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Hip protectors for preventing hip fractures in older people (Review)

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TABLE OF CONTENTS

HEADER 1
ABSTRACT 1
PLAIN LANGUAGE SUMMARY 2
SUMMARY OF FINDINGS 3
BACKGROUND 5
OBJECTIVES 5
METHODS 5
RESULTS 7
Figure 1. 7
Figure 2. 8
Figure 3. 8
DISCUSSION 11
AUTHORS' CONCLUSIONS 13
ACKNOWLEDGEMENTS 13
REFERENCES 14
CHARACTERISTICS OF STUDIES 21
DATA AND ANALYSES 46
Analysis 1.1. Comparison 1 Provision of hip protectors, Outcome 1 Hip fracture: risk ratio; institutional residence. 47
Analysis 1.2. Comparison 1 Provision of hip protectors, Outcome 2 Hip fracture: risk ratio; community residence. 48
Analysis 1.3. Comparison 1 Provision of hip protectors, Outcome 3 Pelvic fracture: risk ratio. 49
Analysis 1.4. Comparison 1 Provision of hip protectors, Outcome 4 Other fractures (excluding pelvis): rate ratio. 49
Analysis 1.5. Comparison 1 Provision of hip protectors, Outcome 5 Pelvic and other fractures: rate ratio. 50
Analysis 1.6. Comparison 1 Provision of hip protectors, Outcome 6 Falls per person year; rate ratio. 51
ADDITIONAL TABLES 51
APPENDICES 59
FEEDBACK 60
WHAT'S NEW 63
HISTORY 63
CONTRIBUTIONS OF AUTHORS 65
DECLARATIONS OF INTEREST 65
SOURCES OF SUPPORT 65
DIFFERENCES BETWEEN PROTOCOL AND REVIEW 65
INDEX TERMS 65

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[Intervention Review]

Hip protectors for preventing hip fractures in older people

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ABSTRACT

Background

Older people living in nursing care facilities or older adults living at home are at high risk of falling and a hip fracture may occur after a fall. Hip protectors have been advocated as a means to reduce the risk of hip fracture. Hip protectors are plastic shields (hard) or foam pads (soft), usually fitted in pockets in specially designed underwear.

This is an update of a Cochrane review first published in 1999, and updated several times, most recently in 2010.

Objectives

To determine if the provision of external hip protectors (sometimes referred to as hip pads or hip protector pads) reduces the risk of fracturing the hip in older people.

Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (December 2012), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 12), MEDLINE (1950 to week 3 November 2012), MEDLINE In-Process (18 December 2012), EMBASE (1988 to 2012 Week 50), CINAHL (1982 to December 2012), BioMed Central (January 2010), trial registers and reference lists of relevant articles.

Selection criteria

All randomised or quasi-randomised controlled trials comparing an intervention group provided with hip protectors with a control group not provided with hip protectors.

Data collection and analysis

Two review authors independently assessed risk of bias and extracted data. We sought additional information from trialists. Data were pooled using fixed-effect or random-effects models as appropriate.

Main results

This review includes 19 studies, nine of which were cluster randomised. These included approximately 17,000 people (mean age range 78 to 86 years). Most studies were overall at low risk of bias for fracture outcomes. Trials tested hard or soft hip protectors enclosed in special underwear in 18 studies.

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Pooling of data from 14 studies (11,808 participants) conducted in nursing or residential care settings found moderate quality evidence for a small reduction in hip fracture risk (risk ratio (RR) 0.82, 95% confidence interval (CI) 0.67 to 1.00); the absolute effect is 11 fewer people (95% CI, from 20 fewer to 0) per 1000 having a hip fracture when provided with hip protectors.

There is moderate quality evidence when pooling data from five trials in the community (5614 participants) that shows little or no effect in hip fracture risk (RR 1.15, 95% CI 0.84 to 1.58); the absolute effect is two more people (95% CI 2 fewer to 6 more) per 1000 people having a hip fracture when provided with hip protectors.

There is probably little to no effect on falls (rate ratio 1.02, 95% CI 0.9 to 1.16) or fractures other than of the hip or pelvis (rate ratio 0.87, 95% CI 0.71 to 1.07). However, the risk ratio for pelvic fractures is RR 1.27 (95% CI 0.78 to 2.08); this is an absolute effect of one more person (95% CI 1 fewer to 5 more) per 1000 having a pelvic fracture when provided with hip protectors.

The incidence of adverse events while wearing hip protectors, including skin irritation, ranged from 0% to 5%. Adherence, particularly in the long term, was poor.

Authors' conclusions

Hip protectors probably reduce the risk of hip fractures if made available to older people in nursing care or residential care settings, without increasing the frequency of falls. However, hip protectors may slightly increase the small risk of pelvic fractures. Poor acceptance and adherence by older people offered hip protectors is a barrier to their use. Better understanding is needed of the personal and design factors that may influence acceptance and adherence.

PLAIN LANGUAGE SUMMARY

Hip protectors for preventing hip fractures in older people

What are hip protectors?

Older people living in nursing care facilities or older adults living at home are at high risk of falling and a hip fracture may occur after a fall. Hip protectors are plastic shields (hard) or foam pads (soft), usually fitted in pockets in specially designed underwear. They are worn to cushion a sideways fall on the hip.

Do they prevent hip fractures?

We conducted a review of the effect of hip protectors to prevent hip fractures. We searched for all relevant studies up to December 2012. We found 19 studies with about 17,000 people who were around 80 years old.

Overall, there was moderate quality evidence from these studies for the following results.

In older people living in nursing care facilities, providing a hip protector
- probably decreases the chance of a hip fracture slightly
- may increase the small chance of a pelvic fracture slightly
- probably has little or no effect on other fractures or falls

In older people living at home, providing a hip protector
- probably has little or no effect on hip fractures

When wearing the hip protectors very few people had side effects, such as skin irritation. However, people often did not wear the hip protectors when they were provided. Better understanding is needed of the personal and design factors that may influence acceptance and adherence.

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SUMMARY OF FINDINGS

Summary of findings for the main comparison. Provision of hip protectors for preventing hip fractures in older people

Provision of hip protectors for preventing hip fractures in older people

Patient or population: older people
Settings: institutional and community settings
Intervention: provision of hip protectors

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	No hip protectors provided	Hip protectors provided			
Hip fractures at 1 year older people living in the community Follow-up: 6-28 months	**Moderate risk[1]**		**RR 1.15** (0.84 to 1.58)	5614 (5 studies)	⊕⊕⊕⊖ **moderate[2]**
	10 per 1000	**12 per 1000** (8 to 16)			
Hip fractures at 1 year older people living in institutions Follow-up: 6-24 months	**Moderate risk[1]**		**RR 0.82** (0.67 to 1.00)	11808 (14 studies)	⊕⊕⊕⊖ **moderate[3]**
	60 per 1000	**49 per 1000** (40 to 60)			
Pelvic fractures at 1 year Follow-up: 6-24 months	**Moderate risk[1]**		**RR 1.27** (0.78 to 2.08)	12408 (9 studies)	⊕⊕⊖⊖ **low[3,4]**
	5 per 1000	**6 per 1000** (4 to 10)			
Other fractures at 1 year (excluding pelvis) Follow-up: 12-24 months	**Moderate risk[1]**		**Rate Ratio 0.87** (0.71 to 1.07)	7671 (6 studies)	⊕⊕⊕⊖ **moderate[3]**
	200 fractures per 1000	**174 fractures per 1000** (142 to 214)			
Number of falls per 1000 people at 1 year Follow-up: 12-24 months	**Low risk[1]**		**Rate Ratio 1.02** (0.9 to 1.16)	11204 (16 studies)	⊕⊕⊕⊖ **moderate[3,5]**
	500 falls per 1000	**510 falls per 1000** (450 to 580)			
	High risk[1]				

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	3000 falls per 1000	**3060 falls per 1000** (2700 to 3480)		
Adverse events: skin irritation Follow-up: 6-28 months	-	The incidence of adverse events, including skin irritation, with hip protectors ranged from 0% to 5%	~6600 (12 studies)	⊕⊕⊕⊕ **high**[6]
Adherence/compliance wearing hip protectors Follow-up: mean 6-28 months	-	The proportion of people who adhered to the hip protector intervention ranged from 24% to 80%	~8000 (19 studies)	⊕⊕⊖⊖ **low**[7]

*The **risk** when hip protectors are provided (and its 95% confidence interval) is based on the baseline risk in people who did not wear hip protectors and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Median risk in people not provided with hip protectors across randomised controlled trials.
[2] Participants were not blinded and results are imprecise due to few reported events; however, baseline risk and absolute effects are small, therefore quality of the evidence was only downgraded from high to moderate quality.
[3] Participants and/or nursing staff not blinded.
[4] Results imprecise as confidence intervals include no effect and appreciable harm, as well as heterogeneity which may be important.
[5] Considerable heterogeneity across studies and unexplained, however results are not imprecise.
[6]Adverse events were not measured in all studies. However, reporting bias is not suspected and a range of event rates reported and results are likely to be precise due to the small absolute event rates.
[7]Adherence reported with a variety of measures; considerable heterogeneity across studies and imprecise results.

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BACKGROUND

Description of the condition

The majority of hip fractures occur in an older population with an average age of around 80 years. Females predominate over males by about four to one (Thorngren 2002). An estimated 1.7 million hip fractures occurred worldwide in the year 1990 (WHO 1994). The number of people sustaining a hip fracture continues to rise due to a combination of an increasingly elderly population and a continued increase in the age-specific incidence in some countries. A prediction for global numbers of 6.26 million hip fractures by the year 2050 has been made (Melton 1993).

The fracture is usually the result of a fall. Falls can be due to multiple factors such as underlying physical illnesses, impaired balance, medications or environmental hazards, often in combination (Kellogg 1987). The aetiology of hip fractures is also multifactorial but the three principal factors can be summarised as a combination of a fall, loss of protective mechanisms (for example, putting out the arms to break the fall) and weaker bone strength (Cummings 1989). These factors are associated with ageing. The fall usually occurs whilst standing or walking and the impact with the ground is usually on the side in the region of the hip (Hopkinson-Woolley 1998). Whilst the hip fracture is usually the only major injury, its frequent combination with other medical problems associated with ageing results in significant mortality and morbidity.

Description of the intervention

Hip fractures affect the proximal femur (the upper part of the thigh bone). The idea of reducing the impact of a sideways fall onto the greater trochanter of the femur (this is the outer facing part of the top of the femur), and thereby the chance of fracturing the hip, began to receive research attention in the late 1980s (Lauritzen 1990; Lauritzen 1992; Wortberg 1988). The first clinical trial of hip protectors was reported in 1993 (Lauritzen 1993) with encouraging results. Much of the early work was summarised in Lauritzen 1996a. Different hip protector designs have been developed by researchers and manufacturers, and some of these have been enthusiastically adopted by health professionals.

How the intervention might work

There are two main types of hip protectors. Hard protectors provide a firm shell over the lateral aspect of the hip, and are usually held within specifically designed underwear. Their main mode of action is to shunt the force of the impact away from the greater trochanter to the soft tissues of the thigh. The pads of soft protectors use compressible materials designed to be mainly energy absorbing. The typical force likely to cause a fracture has been established in biomechanical studies. Different protector designs are now able to be tested in a standard way to confirm that they have properties likely to reduce the forces transmitted to the hip in a sideways fall to a level below the typical fracture threshold (Cameron 2010; Holzer 2009).

Why it is important to do this review

Over the two decades since the concept and outcomes of providing older people with hip protectors were first described, observational studies and some clinical trials have demonstrated effectiveness, but others have not. This updated review (first published in 1999) seeks to provide a critical appraisal and synthesis of the current evidence for the effectiveness of hip protectors.

OBJECTIVES

To determine if the provision of external hip protectors (sometimes referred to as hip pads or hip protector pads) reduces the risk of fracturing the hip in older people.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised and quasi-randomised (method of allocating participants to a treatment that is not strictly random, e.g. by date of birth, hospital record number, alternation) controlled trials (RCTs) evaluating the provision of hip protectors for reducing the risk of hip fractures in older people. We also sought economic evaluations of hip protector use.

Types of participants

Older people living in the community or in institutional care. We accepted studies in which the criterion was residence in a nursing care facility, whether accompanied by a defined minimum age or not, or studies recruiting participants with a minimum age of 65 years or over.

Types of interventions

Allocation individually or within a cluster to the provision of hip protectors (whether or not reported to be accompanied by measures to improve acceptance and adherence) compared with no provision of hip protectors. We excluded trials in which the intervention being tested was a programme designed to reduce the incidence of hip fractures in which provision of hip protectors was just one component. We also excluded trials which studied adherence to wearing protectors but did not report fracture outcomes, and trials which compared the provision of different designs of hip protector without an unprotected control group. Studies reporting no fractures in either group were also excluded from the review.

Types of outcome measures

Primary outcomes

- Risk of sustaining a hip fracture
- Risk of sustaining a pelvic fracture
- Overall rate of pelvic and other fractures
- Rate of fall events

Secondary outcomes

- Acceptance of and adherence to wearing protectors (we use the term 'compliance', which comprises both acceptance and adherence, where it was used by authors of studies, but elsewhere we refer to acceptance and adherence either individually or together)
- Complications relating to use of protectors (including skin damage or breakdown)
- Economic outcomes

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Search methods for identification of studies

Electronic searches

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (December 2012), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 12), the NHS Economic Evaluation Database (*The Cochrane Library* 2012, Issue 12), MEDLINE (1950 to week 3 November 2012), MEDLINE In-Process (18 December 2012), EMBASE (1988 to 2012 Week 50), CINAHL (1982 to December 2012) and BioMed Central (January 2010). For this update, the search results for the databases were limited to from November to December 2009 onwards. There were no restrictions based on language or publication status.

In MEDLINE, the subject specific search strategy was combined with the sensitivity-maximizing version of the Cochrane highly sensitive search strategy for identifying randomised trials (Lefebvre 2011), and modified for use in other databases (*see* Appendix 1). Details of the previous search strategies can be found in past versions of the review, most recently Gillespie 2010.

Ongoing trials were identified using the World Health Organization (WHO) International Clinical Trials Registry Platform, Current Controlled Trials and the UK National Research Register (NRR) Archive (up to April 2013).

Searching other resources

We checked reference lists of relevant articles and contacted trialists for further data.

Data collection and analysis

Selection of studies

Two review authors screened the titles, abstracts and descriptors of identified studies for possible inclusion. From the full texts, two review authors independently assessed potentially eligible trials for inclusion and resolved any disagreement through discussion. We contacted trial authors for additional information if necessary.

Data extraction and management

For each study, two review authors independently extracted data into a Microsoft Excel spreadsheet for the outcomes listed above. Differences were resolved by discussion.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias using the recommendations in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a) (*see* Differences between protocol and review). The following domains were assessed: sequence generation; allocation concealment; blinding of participants and personnel (performance bias); blinding of outcome assessment (separately for fractures of the hip and pelvis, and for falls); whether incomplete outcome data were adequately addressed; and whether there was selective outcome reporting. Details of the criteria used to assess risk of bias for each domain are in Table 1. This table was updated in this review to include the terminology of 'low', 'high' and 'unclear' risk of bias (yes, no and unclear were used in the last version). In addition, 'unclear' was not often used unless no judgement could be made by the review authors.

Measures of treatment effect

We used the generic inverse variance method for the presentation of results and pooling of data for risk ratio (number of participants sustaining an event in each group) and, where appropriate, for rate ratio (number of events in each group). The generic inverse variance option requires entering the natural logarithm of the rate ratio or risk ratio and its standard error; we calculated these in Microsoft Excel. When rate ratios or risk ratios were not provided by the authors but raw data were available, we first used Review Manager 5 to calculate a risk ratio and 95% confidence interval, or Microsoft Excel to calculate an incidence rate ratio and 95% confidence interval. For cluster randomised trials, we performed adjustments for clustering if this had not been done in the published report (*see* Unit of analysis issues).

Risk of fracture

We used a reported estimate of effect (risk ratio (relative risk), odds ratio or hazard ratio for first fracture) and 95% confidence interval if available. If both adjusted and unadjusted estimates were reported we used the unadjusted estimate, unless the adjustment was for clustering. If an effect estimate and 95% confidence interval were not reported and appropriate data were available, we calculated a risk ratio and 95% confidence interval.

Rate of fractures or falls

For aggregated fracture data (pelvic and other) and falls outcomes, where it is more likely that more than one event will occur in a proportion of participants, we presented rate ratio as the main measure of treatment effect.

We used a rate ratio (for example, incidence rate ratio or hazard ratio for all events) and 95% confidence interval if these were reported in the paper. If both adjusted and unadjusted rate ratios were reported we used the unadjusted estimate, unless the adjustment was for clustering. If a rate ratio was not reported we calculated this, and a 95% confidence interval, if appropriate raw data were reported. In calculating rate ratios, we used events per person year of follow-up for hip fractures and falls if these data were reported or were calculable from the reported data. Where only the number of events or of individuals sustaining an event in the protected and unprotected groups were reported, we assumed an equal duration of follow-up surveillance for all participants in each group.

Unit of analysis issues

Data from trials that were cluster randomised by institution (nursing home or other similar facility, or by ward or room within an institution) were adjusted for clustering (using Microsoft Excel) where such adjustment had not already been conducted. We used the intra-class correlation coefficient (ICC) reported by the authors, if this was available, and the average cluster size in each study to calculate the design effect by the approximate method described in Higgins 2011b. Where cluster randomised studies did not provide an intra-class correlation coefficient (ICC), we imputed the ICC reported by O'Halloran 2004.

Dealing with missing data

We obtained missing data from a number of study authors (*see* Characteristics of included studies for details). For studies in which one or more event had occurred in one of the groups but no event

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had occurred in the other, we imputed a value of 0.4 in the zero cell to allow calculation of a risk or rate ratio.

Assessment of heterogeneity

Heterogeneity between pooled trials was assessed using a combination of visual inspection of the graphs along with consideration of the Chi^2 test (with statistical significance set at P < 0.10) and the I^2 statistic (Higgins 2003). The I^2 value was assessed as 'might not be important' (0% to 40%), 'moderate' (30% to 60%), 'substantial' (50% to 90%) or 'considerable' (75% to 100%) as recommended in Deeks 2009b.

Data synthesis

We pooled the results of trials using the generic inverse variance method in Review Manager 5 (Deeks 2009a) and the fixed-effect model. Where there was considerable statistical heterogeneity we pooled the data using the random-effects model.

Subgroup analysis and investigation of heterogeneity

We carried out subgroup analyses of studies that used individual randomisation versus those using cluster randomisation for hip fracture outcomes. Trials conducted in the community were analysed separately from those conducted in institutional settings. We investigated heterogeneity using sensitivity analyses (see below).

Sensitivity analysis

We carried out sensitivity analyses to explore the impact on the pooled results of removing from the analyses studies at high risk of bias in the key domain of allocation concealment.

Quality of the evidence

We used the GRADE approach to assess the quality of evidence related to each of the key outcomes listed in the Types of outcome measures (Chapter 12.2, Higgins 2011).

'Summary of findings' table

We created a 'Summary of findings' table for the main comparison.

RESULTS

Description of studies

Results of the search

The search was updated from between November and December 2009 to December 2012. We screened a total of 105 unique records (after 41 duplicates were removed) from the following databases: Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (8); CENTRAL (66); the NHS Economic Evaluation Database (10); MEDLINE (15); MEDLINE In-Process (0); EMBASE (18); and CINAHL (29). No additional records were identified through other sources.

The search identified a total of four studies for potential inclusion for which full reports were obtained (two studies were published in one article). Three RCTs were full published in full (Cameron 2011; Cameron 2011a; Cameron 2011b); these RCTs were listed under one study awaiting assessment in the previous review (Gillespie 2010). One study (Frohnhofen 2010) awaits classification. No new studies were found that reported an economic evaluation of hip protector use. Details of the process of screening and selecting studies for inclusion in the review are illustrated in Figure 1.

