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## DOCTOR OF PHILOSOPHY

**A cluster randomised controlled trial to evaluate a policy to provide external hip protectors for residents of nursing and residential homes in Northern Ireland**

O'Halloran, Peter

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A cluster-randomised controlled trial  
to evaluate a policy to provide  
external hip protectors for residents  
of nursing and residential homes in  
Northern Ireland

Submitted for the degree of Doctor of Philosophy  
Faculty of Medicine and Health Sciences  
Queen's University Belfast

**Peter Dominic O'Halloran**  
**BSc (Hons) Professional Development in Nursing**  
**MSc Nursing**

**1<sup>st</sup> May 2003**

Now unto the King eternal, immortal, invisible,  
the only wise God,  
be honour and glory  
for ever and ever.  
Amen.

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Dr Tim Beringer, Consultant Geriatrician at the Royal Victoria Hospital, Belfast  
Mrs Hilary Brownlee, Inspector at the EHSSB Registration and Inspection Unit  
Professor George Kernohan, Professor of Nursing at the University of Ulster  
Mrs Louise Dunlop, Department of General Practitioner Audit at the EHSSB  
Mrs Heather Reid, Department of General Practitioner Audit at the EHSSB  
Dr Ciaran O'Neill, Reader in Health Economics and Policy at the University of Ulster  
Mrs Mary McCartney, Research Nurse at Queen's University  
Mr Frank O'Connor, Department of Finance at the EHSSB  
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# Chapter One

## Introduction

Every year increasing numbers of older people fall and break a hip. Hip fracture is painful, usually requires an operation, and can result in disability and an earlier death. It is also expensive for the health service and frequently leads to a loss of independence for the person suffering the fracture. Efforts to prevent hip fractures and other osteoporotic fractures target high-risk groups with lifestyle advice, interventions to reduce the risk of falls, and, where appropriate, drug treatments for osteoporosis (Royal College of Physicians, 1999).

Alongside these established approaches, wearing external hip protectors is increasingly advocated. Hip protectors are protective pads, usually fixed in specially made underwear, designed to sit over the greater trochanter and attenuate the force of a fall sufficiently to prevent a fracture. The high risk of hip fracture experienced by residents of nursing and residential homes, together with the difficulty in reducing the incidence of injurious falls in this population, means residents of these homes are often seen as suitable participants in research into the effectiveness of hip protectors. Early results from trials in nursing and residential homes have been promising, and hip protectors are now widely recommended in the health care literature and in national guidelines (Royal College of Physicians, 1999; National Osteoporosis Society, 2002). However, as with any new intervention, it is important to test the effectiveness of hip protectors in an everyday service environment. Hip protectors may be seen to work under ideal conditions but will they work under the normal circumstances encountered “in the field”?

The research described in this thesis was designed to answer this question for residents of nursing and residential homes in Northern Ireland, and to identify factors that influence the effectiveness of this intervention. Many of these factors will have relevance not only to the introduction and continued use of hip protectors but to the implementation of other interventions and practices.

This chapter will outline the incidence and consequences of hip fracture, identifying the main risk factors and corresponding efforts to reduce that risk, including the use of hip protectors. Finally, the aim of the study will be described.

## **1.1 Incidence of hip fracture**

Proximal femoral fractures, more generally termed “hip fractures”, can be subdivided into intracapsular fractures (those occurring proximal to the attachment of the hip joint capsule to the femur) and extracapsular (those occurring distal to the hip joint capsule) (Parker *et al*, 2000). The world-wide incidence of hip fracture in 1990 was estimated at 1.26 million (WHO 1994). This figure is predicted to double to 2.6 million by 2025, and rise to 4.5 million by the year 2050 (Gullberg *et al*, 1997). There are an estimated 57,000 hip fractures a year in England and Wales (Audit Commission, 1995), with a predicted increase of 70 to 90 percent in the United Kingdom by 2051 (Khaw, 1999). This prediction is based mainly on a projected increase in the numbers of people aged 65 and over during this period, and may well be a conservative figure in the light of evidence that the rate of hip fracture is increasing more rapidly than can be accounted for by demographic changes alone (Gillet and Reginster, 1999; Kannus *et al*, 1999a).

In Northern Ireland (population 1.7 million), the incidence of hip fracture appears to be increasing more quickly than in England and Wales. It rose by 47 percent, from 1,100 in 1985, to 1,623 in 1997, and is projected to rise by more than 70 percent, to 2,800, by 2016 (Beringer *et al*, 2000). However, it should be noted that all such projections are highly sensitive to small changes in incidence and so should be treated with caution (Martyn and Cooper, 1999).

## **1.2 Incidence and impact of hip fracture in residents of nursing and residential homes**

Typically, residents of nursing and residential homes have a greater number and intensity of risk factors for hip fracture than non-institutionalised older people. A greater proportion is female, and there is significant cognitive and physical disability (Melzer *et al*, 1999). Residents are also likely to have a relatively low bone mineral density, so that bones are more easily broken by the force of a fall (Chandler *et al*, 2000; Wallace, 2000). A history of falling is one of the main reasons for admission to a nursing or residential home (Tinetti and Williams, 1997). Once in the home, residents are approximately three times more likely to fall than older people living in private homes, averaging 1.5 falls per bed, per year (Rubenstein *et al*, 1994). Furthermore, it appears that the usual methods of reducing the risk of injurious falls may be ineffective in this group (Gillespie *et al*, 2001). Given all this, it is not surprising that residents have been estimated to be three to seven times more likely to suffer a hip fracture than non-institutionalised older people (Ooms *et al*, 1994; Slemenda, 1997; Norton *et al*, 1999).

## **1.3 Mortality, morbidity and suffering after hip fracture**

### **1.3.1 Mortality**

A recent audit of outcomes for 580 patients with hip fracture, admitted to eight hospitals in the East Anglian area of England, measured mortality at 90 days at 18 percent (Todd *et al*, 1995). Other studies have measured six-month mortality at 28 percent (Keene *et al*, 1993) and mortality at one year of between 12 and 37 percent (Lyons, 1997). In Northern Ireland, a recent audit of 959 patients admitted to the Royal Victoria Hospital in Belfast following hip fracture (Beringer *et al*, 2000) found that mortality was 6.2, 16.5, 19.5 and 29.5 percent at one, four, six and 12 months, respectively. All of these figures for mortality require careful interpretation, as most of the researchers have not recruited a control group. An American study which did include a control group (Wolinsky *et al*, 1997) showed a significant increase in the mortality of older people who suffered hip fracture, compared to those who did not, during the first six months following fracture, but not over the whole eight-year study period.

### **1.3.2 Morbidity**

One audit of the immediate postoperative period following surgery for hip fracture showed that six percent of patients suffered thromboembolism, seven percent had wound infections, nine percent developed pneumonia, 11 percent a urinary tract infection, and 22 percent developed pressure sores (Todd, *et al*, 1995). Older women greatly fear the loss of independence associated with hip fracture (Salkeld *et al*, 2000) and their fears are not groundless. Older people who suffer hip fracture are more likely than those in a control group to require subsequent hospital admission and to suffer limitations in activities of daily living (Wolinsky *et al*, 1997). One year later the majority of survivors are also likely to be less mobile than before the fracture,

and up to 40 percent will have been admitted to nursing or residential homes (Keene *et al*, 1993).

### **1.3.3 Suffering**

The immediate postoperative period can be characterised by severe pain, delirium, anxiety and lack of sleep (Bowman, 1997; Morrison and Siu, 2000). Pain can persist for several years (Lyons, 1997), and even women who return successfully to their own homes report continuing pain and fatigue, together with feelings of unwanted dependency, loss of control, impatience and fear of falling (Robinson, 1999).

## **1.4 Costs of hip fracture**

Every year there are an estimated 310,000 osteoporotic fractures in the UK, resulting in considerable suffering and disability for individuals, at an annual estimated cost to health and social services of £1.7 billion. Thirty-one percent of treated fractures are hip fractures, 31 percent are wrist fractures, and 10 percent are vertebral fractures, with 26 percent at other sites (National Osteoporosis Society, 2002). Hip fractures account for the greater part of the resources utilised, with the total cost of each hip fracture in the UK (estimated at £12,000 – £20,000) much higher than those of wrist, vertebral and other fractures (estimated at £468, £479 and £1338, respectively) (Dolan and Torgerson, 1998).

## **1.5 Causes of hip fracture**

### **1.5.1 Spontaneous hip fractures**

Very few hip fractures occur “spontaneously.” Spontaneous hip fractures have been defined as those where the patient reports that they did not fall prior to the fracture (Horiuchi *et al*, 1988; Nyberg *et al*, 1996; Norton *et al*, 1997) or those where the fracture was preceded by pain in the affected hip (Michelson *et al*, 1995; Parker and Twemlow, 1997). These five studies reported spontaneous hip fracture rates of between one and five percent, the remainder occurring as a result of a fall. Pooling the numbers in these studies provides a figure of 125 spontaneous hip fractures amongst the 3,524 hip fractures reported - a rate of 3.5 percent.

### **1.5.2 Hip fractures occurring as a result of a fall**

Of those hip fractures that are the consequence of a fall, the great majority occur as a result of the impact of a fall onto the greater trochanter (Hayes *et al*, 1993; Parkkari *et al*, 1999). Therefore, factors that are associated with an increased risk of hip fracture can be clustered as:

- factors that increase the risk of falling
- factors that reduce the strength of the bone
- factors that modify the impact of the fall on the bone

These are discussed in more detail below.

### **1.5.3 Factors that increase the risk of falling**

A fall can be defined as

“a sudden, unintentional change in position causing an individual to land at a lower level, on an object, the floor or the ground, other

than as a consequence of sudden onset of paralysis, epileptic seizure, or overwhelming force.” (Feder *et al*, 2000, P. 1007)

Upright movement in humans requires a complex and constantly changing integration of spatial awareness, balance, multiple sensory input, and accurate regulation of muscle tone and contraction. Consequently, many diseases and disabilities associated with ageing can lead to falls (Kroker, 1999). A number of factors have been associated with an increased risk of falling in older people. These include environmental hazards, some medications, impaired neuromuscular function, cognitive impairment, and reduced visual acuity (Effective Health Care, 1996; Slemenda, 1997).

The risk of falling increases with age, with about one third of the population aged 65 and over falling at least once a year. Between five and ten percent of falls result in injury, and the most common serious injuries are fractures, which account for 40 percent of deaths from injury and over half of injury admissions to hospital (Rubenstein *et al*, 1994; Effective Health Care, 1996). It would appear that the incidence of falls may well increase (Kannus *et al*, 1999a).

#### **1.5.4 Factors that reduce the strength of the bone**

The principle cause of reduced strength in bone is osteoporosis. This can be defined as, “a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture.” (NIH Consensus Development Panel on Osteoporosis, 2001, P. 787). Osteoporosis can be further categorised as either primary or secondary. Primary osteoporosis usually occurs in women after the menopause, and in men later in life, whilst secondary osteoporosis occurs as a result of medications or disease. Low bone mineral density is recognised as a diagnostic marker for osteoporosis. Predictors of low bone mineral density include female sex, increased age,

oestrogen deficiency, white race, low weight and body mass index, family history of osteoporosis, smoking, and previous fracture (Cooper, 1993; NIH Consensus Development Panel on Osteoporosis, 2001). Low bone mineral density is therefore associated with an increased risk of hip fracture (Cooper, 1993; Cummings *et al*, 1993; Slemenda, 1997) in both men and women – although men appear to reach similar levels of fragility about five years later than women (De Laet *et al*, 1997).

### **1.5.5 Factors that modify the impact of the fall on the bone**

Reduced body mass index is associated with an increased risk of hip fracture, perhaps because there is reduced soft tissue over the greater trochanter and therefore decreased absorption of the impact of the fall (Greenspan *et al*, 1994; Grisso *et al*, 1994; Cummings *et al*, 1995). However, this may also be due to an association between low body weight and low bone mineral density (Greenspan *et al*, 1998). The direction in which a person falls is also important, with falls to the side (in contrast to falls forward or onto the buttocks) increasing the risk of hip fracture (Greenspan *et al*, 1994, 1998; Slemenda, 1997).

## **1.6 Preventing hip fracture**

Measures taken to prevent hip fracture mirror the causes of hip fracture. These can be divided into measures that reduce the risk of falling, those that increase the strength of the bone, and those that reduce the impact of a fall upon the bone.

### 1.6.1 Reducing the risk of falling

Two recent reviews (Feder *et al*, 2000; Gillespie *et al*, 2001) identified a number of interventions that are likely to be successful in reducing the risk of falls. These are:

- a programme of muscle strengthening and balance retraining, individually prescribed at home by a trained health professional
- Tai Chi classes (including balance training) with individual tuition
- home hazard assessment and modification, that is professionally prescribed for older people with a history of falling
- withdrawal of psychotropic medication
- multidisciplinary, multifactorial, health and environmental risk factor screening and intervention programmes (Gillespie *et al*, 2001)
- individually tailored exercise programmes administered by qualified professionals targeted at those over 80 years of age
- multifactorial interventions, including correction of postural hypertension, rationalisation of drugs, and interventions to improve balance, transfers and gait
- structured, interdisciplinary intervention by doctors and occupational therapists with older people who present at the accident and emergency department with a fall
- risk assessment, and referral to their primary physician for specific preventive measures, of residents of nursing and residential homes with a history of a fall (Feder *et al*, 2000)

The common threads running through most of these interventions are that they are targeted at those at risk; they are structured, multidisciplinary, and multifactorial. Even those interventions that target single risk factors may have an unintended multifactorial component, possibly because they raise

general awareness of fall risks (Gillespie *et al*, 2001). Although these interventions have been shown to reduce the risk of falls, they have not yet been shown to produce a significant reduction in the risk of *injurious* falls, in either the community or in nursing and residential homes (Tinnetti *et al*, 1994; Ray *et al*, 1997; Gillespie *et al*, 2001).

### **1.6.2 Increasing the strength of the bone**

Bone accumulation is not complete until the third decade of life. It is influenced by genetic factors, nutrition, body weight, exposure to sex hormones at puberty, and physical activity (NIH Consensus Development Panel on Osteoporosis, 2001). Maintaining bone in later life can be achieved through adequate intake of calcium and vitamin D, high impact exercise, and hormone replacement therapy for women. Other medical treatments (such as bisophonates, selective oestrogen receptor modulators, and calcitonin) also show promising effects (Slemenda 1997; Levinson and Altkorn, 1998; NIH Consensus Development Panel on Osteoporosis, 2001) and are recommended as treatment choices by the Royal College of Physicians of the United Kingdom where there is a diagnosis of low bone mineral density (Royal College of Physicians, 1999).

### **1.6.3 Reducing the impact of a fall upon the hip – external hip protectors**

The great majority of the clinical studies of external hip protectors report a significant reduction in the rate of hip fracture when hip protectors are used (Lauritzen *et al*, 1993; Jantti *et al*, 1998; Hindso and Lauritzen, 2000; Chan *et al*, 2000; Kannus *et al*, 2000; Harada *et al*, 2001) and only Kannus *et al*, (2000) and Meyer *et al* (2003) report hip fractures when the hip protector was worn. The only adverse effects reported are skin irritation (Ekman *et al*, 1997; Kannus *et al*, 2000) and needing more help when using the toilet (Jantti *et al*,

1998). However, many of the studies suffer from low power, either because of small absolute numbers or (in the case of the larger studies) because of failure to take their randomisation by cluster (rather than by individual) into account when determining sample size and analysing results.

All the studies focus on populations at high risk of suffering a hip fracture: either older people in residential care homes (Lauritzen *et al*, 1993; Jantti *et al*, 1998; Chan *et al*, 2000; Kannus *et al*, 2000; Harada *et al*, 2001; Cameron *et al*, 2001, Meyer *et al*, 2003) or those with previous hip fracture (Hindso and Lauritzen, 2000; Torgerson and Watt, 2002). Consequently, these studies do not provide strong evidence for use of hip protectors in other populations.

All studies report problems persuading older people to wear the hip protectors. Greater use of hip protectors appears to be associated with:

- a history and present experience of falls
- a perception, among both wearers and care staff, of the wearer being at increased risk of falling and fracturing the hip
- female sex
- reduced mobility
- positive attitudes towards hip protectors amongst staff

Reduced use of hip protectors is associated with:

- a lower perception of risk
- a belief that hip protectors are ineffective in preventing hip fracture
- discomfort when wearing hip protectors
- difficulty in managing the garment when using the toilet
- male sex
- night-time

- negative staff attitudes

It is likely that hip protectors reduce the risk of hip fracture in high risk populations, but the magnitude of the reduction has not been clearly established. Acceptability of hip protectors is influenced by real and perceived risk of hip fracture amongst wearers and care staff, various characteristics of wearers, the design of the garment, and the commitment of care staff. The overall effectiveness of hip protectors depends on their efficacy in reducing the impact of a fall on the greater trochanter, their acceptability to wearers, and the degree to which the organisational and social context supports their use.

## **1.7 The aim of the study**

The present study is intended to evaluate the effectiveness of a policy of making hip protectors available free of charge in nursing and residential homes, and supporting the implementation process by employing a nurse facilitator to encourage staff in the homes to promote their use. An attempt has been made to take an approach that might be used by a Health and Social Services Board or other provider of health services, so the results of the study should be of interest to such bodies, as well as managers of nursing and residential homes, individual practitioners, and residents of nursing homes.

# Chapter Two

## Evaluating the effectiveness of hip protectors

The effectiveness of hip protectors depends not only on their efficacy in reducing the impact of a fall on the greater trochanter, but on the characteristics of those who are likely to wear them, and on the social and organisational environment in which they are worn. Consequently, it is vital that the methods employed in evaluating their use reflect the complexity of the processes through which the hip protectors are introduced and the context in which residents wear them.

### 2.1 The approach to evaluation: health services research

A study designed to evaluate the effectiveness of hip protectors in a normal service environment sits best within the paradigm of health services research. Health services research can be defined as “the investigation of the health needs of the community and the efficiency and effectiveness of the provision of services to meet those needs” (Medical Research Council, 2002, P. 1). It includes a major focus on the structure, processes and outcomes of health services, recognising that

“How and why technologies and other interventions are implemented depend on a broad range of political, economic, professional, and attitudinal factors that may have little to do with their value or efficiency.” (Mechanic, 2001, P. 462)

Thus, the effectiveness of hip protectors will depend only partly on their efficacy in preventing hip fracture. Other human, social and contextual factors will exert a vital influence. Health services research seeks to identify these factors in order to allow rational decisions about methods of implementation.

The implementation process itself is crucial to the use of the hip protectors. A conceptual framework for implementation will be described, linked to insights from the fields of health promotion and behaviour in organisations. The older people in question are residents of nursing and residential homes living in small communities with their own norms, roles, and cultural practices. Therefore, the culture of the homes must be taken into account in any analysis of how residents use hip protectors. This culture is profoundly affected by the way in which the home is organised and run, so the organisational factors that may affect residents and staff will also be examined.

Wearing hip protectors is behaviour intended to reduce the risk of hip fracture, and can therefore be described as preventative health care. Consequently, the approaches to introducing the hip protectors, and the responses and decisions of residents and their carers, can be described and analysed in terms of the theory and practice of health promotion, particularly health promotion in an organisational context.

In summary, this account of the context for the study will locate the evaluation of hip protectors under the broad umbrella of health services research, drawing on insights from the literature on health promotion and the sociology and management of nursing and residential homes. The relationship between the context for implementation and the methods of evaluation will be described.

### 2.1.1 The roots of health services research

Thirty years ago, in his book *Effectiveness and efficiency: random reflections on health services*, Cochrane made a distinction between effectiveness and efficiency (Cochrane, 1972). He defined effectiveness as the ability of a particular medical action to alter the natural history of a particular disease for the better as measured in a randomised controlled trial (RCT). He contrasted this with efficiency, which is the effectiveness of a medical action applied in routine clinical practice in a defined community. Cochrane commented:

“Between the scientific measurements based on RCTs and the benefit measurements at two levels of cost in the community there is a gulf which has been much under-estimated. Those patients participating in RCTs are nearly always selected from the general population of patients. Different strategies of management may be needed to achieve levels of effectiveness comparable to those reached in the RCTs.” (Cochrane, 1972, P. 2)

Cochrane (1972) recommended greater use of RCTs in measuring the effectiveness of treatments but also argued that the same methods should be used to measure the *efficiency* of such treatments. He called this “applied medical research,” and suggested that the efficiency of effective treatments should be investigated to throw light on the optimum time, place, duration, and setting for that treatment.

In a confusing development, the intervening years have seen Cochrane’s terms (though not his ideas) modified in the healthcare literature. For example, the Cochrane Collaboration (an international group named in honour of Cochrane and dedicated to the systematic review of randomised controlled trials) defines effectiveness as the “extent to which a specific

intervention, when used under ordinary circumstances, does what it is intended to do.” (Cochrane Collaboration, 2001, P.10). In its focus on “ordinary circumstances”, this definition is closer to Cochrane’s idea of efficiency. The Cochrane collaboration also uses the term “efficacy”, defined as the “extent to which an intervention produces an ideal result under ideal conditions” (Cochrane Collaboration, 2001, P.10), which approximates to Cochrane’s idea of effectiveness. Current usage will be applied in this thesis. Despite these later confusions, Cochrane’s book served to bring such questions and issues to a wider public in Europe and especially in the United States of America, where health services research was gradually developing as recognised field of enquiry (White, 1997).

### **2.1.2 Health services research today**

Health services research has been defined as “the discipline which seeks knowledge which will lead to improvements in the delivery of health care.” (Crombie and Davies, 1996, P. 4). New technologies and techniques, new ways of organising and delivering health care, are constantly being developed, and the associated costs and benefits need to be evaluated (Briggs and Gray, 1999). Health services research brings to bear the methods of clinical science to answer questions of effectiveness, cost, quality, equity of access, and acceptability to patients and clients. To achieve this, the appropriate methods of investigation must be used in settings that are generalisable to everyday practice. An intervention may promise efficacy in laboratory studies, yet prove ineffective once exposed to the multiplicity of factors present in normal service environments. Therefore, to use the Cochrane Collaboration’s (2001) classification, the effectiveness of an intervention may be studied in one way, and its efficacy in another. Figueredo and Sechrest (2001) see these differences in approach at either end of a continuum:

“On one end is an assessment of outcome of application of a procedure under tightly controlled, experimentally ideal, conditions, usually requiring substantial restrictions on samples, context, and variations in treatment. On the other end of the continuum is an assessment of application of a procedure as it would actually be employed in the field, usually with very few restrictions on samples, context, and treatment variations.” (P. 42)

Health services research lies at the latter end of this continuum, underlying this evaluation of the effectiveness of hip protectors as they might actually be employed “in the field.”

## **2.2 A conceptual framework for implementation**

How should hip protectors be employed in the field? Kitson *et al* (1998) propose a conceptual framework for enabling the implementation of evidence-based-practice in healthcare. Using evidence from case studies describing nursing and multi-disciplinary projects, they suggest that successful implementation depends equally on three core elements: the level of evidence, the method of facilitating the change, and the context into which the evidence is being implemented.

### **2.2.1 The level of evidence**

Kitson *et al* (1998) argue that evidence is derived from research, clinical expertise, and patient choice. These concepts can be described according to their value in supporting effectiveness. High value research evidence consists of randomised controlled trials, systematic reviews and evidence-based guidelines. Low value research evidence is anecdotal and descriptive

information. Similarly, clinical experience may reflect high levels of consistency and consensus, or divided expert opinion. Patient preferences may be included through a high value systematic process of allowing input into decision-making, or be completely overlooked.

### **2.2.2 The method of facilitating the change**

Facilitation is defined as “the type of support required to help people change their attitudes, habits, skills, ways of thinking, and working.” (Kitson *et al*, 1998, P. 152). Facilitation is affected by the personal characteristics of the facilitator, the clarity they and others have about the role, and the style of the facilitator. Desirable facilitator characteristics are the ability to show respect and empathy, and to act with authenticity. A clear understanding of the facilitator’s role is needed in terms of their right of access to the organisation, their authority, position, and agenda for change. The facilitator’s style should be flexible, and they should be present consistently and at appropriate times.

### **2.2.3 The context into which the evidence is being implemented**

Context is defined as the setting in which the change is to be implemented. Context is affected by the organisational culture, the style of leadership, and the level of evaluation (McCormack *et al*, 2002). A culture that is supportive of necessary change has a well-defined set of values, promotes learning as a team activity, emphasises relationships and teamwork, and rewards good performance. Leaders should be capable of inspiring staff with a shared vision and empowering them to achieve their goals (known as “transformational leadership”). Evaluation should make use of multiple methods to provide feedback on individual, team and system performance.

Kitson *et al* (1998) suggest the evidence is more likely to be implemented where a full complement of desirable factors are present in all three elements.

Conversely, high quality evidence may not be implemented where context or facilitation are inadequate. This is consistent with the conclusions of a recent systematic review of approaches to getting evidence into practice, which states:

“Whilst individual beliefs, attitudes and knowledge influence professional behaviour, other factors including the organisational, economic and community environments of the practitioner are also important.” (Effective Health Care, 1999, P. 1.)

The organisational and community context affects not only the behaviour of professionals and care staff but also the response of individuals to health promotion initiatives – such as the offer of hip protectors.

### **2.3 The context for implementation: nursing and residential homes**

A nursing home can be defined as “an establishment which provides residential and nursing care for sick, disabled or elderly infirm people, including the elderly mentally ill.” (Royal Commission on Long Term Care, 1999, P. XXIV). A residential home can be similarly described, except that nursing care is not included. In 1999 there were an estimated 157,500 people in nursing homes and 288,750 in residential homes in the United Kingdom (UK); a total of 446,250. This represents approximately one in 20 of all people over 65 years, at an annual cost of over £8 billion. The total number of people over 65 years in the UK is expected to keep growing until 2030, with the number of people 85 years and over peaking at three times the present number in 2050. Thus, the number of people requiring long term

residential care is likely to continue to rise for the foreseeable future (Royal Commission on Long Term Care, 1999). It is estimated that nearly one sixth of those aged 65 years or older in England and Wales are physically or mentally disabled. This figure rises to 99 percent in nursing and residential homes, including 46 percent who are cognitively impaired. Fifty-six percent of residents are aged 85 years or older and 79 percent are women (Melzer *et al*, 1999).

### 2.3.1 Nursing and residential homes in Northern Ireland

In 2001, there were 11,212 people in Northern Ireland receiving long-term care: in residential homes managed by the health and social services boards, and in nursing and residential homes managed by charitable organisations, or private individuals and companies (Table 2.1). Approximately 90 percent of residents had a limiting long-term illness (Northern Ireland Statistics and Research Agency [NISRA], 2001). In 2001, the population of Northern Ireland was nearly 1.7 million, of whom 223,325 (13 percent) were 65 years or older (NISRA, 2001). The number of those aged 65 years or older is predicted to rise by more than 60 percent by 2023 (Northern Ireland Ageing Population Panel, 2001), so the number of people in nursing and residential homes is likely to continue to rise.

**Table 2.1 Older people receiving long-term care in Northern Ireland (2001)**

Type of home	Number of residents	Percentages
Residential (HSSB)	1,387	12
Residential (non-HSSB)	3,038	27
Nursing (non-HSSB)	6,787	61
<b>Total</b>	<b>11,212</b>	<b>100</b>

(Adapted from NISRA, 2001).

## **2.4 The culture of nursing and residential homes**

Eaton (2000) argues that the organisational culture of nursing and residential homes is vitally affected by the managers' philosophy of care. However, this philosophy of care is itself partly determined by existing organisational and societal structures, values and beliefs. In the context of homes in the United Kingdom, this means that managers' styles and the existing culture in the homes will exert a reciprocal influence: the manager shaping the home, but the existing culture of the home influencing the manager. For this reason, a full understanding of the culture of residential and nursing homes must include an appreciation of how the historical roots of residential care affect present practice.

### **2.4.1 The historical development of nursing and residential homes**

In a seminal study, Townsend (1962) traces the development of nursing and residential homes from their origin in the workhouses of the nineteenth century. Poor Houses existed from Elizabethan times, but the growing numbers of citizens needing public relief, together with the rising costs of provision, drove Parliament to pass the Poor Law Amendment Act of 1834. This regularised the provision of support through institutions known as workhouses. Here, the able-bodied poor of all ages were allowed to live, subject to the obligation to work hard for their keep. The general principle was that they should have a standard of living slightly lower than that of the poorest labourers in ordinary employment, in order to encourage them to leave the workhouse as soon as possible. In the absence of any other provision, the sick and aged were drawn into this system, where there were few special arrangements for older people. In fact, the harsh conditions of the workhouse were intended as a deterrent, aiming to stimulate older people and their families to make their own arrangements for support in old age.

Even so, by 1909 there were 140,000 people over 60 years of age in Poor Law institutions, most of them living in crowded dormitories, with no useful occupation and few comforts, and representing around 45 percent of the total population in workhouses.

In the early years of the twentieth century, separate provision for children and mothers removed many younger people from the Poor Law system. However, between 1909 and 1946 the number of people in the United Kingdom over 65 years more than doubled, so that the numbers of older people in workhouses actually increased. Conditions had hardly changed from the nineteenth century, with inadequate accommodation and harsh rules, producing apathetic residents.

#### **2.4.2 Post-war changes**

The National Assistance Act of 1947 saw a renewed impetus to reform residential provision for older people. A drive to provide smaller homes accommodating 30 to 35 residents resulted in 39,000 new places between 1948 and 1960, but large increases in the number of people over 75 years over the same period limited the impact of these improvements. Townsend's original research (Townsend, 1962) consisted of fact-finding visits to a random sample of 173 homes in England and Wales from October 1958 to October 1959, together with interviews with several hundred chief welfare officers, matrons, wardens and elderly residents. He found a wide range of practice and facilities. At one end of the continuum, forming 33 percent of the sample, were institutions converted from the old workhouses with between 100 and 250 or more beds. They retained forbidding buildings and austere interiors, with large, overcrowded dormitories, few staff, little privacy and strict routines. At the other extreme, forming 30 percent of the sample, were homes with 30 or fewer beds built for the purpose by local authorities, or run by a voluntary association or private individual. These might be situated near

town centres, or in desirable country locations, and contain well-equipped communal areas and comfortable single bedrooms. Staffing levels were adequate, and to a certain degree, residents were able to follow their own routines. Between these extremes were homes with between 30 and 100 beds, usually in buildings converted for residential use after the Second World War by local authorities and voluntary associations. Typically, the level of comfort and standard of amenities was better than the large institutions, but not reaching the levels of the smaller homes. Bedrooms were for three to six persons. In all homes, residents enjoyed a regular diet, warmth, a degree of comfort and supervision. However, Townsend summarised the general effect of the prevailing conditions on the residents as,

“...loss of occupation, isolation from family, friends and community, difficulty in forming more than tenuous relationships with members of the staff and other residents, loneliness, loss of privacy and identity and collapse of powers of self-determination.” (Townsend, 1962, P. 434)

Townsend argued that the whole system of communal homes was failing older people. He recommended that a network of services designed to help people remain in their own homes should replace most residential care.

### **2.4.3 Developments since the 1960's**

Peace *et al* (1997) take up the history from the 1960's to the present. They note the piecemeal response to Townsend's recommendations, and chart the various attempts by successive governments to rationalise provision for frail elderly people. The radical, “market-driven” policies of Conservative governments from 1979 onwards led to a transformation of the providers of long-term care. Peace *et al* (1997) present figures to show that in 1976 five out of every six persons accommodated in English residential homes were in

public sector homes. By 1992, this position was reversing, with two out of every three living in private residential homes. This development was driven by changes in government policy that allowed many older people on low incomes to enter private residential homes and claim public funding for the fees, without having their care needs assessed by the local authority. Over this same period, the total number receiving long-term care more than doubled, leading to a massive increase in social security payments. Consequently, from 1993 local authorities took over the responsibility for assessment and placement of older people funded by public money. The resultant shrinkage in the sector was offset by a reduction in long-stay geriatric and psycho-geriatric beds in the NHS – a 30 percent decrease between 1989 and 1994 - with a consequent growth in the numbers of private nursing homes. The quality of care in homes was controlled through a system of regulation and inspection.

#### **2.4.4 Nursing and residential homes today**

Surveying contemporary provision of residential care, Peace *et al* (1997) note that 40 percent of private homes are owned by individuals, often married couples. Corporate providers, defined as individuals, partnerships and voluntary sector organisations with three or more homes, own thirty percent. The remainder are run by voluntary organisations. The majority of homes have fewer than 30 places, 74 percent of them in single rooms, 25 percent in double rooms, and only one percent in rooms with more than two beds. In 1999 there were an estimated 157,500 people in nursing homes and 288,750 in residential homes in the United Kingdom (UK); a total of 446,250 (Royal Commission on Long Term Care, 1999).

Untrained, often part-time, female care assistants give most care in homes. They are supervised by managers with nursing or social work qualifications. Increasingly, care assistants are gaining National Vocational Qualifications in

care, but they remain on low pay, and staff turnover is high, often 100 percent a year (Peace *et al*, 1997). Whilst some residents see residential care as a positive step, the majority enter homes because they believe they have no alternative. If possible, they would prefer to remain in their own homes. This reluctance centres on a feared loss of autonomy, caused by the individual resident's needs and choices being lost amidst the routines and group practices of the home. On the other hand, government policy on residential care stresses the importance of individualised care and respecting the autonomy of residents (Peace *et al*, 1997). The degree to which residents' autonomy is supported or undermined by practices within the homes, and the implications of this for the introduction of hip protectors into the homes, are discussed below.

## **2.5 The “total institution”**

Analysis of how institutions affect their residents has been greatly influenced by the work of Erving Goffman. His book *Asylums* (1962), based on studies of patients in mental hospitals, describes how patients are affected by admission to what Goffman terms a “total institution.” Goffman identified five groupings of total institutions, including those “for persons felt to be both incapable and harmless” (Goffman, 1962, P. 4), such as the aged. He defines and describes a total institution in the following words:

“A basic social arrangement in modern society is that the individual tends to sleep, play and work in different places with different co-participants, under different authorities, and without an over-all rational plan. The central feature of total institutions can be described as a breakdown of the barriers ordinarily separating these three spheres of life. First, all aspects of life are conducted in the same place and under the same single

authority. Second, each phase of the member's daily activity is carried on in the immediate company of a large batch of others, all of whom are treated alike and required to do the same thing together. Third, all phases of the day's activities are tightly scheduled, with one activity leading at a pre-arranged time into the next, the whole sequence of activities being imposed from above by a system of explicit formal rulings and a body of officials. Finally, the various enforced activities are brought together into a single rational plan purportedly designed to fulfil the official aims of the institution." (Goffman, 1962, P. 5-6)

The effect of such institutions on their members is to reduce autonomy, self-worth and individuality, by using rewards and sanctions to induce passivity, humiliation and conformity. Given that residential and nursing homes in the United Kingdom have their roots in the workhouse system, and that highly dependent residents rely on a largely transient, untrained workforce, it would not be surprising if some aspects of the total institution could be found in contemporary homes. Is this the case?

### **2.5.1 Are nursing and residential homes "total institutions"?**

Higgs *et al* (1998) used a questionnaire to measure the satisfaction of a representative sample of 850 residents of 36 nursing homes in the South West Thames Regional Health Authority area in the United Kingdom. Cognitive or other deficits prevented the majority from responding but 377 were able to complete the questionnaire in a face-to-face interview. The vast majority of residents reported high levels of satisfaction with items measuring relations with staff, autonomy, amenities, privacy and the social environment. Higgs *et al* (1998) challenge the accepted thesis that older people experience negative consequences from being controlled by the institutions in which they live. Rather, they argue that older people may be well aware of their need to

depend on others and actively embrace the relative security and support available in the homes:

“While this dependency presents opportunities for control by those providing care, to maintain that this is what always occurs is wrong. Such an approach reduces older people to the position of ciphers...They may be grateful...but they know that their physical limitations would place them in these circumstances no matter where they were being cared for...Consequently, it is not surprising that...our sample of elderly and dependent residents have high levels of satisfaction with institutional care because, here, at least they are receiving care.” (Higgs *et al*, 1998, P. 204)

This view is supported in a study by Mattiasson and Andersson (1997). They interviewed 60 cognitively competent residents of 13 nursing homes in Sweden searching for discrepancies between individual priorities and what was possible in the institution. They found that residents ranked the quality of their relationships with staff and each other as more important than having flexible routines, and that they were generally satisfied with their care. On the other hand, a recent review of the literature related to the social environment of nursing homes in Europe and the United States (Jacelon, 1995) demonstrates that some aspects of the total institution are still present. High levels of dependency amongst residents, loss of control over personal decisions, a focus on residents' medical and physical problems (to the detriment of social and psychological care), the subjugation of individual needs to the routines of the home, and unequal relationships between residents and staff, are widespread. The difficulty older people experience in maintaining meaningful autonomy in nursing and residential homes is well documented (Tobin and Lieberman, 1976; Phillips *et al*, 1988; Dixon, 1991; Gamroth *et al*, 1995).

It is possible that these conflicting accounts can be explained by the low expectations of older people, their resignation to the apparently inevitable decline in their quality of life, and fear that critical comments will lead to reprisals by staff (Townsend, 1962; Jacelon, 1995; Peace *et al*, 1997). However, whether residents are satisfied or not, what is clear from all accounts is that they are relatively powerless. Their satisfaction depends largely on the actions of staff and their autonomy must be facilitated by staff. Every recommendation for improvement in the literature is directed at staff or those who manage them; none are directed towards the residents, thus implicitly recognising their inability to control their environment. The implication for promoting the use of hip protectors amongst residents is clear: this must have the active support of staff, or it will fail.

## **2.6 Health promotion and the implementation process**

As noted above, the process of introducing the hip protectors can be discussed in terms of the concepts and methods of health promotion. The World Health Organisation (WHO) defines health promotion as the process of enabling people to increase control over, and to improve, their health (WHO, 1986).

### **2.6.1 The historical development of approaches to health promotion**

An understanding of present approaches to health promotion is aided by an appreciation of their historical development. The roots of health promotion in the United Kingdom lie in the social and environmental changes produced by the industrial revolution in the early nineteenth century. The mechanisation of the means of production led to the transfer of work from the home to the

factory, and a movement of population from the countryside to the city. These changes gave rise to fears amongst the educated classes that the very fabric of society was crumbling. Traditional relationships based around family, church and the mutual responsibilities of employers and employees were undermined, leading to rising crime and disorder. Appalling living conditions in the cities, coupled with widespread child labour, resulted in an increase in the death rate and in infectious disease. Employers and reformers joined forces to rescue the poor from moral and social decline, forming temperance clubs, work-based educational schemes, insurance associations, and sponsoring suitable cultural pursuits. Middle class women were encouraged to visit the homes of the poor to teach sobriety, economy, and hygiene through their Christian example (Baly, 1995).

By the mid-nineteenth century, the government had stepped in to develop its own policies on public health. These took the form of laws aimed at ensuring clean water, effective sanitation and suitable housing as the prerequisites to health. This emphasis on social factors and the environment was succeeded in the early twentieth century by an increasing focus on the health of individuals, principally expressed through vaccination and immunization programmes. Increasingly the biomedical aspects of disease were emphasised, with fresh attention paid to the lifestyle of the individual. Concentrating on individual behaviours naturally led to efforts to change those behaviours, primarily through providing information on the ingredients of a healthy lifestyle and encouraging individuals to make the necessary adjustments. With the establishment of the Central Council for Health Education in 1927, education became the dominant path to improving health. Relatively little attention was given to social and environmental influences on health (Bunton and Macdonald, 1992). This trend continued into the 1960s, with a continued emphasis on individual health behaviour in relation to such issues as family planning, venereal disease, accident prevention,

immunization, cervical smear checks, weight control, and consumption of cigarettes and alcohol.

## **2.6.2 The community as a context for health promotion**

In the 1970s, evidence was emerging linking unhealthy behaviour with social and environmental factors beyond the control of the individual, particularly amongst the poor (Baric, 1994; Midha and Sullivan, 1998; Ewles and Simnett, 1999). This led to a renewed interest in modifying social structures as a means to empowering people to take control of their health. The World Health Organisation took a leading role in advocating the new approach, stating at the 1978 Alma Ata conference that

“A main social target of governments, international organisations and the whole world community in the coming decades should be the attainment by all people of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life.” (WHO, 1978, P. 1: Section V)

This new approach, known as health promotion, included health education but went beyond recommending changes by individuals, and addressed governments and communities. The “Alma Ata Declaration” was followed by the “Ottawa Charter” (WHO, 1986), which returned to the early focus of public health in the United Kingdom, stating that the fundamental prerequisites for health are peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice and equity. The Charter identified five key areas for health promotion: building healthy public policy, creating supportive environments, strengthening community action, developing personal skills, and reorientating health services. Most current approaches to health promotion, especially in Europe, are underpinned by the approach

advocated by the Ottawa Charter (Baric, 1994; Ewles and Simnett, 1999), although the United Kingdom has been relatively slow to emphasise these developments (Speller *et al*, 1997; Midha and Sullivan, 1998).

### **2.6.3 The nursing home as a health promoting community**

The recognition of the importance of the community as the context for health promotion has important implications for the process of introducing hip protectors into nursing and residential homes. Residents do not take the decision to wear hip protectors in isolation but as part of a specific community. In terms of the implementation framework proposed by Kitson *et al* (1998), the community is the context or setting for implementation. Successful implementation requires not only residents but also care staff and their managers to change their behaviour. Effective health promotion seeks to understand communities in order to increase the power members of those communities have over their health. This approach is designed to produce “health promoting settings,” such as schools, workplaces and hospitals (Speller *et al*, 1997). The health promoting behaviours in such settings, which include nursing and residential homes, are best understood using an organisational rather than a medical model, because they are primarily behaviours carried out as part of the ongoing processes of the organisation, rather than individual lifestyle decisions.

The approach adopted by the proprietor or senior manager has been found to be a crucial influence on the organisation of the homes. Phillips *et al* (1988), interviewed more than 100 owners or managers of residential homes in Devon, England, and carried out a week of participant-observation in three of the homes to evaluate daily life and care. They found that the high turnover amongst staff and residents meant that the “articulated philosophies of the proprietors, with the emphasis variously on skilled professional care, an open

house, and a respectable family atmosphere, were carried through,” and that “the personalities of the persons in charge significantly affect the style of a residential home.” (Phillips *et al*, 1988, P. 90.) Eaton (2000) found a comparable effect in a similar study of 20 nursing homes in North America. The approach adopted by managers, be it “custodial”, “medical-rehabilitative”, or “regenerative”, was reflected not only in the practices within the homes, but in the outcomes for residents in terms of levels of illness, mortality and psycho-tropic drug use.

Again, this is consistent with Kitson *et al*'s (1998) framework for implementation, equating to the concepts of leadership style and organisational culture that help to produce the context for implementation. Is the culture of the home supportive of necessary change, are there a well-defined set of values, is learning promoted as a team activity, are relationships and teamwork emphasised, is good performance rewarded, is evaluation carried out effectively (McCormack *et al*, 2002)? Of course the approach of the home manager is only one of many factors influencing organisational effectiveness, but it has been shown to be one of the most important.

## **2.7 Other organisational factors affecting the quality of care in homes**

A number of other organisational factors have been linked to the quality of care for residents in nursing and residential homes, including: the source of funding (Steffen and Nystrom, 1997; Zinn *et al*, 1998), being part of a nursing home chain or other provider group (Steffen and Nystrom, 1997; Zinn *et al*, 1999), the size of the home (Steffen and Nystrom, 1997; Zinn and Mor, 1998), having a “creative” organisational climate (Mattiasson and Andersson,

1997), the degree of organisational hierarchy and staff supervision (Rohrer *et al*, 1993), nurse staffing (Steffen and Nystrom, 1997; Schmidt *et al*, 1998; Eaton, 2000), and the degree of multi-disciplinary working (Schmidt *et al*, 1998). The relationships between variables are complex, with conflicting evidence on their effects in different cultural and organisational climates (Zinn and Mor, 1998). What is clear, however, is that the organisation of the home, its size, source of funding, level of staffing, and organisational climate are likely to be linked to the quality of care offered to residents.

## **2.8 The relationship between the context and the methods of investigation**

The value of health services research lies in its attempt to produce information for the providers and users of a service on how an intervention can best be implemented, or indeed whether it should be implemented at all. This is achieved by evaluating putatively efficacious interventions in an everyday service environment, seeking to throw light on those factors that influence the success or failure of the intervention. This means paying attention to the efficacy of the intervention itself, optimising the methods of implementation, and evaluating the context for implementation.

This study has been designed with these factors in mind. Cluster randomisation of residents in their nursing and residential homes, and avoidance of narrow exclusion criteria, allow the hip protectors to be introduced as they would be in an everyday service environment. Stratifying the randomisation of homes according to the categories of resident that they serve (residential, nursing, or elderly mentally infirm), their size, and affiliation allows the impact of organisational factors on the quality of care to be assessed. Introducing the hip protectors to residents in their normal social groups, and through the staff who manage the home, recognises the impact

of the context of care. The implementation process is designed to mirror what might reasonably be available, in terms of human and other resources, to Health and Social Service Boards, trusts or other commissioners who might wish to introduce hip protectors to the nursing and residential homes for which they are responsible.

# Chapter Three

## Review of the literature

External hip protectors are designed to reduce the impact of a fall on the bone by absorbing or dispersing the force of the fall. This review will evaluate the literature on laboratory studies of hip protectors, clinical trials of effectiveness (including a systematic review), and the acceptability of hip protectors to older people.

### 3.1 Search strategy for identification of studies

The following databases were searched (up until January 2003):

- The Cochrane Library
- Medline (Ovid)
- CINAHL (Ovid)
- Science Direct

Internet based resources (CRD databases, Bandolier, PubMed, TRIP database, The National Electronic Library for Health, BIOME) were searched and general internet searches of the World-Wide-Web were carried out. The reference lists of articles were examined for further studies. In Medline and CINAHL, the first part of the strategy used in the Cochrane review of hip protectors (Parker *et al*, 2000) was employed. The following terms were used:

1. protective clothing/

2. protective devices/
3. orthotic devices/
4. (hip adj (protector\$ or pad\$)).tw.
5. or/1-4
6. exp hip fractures/
7. (fracture\$ adj (hip or femur\$ or femor\$)).tw.
8. or/6-7
9. and/5,8

In *Science Direct*, the following strategy was employed to search titles, keywords and abstracts:

1. protect! or orthotic or pad!
2. and
3. hip or fractur! or fem\*r

### **3.2 Approach to the literature**

Hip protectors are designed to be worn over the tissue covering the greater trochanter. This presumes that falls resulting in impact on or near that area are a major risk factor for hip fracture. If such falls do substantially increase the risk of hip fracture, and hip protectors are designed to reduce the impact of the fall, then an estimate of the force needed to break the proximal femur will provide a valuable target for developers of hip protectors. Given that most hip fractures occur following a fall from standing height, it is also necessary to estimate the force generated by such a fall, in order to calculate the degree to which a hip protector is likely to attenuate the force. Therefore, before proceeding to the literature directly pertaining to hip protectors, it is important to address three related areas:

- The degree to which a fall onto or near the hip increases the risk of hip fracture, compared to falls that result in impacts elsewhere on the body.
- Estimates of the force needed to fracture the proximal femur.
- Estimates of the force generated by a fall on or near the hip.

### **3.3 The importance of impact near the hip as a risk factor for hip fracture**

A number of studies have shown that most hip fractures occur because of the impact of a fall onto the greater trochanter.

Lauritzen and Askegaard (1992) interviewed 60 patients about the direction of the fall preceding their hip fracture. Of the thirty-nine who were able to state the direction of the fall, thirty-seven had suffered an impact on the greater trochanter.

