

Uptake and adherence with soft- and hard-shelled hip protectors in Norwegian nursing homes: a cluster randomised trial

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Abstract

Summary A comparison between soft- and hard-shelled hip protectors in nursing homes shows no clinically relevant difference in acceptance and probability of continued use. However, significantly more users of the soft hip protector used the protector 24 hours a day.

Introduction and hypothesis Uptake and adherence with the use of hip protectors are poor due to discomfort and impracticality. The aim of the study was to compare uptake and adherence between soft- and hard-shelled hip protectors. We hypothesized a higher uptake and adherence with soft hip protectors than with hard ones.

Methods This cluster randomized study was performed for 18 months in 18 Norwegian nursing homes. Each nursing home was randomly allocated either soft or hard hip protectors. A total of 1,236 participants were enrolled in the study of which 314 and 290 started to use soft and hard hip protectors, respectively.

Results The uptake among participants in nursing homes provided soft hip protectors was not significantly different from the uptake in nursing homes provided hard protectors. The probability of continued use was a little higher among users of soft hip protector. There were significantly more 24-hour users among those people using the soft protector.

Conclusion Our results indicate that changing the design might not solve the compliance issue, but may be a step in the right direction, especially for those people who are in need of 24-hour use.

Keywords Accident prevention · Hard-shelled hip protector · Hip fracture · Nursing homes · Patient compliance · Soft-shelled hip protector

Introduction

Hip fractures are a major cause of disability and functional limitation [1]. The average age of persons with hip fractures is 80 years. Females predominate over males by about four to one [2]. More than 90% of hip fractures occur as a result of falls and primarily by a sideways fall with direct impact on the greater trochanter. Individuals living in institutions are almost four times more likely to sustain a hip fracture than people living in their private home [3,4]. In addition to a high number of falls [5], this can be explained by loss of protective responses, less energy absorbing soft tissue and lower bone mineral density [6].

Hip protectors have the potential to lower the risk of a hip fracture in a fall by more than 50% by reducing the impact on the hip region during falls [7–11]. Many studies have reported conflicting results regarding the effect of hip protectors on reducing the incidence of hip fractures. Low acceptance and adherence due to discomfort and impracticality seem to be a challenge [2]. Reviews by Parker et al. [2] and by Sawka et al. [12] conclude that hip protectors might have a marginally significant effect in reducing the incidence of hip fractures among frail elderly people in institutional care, but that there is little evidence to support the use of hip protectors outside a nursing home setting.

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Before drawing conclusions, it is of great importance to emphasise that these reviews addressed whether a policy of providing hip protectors is effective in reducing the incidence of hip fractures, and cannot be used to confirm that hip protectors are ineffective when they are worn and a fall occurs. It is conceivable that low adherence is one explanation for the lack of effect. In addition, it is important to distinguish between the efficacy and effectiveness of hip protectors.

Compliance rates in different studies have varied from 31 to 68% [12]. The main reasons for not wearing hip protectors seem to be that they are uncomfortable (too tight/poor fit), extra effort is needed to put them on when getting dressed, urinary incontinence and physical difficulties/illnesses [2,13]. Attention has been paid to the features of the hip protector garment concerning comfort, appearance and fit. The hard shells have been thought to be one important reason why hip protectors are perceived as being uncomfortable. Changes in the design of hip protectors making them more comfortable and acceptable to users justify new studies addressing the effect of hip protectors. Such investigations are recommended in the Cochrane review by Parker et al. [2].

The aim of this trial was to compare uptake and adherence between soft- and hard-shelled hip protectors among individuals living in Norwegian nursing homes. We assumed that a higher uptake and adherence would be observed with the soft-shelled hip protectors as compared to the hard ones, especially in terms of 24-hour use, because of presumed better comfort. Randomisation was according to the type of hip protector to be offered. To minimise contamination the unit of randomisation was the nursing home. It would not be feasible to mix soft and hard hip protectors within the same nursing home. However, the analysis was performed at an individual level.

Materials and methods

Participants

Two of Oslo's neighbouring municipalities were invited to participate in this hip protector study. The criteria for inclusion was that all nursing homes in the two municipalities were included, which gave us 18 included nursing homes. The number of beds in each nursing home varied between 18 – 96 and the number of wards varied from 1 – 6. The intervention was conducted during the period between May 18, 2005 and November 30, 2006. During this period all permanent residents in these 18 nursing homes were candidates for inclusion in the study, both as users and non-users of hip protectors. When a resident passed away or was transferred, the bed was replaced. Thus

new permanent residents were included continuously during the intervention period.

The study was recommended by the Regional Committee for Ethics in Medical Research. All residents included in the study received written or oral information about the study. Residents with no cognitive dysfunction provided written informed consent. For participants with cognitive impairment, a member of the staff gave the consent on behalf of the resident. This was in accordance with recommendations from the Regional Committee for Ethics in Medical Research. The residents' relatives were also given oral or written information concerning the study.

