

# Prevention of Hip Fractures by External Hip Protectors

## A Randomized Controlled Trial

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**W**ORLDWIDE, THE ANNUAL number of hip fractures is expected to increase from 1.66 million in 1990 to 6.26 million in 2050.<sup>1</sup> This is caused by not only the increasing number of elderly persons, but also an increase in the age-adjusted incidence.<sup>2-6</sup> The risk for hip fracture is higher among elderly persons who are institutionalized than those living independently.<sup>7</sup> The consequences of hip fractures can be severe. During the year following a hip fracture, the mortality rate is about 17% to 33%; after 1 year, 25% to 33% of patients are severely disabled or cannot walk at all.<sup>8-11</sup> A promising intervention in the prevention of hip fractures is the hip protector.<sup>12</sup> When a person falls on the hip, the hip protector is designed to absorb and/or shunt away the impact toward the soft tissues to keep the force on the trochanter below the fracture threshold.

To date, 10 randomized controlled trials examining the effect of external hip protectors on the incidence of hip fractures have been published to our knowledge.<sup>13-22</sup> In 5 studies, hip protectors led to a statistically significant reduction in the incidence of hip fractures<sup>13,14,16,17,19</sup>, 2 studies were borderline statistically

**Context** Several randomized controlled trials have been performed to examine the effectiveness of external hip protectors in reducing the incidence of hip fractures, but the results are controversial.

**Objective** To examine the effectiveness of hip protectors in reducing the incidence of hip fractures in an elderly high-risk population.

**Design, Setting, and Participants** Randomized controlled trial of elderly persons aged 70 years or older, who have low bone density, and are at high risk for falls. Participants lived in apartment houses for the elderly, homes for the elderly, and nursing homes in Amsterdam and surrounding areas in the Netherlands. They were enrolled in the study between March 1999 and March 2001; the mean follow-up was 69.6 weeks. Of the 830 persons who were screened, 561 persons were enrolled.

**Intervention** External hip protector. Both groups received written information on bone health and risk factors for falls.

**Main Outcome Measure** Time to first hip fracture. Survival analysis was used to include all participants for the time they participated.

**Results** In the intervention group, 18 hip fractures occurred vs 20 in the control group. Four hip fractures in the intervention group occurred while an individual was wearing a hip protector. At least 4 hip fractures in the intervention group occurred late at night or early in the morning. Both in univariate analysis (log-rank  $P = .86$ ) and in multivariate analysis (hazard ratio [HR], 1.05; 95% confidence interval [CI], 0.55-2.03), no statistically significant difference between the intervention group and control group was found with regard to time to first hip fracture. In addition, the per protocol analysis in compliant participants did not show a statistically significant difference between the groups (HR, 0.77; 95% CI, 0.25-2.38).

**Conclusion** The hip protector studied was not effective in preventing hip fractures.

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significant<sup>15,22</sup>; and 3 studies were not statistically significant.<sup>18,20,21</sup> In 2 studies, only the fracture rate per fall was calculated.<sup>16,21</sup> However, 4 of 10 studies were rather small (<200 participants)<sup>14,16,18,19</sup>; and 5 studies did

not use individual randomization to assign persons to the hip protector or control group.<sup>13,15,17,19,22</sup> In 2 relatively large studies that used individual randomization, hip protectors were not effective in preventing hip fractures.<sup>20,21</sup>

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The Amsterdam Hip Protector Study was designed to examine the effectiveness of external hip protectors in the prevention of hip fractures. This large randomized controlled trial used individual randomization to assign persons to the intervention or control group to address some of the limitations of previous studies.

## METHODS

The Amsterdam Hip Protector Study was designed as a randomized controlled trial in which individuals were randomized to the hip protector group or to the control group in a 1:1 ratio. The study enrolled residents of apartment houses for the elderly, homes for the elderly, and nursing homes in Amsterdam and surrounding areas in the Netherlands. Apartment houses for the elderly, homes for the elderly, and nursing homes are characterized by increasing dependence and care. Special adaptations, such as grip bars and adequate illumination, are present in all 3 types of housing. In apartment houses, no nursing staff is present, but home care can be provided.