In a carefully analysed study, Hayes *et al* (1993) studied residents of a residential care facility in the USA who fell during a three and a half year period. Residents and their carers were interviewed within 24 hours of the fall to determine the height of the fall, the direction of the fall, and the location of the impact on the body. Data was also collected on body mass index and mental impairment. The 82 residents who suffered a hip fracture were compared with the 313 who fell without hip fracture. Body mass index was negatively correlated with risk of hip fracture, whilst mental impairment was associated with an increased risk, but the strongest independent risk factor was impact on the hip or side of the leg (Odds Ratio [OR] 21.0, 95% confidence interval (CI) 9.1 to 49.0). In contrast to this, impact on the buttocks was associated with reduced risk.

Hopkinson-Woolley and Parker (1998) studied 552 patients admitted with hip fracture following a fall. Of those able to describe their fall on the day following admission (321 patients), 84 percent described a fall directly onto the affected side. The authors comment that this finding has significance for the argument that hip protectors may be of benefit.

Schwartz *et al*, (1998) interviewed 214 men who had suffered hip fracture following a fall six weeks after their discharge from hospital to ascertain the direction in which they had fallen. They compared their responses with those from 86 matched control subjects who had fallen within the last year without breaking a hip. Of the men suffering hip fracture, 94 percent reported hitting their hip or thigh when they fell, compared to 22 percent of controls (OR 48.6, 95% CI 22.5 to 105).

Greenspan *et al*, (1998) interviewed 132 residents of a single nursing home within five days of their fall. Amongst the 32 residents who suffered hip fracture, 63 percent reported a fall to the side, compared to 27 percent of the 100 fallers who did not fracture a hip (OR 4.6, 95% CI 1.6 to 13).

These studies show a consistent finding in different populations: a fall resulting in an impact on or near the greater trochanter is associated with a much greater risk of hip fracture than a fall where the site of impact is elsewhere. For this reason, one can argue that shielding the greater trochanter with a hip protector that effectively reduces the impact of a fall on the trochanter could reduce the risk of hip fracture following a fall.

### **3.4 Estimating the force needed to cause a femoral fracture**

The degree of force from a fall sufficient to fracture the femur has not been clearly established. The studies reported below used dropped weights (with the exception of Lotz and Hayes [1990], who used a hydraulic actuator to apply a gradually increasing load) to generate an impact on bare cadaverous femora. This obviously ignores the shielding effects of the tissues surrounding and covering the bone in life, and the protective reflexes by which people may attenuate the force of a fall. However, these results indicate a range of values below which fracture is less likely and therefore provide a target for developers of hip protectors.

Lotz and Hayes (1990) measured the force needed to fracture femora removed from 12 fresh cadavers and then refrigerated. The donors (seven men and five women) had a mean age at death of 69 years, with a range from 53 to 81 years. The mean fracture force was measured at 2.11 Kilonewtons (SD 1.06 Kilonewtons), with a range from 0.77 – 4.04 Kilonewtons.

Courtney *et al* (1995) measured the force needed to fracture 17 femora recently removed from fresh, refrigerated cadavers. Eight donors (four men and four women) had a mean age at death of 74 years, with a range from 59 to 83 years. Nine donors (three women and six men) had a mean age at death of 33 years, with a range from 17 to 51 years. The mean fracture force for the older group was 3.44 Kilonewtons, with a SD of 1.33 Kilonewtons. Femora from the younger group were almost twice as strong, with a mean fracture force of 7.2 Kilonewtons, and a SD of 1.09 Kilonewtons. There was a significant positive correlation between bone mineral density and fracture force for both groups. Once bone mineral density was taken into account,

age ceased to be an independent predictor of fracture force. Differences between male and female femora were not reported.

Cheng *et al* (1997) measured the force needed to fracture 64 right femora removed from cadavers at autopsy. The 28 female donors had a mean age at death of 71 years, with a SD of 15 years. The 36 male donors had a mean age at death of 67 years, with a SD of 15 years. The mean fracture force for females was 3.14 Kilonewtons, with a SD of 1.24 Kilonewtons. The mean fracture force for males was 4.63 Kilonewtons – nearly 50 percent greater compared to females - with a SD of 1.55 Kilonewtons. The mean fracture force for all subjects was 3.98 Kilonewtons, with a SD of 1.6 Kilonewtons.

Okuizumi *et al* (1998) measured the force needed to fracture 12 right femora recently removed from embalmed cadavers of nine men and three women. The mean age at death was 72.8 years, with a range from 57 to 91 years. The mean fracture force was 2.17 Kilonewtons, with a SD of 0.94 Kilonewtons and a range of 0.72 to 4.34 Kilonewtons. Differences between male and female femora were not reported. Again, there was a significant positive correlation between bone mineral density and fracture force.

These four studies indicate an association between higher fracture threshold and male sex, younger age, and greater bone mineral density. However, more importantly for the purposes of this review, they report mean fracture forces for older people of between 2.11 and 3.98 Kilonewtons, with considerable variation between individuals. It is also important to note the range of fracture forces reported, and in particular, that some femora fractured at very low forces. To be effective in all cases, hip protectors must reduce the force of a fall to well below the estimated mean fracture forces. However, none of these studies took into account the force attenuating effects of the tissue overlying the greater trochanter, which would enhance the effect of the hip protector.

### 3.5 Estimating the force of a fall on the hip

Falls on or near the hip have been shown to be a major risk factor for hip fracture, and estimates of the force necessary to fracture the femur are available. In order to calculate the reduction in force that a hip protector must achieve to be effective, an estimate of the force generated by a fall from standing height is necessary. Measuring the force of actual falls in the laboratory is impractical and unethical, so the following studies rely on values derived from simulated falls using mathematical models. The values given rely on a number of assumptions and should therefore be treated with caution.

Robinovitch *et al* (1991) devised a system for producing a controlled impact on the hip in a simulated falling position (horizontal to the ground) in seven males and seven females aged 20 to 35 years. The study was designed to take into account the force attenuating effect of the soft tissue over the greater trochanter. The force of the impact was measured on 10 occasions for each subject, five where the subject was relaxed, five with the muscles of the trunk and back contracted. From these results, a mathematical model of body responses allowed calculation of the forces that would strike the greater trochanter in each case following falls from the subject's standing height. This gave mean figures for all subjects of 5.6 Kilonewtons in the relaxed state and 8.6 Kilonewtons in the muscle-active state. (A subsequent study [Robinovitch *et al*, 1997 – reported below] cast doubt on the figures obtained in the muscle active state.)

Using the same system, Robinovitch *et al* (1997) repeated their experiments of 1991 with five males and five females aged between 21 and 33 years. However, on this occasion they also measured the impact force where the trunk was nearly vertical to the ground, reflecting studies showing that this position was most often observed for sideways falls (van den Kroonenberg *et*

*al*, 1996). Improvements in experimental design demonstrated (in contrast to Robinovitch *et al*'s 1991 study) that the degree of muscle relaxation made little difference to the impact force. However, striking the ground with the trunk in a near vertical position did significantly increase the impact force. The mean calculated impact force in this position was 3.56 Kilonewtons (SD 0.95) with a range of 1.45 to 5.29 Kilonewtons. Furthermore, only about 15 percent of this force was absorbed by structures peripheral to the hip, the remainder directly transmitting to the proximal femur region. Robinovitch *et al* (1997) give no explanation for the difference between the mean impact forces measured in this study (3.56 Kilonewtons) and those measured in their previous study (5.6 Kilonewtons). These differences may reflect improvements in the design of the experiment or possibly differences between individual subjects. Whatever the reason, this illustrates the difficulty in estimating such figures, and raises a question as to which of these figures is more reliable.

In one sense these studies confirm what is already apparent through observation: that falls onto the hip can generate forces well in excess of those required to break the proximal femur. They do provide useful targets for developers of hip protectors, but cannot take the place of clinical trials of efficacy.

### **3.6 Laboratory studies of hip protectors**

It is reasonable to suppose that hip protectors could reduce the risk of hip fracture in the event of a fall on or around the hip. However, the first step in determining the most effective design is to test products in the laboratory. It will be useful to bear in mind the range of results from the studies already reviewed. These have measured mean fracture forces from 2.1 – 3.9 Kilonewtons, and the mean force of falls from 3.56 – 5.6 Kilonewtons. These

means are themselves derived from a wide range of values, so it would be reasonable to use the higher figure for falls (5.6 Kilonewtons) and the lower figure for fracture force (2.1 Kilonewtons) in evaluating the efficiency of hip protectors tested in laboratory studies.

Lauritzen and Askegaard (1992) report a series of exploratory studies (including one in the laboratory) into the energy absorption properties of tissue over the hip. First, (as reported above) they established that 37 of 39 patients who suffered hip fracture and were able to state the direction of their fall, had suffered an impact on the greater trochanter. Next, they measured the thickness of tissue over the greater trochanter in 12 women with hip fracture and 27 controls. There was no significant difference between the groups in terms of height, weight or body mass index, but a significant difference was found in the thickness of subcutaneous tissue covering the hip. Those with hip fracture had a mean thickness of 22 mm (range 15-29), compared to 32 mm (range 25-40) for controls. Finally, they measured the energy absorption provided by porcine tissue of varying thickness. Using a 5 kilogram steel weight, falling at a measured acceleration from various heights onto the tissue, they found that tissue 29 mm thick absorbed 60 percent more energy than tissue 20 mm thick. They also experimented with ten mm thick polystyrene foam over 20 mm thick tissue, and found that the foam provided nearly the same degree of energy absorption as porcine tissue of the same thickness.

Taking these three studies together, Lauritzen and Askegaard (1992) argue that their results indicate that the thickness of soft tissue over the hip is an important factor in up to two thirds of hip fractures, and that external protection of the hip may be effective in preventing hip fracture. They acknowledge that the validity of their conclusions rests on the assumptions that porcine tissue has similar mechanical properties to human tissue in life, and that any extra weight associated with thicker tissue over the hip has a

negligible effect on the load of a fall. However, they do not discuss the small sample used to derive norms for tissue thickness in those with fracture and controls. This is significant in light of the wide range of values within the groups and the considerable overlap in tissue thickness between groups. A larger sample would give a more definitive result.

Parkkari *et al* (1994) compared the force attenuation properties of various padding materials. They used a testing system designed to simulate the impact area of the greater trochanter and the typical stiffness and damping characteristics of the pelvis. The peak force of the impact was held at 8.2 Kilonewtons, representing the peak impact forces in experimental falls from a standing height (Robinovitch *et al*, 1991). Impact velocity was set at three metres per second, the average hip impact velocity measured in human volunteers falling on the hip (van den Kronenberg *et al*, 1993). The materials were chosen based on their putative energy-absorbing capacity, durability, low weight, good recovery after compression and reasonable price. Eight materials met these requirements: six polyethylene foams of various densities; a polyethylene foam with a special cross-linked structure (Plastazote); and ethylene-vinyl acetate foam, which is particularly soft and resilient. A thickness of 20 mm was used for each material, as this was thought to be the maximum useable thickness for a garment. The materials provided between 22 and 38 percent attenuation of the impact force, the most effective being Plastazote. The target was to reduce the force below the fracture threshold of 2.0 Kilonewtons (Lotz and Hayes, 1990) but none of the materials reduced the force below 5.0 Kilonewtons. Reducing the force below 2.0 Kilonewtons required a reduction in acceleration to 1.6 metres per second, or an increase in thickness to more than 100 mm.

Parkkari *et al* (1994) acknowledge that they have tested a limited range of materials. It is possible that materials exist, or could be made, that would have the ability to attenuate the force of the fall to the degree required and

also have the attributes necessary for use as a garment. Parkkari *et al* (1994) note the effective force attenuation provided by polystyrene in Lauritzen and Askegaard's (1992) study. However, they point out that polystyrene is brittle and does not recover well from compression. Parkkari *et al* (1994) argue that if the materials used in their study are to be effective, then they must work by some other mechanism than by absorbing the force of the fall. They suggest that protective materials may work if they shunt the force of the fall away from the greater trochanter into the surrounding tissues. It would appear that Parkkari *et al* (1994) did not allow for the impact attenuating properties of tissue over the hip. This would have further reduced the impact force. This study used the figures for forces generated by falls from a standing height provided by Robinovitch *et al*, (1991). In a subsequent study (Robinovitch *et al*, 1997), this figure was revised downwards from 8.2 to 3.56 Kilonewtons. The materials tested might have been more successful at lower forces.

Robinovitch *et al* (1995) tested a prototype hip pad designed to shunt the energy of a fall into the tissue surrounding the greater trochanter. They developed and tested a simulated female pelvis, and employed a pendulum to provide the force of the fall. A number of pads were tested, including one designed by Robinovitch *et al* (1995). This pad lies in an inverted "U" shape over the skin surrounding (not over) the greater trochanter. It consists of a flexible membrane containing a suspension of micro-particles that undergo a dramatic rise in viscosity on impact, forming a bridge over the bone, and dispersing the force of the fall into the surrounding tissues. Robinovitch *et al* (1995) found that their pad reduced the energy of the impact by more than twice as much as the energy absorbing pads, from 5.7 Kilonewtons to just over 2 Kilonewtons (a reduction of approximately 63 percent), well below their estimated fracture threshold of 4.1 Kilonewtons (Courtney *et al*, 1994). However, this result was obtained using a pad 33 mm thick, and this bulk, together with the relatively heavy materials, may well affect the acceptability

of the pad. On the other hand, respectable attenuation to 3.4 Kilonewtons (a reduction of 40 percent) was obtained using an 18 mm pad.

Following their paper in 1994, Parkkarri *et al* (1995) tested an energy shunting hip protector of their own design, using a similar method to Robinovitch *et al* (1995). The protector was made from an outer shield of a semi-flexible polyethylene, with an inner layer of energy-absorbing Plastazote foam. The protector was shaped to be more convex than the anatomy of the female hip, leaving a 1.5 cm gap over the trochanter, in order to prevent direct contact with the tissue over the trochanter and disperse the impact force into the surrounding tissues. The impact on the trochanter was reduced from 5.6 Kilonewtons to 1.04 Kilonewtons (a reduction of 81 percent), and, in a high impact experiment, from 10.4 Kilonewtons to 1.8 Kilonewtons (a reduction of 83 percent).

Parkkari *et al* (1995), raise the possibility that shunting the force of the fall away from the greater trochanter might cause fracture of the pelvis or femoral neck. They also point out that the protector will be ineffective in falls forward or backward, where there is no direct impact on the trochanter. The pad tested was 40 mm at its maximum depth, which may well prove too bulky for many potential wearers.

Mills (1996) tested the force attenuation properties of the Sahva hip protector used by Lauritzen *et al* (1993). The force at the hip was reduced from 3.9 Kilonewtons to 1.67 Kilonewtons (a reduction of 57 percent). Using dropped weights and a simulated pelvis, Mills found that little of the force of the fall was shunted into the surrounding tissues. The hip protector had a clearance of only 5 mm over the tissue covering the greater trochanter, and deformed at higher impacts to lie directly over the trochanter. The softness of the tissue surrounding the trochanter also allowed the protector to move easily down onto the trochanter at higher impact forces. Mills (1996) concludes that for

minor falls from a height of 20 cm the Sahva protector distributes about half the impact force away from the trochanter, with a proportion absorbed by the flexion of the shell and compression of the inner foam lining. However, for falls from 40 cm the trochanter receives most of the force. He argues that a stiffer shell and thicker foam would decrease the impact of major falls on the trochanter, but recognises that the Sahva protector is a compromise between protection and comfort.

The HipSaver Company, Inc., the manufacturers of HipSavers™ hip protectors, provided information on laboratory testing of their hip protector at the Orthopaedic Biomechanics Laboratory, Beth Israel Hospital, Boston, USA (The HipSaver Company, Inc., 1996) using a simulated female pelvis, and a pendulum to provide the force of the fall. The pads are 16mm thick and made from three layers of urethane foam bonded together and sealed in a waterproof nylon pouch. They are intended to both absorb and disperse the force of a fall. The impact energy was 140 Joules (considered to be the average energy produced by the impact of a fall on the hip), and the mean femoral fracture load was taken to be 4.17 Kilonewtons, with a standard deviation of 1.59 Kilonewtons. The HipSavers™ hip protector attenuated the impact force to 4.3 Kilonewtons. Expressing the impact in terms of energy (Joules) and the attenuated force in terms of Kilonewtons means it is difficult to compare these results with those from other studies. There is insufficient information to allow conversion of the impact energy into Kilonewtons.

Parkkari *et al* (1997) studied the effects of impact to the hip in four young (27-37 years), male volunteers who were wearing the hip protector described and tested in their 1995 study. The volunteers wore a hip protector on each hip, with one hip against a concrete wall, whilst the other was subject to a measured impact from a weighted pendulum. Making allowance for the energy absorbed by the protector against the wall, the hip was struck with a force that would have been 5-6 Kilonewtons without the protector. The

subjects reported mild pain on the skin under the contact area of the hip protector, and there was no sign of haematoma or swelling. The measured impact force under the edges of the protector was 2.1 – 2.3 Kilonewtons (a reduction of approximately 65 – 54 percent). This is sufficient to break the hip in some older people. However, as detailed in their previous study (Parkkari *et al*, 1995), the protector leaves a 1.5 cm gap over the trochanter in order to prevent direct contact with the tissue over the trochanter and disperse the impact force into the surrounding tissues. The impact on the trochanter itself may therefore have been less than that under the edges of the protector.

Parkkari *et al* (1997) acknowledge that the subjects were healthy young men rather than older women, and may well have had a greater thickness of tissue over the greater trochanter. Nevertheless, they conclude that it is probable that the impact forces transmitted to the greater trochanter and femoral neck are not sufficient to fracture the hip in an older person.

Okuizumi *et al* (1998) tested a hip protector consisting of a 12 mm thick silicone gel pad with and without a 3 mm thick resin cover. They used nine pairs of femora obtained from cadavers, dropping a metal weight weighing 8.4 Kilograms from a range of heights. The right femur was fractured as a control and the left protected with the silicone gel, or silicone plus resin cover. The mean right femoral fracture force was 2.17 Kilonewtons (range 0.72 – 4.3 Kilonewtons) and this was positively correlated with measured bone mineral density. The mean impact load (with a drop height of 25 cm) was reduced from 3.1 Kilonewtons to 2.2 Kilonewtons by the silicone gel (a reduction of 30 percent) and to 1.7 Kilonewtons by the gel plus resin cover (a reduction of 46 percent). Figures for higher impacts are not reported in the text. However, estimates from a graph presenting height impact against load, indicate an impact load of 4.4 Kilonewtons at 40 cm, reduced to 3.3 Kilonewtons by the silicon pad (a reduction of 25 percent) and to 2.6 Kilonewtons by the gel plus

resin (a reduction of 41 percent). The differences between pads are less evident at lower impact forces.

Okuizumi *et al* (1998) acknowledge a number of limitations in their study. There was no attempt to replicate the effect of soft tissue over the greater trochanter (although this is offset by the relatively low impact forces studied). There was no attempt to simulate a human pelvis but the femora were braced against a rigid structure. The experimental design tested only the impact absorbing properties of the protector, rather than any force shunting effect. However, Okuizumi *et al* (1998) conclude that their design provided effective impact attenuation and fracture prevention. There are difficulties with this conclusion. The results are not reported in terms of the matched pairs of femora, which would have allowed a direct examination of the difference made by the protector; mean values are offered instead. The best figure presented for force attenuation (1.7 Kilonewtons for the gel plus resin pad) is the only case in which the impact force was reduced below the mean fracture force of 2.17 Kilonewtons. Even this figure is well within the range of fracture impact forces (0.72 – 4.3 Kilonewtons), and, as noted above, the attenuation properties of the protector appear to diminish at higher impact forces. It is possible that silicone, a higher density material than that typically used in hip protectors, is more effective at lower impact forces. Parkkari *et al* (1994) report that higher density materials perform better than lower density materials at low impacts but that this difference disappears at higher impact forces. As noted, Okuizumi *et al* (1998) justify using relatively low impact forces on the grounds that they have not inserted any material to compensate for the attenuating effects of tissue over the greater trochanter. However, when their pad was used at higher impact forces, which are closer to the forces produced by a fall, its efficiency was reduced and the attenuated impact was well above the mean fracture force. Consequently, their protector is likely to be less efficient when attenuating the impact of real falls. It may be that a wearable gel plus resin hip protector would have an energy shunting

effect, as well as an energy absorbing effect, but this was not tested. The density of the gel pads would also make them heavier than existing hip protectors, which might well decrease their acceptability to wearers.

Kannus *et al* (1999b) tested the force attenuation properties of four commercially available hip protectors: their own KPH1 (described in Parrkari *et al*, 1995), a modification of that design (the KPH2), the Safehip<sup>®</sup>, and Safetypants hip protectors. Using an impact pendulum and a simulated pelvis and femur (including 20 mm thick polyethylene foam as surrogate trochanteric tissue), they tested the four hip protectors at three impact levels: 4.33 Kilonewtons, 7.23 Kilonewtons, and 10.84 Kilonewtons. They took the fracture threshold to be 3.1 Kilonewtons (plus or minus 1.2 Kilonewtons).

In the low-impact experiment, which produced an impact force of 3.74 Kilonewtons in the surrogate hip, all four protectors reduced the impact force below the fracture range. In the medium impact experiment, the “soft tissue” alone attenuated the force to 6.13 Kilonewtons, the KPH1 to 0.78 Kilonewtons, the KPH2 to 0.76 Kilonewtons, the Safehip<sup>®</sup> to 2.24 Kilonewtons, and the Safetypants to 2.76 Kilonewtons (reductions of 87, 88, 63 and 55 percent respectively, from the force attenuated by the soft tissue). In the high impact experiment, the soft tissue attenuated the force to 9.19 Kilonewtons, the KPH1 to 1.36 Kilonewtons, the KPH2 to 1.17 Kilonewtons, the Safehip<sup>®</sup> to 4.64 Kilonewtons, and the Safetypants to 5.77 Kilonewtons (reductions of 85, 87, 50 and 37 percent respectively, from the force attenuated by the soft tissue).

Kannus *et al* (1999b) comment that, at the medium impact, which approximates the forces produced by a fall from standing height, only the two KPH protectors were outside the fracture range. At the high impact, representing much greater forces than are normally experienced in hip fracture, the KPH protectors still reduced the force to below the fracture

range, whilst the Safehip<sup>®</sup> and Safetypants protectors allowed forces well above it. Kannus *et al* (1999b) attribute the differences in performance to the different designs and modes of action of the hip protectors. The KPH1 is made from an outer shield of a semi-flexible polyethylene, with an inner layer of energy-absorbing Plastazote foam, and is 15 mm thick. The protector is shaped to be more convex than the anatomy of the female hip, leaving a 2.0 cm gap over the trochanter, in order to prevent direct contact with the tissue over the trochanter and disperse the impact force into the surrounding tissues. The KPH2 is similar in design, but with a less convex shape (its maximum depth is 3.5 cm compared with 4.5 cm for the KPH1) and a 1.5 cm gap over the trochanteric tissue. This design is intended to reduce the bulk of the hip protector, making it more acceptable to wearers. The Safehip<sup>®</sup> protector appears to work in a similar way: absorbing and dispersing the force of the fall. However, it is less convex (with a maximum depth of 2.5 cm) and more flexible than either of the KPH protectors (it is just 9 mm thick), and Kannus, *et al* (1999b) argue that this reduces its ability to attenuate impact forces. The Safetypants protector has a 20 mm Plastazote pad that sits directly on the trochanteric tissue and is designed to absorb the impact energy of a fall, rather than shunt it into the surrounding tissues. It produced the worst results of the four, probably because of its inability to disperse the force away from the trochanter. Kannus *et al* (1999b) point out the limitation of all external hip protectors – that they protect only against falls to the side, and cannot protect against twisting, anterior or posterior forces.

The HipSaver Company, Inc. provided further information on laboratory testing of their two HipSavers<sup>™</sup> hip protectors (one 8.4mm thick, the other 12.7mm thick) at the Tampere University of Technology (The HipSaver Company, Inc., 2000) using an identical system to that used by Kannus, *et al* (1999). The fracture threshold was taken to be 3.1 Kilonewtons (plus or minus 1.2 Kilonewtons).

The thinner HipSavers™ hip protector reduced the impact force of 7.2 Kilonewtons to 2.51 Kilonewtons; the thicker protector to 1.79 Kilonewtons. These results can be compared to those obtained by Kannus, *et al* (1999b), where the same impact force was reduced by the KPH1 to 0.78 Kilonewtons, the KPH2 to 0.76 Kilonewtons, the Safehip® to 2.24 Kilonewtons, and the Safetypants to 2.76 Kilonewtons. The thicker HipSavers™ hip protector outperformed all but the KPH1 and KPH2. This is of particular interest because the protector is made from soft, relatively flexible material, which might be more comfortable to wear.

### **3.6.1 Discussion of laboratory studies**

Direct comparison of these studies is not possible because of the different approaches used. Researchers have used a range of impact forces, and various ways of simulating the pelvis. However, some common findings emerge from the data. First, protectors have two modes of action: absorbing the force of the fall, and dispersing the impact of the fall to surrounding tissues. Absorbing the force appears to be a relatively inefficient approach, providing comparatively little attenuation unless very thick pads are used. The exception to this is the HipSavers™ hip protector (The HipSaver Company, Inc., 1996, 2000), which appears to work effectively to absorb the force of a fall using a high-density foam pad. Hip protectors that disperse the force of a fall are shaped to be more convex than the anatomy of the hip, leaving a gap over the trochanter, in order to prevent direct contact with the tissue over the trochanter and disperse the impact force into the surrounding tissues. It appears that the greater the gap over the trochanter and the more rigid the material used to shape the hip protector, the greater the force attenuation provided. A novel design is that described by Robinovitch *et al*, (1995) as a flexible membrane containing a suspension of micro-particles.

Although a radically different technology, this too appears to work by dispersing the force of the impact away from the greater trochanter.

If the force attenuation properties of the hip protectors tested in these studies are evaluated in the light of the figures derived from studies estimating fracture forces and the force of falls (mean fracture force of 2.1 Kilonewtons and mean force of falls 5.6 Kilonewtons), then the hip protectors described by Parkkari *et al* (1995, 1997), Robinovitch *et al* (1995), Kannus *et al* (1999b), and The HipSaver Company, Inc. (2000), should reduce the force sufficiently to prevent most fractures. However, only the design tested by Parkkari *et al* (1995, 1997), and Kannus *et al* (1999b) reduced the force to levels near the lower range of fracture forces described in the literature (less than 1 Kilonewton).

Existing designs and materials mean that hip protectors as presently available are a compromise between efficacy, comfort and appearance. The softer, more flexible HipSavers™ hip protector (The HipSaver Company, Inc., 2000) is a promising development in this respect, although randomised controlled trials of effectiveness are not yet available for this design. Thick, rigid materials that sit up from the hip will be too uncomfortable and obtrusive for everyday wear. No matter how efficient they may be in attenuating the force of a fall, they are useless if they are not worn at the time of the fall. On the other hand, a certain degree of rigidity, thickness and convexity of material is necessary to make the garments worthwhile as protection.

This compromise is reflected in the design of the Safehip® hip protectors used in the present study. Two studies tested this design. Mills (1996) found that the force at the hip was reduced from 3.9 Kilonewtons to 1.67 Kilonewtons but that little of the force of the fall was shunted into the surrounding tissues. The hip protector had a clearance of only 5 mm over the tissue covering the greater trochanter, and deformed at higher impacts to lie directly over the

trochanter. The softness of the tissue surrounding the trochanter also allowed the protector to move easily down onto the trochanter at higher impact forces. Mills (1996) concludes that for minor falls from a height of 20 cm the protector distributes about half the impact force away from the trochanter, with a proportion absorbed by the flexion of the shell and compression of the inner foam lining. However, for falls from 40 cm the trochanter receives most of the force. He argues that a stiffer shell and thicker foam would decrease the impact of major falls on the trochanter, but recognises that the protector is a compromise between protection and comfort. Kannus *et al* (1999b) tested the protector at three impact levels: 4.33 Kilonewtons, 7.23 Kilonewtons, and 10.84 Kilonewtons. They took the fracture threshold to be 3.1 Kilonewtons (plus or minus 1.2 Kilonewtons). In the low-impact experiment, which produced an impact force of 3.74 Kilonewtons in the surrogate hip, the protector reduced the impact force below the fracture range. In the medium impact experiment, the Safehip<sup>®</sup> attenuated the force from 7.23 Kilonewtons to 2.24 Kilonewtons, and in the high impact experiment, from 10.84 to 4.64 Kilonewtons. Other hip protectors attenuated the force more effectively, but only by using a design with more convex shape, which might be less acceptable to wearers. It is likely that the Safehip<sup>®</sup> hip protector, even when worn correctly, would prevent most but not all hip fractures. People with very fragile bones (including many residents of nursing and residential homes) could have a fracture threshold of less than 1.0 Kilonewton (Lotz and Hayes, 1990; Oikuzumi *et al*, 1998), which is well below the forces transmitted through the Safehip<sup>®</sup> hip protector.

### **3.7 Clinical Trials**

Once laboratory studies have been done, the question remains: are hip protectors efficacious in preventing older people who fall from suffering a hip

fracture? This question is best answered through randomised controlled clinical trials. Evidence is provided both by single trials and by the meta-analysis of multiple trials.

### **3.7.1 Systematic review**

Meta-analysis, or systematic review of original clinical research trials is one of the most influential approaches to the analysis of scientific data (Greenhalgh and Donald, 2000; Davey Smith and Egger, 1998). A systematic review collects and analyses the information from the individual trials in an attempt to gauge the cumulative weight of evidence. The only review of the use of hip protectors identified in the literature is *Hip protectors for preventing hip fractures in the elderly* (Parker *et al*, 2000). This review was carried out under the auspices of the Cochrane Collaboration, an international group dedicated to the systematic review of randomised controlled trials. Reviews carried out by Cochrane working groups must accord with strict guidelines, which are well accepted in the literature (Sutton *et al*, 1998). The review can therefore be approached with a degree of confidence in its methodology and findings. The strength of evidence from the review is obviously dependent on the quality of the individual studies reviewed. However, the review itself must be carried out rigorously if its conclusions are to be relied upon. Sutton *et al* (1998) offer a series of recommendations for good practice in carrying out a systematic review, and these will be used to help evaluate the study by Parker *et al* (2000). The evaluation of the review in the light of the recommendations is set out below.

1. *The objectives and methods of the review should be set out before the study is done.* This is to reduce the likelihood of the reviewers altering the terms of the review to favour a certain outcome once the material has

been gathered. Parker *et al* (2000) set out their protocol several months before the publication of the first version of the review in 2000 and have followed it through several subsequent updates of the material. The protocol details the objectives of the review, the search strategy, the criteria for selecting trials, and the methods of data collection and analysis. The main objective was to “determine if external hip protectors reduce the incidence of hip fractures in elderly persons following a fall.” (Parker *et al*, 2000, P.1)

2. *The compilation of studies should be comprehensive and the search methods and sources clearly documented.* The review sets out the search strategy in sufficient detail for a reader to be able to replicate it. The main computerised databases were searched, together with the Cochrane Controlled Trials Register (which lists trials in progress as well as those completed), and the reference lists of articles obtained through the initial search. In addition, the reviewers contacted the authors of the reports seeking additional data. This strategy is likely to have identified the great majority of relevant material. However, Sutton *et al* (1998) also recommend searching SCISEARCH (the Science Citation Index), hand-searching of relevant journals, identifying “grey material” (reports, booklets and conference proceedings), searching the internet, and consulting manufacturers, which Parker *et al* (2000) did not do.
3. *The methodological quality of the trials reported should be assessed, and the assessment criteria reported.* Parker *et al* (2000) list ten areas to be assessed, including the method of randomisation, concealment of allocation, tracking of all participants, an “intention to treat” analysis, description and matching of treatment groups, blinding of outcome assessors, a minimum of 12 months follow-up, adherence to treatment, and the manner of data collection. Randomised controlled trials are considered the most reliable method of determining the effect of an intervention (Sutton *et al*, 1998), so it is reasonable to place the method of randomisation first on this list. The remainder of the assessment areas

involve identifying weaknesses in relation to bias, confounding variables, and validity. Two important areas that are not identified by Parker *et al* (2000) (although they are partly addressed in the body of the review) are the adequacy of the sample (Greenhalgh and Donald, 2000) and the appropriateness of the statistical tests (Sutton *et al*, 1998), both of which affect the validity of the results.

4. *Identification of a common set of outcome variables that is consistent with those in the primary studies.* The review sought data for the incidence of hip and other fractures, reported falls, mortality, adherence, and complications of use of hip protectors. These are consistent with the objective of the review.
5. *Extraction of outcome variables from primary studies using a reproducible, standardised approach designed to avoid extractor bias.* Two reviewers independently extracted outcome variables from each study, and rated their methodological quality using the standardised approach described in 3 and 4 above. Differences were resolved by discussion. This approach would seem to make bias unlikely.
6. *Where possible, perform a quantitative synthesis of primary study data, using methods that allow for important variations between studies.* Parker *et al* (2000) tested for variations between studies by estimating the heterogeneity between comparable trials “using a standard chi-squared test.” (P.3). Studies may be considered homogenous when differences in effect size are due to sampling error. In other words, the samples are taken from a population with the same underlying true effect size (Sutton *et al*, 1998). If this is not the case, then the reasons for heterogeneity of the effect size must be elucidated and taken into account in the analysis. Even apparently similar trials may differ, for example through differing definitions of outcomes, variations in management and analysis of the trial; through differences in inclusion and exclusion criteria, or between baseline states of available participants, or between interventions and settings (Sutton *et al*, 1998).

7. *The results of the review should be evaluated in the light of the issues identified in the preceding recommendations.* Parker *et al* (2000) discuss a number of relevant issues. The methodological quality of the studies was assessed and scored in the light of the ten areas identified in the review, and the scores presented in a table. Reasons for excluding studies are presented, together with significant differences in design between studies and the impact of this factor on the feasibility of combining outcomes for analysis. In particular, the fact that the largest studies were randomised by cluster reduces their power and means that their results cannot be combined with confidence with those from studies randomised by individual. The main outcome variables are reported, and issues related to population and sample size are discussed. Factors contributing to heterogeneity (differences in population, type of hip protector, definition of outcome variables, and length of follow-up) are discussed. The possible impact of publication bias (the observation that trials showing a significant effect in favour of an intervention are more likely to be published than those that do not) is not explored. However, the reviewers identify a number of trials in progress and their subsequent inclusion in the review should help to reduce publication bias in future updates.
8. *The key aspects of the report should be clearly presented in order to enable critical appraisal and to facilitate replication of the review.* Parker *et al* (2000) set out the main elements of the studies in tables, comparing relative risks and giving confidence intervals. Important issues are discussed in the text. A number of graphical displays assist in comparisons between trials.
9. *The report should include a discussion of the methodological limitations of the primary studies and the review itself.* Recommendations should be explicit and detail the evidence on which they are based. Any proposal for future research should also recommend appropriate clinical and methodological requirements. Parker *et al* (2000) discuss the

methodological limitations of the primary studies systematically and in detail. They do not discuss any limitations of their own review. Their recommendations for practice are brief and lack detail. Proposals for future research are consistent with the results of the review, although their recommendations in relation to adherence are limited to exploring different types of hip protector. Other factors that might be usefully explored in this area include the characteristics of wearers and non-wearers, the organisational and cultural environment in which institutionalised older people live, approaches to introducing hip protectors to health care staff and potential users, and encouraging continued use.

Overall, Parker *et al*'s (2000) review is methodologically strong. They were seeking to determine the efficacy of hip protectors in reducing the incidence of older people following a fall, so they focussed on those studies that were randomised by individual. The remaining three, much larger, studies were cluster randomised, which makes them more suitable for measuring effectiveness rather than efficacy. Consequently, Parker *et al* (2000) state that "it was not possible to determine if this difference between groups was statistically significant." (P.1). They conclude that hip protectors appear to reduce the risk of hip fracture within high-risk populations and that acceptability of the hip protectors to wearers is a problem, because of discomfort and practical difficulties.

### **3.7.2 Individual clinical trials**

The randomised controlled trials will be evaluated in the light of the recommendations in the CONSORT (Consolidated Standards Of Reporting Trials) statement (Moher *et al*, 2001). This is a checklist and flow diagram based partly on evidence, partly on consensus amongst an international group of clinical trialists, statisticians, epidemiologists, and biomedical journal

editors. The checklist and flow diagram contain recommendations designed to improve the reporting of randomised controlled trials by encouraging the reporting of information that is essential to judging the reliability or otherwise of the findings. Elbourne and Campbell (2001) have added further recommendations designed to extend the CONSORT statement to include cluster randomised trials. Evaluating the trials involving hip protectors using these recommendations should allow a judgement to be made about the weight that should be given to their results. The randomised controlled trials are summarised in Table 3.1.

The first major clinical trial reported in the literature is that by Lauritzen *et al* (1993). This trial was designed to investigate the effect of external hip protectors on the prevention of hip fractures in residents of a nursing home. The hip protectors were of the relatively rigid, force-dispersing type, fitted into special underwear. The home consisted of 28 wards. Residents of 10 wards (167 women and 80 men) were given three pairs of hip protectors, the remaining 18 wards (277 women and 141 men) acting as controls. Residents were followed over the next 11 months and the number of hip fractures noted in each group. In the intervention group 8 of 247 residents suffered hip fracture. In the control group the figures were 31 of 418 residents. The relative risk of hip fracture in the intervention group was 0.44 (95% confidence interval [CI] 0.01 to 0.94).

In the report, the participants are described in terms of age, sex, mobility, mental status, and markers for osteoporosis, but this is not broken down between intervention and control groups. No eligibility criteria are given. There is little detail about the nursing home or the wards within it (for example the size of wards, whether they differed in terms of their medical or nursing focus, and how they were organised). The method of collecting data on

**Table 3.1 Randomised controlled trials of effectiveness**

Author(s), country and objectives	Setting, population, and intervention	Design	Key results	Commentary
<p>Lauritzen <i>et al</i> (1993)</p> <p>Denmark</p> <p>Objectives: to investigate the effect of external hip protectors on the prevention of hip fractures.</p>	<p>Setting: a large nursing home.</p> <p>Population: men and women aged 70 years or more.</p> <p>Intervention: wearing a force-dispersing hip protector (Sahva) fixed in special underwear.</p>	<p>Cluster randomised by ward: 10 wards (247 participants) in the intervention group, 18 wards (418 participants) in the control group.</p> <p>Intervention period: 11 months.</p>	<p>Intervention group: 8 hip fractures. Control group: 31 hip fractures.</p> <p>Relative risk of hip fracture 0.44 (95% CI 0.01 to 0.94).</p> <p>Adherence (hip protector worn at the time of a fall): 24%.</p>	<p>Randomisation was by cluster but analysis by individual. This may mean the CI has been underestimated.</p> <p>Adherence is based on results from a small sub-sample.</p>
<p>Ekman <i>et al</i> (1997)</p> <p>Sweden</p> <p>Objectives: to investigate the effect of external hip protectors on the prevention of hip fractures.</p>	<p>Setting: Four nursing homes.</p> <p>Population: men and women - no other details given.</p> <p>Intervention: wearing a force-dispersing hip protector attached to participants' underwear.</p>	<p>Cluster randomised by home: one home (302 participants) in the intervention group, 3 homes (442 participants) in the control group.</p> <p>Intervention period: 11 months.</p>	<p>Intervention group, 4 hip fractures. Control group: 17 hip fractures.</p> <p>Relative risk of hip fracture 0.33 (CI 0.11 to 1.0, level not stated).</p> <p>Adherence (not defined): 44%.</p>	<p>Randomisation was by cluster but analysis by individual. This, together with the small number of clusters, may mean the CI has been underestimated.</p> <p>Baseline data does not show gender balance between groups.</p>

**\Table 3.1 continued**

<b>Author(s), country and objectives</b>	<b>Setting, population, and intervention</b>	<b>Design</b>	<b>Key results</b>	<b>Commentary</b>
<p>Jantti <i>et al</i> (1998)</p> <p>Finland</p> <p>Objectives: to investigate the effect of external hip protectors on the prevention of hip fractures.</p>	<p>Setting: a nursing home.</p> <p>Population: able to walk without help, with a history of a fall.</p> <p>Intervention: wearing a force-dispersing hip protector fixed in special underwear.</p>	<p>Randomised by individual (closed envelopes): 36 participants in each of intervention and control groups.</p> <p>Intervention period: 12 months.</p>	<p>Intervention group, 1 hip fracture. Control group: 8 hip fractures.</p> <p>Fisher's exact test <math>p</math> 0.028 (no CI).</p> <p>Adherence (still wearing at 12 months): 36%.</p>	<p>Small sample size and high rate of attrition compromise the power of the study.</p> <p>No baseline characteristics presented.</p> <p>Overall adherence difficult to estimate.</p>
<p>Hindso and Lauritzen (2000)</p> <p>Denmark</p> <p>Objectives: to investigate the effect of external hip protectors on the risk of subsequent hip fractures.</p>	<p>Setting: two hospitals</p> <p>Population: patients aged 75 years or more admitted with hip fracture.</p> <p>Intervention: wearing a force-dispersing hip protector (Safehip<sup>®</sup>) fixed in special underwear.</p>	<p>Case cohort study: one hospital as intervention group (303 participants), the other as control group (244 participants).</p> <p>Intervention period: 12-18 months.</p>	<p>Absolute numbers not given. Zero hip fractures amongst the sub-group of 60 patients who wore the hip protectors regularly.</p> <p>Adherence: Insufficient detail to determine adherence accurately.</p>	<p>Analysis by intention to treat, by those initially accepting the hip protectors, and by continued use, showed a non-significant reduction in risk.</p> <p>No baseline characteristics of individuals or hospitals presented.</p>

**Table 3.1 continued**

<b>Author(s), country and objectives</b>	<b>Setting, population, and intervention</b>	<b>Design</b>	<b>Key results</b>	<b>Commentary</b>
<p>Chan <i>et al</i> (2000)</p> <p>Australia</p> <p>Objectives: to evaluate the effectiveness and acceptability of a softer hip protector.</p>	<p>Setting: nine nursing homes.</p> <p>Population: residents identified by staff as at high risk of falling.</p> <p>Intervention: wearing a new, softer and more flexible hip protector.</p>	<p>Randomised by individual within homes: 40 participants in the intervention group, 31 in the control group.</p> <p>Intervention period: 9 months.</p>	<p>Intervention group: 3 hip fractures. Control group: 6 hip fractures</p> <p>Relative risk of hip fracture 0.264 (95% CI 0.073 – 0.959).</p> <p>Adherence (the percentage of falls when residents were wearing hip protectors): 50%.</p>	<p>The calculation of relative risk may be influenced by the use of the number of falls in each group (rather than the number of participants) as the denominator. Similar problems may arise for estimating adherence.</p> <p>Small sample size reduces the power of the study.</p>
<p>Kannus <i>et al</i> (2000)</p> <p>Finland</p> <p>Objectives: to investigate the effect of external hip protectors on the prevention of hip fractures.</p>	<p>Setting: geriatric long-stay facilities and outpatient units for supported living at home</p> <p>Population: men and women who were 70 years or older, were able to walk, and who had a pre-defined risk factor for hip fracture</p> <p>Intervention: wearing a force-dispersing hip protector (KPH) fixed in special underwear.</p>	<p>Cluster Randomised by treatment units (the number of treatment units is not stated): 653 participants in the intervention group, 1148 participants in the control group.</p> <p>Intervention period: 18 months.</p>	<p>Intervention group: 13 hip fractures. Control group: 67 hip fractures.</p> <p>Relative risk of hip fracture 0.4 (95% CI 0.2 – 0.8).</p> <p>Adherence: (the number of days the hip protector was worn as a percentage of all available follow-up days) 48%.</p>	<p>Randomisation was by cluster but analysis by individual. This may mean the CI has been underestimated.</p> <p>The analysis is not by intention to treat (a significant proportion of eligible residents are not included in the analysis).</p>

**\Table 3.1 continued**

<b>Author(s), country and objectives</b>	<b>Setting, population, and intervention</b>	<b>Design</b>	<b>Key results</b>	<b>Commentary</b>
<p>Harada <i>et al</i> (2001)</p> <p>Japan</p> <p>Objectives: to investigate the effect of external hip protectors on the prevention of hip fractures.</p>	<p>Setting: six nursing homes.</p> <p>Population: female, able to stand, not wheelchair dependent.</p> <p>Intervention: wearing a force-dispersing hip protector fixed in special underwear.</p>	<p>Randomised by individual within homes: 88 participants in the intervention group, 76 in the control group.</p> <p>Intervention period: 12 months (24 months in one home).</p>	<p>Intervention group: 1 hip fracture.</p> <p>Control group: 8 hip fractures.</p> <p>Cox's hazard ratio 0.082 (95% CI 0.009 – 0.746).</p> <p>Adherence (the number of days the hip protector was worn as a percentage of all available follow-up days): 87%.</p>	<p>The limitations of this study are its small sample size and narrow eligibility criteria.</p> <p>Its strengths are the inclusion of other risk factors in the analysis, and the high adherence achieved amongst participants.</p>
<p>Cameron <i>et al</i> (2001)</p> <p>Australia</p> <p>Objectives: to investigate the effect of introducing external hip protectors on the prevention of hip fractures.</p>	<p>Setting: 32 nursing homes and hostels.</p> <p>Population: female, over 75 years, two or more falls in the last month, not bed or chair fast.</p> <p>Intervention: support from a nurse facilitator to wear a force-dispersing hip protector (Safehip®) fixed in special underwear.</p>	<p>Randomised by individual within homes/hostels: 86 participants in the intervention group, 88 in the control group.</p> <p>Intervention period: 18 months.</p>	<p>Intervention group: 8 hip fractures (only one when the hip protector was worn).</p> <p>Control group: 7 hip fractures.</p> <p>Cox's hazard ratio 1.46 (95% CI 0.51 – 4.20).</p> <p>Adherence (the number of days the hip protector was worn in daylight hours as a percentage of all available follow-up days): 57%.</p>	<p>The authors acknowledge that insufficient sample size and low level of adherence mean the study had low statistical power to detect anything but a very large effect.</p>

**\Table 3.1 continued**

<b>Author(s), country and objectives</b>	<b>Setting, population and intervention</b>	<b>Design</b>	<b>Key results</b>	<b>Commentary</b>
<p>Torgerson and Watt (2002)</p> <p>England</p> <p>Objectives: to investigate the effect of external hip protectors on the prevention of subsequent hip fractures.</p>	<p>Setting: private homes.</p> <p>Population: men and women with previous hip fracture.</p> <p>Intervention: wearing a force-dispersing hip protector (Safehip®) fixed in special underwear.</p>	<p>Randomised by individual: 182 participants in the intervention group, 184 in the control group.</p> <p>Intervention period: 14 months.</p>	<p>Intervention group: 8 hip fractures (only one when the hip protector was worn). Control group: 2 hip fractures.</p> <p>OR 3.10 (95% CI 0.62 to 15.58).</p> <p>Adherence: not reported.</p>	<p>Short report: no details of sample size calculation, randomisation procedures, eligibility criteria, or participant characteristics.</p>
<p>Meyer <i>et al</i> (2003)</p> <p>Germany</p> <p>Objectives: to investigate the effect of an intervention programme to increase the use of hip protectors on the prevention of subsequent hip fractures.</p>	<p>Setting: 42 nursing homes.</p> <p>Population: men and women aged 70 years or more, who were not bedridden.</p> <p>Intervention: single education session for nursing staff, who then educated residents; provision of force-dispersing hip protector (Safehip®) fixed in special underwear.</p>	<p>Randomised by cluster: 25 clusters (459 residents) in the intervention group, 24 clusters (483 residents) in the control group.</p> <p>Intervention period: 15 months.</p>	<p>Intervention group: 21 hip fractures (four when the hip protector was worn). Control group: 39 hip fractures.</p> <p>AR -3.5% (95% CI -7.3% to 0.3%, <i>p</i> 0.072).</p> <p>Adherence (proportion of residents who wore the hip protectors during at least one fall): 33%.</p>	<p>Randomisation by cluster taken into account in analysis.</p> <p>8% of control residents wore hip protectors.</p> <p>Only 15% of population in the homes appear to have taken part.</p>

outcomes is not specified. There is no information on calculation of sample size. Randomisation was by an independent doctor selecting numbers representing the wards to receive the hip protectors. This is the only detail given, so the degree to which allocation and assignment were concealed cannot be judged.