Intervention

Hip protectors were accessible to all participants, but participants who were assessed by staff judgement [14] to be at a high risk of falling were especially encouraged. All participants were registered with baseline characteristics based on staff assessment (see Table 1). Barthel ADL index [15] and questions from the stratify risk assessment tool were used [16]. From the Barthel ADL index, we calculated a transfer and mobility score by summarising the transfer and mobility item in Barthel (0–6). Fall risk was based on staff judgement [14]. Questions concerning memory and communication were based on IPLOS (5—point scale, Norwegian Directorate for Health and Social affairs). The study protocol recommended that the staff member closest to the resident should do the baseline registration.

Neither the staff nor the participants enrolled from the beginning knew whether they were allocated soft or hard hip protectors. The type of hip protector to be provided was not concealed from participants recruited after the start of the study. Likewise, this information was not withheld from the staff for participants included after the start of the study.

SAFEHIP® hard and SAFEHIP® soft (Tytex, Denmark) hip protectors were used in the study. While SAFEHIP® hard works by dispersing the energy away from the greater trochanter, SAFEHIP® soft works both by absorbing and dispersing the energy. Other differences include the shape and material of the protective shells, which might influence the comfort of the hip protector. The soft shells are softer and lighter and the shape is like a horseshoe surrounding the trochanter area. SAFEHIP® hard is extensively studied in randomised controlled studies. SAFEHIP® soft had not been used in any randomised trials at the time of this study. However, laboratory evidence supports the efficacy of the soft hip protector [17].

Each user was provided four hip protectors free of charge. Hip protectors were replaced in case of loss or damage.

Each nursing home had one or two study coordinators. The coordinator's function was to be the main contact

between the project manager and the nursing home, and to be a motivating force within the nursing home. In addition, the coordinator had to ensure that all registration forms were completed, that new residents were enrolled in the study and that fractures occurring in the nursing home were recorded.

Prior to intervention and before randomisation, each nursing home was offered one or two sessions of 60 minutes structured education. The session covered information about the risk and consequences of hip fractures, objectives and implementation of the study, and information and instruction about use and laundry of the hip protectors. In addition each department in all nursing homes received a binder with written information that covered the information provided at the educational sessions.

Objectives

In the current study we wanted to investigate the effect on uptake and adherence by offering a soft-shelled hip protector compared to a hard-shelled hip protector. We hypothesised that the soft hip protectors would be assessed and perceived as more comfortable, and we expected higher uptake and adherence through better comfort, especially a higher proportion of 24-hour users among users of the soft hip protector. We did not expect a difference in uptake between soft and hard hip protectors among those included from the beginning and blinded for the type of hip protectors, but we expected the difference to arise among those included continuously.

Outcomes

The primary outcome was the difference in adherence between those people offered soft and those offered hard hip protectors. The secondary outcome was the difference in uptake between the same groups.

Adherence was defined as the “wearing of hip protectors at times when the resident has a risk of falling” [18]. Depending on individual needs, this means either wearing the hip protector from the time of getting out of bed in the morning to the time of going to bed in the evening (day-user) or overnight use (24-hour user). Adherence was registered monthly by the staff in each ward on a registration form. They were asked to state if the user was still a “24-hour user”, “day-user” or had “ended hip protector use”. The reason for not using the hip protector 24 hours a day was registered (either “not in need of” or “uncomfortable at night”). A user was defined as a participant that used the hip protector within the last month. This might have been daily or intermittent. Ended hip protector use was defined as the time the participant or the staff decided not to use hip protector at all anymore. If this decision was taken, the staff was asked to state the reason.

Deceased, transferred, bedridden/in need of great assistance, different kinds of discomfort, impractical issues and unwanted side-effects (soreness, swelling, itchiness, pain) were the possible categories. For each month of hip protector use all users were categorized as either a recommended 24-hour user or as a recommended day-user depending on individual needs (recommended use). To be categorized as a 24-hour user the participant either used the hip protector 24 hours a day or just during the day because the hip protector was perceived as uncomfortable at night. A day-user was a resident assessed by the staff as not needing a hip protector at night.

Uptake was defined as “the percentage of potential users who initially agreed to wear the hip protector” [18]. In this study the potential users included all permanent residents. Uptake rates for those provided soft and those provided hard hip protectors were compared among those included from the beginning and those included continuously. Uptake rates were also compared among those assessed to have a high risk of falling within the same groups. Uptake was registered on the baseline registration scheme. Reasons for not using hip protector were stated as: “assessed by the staff not to have a need for hip protector”, “assessed by the staff to have a need, but participant do not want to use hip protector” and “assessed by the staff to have a need, but hip protector use will not be practicable.