All persons included in the study had to have a high risk for hip fractures. The follow-up duration was at least 1 year for all participants (those who started first continued in the study until the last participants had been followed up for 1 year). The ethical review board at the Vrije Universiteit Medical Center approved the study and all respondents (or their proxies in case of cognitive impairment) gave informed consent.

The screening consisted of a bone density measurement and a fall risk assessment. Bone density was assessed by an ultrasound measurement (broadband ultrasound attenuation [BUA]) of the calcaneus.<sup>23</sup> In addition, the risk factors of (1) 1 or more falls during the previous half year; (2) dizziness while standing up from a chair in the last 2 weeks; (3) having had a stroke in the past with sustained neurological impairment (ie, hemiparesis); (4) urinary incontinence; (5) low physical activity; (6) impaired mobility; and (7) cognitive impairment were assessed.<sup>24,25</sup> The first 5 risk factors were assessed by interview-

ing the participant. When it was not possible to interview the participant (eg, in case of cognitive impairment), a nurse of the ward in which the participant was living was interviewed. Physical activity was assessed by asking the participant if he/she did some walking, cycling, or heavy household tasks during the last 2 weeks. Low physical activity was defined as not performing these activities. Mobility was assessed by the walking observation scale, which ranges from 1 (he/she cannot walk) to 5 (he/she is able to walk independently for 100 m on any surface including stairs).<sup>26</sup> Impaired mobility was defined as a score of 3 or less. Cognitive impairment was defined as a score of 23 or less on the Mini-Mental State Examination (range, 0-30).<sup>27</sup> Individuals living on a psychogeriatric ward were assumed to have a cognitive impairment, but the head of the department was also consulted for confirmation.

Persons were included when they were aged 70 years or older, had low bone density, and/or a high risk for falling as determined by (1) BUA of 40 dB/MHz or less; or (2) BUA between 40 and 60 dB/MHz and at least 2 risk factors for falling; or (3) BUA between 60 and 70 dB/MHz and at least 3 risk factors for falling. Furthermore, persons who were completely immobile or persons who had sustained a hip fracture or had a hip prosthesis on both sides were excluded from the study. We conducted a substudy that validated that persons who were included in the study sustained more falls and fractures than the persons not included in the study because of being at low risk for fractures (data not shown).

Each individual at high risk for hip fracture was randomized to the intervention or control group. Randomization was performed in blocks of 4 after stratification for sex and for age in women ( $\leq 80$  years vs  $> 80$  years). Our statistical department generated randomization lists by computer. All persons living in the same home were first screened by the research assistants, and subsequently randomized by one of the authors (N.M.S.), in the same sequence in which they had been screened. Random-

ization lists were not available to the research assistants.

Both groups received written information on bone health (eg, diet, sunshine exposure) and external risk factors for falls (eg, loose carpets). In the intervention group, all participants received at least 4 hip protectors or 5 in case of urinary incontinence. In the control group, participants did not receive a hip protector. Participants and nurses were taught about the increased risk for hip fracture among institutionalized elderly, and about the causes and consequences of hip fractures. In addition, information and instructions about the use of hip protectors were given. These instructions included information about the mechanism of the protector, the importance of wearing the hip protector at night, and laundering. Newsletters were sent to nurses to emphasize the importance of compliance. Participants were not blinded to group assignment because it is difficult to design a sham protector that does not have a small protective effect. In the intervention group, a hip protector (Safehip) of the energy-shunting type was used (Tytex, Ikast, Denmark). The hip protector consists of 2 shell-shaped protectors, made of polypropylene, which are sewn into special underpants and cover the greater trochanter. Hip protectors were replaced in case of loss or damage.