The method of randomisation (by ward) makes this study a cluster randomised trial, which raises a number of issues for the design of the study and the analysis of the results. Statistical analysis of trials randomised by the individual assumes that all individuals will respond to the intervention independently (Elbourne and Campbell, 2001). However, individuals within a particular cluster (in this case a ward) may be more like each other, than they are like individuals in other clusters (for example because they preferred to be placed with residents from a similar social group, or because different wards serve different categories of resident). Their behaviour may also be influenced by common elements (for example, culture, habits, and environmental factors) in the cluster and in the way it is organised. As a result, variation between clusters may be greater than variation within clusters, which influences the effect size of the intervention. This leads to a loss of statistical power compared to an individually randomised study containing the same number of individuals (this is known as the “design effect” [Ukoumunne *et al*, 1999a,b]), with a consequent need to increase the size of the sample. Lauritzen *et al* (1993) give no rationale for their use of cluster randomisation. It appears to be at odds with their objective, which seems primarily to be an evaluation of the efficacy of hip protectors (in which case randomisation by individual within wards might have been a more useful design). Cluster randomised trials are better suited to testing the effectiveness of interventions in an everyday environment. As noted above, sample size calculation is not reported, so it is not possible to say whether the design effect was taken into account. In fact, although randomisation was by cluster, it appears that in all other respects the trial was carried out and

analysed as if it had been randomised by individual. No further details are given in relation to the results by ward. Failure to take cluster randomisation into account during analysis of the results is likely to produce confidence intervals that are too narrow (Ukoumunne *et al*, 1999a,b). Given that the relative risk of hip fracture in the intervention group was 0.44 and the 95% confidence interval was calculated as 0.01 – 0.94, it is possible that if cluster randomisation had been taken into account, the result would not have been statistically significant.

There is no report of blinding. Obviously, this is not feasible for participants, but blinding of those assessing the outcomes would have been possible. Having said this, the outcomes were not susceptible to biased judgements, as they are dichotomous and readily measurable. The flow of participants through the trial is not clearly described. In particular, the numbers in each ward (which, from the figures on falls, appear to have been highly variable) are not given; nor are the number of participants who died, or their distribution between intervention and control groups. The authors simply report that those who died were replaced immediately by new arrivals. The adherence data are based on a sub-group of two wards from the intervention group (64 residents), and two from the control group (90 residents). The definition of adherence is not stated, but appears to be when the hip protector was worn at the time of a fall. This happened in 11 of 45 falls, giving a figure of 24 percent. This figure is difficult to interpret in that residents who are wearing the hip protectors may fall on multiple occasions, so inflating the figure for adherence. Alternatively, residents may wear the protectors regularly, but not fall, and so make no impact on the figures for adherence. In addition, in the absence of data on the number of falls in the remaining 26 wards, this is a small sample from which to estimate adherence. It also provides no information of how adherence might have changed over time, or of the rate of initial acceptance. Results are stated in absolute numbers, and the statistical methods are clearly stated. However, there is no discussion of possible

confounding factors. The authors conclude that their study indicates that hip protectors can prevent hip fractures in residents of nursing homes. However, if they had analysed their results to allow for the effects of cluster randomisation, it is possible that they would have found that the effect was statistically insignificant.

Buckler *et al* (1997) describe the use of hip protectors in a 25 bed dementia unit for veterans needing continuing care. They present historical data showing an increase in falls (from 18 to 80 a year) in the unit over a four-year period. Hip protectors of the force-dispersing type were introduced for the second two years, targeting veterans at high risk of falling (six veterans in year three, ten in year four). There were two hip fractures in each of the first two years, but none in the next two years. No statistical analysis is presented, and possible confounding factors are not discussed, so nothing can be inferred in relation to the effectiveness of the hip protectors. The main point of the study, which is supported by the observations reported, is that hip protectors appear to be suitable for older people who are demented and remain independently mobile.

Ekman *et al* (1997) tested the effectiveness of a force-dispersing hip protector of a similar type to that used by Lauritzen *et al* (1993), except that it was designed to be held in place by a resident's own underwear, rather than a specially designed garment. In their short report, they describe how one of four nursing homes was randomly assigned to offer the hip protectors, the remaining three acting as controls. There were 302 residents in the intervention home, and 442 in the control homes. Residents were followed up over the next 11 months and the number of hip fractures and falls recorded, together with adherence to use of the hip protectors. In the intervention group, four of 302 residents suffered hip fracture, compared to 17 of 442 in the control group. The relative risk of hip fracture in the intervention group was 0.33, with a confidence interval of 0.11 to 1.0.

Eligibility criteria are not described, and the methods of data collection are not reported. No information is given on how sample size was determined, or of the randomisation process, or of blinding of outcome assessors. The statistical methods are clear, although insufficient data are given to allow independent analysis of sub-group results. The flow of participants through the study is not shown. Baseline data on intervention and control groups is presented, but this leaves out the sex of residents, a major factor influencing risk of hip fracture. Adherence is stated to be 44 percent, but there is no description of how this figure was derived or of the rate of initial acceptance of the hip protectors.

This study suffers from a similar weakness to that of Lauritzen *et al* (1993): it randomises by cluster but analyses by individual, with no discussion of how cluster randomisation might affect sample size or analysis of the results. The distorting effect of this approach is likely to be magnified by the large size of the clusters and their relatively small number (Ukoumunne *et al*, 1999a,b). This must cast doubt on the significance of the findings.

Jantti *et al* (1998) tested the effectiveness of a force-dispersing hip protector amongst residents of a nursing home in Finland. Residents with a history of a fall, and who could walk without help were eligible for the study. Thirty-six participants were offered the hip protectors and 36 acted as controls. The intervention period was 12 months. Seventeen participants in the intervention group and 25 in the control group died or were permanently admitted to hospital during the intervention period. At the end of the study period, 13 of the intervention group were still using the hip protectors. The other six had stopped between one and nine months into the study period. In the intervention group, one participant suffered hip fracture, compared to eight (including a dislocation of a hip prosthesis) in the control group (Fisher's exact test  $p$  0.028).

This report is in the form of a letter and is therefore short of some important information. Randomisation was done by drawing closed envelopes, but no further details are given. Demographic and other baseline data is not reported, which means the influence of confounding variables cannot be assessed. The level of adherence is difficult to estimate from the figures given. This study shows a marked difference between the intervention and control groups in terms of the rate of hip fracture. However, the small sample size and high attrition rate reduce the power of the study. It is not clear whether analysis was on the basis of intention to treat. No confidence intervals are given, so the likely effect of the small sample size is difficult to estimate.

In a study presented as a short abstract, Hindso and Lauritzen (2000) tested the effectiveness of Safehip<sup>®</sup> hip protectors (force-dispersing protectors similar to those used by Lauritzen *et al* [1993]) in preventing hip fracture in older people of more than 74 years who had already suffered a hip fracture. Three sets of hip protectors were offered to 303 patients in one hospital, and 244 patients from another hospital acted as controls. Patients were followed up over 12 to 18 months. Sixty-five percent of patients accepted the hip protectors. The rate of hip fracture in the control group was 4.6 percent. Analysis by intention to treat did not show a significant difference between groups; neither did analysis based on those initially accepting the hip protectors; nor when based on continued use. All of these groups showed a non-significant reduction, but only the sub-group of 60 patients who used the hip protectors regularly or everyday showed a statistically significant reduction: none suffered hip fracture.

This study is difficult to appraise because the short abstract lacks some necessary detail. The objectives of the study are to “evaluate the effect of hip protectors on risk of subsequent hip fractures.” (Hindso and Lauritzen, 2000,

P. S150). However, it is not clear whether this is the effect of offering the hip protectors to this group (which is consistent with the intention to treat analysis), or the effect of wearing the protectors (which is consistent with the final sub-group analysis). The relevance of analysis based on those who accepted, or who continued to use hip protectors intermittently is not made evident. There is no data on the characteristics of groups, sub-groups, or the hospitals from which they came. This means the reader cannot be satisfied that there were no confounding differences between the groups. Sample size is not discussed and confidence intervals are not given. The absence of important methodological information and the relatively small size of the sub-group using hip protectors regularly (60 patients) mean this result should be treated with caution.

Chan *et al* (2000) evaluated the effectiveness and acceptability of a newly designed hip protector amongst residents of nursing homes. In contrast to the relatively rigid force-dispersing hip protector, this protector is made of flexible “EVA foam” that is 25 millimetres thick, and is designed to absorb the force of a fall. Staff from nine nursing homes identified residents that they considered to be at high risk of falling. Forty residents were randomised to receive hip protectors and 31 to act as controls. The hip protectors were not worn at night. Residents were followed up over nine months. Three fractures occurred in the intervention group and six in the control group. The relative risk of hip fracture in the intervention group was 0.264 (95% CI 0.073 to 0.959).

No eligibility criteria for participants are described, and the selection of participants relied on staff perceptions of the residents’ risk of falling, rather than any formal evaluation. This makes it difficult to identify the particular population from which these residents are drawn. The hip protectors are of a different type than those evaluated elsewhere in the literature. They are described in detail and illustrated in a figure. However, there is no evidence

that their properties have been formally tested in the laboratory before their use in this study. Efficacy is assumed from the successful use of the material in matting for martial arts. This seems to be an unwarranted inference, as the populations (frail older people compared to trained athletes) and mode of action in the case of a fall (protecting a bony prominence compared with cushioning the entire body) are very different. Sample size calculation is not described and the small number of participants, together with the relatively short intervention period, means the study is likely to lack statistical power. Randomisation of participants is vaguely reported ("Random assignment of subjects was achieved in most nursing homes..." [Chan *et al* 2000, P.27]). No baseline data on participants is offered.

When calculating the relative risk of hip fracture, the denominator is the number of falls in each group rather than the number of residents in each group. Presumably, this is because efficacy can be defined as preventing hip fracture in the event of a fall. However, there are two important limitations to this approach. First, it assumes that all falls are equally likely to lead to a hip fracture, whereas falls to the side represent a greater risk than those forward or backward (Greenspan *et al*, 1994, 1998; Slemenda, 1997). Chan *et al* (2000) report that 74 percent of falls were of unknown orientation, with only 9.6 percent known to be falls to the side. Second, the figures would be influenced by residents who fall more frequently than do others. In this study, participants in the intervention group fell 191 times (4.78 falls per resident) and those in the control group 101 times (3.26 falls per resident). Relative risk is calculated based on the number of fractures per fall and the intervention group fell proportionately more often than the control group (a fact that in itself tends to support the efficacy of the hip protectors). However, the relative risk is lower than that obtained if the calculation is based (as it is in most other studies) on the number of fractures per participant (RR 0.264 compared to 0.39). Adherence was measured as 50.3 percent and defined as the percentage of falls that took place when residents were wearing hip

protectors. This figure is also difficult to interpret in that residents who are wearing the hip protectors may fall on multiple occasions, so inflating the figure for adherence. Alternatively, residents may wear the protectors regularly, but not fall, and so make no impact on the figures for adherence. Given the limitations in relation to recruitment, sample size, lack of baseline data, and randomisation, together with the wide confidence intervals reported for relative risk, the results from this study should be treated with caution.

Kannus *et al* (2000) evaluated the effectiveness of a force-dispersing hip protector in preventing hip fracture amongst older people in geriatric long-stay facilities and those attending outpatient units for supported living at home in Finland. Treatment units were randomised to intervention and control groups in a 1:2 ratio, giving 650 residents in the intervention group (of whom 204 refused to take part), and 1075 in the control group (of whom 94 refused to take part). Residents were followed up over 18 months and the number of hip, pelvic and other fractures recorded. Adherence was measured through direct observation by caregivers and defined as wearing the hip protectors for at least one hour that day. Thirteen participants in the intervention group and 67 in the control group suffered a hip fracture. The relative risk of hip fracture in the intervention group was 0.4 (95% CI 0.2 to 0.8). There was no significant difference between the groups in the rate of pelvic or limb fractures. Mean adherence (expressed as the number of days the hip protector was worn as a percentage of all available follow-up days) was 48 percent. The number needed to treat for one year to prevent one hip fracture was calculated as 41 persons (95% CI 25 to 115).

The facilities and units taking part in the study were selected by research coordinators from the 22 community health centres who run them. However, the number of units taking part is not clear in the report and there is no indication of the basis on which these units were selected. Within each unit men and women who were 70 years or older, were able to walk, and who had

at least one pre-defined risk factor for hip fracture were eligible for the study. Treatment units were then randomised to intervention or control groups by an independent physician using sealed envelopes. Comprehensive baseline data on all participants is presented in a table, together with a diagram showing the flow of participants through the study.

The relative risk of hip fracture is calculated based on the rates of hip fracture per 1000 person-years (21.3 in the intervention group and 46.0 in the control group). This is reasonable because of the numbers of participants inevitably lost to the study and the numbers joining during the study during the 18-month intervention period. However, in order to evaluate the effectiveness of an intervention, it is usual to include all participants in the analysis according to the intervention to which they were allocated, whether they received it or not (an intention to treat analysis). This reflects the obstacles to adherence that might be found in everyday practice, and the spread of recipients who would normally be offered the treatment (Cochrane reviewers' handbook, 2001). In randomising by treatment unit (rather than by individual), Kannus *et al* (2000) appear to be setting out on such a study. However, they do not include in their analysis the 298 who refused to participate (204 of whom were in the intervention group). They also exclude (from the time they left the study) the 71 participants who subsequently refused to continue with the hip protectors, the 219 who "dropped out" of the intervention group, the 90 who refused to continue with the study in the control group, and the 438 who "dropped out" of the control group. These 1,116 participants represent 53 percent of the 2099 invited to take part in the study over the 18-month period. In the intervention group, the proportion is even greater: 494 of 857 participants (57%). It is also notable that 207 participants were recruited to replace the 219 who dropped out of the intervention group, but only 167 participants were recruited to replace the 438 who dropped out of the control group, again suggesting that an intention-to-treat analysis was not carried out. Had an intention-to-treat analysis been carried out, it is possible that the

intervention effect would be diluted and any difference in relative risk reduced. The number needed to treat might also be greater. In terms of adherence, this dilution effect is even more influential, as participants dropping out of the study are probably no longer using the hip protectors (i.e. their adherence is zero) yet they are no longer included in the analysis for adherence.

These anomalies indicate that the trial perhaps tests efficacy rather than effectiveness. Even here there are difficulties, because randomisation was by treatment unit (and the number of units is not clear) yet the analysis is by individual. A sample size calculation was carried out but it is not stated whether the design effect of randomisation by cluster was taken into account. This raises the possibility that the study has insufficient statistical power. Kannus *et al* (2000) discuss this issue and argue that because hip fracture is a relatively rare event, the reduced variation between individuals within the cluster (the treatment unit) is likely to have had little influence on the results. However, more important than the frequency of the event is the susceptibility of the event to cluster related factors. For example, there are likely to be differences between participants in geriatric long-stay facilities and those attending outpatient units for supported living at home. Residents of nursing and residential homes have been estimated to be three to seven times more likely to suffer a hip fracture than non-institutionalised older people (Ooms *et al*, 1994; Slemenda, 1997; Norton *et al*, 1999). It is possible that a similar disparity exists between the different units in this study, but Kannus *et al* (2000) give no figures for the number of fractures in the different types of units.

Sub-group analysis of all falls within the intervention group shows that there were 4 hip fractures amongst participants wearing the hip protectors and 9 amongst those who were not. Participants falling whilst wearing the hip protectors had a relative risk of hip fracture of 0.2 (95% CI 0.05 to 0.5) compared to those who fell without the hip protectors. However, participants

were not randomised within the intervention group, so the validity of these results must be in question. Overall, the trial shows a marked reduction in the rate of hip fracture amongst those included in the intervention group analysis. However, the failure to analyse on an intention-to-treat basis weakens the study in terms of evaluating effectiveness, whilst neglecting the effects of randomising by cluster reduces its power in terms of measuring efficacy. It is likely that risk is reduced, but perhaps not to the degree described here.

Gross *et al* (2000) investigated the effectiveness of HipSavers™ hip protectors in preventing hip fracture amongst older people who were members of a health care programme providing for those living in their own homes but requiring significant assistance with activities of daily living. The hip protector is made of urethane foam, and is relatively soft and flexible. Twenty-nine members who were assessed as being at high risk of falls because they had had two or more falls in the previous four months were given hip protectors; the remaining 438 were not. The mean age of those wearing the hip protectors was 79 years, compared to 80 years in the remainder, and there were six percent more males in the non-wearer group. Both groups were followed up over 26 months. Some members moved from the non-wearer to the wearer group if their risk of falls increased.

There were 199 falls amongst the 29 wearers (3.17 falls/person/year) and 369 amongst the 438 non-wearers (0.38 falls/person/year). There were 16 hip fractures amongst the non-wearers but none amongst those wearing the hip protectors. Gross *et al* (2000) conclude that HipSavers™ hip protectors are effective in reducing the risk of hip fracture. This conclusion is problematic as participants were not randomised to intervention and control groups and there were far fewer wearers than non-wearers (as Gross *et al* [2000] acknowledge). Consequently, one cannot be satisfied that the lower incidence in the hip protector group was due to the hip protectors. On the other hand, there were far more falls amongst those wearing the hip

protectors, which indicates a protective effect. This observational study suggests rather than supports the effectiveness of HipSavers™ hip protectors. A randomised trial is needed to provide evidence that is more conclusive.

Harada *et al* (2001) investigated the effectiveness of a force-dispersing hip protector in preventing hip fracture amongst older people in six nursing homes in Japan. Residents who were female, able to stand unaided, and who were not dependent on a wheelchair were eligible for the study. Of the 520 residents in the home 164 were eligible and available for the trial. Residents were randomised within homes giving 88 in the intervention group and 76 in the control group. Follow-up was for two years in one home and subsequently for one year in the remaining five. Baseline data was collected on all participants, including body mass index, grip, thigh circumference, and triceps and trochanter skin-fold thickness – all of which have been associated with risk of hip fracture in previous studies. Bone density of the calcaneal bone was estimated using ultrasound measurements as this is thought to be related to bone density of the proximal femur.

There were no significant differences between groups, except that the control group had a greater mean height than the intervention group. Daily adherence was directly observed by care staff, with full daily adherence defined as 24 hour wear, and partial adherence where the protector was worn for part of the day. The proportion of available days where the hip protector was worn gave a percentage adherence of 70 percent for full adherence and 17 percent for partial adherence. There were eight hip fractures in the control group and one in the intervention group (the participant was not wearing a hip protector at the time). Hip protector wear, baseline data, together with the number of falls per subject, were used as variables in a Cox's proportional hazard regression analysis. Only hip protector wear was shown to have a

significant independent effect on the incidence of hip fracture (hazard ratio 0.082, 95% CI 0.009 to 0.746).

Harada *et al* (2001) acknowledge that their sample size is small. However, they calculate that 120 participants give 80 percent power to detect a reduction in the rate of hip fracture of nearly 90 percent at the five percent level of significance. Given that much larger studies have shown smaller reductions of 56 percent (Lauritzen *et al*, 1993) and 77 percent (Ekman *et al*, 1997) it is not clear on what previous research this predicted reduction and sample size is based. No details are given of the randomisation process and no rationale is given for the unusual design of the study (a two year intervention period in one home and subsequently for one year periods in the remaining five). The eligibility criteria are rather narrow, which limits the degree to which the results from the trial could be generalised. However, the researchers have collected data on other risk factors for hip fracture and controlled for these in their analysis, which adds strength to their research as a trial of efficacy. They have also achieved remarkably high adherence, which they attribute to the commitment and good understanding of the care staff. The limitations of this study are its small size and narrow eligibility criteria. Its strengths are that it includes a number of other risk factors in the analysis and the high adherence achieved amongst participants. Overall, the study provides reasonably strong evidence for efficacy.

Cameron *et al* (2001) evaluated the efficacy of hip protectors of the force-dispersing type (Safehip<sup>®</sup>) amongst elderly residents of nursing homes and hostels in Australia, who were considered to be at higher risk of hip fracture. They recruited residents from 32 facilities who met the eligibility criteria (being female, aged over 75 years, with a history of two or more falls in the last month, and not bed or chair-fast). There were 196 eligible residents, of whom 22 refused to take part. The remainder were randomised within facilities. Follow up was over 18 months. Randomisation was by numbered, sealed,

opaque envelopes following enrolment in the study, with stratification by type of facility. The original sample size calculation indicated that 120 subjects in each group would give 80 percent power, at the five percent level of significance, to detect a reduction in the incidence of hip fracture from 15 to four percent (a relative risk reduction of 75 percent) over the 18 month intervention period, assuming 75 percent adherence. Cameron *et al* (2001) report that this sample was not obtained because of limited funding, and neither did adherence reach the necessary level. Consequently, they acknowledge that the study had low statistical power to detect anything but a very large effect.

There were 86 participants in the intervention group and 88 in the control group. Data on baseline characteristics of residents were collected, including level of dependence, mental capacity, use of restraints, a history of falls, and previous stroke or hip fracture. A nurse was employed to supply and fit the protectors, and to encourage staff and residents to continue with their use during the 18 months of the study.

There were 28 deaths in each group during the intervention period. Residents in the intervention group were more likely to require restraint, and less likely to have had a previous hip fracture. There were no significant differences between the number of falls or injurious falls in the two groups. Adherence was measured at about 18, 67, 321 and 544 days, with full adherence defined as the hip protector being worn throughout the day (though not at night). The mean percentage follow up time during which hip protectors were worn was 57 percent (SD 40%). Hip protectors were worn in 54 percent of the 321 falls suffered by residents in the intervention group. There were 28 deaths in each group during the intervention period. There was no significant difference between the groups in the rate of hip fractures. There were eight hip fractures in the intervention group and seven in the control group (Cox's proportional hazard ratio of 1.46, 95% CI 0.51 to 4.20).

Only one of the hip fractures in the intervention group occurred whilst the hip protectors were being worn, and in this case, they were not properly applied.

Torgerson and Watt (2002) provide a short report of a trial to test the effectiveness of hip protectors in preventing a second hip fracture amongst people of 70 years or more living in their own homes. There were 182 participants in the intervention group and 184 in the control group, with follow up over 14 months. There were six hip fractures in the intervention group (five when the participants were not wearing the hip protectors) and two in the control group (OR 3.10, 95% CI 0.62 to 15.58). The authors conclude that their trial does not suggest a benefit from hip protectors outside residential accommodation. However, the truncated nature of the report (details of sample size calculation, randomisation procedures, eligibility criteria, and participant characteristics are absent and there are no figures for adherence or falls) does not allow independent judgement of the validity of this statement. It is possible that with high levels of adherence an effect might be found.

Meyer *et al* (2003) evaluated the effectiveness of a force-dispersing hip protector (Safehip<sup>®</sup>) in preventing hip fracture amongst older people in 42 nursing homes in Hamburg, each with at least 70 residents. Residents who were 70 years of age or more, who were not bedridden, and who had been living in the home at least three months were eligible to receive the hip protectors. Some large homes had independently working wards so altogether there were 49 clusters. Clusters were randomised to intervention and control groups, giving 25 clusters with 459 residents in the intervention group, and 24 clusters with 483 residents in the control group. The impact of cluster randomisation on the power of the study was taken into account in determining the sample size (Ukoumunne *et al*, 1999a,b). The hip protectors were introduced into the homes by staff who had been offered a single,

structured education session by the researchers. Three hip protectors were provided to the residents free of charge.

Baseline characteristics of clusters and residents were similar between intervention and control groups. Follow up was for 15 months. There were 21 hip fractures in the intervention group (four where the resident was reported to be wearing the hip protectors at the time of the fracture) and 39 hip fractures in the control group (RR 0.57, Absolute Risk [AR] -3.5%, 95% CI -7.3% to 0.3%). Adherence, defined as wearing the hip protector at the time of a fall, was 58 percent. That is, the hip protectors were worn in 552 of 946 falls in the intervention group. One hundred and fifty-eight of the 459 residents in the intervention group (34%) and 158 of 237 residents from the intervention group who fell (67%) wore the hip protectors during at least one fall. Interestingly, 40 of the 483 residents in the control group (8%) also wore hip protectors not supplied by the researchers. Hip protectors were worn in 160 of 1409 falls (11%) in the control group and 40 of 274 fallers (15%) wore the hip protectors during at least one fall. Meyer *et al* (2003) argue that this limited use of hip protectors may have prevented a disproportionate number of hip fractures in the control group as those most at risk of hip fracture in the control group might be expected to have chosen to wear hip protectors. This may have affected the relative risk between the groups.

Meyer *et al* (2003) state that all eligible residents in the intervention group were offered the hip protectors and that analysis was based on intention to treat the participating residents. However, it is important to note that 44 of 86 homes declined to participate, which raises the question of the degree to which participating homes were representative of the wider population in nursing homes. This difficulty is compounded by the relatively small proportion of residents who participated. The mean number of residents in homes was 137 for the 25 intervention homes and 116 for the 24 homes in the control group. If these figures are used to provide an estimate of the total

number of residents in the study homes, then the 942 residents in the study represent only 15 percent of the estimated population of 6,209 in the homes. Consequently, the hip fractures reported relate only to the sub-group of residents participating in the study. No figures are provided for the 5,267 residents who did not participate. Without these figures, it is impossible to assess the overall impact of the hip protectors on the incidence of hip fractures in this nursing home population.

A major strength of this study is that the impact of cluster randomisation on the power of the study was taken into account in determining the sample size and in the analysis of data. However, if the purpose of cluster randomisation was to evaluate the effect of the intervention on the cluster as a whole, then this is undermined by excluding non-participating residents, who form the great majority in the homes.

### **3.7.3 Discussion of clinical trials**

Drawing general conclusions from these studies is not straightforward. The variation between studies in terms of population, sample size, and in the definition of key variables, means results cannot be readily compared. However, certain common findings are evident in the randomised controlled trials (Table 3.1).

First, all but three of the studies report a significant reduction in the rate of hip fracture when hip protectors are used (Lauritzen *et al*, 1993; Jantti *et al*, 1998; Hindso and Lauritzen, 2000; Chan *et al*, 2000; Kannus *et al*, 2000; Harada *et al*, 2001). However, the power of the larger studies is compromised by failure to take their randomisation by cluster into account when estimating sample size (Lauritzen *et al*, 1993; Ekman *et al*, 1997; Kannus *et al*, 2000). The only large study that did make allowance for the effect of clusters did not show a

significant reduction in risk (Meyer *et al*, 2003). The studies randomised by individual suffer from relatively small samples and are sometimes incompletely reported. Harada *et al* (2001) provide the strongest evidence for efficacy, largely because of the exceptionally high adherence achieved in that setting. Only Kannus *et al*, (2000) and Meyer *et al* (2003) report hip fractures when the hip protector was worn.

Second, all the studies focus on populations at high risk of suffering a hip fracture: either older people in residential care homes (Lauritzen *et al*, 1993; Jantti *et al*, 1998; Chan *et al*, 2000; Kannus *et al*, 2000; Harada *et al*, 2001; Cameron *et al*, 2001; Meyer *et al*, 2003) or those with previous hip fracture (Hindso and Lauritzen, 2000; Torgerson and Watt, 2002). Within this high-risk group, various sub-groups are targeted – principally those thought to be at greatest risk of falling (Jantti *et al*, 1998; Chan *et al*, 2000; Cameron *et al*, 2001), and female residents (Harada *et al*, 2001; Cameron *et al*, 2001). Consequently, these studies do not provide strong evidence for use of hip protectors in other populations.

All studies report problems persuading older people to wear the hip protectors (this is dealt with in detail below). With the exception of Chan *et al* (2000) and Gross *et al* (2000), all the studies used hip protectors of the force-dispersing type with designs based on those developed following laboratory trials. Chan *et al* (2000) used a more flexible type of hip protector with a novel design, but provided no laboratory evidence for its efficacy in dispersing the force of a fall. Gross *et al*, (2000) used a design found to be efficacious in a laboratory study (The HipSaver Company, Inc., 2000). Those studies that report the incidence of pelvic fracture did not show that the hip protectors had a significant effect on risk (Lauritzen *et al*, 1993; Kannus *et al*, 2000; Cameron *et al*, 2001). The only adverse effects reported are skin irritation (Ekman *et al*, 1997; Kannus *et al*, 2000) and needing more help when using the toilet (Jantti *et al*, 1998).

Meyer *et al* (2003) report a higher number of falls in the control group compared with the intervention group. However, four studies report a higher rate of falls amongst residents wearing hip protectors compared to those in control groups (Lauritzen *et al*, 1993; Jantti *et al*, 1998; Chan *et al*, 2000; Harada *et al*, 2001). It is suggested that this may be due to staff (Jantti *et al*, 1998; Chan *et al*, 2000) and residents (Jantti *et al*, 1998) believing that residents wearing the hip protectors are at less risk of serious injury if they fall, and therefore being willing to risk moving about more freely. This is borne out by Cameron *et al*'s (2000) study of 131 older women living at home, with a history of hospital admission following a fall. Those randomised to use hip protectors developed a greater belief in their own ability to avoid falling than controls. Alternatively, if randomisation procedures were not effectively concealed, staff may have given hip protectors to those they considered to be most at risk of falling.

In summary, there is reasonably strong evidence that hip protectors are efficacious in reducing the risk of hip fracture amongst older people at highest risk. However, the size of the reduction in risk has not been clearly established, and the use of hip protectors in other populations has yet to be investigated.

### **3.8 Acceptability of hip protectors to older people**

Hip protectors can only work if they are worn, so their acceptability to residents is a central issue. Measuring the acceptability of hip protectors has two aspects: initial acceptance (which can be defined as the proportion of those who are asked that is willing to start using them), and adherence (which can be defined as the proportion of those who start that continues with their use). When assessing initial acceptance of hip protectors it is important to establish what population any given sample represents, as these vary

considerably between studies. A related issue is how adherence is to be defined and measured. Researchers define adherence in various ways, and measure with different levels of rigour and frequency. They may also express adherence as a proportion of all persons offered the hip protectors, or of all persons initially accepting them. Both of these approaches offer useful information but will not produce comparable figures. It is also helpful if the researchers can identify salient characteristics of those who accept hip protectors and those who do not, and of those who continue with their use and those who do not. Other factors that may affect the use of hip protectors are the design of the garments themselves and the social context in which they are used.

Studies in this area have taken the form of asking older people whether they would use hip protectors if they were offered them; studies that are designed specifically to measure initial acceptance and adherence; and studies that measure acceptability as part of a trial of effectiveness. There has been one systematic review, which is discussed below.

### **3.8.1 Systematic review**

Van Schoor *et al* (2002) carried out a systematic review of “Acceptance and compliance with external hip protectors.” (van Schoor *et al*, 2002, P. 917). As with the systematic review of trials of effectiveness discussed above, this review will be assessed in the light of the recommendations of Sutton *et al* (1998).

The objectives of the review are described as assessing the determinants of compliance with hip protectors. The reviewers report that the heterogeneity of the studies meant that the results could not be statistically pooled, and they offer instead a qualitative summary of the literature. No standard

methodological assessment criteria are reported. This indicates that they may have changed the methodological protocol for the review rather than assessing the research material in the light of it. Sutton *et al* (1998) argue that this may lead to reviewers favouring a certain outcome once the material has been gathered. The broad inclusion criteria were: that the intervention should be the use of hip protectors; that the outcome measures should include either compliance (adherence) or primary acceptance; that the participants should be 65 years or older.

The research strategy appears to be comprehensive, although there is not sufficient detail to allow replication – such information being available “on request.” Two reviewers independently selected the articles, resolving disagreement through discussion. The median acceptance and compliance were calculated, together with the interquartile range but, as noted above, the results could not be pooled, and there is no standardised approach to data extraction documented.

Data from the studies are clearly presented in tables, including definitions of acceptability from the studies and figures for initial acceptance and adherence, and descriptions of the factors thought to determine adherence. These results are discussed in the text and tentative conclusions are formed. Primary acceptance was found to vary between 37 and 72 percent (median 68%, interquartile range 57-70%) and adherence between 20 and 92 percent (median 56%, interquartile range 41-73%). However, van Schoor *et al* (2002) note that many studies do not define adherence clearly and that definitions vary between studies. A number of different determinants of non-adherence were identified. These were: poor fit; discomfort; the extra effort and time needed to wear the protectors, especially for those suffering urinary incontinence; physical weakness, especially of the upper limbs; and illness, for example dementia. Increased adherence was associated with younger wearers; softer hip protectors; lower grip strength; a positive perception of the

appearance, comfort and usefulness of the hip protector; and a history of falling. Van Schoor *et al* (2002) argue that this last factor may explain the effectiveness of hip protectors in some trials with relatively low adherence.

Van Schoor *et al* (2002) recommend that future studies define acceptance as a percentage calculated from the number of participants who agree to wear the hip protectors divided by the total number asked to wear the hip protector. They argue that adherence is best measured through observing participants during unannounced visits and advocate three ways of calculating adherence: the proportion of participants who wear the hip protectors during the day (or the proportion of follow up days during which hip protectors were worn); the proportion of participants who adhere both day and night; and the proportion of falls with hip protectors in place. Van Schoor *et al* (2002) recommend that hip protectors be re-designed for easier use by older people, and that future studies explore characteristics of those who are likely to adhere to their use.

Although this review is not systematic, in that it does not assess the studies against defined methodological criteria, it is certainly comprehensive, and effectively identifies most of the significant factors affecting the acceptability of hip protectors.

### **3.8.2 Studies describing attitudes to wearing hip protectors**

Three studies investigated the response of older people to a hypothetical offer of hip protectors. Myers *et al* (1995) interviewed 108 patients, 94 percent of whom were living in the community, who were in hospital because of a hip fracture, and who had sufficient mental capacity to give their views. The patients were asked about their receptivity to hip protectors, described as a pair of underpants with padding. Seventy percent indicated that they would be willing to wear hip protectors if a doctor prescribed them. Patients who

reported willingness to wear hip protectors were more likely to report a fall to the side (rather than forwards or backwards) as a cause of their hip fracture, and to perceive the cause of their fall as intrinsic (for example legs giving way) rather than extrinsic (for example tripping or slipping). The most important concerns expressed were that the protector should be effective, and that the garment was comfortable and easy to launder. Less important were cost and appearance.

This study asked patients in hospital after a hip fracture what they would do in a hypothetical situation. It is doubtful that their views can be generalised to people for whom the possibility of hip fracture may seem more remote. Myers *et al* (1995) also studied patients who were unable to respond for themselves, by interviewing their relatives. These results are not reported because the two groups had quite different characteristics (those requiring proxies were older, less mobile, and less mentally capable). The results from this group would have been of interest, because of their increased risk of hip fracture.

Zimmer and Myers (1997) asked 1406 people aged 65 or older and living in the community, whether they would consider wearing a garment that could prevent or decrease injury should they fall. This garment was described as “something like an undergarment worn underneath one’s outerwear.” (Zimmer and Myers, 1997, P. 359). Thirty-six percent answered yes. A positive response was associated with dissatisfaction with social contacts, female gender, mobility problems in the home, previous injury due to an accident, recent home renovations (for health reasons), and being at middle levels of education (not highly educated or with limited education). Receptivity to this garment was measured as part of a larger health needs assessment and appears to be only a small part of that project. This perhaps accounts for the vague description of the garment and its purpose, but it means the results are of limited value in gauging response to a garment specifically designed to prevent hip fracture.

Butler *et al* (1998), used focus groups to elicit opinions on the use of hip protectors from 15 residents and 29 staff in private hospitals and rest homes in New Zealand. Participants were able to examine three different varieties of hip protector, presumably of the force dispersing type. The staff thought the hip protectors were acceptable, although they had concerns that they would be difficult to manage with heavily incontinent residents. However, in terms of workload, they felt this was worth the effort to prevent hip fracture and the resulting increases in workload caused by a more dependent resident. Residents who were at higher risk of falling were thought to be the most suitable wearers. Most residents found the garments acceptable, with men more concerned about comfort and women about appearance. Men wanted a garment with a Y-front opening. All residents were concerned that the garment would be too tight. This is an interesting exploratory study, and highlights concerns that might need to be addressed when introducing hip protectors in this environment.

### **3.8.3 Studies focused on measuring the acceptability of hip protectors**

Hindso *et al* (1996) offered hip protectors free of charge to 38 inpatients in an orthopaedic department before discharge. Twenty-five patients (66%), with an average age of 82 years, agreed to wear the hip protectors (although three could not be successfully fitted with them). Of the thirteen who refused the hip protectors, eight did not consider themselves to be at high risk of subsequent hip fracture. Those who refused reported fewer falls at home, and better balance and mobility before admission, but had a lower mental score. This study is described in a short report, with no information on how the patients were selected, or of their age and sex. This brevity, together with the relatively small sample size, means it is difficult to account for the possible

influence of other variables (such as gender and type of fracture). No data is presented on subsequent adherence. Nevertheless, as an exploratory study, this does indicate the level of initial acceptance that might be expected in this population.

Villar *et al* (1998) studied 626 female residents of 31 “rest homes” in the United Kingdom. Residents were excluded if they were unable to give informed consent because of dementia or communication problems, if they had a history of pressure sores, or if their general practitioner was unwilling for them to take part. Also excluded were women who took an extra large dress size (UK 18 – 20) because they were too big for the garment. The eligible residents were randomised to intervention and control groups on a two-to-one basis. Those in the intervention group were offered three pairs of force dispersing hip protectors free of charge and asked to wear them every day for 12 weeks. Adherence was measured by “randomly timed” fortnightly visits. Staff in the homes kept a record of falls, whether there was direct trauma to the hip, and the outcome. Of the 626 female residents identified, 338 were excluded (235 because of cognitive impairment, 53 due to poor physical health and 40 for other reasons). Of the 288 eligible residents, 147 (51%) decided not to take part. Of the remaining 141, 101 (age range 72 to 98 years) were allocated to the intervention group.

Twenty-seven (27%) of the intervention group wore the hip protectors for 12 weeks. Fifty-four stopped wearing them in the first week, and 20 (including four who died or moved away) stopped over the remaining weeks. Most of those who stopped within one week did so because of discomfort (37%) or poor fit (26%), as did the 20 who subsequently stopped.

This study was a pilot for a trial of efficacy, so participants were randomised and data on falls and fractures collected. However, In terms of the focus on acceptability, the trial is an observational study. The falls data is not used in

the analysis of adherence (it might have been interesting if an association was found between those who fell and use of the hip protectors). This study does provide valuable data on the reasons for which older people may decide to stop wearing hip protectors. Villar *et al* (1998) suggest that making the garment more comfortable could double the rate of adherence. However, these results come from a rather narrowly defined sub-group, which excluded men, and also women with significant cognitive impairment. Villar *et al* (1998) acknowledge that cognitively impaired residents are at higher risk of hip fracture and suggest that adherence may be greater amongst this group. Adherence was measured over three months but to achieve maximum effect hip protectors must be worn for life. No information is provided on the use of hip protectors at night. Fifty-one percent of those eligible declined to take part, which means that initial acceptance was 49 percent. However, Villar *et al* (1998) consider that this was not because of opposition to using the hip protectors but because of reluctance to take part in research. This assumes that all 147 residents who refused would have taken the hip protectors if they had been of proven efficacy but no evidence for this conclusion is offered. It is more likely that a proportion refused because they simply did not want to wear the hip protectors (Kannus *et al* [2000] report that 31 percent of those randomised to receive hip protectors in their trial refused to take part, compared to nine percent in the control group). The difficulty of accurately identifying the reasons why eligible potential participants refuse to take part in a clinical trial of hip protectors is a challenge for all researchers in this area.

Parkkari *et al* (1998) studied adherence to use of hip protectors amongst residents of a nursing home in Finland. The home had 57 residents, 26 of whom were ambulant and therefore considered eligible for the study. The staff of the home were given a one-hour introductory talk on the risk factors for hip fracture, and then asked to select residents whom they believed were at high risk of hip fracture. The 19 selected, four of whom suffered with severe dementia, all needed a walking aid, the remainder walking

independently. The residents selected were asked to use a force dispersing hip protector (as described in Parkkarri *et al* [1994, 1995]) in a specially designed garment. The staff recorded the time each person spent wearing the hip protectors over the next six months, together with a record of falls. Where possible, residents dropping out of the study were replaced by a new resident of the same age and gender.

Twelve of the 19 residents (63%) accepted the hip protectors. There were nine women and three men, with a mean age of 82 (SD 7) years. Two participants became bed bound during the study and were replaced by new residents. Of the seven residents who declined the hip protectors, three refused on the grounds that they were too old to wear such a device. The remaining four rejected the hip protectors after a few days wear, one because the protector was pressing on her hip where she had undergone previous surgery, the other because she did not believe herself to be at risk of falling. Two demented residents simply took the protectors off without offering an explanation. Two of the 12 participants who accepted the hip protectors wore them night and day, the remainder only when awake. During waking hours the mean time spent wearing the hip protectors was 11 hours (SD 4 hours), which represents 91 percent of the days when participants were mobile. After six months, 10 of the participants (including four severely demented residents) continued to wear the hip protectors. None of the 12 participants wearing the hip protectors, or the staff, complained about the appearance, comfort, or fit of the protectors. Both staff and participants complained that the garments were too tight, interfering with independent use of the toilet.

Parkkarri *et al* (1998) reached relatively high initial acceptance (63%) and very high levels of adherence (91%). This was accomplished by relying on home staff to introduce the hip protectors following a short educational talk. These are promising results but only in a small sample of a sub-group of residents

(those walking with an aid), living in one home. It may be that other resident groups, or those in other homes, would respond differently.

Birks *et al* (1999) sent a postal questionnaire to the 82 individuals and institutions who had bought force-dispersing hip protectors through their organisation. Information was sought on their experiences with the hip protectors. Forty-five questionnaires (55%) were returned: 26 from those living in nursing homes or hostels, the remainder from people living in their own homes. Thirty-four questionnaires were completed by staff of the homes, or by relatives of wearers.

The wearers were predominantly female (87%), with a mean age of 80 years (SD 8.6 years). Forty-two percent were living in their own homes, 40 percent in nursing homes, and 18 percent in hostels. The most frequently reported main health problems were dementia (31%), followed by Parkinson's disease, balance problems, and a history of fracture or falls. Sixty percent of wearers reported incontinence. Forty-four respondents indicated their level of adherence to use of the hip protectors: 32 respondents (71%) reported using the protectors during the day, four (9%) used them some of the time, and eight (18%) did not use them at all. The residence of the wearer appeared to make no difference to adherence. Respondents commented positively on the quality, comfort, appearance, effectiveness, and ease of laundering of the garment. Negative comments focussed on the difficulty in pulling the garment up and down to use the toilet, leading to a loss of independence. Other negative comments concerned discomfort at night, the limited sizes available, and the high cost of the hip protectors.

Birks *et al* (1999) acknowledge that the response rate of 55 percent and the small sample size limit the degree to which their results can be generalised. However, this study does provide an insight into the issues that may arise for

people using hip protectors, albeit amongst a highly motivated group who have gone to the trouble of buying their own garments.

Hopper *et al* (1999) offered force-dispersing hip protectors (Safehip®) to 83 older people discharged from hospital to their own homes, supported by a community rehabilitation team, and assessed to be at high risk of falling. Participants were assessed daily for their daytime adherence to using the hip protectors.

The mean length of treatment by the team was 21 days. Thirty-five participants (42%) refused the hip protectors, 29 (35%) stopped wearing the hip protectors within three days, seven (8%) between four and seven days, and eight (10%) between seven and 21 days. Only four (5%) wore them throughout the observation period. Those who stopped within one week gave reasons of discomfort (60%), difficulty with toileting (25%), and pain over a fracture site (15%). Presumably, this last group had suffered previous hip fracture. There were 84 falls, six wrist fractures and two hip fractures during the observation period.

This study is of interest because adherence was very low, despite this group being at high risk of falls and fracture (and in fact suffering a high number of falls, and two hip fractures), and despite daily contact with a rehabilitation team. Hopper *et al* (1999) consider that older people able to live in their own homes but who require help to manage hip protectors when using the toilet are unlikely to use them.

In a letter, Thompson and Jones (2000) report the results of a study amongst older people receiving care in their own homes. Sixty-one people, 90 percent of them female, aged 65 years and older (mean 84 years) were assessed to be at high risk of falling. Of these, fifty agreed to take part in the study and 35 (70%) agreed to wear hip protectors of the force-dispersing type (Safehip®),

which were provided free of charge. During the next three months, they were interviewed to determine how often they had fallen and how often they wore the hip protectors.

Twenty-three of the 35 participants (66%) agreeing to try the hip protectors reported wearing them “on most days.” However, if all those who agreed to take part in the study are included in the analysis, then 23 of 50 participants (46%) offered the hip protectors continued to wear them. Sixty-six percent of those who reported a fall were amongst the group wearing the hip protectors on most days, compared to 27 percent of non-fallers ( $P < 0.01$ ). Thompson and Jones (2000) suggest that those who fall are more likely to wear hip protectors than those who do not. They believe this self-selection may account for the reported success of hip protectors achieved with relatively low levels of use.

Thompson and Jones (2000) have achieved high initial acceptance (35 of 50 who were offered the hip protectors - that is 70 percent) and 46 percent adherence over a three-month period amongst a group at high risk of hip fracture. However, they rely on the self-report of participants with regard to levels of use and number of falls, which may not be reliable due to lapses in memory or the participants’ desire to please the researchers.

Hubacher and Wettstein (2001) set out to study the effectiveness and acceptability of force dispersing hip protectors amongst older people living in 20 nursing homes in Switzerland. This hip protector was not integral to the undergarment but had to be fitted into it before use and removed before laundering. The small number of hip fractures experienced meant that no conclusions on effectiveness could be drawn, so their report centres on the issue of acceptability. Nurses in the homes selected residents who were considered at higher risk of falling according to the following criteria: previous fracture caused by a fall, at least one fall in the last two years, unstable gait,

danger of falling from a chair, prescribed restraints to prevent a fall, impaired vision. Those who were confined to bed for more than three days a week or who had a pressure sore near the hip were excluded from the study. Homes were financially compensated for the extra work involved. Residents were visited 20 times over the 10-month study period to check if they were wearing the hip protector and for any difficulties experienced with the garments. At three, six and 10 months residents were asked for their opinion on the comfort, appearance and usefulness of the hip protectors. A record of all falls and fall-related fractures suffered by residents was kept.

Three hundred and eighty-four residents (126 women and 38 men, with a mean age of 86 years, SD 7.4 years) were offered the hip protectors. Of these, 122 (32%) refused and 262 (68%) agreed to wear them. Of the 262 residents who agreed to wear the hip protectors, 124 (47%) stopped wearing them over the course of the study period. Of the 124 who stopped wearing the hip protectors, 38 percent stopped by the end of the first month, 59 percent had stopped by the end of the second month, and 68 percent by the end of the third month. By the end of the study 138 of the 384 originally offered the hip protectors (36%) were still wearing them. Calculation of overall adherence showed that those who wore the hip protectors regularly did so for 49 percent of the available time (including at night), on average between 11 and 13 hours a day. Those who started but dropped out wore the hip protectors for 10 percent of the available time. If all those who were offered the hip protectors are taken into account, this group wore the hip protectors for 20 percent of the available time. There were a total of 310 falls amongst the group offered the hip protectors. This corresponds to a risk of 1.16 falls per person per year. Women had a lower risk (1.03) than men (1.66: RR 0.66, 95% CI 0.51 to 0.84). Those who wore the hip protectors had a higher risk (2.1) than those who stopped wearing them (0.71: RR 0.54, 95% CI 0.31 to 0.71) and those who refused to accept them (0.74: RR 0.56, 95% CI 0.43 to 0.73). Those who stopped wearing the hip protectors were more

likely to rate them as very uncomfortable, and to find their appearance unattractive. They were much less likely to rate the hip protectors as useful. Resident characteristics associated with initial acceptance of the hip protectors were: being physically restrained (for example through the use of cot sides on the bed), being physically disabled, being at higher risk of falling (as assessed using the study criteria), and being female.