Sample size

For sample size calculation we used data from an earlier hip protector study conducted in Norwegian nursing homes [19]. The adherence outcome was used for the calculation. For the study to have at least 80% power to detect a difference of 20% in the probability for continued use the first 2–3 months a sample size of about 600 users seemed sufficient when adjusted for clusters. A post hoc calculation in Sample Power 2.0 showed an actual power of 0.91. However, adjustment for clusters was not possible.

Randomisation

Each nursing home was allocated either soft or hard hip protectors by randomisation. To secure an approximate equal number of beds in each intervention group, a block randomisation including two nursing homes of approximate equal size in each block was performed. Randomisation to either soft or hard hip protector within each block was undertaken by two researchers not further involved in the study.

Statistics

The statistical analysis was conducted using SPSS version 14.0 and STATA version 9.0. Differences between groups in baseline characteristics were tested by the Chi-square test

and by the independent samples *t*-test for means. Multivariate logistic regression was used to analyse the difference in uptake between soft and hard hip protector adjusted for age, gender and the baseline variables that were significantly different ($p < 0.05$) between the two groups of nursing homes. Kaplan-Meier curves were used to compare the probability of continued use between the two types of hip protectors. Log-rank test was used to test the difference between the curves. Events including death, moving from the institution, not in need of hip protectors anymore and end of observation time were censored, while ending use because of some kind of discomfort, impracticality and unwanted side effects was defined as a failure. The Cox proportional hazards model allowing multiple censorings and failures per resident was applied to investigate the effect of soft and hard hip protectors on the probability of continued use. Confounding variables as age, gender and baseline variables significantly different between the two groups of users were adjusted for in the analysis. The proportional hazard assumption of the Cox model was checked. We also adjusted for the nine blocks of clusters in the logistic regression model by including the blocks as covariates. The Cox regression model was stratified by the nine blocks of clusters.

Results

Figure 1 shows the flow of cluster and participants through each stage of the trial. Four residents refused to participate in the study for reasons not given. The number of participants includes the majority of residents during the actual period. Some residents may not have been included most likely due to the short time between hospitalisation and death, or hospitalisation and transfer to other institutions. Eight hundred and thirty-six participants were included from the beginning with 452 and 384 in nursing homes provided soft and hard hip protectors, respectively, and 400 (208 and 192, respectively) were included continuously.

Table 1 shows baseline characteristics for all participants and the same participants grouped according to living in nursing homes provided either soft or hard hip protectors. Table 1 also shows baseline characteristics for the users of hip protectors grouped into users of soft and hard hip protectors. The groups were similar with a few exceptions.

Uptake

The uptake by the time of inclusion among 1,236 participants included in the study was 45% in nursing homes provided soft hip protectors and 47% in nursing homes provided hard hip protectors. For three participants there was no information about hip protector use (Fig. 1).

In nursing homes provided soft hip protectors the uptake among those enrolled from the beginning was 50% (225 of 452) and 35% (72 of 206) for those included continuously. In nursing homes provided hard hip protectors the uptake rate was 51% (195 of 384) for those enrolled from the beginning and 40% (77 of 191) for those included continuously.

The staff assessed 464 (38%) participants as having a high risk of falling; 225 (34%) and 239 (42%) lived in nursing homes using soft and hard hip protectors, respectively. The uptake rate among those enrolled from the beginning and assessed to have a high risk of falling was 88% (126 of 146) and 85% (122 of 146) in nursing homes provided soft and hard hip protectors, respectively. Among those included continuously and assessed to have a high risk of falling, the uptake rate was 68% in nursing homes provided soft hip protectors and 63% in nursing homes provided hard hip protectors.

