Model-based economic evaluation of ice cleat distribution programmes for the prevention of outdoor falls among adults from a Swedish societal perspective

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ABSTRACT
Background Slipping on snow or ice poses a significant health risk among older adults in Sweden. To combat this problem, about 80 Swedish municipalities have distributed ice cleats to older citizens (65+ years old) over the last decade. This paper details a cost–benefit analysis of such programmes.

Materials and methods We developed a decision-analytical model to estimate the costs and benefits of ice cleat programmes in Swedish municipalities compared with a business-as-usual scenario. The modelled benefits of the programme were based on effect estimates from previous research, data from population and healthcare registers and a survey of attitudes to and actual ice cleat use. The modelled costs of the programme were based on resource use data collected from 34 municipalities with existing ice cleat programmes. We assessed heterogeneity in the potential impact and benefit-to-cost ratios across all Swedish municipalities as a function of the average number of days with snow cover per year. Uncertainty in the cost–benefit results was assessed using deterministic and probabilistic sensitivity analyses.

Results The average benefit-to-cost ratio was 87, ranging from about 40 in low-risk municipalities to 140 in high-risk municipalities, implying that the potential benefits of ice cleat programmes greatly outweigh their costs. Probabilistic and deterministic sensitivity analyses support the robustness of this conclusion to parameter uncertainty and large changes in assumptions about the magnitude of the impact on ice cleat use and injuries.

Conclusion The benefits of distributing ice cleats to older adults appear to outweigh the costs from a Swedish societal perspective.

INTRODUCTION
Pedestrian falls are increasingly being recognised as an important contributor to the burden of transport-related injuries among older adults.1–3 The problem is particularly prominent in colder regions,4,5 where many outdoor falls are caused by icy conditions.1,6–7 As a low-cost complement to conventional strategies for combatting ice-related injuries during the winter season (eg, snow removal and road salting), about 80 Swedish municipalities have implemented programmes to distribute ice cleats to their older residents at some point in recent years.8 Ice cleats can reduce the risk of ice-related falls,9–12 and programmes that distribute ice cleats to older adults have the potential to reduce injury rates at the population level, according to a study from Gothenburg (located in the south-west of Sweden).13 Despite this, there have been no comprehensive economic evaluations of these programmes covering all Swedish municipalities. While empirical data from Gothenburg suggest that the benefits may outweigh the costs,13 the impact of these programmes may vary depending on factors related to local climate conditions, such as current ice cleat use and the local risk of snow-related and ice-related fall injuries. This knowledge gap hampers the possibility for informed decisions about implementing ice cleat distribution programmes elsewhere.

Model-based economic evaluations can help bridge the gap between available empirical evidence and local circumstances that affect the potential impact of an intervention.14 In this study, we develop a decision-analytical model to estimate the impact of ice cleat distribution programmes depending on local climate conditions and apply the model to conduct a cost–benefit analysis of ice cleat programmes in the context of all Swedish municipalities.

MATERIALS AND METHODS
Setting, location and target population
Swedish municipalities are local, self-governing authorities funded by municipal-level income taxes. They are responsible for providing several essential public services at the local level, including local traffic safety interventions. There are 290 municipalities in Sweden, with population sizes varying from about 2000 to 975 000 according to population data from Statistics Sweden. In 2019, we sent out an electronic survey to all Swedish municipalities to collect data on ice cleat programmes. Out of the 228 responses we received, 78 reported having distributed ice cleats at some point during the last decade (four before 2012 and the rest after). Most provided ice cleats (free of charge) to any citizen above the age of 65 years old. We therefore focus on this population in our study.

We also collected data on the number of purchased and distributed ice cleats and resource use (ie, costs) associated with existing programmes. The distribution data show that about 90% of all purchased ice cleats were distributed. Not all
Original research

