Appendix C: Principles of quality for main study designs - summary sheet

	Tick if 'yes'
Systematic reviews	
adequate search strategy	
inclusion criteria appropriate	
quality assessment of included studies undertaken	
characteristics and results of included studies appropriately summarised	
methods for pooling data	
sources of heterogeneity explored	
Randomised controlled trials	
study blinded, if possible	
method used to generate randomisation schedule adequate	
allocation to treatment groups concealed	
all randomised participants included in the analysis (intention to treat)	
Withdrawals/dropouts reasons given for each group	
Cohort studies	
all eligible subjects (free of disease/outcome of interested) selected or random sample	
$\geq$ 80% agreed to participate	
subjects free of outcomes on interest at study inception	
if groups used: comparable at baseline	
potential confounders controlled for	
measurement of outcomes unbiased (blinded to group)	
follow-up sufficient duration	
follow-up complete and exclusions accounted for ($\geq$80% included in final analysis)	
Case control studies	
eligible subjects diagnosed as cases over a defined period of time or defined catchment area or a random sample of such cases	
case and control definitions adequate and validated	
controls selected from same population as cases	
controls representative (individually matched)	
$\geq$ 80% agreed to participate	
exposure status ascertained objectively	
potential confounders controlled for	
measurement of exposure unbiased (blinded to group)	
groups comparable with respect to potential confounders?	
outcome status ascertained objectively	
$\geq$ 80% selected subjects included in analysis	
Cross-sectional/survey	
selected subjects are representative (all eligible or a random sample)	
$\geq$ 80% subjects agreed to participate	
exposure/outcome status ascertained standardized way	
Qualitative	
criteria for selecting sample clearly described	
methods of data collection adequately described	
analysis method used rigorous (i.e. conceptualised in terms of themes/typologies rather than loose collection of descriptive material)	
evidence of efforts to establish validity (truth value)?	

evidence of efforts to establish reliability (consistency)	
respondent validation (feedback of data/researcher's interpretation to participants)	
interpretations supported by data	
Studies of diagnosis	
independent/blind comparison with a reference ('gold') standard of diagnosis	
diagnostic test evaluated in an appropriate spectrum of patients (those in whom it would be used in practice) selected consecutively	
reference standard applied regardless of the diagnostic test result	
test and reference standards measured independently (blind to each other)	
test validated in a second, independent group of patients	
results of the diagnostic study important	
is the test available, affordable, accurate and precise?	
Risk factor studies	
eligible cohort of participants	
high participation at baseline and follow up > 70%	
risk factors conceptually relevant	
baseline measurement of risk factors	
reporting of methods, explicit inclusion criteria and demographic information	
adequate length of follow up > 6 months	
measurement of falls as outcome	
statistical methods detailed - adequate reporting for data extraction.	
methods of adjustment for confounding reported	

Full quality checklists and data extraction forms available on request from the National Collaborating Centre for Nursing and Supportive Care.

Interventions for prevention: quality assessment items and possible scores

Items and scores
Item A: Was the assigned treatment adequately concealed prior to allocation? 3= Method did not allow disclosure of assignment 2= Small but possible chance of disclosure of assignment 1= States random, but no description or quasi-randomised
Item B: Were the outcomes of patients who withdrew described and included in the analysis (intention to treat)? 3= Intention to treat analysis based on all cases randomised possible or carried out 2= States number and reasons for withdrawal but intention to treat analysis not possible 1= Inadequate detail
Item C: Were the outcome assessors blinded to treatment status? 3= Effective action taken to blind assessors 2= Small or moderate chance of unblinding of assessors 1= Not mentioned or not possible
Item D: Were the treatment and control group comparable at entry? 3= Good comparability of groups, or confounding adjusted for in analysis 2= Confounding small; mentioned but not adjusted for 1= Large potential for confounding, or not discussed
Item E: Were the subjects blind to assignment status after allocation? 3= Effective action taken to blind subjects 2= Small or moderate chance of unblinding of subjects 1= Not possible, or not mentioned (unless double-blind), or possible, but not done
Item F: Were the treatment providers blind to assignment status? 3= Effective action taken to blind treatment providers 2= Small or moderate chance of unblinding of treatment providers 1= Not possible, or not mentioned, or possible, but not done
Item G: Were care programmes, other than the trial options, identical? 3= Care programmes clearly identical 2= Clear but trivial differences 1= Not mentioned, or clear and important differences in care programmes
Item H: Were the inclusion and exclusion criteria clearly defined? 3= Clearly defined 2= Poorly defined 1= Not defined
Item J: Were the outcome measures used clearly defined? 3= Clearly defined 2= Poorly defined 1= Not defined
Item K: Was ascertainment of fall and other outcomes reliable? 3= Diary or active registration 2= Interval recall 1= Participant recall at end of study period
Item L: Was the duration of surveillance clinically appropriate? 3= 1 year or more (duration of stay for hospital studies) 2= Less than 1 year 1= Not defined

Hip protectors: quality appraisal

For each study, data for the outcomes listed above were independently extracted by two reviewers. Methodological quality of each trial was assessed by two reviewers independently, without masking of the study names. Differences were resolved by discussion. The main assessment of methodology was by the method of randomisation. A further nine aspects of methodology were assessed, giving a maximum score for each study of 12.

1. Was there clear concealment of allocation? Score 3 (and code A) if allocation clearly concealed (for example, numbered sealed opaque envelopes drawn consecutively). Score 2 (and code B) if there was a possible chance of disclosure before allocation. 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 example quasi-randomisation by even or odd date of birth, or where randomisation was clustered, but analysis was by individual participant)

2. Were the inclusion and exclusion criteria clearly defined? Score 1 if text stated type of participants included and those excluded. Otherwise score 0.

3. Were the outcomes of patients 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.

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 (for example, age, sex, mobility, function score, mental test score) with either no important difference between groups or appropriate adjustment made. Otherwise score 0.

5. Were the care programmes other than the trial options identical? Score 1 if text stated they were or this can be inferred. Otherwise score 0.

6. Were the outcome assessors blind to assignment status? Score 1 if assessors were blinded to study group. Otherwise score 0.

7. Was the timing of outcome measures appropriate? A minimum of 12 months follow-up for all surviving patients. Score 1 if yes. Otherwise score 0.

8. Was loss to follow-up reported and if so were less that 5 per cent of patients lost to follow-up? Score 1 if yes. Otherwise score 0. Deaths during the study period were not included as loss to follow-up.

9. Was compliance of treatment monitored? Score 1 if yes. Otherwise score 0.

10. Was follow-up active/scheduled as opposed to simple reporting of incidents as they occurred? Score 1 if yes. Otherwise score 0.