The primary outcome measurement was time to first hip fracture. Falls and fractures were assessed prospectively by using a participant-kept calendar. Hip fractures and pelvic fractures were verified by the general practitioner. Participants were instructed to complete the calendar on a weekly basis and to mail the pages to the institute at the end of every 3 months for at least 1 year. When a participant was unable to complete the calendar, a nurse acted as a proxy. When the calendar was not fully completed, completed incorrectly, or not returned to the institute at the end of the 3 months, the participant or nurse was contacted by 1 of the authors or research assistants.

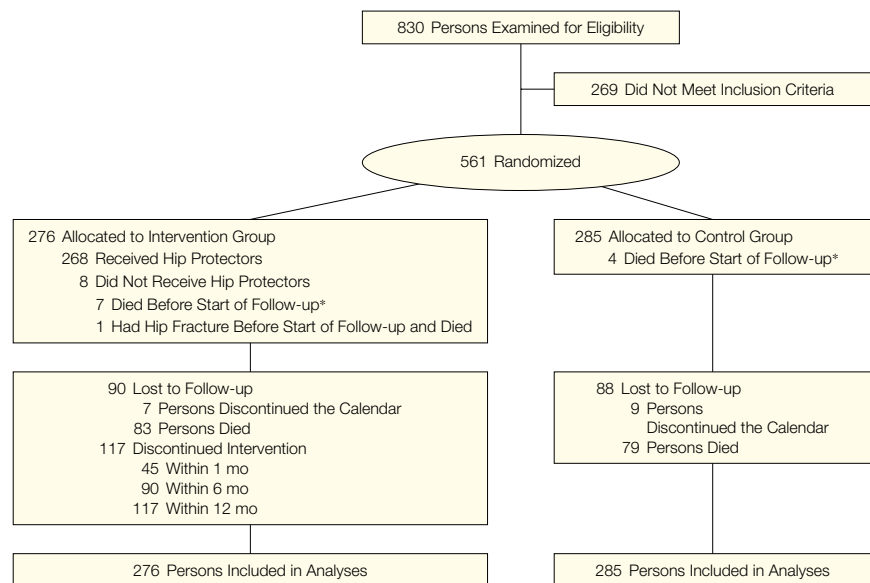
Compliance with wearing hip protectors was assessed by unannounced vis-

its by one of the research assistants at 1, 6, and 12 months after inclusion in the study. At this visit, the participant was checked to see if he/she was wearing the hip protector and was interviewed about hip protector use.<sup>28</sup> In addition, at the end of each period of the fall and fracture calendar (1 period is 3 months), participants were asked whether they were wearing the hip protectors when they fell.

According to our power calculation, 700 elderly persons had to be followed up for 1 year to detect a clinically important reduction in the incidence of hip fractures from 4% in the control group to 1% in the intervention group (1-sided  $\alpha = .05$ ,  $\beta = .20$ ). However, we enrolled only 561 participants, so the power to detect a clinically important reduction (from 4% to 1%) in the incidence of hip fractures was 74%. To increase the number of events and therefore the power, the follow-up duration was extended (mean, 69.6 weeks). This resulted in an incidence of hip fractures of 7% in the control group. The power to detect a reduction (from 7% to 2%) in the incidence of hip fractures was 89% (risk reduction of about 75%).

To examine the effect of external hip protectors on the incidence of hip fractures, the intention-to-treat principle was followed. The unadjusted relationship between the intervention (use of hip protectors) and time to first hip fracture and time to death was examined using Kaplan-Meier survival analysis. Second, the risk ratio for recurrent falling was calculated using the Cox proportional hazards model with equal survival time for all participants. The risk ratio was calculated instead of the odds ratio because the incidence of recurrent falling was higher than 10% and therefore, the odds ratio would have overestimated the effect. Individuals who fell recurrently were defined as participants who fell at least twice within 6 months.<sup>29</sup> Third, type of institution, cognitive impairment, age, sex, and stratum (1 = men; 2 = women aged  $\leq 80$  years; 3 = women aged  $> 80$  years) were examined to determine if they modified the relationship between the use of hip protectors and time to first hip fracture