Table 1  Model parameters, probability distributions and data sources for the decision-analytical model for economic evaluation of municipal ice cleat distribution programmes

| Parameter                                                      | Average (range, if applicable) | SE               | Distribution (probabilistic sensitivity analysis) | Data source                                                                 |
|---------------------------------------------------------------|--------------------------------|------------------|--------------------------------------------------|----------------------------------------------------------------------------|
| Annual number of snow-related or ice-related fall injuries at a function of population size and climate ($y_j$) | 21.6 (2.7, 472.6)              | Municipality-specific SE from regression prediction | Lognormal                                                                      | Municipality-specific and age-specific data from National Patient Register⁴⁷. Population data from Statistics Sweden⁴⁵. Annual number of snow days from the Swedish Meteorological and Hydrological Institute⁴⁶. |
| Initial change in ice cleat use as a function of climate ($\theta_j$) | 0.25 (0.09, 0.35)              | Municipality-specific SE from regression prediction | Logit-normal                                                                   | National survey (random sample, n=4608 aged 65+) conducted in 2007 by the Swedish Civil Contingencies Agency⁴⁹. |
| Compliance over time, multiplicative scaling factor ($\omega_1 \cdot \omega_5$) | Not available                  | None             | Calibrated* simulation model to results from quasi-experimental evaluation in Gothenburg⁴³. |
| Effect of ice cleat use (RR), log scale                       | -0.799                         | 0.333            | Lognormal                                                                      | Randomised controlled trial⁴², RR=0.45 (95% CI: 0.23 to 0.85)⁴. |
| Total programme cost per purchased ice cleat pair in 2018 Euros ($c$), log scale | 1.998                          | 0.100            | Lognormal                                                                      | Electronic survey sent to all Swedish municipalities (n=34 responses with cost data)*. |
| Benefit per averted injury in 2018 Euros                      | 329.783                        | Not available    | None                                                                          | Swedish Transport Administration⁴⁷. |

*Additional information on data and estimation is provided in the online supplemental file.

HR for falls (with or without an injurious outcome). Estimate for injurious falls was 0.1 (95% CI: 0.02 to 0.53) but was only based on a total of 11 events (one in the treatment group and 10 in the control group). Our preferred estimate (for falls) is supported by more data and is more conservative.

RR, relative risk.

municipalities purchased one pair per citizen; in terms of population coverage, the distribution rates imply that the programmes reached roughly 40% of the targeted age group in the average municipality.

Study design

We developed a decision-analytical model to estimate the costs and benefits of implementing an ice cleat distribution programme in a specific municipality $j$ compared with a business-as-usual scenario. The model synthesises previous research with estimates presented in this paper to perform a population impact scenario. The model synthesises previous research with estimates presented in this paper to perform a population impact scenario. The model synthesises previous research with estimates presented in this paper to perform a population impact scenario. The model synthesises previous research with estimates presented in this paper to perform a population impact scenario.

Table 1 provides an overview of the base-case inputs for the model and data sources used in the present investigation. The next section provides an overview of the decision-analytical model and our empirical analyses. The online supplemental file provides additional details on the data sources and estimation strategies. Analyses were performed in R, V.4.0.2.¹⁶

Human subjects statement

This study used anonymised, non-sensitive data and aggregate health data from secondary sources. No human subjects were directly involved.

Decision-analytical model

We used the following model to estimate the net present value (NPV) of an ice cleat distribution programme in municipality $j$ over the period $t = 1, 2, ..., T$:

$$\text{NPV}_j = \left\{ \sum_{t=1}^{T} \left[ \frac{1}{1+\omega_j \theta_j (1/RR-1)} \right] \right\} - cN_j, \quad (1)$$

where $t$ denotes time in years from baseline and $r$ is the discount rate for future benefits (we used 3.5% per year as recommended by the Swedish Transport Administration⁴⁵). The first term in Equation (1) measures the total monetary benefit of the programme. Several parameters determine the benefit of the programme, including the assumed monetary benefit per averted injury, denoted by $b$, and the assumed impact of the programme on the number of snow-related and ice-related fall injuries at year $t$, which is given by

$$y_j = \frac{\omega_j \theta_j (1/RR-1)}{1+\omega_j \theta_j (1/RR-1)} \quad (2)$$

Equation (2) can be used to estimate the impact of reducing the prevalence of a risk factor in a population.¹⁸ In our case, the risk factor is the lack of ice cleat use during icy weather conditions. In Equation (2), $y_j$ is the annual number of older adults (65+ years old) injured due to snow-related or ice-related falls in municipality $j$; $1/RR$ is the multiplicative inverse of the causal risk ratio of ice cleat use on the risk of outdoor fall injuries, and the term $\omega \theta_j$ is the causal effect of the programme on the proportion of ice cleat users, where $\theta_j$ is the initial change and $\omega$ is a scaling factor used to model the longevity of the behaviour change. We used data from a randomised trial of the effects of ice cleats as an estimate of the causal effect of ice cleats (relative risk (RR)=0.45; table 1).¹²