Figure 1. Study flow diagram

Overall, there are now a total 19 included trials, 21 excluded studies, one ongoing trial and one study awaiting classification.

The results from the previous searches (up to 2009) are shown in Appendix 2.

Included studies

The 19 included studies (*see* Characteristics of included studies for details of individual studies) involved approximately 17,000 older people living in nursing care facilities or older adults living at home. The exact number was unclear as one study (O'Halloran 2004) reported occupied beds in participating clusters rather than numbers of individuals. In nine studies, participating facilities were cluster randomised to provision of hip protectors or not (Cameron 2011; Cameron 2011a; Ekman 1997; Harada 2001; Kannus 2000; Koike 2009; Lauritzen 1993; Meyer 2003; O'Halloran 2004). Kiel 2007 used an innovative study design in which each participant was provided with a protector garment in which one or other hip was protected, and each participating cluster was randomly assigned as a left or right-padded facility. Nine studies individually randomised participants to provision of hip protectors or unprotected control (Birks 2003; Birks 2004; Cameron 2001; Cameron 2003; Cameron 2011b; Chan 2000; Hubacher 2001; Jantti 1996; Van Schoor 2003).

Five of the included studies (Birks 2003; Birks 2004; Cameron 2003; Cameron 2011a; Cameron 2011b) involved people living in the community; in Cameron 2011a, participants started off in hospital wards but were then discharged into the community. The remaining trials involved people in institutional care. Ten studies were conducted in European countries, six in Australia, two in Japan and one in the USA. The mean age of participants in the individual studies, where reported, ranged from 78 to 86 years.

The type of protector used was reported by all studies. Three studies in community settings (Birks 2003; Birks 2004; Cameron 2003) used hard protectors, while Cameron 2011a and Cameron 2011b provided participants in the community with either hard or soft protectors. The type of protector used in institutional settings varied. Ten used hard protectors with energy shunting properties, three used soft protectors and one (Kiel 2007) used a hybrid shunting and absorbing design in which the hard component was sandwiched between two foam layers. Ordinary underwear with no special fixation for the hip pad was used in Ekman 1997. In all other included studies the protectors were enclosed in special underwear. Seven studies emphasised the importance of, and details about, staff training to facilitate participant acceptance and adherence (Cameron 2011; Cameron 2011a; Cameron 2011b; Kiel 2007; Meyer 2003; O'Halloran 2004; Van Schoor 2003).

All studies reported hip fracture outcomes. Nine studies (*see* Analysis 1.3) reported pelvic fracture outcomes separately from other fractures. Six of these studies also reported data on other

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fractures sustained by participants (*see* Analysis 1.4). Three studies (Koike 2009; Lauritzen 1993; Meyer 2003) reported pelvic and other fractures as a single group, but we were able to combine data on pelvic and other fracture outcomes from six others to report a rate ratio (*see* Analysis 1.5).

Excluded studies

Twenty-one studies are listed, along with the reasons for exclusion, in the Characteristics of excluded studies.

Ongoing studies

One ongoing trial (Tangtrakulwanich) is described in the Characteristics of ongoing studies.

Studies awaiting classification

One completed study (Frohnhofen 2010) is awaiting classification until a full report is prepared (*see* Characteristics of studies awaiting classification for details).

Risk of bias in included studies

Our assessment of the risk of bias in the individual included studies is shown in Characteristics of included studies. Figure 2 shows the assessment for each individual study, and Figure 3 shows a summary of the risk of bias by domain. The domain judged to have the lowest risk of bias was allocation concealment, whereas the domain with the highest risk of bias was blinding of participants and personnel. As it is not feasible to blind participants, there is a risk of performance bias, i.e. knowledge of the intervention received may affect the outcomes; it is unclear if this would result in an overestimate or underestimate of the effect. For example, would a resident who is wearing a hip protector take more risks and therefore increase the risk of a fracture or would the resident be more aware of the risk of a fracture and take extra precautions? The only trial that was judged to have a low risk of bias in this domain was Kiel 2007, since they were assessing the effect of hip protectors using a design in which participants acted as their own controls (hip protector worn on one side only). Consequently, blinding of outcome assessors is a critical issue to avoid potential biases. Assessment of fractures was judged to have a low risk of bias in 16 out of the 19 trials, whereas assessment of falls was judged to have a low risk of bias in three out of the 19 trials. Although many studies had high loss to follow-up, the risk of bias for outcome assessment was not considered high because in most of those studies the incident rates of fractures were similar to studies with low loss to follow-up. Only three of the 19 trials had selective outcome reporting bias for hip fractures and other fractures. In particular, Kiel 2007, a relatively recent study, did not report the incidence of other fractures.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

Effects of interventions

See: **Summary of findings for the main comparison** Provision of hip protectors for preventing hip fractures in older people

Hip fractures

Studies conducted in an institutional setting

Pooling of data from the 14 studies (11,808 participants) (*see* Table 2 for summary data from studies) conducted in nursing or residential care settings (Analysis 1.1) shows a small reduction in hip fractures with the provision of hip protectors (risk ratio (RR) 0.82, 95% confidence interval (CI) 0.67 to 1.00); the confidence interval, however, includes both no effect and an appreciable benefit of hip protectors. Using a typical baseline risk from studies (*see* Table 3), the calculated absolute effect is 11 fewer people per 1000 (95% CI from 20 fewer to 0) will have a hip fracture when provided with hip protectors in institutional settings. In a sensitivity analysis, the effect is reduced (RR 0.90, 95% CI 0.72 to 1.13; analysis not shown), following exclusion from the analysis of four studies (3092 participants) assessed as being at high risk of bias in the key domain of allocation concealment (Chan 2000; Hubacher 2001; Kannus 2000; Koike 2009). The analysis across studies with individual randomisation and studies with cluster randomisation (adjusted) shows similar results.

Heterogeneity across all of the included studies in Analysis 1.1 is likely to be not important (I^2 = 33%).

Overall, there is moderate quality evidence (due to risk of bias) for a small reduction in hip fractures with hip protectors in institutional settings (*see* Summary of findings for the main comparison).

Studies conducted in a community-dwelling setting

Four individually randomised studies recruited 5306 community-dwelling older people (Birks 2003; Birks 2004; Cameron 2003; Cameron 2011b) and one cluster randomised study recruited 308 community-dwelling older people who were admitted to hospital for hip fracture and later discharged into the community (Cameron 2011a) (*see* Table 4 for data used in analysis). The pooled analysis showed a small increase in or no effect on hip fractures with hip protectors (RR 1.15, 95% CI 0.84 to 1.58) (*see* Analysis 1.2). However, using a typical baseline risk from the included studies (*see* Table 3), the calculated absolute effect was two per 1000 more people (95% CI from 2 fewer to 6 more) with a hip fracture when provided with hip protectors in the community. The results of these studies showed no heterogeneity.

There was moderate quality evidence (due to risk of bias) that hip protectors probably had little or no effect on hip fractures in the community.

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Pubic ramus and other pelvic fractures

Data on the incidence of pubic ramus and other pelvic fracture were available in nine studies (*see* Analysis 1.3). The risk ratio is 1.27 (95% CI 0.78 to 2.08). This result is imprecise due to the small number of events in the analysis (*see* Table 5 for absolute events per study) and the confidence interval include no effect as well as an appreciable harm. However, in absolute effects it would mean one more person per 1000 provided with a hip protector (95% CI from 1 fewer to 5 more) will have a pelvic fracture. Overall heterogeneity across community and institutional settings is I^2 = 20% (no heterogeneity in community and I^2 = 34% in institutions), but due to the small number of events, heterogeneity may have been difficult to detect across studies (in particular between O'Halloran 2004 and the other studies). There are similar effects on pelvic fractures between community and institutional settings, although the point estimate is greater in institutional settings. Overall, the evidence is low quality.

Other fractures

Data on the incidence of other fractures that occurred over the study periods were reported in 11 studies, but were disaggregated from pelvic fractures in six. Pooling of results from the six studies providing disaggregated data on fractures other than in the hip or pelvis shows little or no effect in rate of fractures (RateR 0.87, 95% CI 0.71 to 1.07) (*see* Analysis 1.4). The absolute effect is 26 fewer fractures per 1000 people provided with hip protectors over one year (95% CI from 58 fewer to 14 more). Pooling of data aggregating pelvic and other fractures together shows little or no effect in rate of fractures (RateR 0.88, 95% CI 0.75 to 1.05) (*see* Analysis 1.5). There is no heterogeneity across studies. The quality of evidence is moderate due to risk of bias.

Falls

Sixteen studies reported falls incidence; the pooled analysis shows little or no effect on the frequency of falls (RateR 0.99, 95% CI 0.87 to 1.13, Analysis 1.6). In people at low risk of falls, the absolute effect is 10 more falls per 1000 people (95% CI, from 50 fewer to 80 more); in people at high risk it is 60 more falls per 1000 people (95% CI, from 300 fewer to 480 more). There is however, considerable heterogeneity amongst these studies (Chi^2 = 198.69, df = 15 (P < 0.00001), I^2 = 92%), but it did not result in imprecise results. The overall quality of evidence is moderate.

O'Halloran 2004 reported on the occurrence of injurious falls (falls requiring medical attention): adjusted RateR 1.16 (95% CI 0.77 to 1.76) in a trial authors' analysis. Kannus 2000 reported on falls only in the protector group (1404 falls occurring in the 653 individuals).

Acceptance and adherence (also termed compliance)

Amongst those who were assigned to hip protectors, there was limited compliance with wearing them. Despite special efforts by some research groups (Kiel 2007; Meyer 2003; O'Halloran 2004; Van Schoor 2003) to improve acceptance and adherence through staff and participant education, acceptance and adherence remain low. In view of the different ways in which estimates of acceptance and adherence were presented, we did not attempt any summary estimate of frequency of use.

Birks 2003 gave an overall compliance figure of 34%. In Birks 2004, 17,222 individuals were identified who met the inclusion criteria (aged 70 years or over and having at least one risk factor for hip fracture) but 13,645 (79%) declined to participate. Of those who agreed, only 31% were still wearing the protectors daily by the end of the 28-month study. Cameron 2001 stated that the total compliance was 57%. At the end of this study only 37% were still regular wearers of the protectors. Cameron 2003 approached 1807 potential participants living in their own homes and 34% of these agreed to participate. By two years, the end of this study, only 33% to 38% of participants were wearing the protectors all the time. Cameron 2011a was also conducted in the community; adherence in hospitalised participants who were later discharged was 34% to 37%, and 48% to 51% for participants in the community at six months. Participants wore soft or hard protectors. Cameron 2011 included participants in nursing care facilities who wore hard shell protectors and found at six months that adherence was 34% to 36%. Chan 2000 reported a compliance of 50%, with dementia given as a reason for non-compliance. Ekman 1997 reported an average compliance of 44%, although it is not clear how this was calculated. Harada 2001 reported that 17/88 (19%) of those allocated to the protectors refused to wear them. Complete compliance, estimated by hours worn, was 70% and partial compliance was 17%. Hubacher 2001 reported that for 384 participants allocated to the protector group, 138 were regular wearers, 124 discontinued wearing them and 122 refused to wear them. Even the 138 'regular wearers' only wore the protectors 49.1% of the time. Jantti 1996 stated that of the 19 participants available at one year, 13 (68%) were still using hip protectors. In Kannus 2000, 31% of those who were eligible declined to participate in the study, and a further 71 out of 446 patients discontinued use during the study. Compliance in those who agreed to participate in the study (assessed as the number of days the protector was worn as a percentage of all available follow-up days) was 48% (± 29%, range < 1% to 100%). In Kiel 2007, participating residents were visited by research staff three times per week to assess adherence; this was throughout the trial, including the two-week run-in period. Reported adherence was initially about 60%, rose to 80% by the sixth month of the study and then fell again to less than 70% by the end of the study. Koike 2009 reported that compliance with hip protector use (for at least part of the day) was 79.7% throughout the study period. Of the subgroup of 45 individuals allocated to hip protectors monitored in Lauritzen 1993, only 11 (24%) wore the protectors regularly. Meyer 2003 recorded the compliance rate during fall events and reported that 68% in the intervention group versus 15% in the control group were wearing hip protectors at the time of a fall (*see* Feedback 3). O'Halloran 2004 reported that 37% of those allocated to wear the protectors at the start of the study agreed to do so. By 24 weeks of the study, 24% of those allocated to receive hip protectors were wearing them when visited by the research staff; this fell to 20% by 72 weeks. Van Schoor 2003 used random visits to assess compliance. At one month, 61% were compliant with wearing the protectors. This figure had fallen to 45% at six months and 37% at one year.

Chan 2000, Ekman 1997, Harada 2001 and Lauritzen 1993 all stated that no hip fractures occurred in those who fell while wearing the protectors. Five studies each reported that one hip fracture occurred while protectors were being worn (Birks 2004; Cameron 2001; Cameron 2011; Cameron 2011b; Jantti 1996). In Cameron 2001 the protector was not properly applied, in Birks 2004 the person fell backwards, and in Jantti 1996 the fracture was attributed to the pants being too large and the pads slipping out of place. Kannus 2000 and Van Schoor 2003 each reported

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that four hip fractures occurred whilst protectors were being worn. Cameron 2003 also reported four hip fractures whilst wearing the protectors: two were backward falls, one a spontaneous fracture and one occurred from a road traffic accident. In Meyer 2003, four participants in the intervention group sustained hip fractures that may have occurred while hip protectors were being worn. Kiel 2007 reported that 13 hip fractures occurred in protected hips while residents were wearing hip protectors. In Koike 2009, seven out of the 19 fractures in the intervention group occurred in falls while hip protectors were worn. O'Halloran 2004 stated that 13% of fractures in residents of intervention homes occurred while protectors were being worn.

Complications (including skin damage or breakdown)

Not all studies measured complications, and studies often combined reporting of these with reasons for non-compliance. In studies that did report on complications, there was a range of event rates that were small (~ 0% to 5%). In Birks 2004, one hip fracture resulted from falling while putting on a protector. Minor skin irritation was reported in Cameron 2001, and Cameron 2003 reported minor skin irritation or infection caused by hip protectors in 16 users (5%). Cameron 2011, Cameron 2011a and Cameron 2011b asked participants open-ended questions about complications, but no complications were reported. Chan 2000 indicated that one staff member noted that the underwear had rubbed. Ekman 1997 mentioned that the occurrence of skin irritation was used as a reason for non-compliance. Hubacher 2001 reported that aches and pains and an uncomfortable feeling while wearing the protectors were given as a reason for non-compliance. Kannus 2000 reported skin irritation or abrasion in 15 cases. In addition, one person reported that the protector caused swelling of the legs and another that it caused bowel irritation. In Kiel 2007, no skin-related or mobility-related adverse effects occurred. Koike 2009 reported that "six residents in the intervention group reported skin-related adverse events and refused to wear hip protectors from that time on". Meyer 2003 reported five cases of skin irritation. In addition, some of the care homes reported increased dependency of some of the residents at toileting, more difficulty in dressing and discomfort from wearing the protectors.

Economic evaluation

We found 12 economic evaluations of the use of hip protectors. Economic outcomes were available from two of the included studies (Meyer 2003; Van Schoor 2003). Ten other economic evaluations modelled the possible impact of provision of hip protectors in different health delivery systems in North America and Europe.

Seven economic evaluations conducted in North America assumed efficacy of hip protectors, derived from one or more of the early cluster randomised studies or from pooled data in the 2001 version of this Cochrane review (Parker 2001), and conducted economic modelling relevant to their health system.

Four evaluations were conducted in the USA (Colon-Emeric 2003; Honkanen 2005; Honkanen 2006; Segui-Gomez 2002).

Colon-Emeric 2003 conducted a cost-effectiveness and cost-utility analysis using a societal perspective and an 18-month time horizon. They concluded that “using external hip protectors in nursing facilities is cost saving or economically attractive over a wide range of cost and utility assumptions”.

Honkanen 2005 used a Markov model considering the short-term and long-term outcomes of hip protectors for a hypothetical nursing home population, stratified by age, sex and functional status. Estimates of hip protector effectiveness were derived from Kannus 2000, and costs and transition probabilities between health states were from other published secondary data. From a Medicare perspective, hip protectors appeared to be potentially cost-saving in the nursing home environment across almost all sex and functional groups aged 65 years and older, and for the nursing home population as a whole when adherence was greater than 42% and residents used three hip protectors a year.

Honkanen 2006 used a Markov model similar to that in Honkanen 2005, conducting a cost-utility analysis of using hip protectors in a community-dwelling population compared with no intervention. In this setting, the analysis demonstrated that hip protector use was the dominant strategy only in women who initiated use at the age of 80 or 85 years, and in men who initiated use at the age of 85 years.

Segui-Gomez 2002 modelled two hypothetical cohorts of 500,000 65-year-old men or women with and without hip protectors through to death or the age of 100 years, whichever was earlier, using the data from Kannus 2000 to give an efficacy estimate of 56% (sensitivity analysis range 43 to 69). In this model, everyone in the hip protector cohort was assumed to show 100% adherence for the base case but sensitivity analyses explored the effect of lower levels. At an efficacy estimate of 13% (compatible with the evidence from our Analysis 1.1 and Analysis 1.2), net costs were generated. Hip protectors for women would be cost saving with adherence above 23%.

Three economic evaluations were reported from Canada (Sawka 2007b; Singh 2004; Waldegger 2003).

Sawka 2007b used a pooled odds ratio of 0.40 (95% CI 0.25 to 0.61) from a meta-analysis (Sawka 2007a, which included Ekman 1997; Harada 2001; Jantti 1996; Meyer 2003) in a model-based economic analysis, using estimates of transition probabilities, costs and utilities relevant to Canada. Assumed compliance was as in these four studies. They concluded that if hip protectors could be provided to elderly Ontario nursing home residents without additional labour expenditures, there was a reasonable probability that such a strategy might result in healthcare cost savings.

Singh 2004 modelled the cost-effectiveness of hip protectors in the prevention of hip fractures using data from literature current at that time, and from the care of elderly nursing home residents in a community hospital in British Columbia, Canada. They found that hip protector use was a dominant strategy compared to no treatment and to calcium and vitamin D supplements, and could save money while preventing hip fractures and improving quality of life.

Waldegger 2003 conducted a meta-analysis of five early cluster randomised studies that were at high risk of bias (Chan 2000; Ekman 1997; Harada 2001; Kannus 2000; Lauritzen 1993) assuming a relative risk of hip fracture of 0.40 (95% CI 0.23 to 0.70) and an adherence range of 25% to 50%. Using these assumptions, their economic analysis indicated that hip protectors were a cost-effective method of preventing hip fracture in an institutionalised elderly population.

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Five economic evaluations were conducted in northern Europe, three of which were modelling studies (Fleurence 2004; Gandjour 2008; Kumar 2000), and two had been conducted as a prospectively planned and conducted component of studies included in this review (Meyer 2003; Van Schoor 2003).

Fleurence 2004 (UK) developed a Markov model to follow a hypothetical cohort of males and females at high risk and general risk of fracture. They concluded that "Current information available on interventions to prevent fractures in the elderly in the United Kingdom, suggests that, at the decision-maker's ceiling ratio of $20,000 per quality adjusted life year (QALY), hip protectors were cost-effective in the general female population and high-risk male population, and cost-saving in the high-risk female population, despite the low compliance rate with the treatment".

Gandjour 2008 (Germany) reported the use of a Markov simulation of two cohorts of 100,000 hypothetical patients, one offered hip protectors and the other not. In their analysis, they use the pooled estimate of effectiveness from the previous update of this Cochrane review (RR 0.77, 95% CI 0.62 to 0.97). Adherence of 50% was assumed; so was use of protectors up to a total of two years by other individuals if the first wearer were to stop earlier. The base-case analysis found that wearing hip protectors would lead to savings of EUR 315 and a gain of 0.13 QALYs per patient. The probability of savings was 99%; only with an assumption of low hip protector effectiveness or high mortality rate at six months after fracture would these savings not be realised; however, some uncertainty about cost-effectiveness did remain.