**Figure 1.** Amsterdam Hip Protector Study



Calendar refers to the patient- or proxy-kept fall and fracture record. Asterisk indicates both groups started with the follow-up when the hip protectors were distributed.

using the Cox proportional hazards model. When an interaction was statistically significant ( $P < .10$ ), an interaction term was added to the model. Fourth, potential confounders were added to the model: type of institution, cognitive impairment, age, sex (if no interaction was present), BUA, risk factors for falling, and recurrent falling. Fifth, a per protocol analysis was performed. In this analysis, participants from the intervention group were included in the analysis if they were compliant at all unannounced visits ( $n = 78$ ). In addition, participants and nurses from the control group were asked to report when a participant from the control group started wearing hip protectors. These persons were excluded from the per protocol analyses (4 persons excluded; 281 included). Finally, the fracture rate per fall was calculated for both the intervention and control groups. The fracture rate per fall was also calculated for those who fell in the intervention group who were reported to not have been wearing hip protectors during any of the periods on the fall and fracture calendar vs those who fell who were reported to have been wearing hip protectors during 1 or more

periods. All analyses were performed using SPSS statistical software (version 9.0.1, SPSS Inc, Chicago, Ill).

## RESULTS

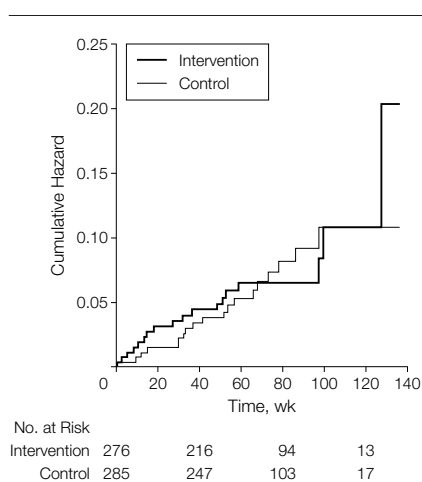
In total, 830 elderly persons from 45 homes or apartment houses for the elderly and nursing homes were screened for risk for hip fracture between March 1999 and March 2001 and followed up for hip fracture through March 2002 (FIGURE 1). Of these, 561 persons had a high risk for hip fracture and were assigned to the intervention ( $n = 276$ ) or control ( $n = 285$ ) group by individual randomization. The hip protectors were marked prior to distribution with the name and room number of the participant (median time between randomization and start was 2 weeks). Both groups started with the follow-up when the hip protectors were distributed. Eight persons in the intervention group and 4 persons in the control group died before distribution of the hip protectors in the intervention group. In addition, one person from the intervention group was not able to start wearing hip protectors because of a hip fracture on the day before randomization and then died. All per-

**Table 1.** Baseline Characteristics of the Intervention and Control Groups

Characteristic	No. (%) of Individuals*	
	Intervention Group (n = 276)	Control Group (n = 285)
Age, mean (SD), y	84.8 (6.2)	85.7 (6.0)
Women	242 (87.7)	259 (90.9)
Live in nursing home	144 (52.2)	133 (46.7)
Hip fracture in the past	28 (10.1)	40 (14.0)
Broadband ultrasound attenuation, mean (SD), dB/MHz	45.9 (12.5)	45.2 (12.1)
≥ 1 Falls in the last 6 mo	143 (51.8)	139 (48.8)
Dizziness†	52 (44.8)	71 (51.4)
Stroke with lasting consequences	28 (10.1)	27 (9.5)
Low physical activity	181 (65.6)	181 (63.5)
Urinary incontinence	198 (71.7)	200 (70.2)
Impaired mobility	198 (71.7)	193 (67.7)
Cognitive impairment	215 (77.9)	215 (75.4)

\*Values expressed as number (percentage) unless otherwise indicated.

