliers from never-takers. A crude option would be to assume that all current non-users will start using ice cleats, but doing so would likely overestimate the effect of the program. Instead, we attempt to estimate the share of potential compliers as a subset of non-users who have a positive attitude towards the efficacy of ice cleats.

To estimate the share of potential compliers in each municipality, we obtained data from a national survey sent to random population sample aged 18-79 years by the Swedish Civil Contingencies Agency in 2007 (n = 4608 respondents aged 65-79 years; response rate: 62.1%). The general aim of the survey was to inquire about individual safety practices and attitudes towards safety measures. Among a large battery of questions, the survey asked respondents if they wear ice cleats during icy road conditions (or similar; e.g., studded footwear), as well as questions about their beliefs about the personal utility of ice cleats as a risk reduction measure. Our best theoretical prediction, based on theories of behavior change related to injury prevention (Gielen & Sleet, 2003), is that individuals who report never or almost never using ice cleats during icy road conditions ("non-users"), but state that they have a positive perception of their efficacy ("I believe that ice cleats are important or very important for increasing my safety during slippery road conditions") could be potential compliers. On the other hand, non-users who have a negative or indifferent perception of the efficacy of ice cleats would likely not change their behavior (i.e., remain non-users even with a program).

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The survey data also contained information about each individual's municipality of residence. We combined the questions about ice cleat use and attitudes to obtain estimates of the proportion of compliers ("non-users with a positive attitude towards the efficacy of ice cleats") in the age group over 65 years in municipality *j*. Specifically, we fit a logistic generalized additive model with cubic splines (using the *mgcv* package for R (Wood, 2011)) to model potential compliance as a function of the annual number of snow days in the municipality (Table S2). This model allows us to estimate the proportion of compliers in a municipality depending on its climate. This number gives us the estimate of the initial change (θ_i in Equation (1)).

On average, our data imply that the baseline proportion of ice cleat users in the target population is 0.52 (52%). This number is close to a more recent estimate from a similar survey from 2014 (Gustavsson et al., 2020), which, unfortunately, lacks the attitude question needed to estimate the share of potential compliers. Nonetheless, the similarity in usage rates between the older and newer surveys implies that time trends in ice cleat use are not a large issue for the validity of our model.

Overall, the estimated share of compliers in the survey data is 0.25 (25%). We stress that the validity of this number is difficult to verify. According our survey of municipalities who have implemented ice cleat programs, about 40% of their target population obtained a free pair of ice cleats during the program. However, this figure likely contains both individuals who already owned a pair of ice cleats in addition to new users. In that sense, our estimate is likely to be closer to the truth.

1.6.1 Uncertainty estimation

We used the conditional mean estimate in each municipality and its associated standard error from the logistic model (on the logit scale; obtained using the *predict* function in R) to simulate the initial compliance in each municipality in the probabilistic sensitivity analysis. We assumed a normal distribution on the logit scale, and then transformed the logits to proportions.

However, the main source of uncertainty in this parameter is not sampling uncertainty; it is the conceptual uncertainty related to the ability of the survey responses to capture true compliance as well

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as uncertainty in the actual causal effect of ice cleat programs on ice cleat use. While we believe that our estimates are closer to the truth than simply assuming that all non-users will begin to use ice cleats as a consequence of the program, our model may still severely overestimate the true number of compliers. In our deterministic sensitivity analysis, we therefore consider an extreme scenario in which the average compliance is considerably lower (5%) than our model-based estimates (25%).

1.6.2 Strengths and limitations

Strengths:

- Our compliance estimates are based on empirical data from a Swedish sample (i.e., are contextually relevant) and have indirect support in behavior change theories related to injury prevention.
- The estimates should reflect a subpopulation of individuals who would pick up a free pair of ice cleats upon being offered, which may consist of both true compliers (new users) and previous users.
- The estimates are likely a more accurate representation of the true number of compliers than assuming that all current non-users would starting using ice cleats as a consequence of an ice cleat distribution program.
- We can model the share of potential compliers as a function of local climate.