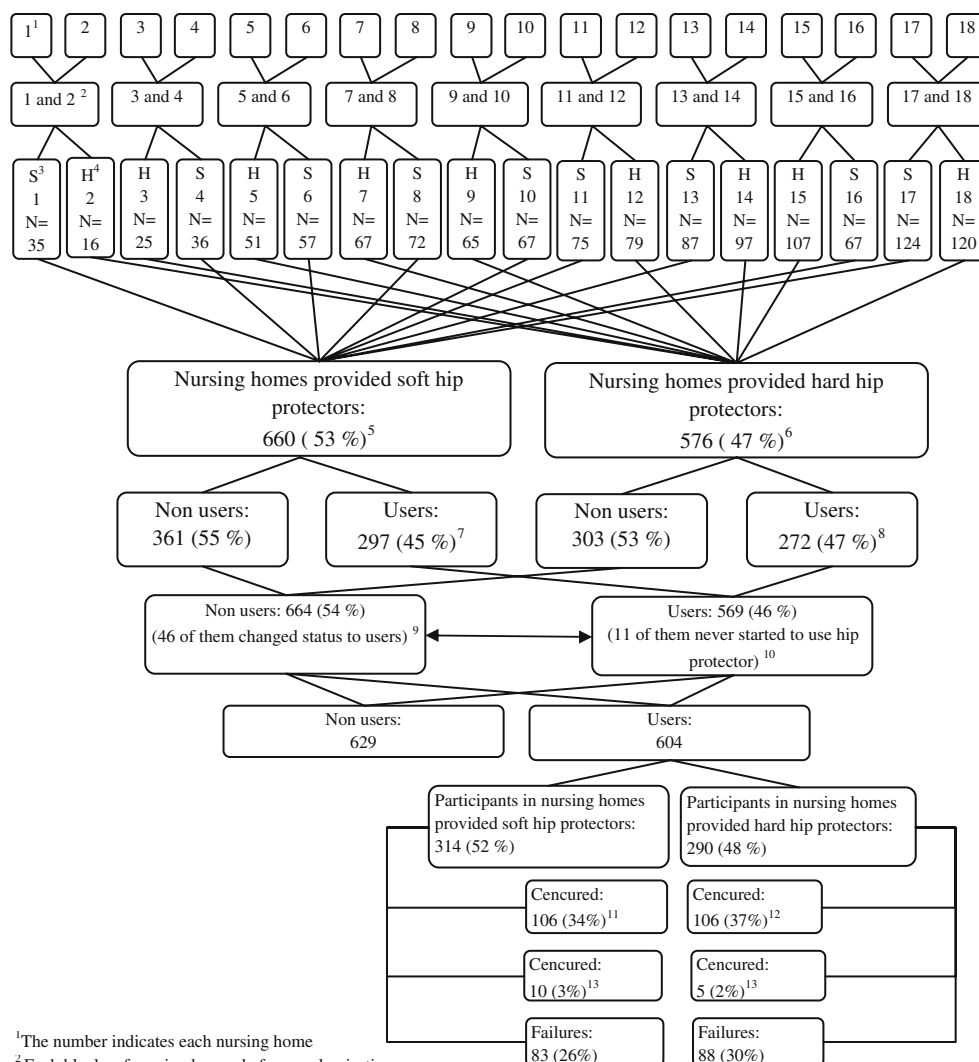
Table 2 shows the difference in uptake rate among those included from the beginning, those assessed by staff judgement to have a high risk of falling within that group, those included continuously and those assessed to have a high risk of falling within the same group.

At the time of inclusion 664 of 1,236 participants were registered as non-users; 341 (51.4%) were assessed by the staff as not needing hip protectors; 142 (21.4%) were assessed as needing a hip protector, but refused use of one; 52 participants (7.8%) were assessed as needing one, but were not offered because of different difficulties associated with use; 129 participants (19.4%) gave no reason. In nursing homes provided soft hip protectors 193 (53.5%) participants were assessed by the staff as not needing a hip protector; 72 (19.9%) did not want to use hip protectors even though they were assessed by the staff as needing one; 27 (7.5%) were assessed as needing one, but were not offered one because of different difficulties associated with use; 69 (19.1%) gave no reason. In nursing homes provided hard hip protectors 148 (48.8%) participants were assessed by the staff as not needing a hip protector; 70 (23.1%) did not want to use hip protectors even though they were assessed by the staff as needing one; 25 (8.3%) were assessed as needing one, but were not offered because of different difficulties associated with use; 60 (20.0%) gave no reason. The percentage of participants assessed as not needing a hip protector was somewhat higher, but not significantly higher in nursing homes provided soft hip protectors ($p = 0.259$).

Adherence

During the 18-month intervention, 604 participants started to use hip protectors. A total of 314 and 290 participants started with a soft hip and hard hip protector, respectively.

Fig. 1 Flow of clusters and participants through each stage of the trial



¹The number indicates each nursing home
²Each blocks of nursing homes before randomisation
³S= Nursing homes provided soft hip protectors
⁴H= Nursing homes provided hard hip protectors
⁵2 participants with missing information about hip protector use
⁶1 participant with missing information about hip protector use
⁷5 of them never started to use hip protector
⁸6 never started to use hip protector
⁹24 with a soft hip protector and 22 with a hard hip protector
¹⁰5 in nursing homes provided soft hip protectors and 6 in nursing homes provided hard hip protectors
¹¹57 died, 14 transferred, 35 not in need anymore
¹²57 died, 6 transferred, 43 not in need anymore
¹³Stopped without giving any reason

Ninety-eight participants (16%) stopped using hip protector within the first month. Of these 14 died, 1 was transferred and 3 were no longer in need. Eighty participants (where 34 (11%) were using soft hip protectors and 46 (16%) were using hard hip protectors) stopped because of different kinds of discomfort. The difference was not statistically significant ($p=0.084$).

At the end of the 18-month intervention period 224 (37%) participants were still users. One hundred and seventy-one failures among 168 participants were registered during the intervention period. Nineteen participants started

a second time, three had another failure and 15 were censored. Among those who gave a reason for ending hip protector use there was no significant difference in stated reasons between soft and hard hip protectors (Table 3). Unwanted side effects did not seem to be a major problem for the soft or the hard hip protector, but problems connected to discomfort and the device being impractical seem to be the main reasons.