†Assessed in persons without cognitive impairment (116 in intervention group and 138 in control group).

**Figure 2.** Cumulative Time Until First Hip Fracture

This analysis was performed to include all participants (including the persons who died) for the time they participated.

sons who were randomized to the intervention or control group were included in the survival analyses. Total follow-up time was 357 person-years for the intervention group and 398 person-years for the control group. The baseline characteristics of both groups are presented in TABLE 1.

There was no significant difference between the intervention and control groups with regard to time to first hip fracture in univariate analysis (log rank  $P = .86$ ; FIGURE 2). In the intervention

group, 18 hip fractures occurred in 18 persons (fracture rate of 5/100 person-years); and in the control group, 20 hip fractures occurred in 19 persons (fracture rate of 5/100 person-years). In both groups, one of the hip fractures occurred between randomization and distribution of the hip protector. When excluding these hip fractures, the log-rank  $P$  value was .85.

Eighty-three persons died in the intervention group and 79 persons died in the control group. Survival time until death was similar in the intervention and control groups ( $P = .31$ ). Furthermore, there were 100 individuals who experienced recurrent falls in the intervention group compared with 119 in the control group (risk ratio, 0.87; 95% confidence interval [CI], 0.67-1.13). Also, the incidence of other fractures was comparable between groups. In the intervention group, 16 other fractures occurred (including 2 pelvic fractures), and in the control group, 14 other fractures occurred (including 3 pelvic fractures).

In multiple analyses, no effect modification was found. After adjustment for confounding, no significant difference between participants from the intervention and control groups was found with regard to time to first hip fracture (hazard ratio, 1.05; 95% CI, 0.55-2.03). To test the assumption of proportionality, an interaction term of treatment  $\times$  70 weeks was added to the model. A cut-

off value of 70 weeks was chosen to test whether the effect of hip protectors on hip fractures was significantly different before and after 70 weeks (in Figure 2, the effect appears to be slightly different before and after 70 weeks). This interaction term was not statistically significant ( $P = .68$ ), which indicates that the effect of hip protectors on hip fractures was not significantly different before and after 70 weeks.

Compliance with hip protectors at unannounced visits was 132 (61%) of 217 individuals after 1 month (42 individuals were visited too late and not included), 110 (45%) of 246 after 6 months, and 85 (37%) of 230 after 12 months.<sup>28</sup> Individuals who died before the compliance visit were not included in the compliance calculation. During the interview, fewer than 16% of the participants were found to be using the hip protectors at night.

While the overall compliance was moderate to good in this study, 4 of 18 persons from the intervention group were wearing hip protectors while fracturing their hip (13 persons were not wearing hip protectors and in one hip fracture, it was not clear). In 9 of 13 hip fractures that occurred without a hip protector in the intervention group, the circumstances are known. One person fell immediately after randomization before the hip protectors were distributed; 4 persons fell late in the evening or early in the morning; 1 person was not wearing hip protectors because the hip protectors were being washed; 1 person stopped wearing hip protectors while bedridden and fell out of bed afterward; and 2 persons fell during the day (1 had stopped wearing hip protectors because of aesthetic reasons).

In the per protocol analysis, 78 compliant participants from the intervention group were compared with 281 participants from the control group. In the intervention group, 4 hip fractures occurred in 102 person-years (fracture rate of 3.9/100 person-years). In the control group, 20 hip fractures occurred in 19 persons in 394 person-years (fracture rate of 5.1/100 person-years). After adjustment for confounding, persons from the



intervention group had a 23% lower probability of fracturing a hip than persons from the control group (FIGURE 3). However, this difference was not statistically significant (hazard ratio, 0.77; 95% CI, 0.25-2.38).