Kumar 2000 (UK) modelled the additional costs of providing three pairs of hip protectors to older people in the catchment area of a district general hospital using: contemporary costs for 1998; an assumption of effectiveness based on the three studies in this review that were published before 2000 (Ekman 1997; Jantti 1996; Lauritzen 1993); and detailed age and gender data based on a four-year observational study. The results suggested that for people aged over 84 years, wearing hip protectors appeared to be cost-effective, but that further evaluation of effectiveness, costs and compliance was desirable.

In Meyer 2003, (Germany), in which a planned economic evaluation was conducted alongside the clinical study, education about and provision of hip protectors did reduce hip fracture incidence but was found to produce a slight increase in costs, although cost savings might be made if the price of the hip protectors could be decreased.

Van Schoor 2003 (Netherlands) conducted an economic evaluation alongside the clinical study, which found that provision of hip protectors was neither effective nor associated with lower costs.

DISCUSSION

Summary of main results

The initial cluster randomised studies, which formed the bulk of the early evidence up to 2001, appeared to indicate that hip protectors significantly reduced the incidence of hip fracture, and their use was widely adopted in institutional settings. In the last decade, the accumulating data has challenged the initial optimism.

Inclusion of all eligible randomised and quasi-randomised studies continues to indicate that providing hip protectors probably slightly reduces the incidence of hip fractures in older people in institutional settings, with little or no effect on falls, other fractures (not including pelvic) and adverse events, such as skin irritation. However, the current best evidence, which is of low quality, suggests that the risk of a pelvic fracture may slightly increase, but this translates to an absolute risk which is very small (1/1000 more people will have a pelvic fracture when provided with hip protectors than when not (95% CI 1 fewer to 5 more)). In the community, hip protectors probably have little or no effect on hip fractures.

The conclusions of the 12 economic evaluations over the last decade have been, overall, optimistic that the provision of hip protectors would be cost effective, which is not surprising given the estimates of effectiveness that were used in modelling. Increasing uncertainty about the size of any protective effect has been reflected, however, in the more cautious conclusions of more recent modelling studies (Gandjour 2008; Sawka 2007b) and the prospective evaluations 'piggy-backed' on clinical trials (Meyer 2003; Van Schoor 2003).

Overall completeness and applicability of evidence

These results, seen from the perspective of biomechanical plausibility and experience from observational studies, have seemed to many health professionals and researchers working in the care of older people to be counter-intuitive. How can it be, they ask, that meta-analysis of randomised comparative studies fails to confirm the effectiveness of a theoretically plausible intervention reported to be effective in the early RCTs (Chan 2000; Ekman 1997; Jantti 1996; Kannus 2000; Lauritzen 1993) and in clinical practice by observational studies (Forsen 2003a). Our review suggests that, first, both acceptance of and adherence to wearing protectors by participants in studies has been consistently poor; clearly it is difficult to measure efficacy if hip protectors are not worn by study participants but it may in fact represent effectiveness and reflect implementation and patient outcomes in practice. Second, the analyses include a variety of hip protectors but heterogeneity was not important in most analyses. On one hand, we could conclude that our results could apply to hip protectors in general. On the other hand, we could not perform subgroup analyses to determine if there were distinguishing features of hip protectors that would exert larger or smaller effects. We also cannot predict the effects of new technology. Third, the design, conduct, analysis and reporting, particularly of outcome measures, may have introduced bias.These issues are complex and difficult to disentangle. They are now well recognised by the research community and ways in which future research may reduce the risk of bias are described in a recent report (Cameron 2010).

Acceptance and adherence (compliance)

Kurrle 2004a defined acceptance as "the percentage of potential users who initially agree to wear hip protectors" and adherence as "the wearing of hip protectors in accordance with the recommendations of the study protocol". In the context of an RCT analysed by intention to treat, poor adherence introduces 'compliance bias' by reducing the number of participants in the intervention group who actually receive the intervention. The definition from Kurrle 2004a of adherence in the use of hip protectors has now been recommended by the International Hip Protector Research Group (Cameron 2010).

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A systematic review of the literature reporting on the acceptance of, and adherence to, the use of hip protectors (Van Schoor 2002) reported that acceptance ranged from 37% to 72% (median 68%) and adherence varied between 20% and 92% (median 56%), and that "the reasons most frequently mentioned for not wearing hip protectors, were: not being comfortable (too tight/ poor fit); the extra effort (and time) needed to wear the device; urinary incontinence; and physical difficulties/illnesses". Cryer 2008 reviewed the literature on adherence concluding that it remains unclear what person-level and environmental factors are positively or negatively associated with hip protector adherence. Bentzen 2008 examined uptake and adherence with soft and hard-shelled hip protectors in a randomised trial in Norwegian nursing homes, finding that participants using soft protectors had only a slightly higher probability of continued use but were significantly more likely to be 24-hour users. Adherence from the RCTs in this review may be more representative of what may occur when implementing hip protectors in nursing care facilities rather than in community settings.

Heterogeneity of study populations

Most analyses show no heterogeneity or heterogeneity that 'might be important'. However, we conducted subgroup analyses in community and institutional settings to explore whether the setting could have an impact. We found differences for hip fractures in that the absolute size of the effect is important in institutional settings but not in the community. For other outcomes, such as pelvic fractures, other fractures and falls, the effects were similar across settings (although there was heterogeneity that might be important between the O'Halloran 2004 study and the other studies). With respect to falls there was little to no effect of hip protectors on the risk of falling (Analysis 1.6), but there was considerable heterogeneity across studies (a post hoc analysis by setting did not reduce heterogeneity). In addition to this exploration of heterogeneity by setting, we saw a wide range of baseline risks (even within community and institutional settings) of the incidence per person year of hip fracture (with 95% CIs) (*see* Table 3).

These observations raise the question of how future research might better identify participants at high risk of hip fracture in any setting. It has been reported that the risk of hip fracture in older people increases exponentially with age (Melton 1993), but it has been suggested (Couris 2007) that the exponential model may overestimate risk amongst people over 85 years of age. Two possible approaches to identify high risk patients use recent biomechanical and epidemiological research. The biomechanical approach (Bouxsein 2007; Keaveny 2008; Riggs 2006; Roberts 2010) focuses on the concept of a fracture threshold, measured as the ratio of the applied impact force to the bone strength. It might, if it were possible to simply measure bone strength in clinical practice, help to define better a population at highest risk. An epidemiological approach using fracture risk algorithms (Ensrud 2009; Kanis 2009) might be simpler in current clinical practice. The International Hip Protector Research Group recommends that in future, "Participants in clinical trials of hip protectors should be at high risk (annual incidence > 3%) of proximal femoral fracture". Suggested indicators include a history of bone fragility fracture, low weight, functional impairment, increased fall risk and older age (Cameron 2010).

Quality of the evidence

Despite the contributions of large numbers of researchers, carers and participants over 20 years, we found the quality of evidence for most outcomes to be of moderate or low quality primarily due to risk of bias and imprecise results because of few fracture events. It could be argued that evidence for hip fractures in the community, and for pelvic fractures, could be assessed as higher quality since the incidence of events is very low and the confidence intervals narrow enough that additional research would not be required. However, the unexplained heterogeneity across studies for pelvic fractures (in particular due to the O'Halloran 2004 study) warrants additional research to determine the effects of hip protectors on pelvic fractures and the evidence was therefore assessed as low quality.

Our assessment of the risk of bias in the included studies is summarised in Figure 1 and Figure 2. We updated the risk of bias tables in this review and, when possible to judge, we made most judgements as high or low risk of bias in lieu of using 'unclear'. Blinding of participants and of carers has usually not been possible, leaving open the possibility of performance bias and detection bias. The risk of selection bias is high in any cluster randomised trial where participants are recruited over time; their admission to a particular nursing home or ward may not have been a random event. Although cluster randomised studies appear to better reflect the real world of health care (Campbell 2001), greater care is needed, compared with individually randomised trials, in their design, conduct, analysis and reporting, particularly to avoid post-randomisation biases occurring.

While we felt confident that most studies provided robust hip fracture data, we assessed the falls data as at high risk of bias due to the lack of blinding of outcome assessors. The heterogeneity between studies in Analysis 1.6 may represent selection bias, through failure of allocation concealment, or detection bias when recording falls. It may also reflect systematic differences in other aspects of care between individual nursing homes or wards, introducing co-intervention bias. For example, the particular attention paid to staff and participant education that was reported in Meyer 2003 and Van Schoor 2003, where provision of hip protectors was associated with a significant reduction in the incidence of falls, might have contributed to that finding.

Hip protector studies are difficult to design and conduct but these elements, and the analysis and reporting, could be improved considerably. Adherence by researchers to the recommendations of the International Hip Protector Research Group (Cameron 2010) should facilitate improvement in the future.

Potential biases in the review process

Although we did not detect publication bias, it is possible none the less. We attempted to reduce bias in the review process to a minimum by searching a range of databases and not limiting the search by language. We also ensured that study identification and inclusion, data extraction and risk of bias assessment were carried out by two review authors working independently. We were not always successful in obtaining missing information from authors; this is not surprising given the passage of time since the earlier studies. In this update, at least two review authors reviewed the risk of bias tables that were previously published and updated the criteria (for example, selective outcome reporting) and

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reconsidered judgements made by past authors (in particular when unclear judgements were made).

Agreements and disagreements with other studies or reviews

We found three other systematic reviews addressing the effectiveness of hip protectors. Comparing these reviews with ours clearly points out some of the difficulties inherent in meta-analysis, particularly the choice of inclusion criteria, interpretation of reports of included studies, and the consequent need for careful appraisal of any systematic review.

Sawka 2005 agreed with our analyses and conclusions on the ineffectiveness of hip protectors to reduce fractures in community-dwelling individuals. Although their inclusion criteria were somewhat stricter than ours, they also concluded that hip protectors were effective in older people in an institutional setting. Their review included Van Schoor 2003 in the community-dwelling analysis. We were puzzled by this as in Van Schoor 2003 the investigators themselves indicated that the study was conducted in a population in institutional care. Dr Van Schoor has confirmed that of the 561 residents, 38 lived in apartment houses for the elderly, 247 in homes for the elderly and 276 in nursing homes (Van Schoor 2005). Admission to either of the two latter categories is based on the need for extra care. We therefore feel justified in including Van Schoor 2003 in the institutional analysis.

Sawka 2007a conducted a Bayesian meta-analysis of the data from four trials (1922 participants) exclusively recruited from nursing homes (Ekman 1997; Harada 2001; Jantti 1996; Meyer 2003), of which the first three were cluster randomised. They reported that the pooled odds ratio (OR) of an elderly nursing home resident sustaining one or more hip fractures with hip protector allocation was 0.40 (95% CI 0.25 to 0.61), concluding that hip protectors decrease the risk of hip fracture in elderly nursing home residents. Their model was robust in multiple sensitivity analyses assuming alternative intra-cluster correlation coefficient (ICC) values. We conducted a sensitivity analysis of our data by including only these four studies (using ICC of 0.02) and our findings (analysis not shown) are similar (RR 0.44, 95% CI 0.26 to 0.72). However, their inclusion criteria excluded a number of studies that were available to them and which we believe should be included in a comprehensive review of evidence.

Oliver 2007 reported a meta-analysis of nine studies "for hip protectors as a single intervention in care homes (no hospital studies were identified)". Eight of these (Cameron 2001; Ekman 1997; Jantti 1996; Kannus 2000; Lauritzen 1993; Meyer 2003; O'Halloran 2004; Van Schoor 2003) were included in this review, and one (Woo 2003) was excluded. Their results for hip fractures were sensitive to the magnitude of the ICC which they used; use of values of 0.026 and lower gave significant results. They reported a rate ratio of 0.67 (95% CI 0.46 to 0.98) for hip fractures. Our calculated rate ratio when including only the same eight studies was 0.76 (95% CI 0.62 to 0.94).

AUTHORS' CONCLUSIONS

Implications for practice

- A policy of provision of hip protectors to older people who are residents of nursing care facilities probably slightly reduces the number of hip fractures, but may need to be balanced with the slight increase in pelvic fractures that may occur.
- Provision of hip protectors will probably have little or no effect on the incidence of hip fractures in older people who remain ambulant in the community.
- Poor acceptance and adherence by older people offered hip protectors may be key barriers to implementation

Implications for research

- Better understanding is needed of the personal and design factors that may influence acceptance and adherence.
- Future studies should have realistic calculations of study power and take into account the likely incidence of hip fractures within the sampling frame, and the probable rates of acceptance and adherence or compliance with wearing protectors in the treatment group. Sample size calculations should allow for clustering in trials of that design. The research community should also address biases when measuring outcomes and adopt the recommendations of the International Hip Protector Research Group (Cameron 2010).
- Researchers should report on the occurrence of pelvic fractures in all future studies of hip protectors.
- The development of internationally recognised standards for biomechanical testing procedures for all forms of hip protectors should be encouraged.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Birks 2003

Methods	Randomisation of individual participants by a telephone randomisation service
Participants	366 community-dwelling individuals recruited while recovering from a hip fracture in orthopaedic wards of York District Hospital, UK, or volunteers from general population who had sustained a hip fracture in the past Mean age: 80 years Proportion male: 12.6% Inclusion criteria: aged 70 years and over; have sustained one hip fracture; had to have one hip intact; able to give informed consent Exclusion criteria: bed or chair-bound; had bilateral hip replacement; a clothing size of 18 or above
Interventions	Allocation to wear hip protectors. "Intervention group participants were issued with three pairs of hip protectors and general advice (in the form of a leaflet) on how to reduce fracture risk" Controls: "people in the control group received only the leaflet" Hip protectors were Safehip (www.tytex.com our_products/hip_protection/)
Outcomes	Length of follow-up: mean 14 months (range 6 - 41 months) All outcomes were self-reported by post "The main outcome was a second hip fracture." Secondary outcomes were: Number of other fractures Compliance with wearing the protectors Falls Fear of falling
Notes	Unpublished information made available from authors

Risk of bias

Bias	Authors' judgement	Support for judgement

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Birks 2003 *(Continued)*

Random sequence generation (selection bias)	Low risk	"Randomisation was stratified by age, gender and recruitment status (i.e. volunteer recruited by publicity or participant recruited from hospital wards) using random selection of block lengths of 4, 6, and 8 (randomisation schedules were produced by computer)."
Allocation concealment (selection bias)	Low risk	"Individual randomisation was undertaken by telephone using the University of York's telephone randomisation service."
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and personnel not blinded
Blinding of outcome assessment (detection bias) Fractures	Low risk	Confirmation of fractures by a blinded radiologist, or radiology panel is not described. However, ascertainment, as well as participant follow-up at 6 monthly intervals for self-reported fractures, used contact with participants' general practitioners (GPs) "for data on any new fracture occurrence and to confirm all self-reported fractures. Fractures not confirmed by the GP were not included in the analysis."
Blinding of outcome assessment (detection bias) Falls	High risk	Falls "were self-reported by post"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data appear balanced in number and reason across groups
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures (There were no data collected for adverse events)

Birks 2004

Methods	Randomisation of individual participants by a telephone randomisation service
Participants	4169 female community residents recruited from general practice registers and by local advertising in five centres (UK) Mean age: 78 years Proportion male: 0% Inclusion criteria: aged 70 years or over and have one risk factor (a history of prior fracture; body weight below 58 kg; family history of a hip fracture or smoker)
Interventions	Allocation to wear hip protectors or not (control group) Hip protectors from Robinson Healthcare Ltd, which are equivalent to those of Safehip, Denmark
Outcomes	Length of follow-up: median 28 months (range 24-42 months) Number of hip fractures Number of other fractures Compliance with wearing the protectors Adverse effects of the protectors Fear of falling Falls Mortality

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Birks 2004 *(Continued)*

Notes	Additional information made available from authors

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A minimization algorithm was used to minimize the allocation on age (80 years and younger, or over 80), ever prior fracture (Yes/No), fall in the previous 12 months (Yes/No). Participants were allocated in a 2:1 ratio in favour of the control group in order to minimize hip protector costs"
Allocation concealment (selection bias)	Low risk	"The trial coordinators identified the women with at least one risk factor and assigned them a unique identification number. Eligible participants were then randomized using the independent computer randomization system at the Health Services Research Unit (HSRU), Aberdeen."
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and personnel were not blinded
Blinding of outcome assessment (detection bias) Fractures	Low risk	"Self-reported hip fractures were confirmed by the participants' general practitioners. For participants not returning questionnaires, and who had not withdrawn from the study, we wrote to their GPs asking whether or not a hip fracture had occurred during trial participation." Confirmation of fractures by a blinded radiologist, or radiology panel, is not described
Blinding of outcome assessment (detection bias) Falls	High risk	Self-reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data appear balanced in number and reason across groups
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures (There were no data collected for adverse events)

Cameron 2001

Methods	Individual randomisation by numbered sealed opaque envelopes
Participants	174 living in residential care facilities in Sydney, Australia Mean age: Protectors 85.6/ Controls 84.0 years. All female Inclusion criteria: aged 75 years and older; have had 2 or more falls in the last 3 months or 1 fall requiring hospital admission; at least 1 hip without prior surgery; able to understand English; have sufficient cognitive function to give informed consent; likely to continue to live at home for 3 months and to survive for at least 1 year; confirmation that the facility staff would assist with encouraging the participant to wear the protector
Interventions	Allocation to wear hip protectors or not (control) Hip protectors equivalent to those of Safehip, Denmark
Outcomes	Length of follow-up: 2 years Number of hip fractures

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Cameron 2001 *(Continued)*

	Number of pelvic fractures Number of other fractures Compliance with wearing the protectors Adverse effects of the protectors Mortality Falls
Notes	Trial data supplied by Ian Cameron, Rehabilitation Studies Unit, Department of Medicine, University of Sydney

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified by type of aged care facility; randomisation in blocks of variable sizes, generated from a table of random numbers
Allocation concealment (selection bias)	Low risk	Numbered and sealed opaque envelope containing allocation details opened by research nurse after enrolling the participant
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and resident staff not blinded
Blinding of outcome assessment (detection bias) Fractures	Low risk	Staff likely not blinded to allocation (objective outcome). Confirmation of fractures by a blinded radiologist, or radiology panel, is not described. Research nurse collecting data was not blinded to study allocation.However, ascertainment of fractures was confirmed by review of medical record of all participants, and examination of incident reports
Blinding of outcome assessment (detection bias) Falls	High risk	Staff likely not blinded to allocation (subjective outcome). Research nurse collecting data was not blinded to study allocation. However, ascertainment of falls was confirmed by review of medical record of all participants, and examination of incident reports
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reported losses were balanced in number between control and treatment groups
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures (Adverse events reported as "the only other adverse effects reported were minor skin irritation; there were no reports of pressure sores.")