Hubacher and Wettstein (2001) note that although those who stopped wearing the hip protectors appear to have done so because they thought the hip protectors uncomfortable, unattractive and ineffective, they, as well as those who refused the initial offer, had a lower assessed risk of falling. The researchers raise the possibility that residents who perceive themselves to be at lower risk of a fall, may also consider themselves to be at less risk of hip fracture, and so see little use for the hip protectors. Hubacher and Wettstein (2001) also report their impression that where nurses and their managers had a positive attitude towards the hip protectors, this was associated with greater use of the hip protectors by residents. This study provides evidence that the acceptability of hip protectors to residents at risk of falling is affected by the design of the hip protectors (the researchers believe that the fact that the protector had to be fitted to the garment made it less acceptable than a garment with an integrated design). Other factors are residents' perceived risk of falling, and possibly the attitudes of the staff in homes towards the garments. They recommend that wearers try a variety of models to find the hip protector that suits them best.

Cryer *et al* (2002) studied the acceptability of force dispersing hip protectors (Safehip<sup>®</sup>) to residents of 17 English residential homes that had the highest rate of hip fracture amongst the homes in a health authority area. Residents who were 65 years or older were offered three pairs of hip protectors free of charge, as part of a comprehensive intervention designed to reduce the risk of falls. This took the form of a structured falls risk assessment to identify

modifiable risk factors (long-term medical problems, postural hypertension, dizziness, gait and balance problems, vision problems, a review of medication, and a falls history). Where risk factors were identified, the home manager made a referral to the appropriate professional to attempt to reduce the risk. Adherence to using the hip protectors was assessed by the care staff in the home during each of four sessions: in the morning, afternoon, evening and overnight, over a six month period. Percentage adherence was calculated by dividing the number of sessions during which the hip protectors were worn by the number of available sessions.

The hip protectors were introduced to the residents and their homes using a thorough implementation process. All staff who were involved (general practitioners, home owners and managers, care staff, primary care staff) were invited to meetings explaining the intervention and its rationale. Project nurses carried out a two-hour teaching session in each home focusing on fall and fracture risk and risk assessment, and provided a teaching resource pack. Home owners and managers, and care staff were sent three letters keeping them informed of the progress of the project and its wider impact. The project nurses spent time with residents showing them the hip protectors and explaining their use. Residents were also given comprehensive written information on all aspects of the study, and those using the hip protectors were visited weekly by a project nurse to assess their progress.

Of the 299 residents who were offered the hip protectors, 153 (51%) agreed to try them. The proportion within homes varied from 24 to 94 percent across the homes. Percentage adherence over 24 hours was 24 percent, with 25 (16%) of the 153 who initially accepted the hip protectors never wearing them. These residents were excluded from calculations of adherence. This means that the percentage adherence rate over 24 hours becomes 29 percent. Daytime adherence was 37 percent (median 34%, range 0 – 80%). Daytime adherence was 47 percent for the first month, over 40 percent for the next

three, and around 30 percent for months five and six. Night-time adherence was three percent.

It is not clear why Cryer *et al* (2002) chose to exclude the 25 residents who accepted the hip protectors but never wore them from their calculations of adherence. If they were included, the figures for adherence would be reduced. On the other hand, these residents are not included amongst those who initially refused the hip protectors. This decreases the number who initially accepted the hip protectors from 153 to 128 (43%). Cryer *et al* (2002) discuss their impression that adherence was best where staff in the homes actively supported their use. They hypothesise that where carers have a positive attitude to the use of hip protectors, adherence will be increased, and that negative attitudes will have the opposite effect. This is borne out by the variation in daytime adherence (0 – 80%) between homes, and by differences between homes in terms of residents beginning to use the hip protectors (In one home, none of the six residents accepting the hip protectors wore them, and in another, only one of eight residents wore them).

#### **3.8.4 Studies that measure acceptability as part of a trial of effectiveness.**

This section will summarise the information on acceptability from the effectiveness studies reviewed above, with a particular emphasis on those factors that are thought to influence acceptance and adherence.

Lauritzen *et al* (1993) offered a force-dispersing hip protector fixed in special underwear to residents of a large nursing home. There is no mention of any cost to the residents. There is no information on the rate of initial acceptance, although the impression is gained that this was high. Adherence was measured at 24 percent over 11 months. The definition of adherence

appears to be when the hip protector was worn at the time of a fall in a relatively small sub-group of two wards from the intervention group and two from the control group. This happened in 11 of 45 falls, giving a figure of 24 percent. As noted above, this figure is difficult to interpret, in that residents who are wearing the hip protectors may fall on multiple occasions, so inflating the figure for adherence. Alternatively, residents may wear the protectors regularly, but not fall, and so make no impact on the figures for adherence. There is no information of how adherence might have changed over time. In the absence of data on the number of falls in the remaining 26 wards, this is a small sample from which estimate adherence. The residents' reasons for not wearing the hip protector are not reported, apart from one complaint that the hip protectors were hot in summer. Lauritzen *et al* (1993) speculate that the protectors were worn preferentially by recurrent fallers, who would also be encouraged by staff, who would see them as having a high risk of hip fracture.

Ekman *et al* (1997) offered residents of nursing homes a force-dispersing hip protector of a similar type to that used by Lauritzen *et al* (1993), except that it was designed to be held in place by a resident's own underwear, rather than a specially designed garment. No information is given on initial acceptance. Adherence was 44 percent but there is no information as to how this figure was derived. The main reasons for stopping use of the hip protectors were reported as being bed bound, and skin irritation.

Jantti *et al* (1998) offered a force-dispersing hip protector to residents of a nursing home in Finland. Residents with a history of a fall, and who could walk without help were eligible for the study. Thirty-six participants were offered the hip protectors and there is no record of any initial refusal. The intervention period was 12 months. Seventeen participants died or were permanently admitted to hospital during the intervention period. At the end of the study period, 13 of the group were still using the hip protectors. The other

six had stopped between one and nine months into the study period. There are insufficient data to allow an accurate estimate of adherence. All that can be said with certainty is that 13 (68%) of the 19 surviving residents were still using the hip protectors after one year. This is a relatively high rate, but what is unknown is the rate of adherence of those who did not survive, or how far the survivors were representative of the whole group. The six residents who stopped wearing the hip protectors did so between one and nine months. They complained that the hip protectors were hot and uncomfortable in bed, and increased the need for help when using the toilet. The 13 residents who were still using the hip protectors at 12 months said that they were warm, produced a feeling of safety, and reduced the fear of falling. This impression was echoed by staff, who felt they could let wearers walk about more freely as the consequences of falls were likely to be less severe. Jantti *et al* (1998) note that most of the nurses taking part had a positive attitude to the use of hip protectors.

Hindso and Lauritzen (2000) offered Safehip<sup>®</sup> hip protectors force-dispersing protectors similar to those used by Lauritzen *et al* (1993) to older people of more than 74 years who were being discharged from hospital having suffered a hip fracture. Sixty-five percent of patients accepted the hip protectors but no figures are given for the number who continued to use them.

Chan *et al* (2000) offered a newly designed hip protector to residents of Australian nursing homes considered by staff to be at high risk of a fall. There was a small charge to the residents for the hip protectors. In contrast to the relatively rigid force-dispersing hip protector, this protector was made of flexible "EVA foam" that is 25 millimetres thick, and is designed to absorb, rather than disperse, the force of a fall. There is no record of the rate of initial acceptance of the hip protectors. Adherence was calculated to be 50.3 percent, based on the number of falls recorded where the hip protectors were worn. As noted above, the figures derived from this method of calculating

adherence are difficult to interpret as it takes no account of participants who do not fall, and gives undue weight to participants who suffer multiple falls. Staff identified a number of factors influencing adherence. These were the bulky appearance of the hip protectors compromising residents' dignity (although none of the residents complained of this), limited cooperation from demented residents (who comprised 65 percent of the sample), and difficulty in dressing residents. Residents who stopped using the hip protectors felt that they were not at risk of hip fracture. Reasons for this included beliefs (for two residents who had suffered hip fracture before the start of the study) that a previous fracture was pathological and not caused by a fall, and a belief that having suffered one fracture another was unlikely. Others had a fatalistic approach to the risk, and felt too old to care. Chan *et al* (2000) note that the rate of falls was higher in the intervention group than in the control group, and speculate that this may be because staff are less likely to restrict the movement of residents wearing hip protectors because of the protection they afford.

Kannus *et al* (2000) offered force-dispersing hip protectors to older people in geriatric long-stay facilities and to those attending outpatient units for supported living at home in Finland. Initially 69 percent accepted the hip protectors. Mean adherence (expressed as the number of days the hip protector was worn as a percentage of all available follow-up days during the 18 month study period) was 48 percent. It was measured through direct observation by caregivers, and defined as wearing the hip protectors for at least one hour that day. However, as noted above, Kannus *et al* (2000) did not include the 57 percent of participants who dropped out of the intervention group for various reasons in their calculation of adherence, once they had dropped out of the study – when their adherence would presumably fall to zero. Had they been included, the figure for adherence would probably be considerably lower. Kannus *et al* (2000) report that 15 participants suffered skin irritation, although this is not given as a cause of non-adherence. It is

also important to note that each of the 22 health care centres taking part in the study had a research coordinator who actively promoted the study in the treatment units. This is likely to have had a positive impact on the use of hip protectors.

Harada *et al* (2001) offered force-dispersing hip protectors to older people in six nursing homes in Japan. Residents who were female, able to stand unaided, and who were not dependent on a wheelchair were eligible for the study. Of the 520 residents in the home 164 were eligible and agreed to take part in the trial. Residents were randomised within homes giving 88 in the intervention group and 76 in the control group. Follow-up was for two years in one home and subsequently for one year in the remaining five.

There is no figure given for initial acceptance of the hip protectors, because only those agreeing to take part in the study (and therefore in principle to wear the hip protectors) were included in the analysis. Daily adherence was directly observed by care staff, with full daily adherence defined as 24 hour wear, and partial adherence where the protector was worn for part of the day. The proportion of available days where the hip protector was worn gave a percentage adherence of 70 percent for full adherence and 17 percent for partial adherence.

This is a remarkably high adherence, which the researchers attribute to the commitment and good understanding of the care staff. Some of this success could stem from the fact that those who may be less likely to comply (for example male residents and those perceived to be at lower risk of hip fracture) are excluded by the narrow eligibility criteria. It may also be that cultural factors had an effect, with residents disposed to submit to the authority of the home (“protectors. ... were given to each subject with instructions to wear the protectors 24 h a day, as a rule.” Harada *et al*, 2001,

P. 216). The researchers note that residents with dementia, once established in the use of the hip protectors, continued to wear them habitually.

Cameron *et al* (2001) offered hip protectors of the force-dispersing type (Safehip<sup>®</sup>) to elderly residents of nursing homes and hostels in Australia, who were considered to be at higher risk of hip fracture. They recruited residents from 32 facilities who met the eligibility criteria (being female, aged over 75 years, with a history of two or more falls in the last month, and not bed or chair fast). There were 196 eligible residents, of whom 22 refused to take part. The remainder were randomised within facilities. Followed up was over 18 months. There were 86 participants in the intervention group and 88 in the control group.

Adherence was measured at about 18, 67, 321 and 544 days, with full adherence defined as the hip protector being worn throughout the day (though not at night). At 67 days, 70 percent of participants were wearing the hip protectors at least half of the day but on subsequent visits, this dropped to 48 and 43 percent respectively. The mean percentage follow up time during which hip protectors were worn was 57 percent (SD 40%). Hip protectors were worn in 54 percent of the 321 falls suffered by residents in the intervention group. Cameron *et al* (2001) report major differences in the level of adherence between different facilities (though no figures are given). They believe higher adherence was influenced by the level of organisational commitment to the project and by the comfort of the hip protectors. It may well have been influenced by the nurse whom they employed to supply and fit the protectors, and to encourage staff and residents to continue with their use.

Meyer *et al* (2003) offered three pairs of force-dispersing hip protectors (Safehip<sup>®</sup>) free of charge to residents of nursing homes in Hamburg. Residents were 70 years of age or more, were not bedridden, and had been

living in the home at least three months. Residents were not approached directly by the researchers. Instead, the hip protectors were introduced into the homes by staff who had been offered a single, structured education session by the researchers. This was a 60-90 minute session, delivered by two researchers, to groups of no more than 12 staff from each cluster. It covered the risk of hip fracture and related morbidity, preventing falls and fractures, the effectiveness of hip protectors, and factors affecting the successful use of hip protectors. Staff members were encouraged to try wearing the hip protectors, and printed materials were made available to residents and staff. Once staff education was complete, at least one member of staff was made responsible for delivering the same education programme to residents, either individually or in small groups. Staff were encouraged to wear the hip protectors whilst educating residents, and to use residents who readily agreed to wear the hip protectors as models for other residents. The researchers re-visited the homes two weeks after the hip protectors were introduced to encourage continued implementation.

Initial acceptance is difficult to determine, as use of the hip protectors was measured only when residents fell. On this basis, it appears that 158 of the 459 residents in the intervention group (34%) accepted the hip protectors. Continued adherence, again defined as wearing the hip protector at the time of a fall, was 58 percent. That is, the hip protectors were worn in 552 of 946 falls in the intervention group. The relatively large proportion of falls where the hip protectors were worn (58%) compared to the proportion of residents using them at least once (34%), indicates that residents who were more likely to fall were more likely to use the hip protectors. This is supported by the figures for the sub-group of residents who experienced a fall. One hundred and fifty-eight of 237 residents from the intervention group who fell (67%) wore the hip protectors during at least one fall.

### **3.8.5 Discussion of studies investigating acceptability of hip protectors**

As in the trials of effectiveness, these studies are difficult to compare because of differing populations and designs. However, there are a number of important common features.

All the clinical trials are focussed on populations at highest risk of falling and fracturing a hip. Further trials are necessary to determine acceptability to older people who are at lower (but not low) levels of risk. Most studies have drawn their samples from older people in residential care homes or in supported living accommodation. The exceptions are Hindso *et al* (1996), Hindso and Lauritzen (2000), Hopper *et al* (1999), and Thompson and Jones (2000). Hindso *et al* (1996) and Hindso and Lauritzen (2000) achieved initial acceptance of 66 percent and 65 percent respectively amongst older people discharged from hospital to their own homes, although no figures are given for subsequent adherence. Hopper *et al* (1999) recorded only five percent adherence three weeks after discharge home. On the other hand, Thompson and Jones (2000) report 70 percent acceptance and 46 percent adherence at three months amongst people living at home. It is possible that older people living in their own homes, lacking both daily assistance and encouragement from care staff, and the example of fellow residents also wearing hip protectors, will have relatively low motivation to continue using hip protectors.

An important motivating factor for hip protector use appears to be the perception of individual residents and the care staff of the risk of hip fracture to that resident. Older people who have suffered a fall in the past appear to be more likely to use hip protectors (Myers *et al*, 1995; Zimmer and Myers, 1997; Hindso *et al*, 1996; Thompson and Jones, 2000), as do those who continue to fall (Hubacher and Wettstein, 2001; Meyer *et al*, 2003), and those perceived by care staff to be at risk (Lauritzen *et al*, 1993; Butler *et al*, 1998).

The corollaries to this are that those who perceive themselves to be at lower risk are less likely to wear hip protectors (Parkkari *et al*, 1998; Chan *et al*, 2000), as are those who believe the hip protectors are ineffective in preventing hip fracture (Hubacher and Wettstein, 2001).

Discomfort, poor fit and skin irritation (especially being too hot and too tight) are barriers to continued use, particularly at night (Butler *et al*, 1998; Villar *et al*, 1998; Parkkari *et al*, 1998; Birks *et al*, 1999; Hopper *et al*, 1999; Hubacher and Wettstein, 2001; Lauritzen *et al*, 1993; Ekman *et al*, 1997; Jantti *et al*, 1998; Kannus *et al*, 2000; Cameron *et al*, 2001), as is pain over the fracture site where the wearer has suffered a hip fracture in the past (Hopper *et al*, 1999). Some residents and staff complained that the hip protector increased the amount of help residents needed when using the toilet (Parkkari *et al*, 1998; Birks *et al*, 1999; Hopper *et al*, 1999). Adherence was much lower at night (Parkkari *et al*, 1998; Cameron *et al*, 2001; Cryer *et al*, 2002), presumably because of discomfort when lying in bed, and perhaps because of difficulty using the toilet at night, when staff may be less available.

Resident characteristics associated with increased use of hip protectors are being female (Zimmer and Myers, 1997; Birks *et al*, 1999; Hubacher and Wettstein, 2001) and having poor mobility (Zimmer and Myers, 1997; Hubacher and Wettstein, 2001). The evidence on the influence of dementia is inconclusive. Some mentally infirm residents refused hip protectors (Hindso *et al*, 1996), others took them off (Parkkari *et al*, 1998; Chan *et al*, 2000), whilst others persisted in wearing them once use had been established (Harada *et al*, 2001).

Residents reported a number of positive experiences associated with wearing hip protectors. They were found to be comfortable, warm, and to increase feelings of safety and decrease fear of falling (Jantti, *et al*, 1998; Birks, *et al*, 1999). Staff reported that they were less worried about residents sustaining

hip fracture and therefore were less inclined to restrict residents' movements (Jantti *et al*, 1998; Chan *et al*, 2000).

A number of studies also suggest that the attitude of staff towards the use of hip protectors greatly affected residents' use of them. Where staff were positive about their use, this increased residents' acceptance and adherence. Where staff were uncommitted, residents' use was adversely affected (Jantti *et al*, 1998; Hubacher and Wettstein, 2001; Harada *et al*, 2001; Cameron *et al*, 2001; Cryer *et al*, 2002). Meyer *et al* (2003) appear to have recognised the crucial importance of staff involvement and devised a comprehensive and structured education and implementation programme for staff. Two studies noted these organisational effects leading to large differences in hip protector use between facilities (Cameron *et al*, 2001; Cryer *et al*, 2002).

It is possible that these organisational and staff factors, together with the characteristics of the various populations, have influenced the wide range of acceptance and adherence rates seen in these studies.

In summary, it appears that greater use of hip protectors is associated with the following: a history and present experience of falls; a perception, among both wearers and care staff, of increased risk of falling and fracturing the hip; with female sex; with reduced mobility; and with positive attitudes towards hip protectors amongst staff. Reduced use of hip protectors is associated with a lower perception of risk; a belief that hip protectors are ineffective in preventing hip fracture; discomfort when wearing hip protectors; difficulty in managing the garment when using the toilet; male sex; night-time; and negative staff attitudes.

It is likely that use of hip protectors can be increased by developing effective but more comfortable hip protectors that can be easily managed by frail elderly people; by greater understanding amongst potential wearers and care

staff of the risk factors for hip fracture and the effectiveness of hip protectors; and, in residential settings, by adopting an approach to implementation that recognises the importance obtaining sustained organisational commitment to promoting the use of hip protectors by residents.

### **3.9 Conclusions**

Hip fracture is associated with falls to the side, which can generate forces well in excess of those required to break an osteoporotic hip. Laboratory studies of hip protectors have demonstrated that dispersing the force of the fall away from the greater trochanter using a relatively rigid convex pad is the most efficient method of reducing impact on the bone. However, even the most efficient designs may not reduce the force of a fall sufficiently in all cases, and the more rigid and convex protectors may be less acceptable to wearers. Consequently, hip protectors are currently a compromise between efficiency, comfort and appearance.

Clinical studies have been focussed on populations at highest risk of hip fracture: some amongst older people recently discharged from hospital following fracture or fall; most amongst those living in nursing and residential homes or hostels. The great majority of studies have shown a reduction in the rate of hip fracture amongst those using the hip protectors. However, the largest of these studies were randomised by cluster, yet analysed by individual, which casts doubt on the strength of their findings. It is likely that hip protectors reduce the risk of hip fracture in high risk populations, but the size of the reduction has not been clearly established. Acceptability of hip protectors is influenced by real and perceived risk of hip fracture amongst wearers and care staff, various characteristics of wearers, the design of the garment, and the commitment of care staff. The overall effectiveness of hip protectors depends on their efficacy in reducing the impact of a fall on the

greater trochanter, their acceptability to wearers, and the degree to which the organisational and social context supports their use.

# Chapter Four

## The exploratory study

This exploratory study was designed to achieve a number of objectives:

- to assess the suitability of two different types of hip protector for the main study
- to test methods and tools for data collection
- to explore issues in relation to implementation of the intervention
- to identify factors that might influence the acceptability of hip protectors to residents and staff

As this was an exploratory study, with a small sample and a short intervention period, definitive answers were not anticipated. However, the study did provide an opportunity to investigate the impact of two different types of hip protector on residents' adherence to their use. At the time that the pilot study was being planned (October 1999), only clinical trials using hip protectors of the relatively rigid, force-dispersing type had been reported in the literature. A new type of hip protector, softer, more flexible, and cheaper than those described in the literature, became available, and this, together with a more established model, was used in the study. If the softer hip protector was significantly more acceptable to residents, then it could be considered for use in the main study.

### 4.1 Methods

Following ethical approval from the Research Ethics Committee of Queen's University, Belfast (Appendix A) and with the agreement of home managers, residents of two nursing homes and seven residential homes in Northern Ireland were invited to take part in the study. As this was an exploratory study with the objective of exploring the factors influencing adherence to use of the hip protectors, no sample size calculations were carried out. Residents temporarily admitted for respite care, those with damaged skin on the hip, and those permanently confined to bed were excluded. All other residents were eligible for inclusion in the study. Informed written consent was obtained from mentally capable residents and, in the case of mentally infirm residents, from the next of kin by post (or in person if the next of kin visited at that time). Residents were recruited prior to randomisation.

Data on relevant characteristics of each resident (age, sex, residential category, falls in the last 12 months, and fear of falling) were obtained from medical and nursing notes, from nursing staff and from the residents themselves, using a standardised data collection form (Appendix B).

The form was supplemented by use of the Barthel Index, (Mahoney and Barthel, 1965; Wade and Collin, 1988), a falls risk assessment tool (STRATIFY: Figure 4.1), (Oliver *et al*, 1997) and the Abbreviated Mental Test (Hodkinson, 1972).

Following data collection, residents were randomised within each home (by a statistician unconnected with recruitment and data collection) to receive three pairs each of either the Safehip® or HipSaver™ hip protectors, free of charge. Residents were stratified by sex and EMI status within their homes, and randomised using a random number generator and restricted randomisation to produce equal numbers using each hip protector in each home.

**Figure 4.1 STRATIFY fall risk assessment tool (modified for use in nursing and residential homes)**

	Assessment	Score																																	
a	Has the resident fallen in the last month? (Yes = 1, No = 0)																																		
	<b>Do you think the resident is: (questions b, c &amp; d)</b>																																		
b	Agitated? (Yes = 1, No = 0)																																		
c	Visually impaired to the extent that their everyday function is affected? (Yes = 1, No = 0)																																		
d	In need of especially frequent toileting? (Yes = 1, No = 0)																																		
	<b>Please calculate the resident's total mobility score:</b>																																		
e	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;"><i>Walking/mobility</i></th> <th style="text-align: left;">Score</th> <th></th> </tr> </thead> <tbody> <tr> <td>Immobile</td> <td>= 0</td> <td>.....</td> </tr> <tr> <td>Independent in wheelchair</td> <td>= 1</td> <td>.....</td> </tr> <tr> <td>Independent with walking aid</td> <td>= 2</td> <td>.....</td> </tr> <tr> <td>Independent</td> <td>= 3</td> <td>.....</td> </tr> <tr> <td colspan="3"><i>Transfers:</i></td> </tr> <tr> <td>Requires hoist</td> <td>= 1</td> <td>.....</td> </tr> <tr> <td>Requires assistance</td> <td>= 2</td> <td>.....</td> </tr> <tr> <td>Independent</td> <td>= 3</td> <td>_____</td> </tr> <tr> <td colspan="2"><i>Total:</i></td> <td>.....</td> </tr> <tr> <td colspan="3"><b>(Total mobility score 3 or 4 = 1, other scores = 0)</b></td> </tr> </tbody> </table>	<i>Walking/mobility</i>	Score		Immobile	= 0	.....	Independent in wheelchair	= 1	.....	Independent with walking aid	= 2	.....	Independent	= 3	.....	<i>Transfers:</i>			Requires hoist	= 1	.....	Requires assistance	= 2	.....	Independent	= 3	_____	<i>Total:</i>		.....	<b>(Total mobility score 3 or 4 = 1, other scores = 0)</b>			
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f	<b>TOTAL STRATIFY SCORE</b> ( <i>A score of 2 or more indicates a high</i>																																		

	<i>risk of falling)</i>	
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#### 4.1.1 The two types of hip protectors

Both types of hip protector have padding sewn in over the area covering the greater trochanter. However, there are significant differences: the Safehip® design which was developed from the type used by Lauritzen *et al* (1993) has a rigid, concave shell, which is designed to disperse the force of a fall away from the greater trochanter into the surrounding tissues; the HipSaver™ design has a flexible foam pad, which is designed to absorb the force of a fall, attenuating the impact on the greater trochanter. The Safehip® garment is closer fitting and appeared less obvious under clothing.

The HipSaver™ garment is looser and the protecting pad is softer and more flexible but its less “figure-hugging” design appears to be more easily seen under clothing. It was also available in a range of sizes (Figure 4.2). In laboratory experiments available at the time of the study, both types of protector attenuated impact forces but the Safehip® design (Mills, 1996; Kannus *et al*, 1999) appeared to be more effective than that of the HipSaver™ (The HipSaver Company, Inc., 1996). The HipSaver™ protector was significantly cheaper than the Safehip® protector, which would have an impact on cost-effectiveness.

Each home was visited on nine occasions spread over the next twelve weeks (at 3, 5, and 7 days; and at [or about] 2, 3, 5, 7, 9 and 12 weeks) to observe whether each resident was wearing the hip protector. Homes were visited more frequently in the first few days in the expectation that this would be the period when most difficulties would occur for residents and staff, and when adherence would reduce most rapidly. All but the first of these visits was unannounced, and at various times of the day, and days of the week. One night-time visit and two night-time enquiries by telephone were made to each

**Figure 4.2. The hip protectors**

	<b>Safehip®</b>	<b>HipSaver™</b>
<b>Description</b>	Cotton, polyamid and lycra pants with sewn in oval, concave, polypropylene shells (16 x 12 CMS, 30 mm deep), lined with soft foam. The material is elasticated and close-fitting. Male and female designs.	“Nursing home” model. Cotton and polyester pants with sewn-in square pad (17 x 17 cms, 16 mm thick) made from three layers of urethane foam bonded together and sealed in a waterproof pouch. The material is slightly elasticated and looser fitting. Male and female designs.
<b>Mode of action</b>	The rigid shell fits over the hip and is designed to disperse the force of a fall away from the greater trochanter into surrounding tissues.	The flexible, damping foam covers the hip, and is designed to absorb the force of a fall, attenuating the impact upon the greater trochanter.
<b>Sizes</b>	One size to fit all. Waist sizes 90 – 122 CMS	XS, S, M, L, XL. Hip sizes 71-127 CMS
<b>Manufacturer/ Supplier</b>	Tytex Group/Robinson Healthcare, ( <a href="http://www.tytex.com/our_products/hip_protection/">http://www.tytex.com/our_products/hip_protection/</a> )	HipSavers™, Inc, Massachusetts, USA ( <a href="http://www.hipsavers.com/">http://www.hipsavers.com/</a> )
<b>Cost in 2000 (including delivery)</b>	£27.50	£16.50

home. The number of day-time visits on which each resident was observed to wear the hip protectors was divided by the total day-time visits to provide the percentage use over 12 weeks for each resident. It was also recorded if the resident was still wearing the hip protectors at the end of the study period.

#### **4.1.2 Statistical analysis**

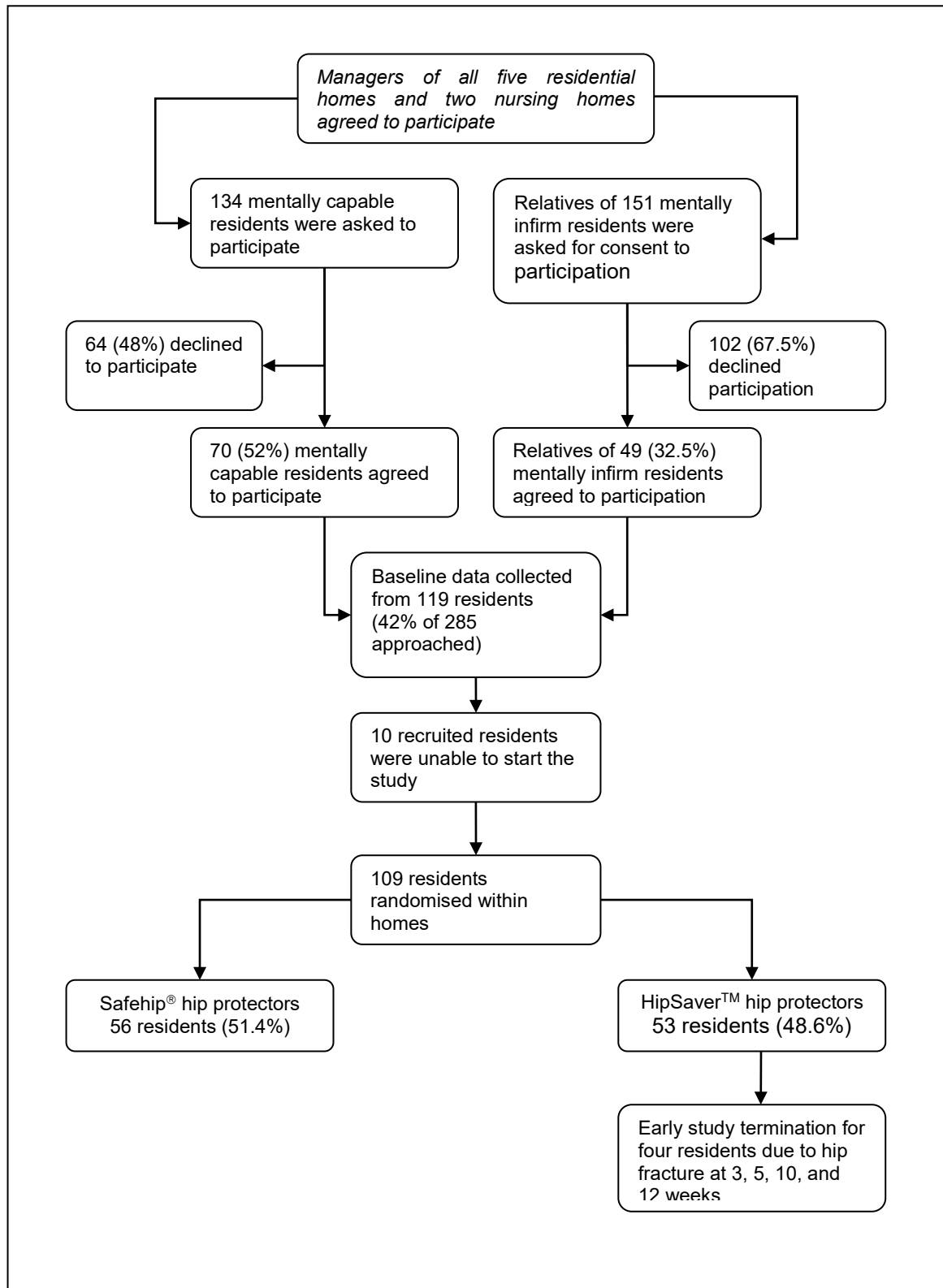
The data on percentage use and on use at 12 weeks were not normally distributed which made parametric tests unsuitable. Consequently, the individual effects of hip protector type and resident characteristics were analysed using the Mann Whitney test and Fisher's Exact test respectively.

### **4.2 Results**

One hundred and nineteen (42%) of 285 eligible residents approached agreed to take part in the study. Residents' ages ranged from 61 to 98 years. Seventy (52%) of the 134 mentally capable residents approached gave informed consent. Relatives of mentally infirm residents were asked to give written consent to the residents' participation. Forty-nine (32.5%) of 151 approached gave consent. Ten recruited residents were unable to begin the study due to illness or leaving the home, so 109 residents started wearing the hip protectors (Figure 4.3).

Participants' ages ranged from 61 to 98 years (median age 82 years). Seventy-six (70%) were female, 40 (37%) lived in units designated for the elderly mentally infirm (EMI units).

**Figure 4.3 The flow of participants through the trial**



**Table 4.1 Mean percentage daytime use of hip protectors during 12 weeks (n = 109)**

<b>Resident characteristic</b>	<b>Frequency (percent)</b>	<b>Mean percentage use during 12 weeks</b>	<b>p value ‡</b>
Female	76 (69.7)	53.2	0.044
Male	33 (30.3)	38.1	
Age 61-79	40 (36.7)	51.3	0.66
Age 80-98	69 (63.3)	47.1	
Elderly mentally infirm (EMI) home	40 (36.7)	75.1	0.0001
Not EMI home	69 (63.3)	33.3	
Mental test score 6/10 or less *	68 (62.4)	54.9	0.001
Mental test score 7-10*	32 (29.4)	29.9	
Barthel score 0-12	64 (58.7)	61.1	0.0001
Barthel score 13-20	45 (41.3)	30.8	
STRATIFY score 2 or more	43 (39.4)	57.3	0.022
STRATIFY score less than 2	66 (60.6)	43	
Fall in the last 12 months	63 (57.8)	56.2	0.029
No fall in the last 12 months	46 (42.2)	38.2	
Injury from a fall in the last 12 months	60 (55)	57.3	0.016
No injury from a fall in the last 12 months	49 (45)	38	
Never afraid of falling †	28 (25.7)	42	0.56
Sometimes, often or always afraid of falling †	48 (44)	37	
Safehip® hip protector	56 (51.4)	51.8	0.56
HipSaver™ hip protector	53 (48.6)	45.3	

**Key**

\* 9 residents (6 EMI and 3 not) had communication difficulties that precluded assessment.

† 33 residents were unable to respond to this question.

‡ Mann-Whitney Test 2-tailed

Two women and two men suffered hip fracture during the study, at 3, 5, 10 and 12 weeks respectively. The two women were not wearing hip protectors at the time of the fracture, and the two men appeared to suffer spontaneous fractures, while wearing the hip protectors, with no record of falls.

The mean percentage daytime use for all participants was 49%. Forty-seven residents (43%) were still wearing the hip protectors at 12 weeks. Fifty-nine residents (54%) never wore the hip protectors at night (8PM-8AM).

Table 4.1 presents the mean percentage daytime use for the two types of hip protectors and for resident characteristics expressed as dichotomous variables. There was no significant difference in percentage daytime use between residents wearing Safehip® or HipSaver™ hip protectors. Being female, being a resident in an EMI unit, having a mental test score of six or less (this is taken to indicate a significant degree of dementia [Hodkinson, 1972]), having a Barthel score of 12 or less (this is taken to indicate a significant level of global dependence [Granger *et al*, 1979] ), having a STRATIFY score of 2 or more (which indicates a high risk of falling), having had a fall in the last 12 months and having been injured in a fall in the last 12 months were all significantly associated (at the 0.05 level) with greater percentage day-time use of the hip protectors. Neither age group nor fear of falling showed a significant difference. For night-time use, only residence in an EMI unit and a Barthel score less than 12 were associated with significantly greater use of hip protectors (Table 4.2).

Table 4.3 presents the results for the 47 residents who continued to use the hip protectors at 12 weeks. Being female, being a resident in an EMI unit, having a mental test score of six or less and having a Barthel score of 12 or less were all significantly positively related (at the 0.05 level) to continued use at 12 weeks. Having a STRATIFY score of 2 or more, having had a fall in the last 12 months and having been injured in a fall in the last 12 months showed

**Table 4.2 Relationship between type of hip protector, resident characteristics and night-time use of hip protectors (observed to be worn at night on at least one of three occasions)**

<b>Resident characteristic</b>	<b>Frequency (percent)</b>	<b>Number wearing at least once (percent)</b>	<b>p value †</b>
All residents	109 (100)	50 (45.9)	
Female	76 (69.7)	37 (33.9)	0.41
Male	33 (30.3)	13 (11.9)	
Elderly mentally infirm (EMI) home	40 (36.7)	28 (25.7)	0.000
Not EMI home	69 (63.3)	22 (20.2)	
Barthel score 0-12	64 (58.7)	36 (33)	0.012
Barthel score 13-20	45 (41.3)	14 (12.8)	
Injury from a fall in the last 12 months	60 (55)	31 (28.4)	0.25
No injury from a fall in the last 12 months	49 (45)	19 (17.4)	
Safehip® hip protector	56 (51.4)	26 (23.9)	1.0
HipSaver™ hip protector	53 (48.6)	24 (22)	

**Key**

† Fisher's exact test 2-sided

no significant difference. Again, there was no significant difference in use at 12 weeks between the two types of hip protector. One hundred residents were assessed using the Abbreviated Mental Test (nine could not be assessed because they had communication difficulties). Of the 68 with scores of 6 or less, 32 were resident in EMI homes. These 32 residents had a significantly higher mean percentage use (73.8%) than both the 36 residents with scores of 6 or less in non-EMI homes (38%,  $p < 0.0005$ ) and those with scores of 7-10 in non-EMI (27.5%,  $p < 0.0005$ ). Mental test score was not associated with significant differences in percentage use in non-EMI homes.

Similarly, a significantly higher proportion of residents with scores of 6 or less in EMI homes (23/32, 72%) continued to use the hip protectors at 12 weeks compared to the proportion of residents with scores of 6 or less in non-EMI homes (11/36, 31%;  $p = 0.001$ ), and to the proportion of residents scoring 7-10 in non-EMI homes (6/30, 20%;  $p < 0.0005$ ). Again, mental test score was not associated with significant differences in use at 12 weeks in non-EMI homes.

#### **4.2.1 Other findings**

A small minority of participants developed erythema under the pads. These were thin, frail residents who spent a large proportion of their time in bed. Staff were advised to take the normal measures to prevent pressure damage to the skin, and to reduce the amount of time the resident wore the hip protectors if necessary. No residents developed any further evidence of pressure damage.

**Table 4.3 Relationship between type of hip protector, resident characteristics and use at 12 weeks**

Resident characteristic	Frequency (percent)	Number using at 12 weeks (percent)	p value ‡
Female	76 (69.7)	39 (35.8)	0.011
Male	33 (30.3)	8 (7.3)	
Age 61-79	40 (36.7)	17 (15.6)	0.1
Age 80-98	69 (63.3)	30 (27.5)	
Elderly mentally infirm (EMI) home	40 (36.7)	29 (26.6)	0.0001
Not EMI home	69 (63.3)	18 (16.5)	
Mental test score 6/10 or less *	68 (62.4)	33 (30.3)	0.015
Mental test score 7-10 *	32 (29.4)	7 (6.4)	
Barthel score 0-12	64 (58.7)	36 (33)	0.002
Barthel score 13-20	45 (41.3)	11 (10.1)	
STRATIFY score 2 or more	43 (39.4)	20 (18.3)	0.69
STRATIFY score less than 2	66 (60.6)	27 (24.8)	
Fall in the last 12 months	63 (57.8)	32 (29.4)	0.078
No fall in the last 12 months	46 (42.2)	15 (13.8)	
Injury from a fall in the last 12 months	60 (55)	31 (28.4)	0.054
No injury from a fall in the last 12 months	49 (45)	16 (14.7)	
Never afraid of falling †	28 (25.7)	10 (9.2)	0.61
Sometimes, often or always afraid of falling †	48 (44)	14 (12.8)	
Safehip® hip protector	56 (51.4)	51.8	0.56
HipSaver™ hip protector	53 (48.6)	45.3	

**Key**

\* 9 residents (6 EMI and 3 not) had communication difficulties that precluded assessment.

† 33 residents were unable to respond to this question.

‡ Fisher's exact test 2-sided

The process of carrying out the study provided an opportunity to assess the culture and everyday practices of the seven homes. A number of characteristics were of note. Firstly, it became evident that residents were more likely to be persuaded to try wearing hip protectors by a member of staff whom they knew, and trusted, and relied on, than they were by the researcher, who was a stranger to them. In some homes, residents who had refused to take part when requested to do so by the researcher, changed their minds when they were asked to reconsider their decision by staff. This was particularly evident in the case of the home managers, who occupy a position of considerable authority and influence in the lives of residents and staff. Secondly, most residents were very dependent on staff (this is reflected in the proportion of participants with low Barthel and Mental Test scores). Many, though they were not formally recognised as being mentally infirm, appeared to be unable to discuss in any great depth the issues involved in deciding whether or not to wear hip protectors. Many residents who expressed a preference for wearing or not wearing the hip protector could not be support their decision with a discussion of risks and benefits. Of course, there were numbers of residents who were able to discuss very effectively the advantages and disadvantages of wearing hip protectors, but these were in a minority. Some residents appeared to be fatalistic about their risk of hip fracture and therefore disinclined to start using the hip protectors. They appeared to feel that having reached old age without the benefit of such a garment, that there was little point in changing their habits to start wearing hip protectors.

### **4.3 Discussion**

The majority of residents (166/285, 58.2%) refused the offer of hip protectors. This group was not investigated further, but it is reasonable to suppose that the factors that influenced adherence to the use of hip protectors might also

influence initial acceptance. So residents in this group might be expected to be more mentally and physically able, and to have had fewer falls. Further investigation is required to understand why relatives of mentally infirm residents were less likely to support the use of hip protectors than were mentally capable residents. It is also disappointing that at 12 weeks the number wearing hip protectors had fallen to 43% (47/109) of those studied and only 16.5% (47/285) of those initially approached. There appear to be two challenges: firstly to persuade residents to try using the hip protectors and secondly to maximise continued use.

The type of hip protector appeared to make no difference to their continued use by residents. This may be because residents who have both the capacity and the inclination to appreciate the special characteristics of a particular type of hip protector are likely to decide not to wear them at all. Alternatively, there might have been little overall difference between the hip protectors in terms of residents' experience of fit, appearance and comfort.

Being female, being a resident in an EMI unit, having a mental test score of six or less and having a Barthel score of 12 or less were all significantly positively related both to greater percentage daytime use and to continued use at 12 weeks. Having a STRATIFY score of 2 or more, having had a fall in the last 12 months and having been injured in a fall in the last 12 months were all significantly associated with greater percentage day-time use of the hip protectors but not with continued use at 12 weeks.

The elderly mentally infirm are at relatively high risk of hip fracture, so the high percentage day-time use amongst residents of EMI units (75.1%), and the high proportion of this group continuing to use the hip protectors at 12 weeks, is a promising result. However, those with a mental test score of 6 or less in non-EMI units were no more likely to wear the hip protectors than fellow residents with mental scores of 7 or above. This may be because

residents in the EMI units typically had more severe dementia, with many day-to-day decisions (such as whether to wear hip protectors) taken by staff. It is likely that many of these residents were unaware that they were wearing hip protectors.

Residents with Barthel scores of 12 or less were more likely to wear hip protectors. Again, this may be because physical dependence makes residents more susceptible to the influence of staff who encourage them to wear hip protectors. Prior to the study a common misgiving amongst staff had been the perceived impracticality of using hip protectors as underwear for incontinent residents, and the possible extra workload associated with toileting and dressing. However, those with lower Barthel scores were also often incontinent and needed help with toileting and dressing. On the other hand, some staff remarked that a small number of residents who had used the toilet independently now needed help to do so because of difficulty in managing the protectors.

Having a higher risk of falling (as evidenced by a STRATIFY score of 2 or more) and a history of falling, particularly if this resulted in injury, was associated with greater use. This may have been because residents with a history of injury perceived themselves to be at greater risk, although this was not confirmed by expressed fear of falling, which was not associated with greater use. Again, it may be that the deciding factor here is the views of staff on a resident's risk of falling. Being female was associated with continued use of hip protectors at 12 weeks but not with percentage daytime use.

This analysis allows a model to be advanced that explains use of hip protectors according to staff perceptions of resident risk, and the susceptibility of residents to staff influence. Thus, staff will try to influence residents at risk of falling to wear the hip protectors, but residents who are physically and mentally more able are less likely to comply. Those residents who are

physically and mentally less able, and therefore more dependent on staff, are more susceptible to staff influence. They may therefore be more likely to agree to continue to wear the hip protectors when encouraged to do so. It may also be that female residents are more easily influenced by staff, who are almost all female.

#### **4.4 Implications for the main study**

This exploratory study suggests that residence in an EMI home, Barthel score of 12 or less, and an injury from a fall in the last 12 months, together with female sex and an increased risk of falling, are variables associated with greater use of hip protectors. The data also allow a model to be proposed in which those residents who are perceived by staff to be at greater risk of falling, and who (because of their relatively high levels of dependency) are susceptible to the influence of staff, are more likely to wear hip protectors. The main implications for the main study are in the stratification of clusters (homes) prior to randomisation, and for the process by which the hip protectors are introduced into the homes.

##### **4.4.1 Stratification of clusters (homes)**

Homes are broadly categorised according to the physical and mental dependency of their residents. Residents of nursing homes are generally more physically dependent than those in residential homes, whilst those with severe dementia live in homes (or units within homes) specially designed for the elderly mentally infirm. This exploratory study suggests that the physical and mental dependency level of residents will influence the degree to which the hip protectors are used, so it is reasonable to stratify homes according to

these (and other) criteria, and randomise to control or intervention groups within those strata.

#### **4.4.2 The process by which the hip protectors are introduced into the homes.**

The majority of residents did not take up the offer of hip protectors. This had major implications for the main study, and was a stimulus to make the process of implementation as effective as possible within the limits of the available resources. The literature on the culture of nursing and residential homes suggests that residents are very much dependent on staff, and that the home manager exerts considerable influence on the overall life of the home. Observation within the homes in the exploratory study confirmed this suggestion, and supported the decision to make the approach to residents through staff. The emphasis was on supporting residents' use of hip protectors by first enlisting the support of staff. Efforts to promote the use of hip protectors among residents of nursing and residential homes were directed at staff, who are in the best position to advise and influence residents and their relatives.

#### **4.4.3 Choice of hip protector**

The type of hip protector appeared to make no difference to their continued use by residents. Consequently, the Safehip<sup>®</sup> protector was preferred on the grounds of the evidence for its efficacy from clinical trials, which was lacking for the HipSaver<sup>™</sup> protector. Three pairs of hip protectors were not quite sufficient to ensure a pair was available at all times, due to the need to regularly launder the garments. Therefore, four pairs were made available for the main study.

#### **4.4.4 Asking staff to carry out baseline data collection and the choice of instruments to measure the dependency of residents**

Collecting baseline data from 119 residents in seven homes proved to be a laborious and time consuming exercise. Repeating this process in 127 homes for over 4,000 residents was not feasible given the resources available to carry out the study. Therefore, it was decided to request the staff in the homes to provide baseline data for residents. This decision had implications for the amount of data that could be requested and the data collection instruments that would be used. The more data that was requested, and the greater the difficulty in using the data collection instruments, the less likely staff were to provide the necessary details. Therefore, in addition to basic data such as age, sex, and history of falls, only data on cognitive capacity and physical dependency were sought. The Abbreviated Mental Test (Hodkinson, 1972) requires an interview with the person being tested, which meant that it could not be carried out on nine residents because of communication difficulties. It would also require extra effort from staff and residents, which would make it less likely that the information would be collected. For these reasons it was decided to use an instrument to measure residents' cognitive capacity known as the *Minimum Data Set Cognition Scale* or MDS-COGS (Hartmaier *et al*, 1994; Cohen-Mansfield *et al*, 1998). This instrument does not require testing of the resident but relies on observation of the everyday behaviour of the resident, enabling the staff to make a rapid assessment (see Section 5.92). The Barthel Index also relies on observation of everyday behaviour and was thought to be suitable for data collection in the main study.