Finally, the fracture rate per fall was calculated. In the intervention group there were 18 hip fractures in 727 falls (fracture rate per fall of 2.5%) and in the control group there were 20 hip fractures in 1075 falls (fracture rate per fall of 1.9%). In TABLE 2, the hip fracture rates per fall are presented according to the number of periods that participants from the intervention group (or their nurses) reported to be compliant on the fall and fracture calendar.

**COMMENT**

Hip protectors were not effective in preventing hip fractures in this study according to the intention-to-treat analysis. To examine whether this was due to low compliance, a per protocol analysis was performed including only those participants who actually wore hip protectors. In this analysis, a 23% nonsignificant reduction in the incidence of hip fractures was observed in the intervention group compared with the control group. In addition, a lower fracture rate per fall was found for those who fell, in the intervention group, and reported compliance for more calendar periods. However, the latter 2 analyses should be interpreted with caution because of low statistical power. Finally, there were 4 persons in this study who fractured a hip while wearing the hip protector, indicating that the impact efficacy of the studied hip protector was less than expected.

To date, results of 11 randomized controlled trials have been published, of which 4 studies (including our own) did not observe a statistically significant reduction in the incidence of hip fractures.<sup>18,20,21</sup> The Cochrane review by Parker et al<sup>12</sup> concludes that hip protectors appear to reduce the risk for hip fracture within a selected population at high risk for sustaining a hip fracture. However, the 4 negative studies were not included in this review. When considering the type of hip protector, the Safe-

hip hip protector was used in 6 randomized controlled trials. In 3 studies, the Safehip hip protector reduced the incidence of hip fractures (1 at borderline statistical significance)<sup>13,19,22</sup>; and in 3 studies it did not (including ours).<sup>18,20</sup>

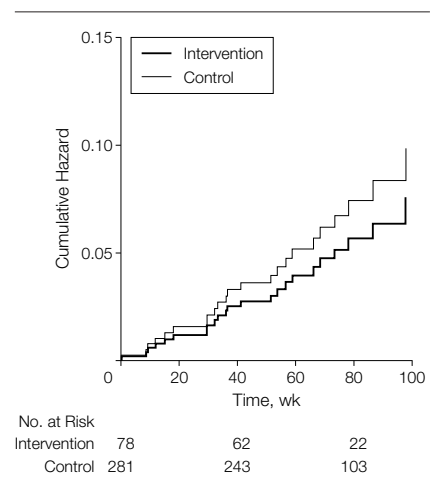
Our study was performed among institutionalized elderly persons at high risk for hip fracture. We believe that the results of this trial can be generalized to most institutionalized elderly persons, because two thirds of the screened population (561/830 persons) were at high risk for hip fracture. According to our screening criteria, more than half of our patients were cognitively impaired (the nursing home patients included were almost all cognitively impaired patients because most patients with chronic medical conditions only were excluded due to immobility). Cognitively impaired patients are an important group to study because they are at high risk for hip fracture. It is unclear how the compliance will be in psychogeriatric patients.<sup>19,30</sup> In the first study, it was reported that when demented patients acquire the habit of wearing the hip protector, they usually continue to wear it. In the second study, it was reported that dementia reduces the compliance.

The main strength of our study is that it was a large randomized controlled trial (N=561) that used individual randomization to assign persons to an intervention (hip protector) or control group. In 2 other studies that were both relatively large (N=384 and N=548, respectively) and used individual randomization, hip protectors were also not effective

in preventing hip fractures.<sup>20,21</sup> However, in the second study, half of the population was selected at random by the head of nursing, which may have resulted in selection bias. In addition, in both studies fewer than 10 hip fractures occurred, indicating that the statistical power may have been insufficient. Another important feature of our study is that it resembles daily practice. The study was performed in 45 different homes for the elderly and nursing homes in which nurses had to supervise the wearing of the hip protectors.

Some of the other studies concluding that hip protectors were not effective in preventing hip fractures indicate

**Figure 3.** Cumulative Time Until First Hip Fracture (per Protocol Analysis)



Cox proportional hazards model was used. The maximum survival time was 97 weeks because the model presents the cumulative hazard curves until the last hip fracture.

