

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

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[Intervention Review]

Hip protectors for preventing hip fractures in older people

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ABSTRACT

Background

Hip fracture in older people usually results from a fall on the hip. Hip protectors have been advocated as a means to reduce the risk of sustaining a hip fracture.

Objectives

To determine if external hip protectors reduce the incidence of hip fractures in older people following a fall.

Search strategy

We searched the Cochrane Bone, Joint and Muscle Trauma Group trials register (January 2005), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* Issue 1, 2005), MEDLINE (1966 to January Week 2, 2005), EMBASE (1988 to 2005 Week 02), CINAHL (1982 to December Week 2 2004), other databases and reference lists of relevant articles. We also contacted trialists.

Selection criteria

All randomised or quasi-randomised controlled trials comparing the use of hip protectors with a control group.

Data collection and analysis

Two authors independently assessed trial quality and extracted data. We sought additional information from trialists. Pooling of uncorrected data from cluster-randomised trials was only done on an exploratory basis.

Main results

Fifteen included trials contributed data to this updated review. One trial, which was a study of compliance (adherence) lasting 12 weeks, contributed no fracture outcome data.

Pooling of data from eleven trials conducted in nursing or residential care settings, including six cluster-randomised studies, showed evidence of a marginally statistically significant reduction in hip fracture incidence (relative risk (RR) 0.77, 95% confidence interval (CI) 0.62 to 0.97). This analysis showed significant statistical heterogeneity.

Pooling of data from three individually randomised trials involving 5135 community dwelling participants, showed no reduction in hip fracture incidence from the provision of hip protectors (RR 1.16, 95% CI 0.85 to 1.59).

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There was no evidence of any significant effect of hip protectors on incidence of pelvic or other fractures. No important adverse effects of the hip protectors were reported but compliance, particularly in the long term, was poor.

Authors' conclusions

Accumulating evidence casts some doubt on the effectiveness of the provision of hip protectors in reducing the incidence of hip in older people. Acceptance and adherence by users of the protectors remain poor due to discomfort and practicality.

PLAIN LANGUAGE SUMMARY

Hip protectors for preventing hip fractures in older people

Hip protectors, which consist of plastic shields or foam pads fitted in pockets within specially designed underwear, aim to reduce the impact of a fall on the hip, and thus the risk of a hip fracture. We found some evidence that in institutions with high rates of hip fracture, the use of hip protectors may help reduce the risk of hip fracture, but with new evidence the effect has become less certain. However, there was no evidence of any benefit from hip protectors for the majority of older people living in their own homes. Many people stop wearing hip protectors because they find them uncomfortable.

BACKGROUND

Hip fractures (which are fractures of the proximal femur: the upper part of the thigh bone) are fractures in the area of bone immediately distal to the articular cartilage of the hip to a level of about five centimetres below the lower border of the lesser trochanter. The majority of these fractures occur in an older population with an average age of around 80 years. Females predominate over males by about four to one (Thorngren K-G 2002). An estimated 1.7 million hip fractures occurred worldwide in the year 1990 (WHO 1994). The number of hip fracture patients 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 the fracture is also multi factorial 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-W 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.

The use of padding worn around the hip has been advocated as a measure of reducing the impact of the fall and thereby the chance of fracturing the hip. The rationale and development of such protectors has been summarised in Lauritzen 1977 and Lauritzen 1996. Various types of padded hip protectors have been developed. Most consist of plastic shields or foam pads, which are kept in place by pockets within specially designed underwear.

OBJECTIVES

To determine if the provision of hip pads or protectors worn about the hip reduce the risk of fracturing the hip in older people.

The following null hypothesis was tested:

There is no difference in the incidence of hip and other fractures between participants allocated to provision of hip protectors and those not allocated to wearing hip protectors (control).

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials comparing the incidence of hip fractures in those allocated to wearing hip protectors with the incidence in those not allocated to using protectors. Quasi-randomised trials (for example, alternation) were also considered for inclusion.

Types of participants

Older people of either gender living in the community or in institutional care.

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 provision of hip protectors was one amongst a number of interventions in a programme designed to reduce the incidence of hip fractures.

Types of outcome measures

- Incidence of hip fractures over the study period.
- Incidence of pubic rami and other pelvic fractures.
- Incidence of other fractures.
- Incidence of reported falls.
- Mortality.
- Acceptance and adherence (compliance) with wearing protectors.

- Reported complications of use of protectors (including skin damage/breakdown).
- Cost effectiveness of provision of hip protectors.

Search methods for identification of studies

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (January 2005), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* Issue 1, 2005), MEDLINE (1966 to January Week 2, 2005), MEDLINE pending (13/01/05), EMBASE (1988 to 2005 Week 02), CINAHL (1982 to December Week 2 2004), BioMed Central (<http://www.biomedcentral.com> accessed 13/01/05) and reference lists of relevant articles. Trialists were contacted, and ongoing trials identified in the National Research Register Issue 4, 2004 (<http://www.update-software.com/national/> accessed 13/01/05) and Current Controlled Trials (<http://controlled-trials.com/> accessed 13/01/05).

In MEDLINE (OVID WEB) the search strategy was combined with the first two levels of the optimal trial search strategy described in the Cochrane Handbook (Higgins 2005a) (see Appendix 1). This search strategy was modified for use in other databases (see Appendix 2).

Data collection and analysis

For each study, two review authors independently extracted data for the outcomes listed above and assessed methodological quality without masking of the study names. Differences were resolved by discussion.