#### **4.45            Assessing residents' risk of falling**

Residents with a history of falling, with a greater assessed risk of future falls, and who would therefore be expected to be at greater risk of hip fracture, were more likely to wear the hip protectors. Consequently, a policy of assessing risk of falling amongst residents in the main study using the STRATIFY falls risk assessment tool and restricting the offer of hip protectors to those at higher risk was considered. The advantage of this approach would be that staff could concentrate their efforts on this sub-group of residents, who might also be more likely to wear the hip protectors. This restrictive approach was rejected for a number of reasons. First, it would have required staff to carry out another assessment process, and then repeat this at regular intervals to identify changes in the residents' level of risk. Such a task might be considered onerous by staff. Second, a proportion of residents (61 percent of those taking part in the exploratory study) would not have been assessed as being at higher risk and would not have been offered the hip protectors. It is likely that a proportion of these lower-risk residents would suffer a hip fracture, which would reduce the effectiveness of the policy. Staff would also be faced with explaining to residents and their relatives why some residents were not offered hip protectors. This might raise issues of equity of treatment, especially if a resident not offered hip protectors subsequently suffered a hip fracture.

# Chapter Five

## Methods

The aim of the study was to evaluate the effectiveness of a policy of making hip protectors available free of charge in nursing and residential homes, and of supporting the implementation process by employing a nurse facilitator to encourage staff in the homes to promote their use.

Policy is normally implemented at the level of the organisation rather than the individual, so it is appropriate to randomise at the level of the organisational groups that will implement the policy. The normal grouping of older people using residential care is the nursing or residential home, and the method of randomisation and analysis reflects this. Randomisation by individual resident ignores the influence of the organisation and culture of particular homes. It does not reflect the normal environment of the homes, where typically interventions are offered to all, according to need, rather than to individuals according to random allocation. Randomisation by individual tests the efficacy of the intervention, rather than its effectiveness in a particular service environment. For all these reasons cluster randomisation was used, with the unit of analysis being the home.

The study was designed as a cluster-randomised controlled trial to test the effectiveness of the hip protectors as they are used in existing groups of older people at high risk of hip fracture. The normal routines and practices of the homes and their residents were to be disturbed as little as possible, and the hip protectors introduced in a manner that could be replicated in everyday practice. Nursing interventions such as hip protectors are normally introduced under the auspices of the authorities in the homes, through the existing nursing and care staff and their managers. This was the approach

taken in the study: home managers and (where the home was part of a larger organisation) senior managers were assisted by the nurse facilitator to introduce the hip protectors to their staff and to residents.

## **5.1 The Steering Group**

A steering group was convened to oversee the development and implementation of the study, and met approximately three times a year. The membership consisted in a Professor of Nursing and a Senior Lecturer in Epidemiology and Public Health (who also jointly supervised this thesis) from Queen's University, a Professor of Nursing and Professor of Health Economics from the University of Ulster, a Consultant Geriatrician from the Royal Victoria Hospital, Belfast, and representatives from the Registration and Inspection Unit and the Departments of General Practitioner Audit and Finance in the Eastern Health and Social Services Board. Each member of the steering group advised in the areas related to his or her particular field of expertise, and discussed issues as they arose. However, final decisions on the design and implementation of the study were made by this writer and the supervisors.

## **5.2 The hip protectors**

The Safehip® hip protectors used in the study were obtained through a local agent of the UK supplier (Robinson Healthcare Ltd, Waterside, Goyt Side Road, Chesterfield, Derbyshire, S40 2YF, United Kingdom). They are cotton, polyamid and lycra pants with a sewn-in hip protector over each hip. This is an oval, convex, polypropylene shell (16 x 12 CMS, 30 mm deep), lined with soft foam. The garment material is elasticated and close-fitting. There are four sizes, for waist (male) and hip (female) sizes 24 to 56 inches, with male

and female designs. Residents in the intervention homes who were eligible to use hip protectors were offered four pairs each. This was the estimated number required to have a pair available at all times whilst others were being laundered. Each garment cost £27.50, so the cost per resident was £110.

### **5.3 The null hypothesis**

The null hypothesis is that the rate of hip fracture in nursing and residential homes randomised to a policy of offering external hip protectors to their residents will be no different to the rate of hip fracture in homes randomised not to introduce this policy.

### **5.4 Population**

The population of interest was people living in nursing or residential homes in the Eastern Health and Social Services Board (EHSSB) area in Northern Ireland. This is consistent with the overall approach taken in this study of respecting existing organisational structures and groupings, in order to evaluate the policy in a normal service environment. The EHSSB area provided a large number of homes within a defined geographical region; all enrolled with the same Registration and Inspection Unit, and all served by the same two hospital orthopaedic services. As noted in chapter one, residents have been estimated to be three to seven times more likely to suffer a hip fracture than non-institutionalised older people (Ooms *et al*, 1994; Slemenda, 1997; Norton *et al*, 1999).

## **5.5 Sample size calculation**

Resource constraints limited the number of hip protectors that could be made available, so the control group was recruited to be twice the size of the intervention group. The sample size estimation is based on the rates of fracture, and reductions in rates, observed in two trials of hip protectors in Scandinavian nursing homes (Lauritzen *et al*, 1993; Ekman *et al*, 1997). Residents in the non-intervention limbs of these studies experienced hip fractures at a mean rate of 5.6 per 100 residents over 12 months. Reductions in fracture rates of between 55 and 65 percent were observed in the treatment limbs. If the expected rate of hip fracture in the non-intervention limb of this study is estimated to be the mean of the rates observed in the Scandinavian studies, and if the rate in a second year of follow up approximates to the first year (giving a fracture rate of 8.4 per 100 residents over 18 months), then randomisation of sufficient homes to provide 716 residents in the intervention group and 1,432 in the control group (a total of 2148), has 80 percent power at the 0.05 level of significance to detect a 40 percent reduction in the rate of fracture in the intervention group over an 18 month period. This calculation was done using *Epi Info* statistical software (CDC, 1999), based on individual randomisation. However, residents were randomised by home and not as individuals, which raises a number of issues.

### **5.5.1 The effect of cluster randomisation on sample size**

Standard calculations of sample size, if applied to cluster randomised controlled trials, assume that the responses of individuals within clusters are independent. They allow for variation within clusters but not between clusters (Ukoumunne *et al*, 1999a,b). However, the responses of individuals within clusters may be correlated for a number of reasons. These individuals (or their families) may have chosen the same social unit (in this case the nursing

or residential home) because they share common characteristics and preferences. The attributes of the cluster (the home) may have a common influence over the individuals in that cluster, thus making them more similar. Individuals may interact within the cluster (which is highly likely in a residential setting), leading to similarities between the individuals (Ukoununne *et al*, 1999a,b). Also, in this study, the policy of offering hip protectors is being implemented at the level of the cluster.

### 5.5.2 The design effect

All of these factors tend to reduce the power of cluster randomised studies in relation to analysing individual outcomes, when compared to studies randomised at the level of the individual. Therefore the sample size calculated for randomisation at the level of the individual must be multiplied by a factor known as “the design effect” to give a sample size with the same power to detect an intervention effect as a study using individual randomisation.

The design effect is calculated using the formula:

$$Deff = 1 + (n_o - 1)\rho$$

where *Deff* is the design effect,  $n_o$  is the average number of individuals per cluster, and  $\rho$  is the intraclass correlation coefficient (Ukoununne *et al*, 1999a,b).

The intraclass correlation coefficient is “the proportion of the true total variation in the outcome that can be attributed to differences between clusters.” (Ukoununne *et al*, 1999a, P. 22) If individuals within a particular cluster are no more likely to have similar outcomes than those in other

clusters, then the intraclass correlation coefficient will be 0. If all individuals in a cluster have the same outcome, then the intraclass correlation coefficient will be 1. The larger the intraclass correlation coefficient, the greater the design effect, and so the greater the required sample size to match the power of a study randomised by individual.

The intraclass correlation coefficient for the present study was calculated as 0.02, based on simulations of frequencies of fractures in homes, assuming a range of home sizes and a fracture rate of 8.4 percent. The average number of residents per home was 36. Therefore, the calculation for the design effect is:

$$1 + (36 - 1)0.02 = 1.7$$

Therefore, the required sample size is the original sample required for individual randomisation multiplied by the design effect:

$$2148 \times 1.7 = 3652$$

However, it is likely that not all eligible residents will go on to participate in the study, so assuming a non-cooperation rate of 20 percent, the final sample size should be:

$$\frac{3652}{0.8} = 4564$$

This was the number of participants aimed for in recruitment: 1521 in the intervention group and 3043 in the control group.

## **5.6 Ethical approval and confidentiality**

Ethical approval for the study was obtained from the Research Ethics Committee of the Queen's University of Belfast (Appendix A).

Data was anonymised wherever possible, and kept in locked cabinets and offices. All electronic data was password protected. Only those directly concerned with data collection or analysis had access to the databases.

## **5.7 Selection, recruitment, and informed consent**

### **5.7.1 Selection**

All nursing and residential homes in the Eastern Health and Social Services Board (EHSSB) area, as identified in the EHSSB *Care Homes Directory – 2000* (EHSSB, 1999), were invited to take part in the study. All residents were eligible for the study. In the intervention group, all residents were offered hip protectors except those meeting the following criteria:

- residents confined to bed 24 hours a day.
- residents with pressure sores on the hip.
- residents temporarily admitted

The rationale for these criteria are that residents in bed 24 hours a day are unlikely to fall; residents with pressure sores on the hip might find that the hip protectors aggravated their condition; in an everyday service environment, staff would be unlikely to offer hip protectors to residents who will shortly be moving out of the home. Other criteria might have been applied, for example excluding all those who were assessed to be at a lower risk of falling. However, this would have placed an extra burden of assessment on the

homes, and might have excluded residents who subsequently suffered a hip fracture. The chosen criteria are believed to reflect those that might reasonably be expected if homes had a policy of using hip protectors.

### **5.7.2 Recruitment**

The researcher wrote to all managers or owners of homes identified in the *EHSSB Care Homes Directory – 2000* (EHSSB, 1999) outlining the study and inviting participation. In the case of homes that were part of larger organisations (Health and Personal Social Services Trusts or for-profit groups), initial contact was with senior managers in those organisations. This letter was followed by a telephone call to further discuss the study and arrange a meeting. At that meeting, the study was discussed in detail, and the manager took a decision to take part or not. Those agreeing to take part were randomised to intervention or control groups.

### **5.7.3 Informed consent**

Written informed consent (Appendix C) was obtained from residents in the intervention homes by nursing staff within the homes. All eligible residents were given an information sheet describing the study in non-technical language (Appendix D) and assuring them that participation was on a voluntary basis. The researcher's name, address and telephone number were on the sheet should the resident require further information. In addition, residents' next-of-kin were also informed by letter that their relative was to be offered the hip protectors (Appendix E), and an information sheet included with the letter.

If a resident was mentally infirm, then the next-of-kin was asked (by letter or, if they were available, in person) to consent to the resident taking part in the study, and a modified information sheet provided (Appendix F). Where the next-of-kin consented to a mentally infirm resident wearing the hip protectors, the nursing staff in the homes were advised to encourage and help the resident to wear the hip protectors, but to withdraw them if the resident showed persistent reluctance to wear them.

The great majority of the data to be obtained on residents in the control homes was already gathered as part of routine data collection, and residents continued to receive usual care, so individual consent to take part in the study was not obtained from these residents. Written permission for access to data was obtained from home managers, and from those who controlled access to the relevant databases (Appendix G). In addition, all General Practitioners in the EHSSB area were informed that the study was to begin, and that residents who were their patients might be invited to take part (Appendix H).

## **5.8 Randomisation of homes**

Before randomisation homes were sorted into strata according to pre-determined categories. These categories were set according to characteristics of the homes and the care categories of residents they admit, that are predicted to influence the uptake of hip protectors in the homes. These are: the presence of dedicated beds for either the Elderly Mentally Infirm or the Old and Infirm, residents categorised as needing either residential or nursing care, the number of residents catered for in the home (30 or more, 29 or less), and whether the home is part of a management group (Table 5.1).

**Table 5.1 Randomisation Strata**

	<i>Stratum number</i>
<b>EMI</b>	
EMI, nursing, 30 or more residents, independent	1
EMI, nursing, 30 or more, management group	2
EMI, nursing, 29 residents or less, independent	3
EMI, residential, 30 or more residents, independent & management group	4
<b>MIXED EMI and O&amp;I</b>	
MIXED, nursing, 30 or more residents, independent	5
MIXED, nursing, 30 or more residents, management group	6
MIXED, residential, 30 or more residents, independent & management group	7
MIXED, residential, 29 residents or less, independent	8
<b>O&amp;I</b>	
O&I, nursing, 30 or more residents, independent	9
O&I, nursing, 30 or more residents, management group	10
O&I, nursing, 29 residents or less, independent	11
O&I, residential, 30 or more residents, independent	12
O&I, residential, 30 or more residents, management group	13
O&I, residential, 29 residents or less, independent	14
<b>KEY</b>	
EMI	Elderly Mentally Infirm
O&I	Old and Infirm
MIXED	Mixture of EMI and O&I beds
Residential	Residential home
Nursing	Nursing home
Independent	A home owned and run independently
Management group	A home managed as part of a group of homes

### **5.8.1 Concealed randomisation**

As homes were recruited, their details (the name of the home and data related to the criteria for stratification) were passed to a statistician who was unconnected with recruitment and who had no prior knowledge of the homes. Homes were randomly allocated within strata by the statistician to either control or intervention groups in a 2:1 ratio.

## **5.9 Baseline data collection**

The large numbers of residents required for the sample (n 4,564) precluded data collection by the researcher, so managers of the homes were asked to provide the data. If this task were onerous, it would be less likely to be done, so the data collection instrument was designed to be quick and easy to use. No special knowledge or skills were needed to complete it beyond those possessed by the nursing staff in the homes, and residents themselves did not need to be tested or asked for information. All the requested information was already routinely collected by the homes, and all assessment relied on observation of everyday activities.

Home managers were asked to fill in a form for each eligible resident providing baseline data (Appendix I). This comprised the following:

front sheet –

- the name of the home
- date on which the data were collected
- surname
- forename
- unique identifier (allocated by the researcher)

anonymised data collection sheet –

- unique identifier (allocated by the researcher)
- sex
- date of birth
- date of admission to the home
- care category
- number of falls in the last four months
- (for residents in intervention homes) if the resident has agreed to wear the hip protectors, or not
- (for residents in intervention homes) if the resident has refused the hip protectors, the reason given by the resident (if any)
- (for residents in control homes) if the resident is wearing hip protectors not supplied through the present study
- cognitive assessment
- dependency assessment

### **5.9.1 Rationale for collecting baseline data**

The data was collected for the following reasons:

- the name of the home allows individual resident data to be linked to the context of the home.
- the date on which the data were collected was taken to be the day the resident entered the study.
- surname and forename, together with date of birth and the name of the home allows the resident to be identified in the hip fracture audit databases and hospital Patient Administration Systems to confirm incidence of hip fracture.

- the unique identifier facilitated identification of the resident in the research databases and helped ensure anonymity and confidentiality as the residents' names could be detached and kept separately from other information about the residents.
- sex was associated with differences in use of hip protectors in the pilot study.
- date of admission to the home allows a measure of the association (if any) between length of stay in the home and acceptance of the hip protectors. For newly admitted residents, it allows a calculation of how soon after admission the resident was offered hip protectors.
- care category (residential, residential EMI, nursing, nursing EMI) is intended to reflect cognitive capacity and physical dependence, both important variables in the use of hip protectors in the pilot study.
- number of falls in the last four months allows an estimation of the resident's relative risk for falling in the future, and gives a picture of the rate of falls in each home.
- for residents in intervention homes, whether they had agreed to wear the hip protectors or not allowed an estimation of levels of initial acceptance.
- for residents in control homes, whether they were already wearing hip protectors not supplied as part of the present study gives an indication of the level of use in the population, and also identifies a possible confounding variable.
- mental incapacity and physical dependence were both associated with greater use of hip protectors in the pilot study. The instruments used are discussed below.

### 5.9.2 Estimating cognitive capacity

The instrument used to measure residents' cognitive capacity is known as the *Minimum Data Set Cognition Scale* or MDS-COGS (Hartmaier *et al*, 1994; Cohen-Mansfield *et al*, 1998). In the United States there is a statutory requirement that all residents of nursing homes are comprehensively assessed using the Minimum Data Set, a standardized assessment tool (OBRA, 1987). The MDS-COGS is a subset of the MDS.

In developing the MDS-COGS, Hartmaier *et al* (1994) assessed the cognitive capacity of 200 residents of eight nursing homes in North Carolina using two widely accepted assessment tools, the Global Deterioration Scale (GDS) (Reisberg *et al*, 1988) and the Mini-Mental State Examination (MMSE) (Folstein, *et al*, 1975), together with the MDS-COGS. The MDS-COGS was highly correlated with both the GDS and MMSE, and was able to discriminate between different degrees of dementia.

The MDS-COGS requires the assessor to rate the resident against five items relating to cognitive capacity and five related to the resident's ability to dress, based on the assessor's observation of the resident's everyday performance (Appendix I). From this is derived a score from 0 – 10. Scores of 0-1 represent a resident who is cognitively intact or mildly impaired, 2-4 represent mild to moderate impairment, 5-8 represent moderate to severe impairment, and 9-10 represent severe to very severe impairment.

The advantage of the MDS-COGS is that it does not require testing of the resident but relies on observation of the everyday behaviour of the resident. Because residents are often living for long periods in the homes, the nurses completing the assessment are likely to be familiar with the residents' abilities, and able to make a rapid assessment.

### **5.9.3 Estimating physical dependency**

Physical dependency was measured using the Barthel Index. First developed in the chronic disease hospitals in Maryland in the United States (Mahoney and Barthel, 1965), the Barthel Index has become a standard measure of physical dependence (Granger *et al*, 1979; Wade and Collin, 1988; Richards *et al*, 2000). The original Index used multiples of 5 to score the subject's level of dependence in 10 activities, giving a score out of 100. Subsequent versions used 1-point increments to give scores between 0 and 20 (Wade and Collin, 1988), a score of 0 indicating the most dependent state, and 20 the least (Appendix I).

The advantages of the Barthel Index are that it does not require direct testing of the subject, it is not disease or condition specific but is suitable for general use, and it is easy and quick to employ.

### **5.10 The implementation process**

The processes described below refer to the homes using the hip protectors. The conceptual framework for implementation follows Kitson *et al* (1998), who suggest that successful implementation depends equally on three core elements: the level of evidence, the method of facilitating the change, and the context into which the evidence is being implemented.

As noted in the review of the literature, the evidence for the efficacy of hip protectors for preventing hip fracture in residents of nursing and residential homes is reasonably strong. Kitson *et al* (1998) argue that the strongest evidence is provided by randomised controlled trials, and positive evidence from two trials was available at the time of implementation (Lauritzen *et al*,

1993; Ekman *et al*, 1997). The hip protectors could therefore be presented to residents and staff with a degree of confidence, and part of the implementation process centred on making the evidence available.

Facilitation was complex. Within individual homes, the facilitator was the senior manager, sometimes in conjunction with a person to whom the manager delegated the responsibility. However, the managers themselves could also be facilitated, and a degree of support was offered.

Limited resources precluded any direct attempt to change the organisational context of individual homes, but the broad features of the cultural context were taken into account when designing the intervention. Residents of nursing homes are relatively powerless. They are heavily dependent on staff, and their autonomy must be facilitated by staff. The implication for promoting the use of hip protectors amongst residents is clear: this must have the support of staff, or it will fail.

### **5.10.1 Introducing the hip protectors**

The recommendations from the Effective Health Care Bulletin, *Getting evidence into practice* (Effective health care, 1999) were followed wherever possible in the execution of the process. *Getting evidence into practice* recommends a three-stranded approach:

- A. The identification of factors likely to influence the proposed change.
- B. A multi-faceted approach to targeting the relevant factors by people with appropriate skills.
- C. Arrangements to monitor and maintain change.

These are discussed below.

### **A. Identifying factors likely to influence the implementation process**

Important factors were identified through a process of consultation and analysis. In addition to reviewing the literature and incorporating important factors learnt from the pilot study, key local informants were interviewed, seeking their opinions on the best way to introduce the hip protectors. These included senior managers from three corporate groups who own a number of homes in Northern Ireland and throughout the United Kingdom, and the senior managers responsible for services to the elderly in the four Health and Social Services Trusts within the EHSSB. Representatives from the voluntary and charitable sectors included the Northern Ireland Manager of the Royal Society for the Prevention of Accidents (ROSPA), and a member of a home accident prevention group. Further insights into the culture and management of the homes were provided by a representative of the EHSSB Registration and Inspection Unit, and in personal conversations with many home managers.

It is recommended that an analysis of factors likely to influence the implementation process should include the following:

- identification of all groups likely to be affected by the change
- assessment of those aspects of the change that might influence its adoption
- assessment of the preparedness of the health professionals to change
- identification of potential external barriers to change.

- identification of likely enabling factors (Effective Health Care, 1999)

*Groups likely to be affected by the introduction of hip protectors*

Pre-eminent amongst the groups likely to be affected by the process are, of course, the residents themselves. In order to derive maximum benefit from the hip protectors, they are asked to wear them 24 hours a day (or as much as possible) for the foreseeable future. Cognitively intact residents must weigh the benefit of a reduction in their perceived risk of hip fracture and its possible consequences, against the perceived and actual inconveniences of wearing the garment.

The crucial role of the senior managers of the homes has been discussed. However, all nursing and care staff are in a relatively powerful position in relation to residents, assisting and advising on many everyday decisions. Indeed, many residents rely on staff to dress them, so in these cases the hip protectors will not be used without the active cooperation of staff. Therefore staff, or at least those in supervisory positions, must be equally convinced of the relative benefits of wearing hip protectors.

The near family and friends of residents are another important group. Whilst some residents have little regular contact with relatives, others retain close, daily, relationships, and may be partly dependent on relatives for financial support. Relatives who are closely involved often expect to be consulted in relation to the resident's care. Where the resident is mentally infirm, homes will obtain the consent of the next of kin before instituting any significant change in care, such as introducing hip protectors. (Where there is no near relative, home managers may take decisions on the resident's behalf, sometimes in consultation with the resident's General Practitioner [GP].)

Relatives can actively influence the decision to use hip protectors, and may also affect the continued use of hip protectors by encouraging or discouraging both residents and staff.

### *Aspects of the change that might influence its adoption*

The literature review identified a number of factors that impacted upon the use of hip protectors. It appears that greater use of hip protectors is associated with the following: a history and present experience of falls; a perception, among both wearers and care staff, of increased risk of falling and fracturing the hip; with female sex; with reduced mobility; and with positive attitudes towards hip protectors amongst staff. Reduced use of hip protectors is associated with a lower perception of risk; a belief that hip protectors are ineffective in preventing hip fracture; discomfort when wearing hip protectors; difficulty in managing the garment when using the toilet; male sex; night-time; and negative staff attitudes.

The attitudes and beliefs of residents will determine their response to the offer of hip protectors. Residents may anticipate that using the hip protectors will be unpleasant or inconvenient. These inconveniences include the possibility of decreased comfort, increased dependence (due to physical difficulties in managing the pants, especially when using the toilet), and an unattractive appearance. Such disincentives are likely to be experienced every time the hip protectors are worn, whereas the main benefit may only be experienced on the rare occasions when residents fall. On the other hand, residents may experience the daily benefit of feeling safer and more confident when wearing the hip protectors (Cameron *et al*, 2000).

Hip protectors are not a highly technical intervention, which should make their introduction relatively easy in comparison to more complicated technologies.

The mode of action of hip protectors is easy to grasp, and no special training is needed in order to wear them. Neither do the staff require any great degree of additional knowledge to care for residents who may use them. The only known hazard they may present is a theoretical increase in the risk of pressure sores under the pads, and the care staff are already experienced in pressure sore prevention.

### *The preparedness of staff to change, and barriers to change*

Whilst the basic idea of hip protectors is easily understood, the many demands of work in nursing and residential homes mean that effective implementation by staff is not unproblematic. Most care staff are not professionally qualified and often work part-time for low pay. Turnover is high, often 100 percent a year (Peace *et al*, 1997). The work itself is demanding, requiring physical and mental stamina to cope with the very considerable bodily needs of residents, to deal with emotional disturbance caused by cognitive or psychiatric disorder, and to meet the administrative demands of the institution (Boeije *et al*, 1997). Residents' hip protectors must be labelled, stored, and laundered at regular intervals in order that they are available for use, and staff must remember to help most residents put them on. Given the transient nature of the workforce, and the urgent competing demands on staff, this is just the sort of simple continuity that may break down. On the other hand, most staff had experience of residents falling and fracturing a hip, and knew from direct observation the serious consequences. This predisposed many to look favourably on anything that might help to avoid fracture. However, a minority of managers openly expressed reservations that their hard-pressed staff would not be able to cope with what was perceived as "one more demand."

### *Enabling factors*

Where homes were part of larger management groups, whether privately or publicly owned, the senior managers were fully supportive in giving access to homes and recommending the use of hip protectors to their subordinates. The majority of individual managers in homes of all types were also broadly supportive. Financial and other costs to the homes were kept to a minimum. The hip protectors were provided free of charge, and the ordering process was made as easy as possible. Once staff had measured residents they simply rang the supplier with their order and the hip protectors were delivered within 48 hours. The intervention itself was offered with the backing of the EHSSB and its Registration and Inspection Unit, the Research and Development Office at the DHPSS, the Geriatric Medical Unit at the Royal Victoria Hospital, and both Universities in Northern Ireland. It is believed that this lent credibility to the intervention.

### **B. A multi-faceted approach to targeting the relevant factors by people with appropriate skills**

The researcher designed the implementation process and made the initial approach to the homes, assisted by a nurse facilitator employed for that purpose. The researcher is a registered general nurse and registered nurse tutor with a recent background as a senior nurse in practice development in an acute hospital trust in Northern Ireland. The nurse facilitator has a background in orthopaedic nursing and research data collection. This provided a team with skills and knowledge appropriate to the process.

The intervention process was designed to target all the relevant groups, providing information and opportunity for questions and discussion. The

approach to residents was through the manager and staff, so these groups will be dealt with first.

### *Home managers*

The initial letter to the home managers identified the researcher and the sponsors of the research, and briefly described the project (Appendix J). A summary of the research proposal was also included, containing a concise review of the rationale and evidence base for hip protectors. The letter was followed by a telephone call to set up a meeting with the manager in the home. At the meeting, the manager was able to discuss the project, examine a pair of hip protectors, and review the protocol for their use (Appendix K). A telephone help line was made available to managers and staff giving direct access to the researcher or nurse facilitator, or to a recorded answer-phone service if they were unavailable. All recorded messages were followed up within one working day, Monday to Friday. No service was available over the weekend. Most homes made several calls in the initial weeks of the study but the number of calls diminished as they became familiar with the hip protectors.

Each manager was issued with a folder of literature appropriate to their home and their limb of the study (Appendix L). The folder contained a table of contents and the following material:

- contact telephone numbers for the researcher and the nurse facilitator
- contact telephone numbers to order the hip protectors
- a letter confirming participation in the study
- a copy of the form they had signed giving permission for access to resident information
- a checklist for the implementation of the study

- a form to list residents ineligible for the study
- a copy of the baseline data collection sheets
- a form to aid in sizing residents for hip protectors
- a copy of the protocol for the use of hip protectors
- a copy of the letter to the resident's relative, to be sent or given to the relative with:
  - the relative consent form, if indicated
  - the relative information sheet
  - a promotional leaflet
  - reply paid envelopes

The aim of providing this folder to managers was to ensure that they had master copies of all the relevant paper work and, more importantly, to set out in simple steps what they must do to cooperate in the research and introduce the hip protectors. The checklist for implementing the study was believed to be essential for this purpose, and was set out on a single page. It is reproduced below (Figure 5.1). Some parts of this checklist would apply to any implementation process (numbers 1, 4, 6, and 7). Other parts were specific to the research (numbers 2, 3, and 5).

### *Nursing and care staff*

With the support of the home manager, a meeting was arranged in each home to introduce the project to the staff. This took the form of an informal talk and discussion with staff, during which they had an opportunity to examine the hip protectors, ask questions, and raise any potential problems with using the hip protectors. They were given an overview of the rationale and evidence base for the use of hip protectors, together with promotional materials produced by the supplier.

**Figure 5.1 Checklist for implementing the study**

## Checklist

1. Identify all those residents who are eligible for the study.
2. Complete the questionnaire for all eligible residents (not only for those who agree to take part).
3. If a resident is ineligible for the study please record this on the form headed "Residents ineligible for the hip protector study."
4. Discuss the hip protectors with each resident (and where appropriate with the resident's family) so that they are able to make an informed decision. An information sheet is provided to assist in this.
5. Obtain written consent from those residents who agree to wear the hip protectors (or where appropriate, from their family). Return consent forms to the researcher.
6. Measure the residents and order the hip protectors.
7. Set a date for giving the hip protectors to the residents and distribute the hip protectors on this date.

### Notes

- All residents are eligible for the study and should be offered the hip protectors, except:
  - Residents confined to bed 24 hours a day
  - Residents with damaged tissue on the hip
  - Residents temporarily admitted for respite care
- Eligible residents admitted at any time during the study period should be offered the hip protectors.
- Residents who are ineligible, but whose status changes during the study period so that they become eligible, should be offered the opportunity to take part in the study.
- A resident or relative does not have to give a reason for deciding not to wear the hip protectors. However, it is important to know why people decide not to wear the hip protectors, so if possible please ask the resident/relative for their reason and record it on the questionnaire.
- When sizing the residents, measure hip circumference for women and waist circumference for men. Match this with the product code on the ordering information slip. A form is provided for this purpose.
- Order the hip protectors by ringing (*name of supplier here*) on (*supplier's telephone number*). Ask for (*name of employee*), or for (*name of employee*), or (*name of employee*). Please have ready the following:
  - The name and address of the home
  - The number of residents requiring each size and sex of hip protector (using the product code provided on the Sizing Form)
- (*The supplier*) will then deliver 4 hip protectors for each resident, with sex and size on the packaging.

Each home was also given a seven-minute videotape professionally produced to the researcher's specifications in the style of a short documentary or news feature, and aimed at both staff and residents. The video programme featured residents and staff from homes in the pilot study, together with expert nursing and medical opinion. It contained a non-technical presentation of the risks of falling and hip fracture, detailing the possible consequences, and promoting the use of hip protectors to reduce the risk of hip fracture. Patients who viewed videotapes regarding treatment options have been shown to have a greater understanding of the associated risks and benefits and to be more likely to be active participants in decision-making. They are also more likely to engage in recommended self-care practices (Krouse, 2001). The video programme was aimed at residents but would also serve as an introduction to staff who were not familiar with the hip protectors.

The objectives of the presentation and discussion with staff were to:

- encourage staff to focus on the risks of hip fracture
- persuade staff of the benefits of hip protectors
- deal with objections to hip protectors
- emphasise the importance of gaining the support of relatives
- discuss approaches to gaining the consent of residents
- instruct staff in the use of the consent form
- discuss ways to maintain use of the hip protectors once the resident has started to use them
- explain the protocol for use of hip protectors
- show the video, and encourage staff to show it to the residents and their relatives.

*Residents*

At the home manager's discretion, residents were given a short talk introducing the hip protectors by the nurse facilitator. However, only a small minority of home managers took advantage of this offer, preferring the approach to come from themselves and their staff. As noted above, staff were provided with a promotional video presentation to show the residents, together with materials produced by the supplier of the hip protectors in the form of leaflets and posters (Appendix M). The resident information sheet (Appendix D) also contained the same contact details and telephone help-line number as were given to managers and staff but no residents made use of these.

#### *Residents' relatives*

The researcher wrote to all relatives listed as next of kin to inform them that the resident was to be offered the hip protectors (and in the case of mentally infirm residents, to seek their written consent). This letter contained an information sheet explaining the use of hip protectors and the process of the research (Appendices E and F), together with a promotional leaflet. Where a decision was taken to wear the hip protectors, the letter also encouraged relatives to help by discussing the risks of falling and the use of hip protectors with the resident and by encouraging the resident to keep wearing the hip protectors once they had started. The usual contact details were given, and a few relatives rang to discuss the use of hip protectors. At the home manager's discretion, relatives were invited to a meeting for a short talk introducing the hip protectors by the researcher or nurse facilitator, although few managers took up this offer.

#### **C. Arrangements to monitor and maintain change.**

### *The nurse facilitator*

The principal method of maintaining and monitoring the change was the employment of the nurse facilitator. Employing a nurse to facilitate defined changes in nursing practice is a common approach and one that would be easily replicated by providers or commissioners of health services. The facilitator visited the intervention homes according to the following schedule.

<b>Visit</b>	<b>Time from start</b>
1.	2 weeks
2.	4 weeks
3.	8 weeks
4.	12 weeks
5.	18 weeks
6.	24 weeks
7.	32 weeks
8.	40 weeks
9.	48 weeks
10.	56 weeks
11.	64 weeks
12.	72 weeks

Visits were more frequent at the beginning of the study because it was anticipated that this would be the period in which most questions and difficulties might arise. The facilitation objectives for each visit were to:

- monitor adherence to the use of the hip protectors (defined as the resident wearing them at the time of the visit).
- invite residents and staff to raise any questions or problems associated with the hip protectors and if possible solve any problems.
- encourage staff and residents to persevere with the hip protectors.
- identify new residents and encourage staff to offer them hip protectors.

### *Protocol for hip protector use*

This was not a research protocol, but a document to guide practice in the homes (Appendix K). The protocol was developed in consultation with managers taking part in the pilot study, and is patterned after typical nursing policies in use in NHS Trusts in Northern Ireland. There is evidence that good practice in nursing homes is more likely to be carried out where there are policies in place related to the area of care in question (Funnell and Herman, 1995; Nichol *et al*, 1996). A researcher is not in a position to impose a policy, and has no managerial authority in the homes, so in that respect the situation is different from where the policy is introduced by the home manager. However, managers were urged to adopt the protocol as policy in their homes, and the majority agreed to this. The protocol was also endorsed by the Registration and Inspection Unit at the EHSSB, which was thought to add weight to its recommendations.

On a single page, the protocol sets out eligibility criteria for residents, references the evidence, and details the responsibilities of managers and staff in the use of hip protectors, and the documentation of that use. Documenting use is important in ensuring consistency of practice in the home. It also helps to shield the home from allegations of negligence if the resident breaks a hip having decided not to wear the hip protectors. It was envisaged that a substantial number of residents might agree to wear the hip protectors and then decide to stop wearing them at a later date. In this case, the protocol instructs nursing staff to document that this is the case, together with the reason given by the resident.

### *Reminders*

The regular visits of the nurse facilitator were designed to be a reminder in themselves. In addition, homes were issued with non-marking stickers (Appendix N) to attach to the residents' wardrobe or mirror – in fact any place where they would draw the attention of the resident and staff to the fact that this resident should be wearing hip protectors. Homes were also offered posters for notice boards and common rooms.

### **5.10.2 Summary of the implementation process**

The process of introducing and supporting the use of the hip protectors in the homes addressed the core elements of implementation by providing the best evidence for the intervention, by well-structured facilitation, and by taking into account the context for the change in practice. In executing the process, the factors likely to influence change were identified and taken into account, and arrangements were made to monitor and maintain use of hip protectors. In practice this meant providing credible evidence for the risk of hip fracture and the efficacy of hip protectors in reducing that risk, to residents, their relatives, staff and managers; supporting the homes as they introduced the hip protectors; then supporting and monitoring the continued use of the hip protectors through the ongoing visits of the nurse facilitator.

### **5.11 Ongoing data collection**

The nurse facilitator collected the routine data for the study during her visits to support continued adherence. She telephoned the home about one week before visiting to make the arrangement, and visited during office hours Monday to Friday according to the following schedules for intervention and control homes, respectively.

<b>Intervention homes</b>	
<b>Visit</b>	<b>Time from start</b>
1.	2 weeks
2.	4 weeks
3.	8 weeks
4.	12 weeks
5.	18 weeks
6.	24 weeks
7.	32 weeks
8.	40 weeks
9.	48 weeks
10.	56 weeks
11.	64 weeks
12.	72 weeks

<b>Control homes</b>	
<b>Visit</b>	<b>Time from start</b>
1.	12 weeks
2.	24 weeks
3.	36 weeks
4.	72 weeks

On each visit to the homes she collected the following data:

- the date of the visit
- whether the resident had left the study since the last visit
- if the resident had left, the reason for leaving:
  - permanently transferred from the home
  - died
- date the resident left the study
- whether the resident had suffered a hip fracture since the last visit
- if the resident had suffered a hip fracture, the date on which this occurred
- whether the resident had suffered a pelvic fracture since the last visit
- if the resident had suffered a pelvic fracture, the date on which this occurred

- whether the resident had suffered an upper extremity fracture since the last visit
- if the resident had suffered an upper extremity fracture, the date on which this occurred
- whether the resident had suffered a lower extremity fracture since the last visit
- if the resident had suffered a lower extremity fracture, the date on which this occurred
- whether the resident had suffered a head injury since the last visit
- if the resident had suffered a head injury, the date on which this occurred
- the name of the hospital attended following the fracture
- the source of information:
  - report from the nursing staff
  - the home's accident book
  - a hospital diagnosis

In addition to the above, the following was collected from homes in the intervention limb of the study:

- whether the resident was observed to be wearing a hip protector at the time of the visit
- the number of falls recorded in the accident book since the last visit
- the number of such falls when the resident was wearing the hip protector
- if the resident had suffered a hip fracture, whether the resident was wearing hip protectors at the time of the fracture:
  - yes
  - no
  - don't know

- if the resident had suffered a pelvic fracture, whether the resident was wearing hip protectors at the time of the fracture:
  - yes
  - no
  - don't know

Information was obtained from the nursing and care staff, and in the case of falls and injuries, from the accident book (homes are required by the Registration and Inspection Unit to keep a record of all untoward incidents, including falls and injuries). In intervention homes, residents were directly inspected to see if they were wearing hip protectors.

Home managers were asked to collect baseline data on all new residents who were eligible to take part in the study and, in the intervention homes, to offer new residents the hip protectors. The nurse facilitator also enquired on each visit whether any new residents had been admitted and reminded managers to collect the data and offer the hip protectors.

#### **5.11.1 Data from external sources**

*The Hip Fracture Audit Database at the Royal Victoria Hospital and the Patient Administration System at the Ulster Hospital Dundonald*

All people suffering hip fracture in the EHSSB Area are treated in only two hospitals: the Ulster Hospital Dundonald (UHD) and the Royal Victoria Hospital (RVH), Belfast. Details of all such patients admitted to the RVH are collected in an audit database. With the written permission of the custodians of the data, this database was interrogated searching for patients admitted from nursing or residential homes during the study period. This process was repeated for the Patient Administration System in the Ulster Hospital. Thus

hip fractures were identified through the admitting hospitals, by the nurse facilitator when visiting the homes, and through the records kept by the Registration and Inspection Unit (see below).

### *The Registration and Inspection Unit*

A range of data was collected from the records of the Registration and Inspection (R&I) Unit. Inspectors from the R&I Unit visit all homes for a formal inspection at least once a year. Inspectors assess homes against specific care and management standards (Appendix O). Discussion with an experienced inspector enabled identification of those elements of the standards that best reflect the overall good management of the home, and this data was collected for each home. Also noted at each inspection is the number of residents accommodated. Homes must also make a return once a year on the number of residents living in the home at that time. This means that the number of residents present in the home was measured on three occasions over the course of the 18-month study period, as well as at the start of the study. The mean of these figures was used as the figure for the number of beds occupied in each home over the period. All homes have a statutory obligation to report injurious falls to the Unit, and these are logged on a database created for that purpose. This allowed the number of injurious falls (including those resulting in hip and other fractures) suffered by residents in each home during the study period to be collected.

## **5.12 Planned analysis**

Analysis was planned at the level of the home and at the level of the individual, for both primary and secondary outcome measures. The twin aims of the analysis were to evaluate the effectiveness of the policy in reducing the rate of hip fracture in the intervention homes, and to explore the factors that might influence effectiveness.

#### **5.12.1 Analysis of the effect of the policy on the rate of hip fractures**

The null hypothesis was that the rate of hip fracture in nursing and residential homes that were randomised to a policy of offering external hip protectors to residents would be no different to the rate of hip fracture in homes that were randomised not to introduce this policy. Therefore, the main outcome measure was the rate of hip fracture in the intervention and control groups and the main analysis was carried out on the basis of intention to treat.

##### *Intention to treat analysis*

This was a comparison of hip fracture rates, i.e. the number of fractures divided by the number of occupied bed-days per home, between all homes in both control and intervention groups, irrespective of how far they followed the study protocol. A subsidiary analysis was planned, with pelvic fractures and other injurious falls as the outcome.

##### *Per protocol analysis*

Seven homes in the intervention group and six in the control group did not cooperate with subsequent full data collection and, in the case of the intervention group, with introducing the hip protectors. Therefore, an analysis was planned that was a replication of the principal analysis but with these “low-cooperation” homes excluded from the dataset.

### *Subgroup analyses*

A comparison of the distribution of hip fracture rates within homes (number of fractures/occupied bed-days), within various home sub-groups. For example between all EMI homes in control and intervention groups, irrespective of how far they followed the protocol.

### *Analysis based on the individual*

Individual based analysis of hip fracture rate was planned, taking into account the effect of clustering at the level of the home. A secondary analysis was to compare the hip fracture rate in those who adhered to wearing the hip protectors and those who did not.

## **5.12.2 Analysis of the acceptability of hip protectors**

The secondary outcome measure was the rate of acceptance and continued adherence to use of the hip protectors by residents in the intervention homes.

### *Defining acceptability.*

Acceptability has two parts: initial acceptance of the hip protectors when they are offered free of charge and continued adherence to their use.

Measurements of adherence were based on the resident who had started wearing the hip protectors being observed to be wearing them when the nurse facilitator visited the home.

#### *Analysis of acceptability at the level of the home*

Acceptability of the hip protectors was predicted to be positively associated with the following home characteristics:

- residence in a home for the EMI
- residence in a nursing home (rather than a residential home)
- residence in a home with a higher rate of compliance with R&I standards
- no change of manager during the study

Use of the hip protectors was predicted to be associated with the following home characteristics (but the direction of the association was not predicted):

- the size of the home (whether 30 or more beds, or fewer than 30)
- whether the home was managed independently or as part of a group

#### *Analysis of acceptability at the level of the individual*

The secondary outcome measure was the rate of acceptance and continued adherence to use of the hip protectors by residents in the intervention homes. Individual adherence was planned to be calculated at a specific point in time and then related to individual characteristics. Use of the hip protectors was

predicted to be positively associated with the following resident characteristics:

- History of higher rate of falls
- EMI status
- Impaired cognition
- Low Barthel score (11/20 or less).
- Female sex

### **5.12.3 Statistical methods**

All statistical analyses were carried out using STATA version 8.0 for Windows (STATA Corporation, 2003). Throughout the thesis, statistical significance was applied at the 5% level.

#### *Home level analyses of fractures and adherence to wearing hip protectors*

The rate of hip fractures, pelvic fractures and injurious falls (intervention compared to control homes) and adherence to hip protectors were examined at the level of the home.

The basic comparison was between the rates of these fractures and falls in intervention and control homes. The hip fracture rate per home was defined as the number of hip fractures in the study period divided by the number of person (resident) days of observation in the home. For each home, the resident days of observation is calculated as the mean number of occupied beds during the study period multiplied by the number of days the home was in the study. Since all homes were observed for the same length of time (504 days), the mean number of occupied beds within the home was the

denominator for the hip fracture rate. Bed occupancy within each home was obtained on four occasions spread over the study period from which the mean number of beds occupied was calculated.

The mean fracture rate (SD), per occupied bed, in the intervention homes was calculated and compared to that in the control homes and a rate ratio and 95% confidence intervals calculated. Because there were some differences in baseline characteristics between control and intervention homes it was decided to model the fracture rates using Poisson regression. This would allow the influence of potential confounders on any differences in fracture rates between control and intervention groups to be examined. Poisson regression, using an offset term,  $\log_e$  (mean number of residents) was used. The dependent variables in the models were hip and pelvic fracture rates and rate of injurious falls. Explanatory variables included randomisation limb, client category of home, type of home, home size etc. Where possible, these were included as categorical variables. The Poisson distribution is considered to be an appropriate probability model for counts of rare, independent events such as the main outcomes (fracture rates) examined in this study (Woodward, 1999, P. 558).

Adherence to wearing hip protectors at 24 weeks was determined at the level of individuals within the home (details are provided in Chapter Six, section 6.7). These data were then aggregated at the level of the home giving the number of subjects who were adherent at 24 weeks and number of eligible subjects in the initial cohort, remaining in the study at 24 weeks.

Adherence at the level of the home amongst the per-protocol homes was analysed using generalised linear modelling (binomial error with over-dispersion), with important potential explanatory variables at the level of the home (e.g. client category, type of home, size of the home etc.) included in the model. Correction for over dispersion was required because the sample

design is clustered. (Aitkin *et al*, 1989). Although the level of adherence in the low-cooperation homes was zero, these home could not be included in this analysis as the binomial model also requires the number of residents eligible to wear the hip protectors (at 24 weeks). These data were not available.

### *Individual level analyses of hip fractures and adherence to wearing hip protectors*

Individual level analyses were performed in relation to the occurrence of hip fracture during the period of the study: individuals in intervention homes were compared to individuals from control homes. Occurrence of hip fractures was treated as a binary outcome variable (the individual either did or did not suffer a hip fracture during the study). Logistic regression analysis was therefore appropriate with occurrence of fracture as the dependent variable and the randomisation limb as the principal explanatory variable of interest. Potential confounders such as age, sex, number of falls prior to the study etc. were included in the models. The clustered nature of the design was taken into account by including the home as the cluster unit in the model. Analyses were performed for all subjects for whom data was available (including those who entered the homes during the period of the study) and also for the cohort of patients in the homes at the start of the study.

The method of determining adherence at 24 weeks is provided in Chapter Six, section 6.7. Residents were classified as either adhering to hip protector use, or not, at this time point, providing a binary outcome variable. Logistic regression was therefore appropriate, with the home included as the cluster unit. Models were constructed with adherence as the dependent variable and important explanatory variables such as age, sex, history of falls prior to the start of the study etc. included. These models were restricted to individuals

within the intervention homes as hip protectors were not provided to the control homes.

### **5.13 Funding the study**

The researcher was supported by a fellowship from the Research and Development Office of the Northern Ireland Health and Social Services Central Services Agency. The costs of the hip protectors were funded by the Eastern Health and Social Services Board and the PPP Foundation. The nurse facilitator was funded by the PPP Foundation. Total funding was £285,000.

# Chapter Six

## Results

### 6.1 Recruitment of homes

One hundred and sixty four homes in the EHSSB were identified as being eligible for the study. All homes registered with the R&I Unit of the EHSSB to offer residential or nursing care to the old and infirm, and the elderly mentally infirm, were eligible. Homes were recruited between May and December 2000. The large number of homes taking part necessitated a staggered start to the study, with most homes starting between January and August 2001 and finishing the study between June 2002 and January 2003. One home did not start until November 2001 and finished in March 2003. Thirty-two homes refused to take part and five homes closed before the start of the study.

One hundred and twenty-seven homes were randomised within 14 strata (Table 6.1) on a 1:2 basis to intervention and control groups, giving 40 homes in the intervention group and 87 in the control group. This was not an exact 1:2 ratio overall because randomisation took place within each stratum. Seven homes in the intervention group and six in the control group did not cooperate with subsequent individual data collection and, in the case of the intervention group, with introducing the hip protectors ("low-cooperation" homes) (Figure 6.1). Some managers said that pressure of work prevented full participation but others did not offer an explanation. In keeping with the purpose of the study as an evaluation of policy, these homes were included in the intention to treat analysis.