Estimation of effects on behaviour

The most challenging aspect to estimate is the effect of ice cleats programmes on ice cleat use, as there is no direct evidence on the effects of these programmes on behaviours. We do not believe that the share of collected ice cleats (90%) would be a good proxy for behaviour change, because a large share of the individuals who collected a pair may already own and use ice cleats. To obtain a reasonable approximation for the initial behaviour change $\theta_j$, we instead relied on data from a national survey conducted by the Swedish Civil Contingencies Agency in 2007 that collected data on ice cleat use and attitudes towards ice cleats (n aged above 65 years old=4608; see online supplemental file for details). The data also contained information on the respondents’ municipality of residence, which enabled
the matching of local climate data to each respondent. As indirectly supported by behaviour change theory,16 we assumed that non-users (respondents who reported that they do not use ice cleats during icy conditions) with a positive attitude towards the efficacy of ice cleats (‘I believe that ice cleats are important or very important for increasing my safety during slippery road conditions’) would be susceptible to change when presented with the option to collect a free pair of ice cleats. On average, 25% of the respondents fit this category, which we refer to as potential compliers. We note that this may be seen as an upper bound for the actual share of new ice cleat users; we therefore also conducted scenario analyses with lower assumed compliance rates (see below). We used a binary indicator for potential compliers as the outcome in a logistic generalised additive model26 to establish a model for the share of potential compliers in municipality \(j\) as a smooth function of the average number of snow days per year (provided by the Swedish Meteorological and Hydrological Institute). The model results are presented in online supplemental table S2 and figure S6.

To estimate the temporal variation in compliance (ie, the scaling factor \(\omega\) in Equation (1)), we calibrated our model to quasi-experimental estimates from Gothenburg, which found evidence of a short-lived effect on injury rates (−45% during the first year and −10% over a 4-year period15; see online supplemental file for calculations). Our calculations assume that this temporal dynamic is driven by a reduction in the effect of the programme on ice cleat use over time. Specifically, we modelled a relatively short-lived effect on behaviour that decreases monotonically over time and disappears completely after 4 years (table 1). We also considered a scenario where the effect is limited to the first year only.

Estimation of baseline injury rates

We modelled the annual number of persons treated for ice-related fall injuries at inpatient or outpatient facilities (International Classification of Diseases, 10th Revision, external case code: W00) at baseline, \(y_{jt}\), as a smooth function of local climate (average number of days with snow cover per year) and population size using a negative binomial generalised additive model.20 We used age-specific and municipality-specific data from the Swedish National Patient Register21 between the periods 2008 and 2017, provided to us in aggregate form (ie, a total for the entire period) by the National Board of Health and Welfare. The model results are presented in online supplemental table S1 and figure S4. To estimate year-to-year variability around the municipality-specific means in our simulations, we relied on relative variation around the mean annual number of hospitalisations due to snow-related or ice-related falls at the national level (online supplemental figure S5). Overall, 61810 persons (aged 65+ years old) were treated for snow-related or ice-related fall during the included period (municipal average: 21.6 injuries per year; table 1). Given the low fatality risk related to snow-related or ice-related falls, we only considered the benefits from averting non-fatal injuries (only 30 deaths in the age group 65+ years old occurred between 20082017 in Sweden).

Estimation of the monetary benefit per averted injury

To convert the expected effect of the programme on injury rates into monetary terms, we relied on the estimated monetary benefit per averted pedestrian fall injury used by the Swedish Transport Administration (€329 783),17 which is based on a combination of material costs (€3592, eg, healthcare utilisation, transportation costs and informal care by family members) and the willingness to pay (WTP) per averted injury (€326 191).17 The WTP is intended to reflect the utility loss from the injured individual’s physical and psychological suffering in monetary terms. Thus, the overall benefit estimate captures both quality-of-life gains and averted material costs to society. Their estimate was obtained by taking the product of the WTP per quality-adjusted life years (QALY) (based on a stated preference survey (n=880) related to fatal and non-fatal traffic-related injuries, conducted in Sweden)22 and the expected QALY loss per pedestrian fall injury from a remaining life-time perspective (1.387 QALYs according to data from a sample of pedestrians injured in pedestrian falls in Sweden (mean age: 64 years; \(n=256\))23 and then adding the estimated material costs per pedestrian fall injury to that estimate (based on the same study as the QALY estimates,23 although we subtracted the estimated production loss for this study as our target population is above the retirement age in Sweden; see online supplemental file for details).