The main assessment of methodology was the method of randomisation. In all, eight aspects of methodology were assessed (see Table 1).

Table 1. Quality assessment items and possible scores

Items	Scores
Item 1. Was there clear concealment of allocation, either of individual participants, or of clusters of individuals ?	Score 3 (and code A) if allocation clearly concealed (e.g. numbered sealed opaque envelopes drawn consecutively. This included cluster randomised trials in which allocation of clusters was clearly concealed, and no participants joined the cluster subsequently). Score 2 (and code B) if there was a possible chance of disclosure before allocation. (This included cluster randomised trials in which initial allocation was clearly concealed but in which recruitment into clusters continued or may have continued after the cluster allocation was known). Score 1 (and code B) if the method of allocation concealment or randomisation was not stated or was unclear. Score 0 (and code C) if allocation was clearly not concealed (for

Table 1. Quality assessment items and possible scores (Continued)

	example quasi-randomisation by even or odd date of birth
Item 2. Were the inclusion and exclusion criteria clearly defined?	Score 1 if text stated type of participants included and those excluded. Otherwise score 0.
Item 3. Were the outcomes of trial participants who withdrew or were excluded after allocation described and included in an intention-to-treat analysis?	Score 1 if yes or text states that no withdrawals occurred or data are presented clearly showing 'participant flow' which allows this to be inferred. Otherwise score 0.
Item 4. Were the treatment and control groups adequately described at entry and if so were the groups well matched, or appropriate co-variate adjustment made?	Score 1 if at least four admission details given (e.g. age, sex, mobility, function score, mental test score) with either no important difference between groups or appropriate adjustment made. Otherwise score 0.
Item 5. Were the care programmes other than the trial options similar?	Score 1 if it was stated or could be inferred that no variable other than the trial option was systematically different between the intervention and control groups. Otherwise score 0.
Item 6. Was loss to follow up reported and if so were less than 5% of participants lost to follow up?	Score 1 if yes. Otherwise score 0. Deaths during the study period were not included as loss to follow up.
Item 7. Was compliance with treatment monitored?	Score 1 if yes. Otherwise score 0.
Item 8. Was follow up active/scheduled as opposed to simple reporting of incidents as they occurred?	Score 1 if yes. Otherwise score 0.

For each study, relative risks (RR) and 95% confidence intervals (CI) were calculated for dichotomous outcomes. Pooling of data from individually randomised and from cluster-randomised studies for which the intra-cluster correlation coefficient (ICC) was known or could be calculated was conducted using generic inverse variance (Higgins 2005b). Heterogeneity between trials included in each analysis was tested using a standard chi squared test in conjunction with the I squared statistic (Higgins 2003). Where there was evidence of statistical heterogeneity this was explored by identifying any results with non-overlapping 95% confidence intervals, creating a subgroup analysis, and seeking to confirm any statistically significant difference between subgroups by comparing the ratio of the difference in the natural logarithm of the relative risks and the standard error of the difference in log relative risks to the standard normal distribution (test for interaction).

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Of the 27 studies identified, 10 (Becker 2003; Forsen 2003; Haines 2004; Heikinheimo 2004; Jensen 2002; Lauritzen 1996; Maki-Jokela 2002; Ross 1992; Wortberg 1998; Woo 2003) were excluded for reasons given in the 'Characteristics of excluded studies' table. Three ongoing trials (Cameron; Haynes; HIP PRO) are described in the 'Characteristics of ongoing studies' table. The prospect of another randomised trial, to be conducted after issues of participant acceptability and compliance were resolved, was alluded to in the report of a cohort study (Wallace 1993) but we have found no subsequent confirmation of this in the literature. The 15 included studies involved a total of over 15,000 elderly rest or nursing home residents or older adults living at home, although the exact number is unclear as one study (O'Halloran

2004) reported occupied beds in participating clusters rather than numbers of individuals. Three of the included studies involved people living in the community and the remainder involved people in institutional care. Four studies were based in the UK, three in Scandinavian countries and three in other European countries, three in Australia and one in Japan. The mean age of participants in the individual studies, where reported, ranged from 78 to 86 years. Further details of individual studies are given in the 'Characteristics of included studies' table. Villar 1998 was a pilot study, which focused primarily on compliance. The contact trialist for this pilot has confirmed that the study intended to follow on after this has not yet started.

In Meyer 2003 and O'Halloran 2004 the intervention was more complex. The provision of hip protectors was supplemented by providing support and information to encourage staff to promote their use. In Meyer 2003, the control group nursing homes received demonstration hip protectors but structured education of staff and participants was provided in the intervention group. Thus, an estimate of the effect of free provision of protectors and education could be compared with awareness alone in an environment where hip protectors were not available on health insurance. The intervention in O'Halloran 2004 was similar (*see* 'Characteristics of included studies' for further details). However, some degree of staff education is almost inevitable with the introduction of any new intervention and is also described in Van Schoor 2003. Protective hip pads placed in the region of the greater trochanter were used in all trials. Ordinary underwear with no special fixation for the hip pad was used in Ekman 1997. The hip pads were fixed or sewn into special underwear in the other 14 studies. All studies except two used an 'energy shunting' design. In Jantti 1996 'energy absorbing' safety pants were used. Chan 2000 used pads of local design which were also 'energy absorbing' (Cameron 2005).