Cameron 2003

Methods	Individual randomisation by numbered sealed opaque envelopes
Participants	600 living in their own homes in Sydney, Australia Mean age: 83 years All female Inclusion criteria: aged 74 years and over; in contact with aged care health services; at least two falls in the last 3 months or 1 fall requiring hospital admission; at least one hip without prior surgery; sufficient cognitive function to give informed consent; likely to continue to live at home for 3 months; likely to survive for at least 1 year; able to understand English
Interventions	Allocation to wear hip protectors or not (control)

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Cameron 2003 *(Continued)*

	Two adherence nurses fitted protectors and encouraged adherence with 3 visits, followed by 2 telephone contacts. Further visits or telephone contact if not adhering Hip protectors equivalent to those of Safehip, Denmark
Outcomes	Length of follow-up: 2 years Number of hip fractures Number of pelvic fractures Number of other fractures Compliance with wearing the protectors Adverse effects of the protectors Mortality Number of falls
Notes	Trial data supplied by Ian Cameron, Rehabilitation Studies Unit, Department of Medicine, University of Sydney

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomly allocated to intervention (use of hip protectors and contact with the “adherence” nurse) and control groups, using stratification by the presence or absence of cognitive impairment (as judged by the nurse recruiting the participant) and whether recruited from home or hospital.The randomisation sequence was computer generated independent of the study staff"
Allocation concealment (selection bias)	Low risk	Randomisation took place after collection of baseline data, using a numbered and sealed envelope containing allocation details
Blinding of participants and personnel (performance bias) Fractures	High risk	"The nature of the intervention (wearing hip protectors or not) meant that participants and the research and adherence nurses were not blinded."
Blinding of outcome assessment (detection bias) Fractures	Low risk	The ascertainment of hip fractures and other injuries was based initially on self report with follow up of radiography reports and hospital records as a secondary check. "The radiologists who diagnosed hip fractures were unaware of participation in the study and thus were blinded."
Blinding of outcome assessment (detection bias) Falls	High risk	"The assessment of falls was based on self report at four monthly telephone interviews." Interviews appear to be conducted by the nurses who also visited participants for adherence
Incomplete outcome data (attrition bias) All outcomes	Low risk	Although 95 participants in treatment group due to permanent withdrawal from wearing hip protectors, the numbers in both groups not completing final follow-up were small, and unlikely to have a clinically relevant outcome
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events were well reported)

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Cameron 2011

Methods	Nursing care facilities were randomised into 3 groups (9 clusters) by a random numbers table and concealed opaque numbered envelopes. Cluster defined as residential aged care facility by itself or an independently working unit within a large facility
Participants	235 people living in 7 nursing care facilities (9 clusters) in Northern Sydney region, Australia Mean age: 86 years 18% male Inclusion criteria: likely to survive more than 12 months as assessed by the Illness Severity Rating; at least 1 hip without previous fracture or arthroplasty; participants assessed as high risk of hip fracture (FREE study algorithm) and able to stand without assistance for at least 5 seconds
Interventions	2 intervention groups (both receiving hip protectors) and control group Control group (n = 96): provided with a brochure about hip protectors that included a contact number for suppliers of hip protectors No cost group (n = 55):received 3 pairs of correctly sized, hard shell hip protectors (Hornsby Healthy Hips (replacement of worn out or lost hip protectors was not offered) plus + brochure with information about their use + educational programme for their use Combined group (n = 84): received 3 pairs of hip protectors - hard shell protectors (Hornsby Healthy Hips) or soft protectors (Hip Saver) plus educational programme
Outcomes	Length of follow-up: 3 and 6 months Primary outcome: adherence 3 and 6 months (at visit; mean adherence during previous month measured by nursing staff, percentage waking hours worn; hip protector worn during falls) Secondary outcomes: falls, injuries, fractures from records and confirmed by other sources (GP or hospital records), treatment complications (open ended question to nursing staff and participants); quality of life (*see* Schaafsma 2012 report)
Notes	Similar study also conducted by same author in community. Schaafsma 2012 reports quality of life for this study and the other Cameron 2011 studies

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"a random numbers table...was used for the randomization procedure" (p.51)
Allocation concealment (selection bias)	Low risk	Authors report "...concealed opaque numbered envelopes of clusters were used for randomization procedure" (p.51)
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and likely nursing staff not blinded
Blinding of outcome assessment (detection bias) Fractures	Low risk	Authors report 'outcome assessors were masked to the allocation.' The occurrence of falls, injuries, and fractures was assessed from the records in the residential aged care facility and confirmed by other sources (general practitioner or hospital records)
Blinding of outcome assessment (detection bias)	Low risk	Authors report 'outcome assessors were masked to the allocation.' The occurrence of falls, injuries, and fractures was assessed from the records in the resi-

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Cameron 2011 *(Continued)*

Falls		dential aged care facility and confirmed by other sources (general practitioner or hospital records)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis conducted. Equal loss to follow-up (primarily due to death) across all groups (˜12%)
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events were well reported)

Cameron 2011a

Methods	Note: Two studies were reported in 1 article (*see* Cameron 2011a and Cameron 2011b) Study 1: 3 hospital wards were cluster randomised and individuals later discharged to community
Participants	308 people in 3 geriatric rehabilitation wards in Northern Sydney, Australia mean age: 82-84 years 30% male across groups Inclusion criteria: likely to survive more than 12 months as assessed by the Illness Severity Rating; at least 1 hip without previous fracture or arthroplasty; assessed as potentially eligible for admission to a residential aged care facility. In addition, at risk of falling using the STRATIFY tool (score ≥2)
Interventions	2 intervention groups and control group Control group: provided with a brochure about hip protectors that included a contact number for suppliers of hip protectors No cost group:received 3 pairs of correctly sized, hard shell hip protectors (Hornsby Healthy Hips) in hospital. Group also received a brochure providing information on their use plus education on their use, and proper fitting and wearing by nurses and other staff Combined group: received 3 pairs of hip protectors - hard shell protectors (Hornsby Healthy Hips) or soft protectors (Hip Saver). Group also received adherence enhancement strategy (nurses providing and fitting the hip protectors) provided by a trained nurse, plus education of nursing stuff in charge of the patients
Outcomes	Length of follow-up: 3 and 6 months Primary outcome: adherence 3 and 6 months (at visit; mean adherence during previous month measured by participants, percentage waking hours worn; hip protector worn during falls) Secondary outcomes: falls, injuries, fractures as reported by participants, treatment complications and negative effects (open ended question to participants); quality of life (*see* Schaafsma 2012 report)
Notes	Similar study also conducted by same author in nursing care facilities. Schaafsma 2012 reports quality of life for this study and the other Cameron 2011 studies

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"...randomisation sequence generated from a random numbers table." p.619

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Cameron 2011a *(Continued)*

Allocation concealment (selection bias)	Low risk	"Both randomisation processes were blinded through the use of opaque numbered envelopes..." p.619
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and personnel were not blinded
Blinding of outcome assessment (detection bias) Fractures	Low risk	Authors report 'outcome assessors were blinded to the allocation. Hip fractures were all measured by the recall of the participant if he or she was living in the community or from records in the hospital ward for the time that the participant had spent in hospital. Confirmation of hip fracture not reported
Blinding of outcome assessment (detection bias) Falls	Unclear risk	Authors report 'outcome assessors were blinded to the allocation. These outcomes were all measured by the recall of the participant if he or she was living in the community or from records in the hospital ward for the time that the participant had spent in hospital
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis conducted. Loss to follow-up even across intervention and control groups in both studies Study 1: Intervention groups: 17 and 13% loss to follow-up; control group: 20% loss to follow-up
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events were well reported)

Cameron 2011b

Methods	Note: Two studies were reported in 1 article (*see* Cameron 2011a and 2011b) Study 2: participants from the community individually randomised
Participants	171 people living in the community from an Aged Care and Rehabilitation Service and a variety of community groups of older people Northern Sydney region, Australia mean age: 82-84 years 26% male across groups Inclusion criteria: likely to survive more than 12 months as assessed by the Illness Severity Rating; at least 1 hip without previous fracture or arthroplasty; assessed as potentially eligible for admission to a residential aged care facility. In addition, occurrence of ≥1 falls in the last year
Interventions	2 intervention groups and control group Control group: provided with a brochure about hip protectors that included a contact number for suppliers of hip protectors No cost group:received 3 pairs of correctly sized, hard shell hip protectors (Hornsby Healthy Hips in hospital or delivered to home. Group also received a brochure providing information on their use plus answering of question at the time of supply Combined group: received 3 pairs of hip protectors - hard shell protectors (Hornsby Healthy Hips) or soft protectors (Hip Saver). Group also received adherence enhancement strategy (education of participant face to face and by telephone) provided by a trained nurse
Outcomes	Length of follow-up: 3 and 6 months

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Cameron 2011b *(Continued)*

	Primary outcome: adherence 3 and 6 months (at visit; mean adherence during previous month measured by participants, percentage waking hours worn; hip protector worn during falls) Secondary outcomes: falls, injuries, fractures as reported by participants, treatment complications and negative effects (open ended question to participants); quality of life (*see* Schaafsma 2012 report)
Notes	Similar study also conducted by same author in nursing care facilities. Schaafsma 2012 reports quality of life for this study and the other Cameron 2011 studies

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"...randomisation sequence generated from a random numbers table." p.619
Allocation concealment (selection bias)	Low risk	"Both randomisation processes were blinded through the use of opaque numbered envelopes..." p.619
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and personnel were not blinded
Blinding of outcome assessment (detection bias) Fractures	Low risk	Authors report 'outcome assessors were blinded to the allocation.' Hip fractures were all measured by the recall of the participant. Confirmation of hip fracture not reported
Blinding of outcome assessment (detection bias) Falls	Unclear risk	Authors report 'outcome assessors were blinded to the allocation. These outcomes were all measured by the recall of the participant
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis conducted. Loss to follow-up even across intervention and control groups in both studies Intervention groups: 3 and 6%; control group: 5%
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events were well reported)

Chan 2000

Methods	Individual randomisation
Participants	71 residents of nine nursing homes in Randwick, New South Wales, Australia Mean age: not stated Proportion male: not stated
Interventions	Allocation to wear hip protectors or not (control group) Type of protector was locally made pads and pants of the energy absorbing design
Outcomes	Length of follow-up: 9 months Number of hip fractures Falls Compliance with wearing the protectors

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Chan 2000 *(Continued)*

Notes	Additional information supplied by authors via e-mail

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"Random assignment of subjects was achieved in most nursing homes with some participants designated as control and some to wear the protectors"
Allocation concealment (selection bias)	High risk	"Random assignment of subjects was achieved in most nursing homes with some participants designated as control and some to wear the protectors"
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants not blinded, very likely that nursing staff not blinded
Blinding of outcome assessment (detection bias) Fractures	High risk	Nursing staff used special form (likely not blinded) and no mention of confirmation from records Confirmation of fractures by a blinded radiologist, or radiology panel, is not described
Blinding of outcome assessment (detection bias) Falls	High risk	Nursing staff used special form (likely not blinded) and no mention of confirmation from records
Incomplete outcome data (attrition bias) All outcomes	High risk	No flow chart provided. Appears that participants loss to follow-up were not included in the analysis or reported
Selective reporting (reporting bias)	High risk	Data for hip fractures were reported but not for other fractures. (Adverse events were reported)

Ekman 1997

Methods	Cluster randomisation. One of four nursing homes 'randomised' - this home's residents were offered external hip protectors and the incidence of hip fracture compared with three 'control' homes
Participants	744 residents of four nursing homes in Uppsala, Sweden Mean age: 84 years Proportion male: not stated
Interventions	Allocation to wear hip protectors (intervention group one nursing home, 302 participants); control group 3 nursing homes, total 442 residents). Type of protector was JOFA AB, Malung, Sweden. No special fixation method was used
Outcomes	Length of follow-up: 11 months Number of hip fractures Mortality Falls Compliance with wearing the protectors
Notes	

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Ekman 1997 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"During the study period, one of the homes was randomly selected, and all 302 residents were offered external hip protectors. The control nursing homes had 442 residents during the same period." Likely selection by a simple method
Allocation concealment (selection bias)	Low risk	"During the study period, one of the homes was randomly selected, and all 302 residents were offered external hip protectors." This suggests that recruitment of individuals may have taken place after allocation, but as all were offered protectors and included in the analysis, this may not have introduced important bias
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and likely nursing staff in home not blinded
Blinding of outcome assessment (detection bias) Fractures	Low risk	Likely nursing staff reporting fractures not blinded, but objective outcome
Blinding of outcome assessment (detection bias) Falls	High risk	Likely nursing staff reporting falls not blinded, but subjective outcome
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	In calculating the risk ratio, all participants were included. In an 11 month follow-up of participants in this age group, deaths may have occurred. However, no information on losses or withdrawals was provided
Selective reporting (reporting bias)	High risk	Data for hip fractures was reported but not for other fractures. (Adverse events were reported but could not be quantified)

Harada 2001

Methods	Participants were individually randomised within each of six nursing homes in Japan, but in each they were clustered by the room or ward number..(personal communication), and each nursing home had an equal percentage of wearer and non-wearer participants. Thus, in adjusting for this 'hidden clustering' we assume a minimum of two wards in each home, and an average cluster size for adjustment of 14 participants per cluster
Participants	164 female nursing home residents Mean age: 83.2 years
Interventions	Allocation to wear hip protectors or not (control) Hip protectors were Safehip, Denmark
Outcomes	Length of follow-up: 19 months Number of hip fractures Number of other fractures Number of falls Compliance with wearing the protectors

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Harada 2001 *(Continued)*

Notes	Bone density was measured in all patients by ultrasonic evaluation of the calcaneal bone Additional information supplied by the authors on method of randomisation and that no patients were excluded after allocation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"A prospective-randomized study was carried out...The remaining 164 female subjects who conformed to our criteria were included in the trial, and divided randomly into 88 hip protector wearers and 76 non-wearers (controls)." Personal communication indicated participants were individually randomised within each of six nursing homes in Japan, but in each they were clustered by the room or ward number. Likely randomisation did not use a low risk of bias method
Allocation concealment (selection bias)	Unclear risk	"The remaining 164 female subjects who conformed to our criteria were included in the trial, and divided randomly into 88 hip protector wearers and 76 non-wearers (controls). Each nursing home had an equal percentage of wearer and non-wearer participants." Trial profile (Fig 1 of study report) indicates that assignment to groups followed individual participant recruitment
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and likely nursing staff not blinded
Blinding of outcome assessment (detection bias) Fractures	High risk	Outcome assessors not blinded. Confirmation of fractures by a blinded radiologist, or radiology panel, is not described. "The care staff observed all participants daily, checked whether and how often they were wearing the hip protector, and recorded all falls and resulting injuries for both wearers and non-wearers."
Blinding of outcome assessment (detection bias) Falls	High risk	Outcome assessors not blinded. "The care staff observed all participants daily, checked whether and how often they were wearing the hip protector, and recorded all falls and resulting injuries for both wearers and non-wearers."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Study authors confirmed that no participants were excluded after allocation. The report states that "Subjects who sustained a hip fracture were excluded from the trial at the time of fracture occurrence", but provides hip fracture rate based on the observation period for each participant (study table 2)
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events were not reported)

Hubacher 2001

Methods	Randomisation was individual rather than clustered, but the method varied between individual nursing homes. For half (10) of these homes randomisation of each participant was by 'computer', for the other half the head of the nursing home randomised fall prone residents in 'random order'. New nursing home residents were assigned in order of their entry (even to the hip protector group, odd to the control group)
Participants	548 residents of 20 nursing homes in Zurich, Switzerland Mean age: 85.5 years

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Hubacher 2001 *(Continued)*

	Proportion male: 22% Excluded were people bedridden for three or more days per week, or with pressure sores in the trochanteric area
Interventions	Allocation to wear hip protectors or not (control group) Type of protector was Safehip, Denmark
Outcomes	Length of follow up: 10 months Number of hip fractures Number of pelvic fractures Number of other fractures Falls Compliance with wearing the protectors Adverse effects of the protectors
Notes	Additional information supplied by trialists

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	The head of nursing was requested to ask the fall-prone occupants in random order whether they would be willing to wear a hip protector. (Attention was drawn to the fact that the order should not be determined by, say, the degree of proneness to fall or any other criteria; however, an algorithm was not specified.) As soon as half the fall-prone occupants indicated such willingness, the recruitment procedure was stopped. These subjects were assigned to the intervention group and the rest to controls. At the other half of the homes the study randomization was processed by computer. New patients to the homes were assigned in order of their entry number: even numbers to the intervention group, uneven ones to controls. The study was carried out from March 1 until December 31 1998
Allocation concealment (selection bias)	High risk	Allocation sequence was not concealed, as described above
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and staff were not blinded to the intervention
Blinding of outcome assessment (detection bias) Fractures	Unclear risk	There is no information of how this outcome was measured
Blinding of outcome assessment (detection bias) Falls	Unclear risk	There is not enough information regarding this outcome measurement. A record kept for every person is mentioned, without further details
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to make a judgment of 'yes' or 'no'
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events reported)

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Jantti 1996

Methods	Individual randomisation by the opening of sealed envelopes for each person in the study
Participants	72 residents of a municipal nursing home in Tampere, Finland Mean age: Protectors 85.5; Controls 84 years (range 71-96) Proportion male: 11%
Interventions	Allocation to wear hip protectors or not (control group) Hip protectors used were designed by first named author of study. Consisted of pants with pockets which contain a 2 cm thick pad of closed-cell polyethylene foam measuring 20 cm by 15 cm
Outcomes	Length of follow-up: 12 months Number of hip fractures Compliance with wearing the protectors Falls
Notes	By the end of the one-year observation period, 33 participants had been lost through death or permanent hospitalisation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"randomized by the closed envelopes method". Therefore, it is likely that a random component was used to generate the allocation sequence
Allocation concealment (selection bias)	Low risk	"randomized by the closed envelopes method" - likely low risk of bias due to allocation concealment
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants were not blinded to the intervention. Staff were not blinded - "The staff were mostly positive about the hip protectors. They felt that the patients could be left to walk around more freely because the consequences of possible falls were less severe."
Blinding of outcome assessment (detection bias) Fractures	Low risk	Objective outcome, likely low risk of bias
Blinding of outcome assessment (detection bias) Falls	High risk	"The staff were mostly positive about the hip protectors. They felt that the patients could be left to walk around more freely because the consequences of possible falls were less severe." LIkely reported by staff and subjective outcome
Incomplete outcome data (attrition bias) All outcomes	High risk	Almost half of the patients enrolled were lost to follow-up, and the proportion was higher in the control group
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures (Adverse events were reported for discontinuation but not for wearers)

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Kannus 2000

Methods	Cluster randomised. Treatment units (number not reported) within 22 community based healthcare centres were randomised by an independent physician using sealed envelopes to either receive the protectors or to act as a control group. Ratio of protector to control group 1:2
Participants	1801 users of 22 community based health care centres in southern and central Finland Each centre had treatment units consisting of long-stay facilities or outpatient care units for supporting living at home Mean age: Protectors 81/ Controls 82 years Proportion male: 23% in intervention group, 21% in control Inclusion criteria: ambulatory; aged 70 years or over; have at least one identifiable risk factor for hip fracture (previous fall or fracture, impaired balance or mobility, use of walking aids; cognitive impairment; impaired vision; poor nutrition; or a disease or medication known to predispose people to falls and hip fractures)
Interventions	Allocation to wear hip protectors (intervention group) or not (control group) Type of protector was KPH Hip Protector, Respecta, Helsinki. Hip protectors were fixed in pockets in special underwear
Outcomes	Length of follow up: 611 person-years (mean 0.94 years per individual) in the protector group and 1458 person-years (mean 1.27 years per individual) in the control group Number of hip fractures Number of pelvic fractures Number of other leg fractures Number of other fractures Falls Compliance with wearing the protectors Adverse effects of the protectors
Notes	1725 elderly adults were eligible for the trial. 204 out of the 650 randomised to the protector group and 94 out of 1075 randomised to the control refused to participate. Further dropouts in the protector group were deaths (51 cases), became unable to walk (58), had a hip fracture (13), refused to continue (71) or other reasons (26). In the control group, drop outs were deaths (137 cases), became unable to walk (108), had a hip fracture (67), refused to continue (90) or other reason (36). To replace the dropouts, eligible adults were recruited from the waiting list over the study period (207 in the protector group and 167 in the control group) Additional information supplied by trialists