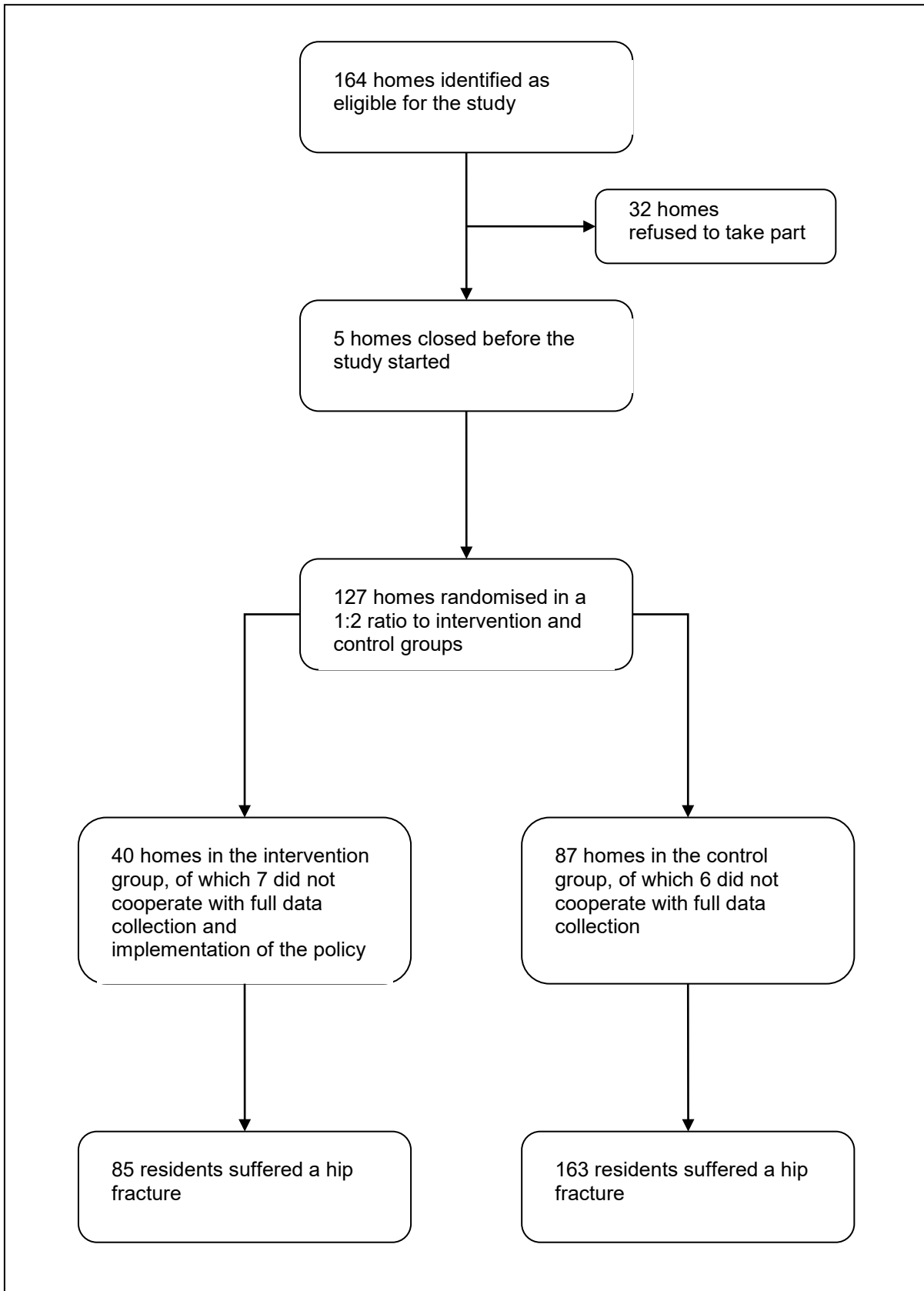
**Table 6.1 Baseline data for the homes: randomisation strata, EMI status, residential or nursing home, size of home**

<b>Randomisation strata</b>	<b>Intervention (%)</b>	<b>Control (%)</b>
EMI, nursing, 30 or more residents, independent	2 (5)	2 (2.3)
EMI, nursing, 30 or more, management group	2 (5)	3 (3.4)
EMI, nursing, 29 residents or less, independent	1 (2.5)	2 (2.3)
EMI, residential, 30 or more residents, independent & management group	2 (5)	4 (4.6)
MIXED, nursing, 30 or more residents, independent	1 (2.5)	2 (2.3)
MIXED, nursing, 30 or more residents, management group	2 (5)	4 (4.6)
MIXED, residential, 30 or more residents, independent & management group	1 (2.5)	3 (3.4)
MIXED, residential, 29 residents or less, independent	1 (2.5)	0 (0.0)
O&I, nursing, 30 or more residents, independent	7 (17.5)	16 (18.4)
O&I, nursing, 30 or more residents, management group	3 (7.5)	11 (12.6)
O&I, nursing, 29 residents or less, independent	4 (10)	11 (12.6)
O&I, residential, 30 or more residents, independent	3 (7.5)	6 (6.9)
O&I, residential, 30 or more residents, management group	2 (5)	4 (4.6)
O&I, residential, 29 residents or less, independent	9 (22.5)	19 (21.8)
<b>Total</b>	<b>40 (100)</b>	<b>87 (100)</b>
<i>EMI status</i>	<i>Intervention</i>	<i>Control</i>
EMI	7 (17.5)	11 (12.7)
EMI and O&I mixed	5 (12.5)	9 (10.3)
O&I	28 (70)	67 (77)
<b>Total</b>	<b>40 (100)</b>	<b>87 (100)</b>
<i>Nursing or Residential homes</i>	<i>Intervention</i>	<i>Control</i>
Nursing	22 (55)	51 (58.6)
Residential	18 (45)	36 (41.4)
<b>Total</b>	<b>40 (100)</b>	<b>87 (100)</b>
<i>Size of the home</i>	<i>Intervention</i>	<i>Control</i>
30 or more beds	25 (62.5)	55 (63.2)
Less than 30 beds	15 (37.5)	32 (36.8)
<b>Total</b>	<b>40 (100)</b>	<b>87 (100)</b>

**Key:**

EMI	Elderly Mentally Infirm
O&I	Old and Infirm
MIXED	Mixture of EMI and O&I beds
Residential	Residential home
Nursing	Nursing home
Independent	A home owned and run independently
Management group	A home managed as part of a larger organisation

**Figure 6.1 Flow of homes through the trial**



## 6.2 Number of residents in the homes

The numbers of individual residents living in the homes taking part in the study over the 72-week study period were estimated by deriving a mean number from figures provided by the homes on four occasions: at the beginning of the study, and at approximately five, 12 and 17 months into the study. This gave a figure of 4,117 resident beds used throughout the study. Multiplying this figure by the number of days in the study period (504 days) gives an estimate of the total for resident bed-days of observation in the study of 2,074,968.

There were 1,366 beds occupied in intervention homes and 2,751 in the control homes. Multiplying these figures by the number of days in the study period (504 days) gives a figure for resident bed-days of observation in each arm: 688,464 in the intervention group and 1,386,504 in the control group (Table 6.2). There were 206 beds occupied in the low-cooperation homes in the intervention group and 105 in the low-cooperation homes in the control group (Table 6.3).

**Table 6.2** The number of homes and the mean number of beds occupied during the study

	Intervention (%)	Control (%)
All homes	40 (31.5)	87 (68.5)
Beds occupied	1,366 (33.2)	2,751 (66.8)
Bed days	688,464 (33.2)	1,386,504 (66.8)
Per-protocol homes	33 (28.9)	81 (71.1)
Beds occupied	1,160 (30.5)	2,646 (69.5)
Low-cooperation homes	7 (53.8)	6 (46.2)
Beds occupied	206 (66.2)	105 (33.8)

**Table 6.3 Characteristics of the low-cooperation homes**

<b>Home characteristic</b>	<b>Number (%)</b>
Number of homes	13
<i>EMI status</i>	
EMI	0
EMI and O&I mixed	0
O&I	13 (100)
<i>Nursing or Residential homes</i>	
Nursing	7 (53.8)
Residential	6 (46.2)
<i>Size of the home</i>	
30 or more beds	5 (38.5)
Less than 30 beds	8 (61.5)
<i>Management group</i>	
Part of a group	1 (7.7)
Independent	12 (92.3)
Mean % standards not met [SD]	29 [25]
Range	0 - 80
Manager changed x 1	5 (38.5)
Manager changed x 2	0
No manager changed	8 (61.5)

**Key:**

EMI	Elderly Mentally Infirm
O&I	Old and Infirm
MIXED	Mixture of EMI and O&I beds
Residential	Residential home
Nursing	Nursing home
Independent	A home owned and run independently
Management group organisation	A home managed as part of a larger organisation

### **6.3 Baseline data for homes and individuals**

The results of the randomisation of the homes are presented in Table 6.1. The intervention and control homes were randomised within strata in a 1:2 ratio. The small number of homes in some strata meant that a 1:2 ratio was not achieved in all cases. However, the desired ratio was achieved in the broad strata of EMI status, nursing and residential homes, and the size of the homes. This is also reflected in the individual data provided by homes on 4,131 residents (Table 6.4).

The number of times the homes changed manager during the study period and the proportion of Registration and Inspection Standards failed (Appendix O) are presented in Table 6.5. The number of resident falls in intervention and control groups (in the per-protocol homes) during the four months prior to starting the study is presented in Table 6.6. The number of residents in intervention and control groups who were lost to the study (through death, hip fracture or permanent transfer out of the home) is presented in Table 6.7.

### **6.4 Analysis of the rate of hip fracture per home**

The hip fracture rate per home is defined as the number of hip fractures in the study period divided by the number of person (resident) days of observation in the home. For each home, the resident days of observation is calculated as the mean number of occupied beds during the study period multiplied by the number of days the home was in the study. Since all homes were observed for the same length of time (504 days), the mean number of occupied beds within the home can be used as the denominator for the hip fracture rate. Bed occupancy within each home was obtained on four occasions spread over the study period from which the mean number of beds occupied was calculated. Data for each home on the mean number of beds

**Table 6.4 Individual resident baseline data from the per-protocol homes (low-cooperation homes excluded)**

<b>Characteristic</b>	<b>Intervention (%)</b>	<b>Control (%)</b>
Number of residents for whom data is available	1,179	2,952
<i>Age</i>		
Mean [SD]	84.2 [7.8]	83.7 [8.7]
Range	47 - 101	34 - 101
Missing data	36	20
<i>Sex</i>		
Female	894 (77.9)	2173 (74.1)
Male	253 (22.1)	761 (25.9)
Missing data	32	18
<i>Care categories:</i>		
Residential	373 (32.4)	788 (26.7)
Residential EMI	109 (9.5)	282 (9.6)
Nursing	381 (33.1)	1431 (48.5)
Nursing EMI	287 (25.0)	448 (15.2)
Missing data	29	3
<i>Cognitive impairment:</i>		
MDS-COGS score 0-4 intact/mild/moderate	489 (43.0)	1615 (55.1)
MDS-COGS score 5-10 moderate/severe/very severe	649 (57.0)	1318 (44.9)
MDS-COGS mean score	4.9	4.3
Missing data	41	19
<i>Physical dependency:</i>		
Barthel Index mean score	11.1	10.3
Barthel Index score 0-11	528 (48.8)	1540 (55.4)
Barthel index score 12-20	553 (51.2)	1241 (44.6)
Missing data	98	171

**Table 6.5 Proportion of Registration and Inspection Unit Standards not met and the number of homes changing their manager during the study period**

<b>Home characteristic</b>	<b>Intervention (%)</b>	<b>Control (%)</b>
Mean % standards not met [SD]	27.6 [21.9]	28.9 [22.0]
Range	0 - 80	0 - 91
Manager changed x 1	13 (32.5)	12 (13.8)
Manager changed x 2	0	6 (6.9)
No manager changed	27 (67.5)	69 (79.3)

**Table 6.6 All resident falls in the four months prior to starting the study (per-protocol homes)**

<b>Variable</b>	<b>Intervention</b>	<b>Control</b>
Number of residents for whom data was available	1,179	2,952
Number of falls	827	2,305
Mean [SD]	0.72 [1.55]	0.79 [1.99]
Range	0 – 13	0 – 38
Missing data	36	26

**Table 6.7 Number of residents lost to the study by cause**

<b>Variable</b>	<b>Intervention (%)</b>	<b>Control (%)</b>
Number for whom data was available	1346	3024
Hip fracture	85 (16.1)	163 (13.7)
Permanent transfer	128 (24.3)	273 (22.9)
Died	314 (59.6)	757 (63.5)
<b>Total</b>	<b>527 (100)</b>	<b>1193 (100)</b>

occupied, the number of hip fractures, the number of pelvic fractures, and the total number of injurious falls are presented in Appendix P for the intervention group, and in Appendix Q for the control group.

The study was designed to investigate the effect of a policy of offering hip protectors on the rate of hip fracture within nursing and residential homes. Therefore, an intention to treat analysis is appropriate based on data from all 127 homes entered into the study. This includes the “low-cooperation” homes that refused to give individual data, or to allow monitoring visits, or (for those in the intervention group) to offer the hip protectors.

Although the study was a randomised controlled trial and the principal comparison of interest was the hip fracture rate in the intervention group of homes compared to that in the control group of homes, it was felt that it would be informative to provide both the unadjusted comparison and the comparison adjusted for other important home characteristics as explanatory variables. These were:

- client category (EMI or O&I; EMI or mixed EMI and O&I)
- type of home (nursing or residential)
- size of home (29 or fewer residents, or 30 or more residents)
- whether the home was independent or part of a larger management group
- the total number of injurious falls in the home during the study period
- the proportion of R&I standards not met
- whether the home had experienced a change of senior manager during the study period

The method of analysis used was Poisson regression, using an offset term,  $\log_e$  (mean number of residents), including a correction for over-dispersion

where appropriate, and considering the first four explanatory variables set out above as categorical. This analysis was repeated excluding the low-cooperation homes – a “per protocol” analysis. An intention to treat analysis was also carried out within the home sub-groups. Finally, an exploratory analysis was carried out where the 11 residents who were reported to have suffered a hip fracture whilst wearing the hip protectors were re-coded as having had no hip fracture – in other words as if they had been wearing a hip protector that could guarantee full protection against hip fracture.

#### **6.4.1 Intention to treat analysis of the rate of hip fracture per home**

The results based on all 127 homes are presented in Table 6.8. Eighty-five residents in the intervention homes and 163 residents in the control homes suffered a hip fracture during the study period. This equates to a mean rate of hip fractures per 100 residents of 6.22 (SD 4.8, range 0 to 22.6) in the intervention group, and 5.92 (SD 6.0, range 0.0 to 31.0) in the control group, over the 72 weeks of the study period. The policy of offering hip protectors was not associated with a reduced rate of hip fractures (Adjusted Rate Ratio [ARR] 1.05, 95% CI 0.76 to 1.45,  $p > 0.05$ ).

The following home characteristics were associated with an increased rate of hip fracture: EMI rather than O&I (ARR 1.98, 95% CI 1.38 to 2.86  $p < 0.01$ ); EMI rather than mixed O&I and EMI (ARR 1.5, 95% CI 0.95 to 2.28,  $p < 0.05$ ); being part of managed group of homes rather than an independent home (ARR 1.42, 95% CI 0.89 to 2.05,  $p = 0.058$ ).

The following home characteristics were not associated with an increased rate of hip fracture: mixed designation for both O&I and EMI, rather than for the O&I alone (RR 1.32, 95% CI 0.91 to 1.93,  $p > 0.05$ ); designated as a

**Table 6.8 Rates of hip fracture, pelvic fracture and injurious falls per home - intention to treat analysis**

Event	Intervention	Control	Unadjusted Rate Ratio (95% CI)	Adjusted Rate Ratio (95% CI)*	<i>P</i> value
Number of hip fractures	85	163			
Rate per 100 residents [SD]	6.22 [4.8]	5.92 [6.0]	1.05 (0.76, 1.45)	1.05 (0.77, 1.43)	> 0.05
Rate range across homes (per 100 residents)	0-22.6	0-31.0			
Number of pelvic fractures	12	6			
Rate per 100 residents [SD]	0.88 [1.56]	0.22 [1.1]	4.03 (1.51, 10.74)	4.03 (1.48, 10.96)	< 0.01
Rate range across homes (per 100 residents)	0-6.2	0-7.5			
Number of injurious falls †	73	122			
Rate per 100 residents [SD]	5.35 [5.5]	4.43 [5.9]	1.21 (0.79, 1.83)	1.16 (0.77, 1.76)	>0.05
Rate range across homes (per 100 residents)	0-22.9	0-29.2			

**Key:**

\* 95% CI adjusted for home characteristics client category (EMI or O&I; EMI or mixed EMI and O&I), type of home (nursing or residential), size of home, whether the home was independent or part of a larger management group, number of injurious falls in the home during the study period, number of care quality standards met by the home (as measured by the RIU), and change of senior manager during the study period.

† Falls resulting in an injury requiring medical attention (excluding hip fractures)

**Table 6.9 Association between home characteristics and the rate of hip fractures: intention to treat analysis (adjusted)**

<b>Variable ratios</b>	<b>Rate Ratio</b>	<b>95% CI</b>	<b>p value</b>
<i>Client category:</i>			
EMI/O&I	1.98	1.45, 2.72	< 0.01
MIXED/O&I	1.32	0.91, 1.93	> 0.05
EMI/MIXED	1.5	1.01, 2.23	< 0.05
<i>Type of home:</i>			
Residential/nursing	0.95	0.71, 1.27	>0.05
<i>Size of home:</i>			
>=30/<30	0.71	0.49, 1.04	> 0.05
<i>Whether in a managed group:</i>			
Group/independent	1.42	1.04, 1.95	< 0.05
<i>Change of manager:</i>			
Unit increase	0.77	0.59, 1.0	< 0.05
<i>Proportion of R&amp;I standards failed:</i>			
Unit increase	0.92	0.51, 1.66	> 0.05

residential home rather than a nursing home (RR 0.95, 95% CI 0.71 to 1.27,  $p > 0.05$ ); having 30 or more beds rather than less than 30 beds (RR 0.71, 95% CI 0.49 to 1.04,  $p > 0.05$ ); having failed a greater proportion of R&I Standards than a comparison home (RR 0.92, 95% CI 0.51 to 1.66,  $p > 0.05$ ) (Table 6.9). The impact of a change in manager on the rate of hip fracture was also investigated. Changing the manager once during the study period was associated with a reduction in the rate of hip fracture (RR 0.77, 95% CI 0.59 to 1.00,  $p < 0.05$ ) (Tables 6.5, 6.9).

#### **6.4.2 Sub-group analysis**

The policy of offering hip protectors was not associated with a reduced rate of hip fractures when the Poisson regression analysis was repeated within the various sub-groups. These were the 32 EMI and mixed EMI and O&I homes, the 95 O&I homes, the 73 nursing homes, the 54 residential homes, the 47 homes with less than 30 residents, the 80 homes with 30 or more residents, the 41 homes that were part of a managed group, and the 86 independent homes.

#### **6.4.3 Per-protocol analysis**

The analysis was based on the data from the 114 homes that took part according to the study protocol (i.e. excluding the low-cooperation homes). The only significant change from the analysis including all homes was that homes with less than 30 residents were associated with a higher rate of hip fracture than those with 30 or more residents (RR 1.6, 95% CI 1.07 to 2.44,  $p < 0.05$ ).

#### **6.4.4 Exploratory analysis**

An exploratory analysis was carried out where the 11 residents who were reported to have suffered a hip fracture whilst wearing the hip protectors were re-coded as having had no hip fracture – in other words as if they had been wearing a hip protector that could guarantee full protection against hip fracture. The policy of offering hip protectors was not associated with a reduced rate of hip fractures, in either the intention to treat analysis (RR 0.92, 95% CI 0.7 to 1.22,  $p > 0.5$ ) or the per-protocol analysis (RR 0.8, 95% CI 0.58 to 1.09,  $p > 0.05$ ).

#### **6.4.5 Pelvic fractures**

There were 18 pelvic fractures recorded during the study: 6 in the control group, 12 in the intervention group, including two where the resident was reported to be wearing the hip protectors at the time of the fracture. The policy was associated with an increased rate of pelvic fractures in both intention to treat analysis (RR 4.03, 95% CI 1.48 to 10.96,  $p < 0.01$ ) and the per-protocol analysis (RR 4.95, 95% CI 1.8 to 13.61,  $p < 0.01$ ) (Table 6.8). An increase in the rate of pelvic fractures was also associated with homes changing their senior manager during the study (RR 2.9, 95% CI 1.27 to 6.65,  $p < 0.05$ ) (Table 6.10)

#### **6.4.6 Injurious falls**

Injurious falls were defined as falls resulting in a fracture (excluding hip fracture) or an injury requiring medical attention. There were 73 such falls recorded in the intervention group and 122 in the control group. The policy was not associated with a reduction in injurious falls in either the intention to

treat analysis (RR 1.16, 95% CI 0.86 to 1.56,  $p > 0.05$ ) (Table 6.8) or the per-protocol analysis (RR 1.07, 95% CI 0.78 to 1.48,  $p > 0.05$ ). An increase in the rate of injurious falls was associated with residential homes when compared with nursing homes (RR 1.76, 95% CI 1.27 to 2.43,  $p < 0.01$ ) and with homes with 30 or more beds compared with homes with less than 30 beds (RR 1.8, 95% CI 1.12 to 2.86,  $p < 0.05$ ) (Tables 6.8, 6.10).

## **6.5 Analysis of the rate of hip fracture by individual**

This analysis was carried out using the 4,131 residents in the per-protocol homes (1,179 in the intervention group and 2,952 in the control group) for whom individual data was available. There were 49 hip fractures in the intervention group and 103 in the control group. Logistic regression analysis was performed, with hip fracture as the dependent variable and the explanatory variables: the intervention variable, age, sex, Barthel index score (0-11 or 12-20), MDS score (0-4 or 5-10), number of falls prior to the study, and taking the cluster design into account. No significant difference was found between intervention and control groups (Odds Ratio [OR] 1.08, 95% CI 0.77 to 1.53,  $p > 0.05$ ).

This analysis was repeated for those residents who made up the initial cohort starting the study in both intervention (862 valid cases, 35 hip fractures) and control (2,211 valid cases, 81 hip fractures) groups. No significant difference was found (OR 1.00, 95% CI 0.66 to 1.55,  $p > 0.05$ ).

The analysis was repeated (again for all those residents who made up the initial cohort starting the study in both intervention and control groups) for initial cohort residents in the intervention group adhering to use of the hip protectors (289 valid cases, 12 hip fractures) compared to a group composed of those in the intervention group who did not adhere to use of the hip

**Table 6.10 Association between home characteristics, pelvic fracture and injurious falls: intention to treat analysis (adjusted). Significant variables only.**

<b>Event</b>	<b>Variable ratios</b>	<b>Rate Ratio</b>	<b>95% CI</b>	<b>p value</b>
Pelvic fracture	<i>Change of manager</i>			
	Unit increase	2.90	1.27, 6.65	< 0.05
Total injurious falls	<i>Type of home:</i>			
	residential/nursing	1.76	1.27, 2.43	< 0.01
	<i>Size of home:</i>			
	>=30/<30	1.80	1.12, 2.86	< 0.05

protectors, together with those in the control group (2,596 valid cases, 95 hip fractures). Because these groups were not achieved by randomisation, it was particularly important that the explanatory variables (age, sex, Barthel index score (0-11 or 12-20), MDS score (0-4 or 5-10), number of falls prior to the study, and the cluster design) were taken into account in the analysis. Again, no significant difference was found (OR 1.17, 95% CI 0.67 to 2.05,  $p > 0.05$ ).

## **6.6 Acceptability of the hip protectors**

Measuring the acceptability of hip protectors to residents requires attention to two aspects: initial acceptance (which can be defined as the proportion of those who are asked who are willing to start using them), and adherence (which can be defined as the proportion of those who start that continue with their use). However, in terms of the implementation of the policy, the first factor to take into account is the response of the homes that agreed to take part in the study to the implementation of the policy.

### **6.6.1 The response of the homes to the implementation of the policy**

As noted above, seven of the 40 homes in the intervention group and six of the 87 homes in the control group did not cooperate with full data collection and, in the case of the intervention group, with introducing the hip protectors. Consequently, residents in the seven “low-cooperation” homes in the intervention group were never offered the hip protectors. However, in line with the intention to treat approach adopted in this study, these homes were included in the analysis (Tables 6.2, 6.3).

When the homes were recruited to the study, they were asked to offer the hip protectors to all eligible residents present in the home at that time. These residents formed the initial cohort. Homes were also asked to offer the hip protectors to all eligible residents subsequently admitted. The initial cohort numbered 938, with 58 residents identified as ineligible for receiving the hip protectors, a total of 996 residents. However, the mean number of beds in use

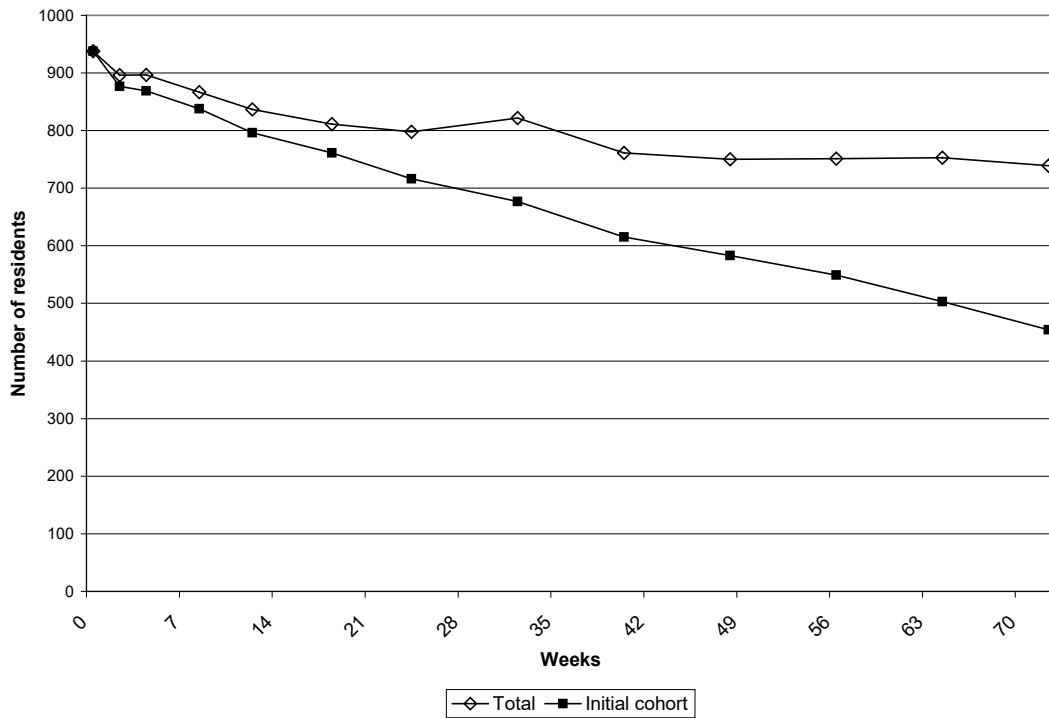
in the intervention homes over the course of the study was estimated at 1,366: 370 more than were identified as possible users of the hip protectors. Of these, 206 occupied beds were in the low-cooperation homes, but this still leaves 164 in the per-protocol homes. This indicates that there were a substantial number of residents who were apparently not offered the hip protectors. It is likely that this pattern persisted over the course of the study. Those leaving the study through death, hip fracture or leaving the home numbered 527 (Table 6.7) but only 408 residents were added to the study over the same period (Figure 6.2), giving a total of 1,346 residents identified as possible users of the hip protectors. It appears that as new residents entered the home, not all were identified as either eligible or ineligible for using hip protectors.

### **6.6.2 Initial acceptance of the hip protectors**

Data on initial acceptance was available for, 1,149 of the 1,366 residents who were offered the hip protectors over the course of the study. Of these, 579 (50.4 %) agreed to wear them and 570 (49.6 %) refused. Home staff were asked to enquire into the reasons mentally capable residents might give for refusing the offer of the hip protectors. Only 33 residents gave a reason for refusing (5.8 percent of those who refused). Of these, 25 (75.8 %) said that the garment was too bulky or uncomfortable and eight (24.2 %) that it was difficult to put on.

Data on initial acceptance was available for 924 residents in the initial cohort. Of these, 508 (55 %) agreed to wear the hip protectors and 416 (45 %) refused. Data on initial acceptance was available for 225 of the 408 residents who were enrolled in the study after the initial cohort. Of these, 71 residents (31.6 %) agreed to wear the hip protectors and 154 (68.4 %) refused.

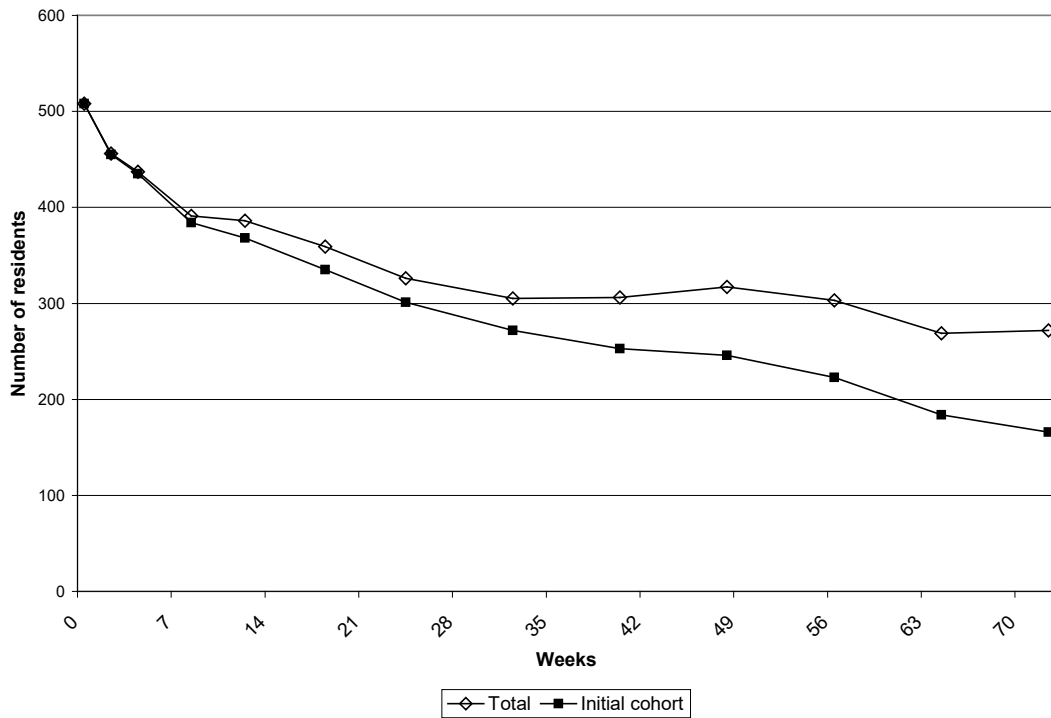
**Figure 6.2 The number of residents for whom data on adherence was available at each observation point**



### 6.6.3 Continued adherence to wearing the hip protectors

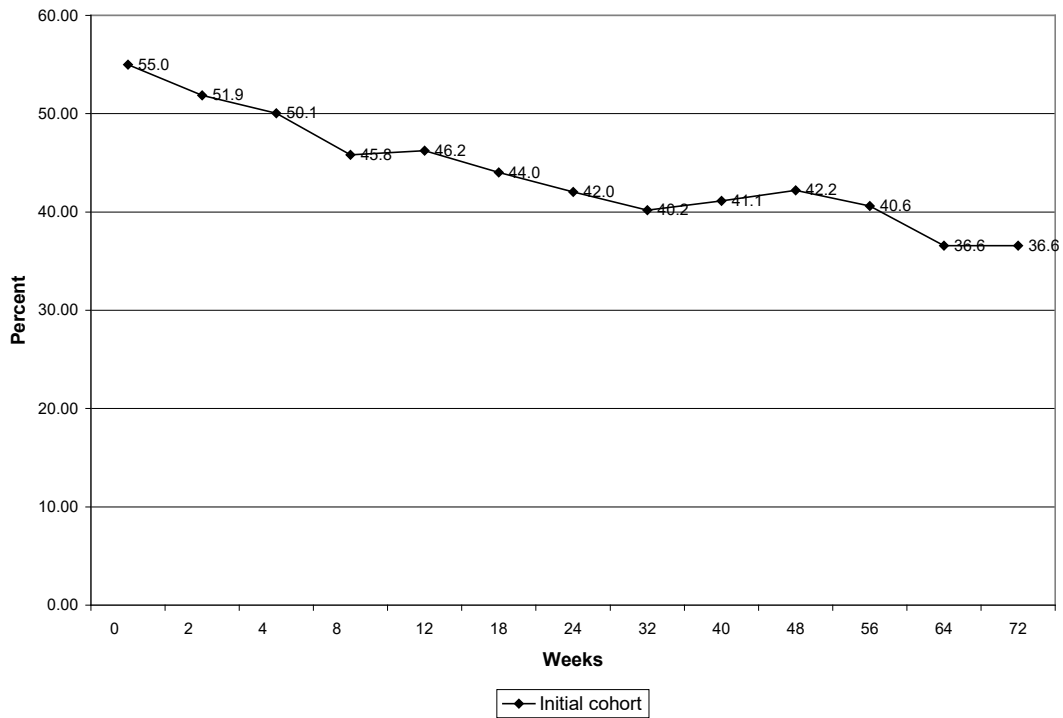
Monitoring and facilitation visits to each home were more frequent near the beginning of the study, so residents joining the study after the start did not receive the same number or frequency of monitoring visits as the initial cohort. Consequently, their pattern of adherence could not be directly compared or included with that of the initial cohort (Figures 6.2 and 6.3). For this reason, analysis of factors influencing adherence to use of hip protectors was based on data from the 938 residents in the initial cohort.

**Figure 6.3** The number of residents wearing the hip protectors for whom data was available at each observation point



Residents in the initial cohort were visited on a total of 9,287 occasions. On 125 of these visits the resident could not be seen, usually because they were temporarily out of the home. The hip protectors were observed to be worn on 4,130 (45.1 %) of the 9,162 visits where the resident was seen. The percentage of residents wearing the hip protectors on each of the 12 visits over the 72 weeks of the study is represented in Figure 6.4.

**Figure 6.4 Percentage of the initial cohort wearing the hip protectors at each observation point**



Whilst the initial cohort are a convenient sample for the purpose of analysing the factors that influence acceptance and adherence, the important figures for assessing the impact of acceptability on the policy are those related to the population in the homes over the entire course of the study period. Therefore, the denominator at any given observation point is equivalent to the mean number of beds occupied in the intervention group over the course of the study (n 1,366). The numerator is the total number of residents wearing the hip protectors at any observation point – those in the initial cohort plus those who subsequently joined the study. This gives figures for initial acceptance of 508/1,366 (37.2%); and adherence of 326/1,366 (23.9%) at 24 weeks; 317/1,366 (23.2%) at 48 weeks; and 272/1366 (19.9%) at 72 weeks. These proportions are considerably less than those calculated at the same points for the initial cohort (estimated at 55.0, 42.0, 42.2 and 36.6%, respectively) (Figure 6.5).

**Figure 6.5 Residents wearing the hip protectors at each observation point as a percentage of the initial cohort and of the total beds occupied**

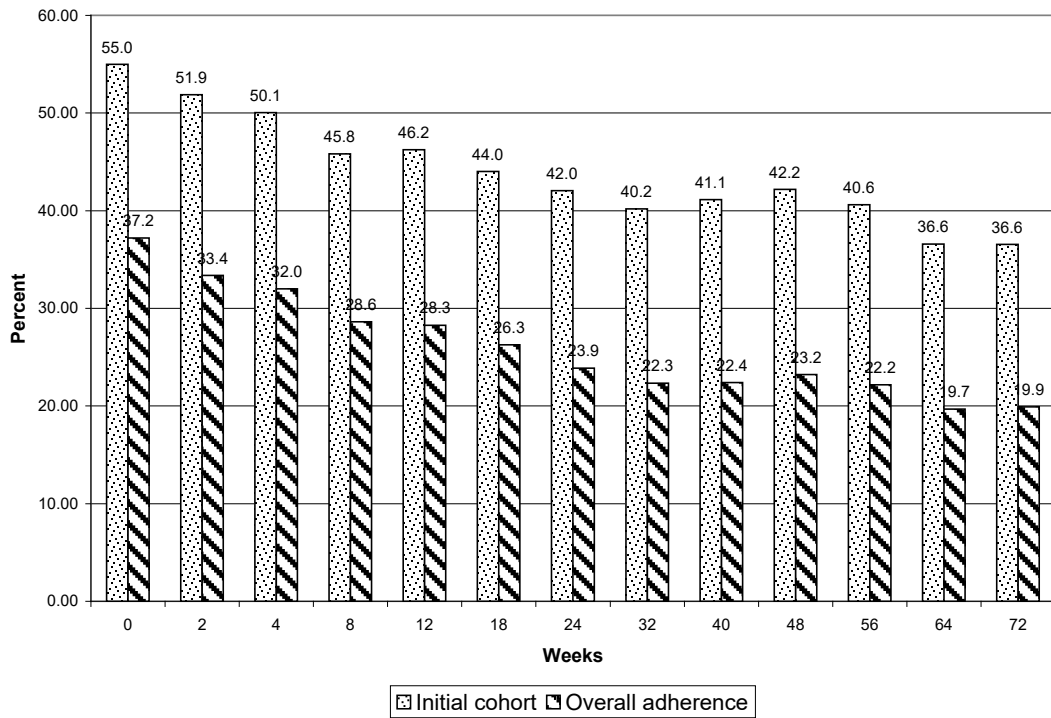
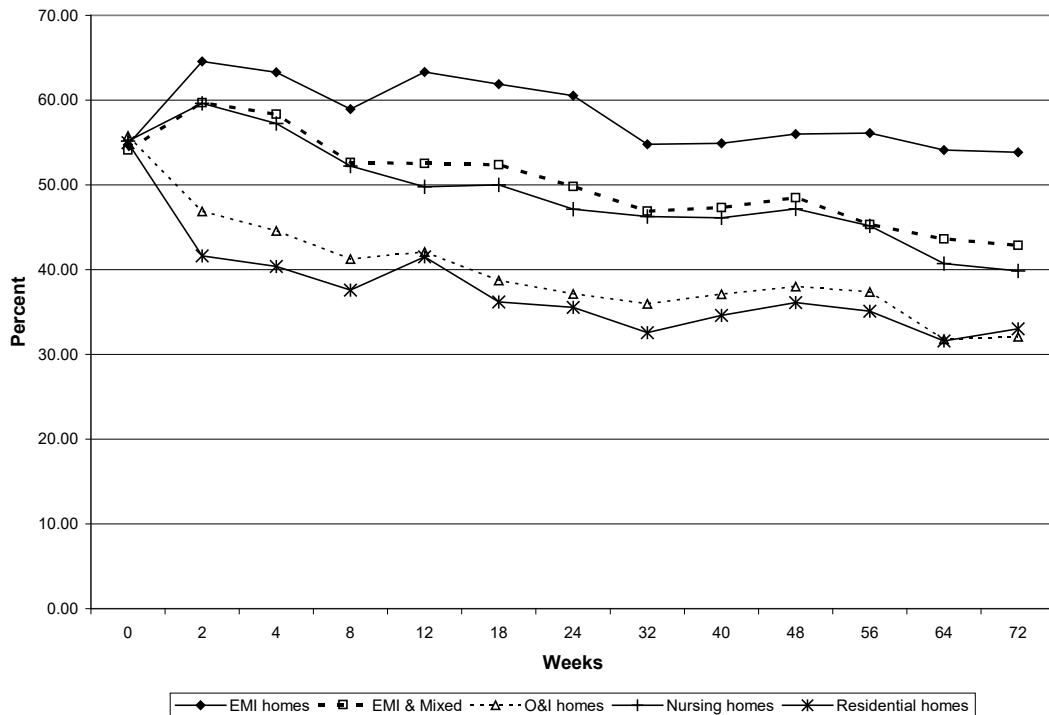


Figure 6.6 shows the percentage adherence in the initial cohort for the following home sub-groups: nursing homes; residential homes; EMI homes; EMI homes and mixed EMI and O&I homes; and O&I homes. Figure 6.7 shows the percentage adherence for residents with intact to moderately

**Figure 6.6 Percentage adherence in the initial cohort by home sub-group**



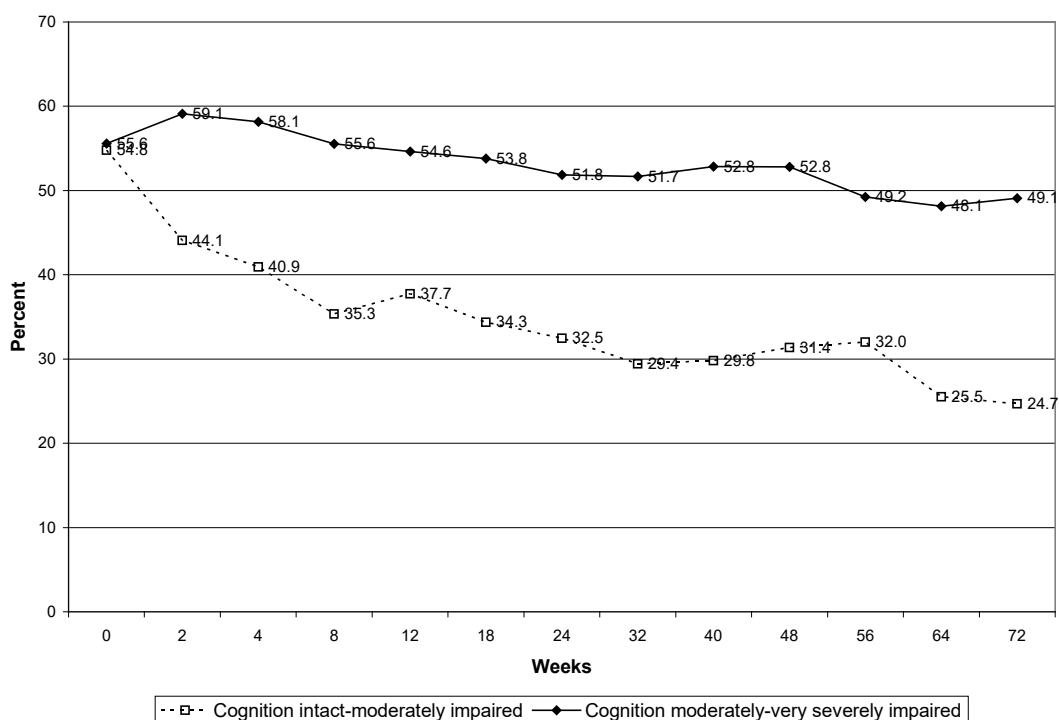
impaired cognition and those with moderate to severe impairment, as measured using the MDS-COGS cognition scale.

## 6.7 Analysis of adherence

### 6.7.1 Identifying residents who adhere to wearing hip protectors

To facilitate analysis, residents who could be characterised as adhering to wearing the hip protectors had to be identified. Examination of the figures for percentage adherence in the initial cohort (Figure 6.4) showed that there was a gradual reduction in adherence until 24 weeks (when adherence was 42 percent). Percentage adherence then stays over 40 percent, returning to 42 percent at 48 weeks, before falling to 36.6 percent at 72 weeks. Twenty-four weeks was chosen as the point at which adherence would be classified. Adherence did not greatly diminish for another 40 weeks following this point and there were still 716 residents from the initial cohort alive and within the

**Figure 6.7 Percentage adherence in the initial cohort by degree of cognitive impairment**



study at 24 weeks, providing a relatively large number for analysis. There were 10 residents not observed at 24 weeks but who were observed immediately before or after 24 weeks. These were included in the analysis to give a total of 726 residents whose use of the hip protectors could be examined. This represents 77.4 percent of the 938 residents in the initial cohort and 53.1 percent of the 1,366 residents estimated to be in the intervention homes at 24 weeks.

Seven residents not wearing the hip protector at 24 weeks were classified as adhering to the use of hip protectors, on the basis that they had exhibited a pattern of consistent use up to and beyond 24 weeks.

Identifying those individuals who can be characterised as adhering or not adhering to wearing the hip protectors, allowed analysis of resident characteristics thought to influence adherence at the level of the individual (Table 6.11).

The level of adherence in each home was based on the proportion of patients from the initial cohort remaining in the home at 24 weeks who were still wearing the hip protectors (Figure 6.8). Amongst the 33 per-protocol homes, mean adherence was 45.6 percent (SD 31.6%), with a range of 0 – 100 percent. The low-cooperation homes, which never introduced the hip protectors, were classified as having zero adherence.

### 6.7.2 Modelling of adherence at home and individual levels

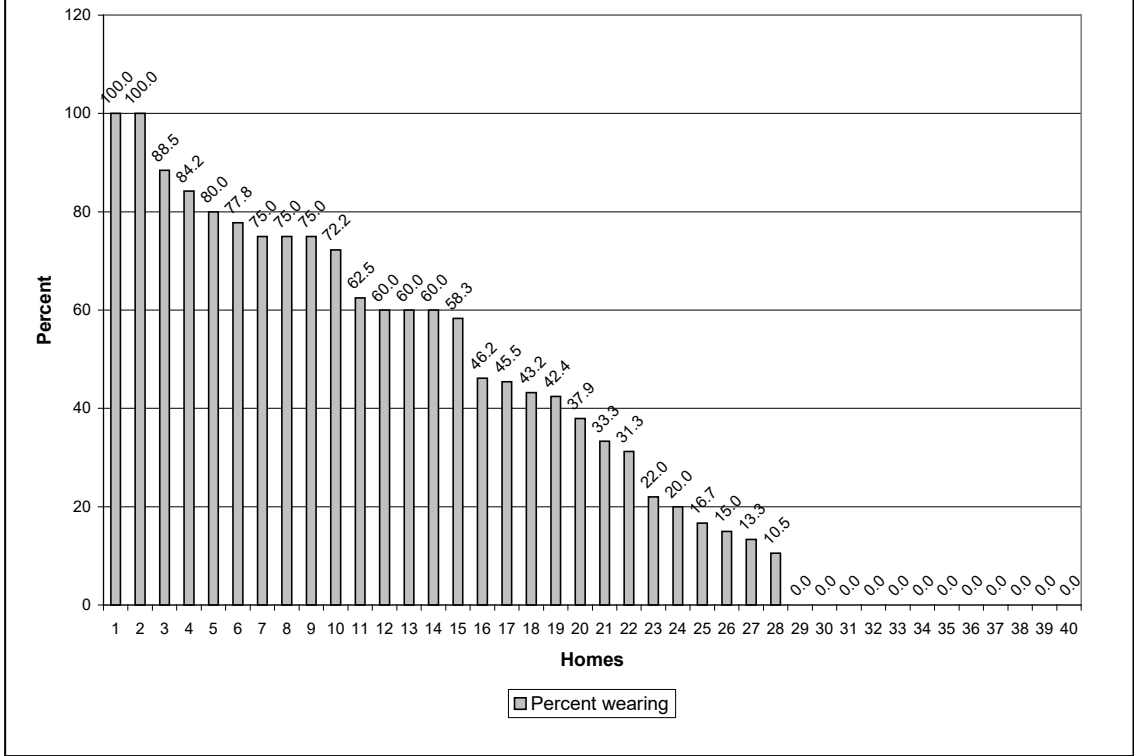
Adherence at the level of the home amongst the 33 per-protocol homes was analysed using generalised linear modelling (binomial error and over-dispersion). Over-dispersion had to be taken into account since the sampling design was clustered. The explanatory variables were: client category (EMI or O&I; EMI or mixed EMI and O&I), type of home (nursing or residential), size of the home (29 or fewer residents, or 30 or more residents), whether the

**Table 6.11 Individual data for residents in the initial cohort who were wearing the hip protectors at 24 weeks**

<b>Characteristic</b>	<b>Wearing (%)</b>	<b>Not wearing (%)</b>
Number of residents for whom data is available	318	408
<i>Age</i>		
Mean [SD]	84.6 [7.6]	84.5 [7.8]
Range	57 – 101	53 – 101
Missing data	5	11
<i>Sex</i>		
Female	241 (77.0)	330 (82.7)
Male	72 (23.0)	69 (17.3)
Missing data	5	9
<i>Cognitive impairment:</i>		
MDS-COGS score 0-4 intact - moderate	118 (37.8)	233 (58.8)
MDS-COGS score 5-10 moderate - very severe	194 (62.2)	163 (41.2)
Missing data	41	19
<i>Physical dependency:</i>		

Barthel Index score 0-11	153 (52.9)	128 (33.2)
Barthel index score 12-20	136 (47.1)	257 (66.8)
Missing data	29	23
<i>Falls in four months before the study</i>		
Mean [SD]	0.69 [1.37]	0.49 [1.19]
Range	0 - 11	0 - 12
Missing data	7	7
<i>Falls during the study</i>		
Mean [SD]	1.13 [1.47]	1.11 [1.63]
Range	0 - 9	0 - 13
Missing data	0	0

**Figure 6.8 Adherence to wearing hip protectors in each intervention home at 24 weeks**  
*(Percentages based on residents in the initial cohort. Includes seven low-cooperation homes with zero adherence)*



home was independent or part of a larger management group, the proportion of R&I standards not met, and the number of times the home had experienced a change of senior manager during the study period. None of these variables was significantly related to adherence.