The probability for continued use was a little higher for the users of the soft hip protector throughout the intervention period (Fig. 2). Using a Cox regression model

Table 1 Baseline characteristics related to all participants and participants using hip protector

Variables	All participants enrolled in the study				Users of hip protectors			
	All participants N=1,236**	Participants at nursing homes provided with soft hip protectors (N=660)	Participants at nursing homes provided with hard hip protectors (N=576)	P-value	All users N=604	Users of soft hip protectors (N=314)	Users of hard hip protectors (N=290)	P-value
Age: mean (std)	84.5 (7.94)	84.8 (7.79)	84.1 (8.10)	0.98	84.9 (9.04)	85.8 (6.51)	84.0 (11.43)	0.20
Gender (%)								
Male	27.8	27.6	28.0		23.5	20.1	27.2	
Female	72.2	72.4	72.0	1.00	76.5	79.9	72.8	0.05 *
BMI: mean (std)	22.7 (4.40)	22.7 (4.70)	22.7 (4.10)	0.96	22.5 (4.14)	22.5 (4.24)	22.6 (4.0)	0.78
Barthel ADL score ¹ mean (std)	9.9 (5.85)	10.3 (5.91)	9.8 (5.79)	0.60	11.0 (4.43)	11.0 (4.7)	11.0 (4.1)	0.92
Transfer and mob. Score ² of 3 or 4. Yes%	24.6	22.1	27.9	0.02*	34.4	30.4	39.4	0.03 *
Memory 4–0 ³ : mean (std)	1.7 (1.33)	1.8 (1.31)	1.7 (1.35)	0.23	1.5 (1.3)	1.6 (1.3)	1.6 (1.3)	0.44
Communication 4–0: mean (std)	2.5 (1.35)	2.5 (1.32)	2.5 (1.38)	0.84	2.5 (1.29)	2.4 (1.3)	2.6 (1.3)	0.17
Use of hip protectors : Yes%	45.3	44.4	46.6	0.32				
Vitamin D supp.: Yes%	13.3	13.3	13.5	0.67	14.6	14.7	14.6	1.00
Calcium supp.: Yes%	7.4	7.2	7.9	0.72	9.6	10.6	8.7	0.52
Osteoporosis medication: Yes%	4.4	5.5	3.3	0.09	6.0	7.7	4.2	0.11
Fractures within last 6 months: Yes%	10.4	9.9	11.0	0.60	15.6	14.6	16.6	0.57
Use of walking aids: Yes%	76.8	75.8	78.6	0.24	76.2	76.4	76.5	1.00
Falls within last 3 months ⁵ : Yes%	31.4	27.9	37.2	0.001*	49.0	45.1	54.9	0.02 *
Visual impairment ⁶ : Yes%	21.6	19.0	25.0	0.01*	22.5	17.9	27.7	0.006 *
Frequent toileting ⁷ : Yes%	17.6	16.4	19.2	0.19	22.0	18.9	25.8	0.05 *
Agitated ⁸ : Yes%	26.1	26.0	26.6	0.74	34.4	33.9	35.2	0.80
Staff judgement of fall risk:%								
No risk:	8.0	9.3	6.6	0.10	0.7	0.6	0.7	1.00
Low risk:	54.2	56.4	51.7	0.18	38.6	41.9	35.3	0.12
High risk:	37.7	34.3	41.6	0.005*	60.4	57.5	64.0	0.12

*Statistically significant at $p < 0.05$

** For all variables except from BMI missing data were between 0% and 2.8%. For BMI missing data were 31.1%.

¹ Barthel total: range 0 – 20, ² A summarised transfer and mobility score in Barthel of 3 or 4, ³ 4=no memory loss, 3=some memory loss, 2=medium memory loss, 1=large memory loss, 0= no memory at all

⁴ 4=no problems, 3=some problems, 2=medium problems, 1= large problems, 0=not able to, ⁵ Has the resident had a fall within the last 3 months?

⁶ Do you think the resident is visually impaired to the extent that everyday function is affected? ⁷ Do you think the resident is in need of especially frequent toileting?

⁸ Do you think the resident is agitated?