Limitations:

- Our definition of potential compliers has uncertain concept validity with respect to true compliers (which is probably a subset of the share of estimated compliers in our data). This may lead to overestimated intervention effects.
- True compliance may also depend on factors other than climate (such as factors related to the quality of implementation or other contextual factors).

1.7 Estimation of the share of potential compliers – change over time

Quasi-experimental evidence from Gothenburg suggests that the effect of ice cleat programs may taper off after the first year (Bonander & Holmberg, 2019). The estimated impact in Gothenburg was relatively large in the first year after implementation (-45%). However, the long-term impact as smaller when averaged over a four-year period (-10%).

We include this dynamic in our model via the time-varying parameter ω_t in Equation (1). Assuming that the reduced effect can be explained by a reduction in the share of compliers over time (i.e., that ice cleat use returns to its previous levels after a certain period of time), we calibrated a monotonically decreasing *compliance curve* to data and estimates from Gothenburg. According to our model, the expected initial in Gothenburg is $\theta_j = 0.291$. Assuming a *RR* of 0.45 for the effect of ice cleats (see separate section above), a simple pattern where compliance decreases by $\theta_j * 0.75$ in the second year, $\theta_j * 0.50$ in the third year and $\theta_j * 0.25$ calibrates well to the estimated 4-year impact in Gothenburg. To err on the conservative side, we assume that the effect is gone after this point. Thus, we set ω_t to 1, 0.75, 0.5 and 0.25 for years 1,2,3 and 4 and 0 for years 5 and beyond in Equation (1).

1.7.1 Uncertainty estimation

In our deterministic sensitivity analysis, we also considered a scenario where the effect on ice cleat use is limited to the first year.

1.7.2 Strengths and limitations

Strengths:

• The compliance curve is calibrated to empirical estimates based on a difference-in-differences study of an ice cleat distribution program in Gothenburg.

Limitations:

• The true shape of the compliance curve is unknown and may vary depending on local contextual characteristics as well as factors related to the implementation of the program (e.g., degree of success in distribution, reach and communication).

2 Supplementary figures

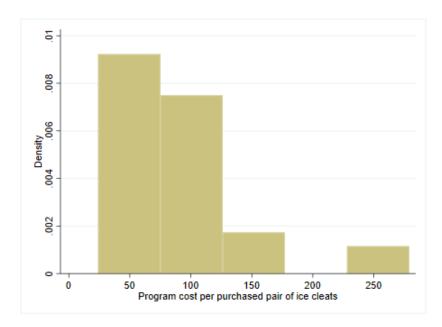


Figure S1. Distribution of reported program costs from 34 municipalities with existing or previous ice cleat distribution programs.

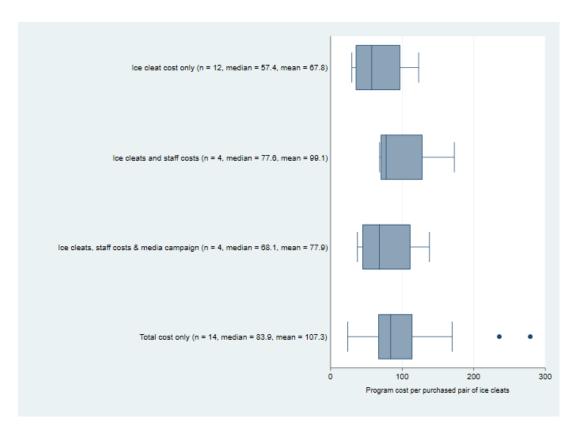


Figure S2. Distribution of reported program costs by groups based on cost item reporting quality.