Risk of bias in included studies

Nine studies were randomised by participant (Birks 2003; Birks 2004; Cameron 2001; Cameron 2003; Chan 2000; Hubacher 2001; Jantti 1996; Van Schoor 2003; Villar 1998). In Birks 2003 and Birks 2004, randomisation was carried out by a remote randomisation service accessed by telephone. Cameron 2001, Cameron 2003 and Jantti 1996 randomised the patients individually by sealed envelopes. Van Schoor 2003 used computer generated random numbers. Chan 2000 stated that the method of randomisation was by "taking draws literally", and the report of the study leaves some uncertainty about whether randomisation was rigorously conducted in all participating institutions. About half the participants in Hubacher 2001 were randomised by the head of the nursing home, the remainder were randomised by a computer. No details of the method of randomisation were provided by Villar 1998.

The remaining six studies were cluster randomised. The unit of randomisation in Lauritzen 1993 was the nursing home ward oc-

cupied by the participants. Ten out of 28 wards were selected to participate by an independent physician drawing the number of the ward. In Ekman 1997, residents of one of four nursing homes were offered the hip protectors with the other three homes acting as controls; there was scanty additional information. Kannus 2000 used an independent physician drawing sealed envelopes to randomise treatment units within 22 community based health care centres at the beginning of the study, but losses within treatment units during the study were replaced from a 'waiting list'. It seems unlikely that selection bias was avoided in this process, since the participants in the protector group differed from those in the control group in respect of a number of variables. In O'Halloran 2004 the outcome analysed was number of events per occupied bed, which introduces some uncertainty into the denominator for the intention to treat analysis. Harada 2001 used the even or odd digit of the patient's room number to allocate participants. The unit of randomisation in Meyer 2003 was a nursing home or independently working wards in large nursing homes. Forty nine clusters were randomised by phone from an external central location using computer generated lists. In Meyer 2003 and O'Halloran 2004, the reported analysis allowed for clustering. Information to allow calculation of cluster effect was available for all the remaining cluster-randomised studies in which the randomisation was by cluster, but the analysis in the primary report was by individual.

The quality assessment for the included studies were as listed below (*see* Table 1 for description of items).

1	2	3	4	5	6	7	8	Study
3	1	1	1	1	0	1	1	Birks 2003
3	1	1	1	1	0	1	1	Birks 2004
3	1	1	1	1	1	1	1	Cameron 2001
3	1	1	1	1	1	1	1	Cameron 2003
1	0	1	0	1	1	1	1	Chan 2000
1	1	1	0	0	1	1	0	Ekman 1997
0	1	1	1	1	1	1	1	Harada 2001
0	1	1	1	1	0	1	0	Hubacher 2001
2	1	1	1	1	0	1	0	Jantti 1996
2	1	1	0	1	1	1	1	Kannus 2000
0	1	1	0	0	1	1	0	Lauritzen 1993
3	1	1	1	1	1	1	1	Meyer 2003
2	1	1	1	1	1	1	1	O'Halloran 2004
3	1	1	1	1	1	1	1	Van Schoor 2003
1	1	1	0	1	1	1	1	Villar 1998

Effects of interventions

Villar 1998 studied compliance with wearing hip protectors in a study with a follow-up period of 12 weeks. As this study excluded mentally incapacitated patients, participants were at lower risk of hip fracture. No hip fractures occurred in either the 101 participants allocated to receive protectors or the 40 participants in the control group; thus, this study contributed no data to the meta-analysis.

Incidence of hip fractures

Results are presented in two graphs, the first using generic inverse variance to pool data from cluster-randomised and individually randomised trials conducted in institutions, and the second for community-based trials.

Incidence of hip fractures (institutional studies) (see Graph 01.01)

For studies which had been conducted in an institutional setting, data from five individually randomised studies (Cameron 2001; Chan 2000; Hubacher 2001; Jantti 1996; Van Schoor 2003) were pooled with six cluster-randomised studies for which intra-cluster correlation coefficients were reported or calculated (Ekman 1997; Harada 2001; Kannus 2000; Lauritzen 1993, Meyer 2003; O'Halloran 2004) using generic inverse variance (see Table 2 for the summary data used to generate the log RR and standard error required for the generic inverse variance calculations). The pooled data showed evidence of a marginally statistically significant reduction in incidence of hip fractures in the groups allocated to provision of hip protectors (RR 0.77, 95 %CI 0.62 to 0.97) (see Graph 01.01). There was evidence of some heterogeneity in the overall analysis ($P = < 0.10$, $I^2 = 39.9\%$) (Higgins 2005c).

Table 2. Institutional studies: summary data for Graph 01.01

Study ID	Randomisation method	Intervention n	Intervention N	Control n	Control N
Cameron 2001	Individually				
Chan 2000	Individual	3	40	6	31
Ekman 1997	Cluster	4	302	17	442
Harada 2001	Cluster	1	88	8	76
Hubacher 2001	Individual	7	384	2	164
Jantti 1996	Individual	1	36	5	36
Kannus 2000	Cluster	13	653	67	1148
Lauritzen 1993	Cluster	8	247	31	418
Meyer 2003	Cluster	21	459	42	483
O'Halloran 2004	Cluster	85	1366	163	2751
Van Schoor 2003	Individual	18	276	20	285

Table 2. Institutional studies: summary data for Graph 01.01 (Continued)