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	The random component in the sequence generation for preparation of the closed envelope allocation was not described (see below)
Allocation concealment (selection bias)	High risk	Allocation of clusters " was performed at the President Urho Kaleva Kekkonen Institute for Health Promotion Research by an independent physician with the use of sealed envelopes". Initial identification of "at risk" individuals in each participating study centre was completed prior to assignment of the cluster. However, consent to participate was not obtained until after randomisation of the clusters, and the proportions of "at risk individuals" who did not agree to participate in the study were 204 of 650 (31%) in the intervention group, but only 94 of 1075 (9%) in the control group. Selection bias may thus have occurred. Nor can it be ruled out in the later stages of the recruitment "the study positions of subjects who dropped out were to be refilled, whenever possible, by new eligible subjects from a waiting list". To replace the dropouts, eligible

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Kannus 2000 *(Continued)*

		adults were recruited from the waiting list over the study period (207 in the protector group and 167 in the control group. This may have caused selection bias. Table 1 of Kannus 2000 shows that the process of sequence generation and allocation did not result in equivalence of risk factors in the intervention and control groups. However, if any bias was introduced in this replacement phase, it is unlikely to have exaggerated the efficacy of hip protectors. Although the participants in the protector group were on average one year younger (81 versus 82 years, P = 0.006), they had lower weight (63.1 kg versus 65.5 kg, P < 0.001), lower body mass index (24.3 versus 25.1, P < 0.001), and were more likely to have dementia (33% versus 26%, P = 0.001), more likely to have a previous stroke, bleeding, or related central nervous system condition (21% versus 15%, P = 0.002), more likely to have impaired mental status (P < 0.001) and more likely to have a history of previous falls (P < 0.001).
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants, and likely personnel, were not blinded to the intervention
Blinding of outcome assessment (detection bias) Fractures	Low risk	"At the end of the study, the research coordinators at each health care center retrospectively reviewed the medical records of the subjects to verify the completeness of the data on any fractures. Each fracture was documented with radiographs."
Blinding of outcome assessment (detection bias) Falls	Low risk	Falls were reported by completing a standardized form that was filled immediately after the fall. Information such as date and place of the fall, the activity being engaged in at the time of the fall, possible reasons for the fall, the circumstances and mechanism of the fall, the height and direction of the fall, the anatomical site of the impact, and injuries, if any were recorded as well
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	It is unclear whether the losses to follow up described in the study report were from the original consenting participants only or from the final totals analysed. If the former, losses were 49% in protector group and 45% in the control group; if the latter, 31% in the protector group and 38% in the control group
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events not measured)

Kiel 2007

Methods	37 nursing homes were randomised to make hip protectors available protecting either the left or right hip. The contralateral hip therefore acted as a control group. Exact method of randomisation not specified
Participants	1042 residents of 37 nursing homes in the Boston, St Louis and Baltimore, USA Mean age: 85 years Proportion male: 21% Inclusion criteria: long-stay resident (not in Medicare-type rehabilitation); evidence of attempt to get out of bed or chair or to walk without human assistance in last four weeks; older than 65 years; absence of terminal illness expected to result in death in less than six months, or severe illness resulting in being bed bound; absence of previous bilateral hip fractures or hip replacements; absence of contagious disease requiring isolation; absence of pressure ulcers, blisters or skin tears over bony prominences that would be covered by the hip protector garment; hip circumference of 122 cm or less; absence of a nurs-

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Kiel 2007 *(Continued)*

	ing home staff recommendation not to enrol a resident because of behavior pertaining to adherence to the protocol (e.g. not willing to wear undergarments)
Interventions	Nursing homes allocated to have eligible residents wear hip protectors on the left or right hip (intervention group) and no hip protector on the contralateral hip (control group) Type of protector was an energy-absorbing/shunting protector containing polyethylene vinyl foam and a high density polyethylene shield. Hip protectors were fixed into pockets in special underwear
Outcomes	Length of follow-up: 676 person years (up to 20 months maximum per individual) Number of hip fractures Falls Fear of falling score Compliance with wearing the protectors Adverse effects of the protectors
Notes	An 'expression of concern' regarding the ethical conduct of this study was issued in 2012 (Bauchner 2012). The editorial stated that "there was no evidence provided that raised concerns about the scientific integrity of the data and the veracity of the study conclusions"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequential computer guided allocation conducted designed to "keep the number of residents balanced between right and left hip protection across all nursing homes." "A dynamic allocation procedure was adopted."
Allocation concealment (selection bias)	Low risk	Recruitment of around one third of participants took place after allocation of cluster to left or right side protection. Each individual participant had both a protected and an unprotected hip. Although individuals recruiting personnel were clearly not blinded to allocation, the design of this study in which the individual participant provided her/his own control seems to make the risk of bias, if any, very small.
Blinding of participants and personnel (performance bias) Fractures	Low risk	Performance bias due to participants or personnel not being blinded is unlikely to had taken place, as each individual was its own control
Blinding of outcome assessment (detection bias) Fractures	Low risk	"Each suspected fracture was reviewed by a geriatrician and orthopedic surgeon who were blinded to the side that was padded. All reviewers were members of a clinical end points committee, which consisted of 2 geriatricians, 2 orthopedic surgeons, and 1 musculoskeletal radiologist". The reviewers decided that (1) a fracture consistent with the study criteria had taken place using explicit criteria
Blinding of outcome assessment (detection bias) Falls	Low risk	Even though this outcome was measured using the facilities fall-reporting system, and interviews with participants and personnel; it is unlikely that this may have introduced bias (patients were their own controls, and thus, any bias may have acted equally in both arms)
Incomplete outcome data (attrition bias) All outcomes	Low risk	585 of 1042 enrolled participants were lost to follow-up. However, the design of this study in which the individual participant provided her/his own control seems to make the risk of bias, if any, very small
Selective reporting (reporting bias)	High risk	Includes data for hip fractures and adverse events. However, other fractures were not measured or reported

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Koike 2009

Methods	"Cluster randomised controlled trial with nursing and residential homes acting as the clusters." "the nursing staff and researchers selected five residents from each home in the intervention group and 15 residents from each home in the control group to be subjects, according to predefined inclusion criteria after cluster randomisation."
Participants	672 participants in 76 homes in Osaka and surrounding areas, Japan Mean age: 85 years Proportion male: 0% Inclusion criteria: female, aged ≥65 years, at least one of the following risk factors: history of any prior fracture, low body-mass index (BMI), family or individual history of hip fracture, frequent faller status, current smoker, or other frail residents Exclusion criteria: history of bilateral hip fractures or hip replacement surgery, bedridden
Interventions	Allocation to wear hip protectors (intervention group) or not (control group) Type of protector was Safehip (Teijin Pharma, Tokyo, Japan compatible with the product by Tytex). Three pairs issued which could be replaced as required in case of loss, damage or shortage Intervention group also received general advice on how to reduce fracture in the form of a leaflet. Control group received only the leaflet and standard care
Outcomes	Length of follow-up: "352 person-years for the intervention group and 495 person-years for the control group for the analysis of hip fractures." Number of hip fractures Number of other fractures including pelvic fractures Falls Compliance with wearing hip protectors (defined as being observed to wear the hip protectors for 24 hours or at least during the daytime)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was generated from a table of random numbers
Allocation concealment (selection bias)	High risk	Allocation of participating clusters was concealed using sealed opaque envelopes, but the selection of participants within each cluster was undertaken after group allocation by staff who were aware of the allocation. "As residents with higher risk factors for hip fracture were enrolled, residents in the intervention group displayed greater risk for osteoporotic fractures than the control group in several characteristics: BMI, medical condition, cognitive status, ability to move, previous falls and previous hip fractures"
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants, and likely personnel, were not blinded to the intervention
Blinding of outcome assessment (detection bias) Fractures	Low risk	"Data on hip and other fractures in all facilities were obtained through information collected by the clinical research nurse or researchers during monthly visits to the homes and cross checked against local hospital records and roentgenograms"

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Koike 2009 *(Continued)*

Blinding of outcome assessment (detection bias) Falls	High risk	Not reported. Likely by clinical nursing staff who were aware of allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	Losses to follow-up during the study period were not balanced between groups. In the intervention group, losses (190 of 345) arose from 'Inability to stand' (n = 87), 'Deceased' (n = 12), 'Moved' (n = 25), and 'Refused hip protector' (n = 66). In the control group losses were fewer (67 of 327) arising from 'Inability to stand' (n = 30), 'Deceased' (n = 28), 'Moved' (n = 9)
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events were reported)

Lauritzen 1993

Methods	Cluster randomised. Participants in 10 out of 28 wards of a nursing home received protectors
Participants	665 residents of a nursing home in Copenhagen, Denmark All aged over 69 years Proportion male: 30%
Interventions	Allocation to wear hip protectors or not (control group) Hip protectors used consisted of a outer shield of polypropylene and an inner part of Plastazote. Hip protectors were fixed in special underwear (Safehip, Denmark)
Outcomes	Length of follow-up: 11 months Number of hip fractures Number of other fractures Falls (subgroup) Compliance with wearing the protectors (subgroup)
Notes	Additional information supplied by trialists

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A ward was selected when its number was drawn by an independent doctor". This indicates that there was a random component in the sequence generation (drawing of lots)
Allocation concealment (selection bias)	Low risk	It is unlikely that the lot drawing results could have been predicted. Also, selection bias is unlikely since all residents (and new residents) in the intervention group received the intervention
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants, and likely personnel, not blinded to the intervention
Blinding of outcome assessment (detection bias) Fractures	Low risk	Not reported. Likely registered by nursing staff, who was not blinded to the intervention (but objective outcome). No report of confirmation of fracture

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Lauritzen 1993 *(Continued)*

Blinding of outcome assessment (detection bias) Falls	High risk	This outcome was measured only in some clusters (2 intervention and 2 control). It was registered by the nursing staff, who was not blinded to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	All patients within the wards were recruited. When patients died, these were replaced in the study with the new patients arriving to the wards. Thus the groups had the same number of patients at risk during the follow-up period
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events not well reported)

Meyer 2003

Methods	Cluster randomisation. 49 clusters, each with over 70 residents. Nursing homes, or "independently working" wards of a large nursing homes randomised using computer generated lists using random permuted blocks of four, six and 10 using external, central telephone
Participants	942 residents of 42 nursing homes with 49 clusters in Hamburg, Germany Age: 70 or over Proportion male: 14% Inclusion criteria: aged 70 years or over; not bedridden; living in the nursing home for more than 3 months
Interventions	Intervention: allocation of 25 clusters to receive free hip protectors provided to intervention groups, structured education of staff based on social learning theory, 60 to 90 minute session in small groups, (covered effectiveness of hip protectors, factors known to reduce use, strategies for successful implementation); educational material for residents, relatives and physicians; one nurse from each intervention cluster delivered same education programme to residents individually or in small groups. Nursing staff encouraged to wear hip protectors for these sessions Control: nominated study co-ordinator for each control cluster (N = 24) received 10 minute session with information and demonstration of hip protector and provided with two free hip protectors for demonstration purposes Hip protectors were Safehip, Denmark
Outcomes	Length of follow-up: 18 months Number of hip fractures Number of other fractures Falls Mortality Compliance with wearing the hip protectors Reasons for non-compliance Hospital admissions Fall-related medical consultations Quality of life Costs
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

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Meyer 2003 *(Continued)*

Random sequence generation (selection bias)	Low risk	"We used computer generated randomisation lists for concealed allocation of clusters by external central telephone. To obviate disparate sample sizes we used random permuted blocks of four, six, and ten"
Allocation concealment (selection bias)	Low risk	In each cluster, "The nursing staff selected 15 to 30 residents according to predefined inclusion criteria: > 70 years old, not bedridden, and living in the nursing home for more than three months". Feedback from Prof Meyer confirmed that all participants were recruited prior to cluster randomisation and none were replaced (*see* Feedback 4)
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and staff were not blinded to the intervention
Blinding of outcome assessment (detection bias) Fractures	Low risk	There is no description regarding the measurement of this outcome. It is not mentioned whether it was confirmed using medical records. Likely similar documentation for falls below. However, is objective outcome
Blinding of outcome assessment (detection bias) Falls	High risk	A specially developed documentation sheet was used for collecting information about this outcome. This sheet was filled by the nursing staff, who were not blinded to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	The initial study publication reported that losses to follow up of individuals during the 18 months of the study were 157 of 459 (34%) in the intervention group and 207 of 483 in the control group (43%). Subsequent correspondence (Torgerson 2003) provided hazard ratios that indicate low risk of bias (*see* Feedback 4)
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures (Quality of life and costs were measured but not reported, and adverse events were not measured or reported)

O'Halloran 2004

Methods	Cluster randomisation in an intervention/ control ratio of approximately 1 to 2, by a statistician unconnected to the recruitment procedure using block (restricted) randomisation with strata determined by the organisational characteristics of each home
Participants	127 residential and nursing homes in Northern Ireland, UK. Total of 4117 occupied beds Mean age: 84 years Proportion male: 24%
Interventions	Intervention: allocation of 40 homes to receive 1. provision of a clear protocol for hip protectors use for participating homes 2. free provision and replacement of hip protectors as necessary to all eligible residents 3. the ongoing support of a trained nurse facilitator 4. one-hour workshop for all relevant home staff 5. distribution of manufacturers leaflets, poster and stickers 6. provision of a videotape on hip fractures and hip protectors 7. information sessions for residents and relatives Control: usual care (87 homes) Hip protectors from Robinson Healthcare Ltd which are equivalent to those of Safehip, Denmark

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O'Halloran 2004 *(Continued)*

Outcomes	Length of follow-up: 72 weeks Number of hip fractures Number of pelvic fractures Number of injurious falls (a fall resulting in injury requiring medical attention) Compliance with wearing the protectors
Notes	The study involved 127 nursing homes for which the bed occupancy for the duration of the study was estimated at 4117 occupied beds or 688,464 resident days of observations. Those patients who died or moved away during the study period were replaced by new admissions to the home. 4117 was therefore taken as the patient number involved for the exploratory analysis. Extra information supplied by Dr O'Halloran

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Cluster randomisation in an intervention to control ratio of approximately 1 to 2, using block (restricted) randomisation with strata determined by the organisational characteristics of each home
Allocation concealment (selection bias)	Low risk	The statistician in charge of the sequence was unconnected to the recruitment procedure. In addition, hip protectors were offered to all eligible residents within the home, which rules out the potential of selection bias within the clusters
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and personnel were not blinded to the intervention
Blinding of outcome assessment (detection bias) Fractures	Low risk	"Data on hip fractures in all homes were obtained and cross-referenced from three sources: information collected by the nurse facilitator during visits to the homes, information systems within local hospitals and mandatory accident reporting from homes to the RIU". It is very likely that the information obtained using these three sources is trustworthy
Blinding of outcome assessment (detection bias) Falls	High risk	There is no description about how this outcome was measured. Likely high due to subjective outcome and nursing staff aware of allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There is no description of the total number of participants. The average of occupied beds in the institutions across the follow-up period is used as the denominator for calculating the treatment effects
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events not measured or reported)

Van Schoor 2003

Methods	Individually randomised in blocks of four after stratification for sex and age using computer generated random lists
Participants	561 residents of apartment homes, homes for the elderly and nursing homes in Amsterdam, Holland Mean age: Protectors 84.8; Controls 85.7 years Proportion male: 11%

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Van Schoor 2003 *(Continued)*

	Inclusion criteria: 70 years and over; low bone density and/or high risk for falling (BUA 40 dB/MHz or less; or BUA 40-60 dB/MHz and at least two risk factors for falling; or BUA 60-70 dB/MHz and at least three risk factors for falling). Risk factors for falling were 1 or more falls in the previous 6 months; dizziness on standing up from a chair in the last 2 weeks; have sustained a stroke with neurological impairment; urinary incontinence; low physical activity; impaired mobility; cognitive impairment Exclusion criteria: completely immobile; previous hip fracture; or with a hip prosthesis on both sides
Interventions	Allocation to wear hip protectors or not (control) Hip protectors were Safehip, Denmark
Outcomes	Mean length of follow-up: 69.6 weeks Number of hip fractures Number of pelvic fractures Number of other fractures Compliance with wearing the protectors Adverse effects of the protectors Mortality Falls
Notes	6.8% of the participants lived in apartment houses for the elderly, often with access to facilities in a home for the elderly nearby

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Our statistical department generated randomization lists by computer."
Allocation concealment (selection bias)	Low risk	"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. Randomization lists were not available to the research assistants." Likely low risk
Blinding of participants and personnel (performance bias) Fractures	High risk	Participants and nurses were not blinded
Blinding of outcome assessment (detection bias) Fractures	Low risk	Even though this outcome was assessed using a participant-kept calendar, which was filled by the nurse if the participant was unable to do it, this outcome was verified by the general practitioner
Blinding of outcome assessment (detection bias) Falls	High risk	Outcome assessed using a participant-kept calendar (filled by the nurse if the participant was not able to do it), filled on a weekly basis and mailed to the researchers every three months. When it was not completed or completed incorrectly at the end of the three months, the participant or nurse were contacted to provide the information
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data are balanced in number and reason for loss across the two groups
Selective reporting (reporting bias)	Low risk	Includes data for hip fractures and other fractures. (Adverse events were not measured or reported)

BUA: broadband ultrasound attenuation

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Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Becker 2003	Randomised trial of 981 long-stay residents of six nursing homes in Ulm, Germany. The homes were randomised (cluster randomisation) to have a multifaceted falls intervention programme (staff and resident education on fall prevention, advice on environmental adaptations, progressive balance and resistance training and hip protectors) or to act as controls. 138 of 509 residents allocated to the intervention group wore the hip protectors, with 108 of them wearing them as per the protocol, which was from arising in the morning to bedtime. 17 hip fractures occurred amongst the 509 allocated to the intervention group as opposed to 15 hip fractures in the 472 residents in the control group. The study was excluded as it was an evaluation of multifaceted intervention programme and not just hip protectors. The co-interventions were designed to reduce falls and fall-related injuries therefore the effect of hip protectors cannot be determined.
Bentzen 2008	Cluster randomised trial of 18 Norwegian nursing homes with 1236 participants. Nursing homes randomised to hard hip protectors or soft hip protectors to study uptake and adherence. Study excluded as no control group with no hip protectors. Nested observational study of hip fracture incidence in protected falls (soft or hard protectors) and unprotected falls.
Colon-Emeric 2007	This was a cluster randomised controlled trial involving 606 residents of 67 care homes. Residents were randomised to receive an early or delayed intervention, consisting of education, feedback and audit on falls and fracture prevention. The study was excluded as it was not a randomised trial comparing the use of hip protectors with a control group.
Cox 2008	This was a cluster randomised controlled trial involving 5637 residents of 230 care homes. Half were allocated to receive a specialist osteoporosis nurses to undertake a short training sessions with care home staff on fracture prevention and falls. The other half of the homes acted at controls. Findings showed an increased prescription of bisphosphonates and calcium and vitamin D in the intervention group. There was no significant difference in the use of hip protectors or the occurrence of falls or fractures between groups. The study was excluded as it was not a randomised trial comparing the use of hip protectors with a control group.
Cryer 2006	Observational study on the use of hip protectors. It was excluded as there was no randomisation of participants.
Forsen 2003	Before and after intervention study on the use of hip protectors. After the introduction of hip protectors to nursing homes in two municipalities in Norway (965 beds), there was a 39% reduction in the incidence of hip fractures. The percentage of daily users of the protectors fell from 35% initially to 22% at the end of the study. The study was excluded as there was no randomisation of participants.
Garfinkel 2008	Observational study on the use of hip protectors. It was excluded as there was no randomisation of participants.
Haines 2004	Randomised controlled trial of a targeted multiple intervention programme implemented within three hospital wards specialising in rehabilitation and care of elderly. 626 participants with an average age of 80 years were involved. In addition to usual care the intervention group received a falls risk alert card with an information brochure, exercise programme, education programme, and hip protectors. Participants in the intervention group had fewer falls (P = 0.045) and a non-statistically significant tendency to less injurious falls. The study was excluded, as it was an evaluation of multifaceted intervention programme and not just hip protectors. The co-interventions were designed to reduce falls and fall-related injuries therefore the effect of hip protectors cannot be determined.
Hayes 2008	Randomised trial of hip protectors in older hospital inpatients. Trialist confirms this was to be a multicentre trial powered to detect hip fracture rates but other two centres dropped out. Predictors of compliance reported in published letter. Excluded as no hip fracture outcomes were available.