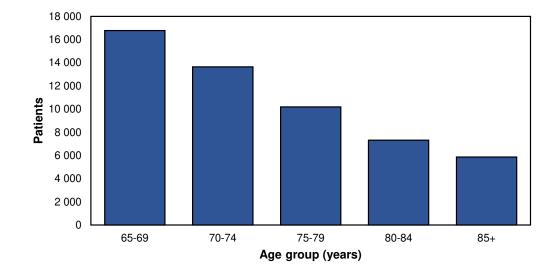


Figure S3. Number of patients (65+ years) treated at outpatient or inpatient facilities for snow or ice-related fall injuries (International Classification of Diseases [ICD-10] external cause code: W00) in Sweden by age group over the period 2008 to 2017. Data source: National Board of Health and Welfare (National Patient Register; Public data access at https://sdb.socialstyrelsen.se/if_ska/val.aspx [accessed 2021-02-16]).

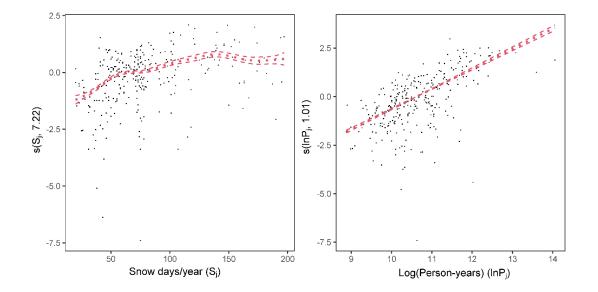


Figure S4. Effect plots for the smooth terms in the negative binomial generalized additive model predicting municipality-specific injury rates. Red lines represent point estimates and their 95% confidence intervals. Dots are residuals.

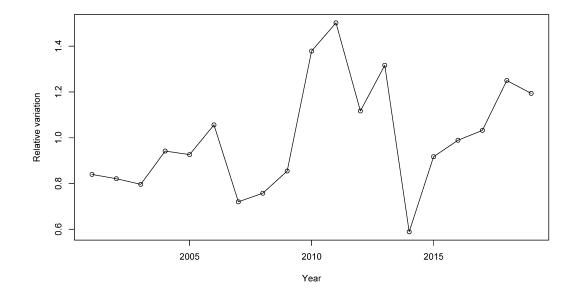


Figure S5. Year-to-year variability in patients treated at inpatient facilities for snow or ice-related fall injuries in Sweden around an average year in the period 2001 to 2019 (1 on the y-axis; multiplicative scale).

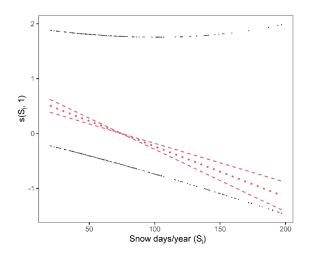


Figure S6. Effect plot for the smooth term in the logistic generalized additive model predicting the probability for compliance with ice cleat programs. Red lines represent point estimates and their 95% confidence intervals. Dots are residuals.

3 Supplementary tables

Table S1. Model output from the negative binomial generalized additive model predicting ice and snow-related injury rates in Swedish municipalities based on annual number of snow days and the logarithm of the person-years of observation.

Parametric coefficients	Estimate	Standard error	p-value
α	4.89	0.02	<0.001
Smooth terms	EDF*		p-value
$f(S_j)$	7.22		<0.001
$f(\ln P_j)$	1.01		<0.001
Model information	Observations	Deviance explained	Negative binomial parameter
	290	92.9%	14.57

*Estimated degrees of freedom for smooth terms, see Figure S4 for a visual representation.

Table S2. Model output from the logistic generalized additive model predicting the probability for compliance with ice cleat programs among older adults (65+ years) in Sweden based on the annual number of snow days in their municipality of residence.

Parametric coefficients	Estimate	Standard error	p-value
α	-1.14	0.03	<0.001
Smooth terms	EDF*		p-value
$f(S_j)$	1.003		<0.001
Model information	Observations	Deviance explained	
	4608	1.5%	

*Estimated degrees of freedom for smooth term, see Figure S6 for a visual representation.

4 References

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