Footnote n: number of hip fractures N: number of participants					
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The statistically significant reduction in hip fracture was not apparent on pooling the individually randomised studies alone (RR 0.86, 95% CI 0.54 to 1.34). This subgroup showed no evidence of significant heterogeneity ($P = 0.68$, $I^2 = 1.6\%$). However, within the cluster-randomised subgroup, there was significant statistical heterogeneity ($P = 0.03$, $I^2 = 59.4\%$). We explored this heterogeneity by conducting sensitivity analyses, and found it to be accounted for by the different outcomes of two large studies (Kannus 2000; O'Halloran 2004), whose 95% confidence intervals did not overlap. The test for interaction described in the 'Methods' showed that the results from Kannus 2000 were statistically significantly different from the rest of the cluster-randomised trials ($P = 0.03$), as were the results from O'Halloran 2004 ($P = 0.001$). If Kannus 2000 was removed from the subgroup of cluster-randomised trials, neither the overall analysis (RR 0.85, 95% CI 0.67 to 1.07, graph not shown) nor the cluster-subgroup analysis (RR 0.84, 95% CI 0.84 to 1.11, graph not shown) provided evidence of significant effectiveness. If, on the other hand, O'Halloran 2004 was removed from the analysis, both the overall analysis (RR 0.60, 95% CI 0.44 to 0.81, graph not shown) and the evidence from the cluster subgroup (RR 0.44, 95% CI 0.29 to 0.67, graph not shown) support a unequivocally significant effect of hip protectors in reducing the incidence of hip fractures. Thus, uncertainty remains on the effectiveness of hip protectors for preventing hip fracture in institutional settings.

Incidence of hip fractures (community studies) (see Graph 01.02)

Three individually randomised studies recruited community dwelling older people (Birks 2003; Birks 2004; Cameron 2003). These studies found no significant reduction in the occurrence of hip fractures between groups (66/1872 (3.5%) versus 90/3263 (2.8%), RR 1.16, 95% CI 0.85 to 1.59). The results of these studies were homogeneous.

Incidence of pubic ramus and other pelvic fractures

Data on the incidence of pubic ramus and other pelvic fracture were available in twelve studies. Pooled data from the seven studies that used individual randomisation showed no statistically signif-

icant protective effect for these fractures (21/2654 (0.8%) in the protector group versus 28/3836 (0.7%) in the control group: RR 0.96, 95% CI 0.54 to 1.69).

Incidence of other fractures/injuries

The use of hip protectors appears to have no effect on the incidence of other fall associated fractures. Data on the incidence of other fractures that occurred over the study periods were reported in 11 studies. Pooling of results from the seven individually randomised studies showed that 142/2654 (5.4%) occurred in the protector group and 262/3836 (6.8%) in the control group (RR 0.85, 95% CI 0.70 to 1.05).

Incidence of falls or fallers

It is unclear whether the use of hip protectors has any impact on the frequency of falls amongst those randomised to their use. Birks 2004 reported a significant reduction in the number of people who had fallen in the intervention group by one year ($P < 0.001$). The mean number of falls per person was also decreased (0.50 versus 0.85 at 24 months, P value < 0.001). Fear of falling was reported to be lower in those allocated to the hip protector group. Ten studies reported a similar proportion of falls in the protector and control group. Cameron 2001 reported 365 falls in the 80 individuals in the protector group versus 384 in the 86 individuals in the control group. Cameron 2003 reported 798 falls in the 302 individuals in the protector group versus 639 in the 298 individuals in the control group. Ekman 1997 reported 294 for 302 individuals in the protector group versus 531 for 442 individuals in the control group. Jantti 1996 noted 197 falls for 36 individuals in the intervention group versus 158 for 36 individuals in the control group. Lauritzen 1993 reported on a subgroup of 116 residents with 45 falls for 45 individuals in the intervention group versus 90 for 71 individuals in the control group. Harada 2001 reported 131 falls (or 1.37 falls per person) for those allocated to protectors against 90 falls (1.09 per person) in the control group. Chan 2000 reported 191 falls in the 40 allocated to protectors against 101 falls in the 31 controls. Hubacher 2001 reported a fall rate of 1.16 per

person per year in the protector group versus 1.21 in the control group, and Meyer 2003 reported no significant difference in the proportion of fallers (mean difference between groups -0.06, 95% CI -0.16 to 0.05) or in the number of falls per resident in each group (mean difference -0.80, 95% CI -1.85 to 0.24). Van Schoor 2003 reported 727 falls in the 276 participants in the protector group against 1075 in the 285 participants in the control group. One hundred participants in the protector group had recurrent falls against 114 in the control group. O'Halloran 2004 reported on the occurrence of injurious falls (falls requiring medical attention); there was no difference between groups (adjusted rate ratio intervention versus control group 1.16, 95% CI 0.77 to 1.76; trial authors' analysis).

Villar 1998 reported a greater but not statistically significant number of individuals suffering falls on the hip in those allocated to hip protectors (8/101 versus 1/40; RR 3.17, 95% CI 0.41 to 24.52). Kannus 2000 only reported on falls in the protector group with 1404 falls occurring in the 653 individuals.

Mortality

There was no evidence that the use of hip protectors had any effect on mortality. Janti 1996 reported that, at one-year follow up, the mortality (6/36 versus 8/36) and incidence of permanent hospitalisation (10/36 versus 9/36) were similar in the two groups. Meyer 2003 reported 157/459 deaths during the study in the protector group against 183/483 in the control group. Results for the five individually randomised studies were 267/2088 (12.8%) versus 408/3488 (11.7%); RR 0.95, 95% CI 0.82 to 1.09

Acceptance and adherence (also termed compliance)

Amongst those who were assigned to their use, compliance with wearing of hip protectors was limited. Despite special efforts by some research groups (Meyer 2003; O'Halloran 2004) to improve acceptance and adherence by staff and participant education, acceptance and adherence remain low.