Estimation of program costs

The final term in Equation (1) determines the total cost of the programme (including administration costs), which is given by the product of the total programme cost per purchased ice cleat pair, \(c\), and the number of purchased ice cleat pairs. To model the municipality-specific programme cost, we assumed that each municipality purchases one pair of ice cleats for each citizen aged 65+ years old (\(N\), in Equation (1)). To estimate the programme cost per ice cleat pair, we used data from 34 municipalities that reported cost and procurement data in our survey. The average reported programme cost was €8.73 per ice cleat pair (range: 2.35–27.37). Following Bonander and Holmberg,13 we assumed that the majority of the programme costs occur at year one in conjunction with the procurement of ice cleats.

Economic evaluation

The evaluation assumes a societal perspective, that is, it includes costs across all societal sectors in the valuation of material costs (including healthcare utilisation, administration costs, material damage to property and informal care) and WTP per averted injury.17 Our programme cost estimates are intended to reflect the total programme costs from a municipal perspective (including the procurement and distribution of ice cleats, administration and communication). We estimated the total NPV summed over all municipalities in Sweden and studied heterogeneity in effectiveness depending on climate conditions. The results are presented in 2018 Euros, converted from 2018 Swedish kronor (SEK) assuming the 31 December 2018 exchange rate (€0.09811 per SEK).

Sensitivity analyses

We used both deterministic and probabilistic sensitivity analysis to assess uncertainty.24 The parameter estimates, SEs and assumed distributions are presented in table 1.

In the probabilistic sensitivity analysis, we ran 100 000 simulations per municipality and used the proportion of simulations that resulted in a positive NPV to estimate the probability that an ice cleat programme would be cost-beneficial in municipality \(j\).

In the deterministic sensitivity analysis, we varied key parameters as described in table 2. We also considered a pessimistic scenario in which we doubled the programme costs, restricted the longevity of the effect to 1 year and halved the assumed increase in ice cleat users and the effect of ice cleats compared with the base-case scenario.
the same period. In the pessimistic scenario, the expected change
a 15% reduction in snow- related or ice- related fall injuries over
In the base- case scenario, the results show a 15 percentage point
RESULTS
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that is approximately zero) using a box- constrained optimisation
this number by solving for the non- negative compliance share
ice cleats for the programme to be cost- beneficial. We obtained
share of the target population who would need to start using
Cost- minimisation analysis (ignore WTP per averted injury) −0.65 (−1.76, 0.62) 0.95 (0.85, 1.07) 0.405 (0.004, 0.720)
Reduce initial compliance rate from 25% to 5% on average 281.86 (245.93, 325.25) 21.66 (18.96, 24.91) 0.986 (0.978, 0.989)
Reduce RR of ice cleat use by half (RR=0.73) 455.86 (401.81, 509.85) 34.75 (31.94, 37.93) 0.989 (0.985, 0.991)
Reduce RR of ice cleat use by three quarters (RR=0.875) 166.5 (148.28, 186.02) 13.21 (11.82, 14.69) 0.985 (0.974, 0.988)
Limit intervention effect to first year 443.49 (391.82, 502.75) 33.51 (29.64, 37.93) 0.989 (0.985, 0.991)
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Injuries averted, total 3751 (3339, 4209) 270 (240, 307) 0.991 (0.987, 0.991)
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RESULTS
In the base- case scenario, the results show a 15 percentage point
increase in the number of ice cleat users over 4 years, resulting in
a 15% reduction in snow-related or ice-related fall injuries over
the same period. In the pessimistic scenario, the expected change
in ice cleat users is only 3 percentage points, with a 1% reduction
injuries. Due to low intervention costs, the results from both
the base- case and the pessimistic scenarios showed a positive
expected NPV in all Swedish municipalities, with municipality-
specific percentages of simulations with a positive NPV ranging
from 98.9% to 99.2% in the base- case scenario and 67.5% to
96.3% in the pessimistic scenario (table 3).