Adherence at the level of the individual was examined using logistic regression modelling, with age, sex, Barthel Index score, MDS-COGS score, falls prior to the study, and falls during the study, as explanatory variables, and clustering on the home (Table 6.11)

The following resident characteristics were associated with greater use of hip protectors: having a Barthel Index score of 0-11 rather than 12-20 (OR 1.80, 95% CI 1.10 to 2.94,  $p$  0.019); being male rather than female (OR 1.66, 95% CI

1.02 to 2.70,  $p$  0.039); having a greater (MDS-COGS score 5-10) rather than a lesser (MDS-COGS score 0-4) degree of cognitive impairment (OR 1.75, 95% CI 1.01 to 3.03,  $p$  0.046).

The following resident characteristics were not associated with greater use of hip protectors: age of residents (OR 1.00, 95 % CI 0.981 to 1.02,  $p > 0.05$ ); having had one more fall than other residents prior to the study (OR 1.03, 95% CI 0.867 to 1.22,  $p > 0.05$ ); having had one more fall than other residents during the study (OR 0.974, 95% CI 0.882 to 1.07,  $p > 0.05$ ).

# Chapter Seven

## Discussion

This is the largest trial of hip protectors yet attempted both in terms of the number of clusters (homes) and the number of individual participants. It also has a distinctive focus in that the stated aim was to evaluate a policy of making the hip protectors available free of charge to nursing and residential homes. Introducing the hip protectors in a way that would be replicable in everyday practice and using a cluster randomised design has allowed the organisational factors that may affect the success of the policy to be examined.

For the purposes of analysis by individual, it was estimated that a sample size of 1,521 in the intervention group, and 3,043 in the control group would have 80 percent power at the 0.05 level of significance to detect a 40 percent reduction in the rate of hip fracture in the intervention group over the study period, taking the cluster design into account (Chapter Five, section 5.5).

This figure assumed a non-cooperation rate of 20 percent, resulting in a minimum sample size of 1,217 in the intervention group and 2,434 in the control group. The homes provided an estimated maximum of 4,117 occupied beds throughout the study period. The numbers achieved for this analysis were 1,179 in the intervention group and 2,952 in the control group, which approximates to the required sample size. However, it should be noted that these individuals were in the study for varying periods, not all of them for the entire 504 days, which may reduce the power of the study to show an effect. On the other hand, any effect that might have been detected would appear to be considerably less than the 40 percent reduction that the study was designed to detect.

Analysis at the level of the individual did not show a significant difference in the incidence of hip fractures between intervention and control groups.

In terms of the principal analysis of the intervention at the level of the home, it appears that the policy has been unsuccessful in reducing the number of hip fractures amongst residents in the intervention homes. The possible reasons for this failure are discussed in detail below.

## **7.1 Possible reasons for the failure of the policy**

The possible reasons for the failure of the policy are that:

- the incidence of hip fractures in the control group was reduced by contamination of the control group by residents wearing hip protectors not supplied as part of the study
- insufficient numbers of residents in the intervention group wore the hip protectors
- residents who wore the hip protectors were not those at highest risk of hip fracture
- the hip protectors, when worn, did not prevent hip fracture in the event of a fall

Each of these possible reasons will be evaluated in turn.

### **7.1.1 Was the incidence of hip fractures in the control group reduced by contamination of the control group by residents wearing hip protectors not supplied as part of the study?**

If the incidence of hip fractures in the control group was reduced by residents in that group wearing hip protectors not supplied as part of the study, then this would reduce any difference in hip fracture rates between the control and intervention groups. This might confound the intervention effect of the policy of introducing the hip protectors in the intervention group. Meyer *et al* (2003)

argue that this may have been the case in their cluster randomised trial, where limited use of hip protectors in the control group may have prevented a disproportionate number of hip fractures, as those most at risk of hip fracture might be expected to have chosen to wear hip protectors. However, of the 2,592 residents in the control group for whom this data was available, only 27 (0.9%) were reported to be already wearing hip protectors at the start of the study. No further residents were noted to be wearing hip protectors at further monitoring visits in the control homes. Such a low rate of use would not have had a significant impact on the incidence of hip fractures in the control homes and can be ruled out as a possible explanation for the failure of the policy.

### **7.1.2 Did insufficient numbers of residents in the intervention group wear the hip protectors?**

Data on initial acceptance was available for 924 residents in the initial cohort of residents in the intervention group. Of these, 508 (55 %) agreed to wear the hip protectors and 416 (45 %) refused. Following this, there was a gradual reduction in adherence until 24 weeks, when adherence was 42 percent. Percentage adherence then stayed over 40 percent, returning to 42 percent at 48 weeks, before falling to 36.6 percent at 72 weeks.

The majority of studies reported in the literature achieved higher levels of both acceptance and adherence, although all but Kannus *et al* (2000) used sub-groups consisting of homes or residents thought to be at higher risk of falling. No such selection took place in our study: all homes in the EHSSB area were invited to participate and the eligibility criteria for wearing hip protectors were not restrictive. Therefore, one might expect that the proportion of residents motivated to wear the hip protectors by perceived risk of falling would be lower than that in populations where the risk of falling was higher. It is also the case that Kannus *et al* (2000) did not include the 57 percent of participants who, for various reasons dropped out of the intervention group in their calculation of adherence, after they had dropped out of the study – when their adherence would presumably fall to zero. Had they been included, the figure for adherence would be considerably lower.

Taking these factors into account, it would appear that initial acceptance of 55 percent and continuing adherence of 42 percent are levels that could reasonably be expected in a sample from the population examined in our study. However, these figures require careful interpretation in terms of their impact on the policy. The policy was intended to reduce the overall rate of hip fracture in intervention homes. Therefore, the important figures for acceptance and adherence are those related to the population in the homes over the entire course of the study period. Acceptance and adherence could be estimated as a proportion of the total number of beds occupied over the course of the study. If the figures provided by the homes for beds occupied are reliable, then the denominator for estimating percentage use of the hip protectors at any observation point in the study should be the mean number of beds occupied (n 1,366) over the course of the study. The numerator should be the total number of residents wearing the hip protectors at any observation point – those in the initial cohort plus those who subsequently joined the study. This gives figures for initial acceptance of 508/1,366 (37.2%); and adherence of 326/1,366 (23.9%) at 24 weeks; 317/1,366 (23.2%) at 48 weeks; and 272/1366 (19.9%) at 72 weeks. These proportions are considerably less than those calculated at the same points for the initial cohort (estimated at 55.0, 42.0, 42.2 and 36.6%, respectively) (Figure 6.5)

It would appear from these figures that not all residents who might be eligible to use hip protectors were identified as such by the homes. There were 938 residents identified for the initial cohort in the intervention homes, with a further 58 classified as ineligible to wear the hip protectors – a total of 996 residents. However, if the beds occupied were at the estimated level of 1,366, then there were 370 residents who were not considered for the study. Of these, 206 occupied beds were in the low-cooperation homes, but this still leaves 164 in the per-protocol homes. This effect seems to have continued throughout the study (Figure 6.2), with the overall number of residents identified as taking part in the study gradually reducing (through death, hip fracture, or transfer out of the home), even though the policy required newly admitted eligible residents to be offered the hip protectors and included in the study. It also seems that residents admitted to the intervention homes after the start of the study were less likely to agree to wear the hip protectors. Data on initial acceptance was available for 225 of the 408 residents who were enrolled in the study after the

initial cohort. Of these, 71 residents (31.6 %) agreed to wear the hip protectors and 154 (68.4 %) refused.

These figures illustrate a phenomenon experienced throughout the study: the difficulty in obtaining and maintaining commitment from the staff in a proportion of the homes, both to implement the policy and to provide full data for the study. Some homes agreed to take part in the study and implement the policy but then refused further cooperation and did not offer the hip protectors (the seven “low-cooperation” homes). Other homes implemented the policy but again to various degrees, with some homes achieving 80 or even 100 percent adherence at 24 weeks, whilst others had fallen to zero adherence (Figure 6.8).

Obviously, lower levels of adherence are likely to reduce the effectiveness of the policy. However, even if the lowest figures for adherence are accepted, this may not be a sufficient explanation for the failure of the policy. Lauritzen *et al* (1993) report a significant reduction in the rate of hip fracture (RR 0.44, 95% CI 0.01 to 0.94) with a rate of adherence (24%) similar to the lowest estimate of adherence observed in our study. The effect seen in Lauritzen *et al*'s (1993) study may partly be explained by a process of selection (by staff or by the residents themselves) that led to those thought to be most at risk of falling wearing the hip protectors. This leads to the third possible explanation for the failure of the policy, discussed below.

### **7.1.3 Were residents who wore the hip protectors those at lower risk of hip fracture?**

In terms of the home-level analysis, the residents identified in this study as being at higher risk of hip fracture were those living in EMI homes (OR 1.98, 95% CI 1.45 to 2.72  $p < 0.01$ ); those living in homes that were part of managed group of homes rather than in an independent home (OR 1.42, 95% CI 1.04 to 1.95,  $p < 0.05$ ); and (in the per-protocol analysis) those in homes with less than 30 residents compared to those with 30 or more residents (OR 1.6, 95% CI 1.07 to 2.44,  $p < 0.05$ ) (Table 6.9). However, analysis of adherence at the level of the home did not detect significant associations with any of the measured home characteristics, including the home being an EMI home.

Having a greater (MDS-COGS score 5-10) rather than a lesser (MDS-COGS score 0-4) degree of cognitive impairment was associated with greater use of hip protectors (OR 1.75, 95% CI 1.01 to 3.03,  $p < 0.05$ ). Therefore, one could argue that cognitively impaired residents are both more likely to wear hip protectors and at greater risk of hip fracture. On the other hand, there were no significant associations between adherence and home (as oppose to individual) characteristics, including the home being an EMI home, so the match between risk and adherence is unclear in this case. It may be that no difference was seen between EMI and non-EMI homes because of the large number of cognitively impaired residents in non-EMI homes. As might be expected, 87.4 percent of the 389 residents in designated EMI beds for whom data was available had an MDS-COGS score of 5-10. However, the equivalent percentage for the 746 residents in O&I beds was also relatively high, at 41.4 percent. The associations between greater use of the hip protectors and greater cognitive impairment, and greater risk of hip fracture and residence in an EMI home are of importance because they suggest that targeting residents who are cognitively impaired may reduce hip fractures in this sub-group. However, even when the EMI homes were analysed as a sub-group, no significant intervention effect was detected.

There was no association between adherence and the size of the home (29 or fewer residents, or 30 or more residents); or whether the home was independent or part of a larger management group.

If generally accepted risk factors for hip fracture, such as a history of falling, increased age and female sex, are examined, no association with adherence is found. In fact, male sex is associated with greater use of hip protectors (OR 1.66, 95% CI 1.02 to 2.70,  $p < 0.05$ ).

It appears that staff (and perhaps residents' relatives) are not persuading residents at high risk of hip fracture to wear the hip protectors. Neither are residents at higher risk of hip fracture deciding to wear hip protectors. This may be because staff and residents are unable to identify those at higher risk, or because the hip protectors are not believed to be efficacious in preventing hip fracture, or because the daily effort of using the hip protectors is perceived to

outweigh the benefit of avoiding a possible hip fracture at some time in the future.

It is possible that an approach targeting those most at risk would prove fruitful. The policy put few limits on those who were eligible to receive the hip protectors, excluding only the small minority residents who were confined to bed 24 hours a day, who had pressure sores on the hip, or who were temporarily admitted. In contrast to this comprehensive approach, a number of studies targeted those assessed to be at higher risk of hip fracture, either because they were thought to be at greatest risk of falling (Jantti *et al*, 1998; Chan *et al*, 2000; Cameron *et al*, 2001), or because they were female (Harada *et al*, 2001; Cameron *et al*, 2001). A targeted approach was rejected in our study because of the extra burden of assessment this would have placed on the homes, and because such an approach might have excluded residents who subsequently suffered a hip fracture. However, the risk factors for hip fracture were discussed with staff as part of the implementation process, with the intention of motivating them to offer the hip protectors to residents who might be at risk. The chosen criteria were believed to reflect those that might reasonably be expected if homes had a policy of using hip protectors. It is possible that introducing a risk assessment process would have alerted both residents and staff to those who might benefit most from wearing the hip protectors. Staff might then be expected to make a special effort to persuade residents at higher risk to wear the hip protectors, and such residents might be more open to wearing them.

#### **7.1.4 Did the hip protectors, when worn, fail to prevent hip fracture in the event of a fall?**

The hip protectors were worn during 332 of 689 falls recorded in the intervention group (46.8%). Eleven residents were reported to have suffered a hip fracture whilst wearing the hip protectors. This information was provided by staff in the homes, who might have felt obliged to state that a resident was wearing hip protectors if the resident fell and suffered a fracture, even if this was not the case. However, there were also cases where the resident had stopped wearing the hip protectors and subsequently suffered a hip fracture, and this

was reported by staff. This indicates that staff were not tailoring their reports to avoid possible criticism.

Assuming the reports to be accurate, it would appear that there were cases where residents fell whilst wearing the hip protectors and suffered a hip fracture. The laboratory studies of the Safehip® hip protector used in this study indicate that, as with all hip protectors currently available, it cannot guard against all hip fractures, especially amongst fallers with very low bone mineral density. So, the occurrence of hip fractures whilst the hip protectors were worn was not entirely unexpected, although 11 of 85 fractures (13%) were more than had been anticipated. This is a relatively large number of fractures, although two other studies reported proportionately larger percentages. Kannus *et al* (2000) report four of 13 hip fractures (31%) occurring whilst the hip protectors were worn and Meyer *et al* (2003) report four of 21 hip fractures (19%). On the other hand, all other studies report no fractures whilst wearing hip protectors.

A question arises: Would the policy have been successful if the hip protectors had been efficacious in preventing all hip fractures when they were worn at the time of a fall? This question cannot be answered directly, but an exploratory analysis was carried out where the 11 residents who were reported to have suffered a hip fracture whilst wearing the hip protectors were re-coded as having had no hip fracture – in other words as if they had been wearing a hip protector that could guarantee full protection against hip fracture. However, even when these fractures were re-coded, the policy of offering hip protectors was not associated with a reduced rate of hip fractures, in either the intention to treat analysis (OR 0.92, 95% CI 0.7 to 1.22,  $p > 0.05$ ) or the per-protocol analysis (OR 0.8, 95% CI 0.58 to 1.09,  $p > 0.05$ ). The conclusion must be drawn that the failure of the policy was not due solely to the limitations of the hip protector.

### **7.1.5 Pelvic fractures**

Previous studies that report on the incidence of pelvic fracture have not shown that wearing hip protectors influences the risk of such fractures (Lauritzen *et al*, 1993; Kannus *et al*, 2000; Cameron *et al*, 2001). However, in our study, the

policy was associated with an increased rate of pelvic fractures in both the intention to treat analysis (OR 4.03, 95% CI 1.48 to 10.96,  $p < 0.01$ ) and the per-protocol analysis (OR 4.95, 95% CI 1.8 to 13.61,  $p < 0.01$ ). It is possible that the mode of action of the hip protectors – dispersing the force of a fall away from the greater trochanter into the surrounding tissues – leads to greater forces being transmitted to the pelvis and so to an increased risk of pelvic fracture. However, of the 12 pelvic fractures recorded in the intervention group, only two were reported to have occurred when the resident was wearing the hip protectors. Therefore, the majority of pelvic fractures were not directly caused by the transmission of the force of a fall through the hip protectors.

Another possibility is that the residents in the intervention group suffered a greater incidence of falls than those in the control group and so increased their risk of pelvic fractures. Four studies report a higher rate of falls amongst residents wearing hip protectors compared to those in control groups (Lauritzen *et al*, 1993; Jantti *et al*, 1998; Chan *et al*, 2000; Harada *et al*, 2001). It is suggested that this may be due to staff and residents (Jantti *et al*, 1998; Chan *et al*, 2000) believing that residents wearing the hip protectors are at less risk of serious injury if they fall, and therefore being willing to risk residents moving about more freely. This explanation is supported by Cameron *et al*'s (2000a) study of 131 older women living at home, with a history of hospital admission following a fall. Those randomised to use hip protectors developed a greater belief in their own ability to avoid falling than those in the control group. If this were the case, then one would expect the intervention group to have a higher overall rate of injurious falls than the control group. However, there was no significant difference between the intervention and control groups in the rate of injurious falls in either the intention to treat analysis (OR 1.16, 95% CI 0.86 to 1.56,  $p > 0.05$ ) or the per-protocol analysis (OR 1.07, 95% CI 0.78 to 1.48,  $p > 0.05$ ).

Although the policy was associated with an increased risk of pelvic fracture, a causal link has not been established, so this may have occurred by chance, especially in the light of the small number of fractures.

### **7.1.6 Summary**

It would appear that the policy failed as a result of a number of factors that, when combined, reduced the effectiveness of the intervention. Principal amongst these is low overall adherence to the use of hip protectors. This is compounded by indications that those most at risk of hip fracture (older, female residents, with a history of falls) were not the most likely to wear hip protectors, and by the fact that the hip protectors did not always prevent hip fractures when worn during a fall.

## **7.2 Explaining the failure of the policy**

The conceptual framework guiding the overall approach to the implementation of the policy was based on the work of Kitson *et al* (1998). Kitson *et al* (1998) suggest that successful implementation depends equally on three core elements: the level of evidence, the method of facilitating the change, and the context into which the evidence is being implemented. The approach to implementation can therefore be reviewed in relation to these three factors.

### **7.2.1 The level of evidence supporting the use of hip protectors**

At the time that the hip protectors were introduced to the homes (between January and August 2001), the level of evidence for the use of hip protectors was not extensive but it was uniformly positive. Randomised controlled trials published in peer reviewed scientific journals strongly supported their use (for example, Lauritzen *et al*, 1993; Kannus *et al*, 2000), and the only systematic review available (Parker *et al*, 2002) confirmed their effectiveness amongst high risk groups, such as residents of nursing and residential homes. Consequently, the hip protectors could be recommended to managers, staff and residents in homes with a relatively high degree of confidence that they would be efficacious in reducing the incidence of hip fracture amongst those residents who wore them.

On the other hand, the fact that the hip protectors were the subject of a research project may have raised doubts about their efficacy. It may have been

difficult for staff to grasp the difference between a trial of hip protectors and a trial to evaluate a policy of making the hip protectors available in homes. Where there are many competing demands on staff, cooperation with research originating from outside the home may have received a low priority. Whilst the intervention was designed to be introduced as if it were a policy of the home, it may well have been seen primarily as research into hip protectors, and therefore as an option (as in fact it was) rather than a requirement for the home.

### **7.2.2 The method of facilitating the change**

Kitson *et al* (1998, P. 152) define facilitation as “the type of support required to help people change their attitudes, habits, skills, ways of thinking, and working.” The main facilitators for the implementation of the policy were the researcher and the nurse facilitator employed for the purpose. The researcher was mainly involved in facilitation during the recruitment and introductory period, with ongoing support provided by the nurse facilitator during the remainder of the study. The nurse facilitator was able to develop friendly relationships with many of the home managers and staff during her regular visits to the homes, and certainly maintained the respectful and empathetic approach, and the consistent support recommended by Kitson *et al* (1998). However, the facilitator had no official position or authority in relation to the homes, and in fact depended on the goodwill of the homes to carry out the study. It was thought that the fact that the intervention was offered with the backing of the EHSSB and its Registration and Inspection Unit, the Research and Development Office at the DHPSS, the Geriatric Medical Unit at the Royal Victoria Hospital, and both Universities in Northern Ireland, would lend authority to the policy. Nevertheless, the home managers and their staff were participating on a voluntary basis, which limited the degree to which the nurse facilitator could influence practice within the homes.

### **7.2.3 The context into which the evidence is being implemented**

Context is defined as the setting in which the change is to be implemented and is influenced by the organisational culture, the style of leadership, and the level of evaluation (McCormack *et al*, 2002). Residents are highly dependent on staff for many basic activities of living, and are therefore likely to be dependent on

staff to assist with the use of hip protectors. These issues were discussed in Chapter Two, where it was argued that the promotion of hip protectors in the homes must have the active support of staff or it would fail. Therefore, the implementation of a policy to use hip protectors will be vitally affected by the context within each home. However, whilst the presentation of the evidence and the quality of the facilitation could be controlled by the researcher and the nurse facilitator, there was no possibility, with the resources available, of diagnosing or changing the organisational context within the 40 homes in the intervention group. Homes received the same level of evidence, and the same degree of facilitation, but made widely differing responses to the introduction of the policy.

This is evident in both the initial response to the introduction of the hip protectors, and the broad range of adherence at 24 weeks. As noted above, seven of the intervention homes, having agreed to take part in the study, did not implement the policy (the low-cooperation homes). This must be balanced against the fact that 32 homes refused to take part in the study from the outset and that six homes in the control group also offered only low-cooperation. Therefore, it is uncertain whether the homes in the intervention group were showing low-cooperation with the policy or simply a reluctance to take part in the research. However, even if the per-protocol homes – those homes that agreed to cooperate with the study and implement the policy - are considered in isolation, adherence at 24 weeks ranged from 0 – 100 percent. The reasons for these differences between homes are not clear. Adherence at the level of the home was analysed using generalised linear modelling (binomial error and over-dispersion), with client category (EMI or O&I; EMI or mixed EMI and O&I), type of home (nursing or residential), size of the home (29 or fewer residents, or 30 or more residents), whether the home was independent or part of a larger management group, the proportion of R&I standards not met, and whether the home had experienced a change of senior manager during the study period as the explanatory variables. However, no significant relationships were detected. It seems that the differences between homes in terms of the degree to which they successfully implemented the policy, are dependent on characteristics of the context that are less easily measured than those captured in this study. Kitson *et al* (1998) suggest that a culture that is supportive of necessary change has a well-defined set of values, promotes learning as a team activity,

emphasises relationships and teamwork, and rewards good performance. They recommend that leaders should be capable of inspiring staff with a shared vision and empowering them to achieve their goals, and that evaluation should make use of multiple methods to provide feedback on individual, team and system performance. There were insufficient resources available in this study to formally evaluate these organisational and cultural factors, but the personal experiences of the researcher and the nurse facilitator in the homes suggest that the response of the senior manager in the home was a crucial factor in the success or failure of the policy within that home. Where the manager was both supportive of the use of hip protectors and also an effective manager of staff, the hip protectors were likely to be used to a greater extent than in homes where this was not the case. This is consistent with the model offered by Kitson *et al* (1998). They suggest that the evidence is more likely to be implemented where a full complement of desirable factors are present in all three elements. Conversely, high quality evidence may not be implemented where context or facilitation are inadequate.

### **7.3 Evaluating the implementation process**

The implementation process, described in Chapter Five, was informed by the recommendations from the Effective Health Care Bulletin, *Getting evidence into practice* (Effective health care, 1999). *Getting evidence into practice* recommends a three-stranded approach:

- the identification of factors likely to influence the proposed change
- a multi-faceted approach to targeting the relevant factors by people with appropriate skills
- arrangements to monitor and maintain change

#### **7.3.1 Identifying factors that are likely to influence the implementation process**

It is recommended that an analysis of factors likely to influence the implementation process should include the following:

- identification of all groups likely to be affected by the change
- assessment of those aspects of the change that might influence its adoption
- assessment of the preparedness of the health professionals to change
- identification of potential external barriers to change.
- identification of likely enabling factors (Effective health care, 1999)

Most of the factors influencing implementation were successfully identified prior to the commencement of the intervention period. For example, all the relevant groups likely to be affected by the change were identified. These were the residents themselves, the senior managers, the staff in the homes, the residents' relatives and General Practitioners. Each of these groups was approached in various ways. The nurse facilitator offered to speak to groups of residents about the hip protectors but only a handful of home managers took advantage of this offer. The implementation plan called for the main approach to residents to be made by staff, because staff members are known to residents and are in a strong position to influence their decision and support the use of the hip protectors. The weakness of this approach is that where staff do not commit themselves to the implementation process, residents may not even be offered the hip protectors.

To a certain extent, any lack of enthusiasm amongst staff could be circumvented by approaching other groups, such as residents' relatives and General Practitioners, in the hope that they would suggest to residents or staff that the hip protectors should be tried. Evidently, this was not sufficient in those homes in which adherence was very low. The approach to GPs was in the form of a letter informing them that their patients in nursing and residential homes might be asked to take part in the study. A more aggressive approach, seeking to enlist the active support of GPs, might have been more fruitful. However, this would probably mean visiting GPs in their surgeries and keeping them abreast of progress through regular reports. Such an approach would require considerable amounts of the nurse facilitator's time and is not guaranteed to produce the desired effect. All relatives of residents in the intervention homes were written to, informing them that the resident was to be asked to take part in the study, and asking them to discuss the offer of hip protectors with the

resident. Again, this seems to have been insufficient to overcome barriers to implementation in the homes with low adherence. On the other hand, this approach appears to have met with some success in the case of relatives of mentally infirm residents. In the exploratory study, 102 of 151 (67.5%) relatives of the mentally infirm refused to let the resident take part in the research (although this was prior to randomisation). In the main study, only 52 percent (205 of 394) of relatives refused permission for residents in EMI beds.

The crucial role of the senior managers of the homes was discussed in Chapter Two. The managers are the gatekeepers for the homes, making the initial decision as to whether to allow the home to take part in the study. The exception to this is where the home is part of a managed group, when the decision to take part is made by the managers of the group, rather than the individual home manager. This is supported by the fact that only one of the 13 low-cooperation homes was part of a managed group (Table 6.3). However, amongst the per-protocol homes, there was no relationship found between adherence and whether the home was independent or part of a larger management group, so the influence of the senior managers of groups of homes obviously had its limits. Even if a home manager, on the instruction of a more senior manager in the organisation, agreed to implement the policy, the effectiveness of the implementation could not be guaranteed.

### **7.3.2 A multi-faceted approach to targeting the relevant factors by people with appropriate skills**

The implementation of the educational and administrative aspects of the policy proceeded as planned. With the exception of the low-cooperation homes, all managers agreed to the nurse facilitator meeting with their staff, and accepted the relevant literature and documentation, together with the video programme promoting the use of the hip protectors. The administrative arrangements for ordering the hip protectors worked well, with only occasional delays in delivery when particular sizes were briefly out of stock.

### **7.3.3 Arrangements to monitor and maintain change**

The nurse facilitator had no difficulty in gaining access to the homes for monitoring the use of the hip protectors, although, as noted above, it appears that not all eligible residents were brought to her attention, and neither was full information on all patients provided by the homes.

#### **7.3.4 Summary**

The implementation process was broadly successful insofar as it depended on the researcher and nurse facilitator and the surrounding administrative processes. The relevant groups were identified and targeted with a multi-faceted process of education and practical support, and the evaluation process was carried out as planned. However, the response of the homes was highly variable. The conceptual framework developed by Kitson *et al* (1998) suggested that this would be the case but the extent of variation between homes was nonetheless unexpected. The decision of the low-cooperation homes in the intervention group to stop short of implementation was difficult to understand. The hip protectors were presented as an efficacious intervention designed to avoid a painful and potentially catastrophic injury for residents in the care of the homes. They were a simple intervention, offered free of charge and with a quick and easy ordering process. The four pairs of hip protectors offered to each resident were worth at least £110, so a home with 30 eligible residents could receive resources to the value of £3,300.

The low-cooperation homes were at one end of the continuum of failure and success but, in addition to these, a number of homes gave minimal cooperation. These homes did not withdraw cooperation but made what appeared to be a token effort to implement the policy. Despite extra visits and practical assistance with data collection from the nurse facilitator, these homes were slow to agree to appointments to arrange implementation, and delayed providing requested data and ordering the hip protectors. Few of their residents started wearing the hip protectors. At the other end of the continuum were homes where the policy was quickly and comprehensively implemented, and both acceptance of the hip protectors and adherence to their use was at a high level. The impression was gained that the deciding factor was the attitude and

practice of the home manager. Where the manager was in favour of the hip protectors and an effective manager of the home, the hip protectors were effectively introduced. Where the manager was either not convinced of the efficacy of the hip protectors, or not managing the home effectively, then the hip protectors were likely to be introduced ineffectively.

## **7.4 The research in the context of the literature**

The majority of studies support the efficacy of hip protectors. All but three report a significant reduction in the rate of hip fracture when hip protectors are used (Lauritzen *et al*, 1993; Jantti *et al*, 1998; Hindso and Lauritzen, 2000; Chan *et al*, 2000; Kannus *et al*, 2000; Harada *et al*, 2001). The reasons for the failure of the policy implemented in our study have been discussed above but it is important to note that the only large study reported in the literature that made allowance for the effect of clusters did not show a significant reduction in risk (Meyer *et al*, 2003). The ability of other large cluster randomised controlled trials to detect a significant effect is compromised by failure to take their randomisation by cluster into account when estimating sample size and analysing results (Lauritzen *et al*, 1993; Ekman *et al*, 1997; Kannus *et al*, 2000).

It is also the case that the degree of efficacy of the hip protectors has not been clearly established. The individual level analysis in our study does not show a significant difference between intervention and control groups (Odds Ratio [OR] 1.08, 95% CI 0.77 to 1.53,  $p > 0.05$ ). Even when those known to have adhered to wearing hip protectors at 24 weeks are compared to all those in both intervention and control groups who did not do so, no significant effect on the incidence of hip fractures is detected (OR 1.17, 95% CI 0.67 to 2.05,  $p > 0.05$ ). It should be noted that these groups were not achieved by randomisation, and might be expected to differ in significant respects. However, the explanatory variables (age, sex, Barthel index score (0-11 or 12-20), MDS score (0-4 or 5-10), number of falls prior to the study, and the cluster design) were taken into account in the analysis, which lends credibility to the result.

Laboratory studies suggest that all presently available hip protectors, even when worn correctly, cannot protect those with the most fragile bones in all

circumstances. This is reflected in the significant minority who fracture their hips whilst wearing the hip protectors. Indeed, a large study published very recently (van Schoor *et al*, 2003) and randomised by individual in order to test the efficacy of Safehip® hip protectors, did not show a significant effect in either an intention to treat or a per-protocol analysis. Four of the 18 hip fractures in the intervention group (22.2%) occurred when the hip protectors were worn.

#### **7.4.1 The methodological approach**

The majority of studies reported in the literature were designed as randomised controlled trials, with randomisation at the level of the individual (Jantti *et al*, 1998; Hindso and Lauritzen, 2000; Chan *et al*, 2000; Harada *et al*, 2001; Cameron *et al*, 2001; Torgerson and Watt, 2002; van Schoor *et al*, 2003). This approach is best suited to evaluating the efficacy of the hip protectors and typically involves selecting from the general population of interest in order to include those participants who will show the greatest effect from the intervention, and to exclude those who have characteristics that may confound or reduce the effect of the intervention. Naturally, all these studies focus on populations at high risk of suffering a hip fracture: either older people in residential care homes (Jantti *et al*, 1998; Chan *et al*, 2000; Harada *et al*, 2001; Cameron *et al*, 2001) or those with previous hip fracture (Hindso and Lauritzen, 2000; Torgerson and Watt, 2002). However, within this high-risk group, various sub-groups are targeted – principally those thought to be at greatest risk of falling (Jantti *et al*, 1998; Chan *et al*, 2000; Cameron *et al*, 2001), and female residents (Harada *et al*, 2001; Cameron *et al*, 2001). Thus, in order to test efficacy, others who might benefit (those at a lesser but not low risk of falling, male residents, those with no history of hip fracture) are excluded. Consequently, these studies can only address the question of the efficacy of the hip protectors, which can be defined as the “extent to which an intervention produces an ideal result under ideal conditions” (Cochrane Collaboration, 2001, P.10).

Once a case for efficacy has been made, the next question to be addressed is that of effectiveness, defined as the “extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do.”

(Cochrane Collaboration, 2001, P.10). This means the intervention must be tested in “ordinary circumstances”, which, in this context, means evaluating the hip protectors as they might be used in an everyday service environment. The best approach to this is to carry out a randomised controlled trial but to randomise at the level of the cluster. This is the approach taken by the remainder of the clinical trials (Lauritzen *et al*, 1993; Ekman *et al*, 1997; Kannus *et al*, 2000; Meyer *et al*, 2003), which randomised at the level of the nursing home or other residential unit. The special challenges involved in the design of cluster randomised trials were discussed in Chapter Five. With the exception of Meyer *et al* (2003), all of these studies encountered difficulties in accounting for the effect of their cluster-level design in determining sample size and in subsequent individual-level analysis.

Our study is a cluster randomised controlled trial seeking to evaluate effectiveness. However, it is intended to address the next stage in evaluation – to test not only the effectiveness of the intervention, but also the effectiveness of the policy of making the intervention available. This means placing oneself in the position of a potential policy-maker, for example a Health and Social Services Board in Northern Ireland, and carrying out a process of policy implementation that would be replicable by such a body in that context. Consequently, all homes and individuals that would be subject to such a policy must be included in the trial and the analysis must be by intention to treat. This entails including all participants in the analysis according to the intervention to which they were allocated, whether they received it or not, in order to reflect the obstacles to adherence that might be found in everyday practice and the spread of recipients who would normally be offered the treatment (Cochrane reviewers’ handbook, 2001).

As discussed above, Meyer *et al* (2003) report the only study with a cluster-level design that took the cluster into account when determining sample size and in subsequent individual-level analysis. However, even this study was not a true test of policy. Only 44 of 86 homes participated, which raises the question of the degree to which participating homes were representative of the wider population in nursing homes. Within the homes, only a small proportion of residents were invited to participate. The analysis was by intention to treat but it appears that Meyer *et al* (2003) intended to treat only 15 percent of the

estimated population of the homes. The results relate only to this sub-group, with no figures for hip fractures provided for the remaining residents in the homes. Consequently, Meyer *et al's* (2003) study had a design suitable for testing the effectiveness of the intervention of offering hip protectors but could not address the effectiveness of a policy of making hip protectors available in nursing and residential homes. Our study seeks to build on previous work by including as many as possible of the eligible homes in the EHSSB area and by including all of their residents in the analysis, whether or not they were offered the hip protectors. The policy was to make hip protectors available free of charge in nursing and residential homes, and to support the implementation process by employing a nurse facilitator to encourage staff in the homes to promote their use. The trial evaluates the effect of this policy by including all homes to which the policy applied, irrespective of the degree to which they implemented the policy.

#### **7.4.2 Introducing the intervention**

The introduction of the intervention in our study was similar to the approach taken in a number of other studies. All studies that report an educational intervention targeted staff rather than residents through 1-2 hour presentations (Parkkari *et al*, 1998; Cryer *et al*, 2002; Meyer *et al*, 2003). Nurses were employed to facilitate the introduction of the hip protectors and to encourage adherence by visiting residents or homes (Kannus *et al*, 2000; Cryer *et al*, 2002; Meyer *et al*, 2003) and written materials provided for staff and residents. An innovation in our study was the use of a videotaped presentation. This was in the style of a television news report presented by a television reporter well known locally. It showed residents and staff from homes in the pilot study recommending the hip protectors, and an older man modelling the hip protectors in everyday situations. The risks of falling and fracturing a hip are discussed by nursing and medical experts, and an older woman is featured talking about her experience of hip fracture and subsequent use of the hip protectors. The video programme was well received by staff and a copy was left in each home for use with new residents or staff.

The most comprehensive approach to introducing hip protectors described in the literature is that used by Cryer *et al* (2002). Suitable residents were identified through a structured falls risk assessment. Where risk factors were identified, the home manager made a referral to the appropriate professional to attempt to reduce the risk. The hip protectors were introduced to the residents and their homes using a thorough implementation process. All staff who were involved (general practitioners, home owners and managers, care staff, primary care staff) were invited to meetings explaining the intervention and its rationale. Project nurses carried out a two-hour teaching session in each home focusing on fall and fracture risk and risk assessment, and provided a teaching resource pack. Home owners and managers, and care staff were sent three letters keeping them informed of the progress of the project and its wider impact. The project nurses spent time with residents showing them the hip protectors and explaining their use. Residents were also given written information on all aspects of the study, and those using the hip protectors were visited weekly by a project nurse to assess their progress. This appears to be a well-structured approach and more comprehensive than the process used in our study in that there was a formal approach to overall risk management, meetings with general practitioners and primary care staff, and weekly visits by project nurses to the residents. However, it may be that this rigorous process would not be readily replicated in an everyday service environment.

### **7.4.3 The importance of the context for the intervention**

It is difficult to envisage a more complete process of introduction and facilitation, within existing resources, than that described by Cryer *et al* (2002). However, despite this intensive approach, only 51 percent of the residents offered the hip protectors agreed to try them and adherence was 30 percent at six months.

It seems that Cryer *et al* (2002) experienced the effect described by Kitson *et al* (1998), where high quality evidence, even if introduced through an expertly facilitated process, may not be implemented if the context is unsupportive. Cryer *et al* (2002) make this point when they discuss their impression that adherence was best where staff in the homes actively supported their use. They hypothesise that where carers have a positive attitude to the use of hip

protectors, adherence will be increased, and that negative attitudes will have the opposite effect. This is borne out by the variation in daytime adherence (0 – 80%) between homes, and by differences between homes in terms of residents beginning to use the hip protectors (in one home, none of the six residents accepting the hip protectors wore them, and in another, only one of eight residents wore them).

Cameron *et al* (2001) describe a similar effect, reporting major differences in the level of adherence between the different nursing homes and hostels in their study. They believe greater adherence was associated with a higher level of organisational commitment to the project. Harada *et al* (2001) give a striking example of this phenomenon. Adherence in six nursing homes in Japan was measured at 87 percent over one year. The researchers attribute this outstanding level of adherence to the commitment and good understanding of the care staff.

#### **7.4.4 Factors influencing the acceptability of hip protectors**

Older people who have suffered a fall in the past appear to be more likely to use hip protectors (Myers *et al*, 1995; Zimmer and Myers, 1997; Hindso *et al*, 1996; Thompson and Jones, 2000), as do those who continue to fall (Hubacher and Wettstein, 2001; Meyer *et al*, 2003), and those perceived by care staff to be at risk (Lauritzen *et al*, 1993; Butler *et al*, 1998). The corollaries to this are that those who perceive themselves to be at lower risk are less likely to wear hip protectors (Parkkari *et al*, 1998; Chan *et al*, 2000), as are those who believe the hip protectors are ineffective in preventing hip fracture (Hubacher and Wettstein, 2001). No information on residents' perceptions of their risk of hip fracture was recorded in our study. However, having a history of falls, or falling during the study, was not associated with greater adherence, which suggests that neither residents nor staff acted on a perception of greater risk.

A number of resident characteristics are associated with increased use of hip protectors. Women have been found to wear hip protectors more readily than men (Zimmer and Myers, 1997; Birks *et al*, 1999; Hubacher and Wettstein, 2001). However, in our study, being male was associated with greater use of

hip protectors. The reasons for this are not clear. Having poor mobility is also associated with greater use of hip protectors (Zimmer and Myers, 1997; Hubacher and Wettstein, 2001). In our study, being more physically dependent (with a Barthel Index score of 0-11 rather than a score of 12-20) was associated with greater use. It is possible that this is because the greater dependence of such residents upon staff means they are more open to persuasion to wear the hip protectors. The evidence on the influence of dementia is inconclusive. Some mentally infirm residents refused hip protectors (Hindso *et al*, 1996); others took them off (Parkkari *et al*, 1998; Chan *et al*, 2000), whilst others persisted in wearing them once use had been established (Harada *et al*, 2001). In our study, greater cognitive impairment was associated with greater use of the hip protectors. Again, this may be because such residents rely on staff to make decisions for them and so are more open to persuasion. This result may be important because cognitive impairment is also associated with a greater risk of hip fracture. Therefore, this may be a sub-group of residents who would benefit from a targeted approach.

Discomfort, poor fit and skin irritation (especially being too hot and too tight) are barriers to continued use, particularly at night (Butler *et al*, 1998; Villar *et al*, 1998; Parkkari *et al*, 1998; Birks *et al*, 1999; Hopper *et al*, 1999; Hubacher and Wettstein, 2001; Lauritzen *et al*, 1993; Ekman *et al*, 1997; Jantti *et al*, 1998; Kannus *et al*, 2000; Cameron *et al*, 2001), as is pain over the fracture site if the wearer has suffered a hip fracture in the past (Hopper *et al*, 1999). Some residents and staff complained that the hip protector increased the amount of help residents needed when using the toilet (Parkkari *et al*, 1998; Birks *et al*, 1999; Hopper *et al*, 1999). In our study, the most common reason given by residents for refusing the hip protectors was that the garment was too bulky or uncomfortable, whilst others found it too difficult to put the hip protectors on. Some staff commented that wearing the hip protectors made previously independent residents dependent when using the toilet because of difficulty in taking the garment down and pulling it up again.

## **7.5 Limitations of the study**

This study was designed as an evaluation of a policy of offering hip protectors free of charge to residents of nursing and residential homes, and supporting the implementation process by employing a nurse facilitator to encourage staff in the homes to promote their use. The intention was to implement the policy using an approach that might be employed by policy-makers, such as a Health and Social Services Board. Therefore, a possible limitation is that the intervention was not simply a policy but was also research, and perceived as such by the managers, staff, and residents in the homes. Arguably, their response to a simple policy might differ from their response to research. If the policy had been introduced directly by the EHSSB, then it might have been attended by a greater degree of general publicity and invested with a greater authority, leading to a more enthusiastic implementation process by some homes that made a poor response to the intervention. On the other hand, it is instructive to note the response of the homes to the care and management standards measured by the Inspectors from the R&I Unit (Appendix O). These are minimum standards that the homes have a statutory requirement to meet, so persistent failure can lead to the closure of the home. Yet the mean failure rate for the homes was 28 percent (SD 22%). If homes struggle to comply with minimum care standards required by their statutory inspectors, then it is not surprising that they also made an inconsistent response to the policy of offering hip protectors.

Ideally, all homes in the EHSSB area would have taken part in the study, but 32 (19.5%) of the 164 homes identified as eligible for the study refused to take part, which would not have been the case if the policy had originated from the EHSSB. No data were collected on these homes, so the degree to which they were typical of the homes that took part in the study is unknown. These homes might have made a significant impact on the effectiveness of the policy had they taken part. Arguably, homes reluctant to take part in research, for whatever reason, might also prove slow to implement policy. If this were the case, their inclusion would have further diminished the effectiveness of the policy. On the other hand, 127 of the homes (80% of the 159 that remained after five homes closed before the start of the study) took part, providing an estimated figure of 4,117 resident beds used throughout the study. Multiplying this figure by the number of days in the study period (504 days) gives a figure for resident bed-days of 2,074,968. This is the largest trial of hip protectors attempted so far, in

terms of both the number of clusters and the number of participants, which means the sample is likely to be representative of this population.

The large number of homes (clusters) in the study, and the fact that the design effect intrinsic to cluster randomised trials was taken into account when determining sample size, means that the study had considerable power to measure the effect of the policy. However, the incompleteness of individual data placed some limitations upon explanatory analyses, particularly in relation to the low-cooperation homes. A considerable number of residents passed through the study without individual level data being captured, which reduced the number of participants who could be included in the explanatory analysis. Nevertheless, individual data was available for 4,131 participants: 1,179 in the intervention group and 2,952 in the control group. These numbers were near the required sample size for analysing the effect of the intervention by individual. The number of participants available for analysis in terms of the acceptability of the hip protectors was further reduced by the necessity of focussing on the initial cohort in the intervention group. However, this still left 938 participants in the initial cohort at the start of the study and 726 at 24 weeks, which compares favourably with the next largest study (Kannus *et al*, 2000).

It was apparent that the context in the homes was exerting a considerable effect on the effectiveness of the policy. An attempt was made to examine this effect by including data on various organisational characteristics of the homes, but none of these appeared to be related to adherence to wearing hip protectors. Evidently, the organisational factors affecting adherence were unrelated to the measured characteristics. However, the policy was implemented using a framework that emphasised the importance of the context for implementation, which allowed a fruitful discussion of the likely factors influencing success and failure.

# Chapter Eight

## Conclusions and Recommendations

This study has shown that the policy of making hip protectors available free of charge to residents of nursing and residential homes, and supporting the implementation by employing a nurse facilitator is not effective in reducing the number of hip fractures suffered by residents in the homes. The null hypothesis - that the rate of hip fracture in nursing and residential homes that introduce a policy of offering external hip protectors to their residents will be no different to the rate of hip fracture in homes that do not introduce this policy – was supported by the evidence. The analysis by individual also strongly suggests that the hip protectors were not efficacious in preventing hip fractures.

The residents at higher risk of hip fracture were those living in EMI homes and those living in homes that were part of managed group of homes rather than in an independent home.

The policy was associated with an increased rate of pelvic fractures. However, there are few grounds to support an argument that the increase was caused by the introduction of the policy or by the use of the hip protectors in individual cases.

It would appear that the policy failed as a result of a number of factors. These were:

- the low overall use of the hip protectors
- that those most at risk of hip fracture (older, female residents, with a history of falls) were not the most likely to wear hip protectors
- that the hip protectors did not always prevent hip fractures when worn during a fall

These factors, when combined, reduced the effectiveness of the intervention. However, the most important of these is the low use of the hip protectors. Use of the hip protectors depends partly on the individual choices of residents but

principally on the degree to which the intervention is supported by the staff in the homes, particularly the senior manager in the home.

Leaving to one side the effectiveness of the hip protectors, the success of the policy implementation process depended on the quality of the evidence supporting the use of hip protectors, the effectiveness of the facilitation of the process, and on the context into which the policy was introduced. The presentation of the evidence and the approach to facilitation were largely under the control of the researcher. However, whilst the organisational and social context of the homes was taken into account in the design of the implementation process, it could not be altered using the available resources. It appears that a policy based on the best available evidence, even if introduced through an effectively facilitated process, may not be implemented if the context is unsupportive. These principles relate not only to the policy evaluated in the present study but also to other policies in other situations. The lessons learned should therefore be of interest to all those concerned with policy implementation. Having said this, it should be noted that the level of adherence was not related to any of the measured home characteristics, so the contextual factors influencing successful implementation have still to be demonstrated.