Table 2 Offering hip protectors in nursing homes; comparison of the uptake in nursing homes provided hard hip protectors (1) with the uptake in nursing homes provided soft hip protectors (0) by means of logistic regression

Variables	Unadjusted			Adjusted*			Adjusted**		
	Odds ratio (OR)	P-value	95% confidence interval	Odds ratio (OR)	P-value	95% confidence interval	Odds ratio (OR)	P-value	95% confidence interval
Participants included from the beginning	1.04	0.773	0.79 – 1.37	1.09	0.558	0.82 – 1.44	0.86	0.388	0.61 – 1.21
Participants included from the beginning and high risk of falling	0.72	0.318	0.37 – 1.38	0.73	0.369	0.37 – 1.45	0.72	0.362	0.35 – 1.47
Participants included continuously	1.26	0.271	0.84 – 1.89	1.28	0.250	0.84 – 1.95	0.91	0.719	0.53 – 1.55
Participants included continuously and high risk of falling	0.82	0.537	0.43 – 1.55	0.78	0.474	0.40 – 1.53	0.64	0.255	0.30 – 1.37

* adjusted for the nine blocks of randomised clusters.

** adjusted for confounders (gender, age, falls within the last 3 months, visual impairments and fall risk) and for the nine blocks of randomised clusters.

allowing multiple failures controlling for confounders and for the nine blocks of clusters shows that the small difference observed was slightly statistically significant (Table 4). The result was the same whether or not multiple failures were included in the model. Much of the difference seems to arise in the first 1 to 3 months. This may indicate that more users give up at an early stage when using the hard hip protector.

24-hour use

A higher proportion of the users of the soft hip protector were 24-hour users. While 57%, 60% and 63% used the soft hip protector for 24 hours at 1 month, 6 month and 12 months, respectively, the corresponding numbers for the hard hip protector were 28%, 34% and 43%. The difference was highly significant at all points of time (Fig. 3).

Among those categorised by the staff as 24-hour users, the proportion was higher in nursing homes using soft hip

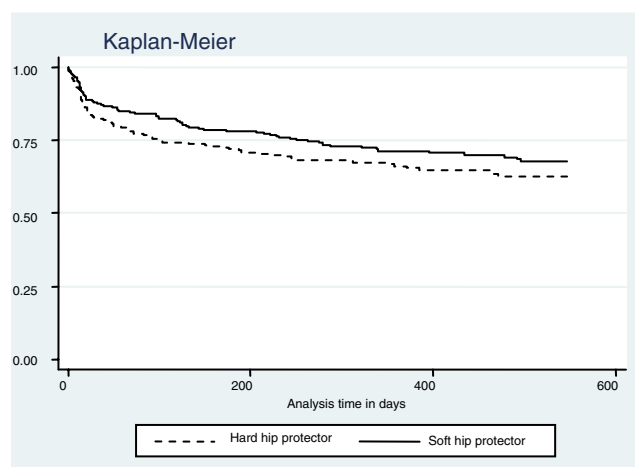
protectors. The difference was not statistically significant. Approximately 11.0% and 9.5% of the residents were not categorized in nursing homes using soft and hard hip protectors, respectively. Among those categorised and recommended 24-hour users, a significantly higher proportion of the users of soft hip protectors followed the recommendation (Fig. 3). The difference between soft and hard hip protectors remained significant in 9 of 12 months even when treating those not categorised as “worst case”.

Discussion

Uptake and adherence to hip protector use among high risk individuals are decisive for the effectiveness of hip protectors. This cluster randomized hip protector study focused on consequences for uptake and adherence when making the protective shells softer and more comfortable.

Table 3 Reasons for terminating hip protector use (failures), differences between users of soft and hard hip protectors

Reasons for terminating use	Soft hip protectors	Hard hip protectors	p-value
Uncomfortable for the resident	35 (42.2%)	35 (39.7%)	0.860
Impractical for the resident	7 (8.4%)	8 (9.1%)	1.000
Time consuming for the staff	1 (1.2%)	1 (1.1%)	1.000
Unwanted side effects (soreness, swelling, itchiness, pain)	8 (9.6%)	2 (2.3%)	0.088
Combination of uncomfortable and impractical	27 (32.5%)	33 (37.5%)	0.600
Combination of uncomfortable, impractical and unwanted side effects	0 (0%)	1 (1.1%)	1.000
Combination of uncomfortable and time consuming	1 (1.2%)	0 (0%)	0.980
Combination of uncomfortable and unwanted side effects	4 (4.8%)	7 (8.0%)	0.589
Combination of uncomfortable, time consuming and impractical	0 (0%)	1 (1.1%)	1.000
Total	83	88	



Log rank test: 0.101

Fig. 2 Kaplan-Meier estimates of the probability of continued use between users of soft and hard hip protectors

We hypothesised that the soft-shelled hip protectors would be assessed and perceived as more comfortable, and we expected higher uptake and higher adherence through better comfort, especially a higher proportion of 24-hour users.

Our results did not support our assumptions of a substantial higher uptake or a higher probability of continued use with the soft hip protector. However, the results verify our assumptions that a higher proportion among users of the soft hip protector was compliant with the recommendation of 24-hour use. Even though the difference in probability of continued use was statistically significant and the clinical relevance of this difference is interesting, the perceived advantages of using soft hip protectors is probably too small to increase adherence. Our data indicate that more users stop using the hard-shelled hip protector at an early stage, but when a resident first becomes accustomed to using a hip protector the particular type does not seem to make a significant difference for the probability of continued use.