Birks 2003 gave an overall compliance figure of 34%. In Birks 2004, 17,222 individuals were identified who met the inclusion criteria (aged 70 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 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. 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 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. Janti 1996 stated that, of the 19 participants available at one year, 13 (68%) were still using hip protectors. In Kannus 2000, 31% of those 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% ($\pm 29\%$, range <1 to 100%). Of the subgroup of 45 individuals allocated to hip protectors monitored in Lauritzen 1993, only 11 (24%) wore the protectors regularly. Meyer 2003 recorded 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 'Comments and Criticisms'*). 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 39% were not compliant with wearing the protectors. This figure had risen to 55% at six months and 63% at one year. In Villar 1998, of the 288 individuals approached only 141 consented to participate. Of the 101 who received the protectors only 27 (27%) wore them throughout the 12-week study period. In a breakdown of the reasons for non-compliance presented by Villar 1998, discomfort and poor fit were the most common reasons for discontinued use.

Chan 2000, Ekman 1997, Harada 2001 and Lauritzen 1993 all stated that no hip fractures occurred in those who fell while wearing the protectors. Three studies reported that one hip fracture occurred while protectors were being worn (Cameron 2001; Birks 2004; Janti 1996). In Cameron 2001 the protector was not properly applied, in Birks 2004 the person fell backwards, and in Janti 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 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. O'Halloran 2004 stated that 13% of fractures in residents of intervention homes occurred while protectors were being worn.

Complications (including skin damage/breakdown)

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%). 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 with 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 the protector caused swelling of the legs and another that it caused bowel irritation. 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. Villar 1998 reported three individuals who were unable to tolerate the special undergarments during a heat wave and also mentioned discomfort as the prime reason for non-compliance.

Cost-effectiveness analysis

Only one study (Van Schoor 2003) included an economic evaluation and this demonstrated that use of hip protectors was not associated with lower costs (Van Schoor 2004). In one excluded trial (Becker 2003), incontinent residents required five hip pads each, rather than the three initially thought to be sufficient (Becker 2000). Van Schoor 2003 allocated four pads each and five to those with incontinence as there were no facilities for washing protectors at weekends.

DISCUSSION

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. This significant protective effect has not been confirmed by data from individually randomised studies. However, inclusion in a pooled analysis of data from both individually randomised and cluster-randomised studies in institutional settings, using generic inverse variance after appropriate adjustment for clustering, showed a marginally significant effect of hip protectors in reducing the incidence of hip fracture amongst participants in nursing homes and in residential care.

This finding is highly sensitive to the heterogeneity between two large cluster-randomised studies which between them contributed over 60% of all participants in our analysis. The results of Kannus 2000 show a statistically significant protective effect but there is evidence of selection bias in the data presented in the primary report (which might not however, have favoured the intervention). O'Halloran 2004, on the other hand, reported no evidence of a protective effect. In O'Halloran 2004 the denominator for the

analysis was number of occupied beds rather than number of individual participants. These design issues may contribute to the heterogeneity. Whether they do or not, some uncertainty now surrounds the effectiveness of hip protectors in institutionalised older people.

There are a number of possible reasons why early studies of the effectiveness of hip protectors may have been somewhat misleading. First, there may have been publication bias, resulting in studies which showed no effect failing to achieve publication. We found no evidence of that, but it is possible nonetheless. Second, although cluster-randomised studies often appear to be easier to design and conduct this is not necessarily the case. Greater care is needed, compared with individually randomised trials, in their design and conduct to avoid post randomisation biases occurring. Differences apparent in the frequency of falls and fractures might be confounded through systematic differences in other aspects of care between individual nursing homes or wards. In addition, there is a risk of selection bias 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. In Kannus 2000 the participants in the protector group, although on average one year younger (81 versus 82 years, $P = 0.006$), had a significantly higher incidence of a number of risk factors for falling or fracture.

In four of the six included cluster-randomised studies, although allocation was by institution, analysis in the primary reports was by individual without allowing for the effect of clustering. Since this leads to an estimate of the treatment effect in which the confidence intervals are inappropriately narrow, there is a risk that a statistically significant effect appears to exist, when in fact it may not. This error was apparent in the reports of the four studies which were particularly influential in encouraging the wider introduction of hip protectors (Ekman 1997; Harada 2001; Kannus 2000; Lauritzen 1993). Two more recent cluster-randomised studies (Meyer 2003, O'Halloran 2004) reported appropriate analyses. For Kannus 2000, the authors correctly pointed out that as the clusters in their study were small the effect on the analysis would be expected also to be small. However, there is now some empirical evidence (Warnke 2004) that even where clusters are relatively small, cluster-related associations may be found.

Also, there is evidence of heterogeneity amongst the populations studied in respect of their baseline risk of fracture. Many of the trials included in this review targeted people at particularly high risk of hip fracture. Lauritzen 1993 reported that the annual incidence of hip fractures in Denmark during the 1989 study period was 18 per 1000 for the general population aged 70 years or over; in the group studied, however, the incidence was 81 per 1000 (95% CI 55 to 108). Table 3 shows the annual incidence of hip fracture per 1000 participants (with 95% confidence intervals) within the

control groups of the included trials.