Resident characteristics associated with greater use of hip protectors were a greater degree of cognitive impairment, greater physical dependence, and male sex. The association with male sex is unsupported in the literature and the reasons for this effect are unknown. The association with greater physical and cognitive disability is consistent with the model advanced in this thesis that residents who are more dependent on staff are more likely to be influenced by staff who encourage them to wear hip protectors. The most common reason given by residents for refusing the hip protectors was that the garment was too bulky or uncomfortable, whilst others found it too difficult to put the hip protectors on.

This study has demonstrated the complexity and the value of pragmatic research. Studying the implementation of the policy in an everyday service environment has led to a reduced ability to control the research processes, reflected principally in the wide variation between homes, both in implementing the policy and providing requested data. However, this variation is itself a

significant subject for the research, and the difficulties experienced in implementation and data collection are those that would face a policy-maker. Ultimately, the problems experienced have proved to be some of the most interesting aspects of the research.

## **8.1 Recommendations for policy-makers and others considering the introduction of hip protectors in their areas of responsibility**

The implementation of policy achieved in this study is not likely to be significantly bettered within existing resources. Even if much higher use of the hip protectors could be achieved, there is insufficient evidence for the efficacy of hip protectors to guarantee that this would lead to a significant reduction in the incidence of hip fractures. Therefore, funding bodies should not introduce a policy of making hip protectors available to residents of nursing and residential homes.

## **8.2 Recommendations for future research**

These recommendations relate to the use of hip protectors and to the implementation of policy.

### **8.2.1 Technical development of hip protectors**

Existing hip protector designs are a compromise between efficiency in reducing the impact of the fall on the greater trochanter and the comfort and convenience needed in underwear. Future research should focus on increasing both efficiency and comfort. No hip protector can offer complete protection but efforts should be made to make a protector that reduces the force transmitted from falls to levels below the lowest estimates for fracture forces. Research into comfort should focus on reducing the bulk and weight of the protective pad, reducing the heat retained by the material, and increasing the ease with which the protector can be put on and off.

### **8.2.2 Clinical trials of hip protectors**

The limited efficacy of hip protectors means that clinical trials are unlikely to show a significant effect. Therefore, further research into effectiveness should await improvements in design that have been shown to increase the acceptability and efficacy of the hip protectors. If a much-improved design becomes available, then a trial of policy, similar to our study, should be undertaken.

Cluster randomised trials of effectiveness should provide details of the number and characteristics of the clusters and should account for all members of the clusters in the research report. Appropriate measures should be taken to allow for the design effect inherent in this approach when estimating sample size and analysing results.

Research into the acceptability of hip protectors should seek to identify characteristics of residents who are more likely to wear the hip protectors and those most at risk of hip fracture, in order to allow a targeted approach. To allow comparison between trials, measures of the acceptability of hip protectors should provide figures for both initial acceptance and continued adherence to use. There is no agreed approach to measuring adherence, so a full set of measures should be used and reported, to allow estimation of the number of participants using the hip protectors over time. Reporting only the number of participants who fell whilst wearing the hip protectors, or the number of falls when the hip protectors were worn is insufficient because different populations may fall at different rates. Studies comparing different types of hip protectors should be randomised by individual, rather than by cluster. More research is needed into the experience of those who wear hip protectors, and how this relates to acceptability.

### **8.2.3 Implementation of policy**

The influence of organisational context on the success of a policy of offering hip protectors free of charge should be investigated. The organisational characteristics identified by Kitson *et al* (1998) and McCormack *et al* (2002) as supportive of necessary change provide a useful starting point. In particular, the impact of the management style of the senior manager in the home on the implementation of policy should be explored.

# References

- Aitkin M, Anderson D, Francis B, Hinde J (1989) *Statistical modelling in GLIM*. Oxford: Clarendon Press.
- Audit Commission (1995) *United they stand: co-ordinating care for elderly patients with hip fracture*. London: HMSO.
- Baly ME (1995) *Nursing and social change. 3<sup>rd</sup> edn*. London: Routledge.
- Baric L (1994) *Health promotion and health education in practice. Module 2: the organisational model*. Altrincham: Barns.
- Beringer TRO, Wilson RA, Swain D, Patterson CC, Beverland D (2000) Proximal femoral fracture in Northern Ireland between 1985-1997 – trends and future projections. *Ulster Med J*. 69: 112-117.
- Birks C, Lockwood K, Cameron I, Kurrle S, Burnside W, Easter S, Venman J, Cumming R, Quine S, Salkeld S, Finnegan T (1999) Hip protectors: results of a user survey. *Australasian Journal on Ageing*. 18 (1): 23-26.
- Boeije HR, Nievaard AC, Casparie AF (1997) Coping strategies of enrolled nurses in nursing homes: shifting between organizational imperatives and residents' needs. *Int J Nurs Stud*. 34(5):358-66.
- Bowman AM (1997) Sleep satisfaction, perceived pain and acute confusion in elderly clients undergoing orthopaedic procedures. *J Adv Nurs*. 26(3):550-64.
- Briggs AH, Gray AM (1999) Handling uncertainty in economic evaluations of healthcare interventions. *BMJ*. 319(7210):635-8.
- Buckler JE, Dutton TL, Macleod HL, Manuge MB, Murray MD (1997) Use of hip protectors on a dementia unit. *Physiotherapy Canada*. Fall.
- Bunton R, Macdonald G, eds (1992) *Health promotion: disciplines and diversity*. London: Routledge.
- Butler M, Coggan C, Norton R (1998) A qualitative investigation into the receptivity to hip protective underwear among staff and residents of residential institutions. *New Zealand Medical Journal*. 111(1075):383-5.
- Cameron ID, Stafford B, Cumming RG, Birks C, Kurrle SE, Lockwood K, Quine S, Finnegan T, Salkeld G (2000) Hip protectors improve falls self-efficacy. *Age Ageing*. 29(1): 57-62.
- Cameron ID, Venman J, Kurrle SE, Lockwood K, Birks C, Cumming RG, Quine S, Bashford G (2001) Hip protectors in aged-care facilities: a randomized trial of use by individual higher-risk residents. *Age Ageing*. 30(6):477-81.
- CDC (Centers for Disease Control and Prevention) (1999), *Epi Info* statistical software: United States Department of Health and Human Services,

Epidemiology Program Office, Division of Public Health Surveillance and Informatics. Available from <http://www.cdc.gov/epiinfo/>

Chan DK, Hillier G, Coore M, Cooke R, Monk R, Mills J, Hung, WT (2000) Effectiveness and acceptability of a newly designed hip protector: a pilot study. *Arch. Geront. Ger.* 30: 25-34.

Chandler JM, Zimmerman SI, Girman CJ, Martin AR, Hawkes W, Hebel JR, Sloane PD, Holder L, Magaziner J (2000) Low bone mineral density and risk of fracture in white female nursing home residents. *JAMA.* 284(8):972-7.

Cheng XG, Lowet G, Boonen S, Nicholson PH, Brys P, Nijs J, Dequeker J. (1997) Assessment of the strength of proximal femur in vitro: relationship to femoral bone mineral density and femoral geometry. *Bone.* 20(3):213-8.

Cochrane AL (1972). *Effectiveness and efficiency: random reflections on health services.* London: Nuffield Provincial Hospitals Trust.

*Cochrane reviewers' handbook* (2001) Version 4.1.4: The Cochrane Collaboration. Available at: <http://www.cochrane.org/cochrane/hbook.htm>, accessed December 2002.

Cohen-Mansfield J, Taylor L, McConnell D, Horton D (1999) Estimating the cognitive ability of nursing home residents from the minimum data set. *Outcomes Manag Nurs Pract.* 3(1):43-6.

Cooper C (1993) Epidemiology and public health impact of osteoporosis. *Baillieres Clin Rheumatol,* 7(3):459-77.

Courtney AC, Wachtel EF, Myers ER, Hayes WC (1994) Effects of loading rate on strength of the proximal femur. *Calcif Tissue Int.* 55(1):53-8.

Courtney AC, Wachtel EF, Myers ER, Hayes WC (1995) Age-related reductions in the strength of the femur tested in a fall-loading configuration. *J Bone Joint Surg Am.* 77(3):387-95.

Crombie IK, Davies HTO (1996) *Research in health care: design, conduct and interpretation of health services research.* Chichester: Wiley.

Cryer C, Knox A, Martin D, Barlow J. (2002) Hip protector compliance among older people living in residential care homes. *Inj Prev.* 8(3):202-6.

Cummings SR, Black DM, Nevitt MC, Browner W, Cauley J, Ensrud K, Genant HK, Palermo L, Scott J, Vogt TM (1993) Bone density at various sites for prediction of hip fractures. The Study of Osteoporotic Fractures Research Group. *Lancet.* 341(8837):72-5.

Cummings SR, Nevitt MC, Browner WS, Stone K, Fox KM, Ensrud KE, Cauley J, Black D, Vogt TM (1995) Risk factors for hip fracture in white women. Study of Osteoporotic Fractures Research Group. *N Engl J Med.* 332(12):767-73.

Davey Smith G, Egger M (1998) Meta-analysis: unresolved issues and future developments *BMJ.* 316(7126):221-5.

- De Laet CE, van Hout BA, Burger H, Hofman A, Pols HA (1997) Bone density and risk of hip fracture in men and women: cross sectional analysis. *BMJ*. 315(7102):221-5.
- Dixon SR (1991) *Autonomy and dependence in residential care: an evaluation of a project to promote self determination in a home for older people*. London: Age Concern England
- Dolan P and Torgerson DJ (1998) The cost of treating osteoporotic fractures in the United Kingdom female population. *Osteoporosis International*. 8(6):611-7
- Eastell R, Reid DM, Compston J, Cooper C, Fogelman I, Francis RM, Hay SM, Hosking DJ, Purdie DW, Ralston SH, Reeve J, Russell RGG, Stevenson JC. (2001) Secondary prevention of osteoporosis: when should a non-vertebral fracture be a trigger for action? *Quarterly Journal of Medicine*. 94: 575 – 597
- Eaton SC (2000) Beyond “unloving care”: linking human resource management and patient care quality in nursing homes. *Int J Hum Res Man*. 11: 591-616.
- Effective Health Care (1996) *Preventing falls and subsequent injury in older people*. York: The NHS Centre for Review and Dissemination, University of York.
- Effective health care (1999) *Getting evidence into practice*. York: The NHS Centre for Review and Dissemination, University of York.
- Ekman A, Mallmin H, Michaelsson K, Ljunghall S (1997) External hip protectors to prevent osteoporotic hip fractures. *Lancet*. 350:563-4.
- Elbourne DR, Campbell MK (2001) Extending the CONSORT statement to cluster randomized trials: for discussion. *Stat Med*. 20(3):489-96.
- Ewles L, Simnett I (1999) *Promoting health: a practical guide*. London: Bailliere Tindall/Royal College of Nursing.
- Fall direction, bone mineral density, and function: risk factors for hip fracture in frail nursing home elderly. *Am J Med*. 104(6):539-45.
- Feder G, Cryer C, Donovan S, Carter Y (2000) Guidelines for the prevention of falls in people over 65. The Guidelines' Development Group. *BMJ*. 321(7267):1007-11.
- Figueredo AJ, Sechrest L (2001) Approaches used in conducting health outcomes and effectiveness research. *Evaluation and Program Planning*. 24 (1): 41-59.
- Folstein MF, Folstein SE, McHugh PR (1975) "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 12(3):189-98.
- Funnell MM, Herman WH (1995) Diabetes care policies and practices in Michigan nursing homes, 1991. *Diabetes Care*. 18(6):862-6.

Gamroth LM, Semradek J, Tornquist EM, Eds (1995) *Enhancing autonomy in long-term care: concepts and strategies*. New York: Springer.

Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, Rowe BH (2001) Interventions for preventing falls in elderly people. *Cochrane Database Syst Rev*. (3):CD000340.

Gillet P, Reginster JY (1999) Increased number of hip fractures. *Lancet*. 353(9170):2160-1.

Goffman E (1962) *Asylums: essays on the social situation of mental patients and other inmates*. New York: Doubleday.

Granger CV, Dewis LS, Peters NC, Sherwood CC, Barrett JE (1979) Stroke rehabilitation: analysis of repeated Barthel index measures. *Archives of Physical Medicine and Rehabilitation*; 60: 14 – 17.

Greenhalgh T, Donald A (2000) *Evidence based health care workbook*. London: BMJ Publishing Group.

Greenspan SL, Myers ER, Kiel DP, Parker RA, Hayes WC, Resnick NM (1998) Fall direction, bone mineral density, and function: risk factors for hip fracture in frail nursing home elderly. *Am J Med*. 104(6):539-45.

Greenspan SL, Myers ER, Maitland LA, Resnick NM, Hayes WC (1994) Fall severity and bone mineral density as risk factors for hip fracture in ambulatory elderly. *JAMA*. 271(2):128-33.

Grisso JA, Kelsey JL, Strom BL, O'Brien LA, Maislin G, LaPann K, Samelson L, Hoffman S (1994) Risk factors for hip fracture in black women. The Northeast Hip Fracture Study Group. *N Engl J Med*. 330(22):1555-9.

Gross G, Chen TH, Flaherty C (2000) Hip pads: effective fracture prevention. *Advance for Physical Therapists*. 11 (22): 45-46.

Gullberg B, Johnell O, Kanis JA (1997) World-wide projections for hip fracture. *Osteoporos Int*. 7(5):407-13.

Harada A, Mizuno M, Takemura M, Tokuda H, Okuizumi H, Niino N. (2001) Hip fracture prevention trial using hip protectors in Japanese nursing homes. *Osteoporos Int*. 12(3):215-21.

Hartmaier SL, Sloane PD, Guess HA, Koch GG (1994) The MDS Cognition Scale: a valid instrument for identifying and staging nursing home residents with dementia using the minimum data set. *J Am Geriatr Soc*;42(11):1173-9.

Hayes WC, Myers ER, Morris JN, Gerhart TN, Yett HS, Lipsitz LA (1993) Impact near the hip dominates fracture risk in elderly nursing home residents who fall. *Calcif Tissue Int*. 52(3):192-8.

Health Promotion England (2001) *Promoting the health of older people: evaluating approaches and methods*. London: Health Promotion England

- Higgs P, Macdonald L, Macdonald J, Ward M (1998) Home from home: residents' opinions of nursing homes and long-stay wards. *Age Ageing*. 27: 199-205.
- Hindso K, Lauritzen J (2000) Intervention study with hip protectors in orthopaedic patients with hip fractures. *Osteoporos Int*. 11 (suppl. 2): S150
- Hindso K, Lauritzen J, Sonne-Holm (1996) Prevention of hip fracture with external hip protector. *Acta Orthop. Scand*. 67 (suppl. 267): 31
- Hodkinson HM (1972) Evaluation of a mental test score for assessment of mental impairment in the elderly. *Age Ageing*, 1:233-8.
- Hopkinson-Woolley JA, Parker MJ (1998) Fractures of the hip: does the type of fall really affect the site of fracture?. *Injury*. 29(8):585-7.
- Hopper A, Oliver D, Parsons M (1999) Compliance with hip protectors in patients discharged with a community rehabilitation team. *Poster presentation at the British Geriatrics Society Spring Meeting*.
- Horiuchi T, Igarashi M, Karube S, Oda H, Tokuyama H, Huang T, Inoue S (1988) Spontaneous fractures of the hip in the elderly. *Orthopedics*. 11(9):1277-80.
- Hosmer DW and Lemeshow S (2000) *Applied Logistic Regression*, 2nd Edition. Wiley: New York.
- Hubacher M, Wettstein A. (2001) Acceptance of hip protectors for hip fracture prevention in nursing homes. *Osteoporos Int*. 12(9):794-9.
- Huusko TM, Karppi P, Avikainen V, Kautianen H, Sulkava R (2000) Randomised, clinically controlled trial of intensive geriatric rehabilitation in patients with hip fracture: subgroup analysis of patients with dementia. *BMJ*, 321: 1107-1111.
- Jacelon CS (1995) The effect of living in a nursing home on socialization in elderly people. *J Adv Nurs*. 22(3):539-46.
- Jantti PO, Aho HJ, Maki-Jokela PL, Heikinheimo RJ (1998) Hip protectors and hip fractures. *Age & Ageing*. 27(6):758-9.
- Kannus P, Niemi S, Parkkari J, Palvanen M, Vuori I, Jarvinen M (1999a) Hip fractures in Finland between 1970 and 1997 and predictions for the future. *Lancet*. 353(9155):802-5.
- Kannus P, Parkkari J, Niemi S, Pasanen M, Palvanen M, Jarvinen M, Vuori I (2000) Prevention of hip fracture in elderly people with use of a hip protector. *NEJ*, 343: 1506-1513.
- Kannus P, Parkkari J, Poutala J. (1999b) Comparison of force attenuation properties of four different hip protectors under simulated falling conditions in the elderly: an in vitro biomechanical study. *Bone*. 25(2):229-35.

- Keene GS, Parker MJ, Pryor GA (1993) Mortality and morbidity after hip fractures. *BMJ*. 307(6914):1248-50.
- Khaw KT (1999) How many, how old, how soon? *BMJ*. 319(7221):1350-2.
- Kitson A, Harvey G, McCormack B (1998) Enabling the implementation of evidence based practice: a conceptual framework. *Qual Health Care*. 7(3):149-58.
- Koval KJ, Zuckerman JD (1994) Current concepts review. Functional recovery after fracture of the hip. *J Bone Joint Surg*, 76-A (5): 751-758.
- Kroker P (1999) The problem of remaining upright. *BMJ*. 319: 1300.
- Krouse HJ (2001) Video modelling to educate patients. *J Adv Nurs*, 33 (6): 748-757.
- Lauritzen JB, Askegaard V (1992) Protection against hip fractures by energy absorption. *Dan Med Bull*, 39(1):91-3.
- Lauritzen JB, Petersen MM, Lund B (1993) Effect of external hip protectors on hip fractures. *The Lancet*, 341: 11-13.
- Levinson W, Altkorn D (1998) Primary prevention of postmenopausal osteoporosis. *JAMA*. 280(21):1821-2.
- Lotz JC, Hayes WC (1990) The use of quantitative computed tomography to estimate risk of fracture of the hip from falls. *J Bone Joint Surg Am*. 72(5):689-700.
- Lyons AR (1997) Clinical outcomes and treatment of hip fractures. *Am J Med*, 103 (2A) Supplement: 51S-63S.
- Mahoney FI, Barthel DW (1965) Functional evaluation: the Barthel Index. *Maryland State Medical Journal*, 14: 61-65.
- Martyn CN, Cooper C (1999) Prediction of burden of hip fracture. *Lancet*. 353(9155):769-70.
- Mattiasson AC, Andersson L (1997) Quality of nursing home care assessed by competent nursing home patients. *J Adv Nurs*. 26(6):1117-24.
- McCormack B, Kitson A, Harvey G, Rycroft-Malone J, Titchen A, Seers K (2002) Getting evidence into practice: the meaning of 'context'. *J Adv Nurs*. 38(1):94-104.
- Mechanic D (2001) Lessons from the unexpected: the importance of data infrastructure, conceptual models, and serendipity in health services research. *Milbank Q*. 79(3):459-77, V.
- Medical Research Council (2002) *MRC Special Research Training Fellowship in Health Services and Health of the Public Research 2002/03ADVICE FOR APPLICANTS*. Available at: [http://www.mrc.ac.uk/txt/doc-hsr\\_notes.doc](http://www.mrc.ac.uk/txt/doc-hsr_notes.doc). Accessed January 2003.

Melzer D, McWilliams B, Brayne C, Johnson T, Bond J (1999) Profile of disability in elderly people: estimates from a longitudinal population study. *BMJ*. 318(7191):1108-11.

Meyer G, Warnke A, Bender R, Muhlhauser I (2003) Effect on hip fractures of increased use of hip protectors in nursing homes: cluster randomised controlled trial. *BMJ*. 326: 76-81.

Michelson JD, Myers A, Jinnah R, Cox Q, Van Natta M (1995) Epidemiology of hip fractures among the elderly. Risk factors for fracture type. *Clinical Orthopaedics & Related Research*. 311: 129-35.

Midha A, Sullivan M (1998) The need to redefine the practice of health promotion in the United Kingdom. *Health Policy*. 44(1):19-30.

Mills NJ (1996) The biomechanics of hip protectors. *Proc Inst Mech Eng [H]*. 210(4):259-66.

Moher D, Schulz KF, Altman DG (2001) The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *J Am Podiatr Med Assoc*. 91(8):437-42.

Morrison RS, Siu AL (2000) A comparison of pain and its treatment in advanced dementia and cognitively intact patients with hip fracture. *J Pain Symptom Manage*. 19(4):240-8.

Myers AH, Michelson JD, Van Natta M, Cox Q, Jinnah R (1995) Prevention of hip fractures in the elderly: receptivity to protective garments. *Arch. Geront. Ger.* 21: 179-189.

National Osteoporosis Society (2002) *Primary care strategy for osteoporosis and falls*. Bath: National Osteoporosis Society.

Nichol KL, Grimm MB, Peterson DC (1996) Immunizations in long-term care facilities: policies and practice. *J Am Geriatr Soc*. 44(4):349-55.

NIH (2001) Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy. Osteoporosis prevention, diagnosis, and therapy. *JAMA*, 285: 785-795.

Northern Ireland Ageing Population Panel (2001) *Report 2001*. Belfast: Office of Science and Technology.

Northern Ireland Statistics and Research Agency [NISRA], 2001 Census 2001: Key statistics tables: Table KS23: communal establishment residents. Available at: <http://www.nisra.gov.uk/census/census2001output/keystatistics/keystatrep.html>. Accessed December 2002.

Norton R, Campbell AJ, Lee-Joe T, Robinson E, Butler M (1997) Circumstances of falls resulting in hip fractures among older people. *Journal of the American Geriatrics Society*. 45(9):1108-12.

Norton R, Campbell AJ, Reid IR, Butler M, Currie R, Robinson E, Gray H (1999) Residential status and risk of hip fracture. *Age Ageing*. 28(2):135-9.

Nyberg L, Gustafson Y, Berggren D, Brannstrom B, Bucht G (1996) Falls leading to femoral neck fractures in lucid older people. *Journal of the American Geriatrics Society*. 44(2):156-60.

OBRA (*Omnibus Budget Reconciliation Act*) (1987) US Congress. Public Law: 101-508.

Okuizumi H, Harada A, Iwata H, Konishi N. (1998) Effect on the femur of a new hip fracture preventive system using dropped-weight impact testing. *J Bone Miner Res*. 13(12):1940-5.

Oliver D, Britton M, Seed P, Martin FC, Hopper AH (1997) Development and evaluation of evidence based risk assessment tool (STRATIFY) to predict which elderly inpatients will fall: case control and cohort studies. *BMJ*, 315:1049-1053.

Ooms ME, Vlasman P, Lips P, Nauta J, Bouter LM, Valkenburg HA (1994) The incidence of hip fractures in independent and institutionalized elderly people. *Osteoporos Int*. 4(1):6-10.

Parker MJ and Twemlow TR (1997) Spontaneous hip fractures, 44/872 in a prospective study. *Acta Orthopaedica Scandinavica*. 68(4):325-6.

Parker MJ, Gillespie LD, Gillespie WJ (2000) *Hip protectors for preventing hip fractures in the elderly*. Cochrane Database Syst Rev. (4):CD001255. Review.

Parkkari J, Kannus P, Poutala J, Vuori I (1994) Force attenuation properties of various trochanteric padding materials under typical falling conditions of the elderly. *Journal of Bone & Mineral Research*. 9(9):1391-6.

Parkkari J, Heikkila J, Kannus P (1998) Acceptability and compliance with wearing energy-shunting hip protectors: a 6-month prospective follow-up in a Finnish nursing home. *Age Ageing*. 27: 225-229.

Parkkari J, Kannus P, Heikkila J, Poutala J, Heinonen A, Sievanen H, Vuori I. (1997) Impact experiments of an external hip protector in young volunteers. *Calcif Tissue Int*. 60(4):354-7.

Parkkari J, Kannus P, Heikkila J, Poutala J, Sievanen H, Vuori I. (1995) Energy-shunting external hip protector attenuates the peak femoral impact force below the theoretical fracture threshold: an in vitro biomechanical study under falling conditions of the elderly. *J Bone Miner Res*. 10(10):1437-42.

Parkkari J, Kannus P, Palvanen M, Natri A, Vainio J, Aho H, Vuori I, Jarvinen M. (1999) Majority of hip fractures occur as a result of a fall and impact on the greater trochanter of the femur: a prospective controlled hip fracture study with 206 consecutive patients. *Calcif Tissue Int*. 65(3):183-7.

Peace S, Kellaher L, Willcocks D (1997) *Re-evaluating residential care*. Buckingham: Open University Press.

- Phillips DR, Vincent J, Blacksell S (1988) *Home from home? Private residential care for elderly people*. Sheffield: Joint Unit for Social Services Research, Sheffield University.
- Ray WA, Taylor JA, Meador KG, Thapa PB, Brown AK, Kajihara HK, Davis C, Gideon P, Griffin MR (1997) A randomized trial of a consultation service to reduce falls in nursing homes. *JAMA*. 278(7):557-62.
- Reisberg B, Ferris SH, de Leon MJ, Crook T (1988) Global Deterioration Scale (GDS). *Psychopharmacol Bull*. 24(4):661-3.
- Richards SH, Peters TJ, Coast J, Gunnell DJ, Darlow MA, Pounsford J (2000) Inter-rater reliability of the Barthel ADL index: how does a researcher compare to a nurse? *Clin Rehabil*. 14(1):72-8.
- Riggs BL, Melton LJ (1995) The worldwide problem of osteoporosis: insights afforded by Epidemiology. *Bone*, 17: 505S-511S.
- Robinovitch SN, Hayes WC, McMahon TA (1997) Distribution of contact force during impact to the hip. *Annals of Biomedical Engineering*. 25(3):499-508.
- Robinovitch SN, Hayes WC, McMahon TA. (1991) Prediction of femoral impact forces in falls on the hip. *J Biomech Eng*. 113(4):366-74.
- Robinovitch SN. Hayes WC. McMahon TA. (1995) Energy-shunting hip padding system attenuates femoral impact force in a simulated fall. *Journal of Biomechanical Engineering*. 117(4):409-13.
- Robinson SB (1999) Transitions in the lives of elderly women who have sustained hip fractures. *J Adv Nurs*. 30(6):1341-8.
- Rohrer JE, Momany ET, Chang W (1993) Organizational predictors of outcomes of long-stay nursing home residents. *Soc Sci Med*. 37(4):549-54.
- Royal College of Physicians (1999; update 2000) *Osteoporosis: clinical guidelines for prevention and treatment*. <http://rcplondon.ac.uk> (accessed September 2002).
- Royal Commission on Long Term Care, (1999) *With respect to old age: long term care – rights and responsibilities*. London: Stationery Office.
- Royal Statistical Society (1992) *GLIM 4 update 8 for IBM*: London: RSS.
- Rubenstein LZ, Josephson KR, Robbins AS (1994) Falls in the nursing home. *Ann Intern Med*. 121(6):442-51.
- Salkeld G, Cameron ID, Cumming RG, Easter S, Seymour J, Kurrle SE, Quine S (2000) Quality of life related to fear of falling and hip fracture in older women: a time trade off study. *BMJ*. 320(7231):341-6.
- Schmidt I, Claesson CB, Westerholm B, Svarstad BL (1998) Resident characteristics and organizational factors influencing the quality of drug use in Swedish nursing homes. *Soc Sci Med*. 47(7):961-71.

- Schwartz AV, Kelsey JL, Sidney S, Grisso JA. (1998) Characteristics of falls and risk of hip fracture in elderly men. *Osteoporosis International*. 8(3):240-6.
- Slemenda C (1997) Prevention of hip fractures: risk factor modification. *Am J Med*, 103 (2A) Supplement: 65S-71S.
- Specht-Leible N, Oster P. (1999) Hip fracture with correctly positioned external hip protector. *Age Ageing*. Sep;28(5):497.
- Speller V, Learmonth A, Harrison D (1997) The search for evidence of effective health promotion. *BMJ*. 315(7104):361-3.
- STATA Corporation (2003) *STATA version 8.0 for Windows*. College Station, Texas: STATA Corporation.
- Steffen TM, Nystrom PC (1997) Organizational determinants of service quality in nursing homes. *Hosp Health Serv Adm*. 42(2):179-91.
- Sutton AJ, Abrams KR, Jones DR, Sheldon TA, Song F (1998) Systematic reviews of trials and other studies. *Health Technol Assess*. 2(19):1-276.
- The Cochrane Collaboration (2001) *Cochrane reviewers' handbook*. Version 4.1.4: Available at: <http://www.cochrane.org/cochrane/hbook.htm>. Accessed July 2001.
- The HipSaver Company, Inc., (1996) A report of laboratory testing of HipSavers™ hip protectors at the Orthopedic Biomechanics Laboratory, Beth Israel Hospital, Boston, MA. Provided by The HipSaver Company, Inc., 7 Hubbard Street, Canton, MA.
- The HipSaver Company, Inc., (2000) A report of laboratory testing of HipSavers™ hip protectors at Tampere University of Technology, Finland. Available at: <http://www.helpmates.on.ca/hipsavers/hipsaver1.pdf> , accessed December 2002.
- Thompson PW, Jones C (2000) Adherence to hip protector use in elderly people requiring domiciliary care is greater in fallers than non-fallers. *Age Ageing*. 29(5):459.
- Tinetti ME, Baker DI, McAvay G, Claus EB, Garrett P, Gottschalk M, Koch ML, Trainor K, Horwitz RI (1994) A multifactorial intervention to reduce the risk of falling among elderly people living in the community. *N Engl J Med*. 31(13):821-7.
- Tinetti ME, Williams CS (1997) Falls, injuries due to falls, and the risk of admission to a nursing home. *N Engl J Med*. 1997 Oct 30;337(18):1279-84.
- Tobin SS, Lieberman MA (1976) *Last home for the aged*. San Francisco: Jossey-Bass.
- Todd CJ, Freeman CJ, Camilleri-Ferrante C, Palmer CR, Hyder A, Laxton, CE, Parker MJ, Payne BV, Rushton N (1995) Differences in mortality after fracture of hip: the East Anglian Audit. *BMJ*, 310: 904-908.

Torgerson D, Watt I (2002) A randomised controlled trial of hip protectors for the prevention of second hip fractures. *Research findings register of the NELH*: <http://www.nelh.nhs.uk>. Accessed December 2002.

Townsend P (1962) *The last refuge: a survey of residential institutions and homes in England and Wales*. London: Routledge and Paul.

Ukoumunne OC, Gulliford MC, Chinn S, Sterne JA, Burney PG (1999a) Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review. *Health Technol Assess*. 3(5):iii-92.

Ukoumunne OC, Gulliford MC, Chinn S, Sterne JA, Burney PG, Donner A (1999b) Methods in health service research. Evaluation of health interventions at area and organisation level. *BMJ*; 319(7206):376-9.

van den Kroonenberg AJ, Hayes WC, McMahon TA (1993) Hip impact velocities and body configurations for voluntary falls from standing height. *J Biomech*. 29(6):807-11.

van Schoor MN, Delville WL, Bouter LM, Lips P (2002) Acceptance and compliance with external hip protectors: a systematic review of the literature. *Osteoporosis Int*. 13: 917-924.

van Schoor NM, Smit JH, Twisk JW, Bouter LM, Lips P (2003) Prevention of hip fractures by external hip protectors: a randomized controlled trial. *JAMA*, 289(15):1957-62.

Villar MTA, Hill P, Inskip H, Thompson P, Cooper C (1998) Will elderly rest home residents wear hip protectors? *Age Ageing*. 27: 195-198.

Wade DT, Collin C (1988) The Barthel ADL Index: a standard measure of physical disability? *Int Disabil Studies*; 10: 64-67.

Wallace RB (2000) Bone health in nursing home residents. *JAMA*. 284(8):1018-9.

White KL (1997) Archie Cochrane's legacy: an American perspective. In: Maynard A, Chalmers I (1997) *Non-random Reflections on Health Services Research: On the 25th anniversary of Archie Cochrane's "Effectiveness and Efficiency"*. London: BMJ Publishing Group.

WHO (1978) *The Alma Ata Declaration* Geneva: World Health organization. Available at: <http://www.who.int/hpr/archive/docs/almaata.html>. Accessed January 2003.

WHO (1986) *The Ottawa Charter*. Geneva: World Health organization. Available at: <http://www.who.int/hpr/archive/docs/ottawa.html>. Accessed January 2003.

WHO (1994) *Assessment of fracture risk and its application to screening for postmenopausal osteoporosis*. World Health Organisation technical report series no. 843.

Wolinsky FD, Fitzgerald JF, Stump TE (1997) The effect of hip fracture on mortality, hospitalization, and functional status: a prospective study. *Am J Public Health.* 87(3):398-403.

Woodward M (1999) *Epidemiology study design and data analysis*, London: Chapman & Hall/CRC.

Zimmer Z, Myers A (1997) Receptivity to protective garments among the elderly. *Journal of Aging & Health.* 9(3):355-72.

Zinn JS, Mor V (1998) Organizational structure and the delivery of primary care to older Americans. *Health Serv Res.* 33(2 Pt II):354-80.

Zinn JS, Mor V, Castle N, Intrator O, Brannon D (1999) Organizational and environmental factors associated with nursing home participation in managed care. *Health Serv Res.* 33(6):1753-67.

Zinn JS, Weech RJ, Brannon D (1998) Resource dependence and institutional elements in nursing home TQM adoption. *Health Serv Res.* 33(2 Pt 1):261-73.

	Home number			Resident number		
Office use						

# Hip protector research

## Resident information

Has this resident agreed to wear the hip protectors? Yes  No

If "No," what reason (if any) was given?

.....

.....

Date of birth: Day   Month   Year

Sex: Male  Female

Date admitted: Day   Month   Year

Care category for this resident:

Residential  Residential EMI  Nursing  Nursing EMI

How many times has this resident fallen in the last 4 months?   
(As recorded in accident book)

Is this resident **already** using hip protectors (other than those supplied for this study)? Yes  No

## Cognition Scale (please tick the appropriate boxes)

**1. Short term memory (able to remember events 5 minutes ago – tick one box)**

Memory problem   
Memory OK

**2. Long term memory (able to remember events long past – tick one box)**

Memory problem   
Memory OK

**3. Decision making (decisions regarding tasks of daily life – tick one box)**

Independent decisions (decisions consistent and reasonable)

Modified independence (some difficulty in new situations only)   
Moderately impaired (decisions poor; prompting/supervision needed)   
Severely impaired (never/rarely makes decisions)

**4. Making self understood (verbally or in any other way – tick one box)**

Understood   
Usually understood (difficulty finding words or finishing thoughts)   
Sometimes understood (ability is limited to making concrete requests)   
Rarely/never understood

5. Orientation (what the resident has normally been able to remember during the last 7 days – **tick all boxes that apply**)

a) Season of the year

b) Location of own room

c) That she/he is in a nursing/residential home

d) None of the above (a,b,c) are remembered

### Dressing self-performance

How the resident puts on, fastens and takes off all items of **day clothes**, including putting on / removing any prosthesis. Please tick **one** box that best describes the resident's usual performance

1. Independent  
(no help or direction – **or** – help/direction provided only 1 or 2 times during the last 7 days)
2. Supervision  
(direction, encouragement or prompting provided 3 or more times during the last 7 days – **or** – supervision [3 or more times] plus physical assistance provided only 1 or 2 times during last 7 days)
3. Limited assistance  
(resident highly involved in activity; received physical help in guiding limbs into clothing or other non-weight bearing assistance 3 or more times – **or** – more help provided only 1 or 2 times during last 7 days)
4. Extensive assistance  
(while resident performed part of activity over the last 7 days, help of the following type[s] provided 3 or more times:
  - Weight-bearing support [resident needed help to sit or stand whilst dressing]
  - Full staff performance during part [but not all] of the last 7 days)
5. Total dependence  
(full staff performance of activity during entire 7 days)

### The Barthel ADL Index – how the resident has performed over the last 7 days

Activity	Score	Activity	Score
<b>1. BOWELS</b> 0 = Incontinent 1 = Occasional accident 2 = Continent		<b>6. TRANSFER</b> 0 = Unable – no sitting balance 1 = Major help – can sit 2 = Minor help 3 = Independent	
<b>2. BLADDER</b> 0 = Incontinent 1 = Occasional accident 2 = Continent (for over 7 days)		<b>7. MOBILITY</b> 0 = Immobile 1 = Wheelchair independent	

		2 = Walks with help of one person 3 = Independent	
<b>3. GROOMING</b> 0 = Needs help with personal care 1 = Independent (implements provided) 2 = Independent		<b>8. DRESSING</b> 0 = Dependent 1 = Needs help 2 = Independent	
<b>4. TOILET USE</b> 0 = Dependent 1 = Needs some help 2 = Independent		<b>9. STAIRS</b> 0 = Unable 1 = Needs help 2 = Independent – up and down	
<b>5. FEEDING</b> 0 = Unable 1 = Needs help 2 = Independent		<b>10. BATHING</b> 0 = Dependent 1 = Independent	

Thank you for your help

APPENDIX P  
Intervention homes

Home number	Beds occupied	Hip fractures	Hip fractures per 100 residents	Injurious falls	Nursing / Residential	EMI/O&I/MIXED	Size of home	Independent/part of group	R&I Standards not met %	Number of times manager changed	Adherence%
1	42.3	1	2.36	1	N	O&I	GE30	I	27	0	75
2	30.5	1	3.28	1	N	O&I	GE30	G	25	0	10.53
3	34.8	2	5.76	4	N	O&I	GE30	I	30	1	72.22
4	54.8	2	3.65	0	N	O&I	GE30	I	36	0	60
5	9.5	0	0	1	R	O&I	LE29	I	30	0	0
6	18.5	1	5.41	0	R	O&I	LE29	I	27	1	46.15
7	16.8	1	5.97	0	N	O&I	LE29	I	0	1	75
8	39.3	1	2.54	9	R	O&I	GE30	I	27	1	0
9	15.0	0	0	0	R	O&I	LE29	I	20	0	58.33
10	20.0	3	15	0	R	O&I	LE29	I	20	0	100
11	11.8	1	8.51	0	R	MIX	LE29	I	11	0	60
12	24.8	1	4.04	1	R	O&I	LE29	I	0	0	16.67
13	27.0	4	14.81	0	R	EMI	GE30	G	10	0	62.5
14	64.3	6	9.34	2	N	EMI	GE30	G	20	1	77.78
15	19.0	1	5.26	0	R	O&I	LE29	I	20	0	60
16	41.8	2	4.79	0	R	O&I	GE30	I	0	0	13.33
17	23.3	4	17.14	1	R	O&I	LE29	I	30	0	31.25
18	40.8	2	4.91	0	R	O&I	GE30	G	18	0	43.24
19	52.8	3	5.69	5	N	MIX	GE30	G	36	1	37.93
20	64.7	1	1.55	9	N	O&I	GE30	G	36	1	33.33
21	41.0	1	2.44	1	N	O&I	GE30	I	10	0	88.46
22	97.5	3	3.08	8	N	MIX	GE30	I	10	0	80
23	35.3	2	5.67	0	R	MIX	GE30	G	18	0	45.45
24	47.0	4	8.51	5	R	EMI	GE30	G	73	0	42.42
25	35.0	0	0	0	N	EMI	GE30	I	27	0	100
27	26.8	1	3.74	3	R	O&I	LE29	I	40	0	15
28	73.0	8	10.96	5	N	MIX	GE30	G	73	1	22
29	25.0	1	4	0	N	EMI	GE30	G	50	0	84.21

30	26.5	6	22.64	1	N	EMI	GE30	I	80	0	75
31	25.5	3	11.76	3	N	EMI	LE29	I	10	0	0

APPENDIX P  
Intervention homes (continued)

Home number	Beds occupied	Hip fractures	Hip fractures per 100 residents	Injurious falls	Nursing / Residential	EMI/O&I/MIXED	Size of home	Independent/part of group	R&I Standards not met %	Number of times manager changed	Adherence%
32	19.8	1	5.06	0	R	O&I	LE29	I	0	0	20
33	21.5	1	4.65	0	N	O&I	GE30	I	20	0	0
34	34.5	1	2.9	0	N	O&I	GE30	G	57	1	0
203	28.5	1	3.51	1	R	O&I	GE30	G	30	0	0
204	24.0	2	8.33	2	N	O&I	GE30	I	55	1	0
206	47.7	5	10.49	6	N	O&I	GE30	I	18	1	0
207	39.0	3	7.69	3	R	O&I	GE30	I	0	0	0
208	20.3	2	9.88	0	N	O&I	LE29	I	27	0	0
209	25.0	1	4	0	N	O&I	LE29	I	0	1	0
210	21.5	2	9.3	1	N	O&I	LE29	I	80	1	0

APPENDIX Q  
Control homes

Home number	Beds occupied	Hip fractures	Hip fractures per 100 residents	Injurious falls	Nursing / Residential	EMI/O&I/MIXED	Size of home	Independent /part of group	R&I Standards not met %	Number of times manager changed
100	22.0	3	13.64	0	R	O&I	LE29	I	38	0
101	29.7	2	6.74	7	R	O&I	GE30	I	27	0
102	37.0	0	0	1	N	O&I	GE30	I	0	0
103	36.5	1	2.74	4	R	O&I	GE30	G	14	0
104	13.3	2	15.09	2	N	O&I	LE29	I	11	0
105	14.0	0	0	1	R	O&I	LE29	I	30	1
106	9.3	0	0	0	N	O&I	LE29	I	30	0
107	33.0	0	0	1	N	O&I	GE30	I	30	0
108	14.8	1	6.78	1	R	O&I	LE29	I	27	0
109	39.5	7	17.72	4	N	EMI	GE30	I	9	0
110	24.0	4	16.67	7	R	EMI	GE30	G	20	0
111	5.0	1	20	1	R	O&I	LE29	I	0	0
112	32.5	3	9.23	1	N	EMI	GE30	G	0	1
113	23.7	1	4.23	1	R	O&I	LE29	I	10	0
114	34.8	2	5.76	2	R	MIX	GE30	G	0	0
115	39.8	4	10.06	1	R	O&I	GE30	G	30	0
116	39.5	4	10.13	1	N	EMI	GE30	I	10	0
117	33.5	0	0	0	N	O&I	GE30	I	64	0
118	32.0	2	6.25	1	R	EMI	GE30	G	56	0
119	46.8	2	4.28	2	N	MIX	GE30	G	40	0
120	30.5	2	6.56	1	R	O&I	GE30	G	20	0
121	35.0	0	0	1	N	O&I	GE30	I	64	0
122	29.8	1	3.36	0	N	O&I	GE30	I	30	2
123	23.0	1	4.35	2	R	O&I	LE29	I	50	0
124	30.0	2	6.67	3	R	MIX	GE30	G	0	0
125	44.5	0	0	1	N	O&I	GE30	I	45	1
126	34.0	3	8.82	1	N	O&I	GE30	G	20	2
127	23.7	3	12.68	0	N	O&I	LE29	I	50	1
128	21.5	2	9.3	0	N	O&I	LE29	I	50	0

129	6.0	0	0	0	R	O&I	LE29	I	0	0
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APPENDIX Q  
Control homes (continued)

Home number	Beds occupied	Hip fractures	Hip fractures per 100 residents	Injurious falls	Nursing / Residential	EMI/O&I/MIXED	Size of home	Independent /part of group	R&I Standards not met %	Number of times manager changed
130	21.7	2	9.23	0	N	O&I	LE29	I	33	0
131	44.3	4	9.04	0	N	O&I	GE30	I	36	0
132	29.0	4	13.79	5	R	EMI	GE30	G	36	0
133	69.3	5	7.21	6	N	O&I	GE30	G	33	0
134	52.8	0	0	1	N	O&I	GE30	I	82	0
135	27.3	6	21.95	2	R	EMI	GE30	G	0	0
136	25.3	0	0	0	N	O&I	LE29	I	64	1
137	62.8	3	4.78	7	N	MIX	GE30	G	0	0
138	48.8	5	10.26	8	N	O&I	GE30	G	50	0
139	80.5	5	6.21	7	R	O&I	GE30	I	45	0
140	79.8	8	10.03	3	N	O&I	GE30	G	50	0
141	29.0	9	31.03	0	N	MIX	GE30	G	9	0
142	29.0	0	0	0	N	O&I	LE29	I	13	0
143	54.3	1	1.84	2	N	MIX	GE30	G	38	0
145	29.3	0	0	0	N	O&I	GE30	I	78	0
146	57.8	7	12.12	1	N	O&I	GE30	G	27	0
147	12.7	0	0	1	R	O&I	LE29	I	30	0
148	34.0	3	8.82	0	N	O&I	GE30	I	9	0
149	30.5	2	6.56	0	R	O&I	GE30	I	0	0
150	63.0	4	6.35	4	N	O&I	GE30	G	45	0
151	40.8	3	7.36	0	N	MIX	GE30	I	40	0
152	13.3	0	0	0	R	O&I	LE29	I	0	1
153	35.0	1	2.86	2	R	EMI	GE30	G	10	0
154	24.8	2	8.08	4	N	EMI	LE29	I	36	2
155	34.3	1	2.92	2	N	O&I	GE30	G	30	0
156	31.3	1	3.2	2	N	O&I	GE30	G	18	0

157	26.0	0	0	0	N	O&I	LE29	I	0	0
158	22.5	1	4.44	0	R	O&I	LE29	I	44	0
159	35.8	1	2.8	0	N	O&I	GE30	I	20	0
160	19.8	0	0	0	N	O&I	LE29	I	64	1

APPENDIX Q  
Control homes (continued)

Home number	Beds occupied	Hip fractures	Hip fractures per 100 residents	Injurious falls	Nursing / Residential	EMI/O&I/MIXED	Size of home	Independent /part of group	R&I Standards not met %	Number of times manager changed
161	43.0	4	9.3	1	N	EMI	GE30	G	11	1
162	31.8	1	3.15	0	N	O&I	GE30	I	10	0
163	33.3	0	0	1	N	O&I	GE30	G	50	2
164	19.8	1	5.06	2	R	O&I	LE29	I	27	0
165	28.0	4	14.29	0	R	O&I	LE29	I	27	0
166	38.3	2	5.23	0	N	O&I	GE30	G	91	0
167	23.0	2	8.7	0	N	EMI	LE29	I	10	0
168	60.5	5	8.26	5	N	O&I	GE30	G	22	0
169	29.0	1	3.45	3	R	O&I	GE30	I	0	0
170	31.3	0	0	0	N	O&I	GE30	I	27	0
171	27.7	0	0	1	N	O&I	LE29	I	30	1
172	13.5	0	0	0	R	O&I	LE29	I	30	0
173	24.5	1	4.08	0	N	O&I	GE30	I	40	1
174	41.3	0	0	2	R	O&I	GE30	I	0	1
175	31.5	3	9.52	0	N	MIX	GE30	I	40	0
176	10.8	2	18.6	0	R	O&I	LE29	I	17	0
177	24.3	0	0	3	R	O&I	GE30	I	44	0
178	60.0	3	5	0	N	EMI	GE30	G	27	2
179	40.5	0	0	0	R	O&I	GE30	G	10	0
180	11.5	1	8.7	0	R	O&I	LE29	I	20	0
181	20.8	0	0	0	N	O&I	GE30	I	90	2
200	17.0	0	0	0	R	O&I	LE29	I	10	0
201	19.3	1	5.19	0	R	O&I	LE29	I	44	1

202	22.0	0	0	0	N	O&I	LE29	I	64	0
205	8.0	0	0	0	R	O&I	LE29	I	33	0
211	30.3	1	3.31	0	N	O&I	GE30	I	10	0
212	8.0	0	0	0	R	O&I	LE29	I	9	0