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Study	Reason for exclusion
Heikinheimo 2004	Observational study on the use of hip protectors. It was excluded as there was no randomisation of participants.
Huang 2006	Observational study on the use of hip protectors. It was excluded as there was no randomisation of participants.
Jensen 2002	Randomised trial with 194 participants in residential care facilities. The facilities were cluster randomised to have a multifactorial fall and injury prevention intervention. General: staff education, environmental modification, post-fall staff conferences and ongoing staff guidance. Resident specific: exercises, supply and repair of aids, medication modification, hip protectors. 47/194 participants offered protectors; 34 agreed to wear them. The study was excluded as it was an evaluation of multifaceted intervention programme and not just hip protectors.
Lauritzen 1996b	Open prospective case-cohort study with intervention cases at one hospital and controls from another hospital. It was excluded as it was not a randomised trial.
Maki-Jokela 2002	Observational study on the use of hip protectors. It was excluded as there was no randomisation of participants.
O'Halloran 2005	Randomised controlled trial with 12 weeks follow up of 109 nursing home residents. Participants were randomised to receive either Safehip or HipSaver hip protectors. The study was to determine levels of adherence for the two types of protectors. Results state that the type of hip protector made no difference to their continued use by residents. The study was excluded as there was no control group without hip protectors.
Ross 1992	Study assessing the feasibility of wearing hip pads for 30 elderly residents of long-term institutions. The report mentioned there was 'random' allocation of residents to one of six interventions but no numbers of patients in each group were given nor outcomes. The individual interventions were not clearly defined. The study was intended as a preparation for a randomised trial. Additional information has been requested from the authors but not provided. The study was excluded because of inadequate information.
Thompson 2005	Observational study on the use of hip protectors. It was excluded as there was no randomisation of participants.
Villar 1998	This study was included in earlier versions of this review, but it was primarily a study of adherence with a short follow up and no hip fractures occurred in the short period of follow-up.
Ward 2010	This was a randomised trial providing multiple interventions so could not isolate the effects of the hip protector.
Woo 2003	A non-randomised trial in convalescent hospitals or nursing homes with 302 subjects wearing hip protectors and 352 age- and sex-matched control subjects. The hip protectors were specially designed for Chinese build and tropical conditions. Mean follow up was 18.6 +/- 10.8 days in treatment group. Compliance ranged from 55 to 70%. The relative risk for hip fracture was 0.18 (0.04 to 0.79), relative risk reduction 82% (2 versus 13 cases). The study is described incorrectly as a randomised controlled trial in Current Controlled Trials (ISRCTN81342808).
Wortberg 1998	This study involved 84 residents of five nursing homes in Ludenscheid, Germany. Forty-seven were allocated to receive the protectors and 37 residents acted as controls. No fractures occurred for the 91 reported falls in the hip protector group, while seven hip fractures occurred in 28 falls without the protectors. The study was excluded, as there was no randomisation of residents into the two groups.

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Characteristics of studies awaiting assessment *[ordered by study ID]*

Frohnhofen 2010

Methods	Randomised controlled trial (abstract)
Participants	650 frail or demented patients with a history of falls in the last 3 months before admission to hospital
Interventions	Hip protector (safe hip soft) versus control group
Outcomes	Adherence, falls, hip fractures
Notes	Unable to locate full published study; insufficient data to include at present

Characteristics of ongoing studies *[ordered by study ID]*

Tangtrakulwanich

Trial name or title	Hip protector for prevention of hip fracture
Methods	Randomised controlled trial
Participants	Inclusion criteria: people with previous unilateral hip fracture; aged 50 to 80 years Exclusion criteria: poor communicative ability; cannot independently ambulate; local skin problem at trochanteric area
Interventions	PSU hip protector versus no hip protector
Outcomes	Hip fracture at 6 months, 1, 2 and 3 years SF 36 at 6 months, 1, 2 and 3 years
Starting date	June 2010 to September 2012
Contact information	Dr B Tangtrakulwanich, MD, PhD Department of Othropaedic Surgery Faculty of Medicine Prince of Songkla university Hat Yai Songkhla 90110 Thailand
Notes	

DATA AND ANALYSES

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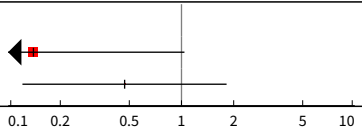
Comparison 1. Provision of hip protectors

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Hip fracture: risk ratio; institutional residence	14	11808	Risk Ratio (Fixed, 95% CI)	0.82 [0.67, 1.00]
1.1 Individually randomised trials	5	1426	Risk Ratio (Fixed, 95% CI)	0.91 [0.57, 1.44]
1.2 Cluster randomised trials (adjusted)	9	10382	Risk Ratio (Fixed, 95% CI)	0.80 [0.64, 1.00]
2 Hip fracture: risk ratio; community residence	5	5614	Risk Ratio (Fixed, 95% CI)	1.15 [0.84, 1.58]
2.1 Any hip fracture	4	5248	Risk Ratio (Fixed, 95% CI)	1.10 [0.80, 1.52]
2.2 Second hip fracture	1	366	Risk Ratio (Fixed, 95% CI)	3.03 [0.62, 14.82]
3 Pelvic fracture: risk ratio	9	12408	Risk Ratio (Fixed, 95% CI)	1.27 [0.78, 2.08]
3.1 Community studies	3	5135	Risk Ratio (Fixed, 95% CI)	1.04 [0.52, 2.09]
3.2 Institutional studies	6	7273	Risk Ratio (Fixed, 95% CI)	1.56 [0.77, 3.13]
4 Other fractures (excluding pelvis): rate ratio	6	7671	Rate Ratio (Fixed, 95% CI)	0.87 [0.71, 1.07]
4.1 Community studies	3	5135	Rate Ratio (Fixed, 95% CI)	0.83 [0.65, 1.04]
4.2 Institutional studies	3	2536	Rate Ratio (Fixed, 95% CI)	1.02 [0.69, 1.52]
5 Pelvic and other fractures: rate ratio	11	10429	Rate Ratio (Fixed, 95% CI)	0.88 [0.75, 1.05]
5.1 Community studies	5	5614	Rate Ratio (Fixed, 95% CI)	0.86 [0.69, 1.06]
5.2 Institutional studies	6	4815	Rate Ratio (Fixed, 95% CI)	0.93 [0.70, 1.23]
6 Falls per person year; rate ratio	16	11275	Rate Ratio (Random, 95% CI)	1.02 [0.90, 1.16]
6.1 Individually randomised studies	8	6503	Rate Ratio (Random, 95% CI)	1.04 [0.85, 1.28]
6.2 Cluster randomised studies	8	4772	Rate Ratio (Random, 95% CI)	1.01 [0.83, 1.22]

Analysis 1.1. Comparison 1 Provision of hip protectors, Outcome 1 Hip fracture: risk ratio; institutional residence.

Study or subgroup	Hip protectors N	Control N	log[Risk Ratio] (SE)	Risk Ratio IV, Fixed, 95% CI	Weight	Risk Ratio IV, Fixed, 95% CI
1.1.1 Individually randomised trials						
Jantti 1996	36	36	-2 (1.022)		1%	0.14[0.02,1.04]
Chan 2000	40	31	-0.8 (0.691)		2.18%	0.47[0.12,1.82]



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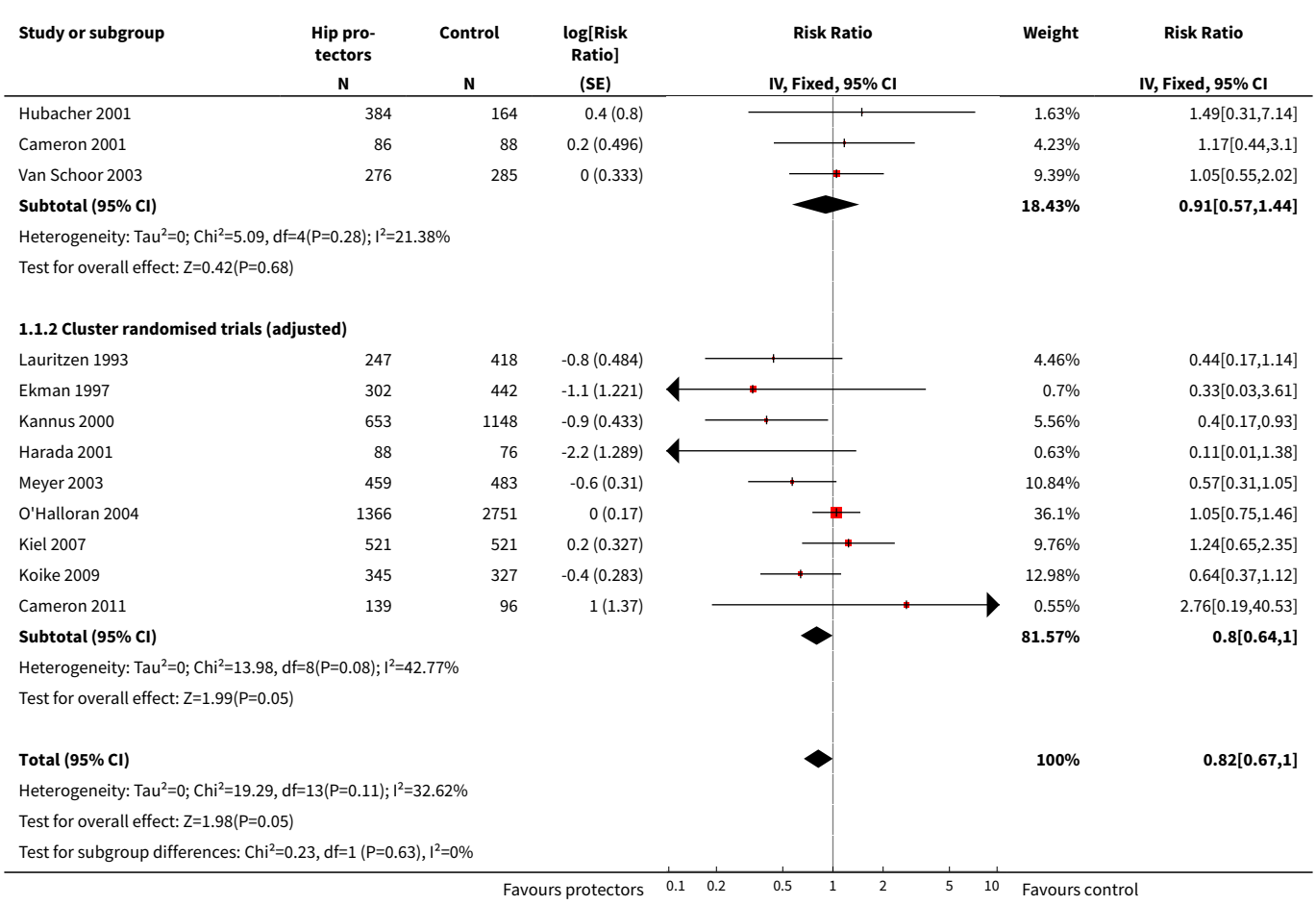
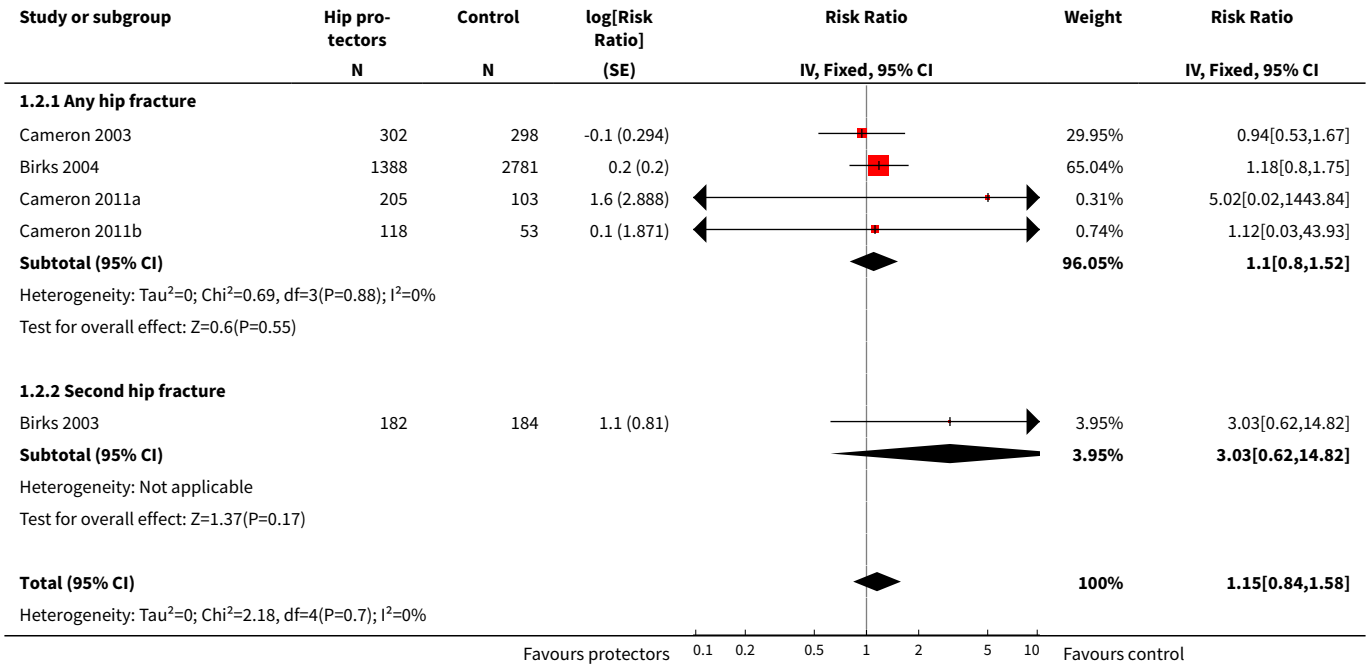


Analysis 1.2. Comparison 1 Provision of hip protectors, Outcome 2 Hip fracture: risk ratio; community residence.



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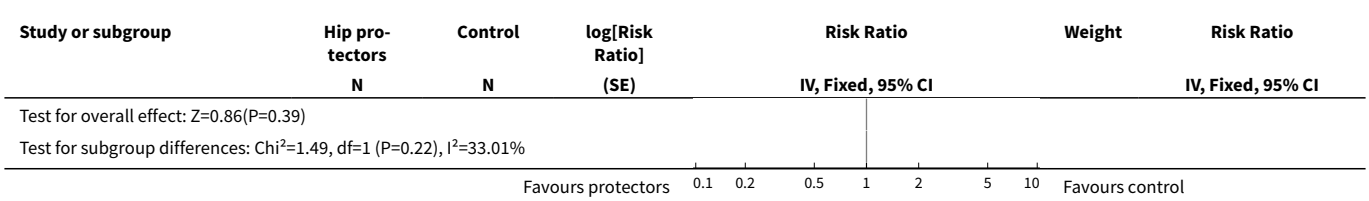
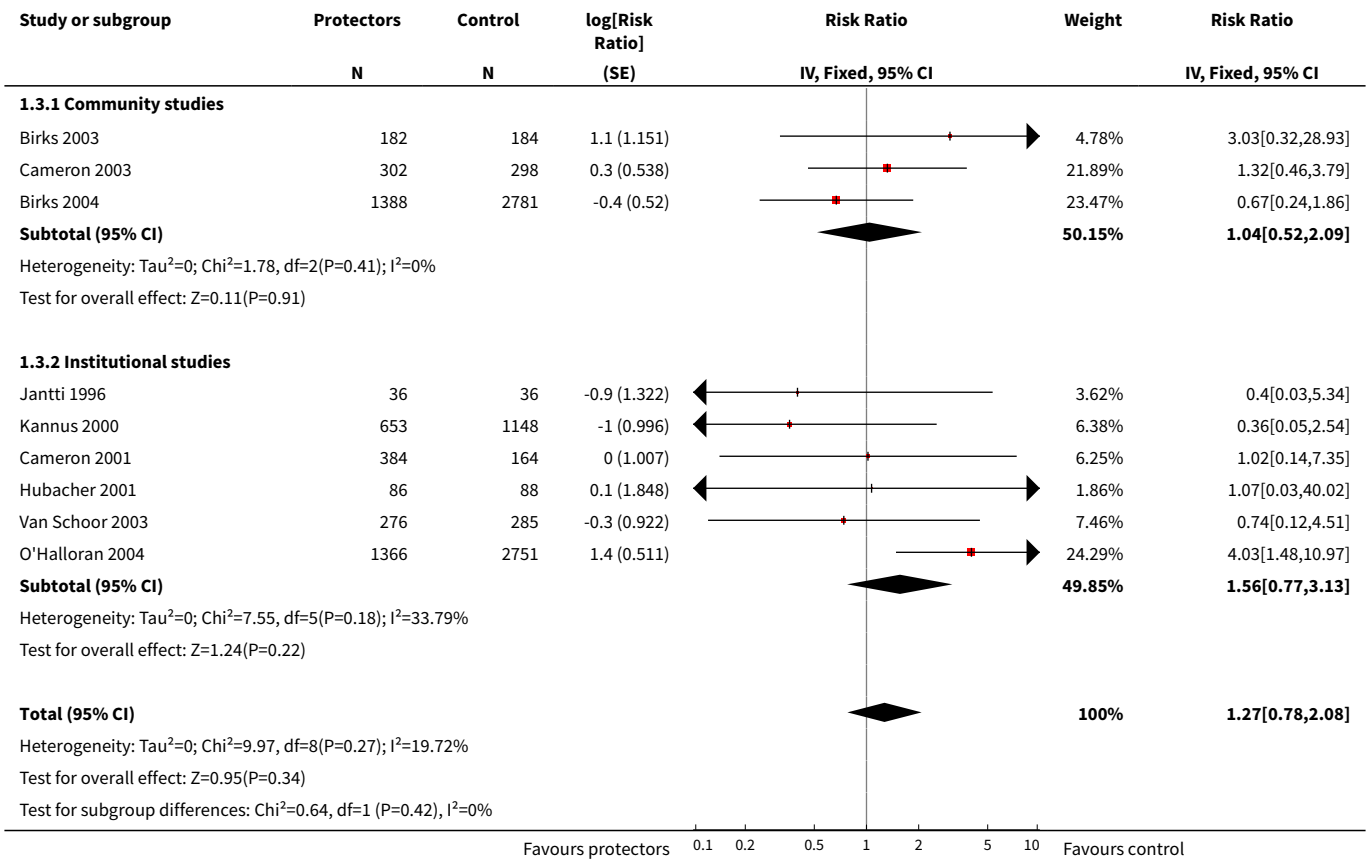
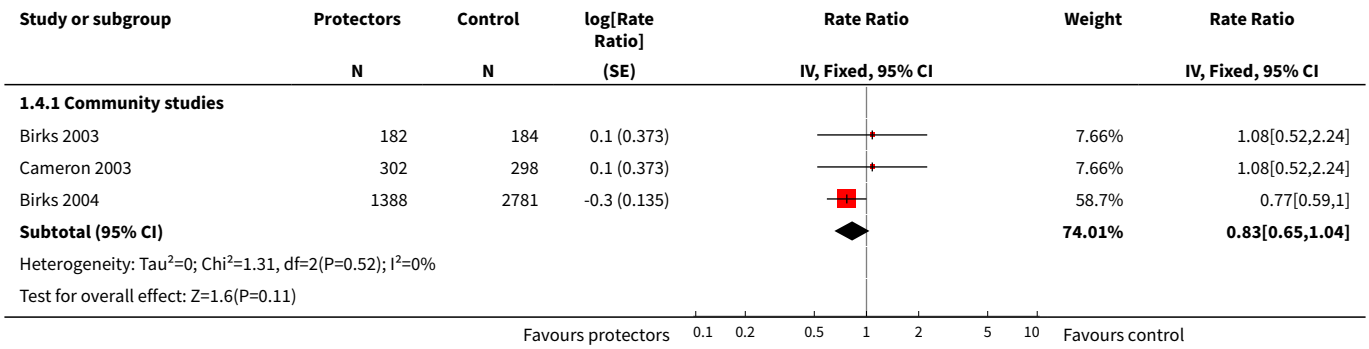


Analysis 1.3. Comparison 1 Provision of hip protectors, Outcome 3 Pelvic fracture: risk ratio.