Table 3. Incidence of hip fractures per year per 1000 control group participants

Study ID	Incidence (95% CI)	Setting	Country	Appear effective	Cluster
Chan 2000	258 (88 to 427)	Institutional	Australia	Yes	No
Jantti 1996	139 (33 to 245)	Institutional	Finland	Yes	No
Harada 2001	102 (39 to 166)	Institutional	Japan	Yes	Yes
Lauritzen 1993	81 (55 to 108)	Institutional	Denmark	Yes	Yes
Meyer 2003	75 (54 to 97)	Institutional	Germany	Yes	Yes
Cameron 2001	53 (17 to 89)	Institutional	Australia	No	No
Van Schoor 2003	52 (33 to 78)	Institutional	Holland	No	No
Kannus 2000	46 (36 to 57)	Institutional & home	Finland	Yes	Yes
O'Halloran 2004	43 (36 to 50)	Institutional	United Kingdom	No	Yes
Ekman 1997	42 (23 to 62)	Institutional	Sweden	Yes	Yes
Cameron 2003	37 (24 to 55)	Home	Australia	No	No
Hubacher 2001	15 (0 to 36)	Institutional	Switzerland	No	No
Birks 2004	10 (8 to 13)	Home	United Kingdom	No	No
Birks 2003	9 (0 to 21)	Home	United Kingdom	No	No

If the size of the effect of hip protectors varies with baseline risk (for which age, and possibly residence are convenient surrogates), it might be expected that community based studies planned using data from institutional studies would be underpowered. In fact most of the early individually randomised studies do appear to have been underpowered. Even [Birks 2004](#), a very large community based study, reported that the power of their study was reduced as a result of a lower than expected incidence of hip fractures, despite extending the follow-up period by an extra 12 months.

The comparison groups were those 'allocated to wearing' hip pro-

tectors and those 'not allocated to wearing hip protectors. In practice, the use of protectors appears to have varied between trials and within trials. Older people helped to dress in institutional care may have had little choice in the matter. Those more independent or assertive may have followed their own inclination more readily. Hip protectors offer a very visible reminder to their wearers and their carers about falls in older people and their consequences. It may be that some of the reduction in the incidence of hip fractures can be attributed to changes in behaviour or care patterns of both participants and carers, rather than to the protectors themselves.

Initial acceptance of, and later compliance with, wearing the hip protectors were reported as problems in all of the studies. Problems were sometimes related to difficulty in putting the undergarments on for patients who were mainly bedridden, confused or infirm. Villar 1998 reported that the garments were difficult to fit and uncomfortable; forgetfulness accounted for 4% of non-compliance. Hubacher 2001 reported that the reasons for poor compliance were that protectors were considered unattractive and uncomfortable. Chan 2000 defined compliance as “the percentage of falls recorded for which hip protectors were worn in the treatment group” and reported dementia as a reason for non-compliance. In this study, residents’ explanations for not using protectors centred on a perceived lack of personal risk, even in participants with a previous hip fracture. Several studies indicated that the undergarments could cause skin irritation (Cameron 2001; Cameron 2003; Ekman 1997; Meyer 2003; Kannus 2000). In a systematic review of the literature reporting on the acceptance of, and compliance with, use of hip protectors Van Schoor 2002 reported that acceptance ranged from 37% to 72% (median 68%) and compliance varied between 20% and 92% (median 56%). Different definitions of these concepts have been used making comparisons difficult. Standardised definitions for adherence with the use of hip protectors have now been proposed (Kurrle 2004a).

Whatever the reasons for non-compliance, it presents both practical challenges in the health care workplace, and problems in analysis and interpretation of data. It may be possible in future to design devices that are highly acceptable to users and carers. In principle, it should be possible to refine clinical risk assessment to identify individuals most at risk of fracture and least susceptible to abandoning the use of protective devices. More evidence about behaviours and specific predictors that determine compliance are emerging (Kurrle 2004b).

The studies included in this review involved a number of different designs of hip protector. We note that the production of hip protectors has been largely unregulated. It is not possible to be sure that the different types of hip protector used had equal effectiveness for preventing fractures. In addition, the compliance may vary for the different types of hip protector. Trials currently in progress are examining both effectiveness in a range of institutional and community settings, and ways of improving acceptance and adherence. Their results may contribute to resolution of the current uncertainty. Further new studies on hip protectors might be indicated if changes to the design of the hip protectors improve acceptance and adherence. Such studies should have realistic calculations of study power.

Since the previous update of this review, another systematic review on this topic has been published (Sawka 2005). These investigators agreed with our earlier analyses and conclusions on the ineffectiveness of hip protectors in community-dwelling individuals. Although their inclusion criteria were somewhat stricter than ours, they also concluded that hip protectors were effective in older peo-

ple 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.

AUTHORS’ CONCLUSIONS

Implications for practice

- The evidence in support of the effectiveness of hip protectors has become weaker as new data have accumulated in the last few years.
- Pooled data from individually-randomised studies and appropriately analysed cluster-randomised studies of hip protectors indicate a marginally significant effectiveness of hip protectors in frail older people in institutional care.
- Provision of hip protectors does not reduce the incidence of hip fractures in older people who remain ambulant in the community.
- The only reported adverse effects of hip protectors are skin irritation, abrasion and local discomfort.
- Adherence/compliance with wearing hip protectors remains a problem.

Implications for research

- Future studies on the effectiveness of provision of hip protectors might be indicated if changes to their design improve acceptance and adherence. Any such studies should have realistic calculations of study power and take into account the likely incidence of hip fracture within the sampling frame, and the probable rates of acceptance and adherence/compliance with wearing protectors in the treatment group. Sample size calculations should allow for clustering in trials of that design.
- Future reports of trials examining the effectiveness of hip protectors should conform to the CONSORT standards for both individually (Moher 2001) and cluster-randomised studies (Campbell 2004).
- Adoption, after debate and modification if necessary, of the suggested definitions for adherence with use of hip protectors (Kurrle 2004a) should be considered in order to aid understanding of the factors which predict compliance.
- Comparisons with alternative fracture prevention strategies in high-risk groups should be encouraged.