The average benefit-to-cost ratio was 87.4. This number varied from approximately 40 in southern municipalities to
140 in some of the northern parts of Sweden (figure 1A), in a
geographical pattern that closely follows that of snow-related or
ice-related fall injury rates per person-year (figure 1B). Our data
suggest that the number of potential compliers is lower in the
north due to higher baseline ice cleat use in high-risk municipalities
(figure 1C,D). This indicates that there is a risk of ceiling

Table 3 Results from the cost–benefit analysis under base-case and pessimistic scenarios in which ice cleat programmes are implemented in all Swedish municipalities compared with a business-as-usual scenario without ice cleat programmes

| Estimate                        | Base-case* | Pessimistic scenario† |
|---------------------------------|------------|-----------------------|
| Incremental benefit, total (million Euros) | 1192.62 (1061.77, 1338.12) | 89.16 (78.05, 101.09) |
| Incremental cost, total (million Euros) | 13.64 (13.35, 13.94) | 27.28 (26.70, 27.88) |
| Net present value, total (million Euros) | 1178.98 (1048.42, 1234.18) | 61.89 (52.35, 73.21) |
| Benefit-to-cost ratio | 87.44 (77.69, 98.31) | 3.27 (2.89, 3.71) |
| Percentage point change in ice cleat users over 4 years, mean | 15.02 (14.96, 15.09) | 3.00 (2.99, 3.02) |
| Expected number of injuries without programmes, total | 25 192 (24 436, 26 008) | 25 192 (24 440, 26 009) |
| Expected number of injuries with programmes, total | 21 441 (20 681, 22 253) | 24 921 (24 176, 25 731) |
| Injuries averted, total | 3751 (3339, 4209) | 270 (240, 307) |
| Relative intervention effect (rate ratio) | 0.85 (0.83, 0.87) | 0.99 (0.99, 0.99) |
| Absolute intervention effect (rate difference, 100 000 person-years) | −50.96 (−45.36, −57.18) | −3.67 (−3.26, 4.17) |
| Pr(cost-beneficial), mean (min–max) | 0.991 (0.987, 0.991) | 0.915 (0.675, 0.963) |

The estimates in the table reflect totals or means for all Swedish municipalities averaged across 100 000 simulations, with the 2.5th and 97.5th percentiles of the simulated estimates in parentheses unless otherwise noted. The simulations are run over a 4-year period. The net present value (NPV) is given by Equation (1), which, if positive, implies that the interventions are cost- beneficial. The benefit-to-cost ratio expresses how much the estimated benefits outweigh the costs in relative terms. The remaining estimates reflect estimated effects on the average change in ice cleat users and on injury rates. Pr(cost-beneficial) is the proportion of the 100 000 simulations in which the NPV is positive, which gives an overall estimate of how likely it is that an ice cleat programme would be cost- beneficial according to the model (for this parameter, the numbers in parentheses reflect the least to most certain municipal-specific estimate).

*Scenario using the best available estimates from table 1.
†Doubled costs, increase in ice cleat use limited to the first year, halved initial compliance and halved effect of ice cleats (compared with the base-case scenario).
Bonander C, et al. Inj Prev 2022;28:125–130. doi:10.1136/injuryprev-2021-044203

Figure 1  Maps of Sweden’s 290 municipalities that illustrate the geographical variation in (A) estimated benefit-to-cost ratios from our economic simulations (base-case scenario), (B) baseline snow-related or ice-related fall injury rates per 100,000 person-years, (C) the estimated proportion of ice cleat users per municipality without ice cleat distribution programmes and (D) the estimated proportion of the population susceptible to change as a consequence of an ice cleat distribution programme (non-users with a positive attitude towards the efficacy of ice cleats).

effects concerning the magnitude of the behaviour change that could be brought about by ice cleat programmes in some areas. However, given the high injury rates in this region, our model still expects that the economic benefits of an ice cleat programme would be the largest in these municipalities.