Analysis 1.4. Comparison 1 Provision of hip protectors, Outcome 4 Other fractures (excluding pelvis): rate ratio.



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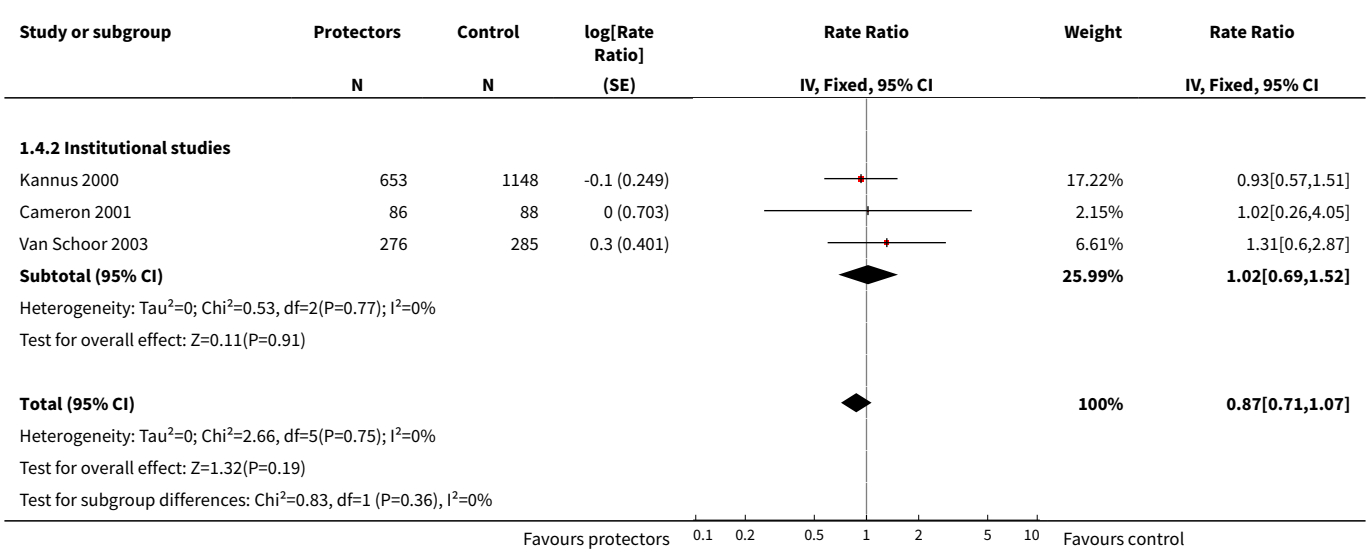
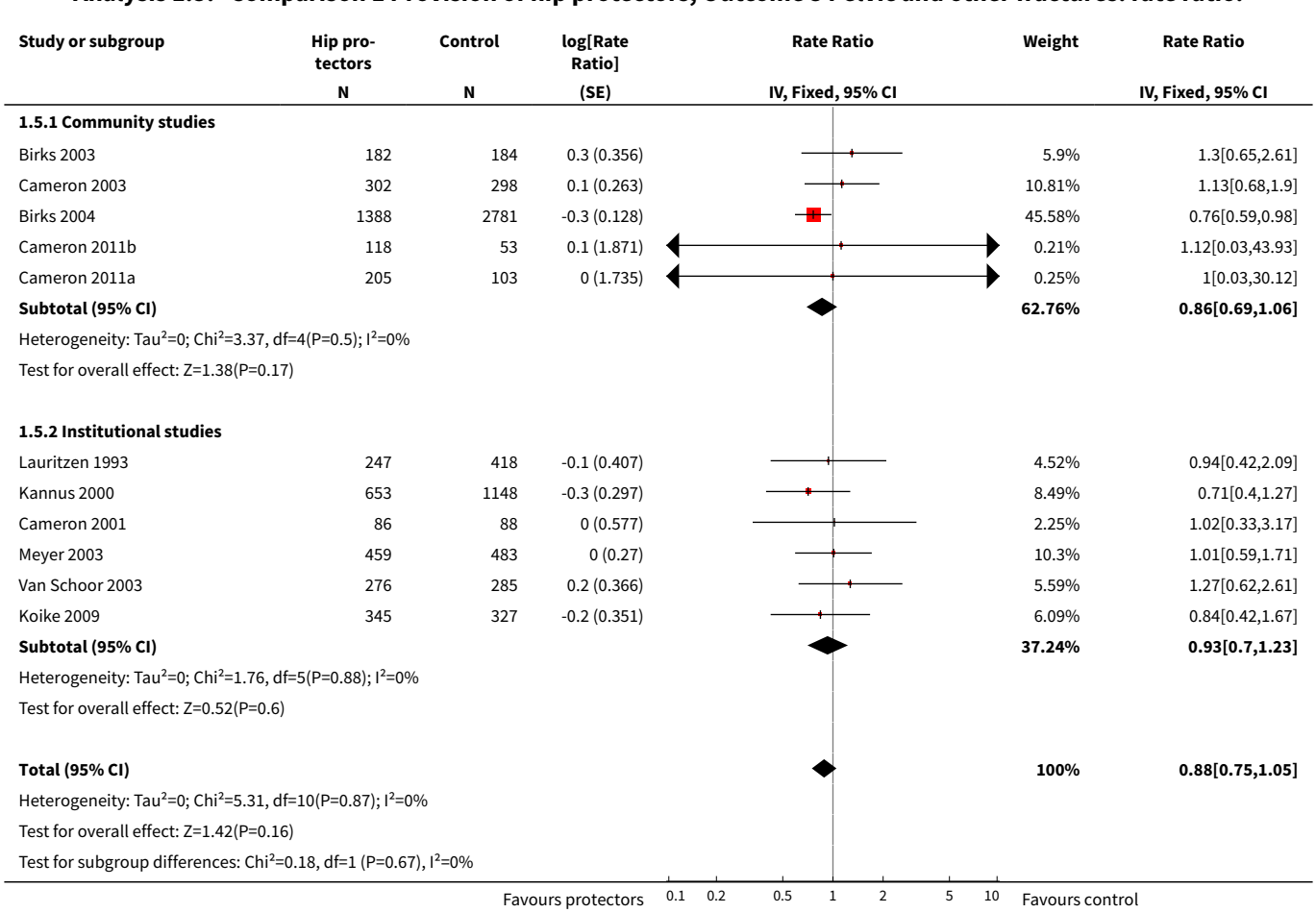


Analysis 1.5. Comparison 1 Provision of hip protectors, Outcome 5 Pelvic and other fractures: rate ratio.



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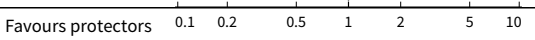
Analysis 1.6. Comparison 1 Provision of hip protectors, Outcome 6 Falls per person year; rate ratio.

Study or subgroup	Hip protectors N	Control N	log[Rate Ratio] (SE)	Rate Ratio IV, Random, 95% CI	Weight	Rate Ratio IV, Random, 95% CI
1.6.1 Individually randomised studies						
Jantti 1996	36	36	0.2 (0.108)		6.66%	1.25[1.01,1.54]
Chan 2000	40	31	0.4 (0.124)		6.29%	1.47[1.15,1.87]
Hubacher 2001	384	164	-0 (0.103)		6.75%	0.98[0.8,1.2]
Cameron 2001	86	88	-0 (0.073)		7.36%	0.97[0.84,1.12]
Cameron 2003	302	298	0.2 (0.054)		7.68%	1.23[1.11,1.37]
Van Schoor 2003	276	285	-0.3 (0.047)		7.77%	0.75[0.68,0.82]
Birks 2004	1388	2781	-0.3 (0.07)		7.41%	0.72[0.63,0.83]
Cameron 2011b	205	103	0.8 (0.416)		1.91%	2.12[0.94,4.79]
Subtotal (95% CI)					**51.83%**	**1.04[0.85,1.28]**
Heterogeneity: Tau^2=0.07; Chi^2=86.59, df=7(P<0.0001); I^2=91.92%						
Test for overall effect: Z=0.43(P=0.67)						
1.6.2 Cluster randomised studies						
Lauritzen 1993	247	418	0.2 (0.165)		5.37%	1.2[0.87,1.66]
Ekman 1997	302	442	-0.2 (0.073)		7.37%	0.81[0.7,0.93]
Harada 2001	88	76	0.5 (0.137)		6.01%	1.61[1.23,2.1]
Meyer 2003	459	483	-0.4 (0.039)		7.88%	0.66[0.61,0.71]
Kiel 2007	521	521	0 (0.028)		7.98%	1[0.95,1.06]
Koike 2009	345	327	-0 (0.05)		7.74%	0.97[0.88,1.07]
Cameron 2011a	205	103	0.9 (0.447)		1.71%	2.55[1.06,6.14]
Cameron 2011	139	96	-0 (0.227)		4.12%	0.98[0.63,1.53]
Subtotal (95% CI)					**48.17%**	**1.01[0.83,1.22]**
Heterogeneity: Tau^2=0.06; Chi^2=109.55, df=7(P<0.0001); I^2=93.61%						
Test for overall effect: Z=0.09(P=0.93)						
Total (95% CI)					**100%**	**1.02[0.9,1.16]**
Heterogeneity: Tau^2=0.05; Chi^2=198.69, df=15(P<0.0001); I^2=92.45%						
Test for overall effect: Z=0.33(P=0.74)						
Test for subgroup differences: Chi^2=0.06, df=1 (P=0.8), I^2=0%						



ADDITIONAL TABLES

Table 1. Risk of bias assessment criteria

Domain	Scoring rules
	"Yes" = Low risk of bias. "No" = High risk of bias. "Unclear" = insufficient information to make judgment
Adequate sequence generation? Was the allocation sequence adequately generated?	**Score "low risk" if** a random component in the sequence generation was described e.g. use of a random number table, computer random number generator, coin-toss, minimization. **Score "high risk" if** a non-random method was used e.g. date of admission, odd or even date of birth, case

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Table 1. Risk of bias assessment criteria *(Continued)*

	record number, clinician or institutional judgment, participant preference, patient risk factor score or test results, availability of intervention. **Score "Unclear" if** there was insufficient information to make a judgment of "low risk" or "high risk".
Allocation concealment? Was allocation adequately concealed?	**Score "low risk" if** **in studies using individual randomisation** allocation concealment was described as by central allocation (telephone, web-based, or sequentially numbered, opaque, sealed envelopes). **in studies using cluster randomisation** allocation of all cluster units was performed at the start of the study **AND** individual participant recruitment was completed prior to assignment of the cluster, and the same participants were followed up over time **OR** recruitment of individual participants after cluster assignment was carried out by a person unable to influence group allocation **OR** individual participants in intervention and control arms were invited by mail questionnaire with identical information. **Score "high risk" if** **in studies using individual randomisation** investigators enrolling participants could possibly foresee assignment to a particular cluster and thus introduce selection bias, e.g. assignment envelopes unsealed, non-opaque, or not sequentially numbered, date of birth, case record number, clinician judgment, participant preference. **in studies using cluster randomisation** individual participant recruitment was undertaken post group allocation by a person who was unblinded and may have had knowledge of participant characteristics. **Score "Unclear" if** there was insufficient information to make a judgment of "low risk" or "high risk".
Blinding of participants and personnel? Was knowledge of the allocated intervention adequately prevented during the study?	**Score "low risk" if** patients and staff (personnel) were not aware of the intervention to which they were allocated **OR** knowledge of the intervention to which participants were allocated was unlikely to introduce bias. **Score "high risk" if** it is clear that patients and/or staff (personnel) were aware of the intervention to which participants had been allocated. **Score "unclear" if** there is not enough information to make a judgment of "low risk" or "high risk".
Blinding of outcome assessment? **1. Fracture of the hip or pelvis**	**Score "low risk" if** presence and site, or absence, of any recorded fracture event was diagnosed by radiological examination and the outcome confirmed either by a report to the research team from a radiologist blinded to group allocation **OR** where self reporting of fracture was used, the date, presence and site of a fracture was confirmed in hospital or primary care case records scrutinized by the research team **AND** absence of fracture in participants not self-reporting was confirmed in primary care case-records. **Score "high risk" if**

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Table 1. Risk of bias assessment criteria *(Continued)*

	it is clear that neither of the above conditions was met. **Score "Unclear" if** there was insufficient information to make a judgment of "low risk" or "high risk".
2. Falls	**Score "low risk" if** blinding, of outcome assessors was reported, and review authors judge that the outcome and outcome measure are not likely to be influenced by lack of blinding of carers **OR** participants (e.g. falls are recorded in incident reports as normal practice in all participating institutions). **Score "high risk" if** outcome assessors were not blinded to participant status **AND** in community studies, ascertainment relied on participant recall at intervals during the study or at its conclusion **OR** In institutional studies, incident reporting of falls was not standard practice amongst all participating institutions. **Score "Unclear" if** outcome assessors were not blinded to participant status, but the review authors judge that there was insufficient information to permit judgment **OR** the study did not address this outcome.
Incomplete outcome data addressed? Were incomplete outcome data adequately addressed?	**Score "low risk" if** there are no missing outcome data **OR** reasons for missing outcome data are likely to be unrelated to true outcome **OR** missing outcome data are balanced in number and reason for loss across groups **OR** the proportion of missing outcomes, compared with the observed event risk, is unlikely to have a clinically relevant impact **OR** missing data have been imputed using appropriate methods. **Score "high risk" if** there were missing outcome data, and these were likely to bias the result, since they appear related to the true outcome **OR** show important imbalance between intervention and control groups **OR** are likely, on account of their proportion compared with the observed event risk, to have a clinically relevant impact. **Score "Unclear" if** details of losses are insufficient to make a judgment of "low risk" or "high risk".
Selective outcome reporting?	**Score "low risk" if** the published report includes adequate data which could be entered for meta-analysis for hip fractures and other fractures. **Score "high risk" if** hip fractures and other fractures were not measured or reported. **Score "unclear" if** there was insufficient information to make a judgment of "low risk" or "high risk".

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Table 2. Institutional studies: summary data for Analysis 1.1

Study ID	Randomisation method	Protector design	Intervention n	Intervention N	Control n	Control N	Design effect applied to clustered studies
Cameron 2001	Individual	Hard (Safehip)	8	86	7	88	NA
Chan 2000	Individual	Soft	3	40	6	31	NA
Ekman 1997	Cluster	Soft, inserted under normal underwear	4	302	17	442	4.7
Harada 2001	Cluster	Hard (Safehip)	1	88	8	76	1.3
Hubacher 2001	Individual	Hard (Safehip)	7	384	2	164	NA
Jantti 1996	Individual	Soft	1	36	5	36	NA
Kannus 2000	Cluster	Shunting/ absorbing (KPH)	13	653	67	1148	1.5
Kiel 2007	All Individual participants had one protected and one unprotected hip. Protected side randomised by cluster	Shunting/ absorbing	17	1042	21	1042	NA
Koike 2009	Cluster	Hard (Safehip)	19	345	39	327	1.3
Lauritzen 1993	Cluster	Hard (Safehip)	8	247	31	418	1.6
Meyer 2003	Cluster	Hard (Safehip)	21	459	42	483	1.4
O'Halloran 2004	Cluster	Hard (Safehip)	85	1366	163	2751	1.7*
Van Schoor 2003	Individual	Hard (Safehip)	18	276	20	285	NA
Cameron 2011	Cluster	Hard (Hornsby Health Hips) and soft (Hip Saver)	4	139	1	96	2

n: number of hip fractures
N: number of participants analysed
NA: not applicable
* Cluster design effect and intra-class correlation (ICC) reported by study authors

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Calculation of cluster design effect for other studies used ICC of 0.02 reported in O'Halloran 2004

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Table 3. Incidence of hip fractures per person year (control group participants) in descending order of incidence

Study ID	Incidence (95% CI)	Setting	Country	Protection reported as effective	Randomisation
Chan 2000	**0.261** (0.123 to 0.468)	Institutional	Australia	Yes	Individual
Jantti 1996	**0.194** (0.095 to 0.353)	Institutional	Finland	Yes	Individual
Harada 2001	**0.096** (0.047 to 0.181)	Institutional	Japan	Yes	Cluster
Koike 2009	**0.079** (0.058 to 0.106)	Institutional	Japan	Yes	Cluster
Meyer 2003	**0.076** (0.057 to 0.102)	Institutional	Germany	Yes	Cluster
Lauritzen 1993	**0.068** (0.048 to 0.095)	Institutional	Denmark	Yes	Cluster
O'Halloran 2004	**0.059** (0.050 to 0.102)	Institutional	United Kingdom	No	Cluster
Cameron 2001	**0.053** (0.024 to 0.107)	Institutional	Australia	No	Individual
Van Schoor 2003	**0.050** (0.032 to 0.077)	Institutional	Netherlands	No	Individual
Ekman 1997	**0.042** (0.026 to 0.067)	Institutional	Sweden	Yes	Cluster
Kiel 2007	**0.025** (0.016 to 0.040)	Institutional	USA	No	Individual
Cameron 2011	**0.021** (0.006 to 0.073)	Institutional	Australia	No	Cluster
Hubacher 2001	**0.017** (0.001 to 0.065)	Institutional	Switzerland	No	Individual
Kannus 2000	**0.046** (0.036 to 0.058)	Institutional and supported living in community	Finland	Yes	Cluster
Cameron 2003	**0.037** (0.025 to 0.056)	Living in community	Australia	No	Individual
Birks 2004	**0.013** (0.010 to 0.016)	Living in community	United Kingdom	No	Individual
Birks 2003	**0.012** (0.000 to 0.029)	Living in community	United Kingdom	No	Individual
Cameron 2011a	**0.0** (-0.018 to 0.018)	Living in community	Australia	No	Cluster
Cameron 2011b	**0.000** (-0.034 to 0.034)	Living in community	Australia	No	Individual

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Table 4. Community studies: summary data for hip fractures (Analysis 1.2)

Study ID	Randomisation method	Protector design	Intervention n	Intervention N	Control n	Control N	Design effect applied to clustered studies
Cameron 2003	Individual	Hard (Safehip)	21	302	22	298	NA
Birks 2004	Individual	Hard (Robinson Healthcare Ltd)	39	1388	66	2781	NA
Cameron 2011b	Individual	Hard (Hornsby Healthy Hips) or soft (Hip Saver)	1	118	0	53	NA
Cameron 2011a	Cluster	Hard (Hornsby Healthy Hips) or soft (Hip Saver)	4	205	0	103	3
Birks 2003	Individual	Hard (Safehip)	6	182	2	184	NA

n: number of hip fractures
N: number of participants analysed
NA: not applicable
***** Cluster design effect and intra-class correlation (ICC) reported by study authors
Calculation of cluster design effect for other studies used ICC of 0.02 reported in O'Halloran 2004

Table 5. Pelvic fractures: summary data for analysis 1.3

Study ID	Randomisation method	Protector design	Intervention n	Intervention N	Control n	Control N	Design effect applied to clustered studies
Birks 2003	Individual	Hard (Safehip)	3	182	0	184	NA
Cameron 2003	Individual	Hard (Safehip)	8	302	6	298	NA
Birks 2004	Individual	Hard (Robinson Healthcare Ltd)	5	1388	15	2781	NA
Jantti 1996	Individual	Soft	0	36	2	36	NA
Kannus 2000	Cluster	Shunting/absorbing (KPH)	2	653	12	1148	1.5