**Table 2.** Hip Fracture Rate per Fall in Intervention Group\*

Group	No. of Individuals	No. of Falls	No. of Hip Fractures†	Hip Fracture Rate per Fall, %‡
Intervention hip protector compliance period				
0	59	208	9	4.3
≥1	104	513	7	1.4
≥2	51	364	4	1.1
≥3	30	257	1	0.4
≥4	14	161	1	0.6
Control	285	1075	20	1.9

\*According to the number of periods (1 period is 3 months on the fall and fracture calendar; this question was only asked when a participant had fallen during this period) that participants were compliant in wearing hip protectors.

†Two hip fractures are missing (1 hip fracture occurred before hip protectors were distributed and the second hip fracture was in a participant who died shortly after the first period and information was missing).

‡Calculated as (number of hip fractures/number of falls) multiplied by 100.

that this may be due to a lack of power. The realized power of our study to detect a clinically important reduction from 4% to 1% in the incidence of hip fractures was 74%. We chose an expected risk reduction of 75% because in 2 large studies that were performed before we started our trial, risk reductions of 56% to 67% were found with a compliance lower than 50%.<sup>13,15</sup> However, now that more studies are published, this risk reduction probably was overestimated.

The compliance in our study was moderate to good and similar to the compliance in most other studies.<sup>13,15-18,21,28</sup> Compliance was aided by newsletters, which emphasized points such as the importance of wearing hip protectors at night. In addition, the unannounced visits may have had a small positive effect because noncompliant participants were encouraged to wear hip protectors at the end of the visit. The compliance at the unannounced visits changed from 61% to 37% during follow-up. At the moment of hip fracture, 22% of the participants were wearing a hip protector (4/18 participants). An important reason for this discrepancy in compliance is that fewer than 16% of the participants were wearing hip protectors at night, and 4 hip fractures in the intervention group occurred late in the evening or early in the morning. In the study by Jantti et al,<sup>31</sup> which was performed in nursing home residents, 59 of 207 falls occurred during the night. Compliance at night might increase if the hip protector is made more comfortable. Another possibility is to combine the hip protector with other interventions, such as a movement sensor, which alerts the nurse when the patient is getting out of bed; a softer hip protector during the night; or fall prevention strategies.<sup>32</sup>

Another problem we encountered is that the number of hip protectors provided was not always sufficient. In some homes, it was not possible to wash the hip protectors during the weekends and sometimes this resulted in a shortage, especially in persons who were incontinent of urine. In our study, 1 person fractured a hip while all hip protectors were being washed. It is possible

that persons who were noncompliant at night or due to a shortage of hip protectors were compliant during the unannounced visits and were included in the per protocol analysis. This may have diluted the effects of this analysis.

In future research, it would be interesting to examine whether the use of hip protectors influences the activity level of the participant. None of the studies to date used a sham hip protector. Because the participants and their nurses were not masked to the intervention, it is possible that the presence of the hip protector changed the person's activity level, and subsequently the risk for falls and fractures.

In conclusion, the studied hip protector was not effective in preventing hip fractures in this study. Possible causes for this lack of effectiveness include compliance, which was moderate to good during the day, but low at night; and lower impact effectiveness than expected.

**Author Contributions:** *Study concept and design:* van Schoor, Bouter, Lips.

*Acquisition of data:* van Schoor.

*Analysis and interpretation of data:* van Schoor, Smit, Twisk, Bouter, Lips.

*Drafting of the manuscript:* van Schoor, Smit, Lips.

*Critical revision of the manuscript for important intellectual content:* Smit, Twisk, Bouter, Lips.

*Statistical expertise:* van Schoor, Smit, Twisk, Bouter.

*Obtained funding:* Bouter, Lips.

*Administrative, technical, or material support:* van Schoor.

*Study supervision:* Bouter, Lips.

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