To our knowledge there are few studies comparing adherence between soft-shelled and hard-shelled hip protectors. O'Halloren et al. found no difference in compliance between soft-shelled and hard-shelled hip protectors [20].

Unfortunately their study did not focus on the difference in 24-hour use between the two types of hip protectors. Yasumura et al. found that considerably more persons used soft than hard hip protectors [21]. Suzuki et al. found that compliance with soft protectors was better than with hard protectors among community dwelling elderly people, but the difference was not statistically significant [22]. These studies have few participants, and thus the results must be interpreted with caution.

Comparing uptake and adherence across studies is difficult because of different definitions and different assessments [23]. Preselection of participants is another source of variation between studies. Even though nursing home residents are regarded as a high risk population for falls and fractures, not all residents in nursing homes are prone to falling and in need of hip protectors. The risk factors for those at high risk are multitude and inconsistent, and, to our knowledge, there are no predictive tools that represent the “gold standard” for predicting falls in a nursing home setting. In our study “staff judgement” was used as a criterion for identifying high risk individuals. In another study, “staff judgement” was shown to have the same predictive value as a “mobility interaction fall” and a history of a fall recalled by the staff [14]. Our “over all” uptake rate of approximately 47% corresponds with the uptake in the study of Forsén et al. who used the same strategy in selecting users in a hip protector study in Norwegian nursing homes [19]. An uptake rate of about 80% among residents regarded to have a high risk of falling is good compared to other studies using different risk factors for selecting users [13]. However, the predictive value of our “staff judgement” and whether or not the high risk individuals were identified remains to be analyzed.

The uptake rate decreased equally for both types of hip protector among participants enrolled continuously. This may reflect the staff's confidence in selecting residents in need of hip protectors.

“Staff judgement” is connected to the clinical experience, which might have improved during the intervention period, but this experience should be equal in the two groups of nursing homes. Alternatively, the decrease may

Table 4 Adherence with hip protectors; comparison of the risk of terminating use of hard hip protectors (1) with terminating use of soft hip protectors (0) by means of Cox regression

Variables	Relative risk (RR)	P-value	95% confidence interval of RR
Unadjusted	1.284	0.102	0.951 – 1.734
Adjusted **	1.264	0.135	0.929 – 1.720
Adjusted ***	1.381	0.048*	1.002 – 1.902

* Statistically significant.

** Adjusted for nine blocks of randomised clusters.

*** Adjusted for confounders (age, gender, transfer and mobility score, falls within last 3 months, visual impairment and frequent toileting) and for the nine blocks of randomised clusters.

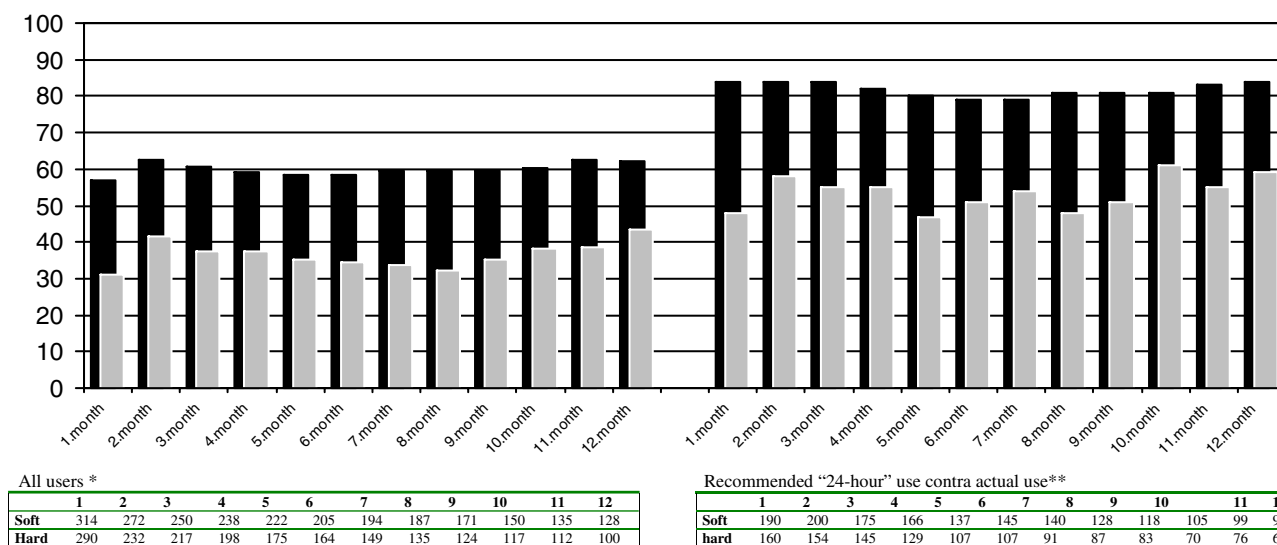


Fig. 3 Bar graph showing 24-hour use (%) within users of soft and hard hip protectors among all users and among those recommended 24-hour use (%)

reflect negative attitudes to the use of hip protector among the staff and/or residents.