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Table 5. Pelvic fractures: summary data for analysis 1.3 *(Continued)*

Hubacher 2001	Individual	Hard (Safehip)	1	384	0	164	NA
Cameron 2001	Individual	Hard (Safehip)	2	86	2	88	NA
Van Schoor 2003	Individual	Hard (Safehip)	2	276	3	285	NA
O'Halloran 2004	Cluster	Hard (Safehip)	12	1366	6	2751	1.7*

n: number of hip fractures
N: number of participants analysed
NA: not applicable
***** Cluster design effect and intra-class correlation (ICC) reported by study authors
Calculation of cluster design effect for other studies used ICC of 0.02 reported in O'Halloran 2004

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APPENDICES

Appendix 1. Search strategies

The Cochrane Library (Wiley Online Library)

2012, Issue 12

#1 MeSH descriptor: [Protective Clothing] explode all trees (370)
#2 MeSH descriptor: [Orthotic Devices] explode all trees (724)
#3 hip near (protector* or pad*):ti,ab,kw (92)
#4 MeSH descriptor: [Protective Devices] explode all trees (1814)
#5 #1 or #2 or #3 or #4 (2565)
#6 MeSH descriptor: [Hip Fractures] explode all trees (955)
#7 (hip or femur* or femor*) near fracture*:ti,ab,kw (2208)
#8 #6 or #7 (2208)
#9 #5 and #8 (66 in Trials) (10 in Econonic Evaluations)

MEDLINE (OvidSP interface)

November 2009 to week 3 November 2012

1 Protective Clothing/ (4525)
2 Protective Devices/ (5666)
3 Orthotic Devices/ (4830)
4 (hip adj (protector$ or pad$ or cushion$)).tw. (354)
5 or/1-4 (14840)
6 exp Hip Fractures/ (16801)
7 (fracture$ adj2 (hip or femur$ or femor$)).tw. (17940)
8 or/6-7 (25070)
9 and/5,8 (347)
10 randomized controlled trial.pt. (342334)
11 controlled clinical trial.pt. (85694)
12 randomized.ab. (244919)
13 placebo.ab. (136550)
14 drug therapy.fs. (1588363)
15 randomly.ab. (175193)
16 trial.ab. (253825)
17 groups.ab. (1145730)
18 or/10-17 (2960405)
19 exp Animals/ not Humans/ (3812817)
20 18 not 19 (2515366)
21 9 and 20 (116)
22 (200911* or 200912* or 2010* or 2011* or 2012*).ed. (2476490)
23 21 and 22 (15 in MEDLINE) (0 in MEDLINE in-process)

EMBASE (OvidSP interface)

2010 to 2012 Week 50

1 Hip Protector/ (37)
2 Protective Clothing/ (9343)
3 Protective Equipment/ (8891)
4 Orthotics/ (3095)
5 (hip adj (protector$ or pad$)).tw. (454)
6 or/2-5 (21091)
7 exp Hip Fracture/ (26284)
8 ((hip or femur$ or femor$) adj2 fracture$).tw. (22999)
9 or/7-8 (35211)
10 and/6,9 (462)
11 or/1,10 (471)
12 exp Randomized Controlled trial/ (334017)
13 exp Double Blind Procedure/ (112280)
14 exp Single Blind Procedure/ (16758)

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15 exp Crossover Procedure/ (35737)
16 Controlled Study/ (3923787)
17 or/12-16 (4004024)
18 ((clinical or controlled or comparative or placebo or prospective$ or randomi#ed) adj3 (trial or study)).tw. (661628)
19 (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw. (161062)
20 ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw. (149581)
21 (cross?over$ or (cross adj1 over$)).tw. (63934)
22 ((allocat$ or allot$ or assign$ or divid$) adj3 (condition$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group $)).tw. (202997)
23 or/18-22 (987275)
24 or/17,23 (4494169)
25 limit 24 to human (2729889)
26 and/11,25 (159)
27 (2010* or 2011* or 2012*).em. (3233474)
28 26 and 27 (18)

CINAHL Plus (EBSCO interface)

2009 to December 2012

S1 (MH "Protective Clothing") (2,185)
S2 (MH "Protective Devices") (2,536)
S3 (MH "Orthoses") (4,019)
S4 TX hip AND TX (protector* or pad*) (442)
S5 S1 OR S2 OR S3 OR S4 (8,958)
S6 (MH "Hip Fractures") (4,820)
S7 TX (hip or femur* or femor*) and fracture* (10,320)
S8 S6 OR S7 (10,320)
S9 S5 AND S8 (319)
S10 (MH "Clinical Trials+") (152,382)
S11 (MH "Evaluation Research+") (19,032)
S12 (MH "Comparative Studies") (69,705)
S13 (MH "Crossover Design") (9,958)
S14 PT Clinical Trial (74,592)
S15 (MH "Random Assignment") (33,960)
S16 S10 or S11 or S12 or S13 or S14 or S15 (244,640)
S17 TX ((clinical or controlled or comparative or placebo or prospective or randomi?ed) and (trial or study)) (421,108)
S18 TX (random* and (allocat* or allot* or assign* or basis* or divid* or order*)) (59,647)
S19 TX ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)) (649,695)
S20 TX (crossover* or 'cross over') or TX cross n1 over (12,502)
S21 TX ((allocat* or allot* or assign* or divid*) and (condition* or experiment* or intervention* or treatment* or therap* or control* or group*)) (74,928)
S22 S17 or S18 or S19 or S20 or S21 (991,006)
S23 S16 or S22 (1,051,168)
S24 S9 AND S23 (201)
S25 EM 2009 OR EM 2010 OR EM 2011 OR EM 2012 (1,402,888)
S26 S24 AND S25 (29)

Appendix 2. Results of previous search (to Nov/Dec 2009)

Our search identified the following number of records: MEDLINE (108); MEDLINE in Process (18); EMBASE (103); *The Cochrane Library* (CENTRAL) (56). We identified two new studies for inclusion (Kiel 2007; Koike 2009). Seven studies published since the previous update (Bentzen 2008; Colon-Emeric 2007; Cox 2008; Cryer 2006; Garfinkel 2008; Hayes 2008; Huang 2006) were identified but excluded (*see* the Characteristics of excluded studies).

F E E D B A C K

Update?

Summary

1. When will this review be updated? (comment submitted 24/01/2003)
2. Will future versions include a cost-benefit analysis?

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Reply

1. We are currently working on an update which should be published in *The Cochrane Library* Issue 3, 2003.
2. These will be included when trials with valid economic analyses are published.

Contributors

Comment from Dr David Gibson (Geriatrician) (24/01/2003)
Response by MJ Parker, WJ Gillespie, LD Gillespie (12/03/2003)

Methodological aspects 1

Summary

Comment from Gabriele Meyer (Research Fellow) and Ingrid Mulhauser (Professor) (29/09/2003)

1. Observation on objectives of the review.
2. Comment questioning pooling of data from Meyer 2003 with other studies.
3. Comment on quality assessment scores for Meyer 2003 for items 4 and 10.
4. Comment on compliance data reported in review.

Reply

1. Comment noted. Wording unchanged.
2. Comment noted. No change to the analysis, which was exploratory only.
3. Scores for items 4 and 10 changed to 1.
4. Compliance data used in the review was taken from Table 4 of Meyer 2003. No change made to data but explanatory sentence inserted stating that four participants in the intervention group sustained hip fractures that may have occurred while hip protectors were being worn.

Contributors

Comment by Gabriele Meyer (Research Fellow) and Ingrid Mulhauser (Professor) (29/09/2003)
Response by MJ Parker, WJ Gillespie and LD Gillespie (22/10/2003)

Methodological aspects 2

Summary

Comment from Gabriele Meyer and Ingrid Mulhauser received 01/09/2004

Suggest that the results from Meyer 2003 not be combined with other cluster randomised trials in the exploratory analysis as the other trials investigated only one component (provision of hip protectors) compared with no treatment, whereas Meyer 2003 investigated the effects of an intervention programme comprising education and the provision of hip protectors compared to optimised usual care.

Furthermore, we still want to emphasize that we did not report a compliance rate of 34%. The true compliance rate is not known, as it was not a topic of our investigation. The given figure is based on a worst case scenario estimate as explained in our letter to the BMJ. Therefore, we would like to suggest to use compliance rate during fall events as investigated and reported in our publication.

Reply

We thank Dr Meyer and Professor Mulhauser for their comments. We have changed the text as requested and now report the compliance rate during fall events. The figure of 34% previously reported was taken from Table 04 in Meyer 2003.

We believe that some degree of educational component to encourage compliance is a feature of many if not all trials in which hip protectors are provided. Were our review comparing a strong educational component with a weak educational component in improving compliance, Dr Meyer's study would be included in the strong educational component group. However, we are actually interested in the evidence overall for the effectiveness of provision of hip protectors to older people. In that context we find Dr Meyer's study to be well conducted and reported and entirely worthy of inclusion in our analysis.

Contributors

Comment by Gabriele Meyer (Research Fellow) and Ingrid Mulhauser (Professor) (01/09/2004)
Response by MJ Parker, WJ Gillespie, and LD Gillespie (19/05/2005)

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Methodological aspects 3, 25 August 2011

Summary

We have carefully read the updated version of the Cochrane review on "Hip protectors for preventing hip fractures in older people". We do not agree with some issues of the critical appraisal of our study (Meyer et al, BMJ 2003;326:76-8).

Allocation concealment has been judged as unclear. We refer the Cochrane reviewers to our article where the flow through the trial (Figure 1) outlines that residents were selected prior to random allocation of clusters. Cluster randomisation took place at the start of the study. Residents were not replaced during follow up (see discussion section of the article). Thus, the quality criterion has been fulfilled according to the reviewer's definition.

Concerning the quality criterion "incomplete outcome data addressed", we do not agree to judge nursing home residents who deceased during 18-month follow-up as losses to follow-up. The difference between the study groups in mean follow-up as a result of the different proportion of residents with early study termination was not statistically significant. We refer the reviewers to our Letter to the Editor (Meyer et al, BMJ 2003;326:930) where this issue has been explicitly discussed.

We kindly ask the reviewers to reconsider their quality assessment.

Some further concerns remain:

The hypothesis on the causal relationship between pelvic fractures and hip protectors is not clear. Why do the Cochrane reviewers investigate pelvic fractures as separate outcome? Which effect of the hip protector do they assume?

We wonder why blinding of outcome assessors towards falls has been defined as similarly relevant quality criterion as blinding of hip fractures. Falls are always secondary outcomes in hip protector trials, although – without doubt – important for study group comparison purposes.

It is unsatisfactory and decreases transparency of reporting that fall event rates and/or number of persons with at least one fall are not mentioned in the figures and only rate ratios are displayed. This is also the case with all other comparisons, except for the primary outcome hip fracture.

Reply

We thank Dr Meyer for her comments. The introduction of Risk of Bias assessment in Cochrane Reviews has been difficult for many reviewers, who are asked not only to make judgments on the basis of reports, but to provide text quotations to justify their assessments. In the presence of any doubt, Cochrane Review authors have sometimes preferred assignment of 'Unclear risk' of bias, since in the absence of unequivocal evidence of low risk it avoids the risk of assigning 'High risk' of bias in a study which seems overall to have been conducted with care and attention to detail. And of course, "risk of bias" does not mean "evidence of bias".

Allocation concealment

Under 'Participants and methods' in Meyer 2003, we found "*A cluster was defined as a nursing home by itself or an independently working ward of a large nursing home. Recruitment took place from March to November 1999. In each cluster a study coordinator was nominated. The nursing staff selected 15 to 30 residents according to predefined inclusion criteria: >70 years old, not bedridden, and living in the nursing home for more than three months".*

Although the flow chart (Figure 1 of Meyer 2003) makes it clear that an initial group of 942 participants in 49 clusters in 42 nursing homes were recruited prior to randomisation of clusters, it would have been possible, after June 1999, for a "replacement" to have been found.

Under 'Discussion' we found *"To avoid violation of randomisation and selection bias we did not exclude participants who declined to use the hip protector. In contrast, Kannus et al excluded 31% of participants who were assigned to the hip protector group but who declined to participate after randomisation, and people who dropped out were replaced from a "waiting list".*"

We were unable from the published text to be sure that replacement from amongst new admissions did not occur, and are happy to have Dr Meyer's assurance that no residents were recruited after clusters were randomised. We have changed the assessment of risk of bias to 'Low risk'.

Incomplete outcome data addressed

The correspondence to which Dr Meyer refers had escaped our attention. The letter from Torgerson and Porthouse (BMJ 2003; 326:930-1) was, we think, fair comment based on the originally published data, but the response from Dr Meyer and colleagues provided hazard ratios which indicate that bias was indeed unlikely. We have added this correspondence to the references (Torgerson 2003) and changed the risk of bias for that item to 'Low risk'.

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Causal relationship between pelvic fractures and hip protectors

Some AO type B pelvic ring fractures are believed to be caused by lateral compression, and it is not inconceivable that they might occur in a fall from standing height onto the greater trochanter, and be mitigated by hip protectors. Nine of the studies included in the review reported pelvic fractures and so we included their data.

Blinding of fall assessors

In Meyer 2003, attention is drawn to falls in an analysis which although secondary is relevant - *"After adjustment for the cluster randomisation the proportions of fallers who used a hip protector were 68% and 15% respectively (mean difference 53%, 38% to 67%, P = 0.0001)."*

Risk of ascertainment bias may differ between falling and fracture outcomes, particularly in studies conducted in the community. For fractures, the standard for low risk of bias is radiological confirmation. In studies conducted in institutional situations, as in Meyer 2003, reporting of falls is likely to have been by staff aware of group allocation, and risk of bias is certainly possible. We note once more that "risk of bias" does not mean "evidence of bias".

Rate ratios but not raw data for event rates in Generic Inverse Variance (GIV) Analyses

In our review the raw data for hip fractures in institutional studies are provided in Table 2. Interestingly, Dr Meyer refers to fall event rates in particular despite their being, as she puts it, "always secondary outcomes in hip protector studies". Where data on falls have been analysed by GIV, we used the information reported in each individual included study. If Dr Meyer can provide us with the confidence intervals of the cluster-adjusted hazard ratio mentioned in her reply to the letter of Torgerson and Porthouse (Torgerson 2003), we can ensure that our analysis correctly reflects hers in the next update of this review.

Contributors

Comment by Gabriele Meyer (Professor for Clinical Nursing Research) (25.08.11)
Response by WJ Gillespie, MJ Parker and LD Gillespie (23.09.11)

WHAT'S NEW

Date	Event	Description
1 February 2014	New citation required and conclusions have changed	1. There has been a change in authorship. 2. The conclusions have changed with the possibility raised of a slight increase in the risk of pelvic fractures. There was a change to the framework for generating conclusions, with an assessment of the quality of the evidence using GRADE and interpretation of the results in terms of absolute effects.
1 February 2014	New search has been performed	1. The search was updated to December 2012. 2. Three new trials were added to the results. One trial was added to 'Studies awaiting assessment'. 3. Risk of bias assessment was updated to include the revised blinding domain and selective reporting. All trials were assessed. 4. The quality of evidence was assessed using GRADE and a 'Summary of findings' table was added.

HISTORY

Protocol first published: Issue 4, 1998
Review first published: Issue 3, 1999

Date	Event	Description
23 September 2011	Feedback has been incorporated	Feedback incorporated involving changes to the risk of bias assessments for one trial upon receipt of new information.
21 August 2010	New search has been performed	Sixth update: Issue 10, 2010

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Date	Event	Description
		1. Converted to new review format, requiring changes to text throughout. 2. The search was updated to December 2009 and two new studies included (Kiel 2007; Koike 2009). 3. Seven studies (Bentzen 2008; Colon-Emeric 2007; Cox 2008; Cryer 2006; Garfinkel 2008; Hayes 2008; Huang 2006) were identified but excluded. 4. Risk of bias assessment replaces previous methodological quality assessment. 5. Correction of data entry error in previous Analysis 1.1. 6. New analyses 1.5 (Pelvic and other fractures) and 1.6 (Falls per person year). 7. Updated 'Background', 'Discussion' and 'Authors' conclusions'.
20 August 2010	New citation required and conclusions have changed	1. There have been changes to the conclusions. 2. There was a change in authorship.
19 May 2005	New citation required and conclusions have changed	Fifth update: Issue 3, 2005 1. The title was changed from "Hip protectors for preventing hip fractures in the elderly". 2. Update of search to January 2005. 3. Changes were made to Item 1 (allocation concealment) in the methodological assessment and former Items 6 (outcome assessor blinding) and 7 (timing of outcome measurement) were deleted and scores adjusted accordingly. 4. One new trial (O'Halloran 2004) included. 5. Two ongoing trials identified (Cameron; Haynes). 6. Four studies (Forsen 2003; Haines 2004; Heikinheimo 2004; Maki-Jokela 2002) were excluded. 7. The conclusions of the review were changed following inclusion of the new included study, and the conduct of analyses using generic inverse variance. 8. Comment and response added to 'Comments and Criticisms'.
25 May 2004	New search has been performed	Fourth update: Issue 3, 2004 One new study, Birks 2004, included. Changes made to the conclusions of the review and synopsis.
28 May 2003	New search has been performed	Third update: Issue 3, 2003 Inclusion of six new studies (Birks 2003; Cameron 2001; Cameron 2003; Hubacher 2001; Meyer 2003; Van Schoor 2003). Substantive changes made to the conclusions of the review.
1 March 2001	New search has been performed	Second update: Issue 2, 2001 Update of trial search to January 2001. One new study, Kannus 2000, included. There were no significant changes to the conclusions of the review.
29 August 2000	New search has been performed	Review first updated: Issue 4, 2000 Synopsis added. Update of trial search to July 2000. One new study, Chan 2000, included. Relative risks instead of Peto odds ratios presented for dichotomous outcomes. There were no significant changes to the conclusions of the review.

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CONTRIBUTIONS OF AUTHORS

Martyn Parker (MP) initiated the review and wrote the first drafts of the review and subsequent updates until 2005. WJ Gillespie (WJG) and LD Gillespie (LDG) were authors of the previous update. Nancy Santesso edited this update with support from Alonso Carrasco-Labra and Romina Brignardello-Petersen, and all three screened studies, abstracted and recorded data, revised the risk of bias tables, and reviewed the final version of this update.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Peterborough and Stamford Hospitals NHS Foundation Trust, Peterborough, UK.
- University of Otago, Dunedin, New Zealand.
- Hull York Medical School, Universities of Hull and York, UK.

External sources

- Cochrane Bone, Joint and Muscle Trauma Group (funded by Department of Health) incentive payment, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The original protocol included mortality as a secondary outcome. This has been removed. Successive revisions of the *Cochrane Handbook for Systematic Reviews of Interventions* and Review Manager Software (RevMan) have introduced changes to the format, and have replaced assessment of methodological quality of included studies with assessment of risk of bias; which has been augmented in this version to include additional domains and criteria including the assessment of selective outcome reporting. GRADE assessment of the results of the review has also been conducted. A 'Summary of findings' table is newly included; this is based on the primary and important outcomes identified in earlier versions of the review. These revisions have also allowed use of rate ratios, where appropriate, for outcomes in which participants may experience more than one event during follow-up (other fractures and falls). Economic evaluations of the use of hip protectors were not included in the original protocol.

INDEX TERMS

Medical Subject Headings (MeSH)

*Orthotic Devices; *Protective Clothing; *Protective Devices; Hip Fractures [epidemiology] [*prevention & control]; Incidence; Patient Compliance; Randomized Controlled Trials as Topic

MeSH check words

Aged; Aged, 80 and over; Female; Humans; Male

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