- The development of national and international testing procedures for all forms of hip protectors should be encouraged.

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Wallace RB, Ross JE, Huston JC, Kundel C, Woodworth G. Iowa FICSIT trial: the feasibility of elderly wearing a hip joint protective garment to reduce hip fractures. *Journal of the American Geriatrics Society* 1993;**41**(3):338–40.
- Warnke 2004**
Warnke A, Meyer G, Bender R, Muhlhauser I. Predictors of adherence to the use of hip protectors in nursing home residents. *Journal of the American Geriatrics Society* 2004;**52**:340–5.
- WHO 1994**
WHO study group. Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. WHO; 1994 WHO technical report series no. 843.

* 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 or not (control group). Hip protectors from Robinson Healthcare Ltd which are equivalent to those of Safehip, Denmark.	
Outcomes	Length of follow up: mean 14 months (range 6 - 41 months). Number of hip fractures. Number of other fractures. Compliance with wearing the protectors. Adverse effects of the protectors.	
Notes	Unpublished information made available from authors	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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.	

Birks 2004 (Continued)

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.	
Notes	Additional information made available from authors	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Cameron 2001

Methods	Individual randomisation by numbered sealed opaque envelopes.	
Participants	174 living in residential care facilities in Sydney, Australia. Mean age: 85.6/84.0 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. 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, PO Box 6, Ryde NSW 1680, Australia, e-mail ianc@pub.health.usyd.edu.ac	

Risk of bias

Cameron 2001 (Continued)

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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). 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, PO Box 6, Ryde NSW 1680, Australia, e-mail ianc@pub.health.usyd.edu.ac

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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.

Chan 2000 (Continued)

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.	
Notes	Additional information supplied by authors via e-mail	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Harada 2001

Methods	Cluster randomisation by the room or ward number (personal communication).
Participants	164 residents of a nursing home in Japan. Mean age: 83.2 years. All female.
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.
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

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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. 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.

Hubacher 2001 (Continued)

Notes	Additional information supplied by trialists.	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Jantti 1996

Methods	Individual randomisation by the opening of sealed envelopes for each person in the study.	
Participants	72 residents of a municipal old peoples home in Tampere, Finland. Mean age: groups 85.5/84 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.	
Notes	By the end of the one year observation period, 33 participants had been lost through death or permanent hospitalisation.	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Kannus 2000

Methods	Cluster randomised. Treatment units (number not reported) within 22 community based health care 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: 81/82 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;	

Kannus 2000 (Continued)

	<p>impaired vision; poor nutrition; or a disease or medication known to predispose people to falls and hip fractures).</p> <p>The participants in the protector group were on average one year younger (81 versus 82 years, $P = 0.006$), of lower weight (63.1 kg versus 65.5 kg, $P < 0.001$), lower body mass index (24.3 versus 25.1, $P < 0.001$), 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 were more likely to have a history of previous falls ($P < 0.001$).</p>
Interventions	<p>Allocation to wear hip protectors (intervention group) or not (control group).</p> <p>Type of protector was KPH Hip Protector, Respecta, Helsinki. Hip protectors were fixed in pockets in special underwear</p>
Outcomes	<p>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.</p> <p>Number of hip fractures.</p> <p>Number of pelvic fractures.</p> <p>Number of other leg fractures.</p> <p>Number of other fractures.</p> <p>Falls.</p> <p>Compliance with wearing the protectors.</p> <p>Adverse effects of the protectors.</p>
Notes	<p>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).</p> <p>Additional information supplied by trialists</p>

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Lauritzen 1993

Methods	Cluster randomised. Participants in 10 out of 28 wards of a nursing home received protectors.
Participants	<p>665 residents of a nursing home in Copenhagen, Denmark.</p> <p>All aged over 69 years.</p> <p>Proportion male: 30%.</p>
Interventions	<p>Allocation to wear hip protectors or not (control group).</p> <p>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).</p>

Lauritzen 1993 (Continued)

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		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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 ten 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 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, 60-90 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.	

Meyer 2003 (Continued)

Notes		
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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 (cluster randomisation).	
Participants	127 residential and nursing homes in Northern Ireland, UK. Total of 4117 occupied beds. Mean age participants: 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.	
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		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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: 84.8/85.7 years. Proportion male: 11%. 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 of 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

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Villar 1998

Methods	Individual randomisation. Treatment/control ratio 2:1.
Participants	141 residents in 31 rest homes in Dorset, UK Age: range 64 - 98 years. All female. Exclusion criteria: dementia; communication problems; previous pressure sores; General Practitioner unwilling to involve participant; dress size 18 or above (no suitable undergarment available).
Interventions	Allocation to wear hip protectors or not (control). Hip protectors (Safehip, Denmark) made of an outer layer of polypropylene with an inner Plastazote lining were sewn into special underwear.

Villar 1998 (Continued)

Outcomes	Length of follow up: 12 weeks. Number of hip fractures. Number of falls on hip. Compliance with wearing the hip protectors.	
Notes	This was a feasibility study set up as a pilot for a randomised trial of hip protectors. The primary aim was to evaluate compliance and reasons for non-compliance.	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Characteristics of excluded studies [ordered by study ID]

Becker 2003	This was a 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.
Forsen 2003	This was a 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 patients.
Haines 2004	This was a 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.
Heikinheimo 2004	This was an observations study on the use of hip protectors. It was excluded as there was no randomisation of participants.