It is a well-known fact that the staff’s attitude towards hip protectors is of great importance for both uptake and adherence, both to remind and convince the resident to put them on and to assist residents in dressing and toileting while wearing hip protectors [24]. The staff’s attitude can be positively influenced by structured education [23,25]. Except from the educational section prior to intervention, our study did not include any regular structured education. However, we cannot ignore the probability that our results have been influenced by the initial educational training. Regardless, we do not understand how the education provided could explain the differences in 24-hour use between users of soft and hard hip protectors.

We cannot be sure that the staff in the two groups of nursing homes supplied an equal amount of encouragement to the participants deemed at high risk for falls which might have influenced the uptake rate. However, we believe that this potential difference is minimised by our randomisation.

For hip protectors to be effective, 24-hour use is important. In our study we found that a significantly larger portion of the regular users of the soft hip protector were adherent to the 24-hour use recommendation. This may indicate that when a person first accepts using a hip protector, the soft-shelled protector is perceived to be more comfortable at night. It may also reflect the staff’s attitude towards the comfort of the soft hip protector and the effect this had on helping residents overcome barriers concerning overnight use. Regardless, our results imply that among those using hip protectors, users of the soft hip protectors

will be protected for more hours than users of hard protectors. If the soft hip protector shows to have the same biomechanical efficacy in a clinical setting as in the laboratory test, it may be possible to conclude that the soft hip protector is preferable to the hard hip protector, especially among those who are in need of 24-hour use. The biomechanical efficacy of the soft hip protector used in this study remains to be tested in clinical fracture prevention studies. For both the soft and hard hip protectors, we had a higher proportion of 24-hour users compared to the Amsterdam study [26]. This difference can be explained by the differences in the study populations.

Examining the reasons given for ending hip protector use, we did not find any indication that more users stopped regular use because they experienced the hard hip protector as being more uncomfortable than the soft ones. Surprisingly, the reasons provided were very much the same for the two types of hip protectors. The distribution between impracticality, lack of comfort and unwanted side effects were equal for the two types of hip protectors.

Our impression, while not documented, was that staff members were more positive towards the soft hip protector. Surprisingly, except from a higher and probably clinically relevant proportion of 24-hour users, we did not find any indication that this positive attitude was verified clinically. Except for the weight and softness of the protective shells, the soft hip protector did not have any considerable practical advantages compared to the hard protectors. In addition, the soft shells were destroyed when the washing and drying instructions were not followed. Some nursing homes did not follow the recommended washing and

drying temperature of 60 degrees centigrade, and thus a large number of the soft hip protectors were destroyed.

The strength of our study was the randomisation, the high number of residents included, the duration of the intervention and our differentiation between day-user and 24-hour use. The cluster design might erode the study's power by making the effective sample size smaller [27]. However, in the analyses we adjusted for the clusters and this adjustment did not influence the outcome estimate markedly which indicate a small intracluster effect. The monthly records of adherence might have overestimated the true adherence. Regardless, the potential overestimate should not differ between nursing homes using soft and hard hip protectors. A daily diary would have been able to capture the true adherence in a more reliable and exhaustive way, but that would not be possible within the scope of this study. The staff doing the adherence registration was not blinded to the type of hip protector being used. However, the registration did not involve any assessment, just a statement of hip protector use or not as defined above. We cannot see some reason why not being blinded to the type of hip protector could influence the statement of the outcome and be different between the two groups of nursing homes.

Our study design did not allow the resident or the staff to choose the type of hip protector. The results concerning uptake and adherence might have been different if the resident and/or staff were involved in the choice of protector.

The study population in our study is probably similar according to age and gender distribution for Norwegian nursing homes residents [28, 29]. To our knowledge there are no data comparing Norwegian nursing home residents with residents in other countries. The fact that the nursing homes were invited to participate and not randomly allocated to intervene might have influenced the results. General conclusions must be drawn with caution, and no conclusion is possible concerning use of these two types of protectors outside a nursing home setting.

Conclusion

Our results indicate that soft-shelled contra hard-shelled hip protectors do not appear to make any large significant difference for uptake or probability of continued use. However, soft protectors are preferable for 24-hour use. Our results indicate that changing the design of the hip protector might not solve the compliance issue, but may be a step in the right direction. Further research with this focus combined with more attention paid to the attitude among both residents and staff towards use of hip protectors should be encouraged. This study shows the effectiveness of hip

protectors related to compliance; however, further research on the effectiveness regarding efficacy is in progress.

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