Deterministic sensitivity analyses
We constructed a set of scenarios, each presented in table 2, to probe the sensitivity of the results to changes in key parameters (their rationale and additional details are provided in the online supplemental file). In addition to these scenarios, we also conducted a cost-minimisation analysis that ignores the valuation of health benefits (ie, the WTP per injury averted) and compares only the material costs averted to the cost of the programme. The results from these analyses are presented in table 2. Although the expected NPV varies greatly in magnitude when we modify parameters related to the expected monetary benefit per injury averted and effects of the ice cleat programmes, each cost-benefit-related scenario still indicates a positive expected NPV. The cost-minimisation analysis implies that ice cleat programmes are almost cost-neutral even if we ignore the monetary valuation of health benefits, although the total material costs are likely to increase slightly compared with a business-as-usual scenario.

Breakeven analysis
The breakeven analysis showed that at least 0.15% of the population would need to start using ice cleats for a programme to be cost-beneficial in the average municipality (range: 0.038%–0.463%), which implies that at least one person would need to start using ice cleats per approximately 670 purchased pairs for an ice cleat programme to be beneficial in expectation. In terms of injury rates, the estimated breakeven point is one injury averted per 37,800 purchased ice cleat pairs.

DISCUSSION
Pedestrian falls are underprioritised in road safety policy despite their considerable contribution to the burden of transport-related injuries.2 3 One reason may be that decision-makers are reluctant to implement population-based programmes due to a lack of evidence on their effectiveness.1 8 Our study implies that ice cleat distribution programmes can be an effective method to reduce ice-related falls, which is a major cause of outdoor fall injuries in the Nordic countries and regions with similar climates.1 3 12 The results suggest that the implementation of ice cleat distribution programmes would be cost-beneficial for Swedish municipalities, which is also supported by an empirical study from Gothenburg.13 We can now extend this conclusion to the entirety of Sweden, which supports the programmes already implemented in 78 Swedish municipalities and suggests that the remaining municipalities should consider distributing ice cleats to older adults.

A key strength of our study is the use of a model-based design grounded in high-quality data, which allowed us to thoroughly examine the potential benefits of ice cleat programmes in all Swedish municipalities under multiple realistic scenarios. That said, the study also has several noteworthy limitations. Our main concern is the estimated effect of ice cleat programmes on ice cleat use, which may be overstated. Despite this potential source of bias, our sensitivity and breakeven analyses suggest that an ice cleat distribution programme would have to be almost completely ineffective (affecting only one person per 670 targeted individuals) for it not to be cost-beneficial, which appears unlikely given previous research on ice cleats and ice cleat distribution programmes.1 9 12 13 as well as general research on behaviour change interventions on health and safety behaviours.20 Even so, it is important to continue monitoring and evaluating the impact of ice cleat programmes with empirical evaluation designs. However, the non-randomised nature of the implementation of these programmes presents a challenge for credible evaluation.13 Our model, which relies partly on data from a randomised trial,12 offers a way to assess the potential impacts of ice cleat programmes without reliance on the strong assumptions required for a causal interpretation of non-randomised data.27

This study only included the potential benefits of ice cleat programmes on injury outcomes. Access to ice cleats may also increase walking,9 which suggests that ice cleat programmes may have other health benefits that are not included in our estimates.28 Further, the economic data reflect a Swedish societal perspective. We expect that the conclusions may extend to older adults.

What is already known on the subject

► Icy weather conditions are a major cause of outdoor fall injuries in colder regions.
► Ice cleats can reduce the risk of injurious falls during icy conditions.
► Distribution programmes may increase usage and reduce injury rates among older adults.

What this study adds

► This is the first comprehensive economic evaluation of ice cleat programmes.
► We model effects depending on local climate in Swedish municipalities.
► The potential benefit of distributing ice cleats to older adults outweighs the costs.
to countries with similar climates, but the context dependency of economic data may still warrant replication in other countries before drawing a conclusion on the transferability of the results. Additional research is also needed to assess how these programmes can be most effectively designed to combat the potential reduction in compliance over time.

CONCLUSION

The potential benefits of distributing ice cleats free of charge to older adults appear to greatly outweigh the costs. Our results imply that the municipalities that have already implemented these programmes should continue to provide ice cleats. The remaining municipalities should consider implementing ice cleat distribution programmes.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The data used in this study reflect anonymised, non-sensitive information or aggregate health data from public and administrative data sources, which are exempt from the need for ethical approval according to the Swedish law of research ethics. Nonetheless, ethical approval was sought and approved by the Regional Ethics Board in Uppsala (DNR 2018/480, with addendum (DNR 2021–10338) approved by the Swedish Ethical Review Authority).

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