(Continued)

Jensen 2002	This was a 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 1996	This study was an 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	This was an observational study on the use of hip protectors. It was excluded as there was no randomisation of participants.
Ross 1992	This study was a report on 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.
Woo 2003	Described as a randomised controlled trial in Current Controlled Trials.com (listed under Hong Kong Health Services Research Fund's contact Professor Johnston). The published article indicated it was a non population based cohort study with 302 subjects wearing hip protectors and 352 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 was excluded as it was not a randomised control trial.
Wortberg 1998	This study involved 84 residents of five nursing homes in Ludenscheid, Germany. 47 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.

Characteristics of ongoing studies [ordered by study ID]

Cameron

Trial name or title	Improving adherence with hip protectors
Methods	
Participants	Substudy 1: Frail older people living in the community. Substudy 2: Older people living in residential aged care facilities. Substudy 3: Older people recruited from subacute hospital wards.
Interventions	Intervention 1: provision of hip protectors at no cost. Intervention 2: as for intervention 1, plus an individualised adherence strategy. Control group: provision of a brochure about hip protectors.

Cameron (Continued)

Outcomes	1. Adherence with use of hip protectors. 2. Falls, and fall injuries (including hip fractures).
Starting date	December 2004
Contact information	Ian Cameron Rehabilitation Studies Unit, University of Sydney Telephone: +61 2 9808 9236 Fax: +61 2 9809 9037
Notes	For substudy 1 there is individual randomisation while for substudy 2 and 3 there is cluster randomisation.

Haynes

Trial name or title	Using hip protectors with older inpatients: can the rate of hip fractures in hospital be reduced? A randomised controlled trial
Methods	
Participants	Older hospital inpatients
Interventions	Intervention: use of hip protectors. No further details available
Outcomes	Rate of hip fracture
Starting date	1 March 2002 Completion date: 01 December 2004
Contact information	Ms N Haynes King's College Hospital (Dulwich) East Dulwich Grove London SE22 8PT
Notes	

HIP PRO

Trial name or title	HIP PRO: a multicentre, randomized, controlled trial of hip protectors in nursing home (NH) residents
Methods	
Participants	Elderly (over 65 years) nursing home residents in Boston, Baltimore and St Louis (USA). Expected total enrolment: 546

HIP PRO (Continued)

Interventions	Intervention: external hip protectors containing only one pad. Subjects randomised to hip protector containing either a left or right pad. Also compliance enhancing strategy.
Outcomes	Main outcome measure: Hip fracture Secondary outcomes: factors influencing compliance
Starting date	Sept 2001 Expected completion: August 2006
Contact information	DP Kiel Hebrew Rehab Centre for the Aged Boston MA USA
Notes	Recruiting for 3.5 years to achieve 1500 resident-years of observation.

DATA AND ANALYSES

Comparison 1. Provision of hip protectors

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of hip fractures: institutional residence	11	9859	RR (Fixed, 95% CI)	0.77 [0.62, 0.97]
1.1 Individually randomised trials	5	1426	RR (Fixed, 95% CI)	0.86 [0.54, 1.34]
1.2 Cluster-randomised trials (adjusted)	6	8433	RR (Fixed, 95% CI)	0.75 [0.58, 0.97]
2 Incidence of hip fractures: community residence	3	5135	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.85, 1.59]
3 Incidence of pelvic fractures	7	6490	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.54, 1.69]
3.1 Individually randomised trials: institutional and community	7	6490	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.54, 1.69]
4 Incidence of other fractures	6	5942	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.69, 1.05]
4.1 Individually randomised trials: institutional and community	6	5942	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.69, 1.05]
5 Mortality	5	5576	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.82, 1.09]
5.1 Individually randomised trials: institutional and community	5	5576	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.82, 1.09]

FEEDBACK

Update?

Summary

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

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 (Prof) (29/09/2003)

See <http://www.update-software.com/comcritusers/for> full comment.

- 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

See <http://www.update-software.com/comcritusers/for> full response.

- 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 (Prof) (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

See <http://www.update-software.com/comcritusers/for> full comment.

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 Prof Mulhauser for their comments. We have changed the text as requested and now report the compliance rate during fall events. The figure of 34% percent 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).

WHAT'S NEW

Last assessed as up-to-date: 18 May 2005.

8 September 2008	Amended	Converted to new review format.
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HISTORY

Protocol first published: Issue 4, 1998

Review first published: Issue 3, 1999

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.

(Continued)

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.
21 May 1999	New citation required and conclusions have changed	In this review, we have used the term 'compliance' as it has been the term most frequently used in reports of included trials. In doing so, we imply no value judgment, and recognise the right of participants not to wear offered hip protectors. Other terms such as 'adherence' and 'acceptance' also have difficulties. 'Concordance' may become the accepted term in future.

CONTRIBUTIONS OF AUTHORS

Martyn Parker (MP) initiated the review and wrote the first drafts of the review and subsequent updates. All authors independently assessed trial quality and extracted data and later checked these results and contributed to the review text. All authors critically reviewed successive drafts of the review and updates. WJ Gillespie is the guarantor of this update of the review.

DECLARATIONS OF INTEREST

None known.

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INDEX TERMS

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MeSH check words

Aged; Female; Humans; Male